Study to support the review of the list of **restricted** substances and to assess a new exemption request under RoHS 2 (Pack 15)

Final report

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Study to support the review of the list of **restricted** substances and to assess a new exemption request under RoHS 2 (Pack 15)

Final report

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1. Executive summary

1.1. Background of the study

The key provisions of Directive 2011/65/EU (RoHS 2) can be found in Article 4(1), requiring Member States to ensure that electrical and electronic equipment (EEE) placed on the market, including cables and spare parts, does not contain the substances listed in Annex II (restricted substances) in excess of the specified maximum tolerated value in the homogeneous material. The directive annex initially listed the following substances: lead, mercury, cadmium, hexavalent chromium, polybrominated biphenyls and polybrominated diphenyl ethers.

Article 6 of RoHS 2 requires that the list of restricted substances in Annex II be reviewed periodically and stipulates rules for amending the list. A first review of the annex was performed in the course of two studies between 2012 and 2014, resulting in the addition of four phthalates to the annex (the restrictions entered into force as of 2019).

Under Framework Contract no. ENV.A.2/FRA/2015/0008 of 27/03/2015, a consortium led by Oeko-Institut was requested by DG Environment of the European Commission to prepare a study to support the review of the list of restricted substances and to provide technical and scientific support for the evaluation of exemption requests under the RoHS 2 regime. The work was undertaken by Oeko-Institut together with the Fraunhofer Institute IZM.

The work was requested with a view to providing technical and scientific support for the following tasks:

- Part 1: Substance review:
  - Task 1: Update of the existing methodology to identify and assess substances for possible restriction;
  - Task 2: Assess substances with a view to their possible future restriction;
  - Task 3: Determination of the quantitative usage data for substances used in EEE;
- Part 2: Exemption evaluation:
  - Task 4: Exemption methodology
  - Task 5: Exemption assessment
- A horizontal task (task 6) was devoted to the consultation of stakeholders throughout the project.

1.2. Objectives and scope

The Terms of References (ToR) of the study request outline the objectives of the study as follows:

Part 1:

- Task 1: Update of the existing methodology to identify and assess substances based on the criteria in Recital 10 and Article 6(1) and 6(2). The methodology explains the link with methodological guidelines on exemptions, developed under the second part below.
- Task 2: Detailed assessment in line with the methodology, developed under Task 1, of seven substances listed in the TOR under Task 2 in the form of a substance dossier. This exercise includes an assessment of impacts in case of a possible restriction and the related substance dossiers. The assessment addresses the following substances or groups of substances: Diantimony trioxide (flame retardant)
    - Beryllium and its compounds
    - Five Cobalt salts
    - Diantimony trioxide (ATO, flame retardant)
    - Indium phosphide (InP)
    - Medium chain chlorinated paraffins (MCCPs) - Alkanes, 14-17, chloro
    - Nickel sulphate and nickel sulfamate
    - Tetrabromobisphenol A (TBBP-A, flame retardant)
- Task 3: Determination of quantitative usage data for a list of substances used in EEE (substance inventory prepared as part of Task 1 of the TOR) or where this is not possible, of a magnitude ranking, with a view to a refined prioritisation for future restriction review cycles.

Part 2:

- Task 4: Update of the existing methodology for the decision on exemption applications pursuant to the criteria in Article 5(1), by also taking consideration of methods applied in previous exemption evaluations performed under the RoHS 2 regime. The guidance also contains elements based on life-cycle analysis (LCA) as to how quantified impacts are to be compared in cases where an exemption is justified on the basis of the criterion specified in the third bullet of Article 5(1)(a)[1]. A life cycle perspective is to be adopted in particular where the application of EEE containing a RoHS-restricted substance results in environmental benefits, such as energy efficiency improvements or the use of recycled materials.
- Task 5: Evaluation of an exemption request for the use of cadmium in luminescent material for on-chip application on LED semiconductor chips. This

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[1] The criteria referred to is understood to be "*the total negative environmental, health and consumer safety impacts caused by substitution are likely to outweigh the total environmental, health and consumer safety benefits thereof*."

task was extended to cover two additional requests for exemption through an amendment of the ToR of this service request.

In order to fulfil the above objectives, stakeholder consultations were also performed in the course of the study.

1.3. Key findings

1.3.1. Update of the methodology and results of substance prioritisation and assessments

Task 1: Update of the existing methodology to identify and assess substances for possible restriction

The methodology for identification, prioritisation and assessment of substances for possible future restriction in the RoHS Directive, published in 2014 by the Austrian Umweltbundesamt (AUBA) was updated. In relation to the preceding AUBA methodology, the following aspects have been subject to a thorough revision:

- The interpretation of the criteria specified in Article 6 has been revised, fulfilment of which is to be established to justify the listing of additional substances in Annex II of the Directive (the list of restricted substances). In cases where the use of a substance in EEE could give rise to uncontrolled or diffuse releases into the environment (Article 6(1)(b)), a restriction may now also be justified. To this end, the methodology has been revised to take into consideration the occurrence of such impacts.
- The link to other legislations and policies of relevance has been detailed in relation to the Waste Framework Directive and in relation to the Communication on the interface between chemical, product and waste legislation.
- Detail as to the relation between the REACH Regulation and the RoHS Directive has been revised, following the publication of the Common Understanding Paper (COM 2014) as to the relation between these two legislations.
- The various sources specified for collection of information for the update of the substance inventory and for the assessment of substances have also been updated - revising links to such sources in some case and adding further sources where relevant.
- Additional detail has been added on how the precautionary principle is to be applied.
- Additional detail has been added on when RoHS restrictions can be considered justified based on the 6(1) criteria in connection with the Article 6(2) information requirements, in particular when the benefits expected to incur through a restriction are considered proportionate to the costs of its implementation.
- Information on endocrine disruptive properties of substances has been updated on the basis of the Communication Towards a comprehensive European Union framework on endocrine disruptors.

- Some clarifications have been added regarding Member State proposals.
- Criteria have been added to the methodology for substance assessment to demonstrate when the Article 6(1) criteria are considered to be fulfilled.
- Reference to sources on data emissions and monitoring data results have been added in the assessment methodology step on exposure estimation.
- Appendices have been added with guidance on Substance grouping and on Data quality and dealing with data gaps, based on a revision of the documents prepared by the RoHS Substance Working Group.
- The methodology for the pre-prioritization of the substances in the inventory has been revised to account for data gaps regarding the amounts of substances used in EEE. The stage for evaluating the potential for fulfilment of the Article 6(1) criteria of specific substances has been shifted from the inventory (P I) to the prioritisation (P II). This shift has been performed for pragmatic reasons and should allow a further fine-tuning of the internal ranking of the prioritised substances, i.e. the RoHS shortlist. The pre-prioritization now gives higher priority to substances with hazard classifications in the top two priority categories also in cases where no data as to use is available.

Task 2: Assessment results of seven substances with a view to their possible restriction under RoHS

The seven substances specified in the ToR were assessed according to the methodology for substance assessment updated in Task 1 of this study. The assessment has resulted in the following recommendations:

Beryllium and its compounds

> It is not recommended to include beryllium and its compounds in Annex II of the RoHS 2 Directive. However, a selective restriction of beryllium bearing alloys in abrasive EEE components, such as electric motor brushes, should be considered.

Cobalt dichloride, cobalt sulphate, cobalt dinitrate, cobalt carbonate and cobalt di(acetate)

> It is not recommended to include either of the cobalt salts in Annex II of the RoHS 2 Directive.

Diantimony trioxide (ATO, flame retardant)

> It is not recommended to include diantimony trioxide in Annex II of the RoHS 2 Directive. An additional recommendation suggests a combined assessment of the functional system of flame retardants consisting of halogenated compounds with ATO as a synergist.

Indium phosphide (InP)

> Currently, it is not recommended to include InP in Annex II of the RoHS 2 Directive.

Medium chain chlorinated paraffins (MCCPs) - Alkanes, 14-17, chloro

> An inclusion of MCCPs in Annex II of the RoHS 2 Directive is recommended.

Nickel sulphate and nickel sulfamate

> It is not recommended to include either of the nickel salts in Annex II of the RoHS 2 Directive.

Tetrabromobisphenol A (TBBP-A, flame retardant)

> An inclusion of additive uses of TBBP-A in Annex II of the RoHS 2 Directive is recommended.

Task 3: Identification and Prioritisation of Substances for Inclusion in the List of Restricted Substances (Annex II) under the RoHS 2 Directive (previously Determination of the quantitative usage data for substances used in EEE)

The results of this task describe the identification and prioritisation of substances used and/or present in EEE, which may have negative impacts on human health, the environment or resource efficiency during use and/or during WEEE management according to RoHS Article 6(1). The ToR specifies the updating of the substance inventory under task 1, and “determination of the quantitative usage data for substances used in EEE” under task 3. However, the results of both parts are linked and thus presented together for convenience. In this sense, the report for task 3 explains how the substance inventory was updated and how it was prioritised. The methodology for identifying and prioritising substances was revised as part of task 1 and provided the basis for updating the substance inventory established by AUBA in 2013 and for its prioritisation.

The **substances inventory** has been amended regarding the hazard properties and data regarding possible amounts of use and/or presence of the listed substances in EEE. This list was subjected to a pre-prioritisation, categorising the substances into groups of higher and lower priority on the basis of criteria specified in the methodology. The inventory was subject to a stakeholder consultation to gather information and validate the initial ranking of substances on the list as well as to identify new substances. The pre-prioritisation was then revised, resulting in the Pre-prioritised substance inventory.

Pre-prioritised substance inventory:

The substance inventory consists of a spreadsheet format list containing more than 900 substances that are indicated to be present in EEE or used in the manufacture of EEE. It includes information on:

- their identity (CAS number, EC number, substance name),
- their legal status under various directives and regulations (CLP, REACH, RoHS, POPs Regulation, among others),
- their hazardous properties (CMR, PBT/vPvB, endocrine disrupting properties, etc.), and
- their volumes of use in EEE.

The substances in this list have been pre-prioritised in accordance with criteria described in the manual, into ten priority groups, with group I associated with the highest and group X with the lowest priority (refer to manual P I Step 2: Priority pre-assessment of inventory sub-stances).

<u>List of prioritised substances:</u>

Additional information was collected for the 44 substances listed in the priority group I of the Pre-prioritised substance inventory specified above. Data was compiled into a spreadsheet format list containing information on the use (applications) of the substances in general and in EEE as well as their volumes of use in general and in EEE, where such information was available. Substances on this list were further sorted into five clusters to improve the clarity of results.

1.3.2. Development of an exemption evaluation methodology and results of an exemption evaluation

Task 4: Exemption evaluation methodology

A methodology for the evaluation of exemption applications pursuant to the criteria in Article 5(1) of Directive 2011/65/EU (RoHS 2) has been developed. It provides guidance on how applications for new exemptions, and for renewing or revoking exemptions are assessed in relation to these criteria.

The methodology gives guidance for the comparison of quantified impacts, on the basis of life cycle analyses, in cases where the justification of an exemption is argued by the applicant relying on the third Article 5(1)(a) criterion.[2] This may be the case where the use of a RoHS substance may result in lower environmental impacts in comparison to alternatives, stemming for example from energy efficiency gains or from the use of recycled materials.

The methodology is to be applied following the submission of exemption requests to the Commission and provides guidance as to how the technical and scientific

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[2] The criterion referred to: "*the total negative environmental, health and consumer safety impacts caused by substitution are likely to outweigh the total environmental, health and consumer safety benefits thereof*."

assessment of requests is performed. The methodology describes the elements of the evaluation process in four consecutive phases. They cover all relevant aspects related to the criteria listed in Article 5(1)(a) and their consideration in the consultants' recommendation:

- The clarification phase encompasses a screening of the application for exemption (new/renewal/revoke);
- The consultation phase encompasses an online stakeholder consultation;
- The evaluation phase encompasses the evaluation of the exemption request following the criteria of Art. 5(1)(a) of the RoHS Directive under consideration of information provided by stakeholders;
- The reporting phase encompasses the compilation of a public report.

Task 5: Exemption assessment of cadmium in quantum dot applications in displays and lighting

The exemption requests covered in this task concern the use of cadmium in quantum dot applications for displays and lighting equipment. The evaluation of the three requests was undertaken in a joint assessment. The final recommendations and proposed expiry dates are summarised in the table below (Table 1-1).

Table 1.1: Overview of the exemption requests, associated recommendations and expiry dates

Ex. Req. No.	Requested exemption wording	Applicant	Recommendation	Expiry date and scope
Requests for new exemption				
Request 2018-1	“Cadmium (<1000 ppm) in luminescent material for on-chip application on LED semiconductor chips for use in lighting applications of at least CRI 80”	LE	“Cadmium in downshifting semiconductor nanocrystal quantum dots I. *directly deposited on LED semiconductor chips for use in display and projection applications (< 5 µg Cd per mm² of light emitting LED chip surface)* II. *directly deposited on LED semiconductor chips for use in lighting applications of at least CRI 90 (< 1.000 ppm in the luminescent material), provided that applications comply with entry 72 of Annex XVII of Regulation 1907/2006.”*	5 years
Annex III, Ex. 39a	“Cadmium in downshifting semiconductor nanocrystal quantum dots directly deposited on LED chips for use in display and projection applications (< 5 µg Cd per mm² of light emitting LED chip surface)” requested to be valid for 5 years	Osram		
Annex III, Ex. 39a	“Cadmium selenide in downshifting cadmium-based semiconductor nanocrystal quantum dots for use in display lighting applications (<0.1 µg per mm2 of display screen area)” requested to be valid until October 31, 2021	Najing	Denied	

Note: As in the RoHS legal text, commas are used as a decimal separator for exemption formulations appearing in this table, in contrast to the decimal point used throughout the rest of the report as a separator

2. Executive summary: French - Note de synthèse: Français

2.1. Contexte dans lequel l'étude a été réalisée

Les principales dispositions de la directive 2011/65/UE (LdSD 2) figurent à l'article 4, paragraphe 1, qui impose aux États membres de veiller à ce que les équipements électriques et électroniques (EEE) mis sur le marché, y compris les câbles et les pièces de rechange, ne contiennent pas les substances énumérées à l'annexe II (substances réglementées) en quantité supérieure à la valeur maximale tolérée spécifiée dans le matériau homogène. L'annexe de la directive énumère initialement les substances suivantes : plomb, mercure, cadmium, chrome hexavalent, polybromobiphényles et polybromodiphényléthers.

L'article 6 de la directive RoHS 2 exige que la liste des substances restreintes de l'annexe II soit révisée périodiquement et stipule les règles de modification de la liste. Une première révision de l'annexe a été effectuée au cours de deux études entre 2012 et 2014, ce qui a entraîné l'ajout de quatre phtalates à l'annexe (les restrictions sont entrées en vigueur à partir de 2019).

Dans le cadre du contrat-cadre no. ENV.A.2/FRA/2015/0008 du 27/03/2015, un consortium dirigé par l'Oeko-Institut a été chargé par la DG Environnement de la Commission européenne de préparer une étude afin de soutenir la révision de la liste des substances restreintes et de fournir un soutien technique et scientifique pour l'évaluation des demandes d'exemption dans le cadre du régime RoHS 2. Le travail a été entrepris par l'Oeko-Institut en collaboration avec l'Institut Fraunhofer IZM.

Les travaux ont été demandés en vue de fournir un soutien technique et scientifique pour les tâches suivantes :

- Partie 1 : Examen des substances:
  - Tâche 1: Mise à jour de la méthodologie existante pour identifier et évaluer les substances en vue d'une éventuelle restriction;
  - Tâche 2: Èvaluation des substances en vue de leur éventuelle restriction future;
  - Tâche 3: Détermination des données quantitatives d'utilisation des substances utilisées dans les EEE;
- Partie 2: évaluation de l'exemption:
  - Tâche 4: Méthodologie des exemptions
  - Tâche 5: Évaluation de l'exemption
- Une tâche horizontale (tâche 6) a été consacrée à la consultation des parties prenantes tout au long du projet.

2.2. Objectifs et champ d'application

Les termes de référence (TdR) de la demande d'étude décrivent les objectifs de l'étude comme suit:

Partie 1:

- Tâche 1: Mise à jour de la méthodologie existante pour identifier et évaluer les substances sur la base des critères du considérant 10 et de l'article 6, paragraphes 1 et 2. La méthodologie explique le lien avec les lignes directrices méthodologiques sur les exemptions, développées dans la deuxième partie ci-dessous.
- Tâche 2: évaluation détaillée, conformément à la méthodologie, développée dans le cadre de la tâche 1, de sept substances figurant dans le cahier des charges de la tâche 2, sous la forme d'un dossier de substance. Cet exercice comprend une évaluation des impacts en cas d'une éventuelle restriction et les dossiers de substances connexes. L'évaluation porte sur les substances ou groupes de substances suivants Trioxyde de diantimoine (retardateur de flamme)
  - Béryllium et ses composés
  - Cinq sels de cobalt
  - Trioxyde de diantimoine (ATO, retardateur de flamme)
  - Phosphure d'indium (InP)
  - Paraffines chlorées à chaîne moyenne (PCCM) – Alcanes, 14-17, chloro
  - Sulfate de nickel et sulfamate de nickel
  - Tétrabromobisphénol A (TBBP-A, retardateur de flamme)
- Tâche 3: détermination des données quantitatives d'utilisation pour une liste de substances utilisées dans les EEE (inventaire des substances préparé dans le cadre de la tâche 1 du cahier des charges) ou, lorsque cela n'est pas possible, d'un classement par ordre de grandeur, en vue d'une hiérarchisation plus précise des priorités pour les futurs cycles de révision des restrictions.

Partie 2:

- Tâche 4: mise à jour de la méthodologie existante pour la décision sur les demandes d'exemption conformément aux critères de l'article 5, paragraphe 1, en prenant également en considération les méthodes appliquées dans les évaluations d'exemption précédentes effectuées dans le cadre du régime LdSD 2. Le guide contient également des éléments basés sur l'analyse du cycle de vie (ACV) concernant la manière dont les impacts quantifiés doivent être comparés dans les cas où une exemption est justifiée sur la base du critère spécifié au troisième point de l'article 5, paragraphe 1, point a)[3]. Une perspective de cycle de vie doit être adoptée en particulier lorsque l'application

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[3] Le critère auquel il est fait référence s'entend comme "le total des incidences négatives sur l'environnement, la santé et la sécurité du consommateur causées par la substitution est susceptible de l'emporter sur le total des avantages qui en découlent pour l'environnement, la santé et la sécurité du consommateur".

d'EEE contenant une substance soumise à la directive LdSD entraîne des avantages environnementaux, tels que des améliorations de l'efficacité énergétique ou l'utilisation de matériaux recyclés.

- Tâche 5: évaluation d'une demande d'exemption pour l'utilisation du cadmium dans les matériaux luminescents pour l'application sur puce sur les puces semi-conductrices LED. Cette tâche a été étendue pour couvrir deux demandes d'exemption supplémentaires par une modification des termes de référence de cette demande de service.

Afin d'atteindre les objectifs susmentionnés, des consultations des parties prenantes ont également été menées au cours de l'étude.

2.3. Principales conclusions

2.3.1. Mise à jour de la méthodologie et des résultats de la hiérarchisation des substances et des évaluations

Tâche 1: Mise à jour de la méthodologie existante pour identifier et évaluer les substances en vue d'une éventuelle restriction

La méthodologie d'identification, de hiérarchisation et d'évaluation des substances en vue d'une éventuelle restriction future dans la directive LdSD, publiée en 2014 par l'Umweltbundesamt autrichien (AUBA; agence fédérale pour l'environnement), a été mise à jour. Par rapport à la précédente méthodologie de l'AUBA, les aspects suivants ont fait l'objet d'une révision approfondie :

- L'interprétation de l'article 6 a été révisée. En particulier, l'interprétation des critères qui y sont spécifiés a été révisée, dont le respect doit être établi pour justifier l'inscription de substances supplémentaires à l'annexe II de la directive (la liste des substances faisant l'objet de restrictions). Dans les cas où l'utilisation d'une substance dans les EEE pourrait donner lieu à des rejets non contrôlés ou diffus dans l'environnement (article 6, paragraphe 1, point b)), une restriction peut désormais également être justifiée. À cette fin, la méthodologie a été révisée pour prendre en considération l'occurrence de tels impacts.
- Le lien avec d'autres législations et politiques pertinentes a été détaillé par rapport à la directive-cadre sur les déchets et par rapport à la communication sur l'interface entre la législation sur les produits chimiques, les produits et les déchets.
- Le détail de la relation entre le règlement REACH et la directive RoHS a été révisé, suite à la publication du document d'interprétation commune (COM 2014) sur la relation entre ces deux législations.
- Les différentes sources spécifiées pour la collecte d'informations pour la mise à jour de l'inventaire des substances et pour l'évaluation des substances ont également été mises à jour – en révisant les liens vers ces sources dans certains cas et en ajoutant d'autres sources le cas échéant.
- Des détails supplémentaires ont été ajoutés sur la manière dont le principe de précaution doit être appliqué.

- Des précisions supplémentaires ont été ajoutées sur les cas dans lesquels les restrictions LdSD peuvent être considérées comme justifiées sur la base des critères de l'article 6, paragraphe 1, en liaison avec les exigences d'information de l'article 6, paragraphe 2, en particulier lorsque les avantages escomptés d'une restriction sont considérés comme proportionnels aux coûts de sa mise en œuvre.
- Les informations sur les propriétés de perturbation endocrinienne des substances ont été mises à jour sur la base de la communication intitulée "Vers un cadre global de l'Union européenne concernant les perturbateurs endocriniens".
- Certaines clarifications ont été ajoutées concernant les propositions des États membres.
- Des critères ont été ajoutés à la méthodologie d'évaluation des substances afin de démontrer quand les critères de l'article 6, paragraphe 1, sont considérés comme remplis.
- Des références aux sources sur les émissions de données et les résultats des données de surveillance ont été ajoutées dans l'étape de la méthodologie d'évaluation relative à l'estimation de l'exposition.
- Des annexes ont été ajoutées avec des conseils sur le regroupement des substances et sur la qualité des données et le traitement des lacunes en matière de données, sur la base d'une révision des documents préparés par le groupe de travail LdSD sur les substances.
- La méthodologie de priorisation des substances de l'inventaire a été révisée pour tenir compte des lacunes dans les données concernant les quantités de substances utilisées dans les EEE. La phase d'évaluation du potentiel de réalisation des critères de l'article 6, paragraphe 1, pour des substances spécifiques a été déplacée de l'inventaire (P I) à la hiérarchisation (P II). Ce changement a été effectué pour des raisons pragmatiques et devrait permettre d'affiner encore le classement interne des substances prioritaires, c'est-à-dire la liste restreinte de la directive LdSD. La pré-priorisation accorde désormais une plus grande priorité aux substances dont les classifications de danger se situent dans les deux premières catégories prioritaires, même dans les cas où aucune donnée quant à leur utilisation n'est disponible.

Tâche 2: résultats de l'évaluation de sept substances en vue de leur éventuelle restriction dans le cadre de la directive LdSD

Les sept substances spécifiées dans le cahier des charges ont été évaluées selon la méthodologie d'évaluation des substances mise à jour dans la tâche 1 de cette étude. L'évaluation a donné lieu aux recommandations suivantes :

Béryllium et ses composés

> Il n'est pas recommandé d'inclure le béryllium et ses composés dans l'annexe II de la directive RoHS 2. Toutefois, une restriction sélective des alliages contenant du béryllium dans les composants abrasifs des EEE, tels que les brosses de moteurs électriques, devrait être envisagée.

Dichlorure de cobalt, sulfate de cobalt, dinitrate de cobalt, carbonate de cobalt et di(acétate) de cobalt

> Il n'est pas recommandé d'inclure l'un ou l'autre des sels de cobalt dans l'annexe II de la directive RoHS 2.

Trioxyde de diantimoine (ATO, retardateur de flamme)

> Il n'est pas recommandé d'inclure le trioxyde de diantimoine dans l'annexe II de la directive RoHS 2. Une recommandation supplémentaire suggère une évaluation combinée du système fonctionnel des retardateurs de flamme constitués de composés halogénés avec l'ATO comme synergiste.

Phosphure d'indium (InP)

> Actuellement, il n'est pas recommandé d'inclure l'InP dans l'annexe II de la directive RoHS 2.

Paraffines chlorées à chaîne moyenne (PCCM) - Alcanes, 14-17, chloro

> Il est recommandé d'inclure les PCCM dans l'annexe II de la directive RoHS 2.

Sulfate de nickel et sulfamate de nickel

> Il n'est pas recommandé d'inclure l'un ou l'autre des sels de nickel dans l'annexe II de la directive RoHS 2.

Tétrabromobisphénol A (TBBP-A, retardateur de flamme)

> Il est recommandé d'inclure les utilisations d'additifs du TBBP-A dans l'annexe II de la directive RoHS 2.

Tâche 3: Identification et hiérarchisation des substances à inclure dans la liste des substances restreintes (annexe II) en vertu de la directive RoHS 2 (précédemment Détermination des données quantitatives d'utilisation des substances utilisées dans les EEE)

Les résultats de cette tâche décrivent l'identification et la hiérarchisation des substances utilisées et/ou présentes dans les EEE, qui peuvent avoir des impacts négatifs sur la santé humaine, l'environnement ou l'efficacité des ressources pendant leur utilisation et/ou pendant la gestion des DEEE conformément à l'article 6, paragraphe 1, de la directive LdSD. Les termes de référence précisent la mise à jour de l'inventaire des substances dans le cadre de la tâche 1, et la "détermination des données quantitatives d'utilisation des substances utilisées dans les EEE" dans le cadre de la tâche 3. Cependant, les résultats des deux parties sont liés et donc présentés ensemble pour des raisons de commodité. En ce sens, le rapport de la tâche 3 explique comment l'inventaire des substances a été mis à jour et comment il a été hiérarchisé. La méthodologie d'identification et de hiérarchisation des substances a été révisée dans le cadre de la tâche 1 et a servi de base à la mise à jour de l'inventaire des substances établi par l'AUBA en 2013 et à sa hiérarchisation.

L'inventaire des substances a été modifié en ce qui concerne les propriétés de danger et les données relatives aux quantités possibles d'utilisation et/ou à la présence des substances répertoriées dans les EEE. Cette liste a fait l'objet d'une pré-priorisation, classant les substances en groupes de priorité plus élevée et plus faible sur la base des critères spécifiés dans la méthodologie. L'inventaire a fait l'objet d'une consultation des parties prenantes afin de recueillir des informations et de valider le classement initial des substances figurant sur la liste, ainsi que d'identifier de nouvelles substances. La hiérarchisation préalable a ensuite été révisée, ce qui a donné lieu à l'inventaire des substances prioritaires.

Inventaire des substances pré-prioritaires:

L'inventaire des substances consiste en une liste au format tableur contenant plus de 900 substances dont la présence dans les EEE ou l'utilisation dans la fabrication d'EEE est indiquée. Il comprend des informations sur:

- leur identité (numéro CAS, numéro CE, nom de la substance),
- leur statut juridique en vertu de diverses directives et règlements (CLP, REACH, RoHS, règlement POP, entre autres),
- leurs propriétés dangereuses (CMR, PBT/vPvB, propriétés de perturbation endocrinienne, etc.
- leurs volumes d'utilisation dans les EEE.

Les substances de cette liste ont été pré-priorisées conformément aux critères décrits dans le manuel, en dix groupes prioritaires, le groupe I étant associé à la priorité la plus élevée et le groupe X à la priorité la plus faible (voir le manuel P I, étape 2: Pré-évaluation prioritaire des substances de l'inventaire).

Liste des substances prioritaires:

Des informations supplémentaires ont été recueillies pour les 44 substances figurant dans le groupe prioritaire I de l'inventaire des substances prioritaires précisées ci-dessus. Les données ont été compilées dans une liste au format tableur contenant des informations sur l'utilisation (les applications) des substances en général et dans les EEE ainsi que leurs volumes d'utilisation en général et dans les EEE, lorsque ces informations étaient disponibles. Les substances figurant sur cette liste ont ensuite été triées en cinq groupes afin d'améliorer la clarté des résultats.

2.3.2. Élaboration d'une méthode d'évaluation de l'exemption et résultats d'une évaluation de l'exemption

Tâche 4 : Méthodologie d'évaluation de l'exemption

Une méthodologie pour l'évaluation des demandes d'exemption conformément aux critères de l'article 5, paragraphe 1, de la directive 2011/65/UE (LdSD 2) a été développée. Elle fournit des orientations sur la manière dont les demandes de nouvelles exemptions, et de renouvellement ou de révocation d'exemptions sont évaluées en fonction de ces critères.

La méthodologie donne des orientations pour la comparaison des impacts quantifiés, sur la base d'analyses du cycle de vie, dans les cas où la justification d'une exemption est invoquée par le demandeur en se fondant sur le troisième critère de l'article 5, paragraphe 1, point a).[4] Cela peut être le cas lorsque l'utilisation d'une substance LdSD peut entraîner des incidences environnementales moindres par rapport aux autres solutions, résultant par exemple de gains d'efficacité énergétique ou de l'utilisation de matériaux recyclés.

La méthodologie doit être appliquée après la soumission des demandes d'exemption à la Commission et fournit des orientations quant à la manière dont l'évaluation technique et scientifique des demandes est effectuée. La méthodologie décrit les éléments du processus d'évaluation en quatre phases consécutives. Elles couvrent tous les aspects pertinents liés aux critères énumérés à l'article 5, paragraphe 1, point a), et leur prise en compte dans la recommandation des consultants:

- La phase de clarification comprend un examen de la demande de dérogation (nouvelle/renouvellement/révocation);
- La phase de consultation comprend une consultation en ligne des parties prenantes;
- La phase d'évaluation comprend l'évaluation de la demande d'exemption selon les critères de l'article 5, paragraphe 1, point a) de la directive LdSD en tenant compte des informations fournies par les parties prenantes;
- La phase de rapport comprend l'élaboration d'un rapport public.

Tâche 5 : Évaluation de l'exemption du cadmium dans les applications de points quantiques dans les affichages et l'éclairage

Les demandes d'exemption couvertes par cette tâche concernent l'utilisation du cadmium dans les applications de points quantiques pour les écrans et les équipements d'éclairage. L'évaluation des trois demandes a été réalisée dans le cadre d'une évaluation conjointe. Les recommandations finales et les dates d'expiration proposées sont résumées dans le tableau ci-dessous (tableau 2.1).

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[4] Le critère auquel il est fait référence : *"le total des incidences négatives sur l'environnement, la santé et la sécurité des consommateurs résultant de la substitution est susceptible de l'emporter sur le total des avantages qui en découlent pour l'environnement, la santé et la sécurité des consommateurs"*.

Tableau 2.1: Aperçu des demandes d'exemption, des recommandations associées et des dates d'expiration

Demandes d' exemp. N°	**Exemption demandée**	**Demandeur**	**Recommandation**	**Date d'expiration et champ d'application**
Demande 2018-1	"Cadmium (<1000 ppm) dans un matériau luminescent pour une application sur puce sur des puces à semi-conducteurs LED pour une utilisation dans des applications d'éclairage d'au moins 80 CRI", dont la validité est demandée pour 5 annés	LE	*"Le cadmium dans les points quantiques des nanocristaux semi-conducteurs* *I. directement déposés sur des puces semi-conductrices à LED destinées à être utilisées dans des applications d'affichage et de projection (< 5 µg Cd par mm² de surface de puce LED émettant de la lumière)* *II. directement déposés sur des puces à semi-conducteurs LED destinées à être utilisées dans des applications d'éclairage d'un IRC d'au moins 90 (< 1 000 ppm dans le matériau luminescent)* *à condition que les demandes soient conformes à la rubrique 72 de l'annexe XVII du règlement 1907/2006".*	5 années
Annexe III, Ex. 39a	"Cadmium dans les nanocristaux quantiques de semi-conducteurs rétrogradants déposés directement sur des puces LED pour une utilisation dans des applications d'affichage et de projection (< 5 µg Cd par mm² de surface de puce LED émettant de la lumière)" dont la validité est demandée pour 5 années	OSRAM		

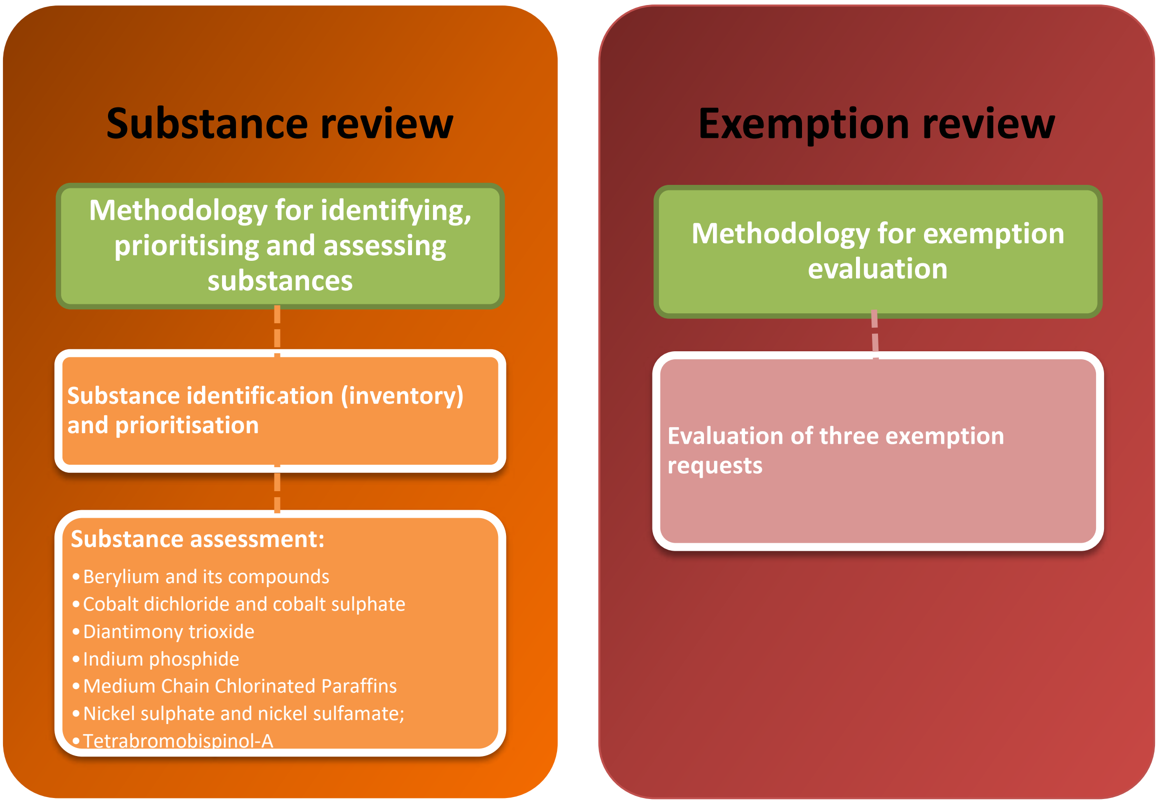
Demandes d' exemp. N°	Exemption demandée	Demandeur	Recommandation	Date d'expiration et champ d'application
Annexe III, Ex. 39a	"Séléniure de cadmium dans les nanocristaux quantiques de semi-conducteurs à base de cadmium rétrogradant pour utilisation dans des applications d'éclairage d'affichage (<0,1 µg par mm^2 de surface d'écran d'affichage)" dont la validité est demandée jusqu'au 31 octobre 2021	Najing	Refusée	

3. Introduction

3.1. Project scope and approach

The study consisted of two parts: the first including tasks related to the review of the list of restricted substances specified in Annex II of the RoHS Directive and the second consisting of tasks related to the review of exemptions from the substance restrictions. Both parts of the study started with the development of assessment methodologies and concluded with the application of these methodologies and approaches in further tasks. Figure 3.1 shows how the various tasks related to these two parts as well as this relation to methodological and applicative work within the study tasks.

Figure 3.1: Substance tasks and essence



The scope of the tasks of the study is summarised below. The final versions of the separate task reports are presented in the appendices and give further detail as to the scope addressed under each task, the methodology and approach taken and the results.

Substance assessment methodology

This study serves a request[5] by the Commission from 13 November 2017 under the Framework Contract ENV.A.2/FRA/2015/0008[6] for an update of the methodology for identifying and assessing substances based on the criteria in Recital 10 and Articles 6(1) and 6(2). The substance assessment methodology serves for the identification of substances of relevance for possible future assessment. Moreover, it explains the link to the evaluation methodology for substance exemption requests (Task 4 of the study).

The ToR for this study also required the updating of the RoHS substances inventory based on the revised methodology. This sub-task has been performed together with task 3 and is specified therein.

Assessment of seven substances

The methodology (Part III) developed in task 1 was applied in the assessment of the following seven substances specified in the TOR in order to evaluate whether they should be restricted by the RoHS Directive in the future.

- Beryllium and its compounds
- Five Cobalt salts
- Diantimony trioxide (ATO, flame retardant)
- Indium phosphide (InP)
- Medium chain chlorinated paraffins (MCCPs) - Alkanes, 14-17, chloro
- Nickel sulphate and nickel sulfamate
- Tetrabromobisphenol A (TBBP-A, flame retardant)

For each of the substances, an evaluation dossier was compiled, presenting the data and information collected and how it has been assessed in relation to the Article 6(1) criteria for the review of the RoHS Annex II list of restricted substances. The dossiers contain the rational and a recommendation as to whether the substance (or group of substances) should be included in Annex II.

Substance identification and prioritisation

On the basis of the methodology developed (Part I and Part II) in task 1 an inventory of substances contained or used in the manufacture of EEE was prepared. Data was compiled for such substances as to their identity, their hazardous properties and use in EEE. The inventory was subject to a pre-prioritisation, classifying the included substances into several groups, based on their priority for further assessment. Substances in the group of highest priority were subject to a further prioritisation, through which additional data was collected to conclude as to the magnitude ranking of

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[5] Entitled: "Study to support the review of the list of restricted substances and to assess a new exemption request under RoHS 2 (Pack 15)"

[6] Entitled: "Assistance to the Commission on technical, socio-economic and cost-benefit assessments related to the implementation and further development of EU waste legislation"

their use in EEE and their potential to fulfil the Article 6 criteria for restriction. These substances were further clustered to add further clarity as to the additional information and as to their prioritisation for assessment during future review cycles of the RoHS 2 Directive Annex II list of restricted substances.

Exemption assessment methodology

A methodology was developed to provide guidance as to how applications for exemptions (new, renewal, revoke) are assessed in relation to the criteria for the justification of exemptions stipulated in Article 5(1)(a) of the RoHS Directive. The methodology reflects the practice applied since entry into force of RoHS 2 and covers the various stages of exemption assessment, elaborating as to the involvement of various actors in each stage, what is performed and how information is reviewed and assessed. The methodology details how the information provided in exemption applications and by stakeholders is assessed according to the Article 5(1)(a) criteria to conclude for a specific case whether:

- it is scientifically or technically practical to eliminate or substitute a RoHS substance currently contained in materials and/or components of EEE;
- the reliability of substitutes is ensured;
- the total negative environmental, health and consumer safety impacts of substitution are likely to outweigh the total benefits thereof;

It is also explained how the availability of substitutes and the socioeconomic impacts of substitution are taken into consideration in relation to the justification of exemptions and their duration as well as how potential adverse impacts on innovation and life-cycle thinking on the overall impacts of the exemption may be taken into account.

Exemptions from the RoHS Directive

Article 5(1)(a) provides a basis for requesting exemptions for certain EEE applications that use substances, materials and components that are subject to restriction under RoHS. This article further specifies the criteria on which such exemptions can be justified: in cases where the environmental and health protection afforded by Regulation 1907/2006/EC (REACH) is not weakened, exemptions can be justified in cases where at least one of the following criteria is fulfilled:

- “their elimination or substitution via design changes or materials and components which do not require any of the materials or substances listed in Annex II is scientifically or technically impracticable,
- the reliability of substitutes is not ensured,
- the total negative environmental, health and consumer safety impacts caused by substitution are likely to outweigh the total environmental, health and consumer safety benefits thereof.”

Furthermore, the availability of substitutes; the socio-economic impacts of substitution; any potential adverse impacts on innovation and life-cycle thinking information can also be considered to determine the duration of exemptions.

Article 5(2) of the RoHS Directive stipulates that exemptions listed in Annex III and Annex IV shall have an expiration date. Where a specific date is not specified, this article lists provisions to clarify the validity. Article 5(3) requires stakeholders to submit applications for granting, renewing or revoking exemptions to the European Commission. The Directive includes the provision that applications for exemptions have to be made in accordance with Annex V. Stakeholders submit requests for new exemptions as well as for the renewal, the amendment or the revocation of existing exemptions. The applications provide the basis for the Commission to initiate evaluations of the exemptions listed in the annexes (or evaluations of requests for new exemptions).

The Commission has received a request for a new exemption to be added to Annex III with the following formulation:

> *“Cadmium in luminescent material for on-chip application on LED semiconductor chips”.*

Two further requests for the renewal of Ex. 39a of Annex III of the RoHS Directive were also received. This exemption currently reads as follows:

> *“Cadmium selenide in downshifting cadmium-based semiconductor nanocrystal quantum dots for use in display lighting applications (< 0,2 µg Cd per mm^2 of display screen area)”*

An evaluation of these exemptions has thus also been performed as part of the study. The requests have been evaluated in order to assess, whether they are justified according to criteria of Article 5 of the RoHS Directive.

As all three requests concerned the use of cadmium in quantum dot material in various application, the assessment has been carried out as a joint one.

Stakeholder consultations

As part of the study, five stakeholder consultations and three stakeholder meetings were carried out in order to receive information and feedback from stakeholders and to present the various results. The details of these instances of stakeholder involvement are detailed in Table 3.1 below.

Table 3.1: Stakeholder consultations and meetings

Stakeholder consultations and meetings	
Consultation duration	**Contents**
27.03.2018	Meeting: Project Overview, Approach, Schedule
20.04.2018 - 15.06.2018	Collect information on the seven substances
26.10.2018 - 21.12.2018	Substance methodology and substance inventory
18.03.2019 - 13.05.2019	Three exemption requests
24.04.2019	Meeting: Substance methodology update
07.11.2019 - 06.09.2019	4 substance dossiers & substance inventory
05.12.2019 - 13.02.2020	3 substances dossiers & substance prioritisation
27.04.2020	Meeting: Project results

3.2. Project set-up

Assignment of project tasks to Oeko-Institut, started on 12 December 2018. The overall project has been led by Carl-Otto Gensch. At Fraunhofer IZM the contact person is Otmar Deubzer.

4. The appendices to this report

The following appendices include reproductions of the final reports of the various tasks of this study. The appendices relate to the study tasks as follows:

Task		Appendix
1	Update of the existing methodology to identify and assess substances for possible restriction	A.1.0 Methodology for Identification and Assessment of Substances for Inclusion in the List of Restricted Substances (Annex II) under the RoHS 2 Directive
2	Assess substances with a view to their possible future restriction	A.2.0 Beryllium and its compounds A.3.0 Five Cobalt salts A.4.0 Diantimony trioxide A.5.0 Indium phosphide A.6.0 Medium chain chlorinated paraffins (MCCPs) - Alkanes, 04-17, chloro A.7.0 Nickel sulphate and nickel sulfamate A.8.0 Tetrabromobisphenol A (TBBP-A, flame retardant)
3	Determination of the quantitative usage data for substances used in EEE – report includes substance inventory and substance prioritisation	A.9.0 Report on the Identification and Prioritisation of Substances for Inclusion in the List of Restricted Substances (Annex II) under the RoHS 2 Directive
4	Exemption evaluation methodology	A.10.0 Exemption methodology
5	Exemption assessment of three exemption applications	A.11.0 Exemption evaluation

A.1.0 Methodology for Identification and Assessment of Substances for Inclusion in the List of Restricted Substances (Annex II) under the RoHS 2 Directive

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Institute for Applied Ecology

Manual Methodology for Identification and Assessment of Substances for Inclusion in the List of Restricted Substances (Annex II) under the RoHS 2 Directive

Prepared in the framework of the Study to support the review of the list of restricted substances and to assess a new exemption request under RoHS
(RoHS Pack 15)

Freiburg,
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Disclaimer

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Abbreviations and definitions

AEL	Acceptable exposure level
BCF	Bioconcentration factor
BAT	Best available technology
BREF	Best available technology references document
CLP	Classification and Labelling Regulation
CMR	Carcinogenic category 1 or 2; mutagenic category 1 or 2, toxic for reproduction category 1 or 2
CSR	Chemical safety report
DMEL	Derived minimum exposure level
DNEL	Derived no effect level
ECHA	European Chemicals Agency
EEE	Electrical and electronic equipment
IT	Information technology
Log K_{ow}	Logarithm of the octanol/water partition coefficient
MBT	Mechanical-biological treatment
NOAEC	No observable adverse effect concentration
NOAEL	No observable adverse effect level
OEL	Occupational exposure level
PBT	Persistent, bio-accumulative and toxic
PNEC	Predicted no effect concentration
POPRC	Persistent Organic Pollutants Review Committee
RAC	Risk assessment committee
RAR	Risk assessment report
REACH	Registration, Evaluation and Authorisation of Chemicals
RoHS	Restriction of Hazardous Substances
RCR	Risk characterisation ratio
SCCS	Scientific Committee on Consumer Safety
SCENIHR	Scientific Committee on Emerging and Newly Identified Health Risks
SCHER	Scientific Committee on Health and Environmental Risks
SCOEL	Scientific Committee on Occupational Exposure Limits
SEAC	Socio-economic Committee
STOT SE	Specific target organ toxicity: single exposure
STOT RE	Specific target organ toxicity: repeated exposure
SVHC	Substance of very high concern
vPvB	Very persistent and very bio-accumulative
WEEE	Waste electrical and electronic equipment

I Summary

The following report constitutes the Manual Methodology for Identification and Assessment of Substances for Inclusion in the List of Restricted Substances (Annex II) under the RoHS Directive. This manual is based on a revision of a manual prepared in 2013 by the Austrian Umweltbundesamt (AUBA 2013).

In relation to the AUBA methodology, the following aspects have been subject to a more thorough revision:

- The interpretation of Article 6 has been revised. In particular, a revision has been undertaken of the criteria specified therein, fulfilment of which is to be established to justify the listing of additional substances in Annex II of the Directive (the list of restricted substances). In cases where the use of a substance could give rise to uncontrolled or diffuse releases into the environment (Article 6(1)(b)), a restriction may now also be justified. To this end, the methodology has been revised to take into consideration the occurrence of such impacts.
- The link to other legislations and policies of relevance has been detailed in relation to the Waste Framework Directive and in relation to the Communication on the interface between chemical, product and waste legislation.
- Detail as to the relation between the REACH Regulation and the RoHS Directive has been revised, following the publication of the Common Understanding Paper (COM 2014) as to the relation between these two legislations.
- The various sources specified for collection of information for the update of the substance inventory and for the assessment of substances have also been updated - revising links to such sources in some case and adding further sources where relevant.

A first draft of this methodology was subject to a stakeholder consultation held between 26 October 2018 to 21 December 2018. A list of stakeholders who have made a (non-confidential) contribution has been added in Appendix A.7. A summary of the main issues addressed through contributions is available on the consultation website[1]. Among others, the following issues raised through contributions have furthermore been integrated into the current methodology:

- Reference to Directive 2018/851/EU (Waste Framework Directive) and to Communication on the interface between chemical, product and waste legislation has been revised.
- Additional detail has been added on how the precautionary principle is to be applied.
- Additional detail has been added on when RoHS restrictions can be considered justified based on the 6(1) criteria in connection with the Article 6(2) information requirements, in particular when the benefits expected to incur through a restriction are considered proportionate to the costs of its implementation.
- Information on endocrine disruptive properties of substances has been updated on the basis of the Communication Towards a comprehensive European Union framework on endocrine disruptors.
- Some clarifications have been added regarding Member State proposals.

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[1] See: https://rohs.exemptions.oeko.info/index.php?id=341

- Criteria have been added to the methodology for substance assessment to demonstrate when the Article 6(1) criteria are considered to be fulfilled.
- Reference to sources on data emissions and monitoring data results have been added in the assessment methodology step on exposure estimation.
- An appendix has been added with guidance on Data quality and dealing with data gaps, based on a revision of the document prepared by the RoHS Substance Working Group.
- The methodology for identifying and prioritising substances has been revised: At the onset of the study, the inventory established by the Austrian Umweltbundesamt was updated and subjected to a stakeholder consultation to collect further data. The list posted for consultation included over 800 substances and information was asked among others as to the actual use and/or presence of substances in EEE and relevant volumes of use. This exercise returned additional information for only a small sub-set of substances and it was concluded, that such exercises required more focus to allow stakeholders to allocate their resources more efficiently in relation to a smaller number of substances. It was thus decided in coordination with the EU Commission to revise the methodology in this respect. Following the initial updating of the list of substances in the inventory in relation to data on hazard properties and data on possible use and/or presence in EEE, the inventory is now submitted to a pre-prioritisation prior to a stakeholder consultation. This allows specifying the focus of the consultation on the substances in the higher priority groups of the inventory, whereas stakeholders may still submit information as to other substances on the list as well as identifying new substances of relevance. A further change is the shift of the stage for evaluating the potential for fulfilment of the Article 6(1) criteria of specific substances from the inventory (P I) to the prioritisation (P II). This shift has been performed for pragmatic reasons and should allow a further fine-tuning of the internal ranking of the prioritised substances, i.e. the RoHS shortlist.

A second draft of this methodology was submitted to the EC on 14 August 2019 for final approval. The methodology described in this manual was applied in the assessment of 7 substances (two cobalt compounds, two nickel compounds, indium phosphide, antimony trioxide, TBBPA and beryllium and its compounds) and in the preparation of the RoHS inventory of substances and its prioritisation. During the first application of the revised methodology a few shortcomings were identified and thus the following aspects have been fine-tuned:

- In the methodology for compiling the inventory, substances under assessment should not be erased, but rather kept in the inventory and specified as such.
- The methodology for the pre-prioritization of the substances in the inventory has been revised in light of the limited data available as to the volumes of substances used in EEE. The pre-prioritization now gives higher priority to substances with hazard classifications in the top two priority categories also in cases where no data as to use is available. For further details see Section 1.3.1 P I Step 2a) Pre-prioritisation of substances, Part 3) “How to determine the overall priority of substances /substance groups”.

II Introduction

Electrical and electronic equipment (EEE) contains an increasing variety of organic and inorganic chemical substances. Some of these substances have properties which are hazardous, and which can lead to adverse impacts on human health and/or the environment when they are present in EEE applications.

According to Directive 2002/95/EC (RoHS 1), the use of lead, mercury, cadmium, hexavalent chromium, polybrominated biphenyls (PBB) and polybrominated diphenyl ethers (PBDE)[2] in EEE has been banned / restricted since 2006. Maximum concentration values by weight in homogeneous materials were specified[3]. Furthermore, for particular applications of lead, mercury, cadmium and hexavalent chromium, exemptions from these restrictions were laid down, partly indicating acceptable maximum concentration values or total contents.

In 2008, a proposal for a **recast of the RoHS Directive** was made[4]. The recast (RoHS 2) came into force in July 2011 (Directive 2011/65/EU - hereafter RoHS). It aims at developing a better regulatory environment and at specifying the conditions for adapting the RoHS Directive to the technical and scientific progress. This includes adaptation of the list of substances being restricted in EEE and the exemptions from these restrictions. Furthermore, it aims at a better prevention of risks to human health and the environment, with a particular focus on workers involved in the management of waste electrical and electronic equipment (WEEE).

Another objective of the recast of the RoHS Directive was to ensure coherence of RoHS with other pieces of EU legislation such as chemicals legislation, in particular the system of Registration, Evaluation, Authorisation and Restriction of Chemicals introduced by Regulation (EC) No 1907/2006 (REACH) and provisions related to waste management; in particular the Directive 2012/19/EU (WEEE).

Annex II of RoHS specifies the list of restricted substances. Article 6 of the Directive stipulates that the list is to be reviewed periodically[5] and amended periodically, also specifying various aspects to be considered as well as the criteria to be taken into account in the review of substances for possible future restrictions. Against this background, a methodology for the identification, prioritisation and assessment of substances present in EEE and for the review and amendment of the list of restricted substances provided in Annex II of RoHS was prepared in 2012-2013 by the Austrian Umweltbundesamt (AUBA 2013). This document has been revised in relation to various developments in policy and is now being published for consultation with stakeholders.

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[2] For lead, mercury, cadmium, hexavalent chromium the restriction is on the use of these elements and their compounds. For PBB and PBDE the restriction applies to all members of these substance groups.

[3] Decision 2005/618/EC

[4] Proposal for a Directive on the restriction of the use of certain hazardous substances in electrical and electronic equipment (COM(2008) 809)

[5] Article 6(1) further specifies that the periodic reviews should take place on the Commissions own initiative or following the submission of a Member State restriction proposal.

Please note

The following divergent formatting style is used for emphasis throughout this document:

INTERPRETATION

Where the Directive legal text or statements from other documents published by the European Union are interpreted, the text appears as an **INTERPRETATION** and is formatted as grey text.

II.I Background

During the preparation of RoHS, an expansion of the list of restricted substances was discussed. Preparatory studies, in particular the review of restricted substances under RoHS 1 (Groß et al. 2008), revealed that certain hazardous substances associated with negative impacts on the environment and/or on health are widely used in EEE in considerable quantities, which are not regulated under the Directive yet. For several substances negative health and environmental impacts were documented, which could justify a restriction of further use in EEE. Namely the flame retardants tetrabromobisphenol A (EU RAR 2006, 2007a[6]) and hexabromocyclododecane (EU RAR 2007b[7]) and the phthalates bis (2-ehtylhexyl) phthalate, butyl benzyl phthalate and dibutyl phthalate (EU RAR DEHP 2008, EU RAR BBP 2007 and EU RAR DBP 2003[8]) were identified as high priority substances. Due to insufficient data on environmental, economic and social impacts, in particular on possible substitutes at that point, it was decided to postpone the review of the list of restricted substances to after the approval of RoHS. For his purpose the recast required a first review to be carried out by 22 July 2014 under Article 6(1), which inter alia specifies when a review of the list of restricted substances by the European Commission (the Commission) is to be carried out. For the first review, priorities as to the substances to be reviewed were assigned in Recital 10 to the following substances:

- Hexabromocyclododecane (HBCDD);
- Bis (2- ethylhexyl) phthalate (DEHP);
- Butyl benzyl phthalate (BBP);
- Dibutyl phthalate (DBP).

The first review of the substances specified in Recital 10 was carried out in 2012-2013 by the Austrian Umweltbundesamt (AUBA 2013), followed by a further review of diisobutyl phthalate (DiBP) carried out on behalf of the Commission by the Oeko-Institut in 2014 (Baron et al. 2014). As a result of this process, the four phthalates were included in Annex II of the RoHS Directive following an amendment published in March 2015 (COM 2015).

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[6] Specified in Groß et al. (2008) among others on the basis of: EU Risk Assessment Report 2,2',6,6'-Tetrabromo-4,4'-Isopropylidene Diphenol (Tetra-bromobisphenol-A), Final Environmental Draft (2007); EU Risk Assessment Report 2,2',6,6'-Tetrabromo-4,4'-Isopropylidenediphenol (Tetra-bromobisphenol-A or TBBP-A), Part II – Human Health, Final Report (2006); and Johnson-Restrepo, B. et al. (2008): Tetrabromobisphenol A (TBBPA) and hexabromocyclododecanes (HBCDs) in tissues of humans, dolphins, and sharks from the United States; Chemosphere 70 (2008) 1935–1944.

[7] Specified in Groß et al. (2008) among others on the basis of: Risk Assessment Hexabromocyclododecane. Final Draft October (2007)

[8] Specified in Groß et al. (2008) among others on the basis of: EU Risk Assessment Report bis(2-ethylhexyl)phthalate (DEHP), Final Report (2008); EU Risk Assessment Report Benzyl butyl phthalate (BBP), Final Report (2007); and EU Risk Assessment Dibutylphthalate (DBP), Final Report (2003).

In the course of the AUBA review, an inventory of substances of relevance for EEE was also generated[9] with the aim to provide support to the Commission in identifying substances for assessment in future reviews.

II.I.I Requirements related to substance review and restriction under RoHS

Article 6(1) of RoHS stipulates various **requirements related to substance review and restriction under RoHS**. It requires that the review and amendment of the list of restricted substances in Annex II shall be based on a "thorough assessment", "*taking account of the precautionary principle".* Recital 10 of RoHS also refers to the **precautionary principle.**

Within the methodology described in this manual, the precautionary principle shall be applied according to the Commission guidelines (COM 2000 1 final)[10], following basic principles of proportionality, consistency, responsibility, taking into account impacts on society and on the environment. Decisions taken might be subject to review in case where additional data becomes available, as laid down in the Commission's communication.

Though a methodology for the evaluation of chemical substances to be listed in Annex II is not detailed in the RoHS Directive, elements to be assessed during the review and amendment of Annex II are specified in Article 6(1 and 2) .

According to Article 6(1) of RoHS, "*the review and amendment of the list of restricted substances in Annex II shall be coherent with other legislation related to chemicals, in particular Regulation (EC) No 1907/2006, and shall take into account, inter alia, Annexes XIV and XVII to that Regulation. The review shall use publicly available knowledge obtained from the application of such legislation*".

Special account shall be given to "*whether a substance, including substances of very small size or with a very small internal or surface structure, or a group of similar substances:*

(a) could have a negative impact during EEE waste management operations, including on the possibilities for preparing for the reuse of waste EEE or for recycling of materials from waste EEE;

(b) could give rise, given its uses, to uncontrolled or diffuse release into the environment of the substance, or could give rise to hazardous residues, or transformation or degradation products through the preparation for reuse, recycling or other treatment of materials from waste EEE under current operational conditions;

(c) could lead to unacceptable exposure of workers involved in the waste EEE collection or treatment processes;

(d) could be replaced by substitutes or alternative technologies which have less negative impacts."

The criteria focus on possible environmental and health impacts that could arise during use and/or during waste management. However, for the implementation of the RoHS Directive, product de-

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[9] See AUBA (2013) inventory under: http://www.umweltbundesamt.at/fileadmin/site/umweltthemen/abfall/ROHS/finalresults/Annex3_EEE-substance-inventory.xls

[10] The European Commission outlines its approach towards applying the precautionary principle in a communication published in 2000. This document provides guidelines and builds a common understanding of how to assess, appraise, manage and communicate risks that science is not yet able to evaluate fully. The aim of this guidance is to avoid unwarranted recourse to the precautionary principle, as a disguised form of protectionism. Recourse to the precautionary principle presupposes that potentially dangerous effects deriving from a phenomenon, product or process have been identified, but that scientific evaluation does not allow the risk to be determined with sufficient certainty. (COM 2000 1 final)

sign and manufacturing necessarily need to be taken into account and may also be affected from the Directive provisions. In this respect, though RoHS "*does not specifically regulate the manufacturing process itself, the methodology behind the listing of substances in Annex II to RoHS could address risks arising at this stage*" (COM 2014).

Furthermore, RoHS specifies that interested parties, including economic operators, recyclers, treatment operators, environmental organisations and employee and consumer associations shall be consulted during the review of the list of restricted substances.

INTERPRETATION:

Though the title of the RoHS Directive refers to the restriction of **hazardous substances**, it does not include a definition for this term, referring only to the "List of restricted substances", for example in Article 6 and Annex II. According to Article 3(1) of REACH (or Article 3(8) of CLP) "***substance****: means a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition*". The term **hazard** is not defined, however, Recital 10 of CLP explains its objective to "*be to determine which properties of substances and mixtures should lead to a classification as hazardous, in order for the hazards of substances and mixtures to be properly identified and communicated. Such properties should include physical hazards as well as hazards to human health and to the environment, including hazards to the ozone layer*".

Coherence with other legislation is required in Article 6.

In this respect, Directive 2008/98/EC on waste (Waste Framework Directive - WFD (EP 2008)) should be noted. The WFD "*defines key concepts such as waste, recovery and disposal and puts in place the essential requirements for the management of waste*" (Recital 1). It also provides clarification on "*the distinction between waste and non-waste, and for the development of measures regarding waste prevention and management*" (Recital 2). The first objective of the WFD is to minimise negative effects of waste generation and management on human health and the environment (Recital 6). In this sense, Article 13 of the WFD requires Member States to take the necessary measures to ensure that waste management does not endanger human health and/or the environment. This is understood to be an overarching objective of all Waste legislation, and thus also relevant for RoHS, which calls for the substitution of hazardous substances used in EEE as a means to prevent such impacts. Annex III of the WFD furthermore specifies properties of waste which render it as hazardous. Properties mentioned are parallel to many of the hazards requiring classification under the CLP Regulation, including also hazards of relevance for use and for waste management such as irritant, toxic, carcinogenic, etc.

In the recent amendment of the WFD (Directive 2018/851/EU), waste management has been defined as "the collection, transport, recovery (including sorting), and disposal of waste, including the supervision of such operations and the after-care of disposal sites, and including actions taken as a dealer or broker". This definition clarifies what is in the scope of waste management and which actions are included therein. This is to be considered in assessing whether a substance fulfils the RoHS Article. 6(1)(a) criterion. Of further interest is the amendment of Article. 9 of the WFD, which concerns the prevention of waste, and requires Member States to take measures to prevent waste generation:

> *“(i) promote the reduction of the content of hazardous substances in materials and products, without prejudice to harmonised legal requirements concerning those materials and products laid down at Union level, and ensure that any supplier of an article as defined in point 33 of Article 3 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council (*5) provides the information pursuant to Article 33(1) of that Regulation to the European Chemicals Agency as from 5 January 2021*;”

Information provided to ECHA pursuant to this Article in connection with Article 33(1) of REACH regarding the presence of hazardous substances in EEE could provide an important source of information on substances present in EEE and should be used in the future to support the identification, prioritisation and assessment of substances in the context of RoHS.

> *“(j) reduce the generation of waste, in particular waste that is not suitable for preparing for re-use or recycling;*”

This reference suggests that waste, containing hazardous substances, that is not suitable for preparation for re-use or recycling could be of particular interest in assessing the fulfilment of the Article 6(1) criteria.

Furthermore, the Communication on the interface between chemical, product and waste legislation published by the European Commission in 2018 (COM 2018 32 final) is to be mentioned. The Communication indicates possible future developments of legislation and should thus be noted and followed for possible future linkage. The Communication explains that recycling and re-use can be hampered by the presence of certain chemicals. In parallel, a growing number of chemicals hazardous to humans or the environment are being subjected to legal restrictions. In both cases, removal of such substances from the waste stream is understood to contribute to recycling of waste and to the reuse of secondary materials. The Communication thus identifies the four most critical issues “*in the way the legislation on chemicals, products and waste work together and how these are hampering a circular economy development”*:

- Lacking information on the presence of substances of concern in materials and components that are part of the waste stream;
- Substances already subject to restrictions may still be contained in material and components to be subject to waste management;
- The rules defining “end of waste” (when waste ceases to be seen as such) are not harmonised in EU legislation;
- Rules as to when wastes and chemicals are to be considered hazardous are not aligned between chemical and waste legislation, affecting possible uptake of secondary materials.

Further details as to these issues are given in the document.

RoHS restricts the presence of hazardous substances in EEE, in this sense contributing to the presence of substances of concern in the waste stream and subsequently to the ability to recycle materials and use secondary materials in new production has various links to the issues raised in the Communication on the interface between chemical, product and waste legislation. Measures to be initiated as a result of the Communication could affect how substance restriction is to be practiced in the future and should be taken into consideration as they develop.

Article 6 particularly requires coherence with chemical legislation and REACH. Moreover, the Directive in its Article 2(3) sets the obligation to observe Union legislation on safety and health as well as waste management. There is however, neither a legal mandate nor an obligation to copy the procedure of substance restriction developed under REACH nor to involve ECHA and its scientific committees (RAC, SEAC) in the assessment process of substances under RoHS. Coherence is interpreted to mean that amendments of Annex II shall not result in contradictions, duplication and uncertainties between RoHS and other chemical legislation and in particular between RoHS and REACH. The relation between these two legislations has been established and published in the document "REACH and Directive 2011/65/EU (RoHS) - A Common Understanding" (COM 2014). This document provides guidance for various scenarios in which substances are regulated under these legislations in various ways. A summary of the considerations and action courses to be taken during an assessment of a substance for restriction under RoHS, in cases where regulation already exists under REACH is provided in Table I.

Table I: The relation between REACH and RoHS in respect of the restriction or authorisation of substances

REACH Restrictions and RoHS

Case	REACH Annex XVII Restriction	RoHS Annex II Restriction	Rational	Action under REACH	Conclusion / Action
I	Under Consideration	In force	RoHS Restriction affords the same or a higher level of protection to that proposed in the REACH Restriction.	REACH: Exclude EEE in scope of RoHS from restriction; indicate the use of substance in EEE to be restricted by RoHS. RoHS: No action	Irrelevant
			Proposed REACH restriction affords higher level of protection	Not detailed in common understanding paper. Consultants' interpretation: REACH measure to be preferred to achieve a higher level of protection, for example where RoHS is not effective in this respect.	
II	In force	Under Consideration	If REACH restricts the use of a substance inter alia in EEE, RoHS restriction may be redundant.	REACH: No action RoHS: No need to restrict as substance already restricted through REACH.	No need to restrict under RoHS where REACH restriction affords higher level of protection.
			If the same or more stringent measures (restriction) are proposed under RoHS:	REACH: Exclude EEE in scope of RoHS from restriction; indicate the use of substance in EEE to be restricted by RoHS. RoHS: Restrict substance	Restrict under RoHS where it can achieve the same or a higher level of environmental and health protection.
III	Under Consideration	No measure	A REACH restriction could be imposed. Should RoHS restrict in the future, EEE could be excluded from REACH measure subsequently.	Restriction under REACH. RoHS: No action.	Should a RoHS restriction be considered in the future, case II is to be followed.

REACH Restrictions and RoHS

Case	REACH Annex XVII Restriction	RoHS Annex II Restriction	Rational	Action under REACH	Conclusion / Action
			Alternatively: REACH restriction procedure could be used to prepare a RoHS Annex II amendment outside the periodic review period.	REACH and RoHS amendments to be synchronised: REACH: REACH restriction not to address EEE. RoHS: Amendment of RoHS Annex II to restrict substance	If necessity to restrict under RoHS identified at early stages of REACH substance assessment, this could trigger a substance review under RoHS.

REACH Authorisation and RoHS

Case	REACH Annex XIV Authorisation	RoHS Annex II Restriction	Rational	Conclusion / Action
I	Under Consideration	In force	No exemptions under RoHS: Use in EEE placed on EU market prohibited in all applications. Listing in Annex XIV of REACH shall prohibit use of substance in EU manufacture of EEE, i.e., for export.	Measure consistent with existing regulation.
			Exemptions exist: Measure shall apply to EEE manufactured in EU*.	Alternative 1: EEE covered by RoHS restriction (and by exemptions) could be excluded from REACH Annex XIV listing pursuant to Article 58(2).
				Alternative 2: if the RoHS restriction does not constitute proper control according to Article 58(2) of REACH, the REACH authorisation requirement could apply to EEE, though only affecting EU manufacturers.
II	In force	Under Consideration	Listing in Annex XIV of REACH already prohibits use of substance in EU manufacture.	Alternative 1: RoHS restricts without exemptions - if REACH Authorisations have been granted, they shall become redundant unless parallel exemption granted under RoHS.
				Alternative 2: RoHS restricts with exemptions. It may be considered if there is added value in continuing the REACH authorisation requirement for RoHS exempted applications.
III	Under Consideration	No measure	Introduce REACH authorisation requirement.	Should a RoHS restriction be considered in the future, Case II to be followed.
			Delay REACH measure until substance can be included in RoHS Annex II (restriction).	REACH substance assessment can be used to trigger RoHS substance evaluation to avoid Case II situation.

*Authorisations could be applied for RoHS exempted EEE and granted to allow use for a limited duration, assuming they are justified.

Source: Own compilation on the basis of COM (2014)

Furthermore, the RoHS Directive interpretation of the precautionary principle may differ from that of the REACH Regulation. From REACH (Article 7(5)(b)) it can be understood that release of a substance classified as hazardous, for example from an article, is a precondition for the assessment of the risk[11].The REACH Restriction process is further based on the criteria that a risk to human health or the environment exists, which is not adequately controlled and which needs to be addressed (Article 69). However, looking at the RoHS Article 6(1) criteria suggests that it suffices for a substance to have a potential for risk (“could have...”) during use and/or during waste management in order to justify its restriction under RoHS. In this sense, if a substance is classified with a hazard potentially resulting in risk in these phases, a restriction would be justified regardless of actual occurrence and risk management options. It is thus interpreted that a stricter approach can be taken by RoHS, provided that scientific and technical information show that there is a probability that at least one of the Article 6(1) criteria is fulfilled. It is nonetheless noted that the need for costs of a restriction to be proportionate to expected benefits suggests that a restriction would only be possible where negative impacts on health and/or on the environment are expected in connection to the fulfilment of Article 6(1) (see following detail). Furthermore, costs of implementing a restriction in such a case are to be proportionate to the benefit a restriction would generate through the prevention of such impacts:

- negative impacts occurring during EEE waste management operations, including on the possibilities for preparing for the reuse of waste EEE or for recycling of materials from waste EEE (Article 6(1)(a));
- negative impacts as a result of uncontrolled or diffuse release of a substance used in EEE into the environment during use (Article 6(1)(b)(first part));
- negative impacts as a result of hazardous residues, or transformation or degradation products of a substance released in the waste phase that occur through the preparation for reuse, recycling or other treatment of materials from waste EEE under current operational conditions (Article 6(1)(b)(second part);
- unacceptable impacts on the health of workers involved in the waste EEE collection or treatment processes (Article 6(1)(c));
- in relation to the above criteria, negative impacts of the use of a substance are higher than those of a possible substitute or alternative technology (Article 6(1)(d)).

Article 6(1) specifies that the review shall be based on a thorough assessment, taking account of the precautionary principle and that it shall also:

- *Be coherent with other legislation related to chemicals, and particularly REACH.*
  Though it is understood that discrepancies should be avoided, coherence is not interpreted to mean that RoHS could not be stricter in certain cases. This could occur where action taken through REACH provides a lower level of environmental and health protection as the level that could be achieved through RoHS. For example, in the case of a REACH Authorisation that prohibits the use of a substance in EU manufacture and thus also its presence in EEE, the Authorisation obligation only prevents impacts related to use of the substance in EU manufacture. Where the substance is used in manufacture outside the EU, a RoHS restriction could addition-

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[11] Under REACH, it can be understood that the Agency (ECHA) may require a substance to be registered when it has grounds to suspect that the substance is released from articles and where the release may present a risk to human health or the environment.(Article 7(5)(b)). It is thus understood that though hazards may be associated with a substance, this does not necessarily mean that a risk is present.

ally prevent impacts related to the presence of the substance in imported EEE during use and/or during the waste phase. See further detail below.

- *take account inter alia of Annexes XIV (Authorisations) and XVII (Restrictions) of the REACH Regulation* – Seeing as restrictions and authorisations for using certain substances may affect the need to restrict a chemical under RoHS (or the scope of such a restriction), changes of the Annexes should be taken into consideration. See further details below.
- *use publicly available knowledge obtained from the application of other legislation related to chemicals.* The knowledge base generated in relation to other legislation should be used where available in the review process of substances under RoHS. In this respect, information generated by REACH and other chemical related legislation is to be used for the restriction process under RoHS. The most recent information should be taken into consideration where multiple versions exist. This does not necessarily give priority to such information and data, assuming other sources shall be available with a similar level of certainty, but specifies a first basis of available knowledge, seeing as the reviews are to be carried out on the basis of available information.
- Consideration should be given as to the level of certainty of information and data used in the assessment of substances. It can be assumed that knowledge (documents, data) generated through the application of other legislation has been submitted to scrutiny and can be assumed to have a relatively high level of certainty. For the purpose of this study, the weight of evidence approach may be applied to consider the certainty of different sources and the weight which is attributed to data and information provided therein (see “Part III DETAILED ASSESSMENT OF SUBSTANCES”, Section II, for details).

Furthermore, Article 6(1) specifies four criteria which also have to be taken into account while reviewing and amending Annex II. Fulfilment of each of these criteria is interpreted as a possible justification for a future restriction; however, a differentiation might be necessary in relation to the range (time, geography) and magnitude (volume) of impacts specified in these criteria. There are two reasons for this differentiation: It is to serve as a basis for deciding on the proportionality of a restriction, as well as allowing a prioritisation between substances.

The criteria are interpreted as follows:

- Criterion 6(1)(a) refers to substances whose presence in EEE may lead to negative impacts at the end-of-life of that article when it is subjected to waste management. This includes impacts arising through operations related to the treatment and handling of waste, including but not limited to: sorting, shredding, preparing for the reuse of waste EEE or preparing for the recycling of materials from waste EEE;
- Criterion 6(1)(b) refers to substances whose presence could give rise to impacts during the use of the article and/or at its end-of-life, when it is subjected to waste management. This includes:
  - uncontrolled or diffuse release of the substance into the environment during its use; or
  - generation and release of hazardous residues of the substance through the preparation for reuse, recycling or other treatment of materials from waste EEE under current operational conditions.
  - generation and release of transformation or degradation products of the substance through the preparation for reuse, recycling or other treatment of materials from waste EEE under current operational conditions
- Criterion 6(1)(c) refers to substances whose presence in EEE may lead to unacceptable exposure of workers involved in the waste EEE collection or treatment processes;

- Criterion 6(1)(d) refers to substances present in EEE which lead to various negative impacts on the environment and/or on health throughout the lifecycle of the product and which could be replaced by substitutes or alternative technologies which have less negative impacts and which would thus lead to a decrease in total negative impacts on environment and health.

As regards substance groups[12] mentioned in Article 6(1), the grouping of similar substances[13] describes the approach for considering more than one single substance at the same time in the various steps of the methodology. Assessing a group of substances could in some cases provide an alternative to the individual assessment and restriction of individual substances, mainly in order to maximise efficiency both, in the review and amendment of the list of restricted substances as well as during implementation, e.g. to ensure market surveillance. This could be relevant for example when individual group members of a certain group exhibit the same hazard properties, and where similar exposures could arise within the waste management processes. This could be the case, for example, if group members are transformed into particular hazardous transformation or degradation products. Basically, categories of chemicals are selected due to the hypothesis that the properties of chemicals with identical structural features may show similar trends in their physico-chemical properties, and even more importantly, in their toxicological profile, which includes human health and ecotoxicology and environmental fate properties.

Article 6(2) of RoHS requires that "*proposals to review and amend the list of restricted substances, or a group of similar substances, in Annex II"* contain certain types of information and these requirements are to be taken into consideration in the assessment of a substance under RoHS and in the preparation of a proposal for restriction (RoHS dossier). See "Introduction", Section II, for further detail.

According to Article 6(3) of RoHS the measures related to the review and amendment of the list of restricted substances shall be adopted by the Commission by means of delegated acts in accordance with Article 20 and subject to the conditions laid down in Articles 21 and 22 of the Directive.

II.II Objective of the manual

This manual describes how to identify substances used in EEE which may have a negative impact on human health and or the environment during use and/or during WEEE management[14] and how to assess them in order to conclude if their future restriction under RoHS is justified.

II.III Scope of the manual

Primarily, the methodology described in this manual is addressed to the Commission and provides guidance for future reviews of Annex II (list of restricted substances) to RoHS.

Two triggers are possible for future reviews:

- A review on the Commission's initiative (periodic or triggered through the assessment of substances under REACH – see Table I, p. 16);
- A review following submission of a restriction proposal by a Member State.

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[12] For example the restriction of cadmium applies to cadmium metal and to its compounds.

[13] Appendix A.6 0provides guidance on groups of similar substance.

[14] Impacts during the production and use of EEE are not a part of the criteria specified under Article 6(1) for justifying a restriction of substances under RoHS.

In addition, the manual could be used as guidance by Member States when they intend to prepare a restriction proposal, though this is not obligatory (see further detail in P III).

II.IV Overview of the methodology

The methodology described in this manual consists of three parts:

- PART I: Identification of substances[15] used and/or present in EEE, which may have negative impacts on human health, the environment or resource efficiency during use and/or during WEEE management according to RoHS Article 6(1). In this stage a first inventory of substances used in EEE is created (updated). Existing databases and computer-based tools are then used to establish a comprehensive database with information on the substances concerned (hazard properties, use aspects). Finally, chemicals are selected by applying defined criteria (hazardous properties, evidence that the substance is used in EEE). The information collected is used for further substance assessment and considerations;
- PART II: Prioritisation of substances used in EEE, which may most likely have negative impacts on human health, the environment or resource efficiency during use and/or during WEEE management according to RoHS Article 6(1). This part is applied to a sub-selection of the substances identified in P II, understood to have the highest priority for assessment in P III. Information is collected and reviewed on actual volumes of use and on typical applications in EEE. Based on this information and the hazard properties of the substance a first estimation is made as to whether the use and/or presence of the substance in EEE could result in the fulfilment of the Article 6(1 criteria). On this basis the prioritisation for assessment is further refined.
- PART III: Detailed assessment of high priority substances with a view to concluding on the necessity for restriction under RoHS. In addition to the substance's impacts on health, environment and resource efficiency, the availability and hazardous properties of potential substitutes/alternatives and socio-economic aspects of a potential future restriction are investigated.

According to RoHS Article 6(1), the focus of assessment lies on the impacts on human health and environment during use and/or during waste treatment.

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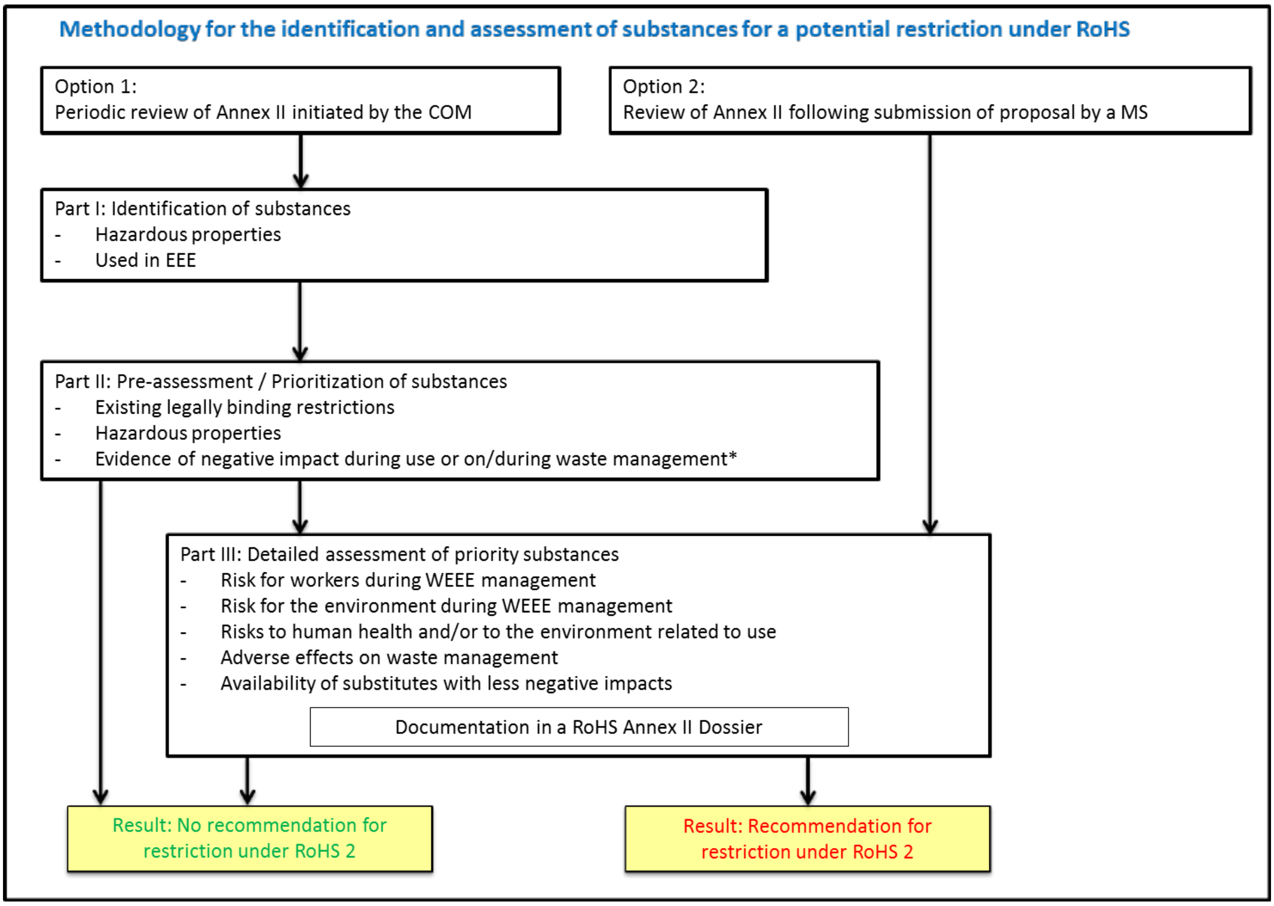
[15] Means substances and substance groups, for reasons of readability "substances" is used throughout this manual.

Figure I provides an overview of the overall methodology described in detail in this manual.

Figure I: Overview of the methodology (*as specified by Article 6(1) of RoHS2)



Source: Adapted with revisions from AUBA (2013)

1. Part I IDENTIFICATION OF SUBSTANCES

The **aim** of Part I is to identify all substances in EEE, which may cause risks for the environment during use[16] or risks for the environment and workers during WEEE management or have any other negative impacts during waste management, as specified by RoHS 2, Article 6.

Article 6(1) requires taking special account of whether a substance, including substances of very small size, or with a very small internal or surface structure, or a group of similar substances:

a) "*could have a negative impact during EEE waste management operations, including on the possibilities for preparing for the reuse of waste EEE or for recycling of materials from waste EEE*;

b) *could give rise, given its uses, to uncontrolled or diffuse release into the environment of the substance, or could give rise to hazardous residues, or transformation or degradation products through the preparation for reuse, recycling or other treatment of materials from waste EEE under current operational conditions*;

c) *could lead to unacceptable exposure of workers involved in the waste EEE collection or treatment processes;*

d) *could be replaced by substitutes or alternative technologies which have less negative impacts*."

Approach: The standardised methodology as described below shall allow for a stepwise procedure for assessing substances for possible future restriction under RoHS in order to fulfil the overall goal of protecting human health and the environment from negative impacts related to use or to WEEE management.

The identification of potentially RoHS-relevant substances used in EEE involves three major tasks:

- Creation of an inventory of substances (P I Step 1):
  - Updating information on substances classified or suspected as hazardous (P I Step 1a);
  - Updating information on substances used and/or present[17] in EEE (P I Step 1b);
- Pre-assessment of priority of substances listed in the inventory (P I Step 2):
  - First run of the pre-assessment to establish classification of substances to priority groups (P I Step 2a);
  - Stakeholder consultation for collecting information on substances in the inventory with focus on the substances in the highest priorities (P I Step 2b);
- Update information in the inventory and re-run pre-assessment to conclude on substances in highest priorities[18] to be subject refined prioritisation in P II (P I Step 3).

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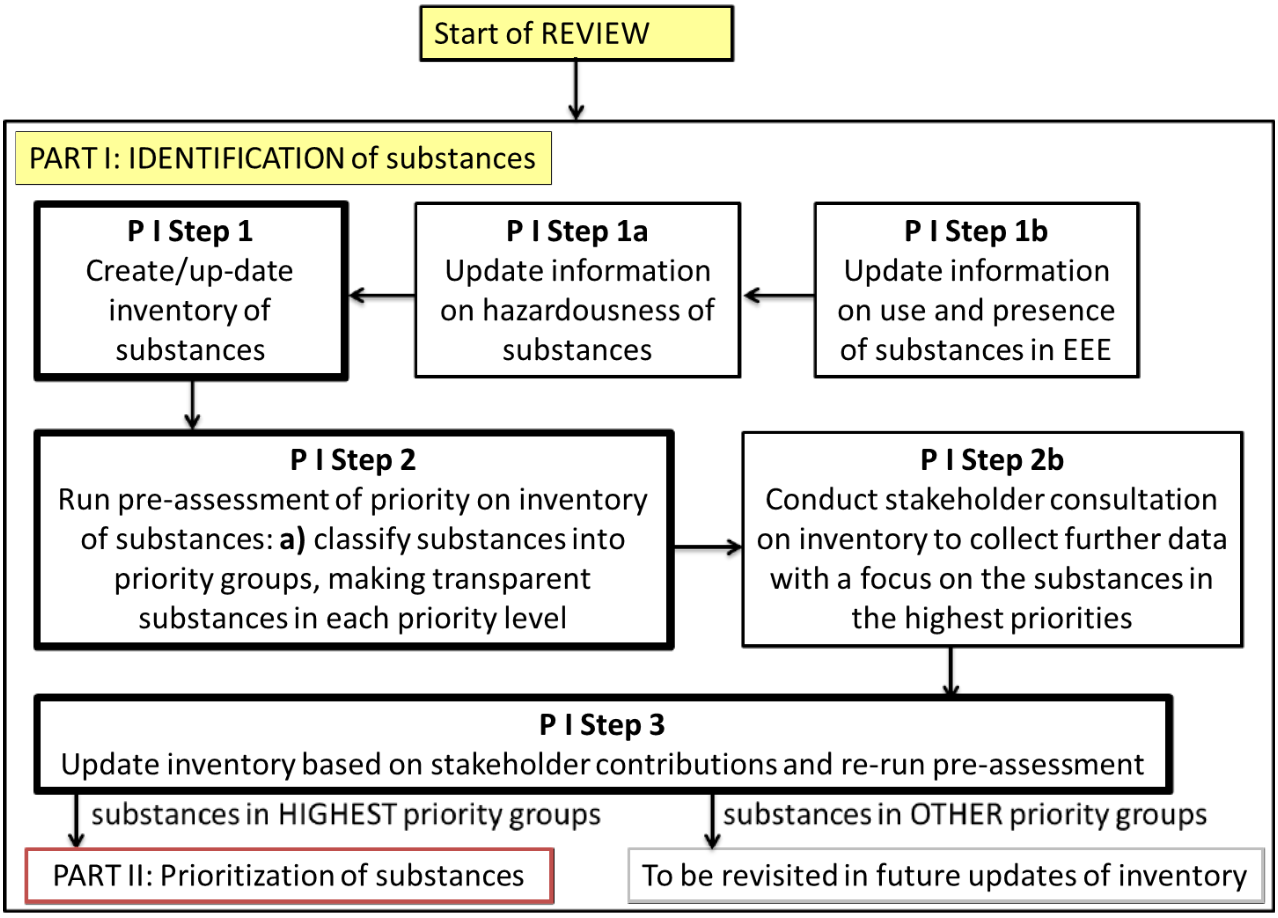
[16] Article 6(1)(b) provides inter alia the basis for restricting a substance, should its uses give rise to uncontrolled or diffuse release into the environment of the substance. This is understood to refer to possible releases related to the intended use of a substance but also to non-intended use, for example in the case of breakage.

[17] Substances used in manufacture of EEE may or may not be present in the final product. Similarly, substances present in EEE may or may not have been applied in this form in the manufacture. The inventory shall update information on substances used in manufacture and on substances present in EEE, specifying presence where this data is found to allow a differentiation at later stages.

[18] The number of substance (priority classes) to be subjected to the prioritisation of P II shall be discussed and approved with the EC, also depending on the study framework.

Figure 1-1 below provides an overview of how to identify these substances and illustrates the flow of decisions.

Figure 1-1: Workflow of identifying substances used in EEE with a potential negative impact during use, and/or on or during waste management



Source: Adapted with revisions from AUBA (2013)

An inventory of substances used in EEE was established during the first review of Annex II of RoHS in 2013-2014. The inventory established in 2013 AUBA provides a first basis to be updated in the following periodic reviews. Each further revision should use the initial inventory of the last revision as a first basis to be updated, adding and updating existing data before applying the various selection and prioritisation stages. For establishing the 2013 inventory, two main sources of information were used:

- Existing databases on substances where information is gathered and presented on the use of substances in products:
  - IEC 62474 database on material declaration
  - ZVEI-Umbrella specifications
  - ECHA-registered substances with the use descriptor “SU 16: Manufacture of computer, electronic and optical products, electrical equipment”

  - SPIN (Substances in Preparations in Nordic Countries) listed substances with NACE codes C26 “Manufacture of computer, electronic and optical products” and C27 “Manufacture of computer, electronic and optical products”

- Several studies conducted in past years dealing with the identification and evaluation of specific harms occurring from the use of hazardous substances in EEE.

A compilation of the databases and studies which were used for the 2013 inventory is provided in the Appendix, Section A.1.

On the basis of the information used, it is concluded that for substances in the 2013 AUBA inventory, evidence exists or existed at the time that the substance is present in EEE or suspected of such. In this sense, it is assumed that all substances in the 2013 AUBA inventory are in use in the manufacture of and/or present in EEE, though the range of volumes used is not known for most substances[19].

1.1. P I Step 1: Compile inventory of substances

Approach/Criteria: The final inventory (list of substances in excel form) from the last revision is to be used as a first basis and to be updated where relevant in relation to additional substances present in EEE or used in the manufacturing of EEE (e.g. new substances). Information for substances on the list should be updated where relevant in relation to hazard properties of the substances and their use or presence is EEE where such information is available.

Additional substances to be added to the inventory may be derived from sources that are specific for EEE in products or for manufacturing of EEE (e.g. IEC 62474, ZVEI umbrella specifications, and relevant studies/reports). The review of such sources is performed in P I Step 1b which runs in parallel to P I Step 1a and not included as a separate step.

1.1.1. P I Step 1a): Update information on substances which are hazardous

Approach/Criteria: To establish the initial inventory, data on hazardous properties of substances shall be updated in the list as relevant (i.e., where there have been changes). This shall include actual classifications and information for substances suspected of having hazardous properties, specifying the hazard properties of relevance.

On the one side, substances which have a harmonised classification of their hazardous properties (substances listed in Annex VI of the CLP regulation), and/or which have been identified as having PBT, vPvB and/or PB[20] properties and/or as having endocrine disruption properties shall be included in the inventory. Additionally, substances that are suspected of having such properties shall also be included, based on the process described below.

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[19] In its final report AUBA wrote that the list compiled on the basis of the above mentioned sources was manually screened for those substances, whose presence in EEE is not plausible, e.g. solvents. Some of those were subsequently removed from the EEE inventory and listed in a separate list titled “substance removed.

[20] In some cases a substance could be classified as persistent and bio-accumulative (PB), but not as toxic (T) seeing as existing classifications do not comply with the REACH Annex XIII, 1.1.3 criteria for fulfilling the PBT toxicity criterion. In other cases, a substance may be persistent and bio-accumulative (PB) but not toxic and still have negative impacts on the environment, such as for example in the case of micro plastics. For such cases it is of relevance to check possible fulfilment of the Article 6(1) criteria of the substance, depending on the priority assigned to the substance in the pre-prioritisation.

It is noted that though the term substance is not defined under RoHS, its definition under REACH and CLP are considered to clarify how this term is to be understood (see "Background", Section II.I):

> *"substance: means a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition"*

In this respect it is also noted that both regulations define the term polymer to mean "*a substance consisting of molecules characterised by the sequence of one or more types of monomer units [...]*" (REACH Article 3(5); CLP Article 3(11)). As polymers are considered to be substances it stands to reason that they could be considered for restriction under RoHS, i.e. included in the inventory list.

Table 1-1 gives an overview of the selection criteria.

Table 1-1: Criteria for the identification of candidates in the inventory master list as hazardous

The substance is/shows
Listed in Annex VI CLP (or fulfils the criteria that would justify a listing in Annex VI CLP)
Carcinogenic OR mutagenic OR reprotoxic [Categories 1A and 1B and 2]
PBT (persistent, bio-accumulative, toxic)
vPvB (very persistent, very bio-accumulative)
PB (persistent, bio-accumulative)
Substance of very high concern (SVHC) under REACH
Considered to have endocrine disrupting and/or other properties identified in accordance with Article 57(f) of REACH]
Suspected as any of the above (based on CoRAP; SIN List)

Source: Adapted with revisions from AUBA (2013)

Database on substance information: In order to update hazard information for substances in the list information on the identified or suspected priorities is to be compiled. A differentiation between identified properties (e.g., classification category) and between suspected properties shall be applied to allow prioritising substances identified as having hazardous properties at later stages. Exploration of the data is to be enabled by the filtering and sorting functionality supplied by standard spreadsheet software. Finally, a "flat table", using separate columns for the various hazard categories shall be generated.

Databases on hazardous substances on one side, as well as governmental lists on European, national and international level and lists from non-governmental organisations shall be screened or compiled and used for the identification of hazardous substances in the EEE inventory. The lists associated with a substance, hazard classifications and additional data can be gathered easily in the process and will facilitate selection and pre-assessment of specific substances later on.

The following references are to be used for the purpose of the update at hand:

- Classification and Labelling

Occurrence of a substance in Annex VI to the CLP Regulation (EC) No 1272/2008 is documented in the ECHA Table of harmonised entries in Annex VI to CLP[21]. Annex VI to the CLP Regulation lists the harmonised classifications and labelling for certain substances or groups of substances which are legally binding within the European Union.

- SVHC substances

Substances of very high concern which are candidates for future mandatory authorisation of use are found in the so-called “candidate list”[22]. The list currently contains 197[23] substances, and the respective reasons for concern are documented in Annex XV dossiers of the Member States (accessible under 'Details' in the Candidate List).

- Substances subject to Authorisation

SVHCs on the Candidate List can be prioritised for inclusion in Annex XIV (Authorisation List)[24]. There are currently 43 substances on the Authorisation List[25], which means that these substances cannot be placed on the Union market or used after a given date, unless an authorisation is granted for their specific use, or the use is exempted from authorisation. Information on substances recommended to be added to the Annex XIV list should also be compiled in the inventory master list in order to include information on substances where the process is still pending[26].

- Substances subject to restriction

When there is an unacceptable risk to human health or the environment, arising from the manufacture, use or placing on the market of substances, which needs to be addressed on a community-wide basis, a restriction may be added to Annex XVII of REACH for the substance or group of substances. The specified substance (or substances) on its own, in a mixture or in an article, for which restrictions are specified in Annex XVII shall not be manufactured, placed on the market or used unless it complies with the conditions of that restriction.[27] There are currently 69[28] substances listed on the list of restrictions.

- PBT properties

Data and results of the PBT working group of ECHA shall be considered for future reviews[29]. Furthermore, results of PBT/vPvB assessments performed under the previous EU chemicals legislation can be found on the ECHA website[30]. 127[31] substances are included in this data base, though not all have been found to comply with PBT or vPvB criteria.

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[21] https://echa.europa.eu/information-on-chemicals/annex-vi-to-clp

[22] http://echa.europa.eu/candidate-list-table

[23] Last viewed on 11.04.2019

[24] https://echa.europa.eu/authorisation-list

[25] Last viewed on 11.04.2019

[26] https://echa.europa.eu/previous-recommendations

[27] The list of restriction is available under https://echa.europa.eu/substances-restricted-under-reach

[28] Last viewed on 11.04.2019

[29] https://echa.europa.eu/de/pbt-expert-group

[30] https://echa.europa.eu/information-on-chemicals/pbt-vpvb-assessments-under-the-previous-eu-chemicals-legislation

[31] Last viewed on 11.04.2019

- High PB-score (RIVM-list)

RIVM, the National institute of Public Health and the Environment of the Netherlands, has developed a methodology to screen long-term fate and bio-accumulation potential in the environment. RIVM published a list of the 250 highest scoring PB substances[32].

- Endocrine disruptors

On 7 November 2018, the Commission published a communication "*Towards a comprehensive European Union framework on endocrine disruptors*" (COM 2018 734 final). This communication specifies that among others the Commission has taken action over the years "*against endocrine disruptors in line with the different requirements laid down in the relevant legislation*" with specific provisions for addressing endocrine disruptors having been included in the legislation on pesticides and biocides, in the REACH Regulation, and in relation to medical devices and water. "*These requirements vary depending on the specific legislation*". The Communication further specifies that "*substances with endocrine disrupting properties are subject to case-by-case regulatory action on the basis of the general requirements of the legislation*". It is thus understood that, substances with endocrine properties could be restricted under RoHS on a case-by-case basis, i.e. where justified on the basis of the Article 6(1) criteria.

The 7th Environment Action Programme (EAP), adopted in 2013 by the European Parliament and the Council, provided for the harmonisation of hazard-based criteria for the identification of endocrine disruptors. Scientific criteria have been established to identify substances with endocrine disrupting properties under the Plant Protection Products (PPP) Regulation (EC) 1107/2009[33] and the Biocidal Products (BP) Regulation (EU) 528/2012[34]

The REACH legislation (Article 57(f)), associates endocrine disrupting properties with a potential to generate both human and environment impacts. This approach has also been adopted here, meaning that consideration of a substance as endocrine disruptive would be taken into consideration for both environmental and health impacts and in relation to fulfilment of the Article 6(1) criteria on a case-by-case basis.

For the purpose of determining whether substances in the inventory have endocrine disrupting properties, the following sources shall be taken into account:

- Endocrine Active Substances Information System (EASIS): https://easis.jrc.ec.europa.eu/

  EASIS is a web-based application that allows searching and collecting results from different scientific studies on chemicals related to endocrine activity.

- ECHA's endocrine disruptor (ED) assessment list: https://echa.europa.eu/de/ed-assessment

  This list includes the substances undergoing an ED assessment under REACH or the Biocidal Products Regulation that have been brought for discussion to ECHA's ED Expert Group

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[32] http://www.rivm.nl/bibliotheek/rapporten/601356001.pdf

[33] Commission Regulation (EU) 2018/605 of 19 April 2018 amending Annex II to Regulation (EC) No 1107/2009 by setting out scientific criteria for the determination of endocrine disrupting properties; https://eur-lex.europa.eu/eli/reg/2018/605/oj

[34] Commission Delegated Regulation (EU) 2017/2100 of 4 September 2017 setting out scientific criteria for the determination of endocrine-disrupting properties pursuant to Regulation (EU) No 528/2012 of the European Parliament and Council; https://eur-lex.europa.eu/eli/reg_del/2017/2100/oj

Data and results of the Endocrine Disruptor working group of ECHA shall also be considered for future reviews.[35]

- The Community Rolling Action Plan (CoRAP)

CoRAP indicates substances that are to be evaluated by the Member States over the next three years. It is updated each year in March. ECHA prepares and adopts the CoRAP list in cooperation with the Member States on an annual basis, taking into account the criteria for selection of substances.

The initial concerns are related to potential hazardous properties: persistency, bio-accumulation and toxicity (PBT), endocrine disruption, or carcinogenicity, mutagenicity and toxicity to reproduction (CMR); in combination with wide dispersive use or consumer uses. The evaluation aims to clarify the initial concern, i.e. whether the manufacture and/or use of these substances could pose a risk to human health or the environment. Substances added to the inventory from the CoRAP list are to be specified as “suspected” of having respective properties, unless the properties are also identified in international and/or EU legislation. The current CoRAP list[36], published in March 2019, contains 375 substances.

- The ECHA public activities coordination tool (PACT)

The ECHA website includes a public activities organisation tool (PACT) [37] which gives an overview of the activities that authorities are performing under REACH and the CLP Regulation in relation to specific substances, as well as providing access to information generated through such activities. The data base is updated every 48 hours and specifies activities planned, ongoing or completed by the various authorities (ECHA, MS) in line with ECHA’s Integrated Regulatory Strategy in the following areas:

  - Data generation and assessment related to the evaluation of substance dossiers, substance evaluation, information generated through informal hazard assessment (PBT/vPvB/ED), etc.
  - Activities related to the Regulatory management option analysis (RMOA).
  - Activities related to regulatory risk management, such as in the process of harmonised classification and labelling (CLH) and of SVHC identification and restriction.

- The International Chemical Secretariat (ChemSec) SIN List

The International Chemical Secretariat (ChemSec) has specified and updates the SIN List, which identifies potential substances of concern based on the criteria defined within REACH. The list is explained to be a measure for putting pressure on legislators to assess and where relevant address substances identified therein in the future in respect of relevant chemical legislation. It is also understood to give indication to manufacturers as to substances the use of which should be avoided, as listed substances are suspected as hazardous and could be regulated in the future. Based on the EU REACH criteria for identifying substances as SVHC, Chemsec applies a number of categories for adding substances to the SIN List, including substances that can cause cancer, alter DNA or damage reproductive systems (CMR properties); substances that do not easily break down and that accumulate in the food chain (PBT/vPvB substances); and substances of equivalent concern that give rise to an equivalent level of concern in terms of potential damage to health and environment (such as substances with endocrine disrupting properties). The rational for in-

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[35] https://echa.europa.eu/endocrine-disruptor-expert-group

[36] https://echa.europa.eu/de/information-on-chemicals/evaluation/community-rolling-action-plan/corap-table

[37] https://echa.europa.eu/de/pact

cluding substances in the SIN List is based on a scientific review and the reasons for the addition of substances to the list are specified.[38] Substances added to the inventory from the SIN list are to be specified as "suspected" of having respective properties, unless the properties are also identified in international and/or EU legislation.

- Nano Materials

According to the RoHS Directive, special account shall be given to nanomaterials[39]. This is taken into account through adding information on the possible use and/or presence of substances in nanomaterial form in EEE. Following the precautionary principle, it is relevant to gather information as to the possible use of a substance in nanomaterial form alongside information on the hazardous properties of a substance. This should support the assessment of actual impacts in use and or WEEE management at a later stage on a case-by-case basis. In this sense, the fact that a substance may be applied in nanomaterial form does not on its own comprise a hazard. However, for some substances, the size of the particle applied, in combination with its hazards, may affect the severity of impacts to occur[40] or under which conditions they occur. In this sense, adding such information to the inventory at this stage is to indicate for the prioritisation and assessment stages that it should be reviewed whether the substance is applied in EEE among others also in nanomaterial form and whether such applications actually lead to impacts of relevance for the Article 6(1) criteria.

General information on nanomaterials can be found on the European Commission website on nanotechnologies[41]. In 2012, the Commission published a "Communication on the Second Regulatory Review on Nanomaterials" that assesses the adequacy and implementation of EU legislation for nanomaterials and indicates follow-up actions in order to improve EU law and its application to ensure their safe use.[42] This document is accompanied by a Commission Staff Working Paper on nanomaterials, which provides an overview of available information on nanomaterials on the market, their types and uses, as well as on safety aspects[43]. Additional information on data sources on the use of nanomaterials is provided in Annex A.1.1.

In future reviews of the inventory, following the initial update of the list established in the past review in P I Step 1, information on hazardous properties shall be updated in Step 1a concerning:

- additional substances that have been added to the inventory in light of evidence on use and/or presence in EEE;
- changes in identification of the hazard properties of the substances already appearing in the list.

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[38] http://chemsec.org/business-tool/sin-list/about-the-sin-list/, last viewed 24.07.2018

[39] Various uses of nanomaterials in electronics are reported. Nanomaterials are used in energy generation (e.g. photovoltaics) and storage (e.g. fuel cells and batteries), information and communication technologies, electronics and photonics (e.g. semiconductor chips, new storage devices and displays); security (e.g. sensors). Whereas exposure to humans and the environment at the use stage is considered to be low because it is bound in a matrix in most uses, there are ongoing discussions whether release at the waste stage could lead to exposure to significant amounts of nanoparticles. Impacts on recycling are also under investigation.

[40] For example, impacts occurring in the case of substances used in nano-form and identified with hazard properties related to respiration and inhalation (e.g. H330 - fatal if inhaled, etc.) may be more severe than when the substance is used in bulk form. In such cases, exposure to the nano-form of a substance, may allow the substance to penetrate deeper in the respiratory system. Additional information can be found in the various studies referenced here and in Appendix A.1.1.

[41] See: http://ec.europa.eu/research/industrial_technologies/nanoscience-and-technologies_en.html

[42] For further information see: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A52012DC0572

[43] For further information see: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52012SC0288

1.1.2. P I Step 1b): Update information on use and presence of substances in EEE

Approach/Criteria:

EEE contain a wide variety of substances and materials, including toxic or otherwise hazardous ones. Possible impacts of relevance to Article 6(1) can only be expected to be relevant for substances actually present in EEE. It is thus of importance to identify whether substances in the inventory are used or could be used (potential substitutes) in EEE as a step towards prioritisation. It is noted that the fact that information on use in the public realm is lacking shall not be a basis of excluding potential use, but rather feed into the later prioritisation stages. It is also noted that substances that react during use or are intermediates nonetheless are to be kept in the inventory and prioritised (see 1.1.2.1 for further detail).

The list updated through Step 1a is to be updated in parallel in relation to available information as to the use and/or presence of the substance in EEE. Where such data includes information as to volumes of use, this information should also be specified in the inventory. This step can be performed in parallel to PI Step 1a. Where substances are identified in this stage that were not on the initial list, care should be taken to check and add information as to their hazard properties as described n P I Step 1a.

For the purpose of this up-date stage, among others, the following lists and sources should be consulted with:

- Substances listed in the IEC 62474 Database „Declarable substance groups and declarable substances“ (IEC 62474 - Material Declaration for Products of and for the Electrotechnical Industry). It is understood that substances or substance groups are added to the list of declarable substances on the basis for example of regulatory requirements or requirements of industry standards that set reporting thresholds[44]. Three categories are specified in this respect:
  - Criteria 1: Currently Regulated;
  - Criteria 2: For assessment;
  - Criteria 3: For information only.
- ZVEI-Umbrella specifications[45]: A copy of the last version of the Umbrella specifications published online, still available in 2009, was submitted to the Commission and should be used for this step as far as newer versions do not become available.
- Information on substance uses as available from the registration process under REACH: substances with the use descriptor SU 16 "Manufacture of computer, electronic and optical products, electrical equipment" (to be specified in search under Uses and exposures>Sector of use)[46].
- Information on substance uses (Nace-codes C26 "Manufacture of computer, electronic and optical products" and C27 "Manufacture of computer, electronic and optical products"[47]) as availa-

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[44] For further details see: http://std.iec.ch/iec62474/iec62474.nsf/MainFrameset

[45] See: https://www.zvei.org/verband/fachverbaende/fachverband-electronic-components-and-systems/materialdatendeklaration-auf-produktebene-und-mittels-umbrella-specifications-auf-basis-von-produktgruppen-als-effizientes-beispiel/

[46] See: https://echa.europa.eu/information-on-chemicals/registered-substances

[47] Relevant uses to be selected

ble from the Nordic Product Register (SPIN – substances in preparations in Nordic countries - register)[48];

- Information from requests for new RoHS exemptions / renewal of exemptions / withdrawal of exemptions, in which potential substitutes are addressed.

1.1.2.1. P I Step 1b.1) Quality check of the inventory of substances used in EEE

Due to the different nature of the above-mentioned substance lists an initial comparative screening of the obtained substances has to be performed. The purpose of this screening shall be to identify where there are discrepancies related to the use and presence of substances in the various sources consulted. Such discrepancies should be noted, however even where clear evidence exists that a substance is not present in EEE, it should not be excluded from the list, but rather the information should be noted. As clear from the following examples, lack of presence does not always indicate no risk of impacts on health and environment:

- Some substances may be potential regrettable substitutes for others[49]. Should the latter be restricted or proposed for restriction, it may become relevant to restrict a substance that is not present in EEE in order to prevent regrettable substitution.
- Some substances are used as intermediates/process chemicals, particularly as reacting agent within a process. In such cases, the substance may not be present in the final component, or may be present in non-relevant quantities. Nonetheless, assessment of such substances should not be excluded as in some cases, this is a starting point for identifying residues, transformation or degradation products of the substance[50] of hazardous nature which remain in the final component and could be eligible for restriction in the future.

Reference to the discrepancies is thus relevant to later stages, for considering how to proceed with prioritisation and how this information should be considered in an assessment of the substance or of substances for which it may be a substitute.

1.2. P I Step 2: Priority Pre-assessment of priority of inventory substances

Approach/ Criteria: Pre-assessment of the identified relevant substances **aims** at determining which substances / substance groups have the highest potential for fulfilling the Article 6(1) criteria and should be subjected to the prioritisation in P II. The process described in this section aims at establishing a sub-selection of the substances initially identified for the inventory in relation to the priority for further assessment.

Substances addressed through existing restrictions that cover EEE shall be excluded from the inventory.

In order to select the substances with the highest potential for fulfilling the Article 6(1) criteria, a pre-assessment of the priority of the substances in the inventory shall be applied. This shall result in substances being classified into priority groups based on information of their hazard properties and of their volume of use/presence in EEE. This shall make transparent which substances are in each priority level and allow stakeholders to identify which substances shall be submitted to the

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[48] See: http://spin2000.net/

[49] For example, di-isobutyl phthalate (DiBP) was restricted on the basis of its potential to be used as a substitute for other restricted phthalates.

[50] An example is AsO3, where – even if not contained in a glass matrix as AsO3 - in cases of use, contained compounds may be released during the crushing or milling of glass.

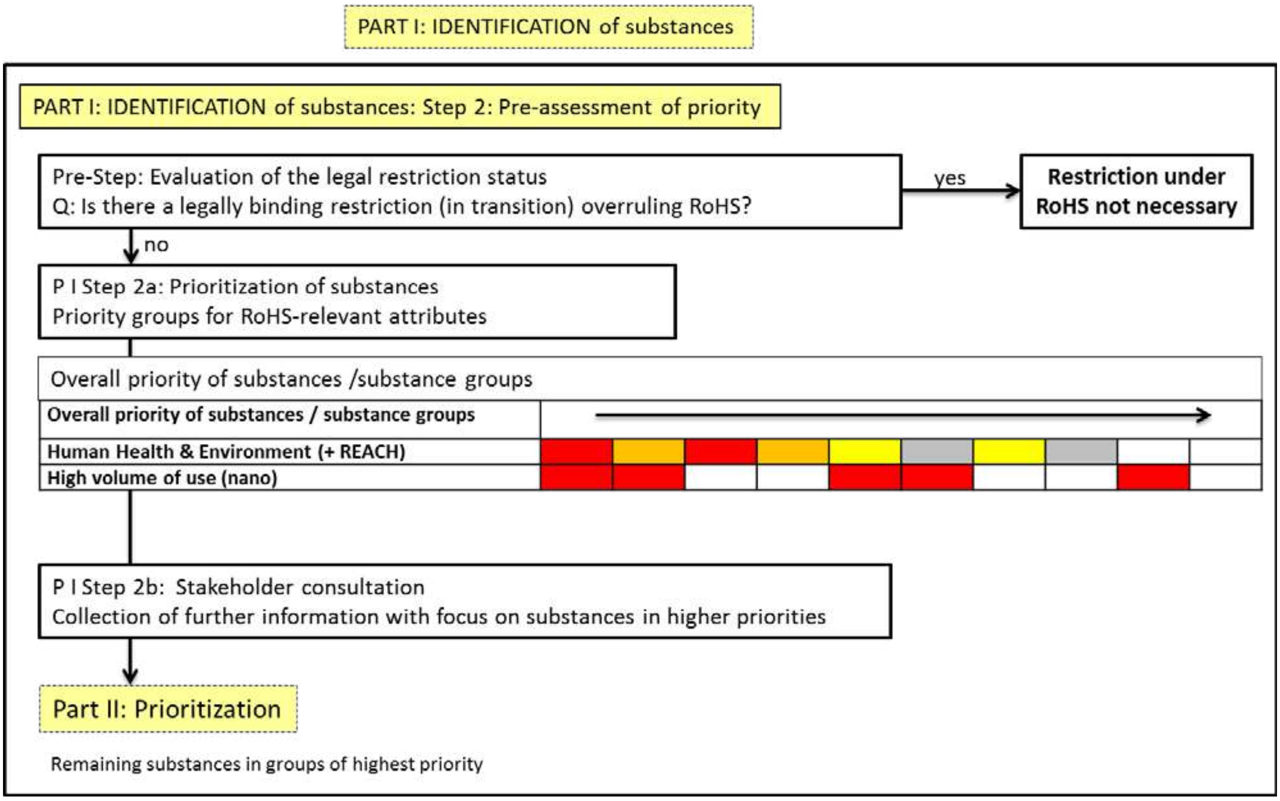
prioritisation in P II, assuming additional data is not available through stakeholder consultation prior to the final pre-assessment of priority to be carried out in P I Step 3.

The exclusion of a substance from the inventory at this stage (or allocation of a lower priority for its review) is applied during a revision of the substance inventory. However, the substance is not removed from the initial inventory to be processed in future reviews, i.e., the relevant legal status and fulfilment of Article 6(1) are to be revised during each periodic review. Substances with no data in relation to hazard properties and use/presence shall be classified in a group of the lowest priority and shall not be explicitly viewable in the inventory.

Additional information shall then be collected through a stakeholder consultation, with a focus on the substances classified with higher priority in the inventory. See 1.3.2 P I Step 2b): Stakeholder consultation of substances in inventory with focus on substances in higher priority groups in this respect.

Figure 1-2 below provides an overview of the individual steps of the pre-assessment and illustrates flows of information and decisions.

Figure 1-2: Workflow of priority pre-assessment of identified substances (the arrow displays decreasing priority)



Source: Adapted with revisions from AUBA (2013)

1.3. P I Pre-Step 2 Evaluation of the legal restriction status

The **aim** of the Pre-step is to exclude substances, where a restriction under RoHS is not required, as the substance is already restricted under RoHS or at a level overruling RoHS in other legislation or where a legally binding restriction is underway, i.e., expected in the foreseeable future.

- **Criteria**: The substance is excluded if it is:
- Restricted or to be restricted (within duration of the transition period) under the RoHS Directive. Generally, substances that are under assessment for a possible RoHS restriction could be excluded from the inventory, however a future assessment may be needed in cases where information is identified as lacking or where in the future new evidence becomes available. Thus, substances under assessment should be left in the inventory and specified as such. Substances assessed in the past and found not to fulfil the Article 6(1) criteria should also be noted as such and only submitted to the pre-prioritisation where new evidence has become available.
- Restricted in accordance with the REACH Regulation (Annex XVII), provided that the scope of the restriction would make a RoHS restriction redundant;
- Prohibited and/or restricted in accordance with the POPs Regulation (EC) No 850/2004 and its amendments, provided that the scope of the decision (exemptions/acceptable uses) would make a RoHS restriction redundant;
- A decision to list the substance (or substance group) in Annex A (elimination) and/or Annex B (restriction) of the Stockholm Convention has been taken by the Conference of the Parties (COP) and its implementation is pending, provided that the scope of the decision (exemptions/acceptable uses) would make a RoHS restriction redundant[51]:
  - Identification of the substance as a candidate for listing in the Convention shall not result in the exclusion of a substance. If the Persistent Organic Pollutants Review Committee (POPRC) has recommended inclusion in Annex A and/or Annex B of the Convention[52], and provided that the scope of the decision (exemptions/acceptable uses) would make a RoHS restriction redundant, the substance should be specified with a lower prioritisation.
- Covered by the Montreal Protocol, the Regulation (EC) No 1005/2009 on substances that deplete the ozone layer, and the F-gas Regulation (EC) No 842/2006[53].

1.3.1. P I Step 2a) Pre-prioritisation of substances

The **aim** of step 2 is to identify those substances or groups of substances which are of highest concern regarding their potential negative impact on human health and/or the environment during use and/or WEEE management.

The pre-prioritisation at this stage is performed to allow a differentiation between substances that should be assessed earlier than others. To refine this prioritisation a first estimation of fulfilment of the Article 6(1) criteria is to be performed in the prioritisation (P II), whereas an actual assessment of the actual range and severity of possible impacts shall be investigated in more detail during the assessment of a substance (P III). In this sense the pre-prioritisation should not be seen as an actual assessment of impacts but rather of the potential for various impacts to occur.

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[51] See further information under:

- Convention text and amendments: http://chm.pops.int/TheConvention/Overview/TextoftheConvention/tabid/2232/Default.aspx
- Reports and decisions of the COP: http://chm.pops.int/TheConvention/ConferenceoftheParties/ReportsandDecisions/tabid/208/Default.aspx

[52] See POPRC “reports and decisions” and “recommendations” under following links:

- http://www.pops.int/TheConvention/POPsReviewCommittee/ReportsandDecisions/tabid/3309/Default.aspx
- http://www.pops.int/TheConvention/POPsReviewCommittee/Recommendations/tabid/243/Default.aspx

[53] See: http://ozone.unep.org/montreal-protocol-substances-deplete-ozone-layer/32506

Approach: In order to prioritise substances / substance groups, a grouping system based on the assessment of the following three attributes shall be applied:

- Hazardous properties / Human Health & Environment (including special consideration where substances appear in Annex XIV or Annex XVII of REACH);
- High volumes of use and/or presence in EEE (including special consideration for substances used among others in nano material form); and
- Possible use of a substance as a substitute for a substance restricted or to be restricted (in transition period) under RoHS.

1) Hazardous properties

The grouping system for hazardous properties developed for this methodology is based on the following considerations:

- hazard categories according to CLP;
- criteria for PBT/vPvB/endocrine disrupting properties as specified in REACH;
- PB properties (seeing as in some cases, toxic properties may not yet be classified, but evidence of impacts may exist in test results or other information and data).
- hazardous properties of waste specified in Annex III of the WFD; and
- properties according to the SVHC criteria.

In general, the CLP hazard categories (1, 1A, 1B) as well as substances identified as SVHC substances according to REACH (PBT; endocrine, equivalent level) are considered to represent the most severe effects in relation to a specific hazard property, whereas the CLP category 4 stands for the least severe hazard in relation to a specific hazard property.

Two main hazard categories, i.e. Human Health Hazards and Environmental Hazards, with three groups (Group I, Group II, Group III) each have been defined (see Table 1-2 and Table 1-3). The differentiation between the respective hazard groups is based on a combination of hazard properties (and where relevant also category) of substances on the REACH Candidate list (SVHC) with the Hazard Statement weighting factors of the Technical Rules for Hazardous Substances (TRGS) of the German BAuA [54]. Hazard properties (and where relevant also category) that fulfil the SVHC criteria are included in Group I. Such properties typically have a weighting factor (WF) of 1000 and above. In some cases (Toxic for reproduction Cat. 1 and 2; Respiratory sensitisation Cat. 1), properties with a WF of 500 are also on the REACH Candidate list (i.e. SVHC) and thus would also be included in Group I. Group II includes properties (and where relevant also category) with a weighting factor of 500, which not on the Candidate list and Group III includes properties with a weighting factor of 100 or below.

The hazardous properties prioritisation is specified below:

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[54] See Technical Rule for Hazardous Substances (TRGS) 600 Substitution, established by the Committee on Hazardous Substances (AGS) and announced by the German Federal Ministry of Labour and Social Affairs, Edition: August 2008 (unofficial version; mandatory is the current German version), Annex 2 Comparative assessment of the health and safety hazards (column and effect factor model), 2: The effect factor model, pg. 21: https://www.baua.de/EN/Service/Legislative-texts-and-technical-rules/Rules/TRGS/pdf/TRGS-600.pdf?__blob=publicationFile&v=2

1a) Hazardous properties / **Human health**

Table 1-2 shows the allocation of individual substance properties to three human health hazard groups.

Table 1-2: Human Health Hazard Groups

Human Health Hazard – Group I
Carcinogenic (CLP Category 1A or 1B)* (WF 1000)
Germ cell mutagenic (CLP Category 1A or 1B)* (WF 1000)
Toxic for reproduction (CLP Category 1A, 1B, or 2)* (WF 500)
Specific target organ toxicity after repeated exposure (CLP STOT RE Category 1)* (WF 500)
Specific target organ toxicity after single exposure (CLP STOT SE Category 1) (WF 1000)
Endocrine disruptive
Respiratory sensitisation (CLP Category 1) WF 500 (where included in the candidate list)
Acute toxic (CLP Category 1 and 2) WF ≥1000
Aspiration toxicity (CLP Category 1) (WF 1000)
Human Health Hazard – Group II
Skin sensitisation (CLP Category 1) (WF 500)
Respiratory sensitisation (CLP Category 1) WF 500 (other)
Respiratory sensitisation (CLP Category 2)
Human Health Hazard – Group III
Specific target organ toxicity at single exposure (CLP STOT-SE Category 2 and 3) (WF ≤100)
Acute toxic (CLP Category 3 and 4) (WF ≤100)
Carcinogenic (CLP Category 2) (WF 100)
Reprotoxic (CLP Category 2; Lact.) (WF ≤100)
Mutagenic (CLP Category 2) (WF 100)
Skin corrosion/irritation (CLP Category 1A, 1B, 1C, 2) (WF ≤100)
Serious eye damage/eye irritation (CLP Category 1, 2) (WF ≤100)

Source: Adapted and revised from AUBA (2013)

Notes: *The criteria for toxicity of a substance as specified under Annex XIII, 1.1.3 of REACH refer to STOT RE 1 and 2, however this is assumed to be in group 1 only when PBT are all identified, whereas where only T is identified, the weighting factors are considered.

1b) Hazardous properties / **Environmental hazards**

Table 1-3 below provides the allocation of individual substance properties to three environmental health hazard groups. As there is no CLP classification on PB properties (persistency and bio-accumulation potential), other data sources are used and shall be checked to gain additional information on potential P and B properties. The listed sources should only be deemed relevant if final conclusions on assessment are available.

For example:

- Results of the PBT- working group at ECHA[55];

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[55] See: https://echa.europa.eu/pbt-expert-group

- Evaluations of UNEP, UNECE and POP-RC[56];
- The European Commission's Joint Research Centre (JRC) Risk assessment reports/Existing substances information system/PBT assessment[57]:
- US National Library of Medicine, Toxicology Data Network (Toxnet)[58]

Table 1-3: Environmental Hazard Groups

Environmental Hazard Group I
PBT (persistent, bio-accumulative, toxic) according SVHC criteria REACH
vPvB (very persistent and very bio-accumulative) according SVHC criteria REACH
Endocrine Disruptive
Hazardous to the aquatic environment (CLP Chronic Category 1, 2) (WF 1000)
Hazardous to the aquatic environment (CLP Acute Category 1) (WF 1000)
Hazardous to the ozone layer (CLP Category 1) (WF 1000)
Environmental Hazard Group II
PB (persistent and bio-accumulative)*,**
Environmental Hazard Group III
Hazardous to the aquatic environment (CLP Chronic category 3, 4)
Persistent (REACH criterion)* or bio-accumulative (REACH criterion)**

Source: Adapted and revised from AUBA (2013)
Notes: * REACH Annex XIII, 1.1.1
** REACH Annex XIII, 1.1.2

The information required under Part I, Step P I-2b1a, shall be analysed systematically and shall constitute the following criterion:

- Criterion A: There is evidence that the substance/ substance group has relevant hazard properties.

Fulfilment of this criterion shall be decided considering the hazard level resulting from the classification conducted on the basis of Table 1-2 and Table 1-3. Where substances are only suspected of a certain hazard (overall hazard group IV - see Table 1-4 below), this shall be updated in the inventory (grey colour), and reviewed in the future if evidence becomes available.

Refinement of the Criteria A Prioritisation due to authorisation/restriction under REACH

In certain cases, a substance may be addressed under the REACH Regulation (Authorisation, Restriction) or regulation may be under consideration. On the basis of the Common Understanding (COM 2014), and to ensure coherence with REACH, in such cases, as explained below, it shall be of a higher priority to assess whether such substances when used and/or present in EEE fulfil the RoHS Article 6(1) criteria and whether a RoHS restriction would achieve a higher level of protection than the REACH route.

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[56] See: www.pops.int/TheConvention/POPsReviewCommittee/Meetings/POPRC14/Overview/tabid/7398/Default.aspx

[57] See: https://ec.europa.eu/jrc/en/publications-list/pbt

[58] See: http://toxnet.nlm.nih.gov/

If the substance is listed in Annex XVII[59] under REACH (Restriction on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles) and the restriction covers applications in EEE or if such a restriction has been proposed, the substance shall be prioritised for assessment. Substances proposed for restriction shall be specified with the highest priority, so that the assessment process under RoHS is completed so as to allow the restrictions under REACH and RoHS to be amended in proximity. The logic behind this prioritisation is related to REACH having a focus on the manufacturing and use phases in contrast to RoHS which focuses on the waste phase as well as the use phase. In this sense, it is possible that for certain substances, impacts during the waste phase would justify a stricter restriction (e.g. threshold, scope) to allow prevention of impacts during the waste phase. Where a restriction is under consideration, it would also be of importance to conclude under which legislation the restriction would be more effective so as to avoid uncertainties related to double legislation. In this sense, the parallel or proximate assessment under RoHS could in some cases be important to conclude if EEE should be excluded from a REACH restriction where RoHS could ensure a higher level of environmental protection (i.e. similar level in relation to use along with prevention of waste phase impacts not addressed through REACH).

If the substance is listed in Annex XIV[60] of REACH (List of substances subject to authorisation) and is used and/or present in EEE or if it has been proposed to add the substance to Annex XIV, it should then be prioritised for assessment under RoHS. Such substances shall be specified with the highest priority, to complete the assessment process under RoHS so as to allow the authorisations under REACH and the restriction under RoHS to be amended in proximity. Substances, for which an authorisation for manufacture and use is required under REACH, cannot be used in EEE manufacture that takes place within the EU. Nonetheless, such substances could still be placed on the EU in imported EEE articles, i.e. manufactured outside the EU. Thus, the REACH authorisation route in this case would not prevent impacts related to the use of a substance in an imported article. Therefore, the aim of the assessment is to clarify if the use and presence of the substance in (imported) EEE results in the fulfilment of the Article 6(1) criteria.

Therefore, where a substance is listed in Annex XIV and/or in Annex XVII of the REACH Regulation or if such a listing is under consideration, a RoHS assessment should be prioritised for this purpose and would result in the substance being moved to Group I in relation to its hazard group prioritisation (i.e. red colour).

2) Use relevance

For evaluating the relevance of a substance / substance group in relation to its use and/or presence in EEE, the grouping system described as follows shall be applied.

Where information indicates use and/or presence of the substance /substance group in EEE in high volumes it is assumed to indicate a higher potential for the criteria specified in Article 6(1) of RoHS to be fulfilled. Thus, for the following grouping system, the information required under P I, Step 1b, shall be analysed systematically and shall constitute the following criterion:

- Criterion B: There is evidence that the substance/ substance group is used and/or present in EEE in high volumes;

For the purpose of determining this criterion, the REACH registration volume principles are to be used. High volume of a substance is to be assumed when

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[59] See list of restrictions under REACH under: https://echa.europa.eu/substances-restricted-under-reach

[60] See list of authorisations under REACH under: https://echa.europa.eu/authorisation-list

- the annual use is ≥ 1 tonne for substances exhibiting CMR properties; or
- the annual use is ≥ 100 tonnes for substances classified as very toxic to aquatic organisms; or
- the annual use is ≥ 1000 tonnes for all other substances.

Where there is information that a substance is used in such volumes, criterion B shall be considered fulfilled (red colour).

It can be understood that in some cases, impacts of a substance used in nanomaterial form may be more severe than when used in bulk form. It should thus also be considered for the interpretation of high-volume use, whether the substance could be applied as a nanomaterial in EEE applications. Where this is the case, it is possible that a smaller volume of use would result in severe impacts in relation to the Article 6(1) criteria. To take consideration of this aspect in the pre-prioritisation, criterion B is to be considered fulfilled (red colour) when a substance may be used in nanomaterial form in certain EEE applications, despite its EEE use volume being below the above specified thresholds.

Fulfilment of criteria B shall be concluded on a yes/no basis depending on whether supporting information exists or not.

3) How to determine the overall priority of substances / substance groups

To determine the overall priority of a substance, all data compiled are to be reviewed and categorised.

Fulfilment of criterion A shall be based on the colour coding specified in Table 1-2 and Table 1-3 and shall result in priority groups being associated with the relevant colour coding for the (health and environmental) hazard groups. The overall relevance of a substance / substance group regarding its hazardous properties (human health & environment) is determined as described in Table 1-4 below.

Table 1-4: Hazard Groups

Hazard Group (Human Health & Environment) I
Properties of the substance/substance group are allocated either to Human Health Hazard – Group I or* to Environment Hazard – Group I
Hazard Group (Human Health & Environment) II
Properties of the substance/substance group are allocated either to Human Health Hazard – Group II or* to Environment Hazard – Group II (none to Group I)
Hazard Group (Human Health & Environment) III
Properties of the substance/substance group are allocated either to Human Health Hazard – Group III or* to Environment Hazard – Group III (none to Group I or II)
Hazard Group (Human Health & Environment) IV
Substance is only suspected of one or more of the hazard properties specified in Table 1-2 or Table 1-3.

Source: Adapted with revisions from AUBA (2013)

Notes: * properties of a substance could be allocated in some cases to both human health and environment hazards. Nonetheless, it suffices that one hazard is allocated to the groups described above to result in the specified ranking, thus the term “or” is used.

Fulfilment of criterion B shall be based on the information on use relevance (high volume of use and nanomaterials). Criterion B (high volume) shall be specified either as fulfilled (red) or not (no colour):

- where there is evidence that a substance/substance group is used/present in high volumes in EEE; or
- where there is evidence that a substance/substance group is used/present in EEE and may be applied in nanomaterial form.

The differing colour coding of the two criteria result in evidence related to use relevance having a higher weight than the hazard class of a substance alone. This is justified with the understanding that despite the hazard class of a substance, impacts related to the Article 6(1) criteria would not be expected where the substance is not in use/present in EEE. Seeing as data on volumes of use if not always available, here a staggered approach is used: The final prioritization gives preference:

- first, to cases where there is indication of higher use volumes in the higher hazard classes (high and moderate),
- then to cases in these hazard classes with no data on use;
- and then to other hazard classes depending on the availability of data as to use.

The higher weight of data on waste is related to the possibility that there may be cases where the hazard class suggests no or low hazard, but where use results point to negative impacts during the use and/or waste phase nonetheless (particularly in cases of “new” substances where evidence supporting classification has not yet been established or processed)[61]. For example, if the substance could give rise to uncontrolled or diffuse release into the environment or could give rise to hazardous residues. Nonetheless, the objective of the RoHS Directive is understood to be “*contributing to the protection of human health and the environment, including the environmentally sound recovery and disposal of waste EEE*” (Article 1). Against this background, it is assumed that where Article 6(1)(a-c) criteria are fulfilled, the substance/substance group would likely be associated with human health or environmental hazards.

The awarded colour coding is to be compiled and the overall priority determined based on Table 1-5 below. The overall priority of a substance or substance group is defined by the frequency of particular priority groups (colours) for criterion A (human health hazards & environmental hazards) and for criterion B (high use volume/use+nano).

Table 1-5: **Overview of possible colour combinations for the highest overall priority categories**

Criteria	**Colour coded priority**									
Human Health & Environment (REACH Annexes)	🟥	🟧	🟥	🟧	🟨	▒	🟨	▒		
High volume of use (nano)	🟥	🟥			🟥	🟥			🟥	
Resulting overall priority of substances / substance groups	I	II	III	IV	V	VI	VII	VIII	IX	X

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[61] It is noted that that in such cases, there would need to be evidence of negative impacts related to the Article 6(1) criteria. The mere use and/or presence of a substance in high volumes in EEE would not on its own justify a restriction.

Source: Adapted with revisions from AUBA (2013)

Substances where the human health & environmental hazards are of high priority (red) and where criteria B is fulfilled are classified with the highest priority.

Substances where the human health & environmental hazards are of moderate (orange) priority and where criteria B is fulfilled are classified with the second highest priority.

Substances where the human health & environmental hazards are of high priority (red) or moderate priority and where criteria B is not fulfilled are classified with the third and fourth highest priorities, respectively.

Substances, where the human health & environmental hazards are of low priority (yellow) and criterion B is fulfilled are classified as the fifth highest priority.

Substances, where the human health & environmental hazards are only at suspicion level (grey) and criterion B is fulfilled are classified as sixth highest priority.

Substances, where the human health & environmental hazards are of low priority (yellow) or at suspicion level (grey) and criterion B is not fulfilled are classified as seventh highest priority

Further priority (colour) combinations are displayed in Table 1-5 above.

1.3.2. P I Step 2b): Stakeholder consultation of substances in inventory with focus on substances in higher priority groups

Approach: For a further differentiation of substances / substance groups of equal priority, further information on volumes used in EEE should be sought through a stakeholder consultation. This consultation should be held according to the specifications of the EU guidelines for stakeholder consultations.[62]

Following the pre-assessment of priority, the substances in the lowest priority group (X) shall be kept in the database but not be explicitly listed in the inventory. Substances in the highest priorities shall be highlighted. Decision on the highest priorities to be highlighted shall be taken after consultation and approval by the Commission, depending on the number of substances to be subject to the prioritisation in P II. Questions should be prepared for stakeholders, emphasizing that the substances included in the highest priority groups shall be subjected to the prioritisation in P II provided further information collected shall not change the group classification. In this way, stakeholders shall be asked to concentrate their efforts in collecting and providing further information on substances in the higher priority groups with the aim of either:

- Providing evidence that a substance in the highest priorities should have a lower priority based on new evidence related to, e.g. a lower volume of use or no suspected use in EEE;
- Providing evidence that a substance in a priority group not subject to the prioritisation in P II should have a higher priority, based on new evidence related to, e.g. a high volume of use in EEE or evidence of impacts related to the Article 6(1) criteria;

A substance could fulfil the Article 6(1) criteria in some cases regardless of its hazardous substance properties or their severity. Thus, care should be taken that stakeholders invited to partici-

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[62] The online stakeholder consultation shall be conducted following the minimum standards for consultation of interested parties set out in the Commission Communication COM (2002) 704 final of 11.12.2002, COM(2012) 746, COM(2012) 746, SWD(2012) 422, COM(2014) 368, and SWD(2015) 111.

pate in the stakeholder consultation represent "*interested parties, including economic operators, recyclers, treatment operators, environmental organisations and employee and consumer associations*" (Article 6(1)) and not just manufacturers and the supply chain. For example, waste operators shall be able to contribute relevant information for cases where a substance should be prioritised as it "*could have a negative impact during EEE waste management operations, including on the possibilities for preparing for the reuse of waste EEE or for recycling of materials from waste EEE*".

Stakeholders should also be asked to provide information as for substances that should be considered in the prioritisation and or in the assessment as members of a substance group.

1.4. P I Step 3: Update inventory based on stakeholder contributions and re-run pre-assessment

Approach: Information on the volumes of the substance / substance groups used in EEE entering the Union market and other information gathered through the stakeholder consultation held in P I Step 2b (see Section1.3.2) should be added to the inventory. Subsequently the pre-assessment of priority run in P I Step 2a should be performed a second time to determine which substances are in the highest groups and thus which substances shall be subjected to the prioritisation in P II.

At this stage, it should also be considered that substitutes for substances that are already restricted, soon to be restricted (transition) or that shall possibly be restricted (recommended for restriction) should be attributed a higher priority if it has been determined during a substance assessment that they have a similar potential for fulfilling the Article 6(1) criteria and thus could be considered a regrettable substitution. In cases of a substance being recommended for restriction, the Commission could conclude on regrettable substitution based on the information available and could initiate a substance assessment bypassing the identification and prioritisation process.

Substances in the highest priority groups shall be put on a short list, creating a so called "RoHS-Working-List"[63]. This list shall be subjected to the prioritisation in P II.

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[63] The groups for which the refinement is to be performed shall be discussed and approved with the Commission. The selection can be performed automatically using the features of the established substance database (RoHS-working-list.xls)

2. Part II: PRIORITISATION OF SUBSTANCES: Targeted approach for refined prioritisation of high priority substances

Approach: For substances / substance groups of the highest priority, additional information shall be compiled to allow a refined prioritisation of substances in the "RoHS-Working-List" according to the following approach.

For all substances from the highest priority groups, information shall be collected from publicly available sources and compiled into a tabulation[64] based on the template provided in the Appendix, Section A.2. The tabulation should include the information for each substance regarding the following parameters and topics:

- Substance identity (Name, CAS and EC identifiers);
- Information on the substance classifications as collected in the inventory.
- Information on uses (i.e. typical general uses and applications, and typical EEE uses and applications);
- Quantities of use (i.e. typical use volumes and EEE use volumes for the EU and/or globally, depending on availability of information);
- First indication if the use and presence of the substance in EEE could potentially lead to impacts related to Article 6(1). This should be estimated based on a short review of the most recent available REACH documents (Annex XV Dossier, SEAC and RAC opinions, etc. and in relation to the information available on hazards and use ad presence of the substance in EEE);

The tabulation shall be supplemented with questions for stakeholders (see template provided in the Appendix, Section A.3). A stakeholder consultation shall be held to collect additional information on the substances. Stakeholders shall be asked to use the excel format to provide information for all substances subject to the refined prioritisation, though provision of additional data and information shall also be possible. This consultation should be held according to the specifications of the EU guidelines for stakeholder consultations.[65] Given that it is targeted at a limited number of substances a shorter period may suffice, provided that the consultation does not overlap with common holiday periods (summer holidays, X-mas).

Grouping of substances may also be relevant at this stage e.g. in line with a simultaneous presence of substances and/or same behaviour of individual group members within the use phase or within waste management processes. This could be the case, for example, if group members are transformed into particular hazardous transformation or degradation products. Whether a grouping approach is reasonable or not has to be decided on a case-by-case basis. Guidance on grouping of substances is provided in Appendix A.6 Guidance on groups of similar substances.

It is important that, following the precautionary principle, the most hazardous group member will be taken into consideration for the prioritisation of members of the substance group for which data as to hazardous classification is missing (see data from P I Step 1a).

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[64] This format was developed in the course of a study prepared by Baron et al. (2014). An example can be viewed here: http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Substance_Review/Substance_Profiles/Questionaire_Background_Info_Substances_prioritisation.xlsx.

[65] The online stakeholder consultation shall be conducted following the minimum standards for consultation of interested parties set out in the Commission Communication COM (2002) 704 final of 11.12.2002, COM(2012) 746, COM(2012) 746, SWD(2012) 422, COM(2014) 368, and SWD(2015) 111.

Detailed information on principles of the grouping approach is also given in the guidance provided by ECHA: http://echa.europa.eu/de/support/grouping-of-substances-and-read-across.

Following the consultation, all information shall be compiled into a substance background document format including the following sections:

- Substance classifications;
- Uses and quantities;
- Presentation and review of stakeholders' contributions;
- Summary of the aspects identified as crucial for concluding the priority to perform a RoHS substance assessment of the substance in view of a possible future restriction, including first estimation as to fulfilment of Article 6(1); and
- References.

The substance specific background documents shall be compiled into a report, which shall be followed with recommendations as to the refined priority of the substances reviewed, explaining the general approach in the refined prioritisation and general aspects of relevance and including a usage magnitude ranking and recommendations for each substance[66].

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[66] This reporting format was developed in the course of a study prepared by Baron et al. (2014). An example can be viewed here: http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Substance_Review/20140806_Substance_Review_revised_version_final_plus_Dossier.pdf

3. Part III DETAILED ASSESSMENT OF SUBSTANCES

The **aim** of the detailed assessment is to conclude whether a substance or substance group[67] should be recommended for restriction under RoHS or not.

The decision on which substances are to undergo a detailed assessment is to be taken by the Commission. Prioritisation of substances, performed according to Part II, shall feed into such decisions. Nonetheless, the Commission may decide to prioritise substances for assessment that were not specified with the highest priority or with any priority for that matter. This may be the case for example:

- when a RoHS assessment is initiated in the context of the various assessments performed under REACH, for example under the risk management option analysis (RMOA) or under the restriction procedure; or
- when a Member State submits a proposal for a RoHS restriction.

Article 6(2) of RoHS stipulates which types of information shall be included in a proposal to review and amend the list of restricted substances specified in Annex II of the Directive (see detail below). It is thus concluded that an assessment may address both, new substances as well as possible changes to substances already specified in the Annex, for example when it becomes relevant to change the scope of substances restricted or the conditions of the restriction (e.g. specified threshold) in light of scientific and technical progress.

Article 6(1)(a-d) of RoHS specifies criteria which have to be taken into account while assessing a possible amendment of the restriction list (see detail in “Background”, Section II.I.I). A substance assessment shall thus focus on information of relevance to allow assessing whether the criteria are fulfilled and whether a restriction would be justified.

Approach: The objective of the detailed assessment is to determine whether the Article 6(1) criteria in connection with information requirements set out in Article 6(2) are fulfilled, justifying a restriction. The following guidance has been prepared to allow the documentation of the assessment in the form of a RoHS dossier which fulfils the information requirements of Article 6(2) of the Directive. This includes the following (interpretations follow the cited requirements and appear in grey):

“(a) precise and clear wording of the proposed restriction;”

This element is interpreted to be the formulation of the recommended restriction and should include at least:

- The name of the substance/compound;
- A threshold above which the substance is restricted
- A date for application (category specific if relevant[68])

Additionally, in some cases, it may be relevant to specify equipment groups or sub-groups to be excluded from the scope of the restriction[69].

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[67] For simplicity’s sake, within this manual, reference is always made to a substance, with substance groups being implied

[68] For example, in the case of the DEHP, BBP and DBP restriction under RoHS, longer transition periods were granted to categories 8 and 9 (medical devices and monitoring and control instruments, respectively).

“(b) references and scientific evidence for the restriction;”

If relevant, distinction should be made as to the certainty of information provided by various references – harmonised classifications for example shall be assumed to have a higher certainty than self-classifications[70] made by suppliers in safety data sheets. Various sources may also differ in their certainty and this should be taken into consideration and be communicated where relevant. For the purpose of evaluating the certainty of various sources, the so-called weight of evidence approach may be applied[71]. This approach involves an assessment of the relative values/weight of different pieces of available information that have been retrieved and gathered in previous steps. The quality and consistency of the data of cited references shall be given appropriate weight. It shall be documented and justified in a clear and transparent manner. The principles of weighing of evidence shall be considered in order to decide whether certain sources should be considered to have a higher weight than others in light of their higher certainty. For further information as to data quality and dealing with data gaps, see Appendix A.7.

“(c) information on the use of the substance or the group of similar substances in EEE;”

Such information should include detail of relevant products and components in which the substance (or group of substances) is used and/or present, detail of its function in applications in which it is used and/or present and estimated volumes of use and/or presence in EEE in the EU and globally. An estimated distribution of the total volume between typical uses in EEE should be detailed.

“(d) information on detrimental effects and exposure in particular during waste EEE management operations;”

Information should relate to impacts addressed under Article 6(1)(a-d), so as to clarify the types of impacts and the range at which they are expected to occur and subsequently to what degree the criteria specified under Article 6(1)(a-d) are fulfilled.

“(e) information on possible substitutes and other alternatives, their availability and reliability;”

Information should allow understanding in which applications substitutes or alternative technologies are already applied and subsequently to what degree the substance (or substance group) has been phased-out. Where differences occur related to substitute or alternative technology implementation, such as between manufacturers of certain regions, product or component categories, etc., this should be specified. It should also be specified whether substitutes or alternative technologies can be considered to have less negative impacts (interpreted in comparison with the impacts of the substance in relation to the Article 6(1)(a-c) criteria).

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[69] As performed in the case of the DEHP, BBP and DBP restriction under RoHS and its applicability to toys, for which a restriction for use in toys was already valid at the time of recommendation through entry 51 of Annex XVII to Regulation (EC) No 1907/2006 (REACH), see http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32015L0863 for detail.

[70] The CLP Regulation requires suppliers of substances and mixtures to decide on the classification of a substance or mixture to be placed on the market. This information needs to be taken into consideration for example in the labelling of the substance, in its safety data sheets, etc. This is called a self-classification.

[71] The so-called weight of evidence approach is described more precisely in ECHA’s practical guide: “How to report weight of evidence?” (published in 2010) as well as in Annex I of the CLP regulation (EC) No 1272/2008 and is also outlined in the general approach for prioritisation of SVHC substances for inclusion in the list of substances subject to authorisation. It is also well described in the 2012 memorandum of the Scientific Committees on Emerging and Newly Identified Health Risks (SCENIHR).

“(f) justification for considering a Union-wide restriction as the most appropriate measure;”

The assessment should detail the rationale for recommending a restriction under the RoHS Directive and why legislation at this level is understood to have benefits over the alternative of national legislation.

“(g) socioeconomic assessment.”

Information should analyse whether the benefits related to a restriction scenario under RoHS are considered proportionate in relation to costs expected to arise through the enforcement of the restriction. Proportionality is interpreted to mean that while some costs may be acceptable and justified as improving the protection of environment and of health can be assumed to have a price, where costs are significantly higher than expected benefits this relation is to be considered for the purpose of establishing whether the benefits justify the restriction and its costs. For this purpose, the following socio-economic impacts should be considered (non-exhaustive- see further detail in Section 3.12):

- Impact on chemicals industry (EU and non-EU, substance manufactures and substitute manufacturers);
- Impact on EEE-producers, industry (EU and non-EU), suppliers and manufacturers of substance and substitute-based technologies);
- Impact on EEE users (private users, commercial users);
- Impact on waste management (impacts related to EEE containing the substance or EEE containing substitutes or alternative technologies);
- Impact on public administration (for regulators at EU level and national level);
- Impacts on environment (during use, during waste management; impacts on different media, e.g. air, water, soil);
- Impacts on health (consumers, workers, residents in proximity of waste management facilities)
- Total socio-economic impact (relation of costs and benefits);

It is stated in the Directive (Recital 10, Article 6,) that the amendment of the list of restricted substances in Annex II shall be coherent with other legislation related to chemicals, in particular the REACH Regulation and shall use publicly available knowledge obtained from the application of such legislation. Therefore, the methodology for assessment of substances under RoHS relies on existing data from the REACH Regulation, and will take into account, inter alia, Annexes XIV and XVII to that Regulation and documents established in relation to their entries. Further, Annex XV dossiers for Restriction and other documents prepared for regulatory purposes under REACH will be considered. Impact Assessments and Risk Assessment Reports of the European Commission (in the framework of Council Regulation (EEC) No 793/93 also known as Existing Substances Regulation (ESR), scientific opinions of any of the European scientific committees e.g. SCHER, SCENIHR, SCCP, SCCS, RAC, SEAC, SCOEL[72] shall be considered. International guidelines and recommendations and other relevant available scientific and technical information shall be taken into account. In general, the main principles of a risk assessment as implemented by ECHA shall

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[72] SCHER: Scientific Committee on Health and Environmental Risks; SCENIHR: Scientific Committee on Emerging and Newly Identified Health Risks; SCCS: Scientific Committee on Consumer Safety; RAC: Committee for Risk Assessment; SEAC: Socio-Economic Analysis Committee, SCOEL: Scientific Committee on Occupational Exposure Limits

be followed. A short overview is given in the ECHA guidance “Chemical safety assessment: guidance in a nutshell”[73]. Further in-depth guidance documents are provided on the ECHA website[74].

A proposal for the template RoHS-Annex II-Dossier will be provided as a separate Document (attached to this report). In the preparation of a dossier for a specific substance:

- information is to be collected and documented in the dossier in relation to:
  - the substance identification, classification and labelling and legal status (Figure 3-1, step 1a);
  - the substances use in EEE (typical function and applications, volumes of use) (Figure 3-1, step 1b);
  - the hazard risk of the substance for health (Figure 3-1, step 1c);
  - the hazard risk of the substance for the environment (Figure 3-1, step 1d);
  - the fate of components and materials containing the substance during use and during waste management (Figure 3-1, step 2); and
  - possible exposures during use and during waste management (Figure 3-1, step 3).
- The analysis undertaken and findings related to impacts related to the use of the substance in EEE is to be documented in the dossier in relation to:
  - Impacts expected during use and/or during waste management (Figure 3-1, step 4a). To estimate whether impacts are to be expected during the use phase and/or during the waste phase, the expected exposure under certain conditions needs to be estimated as part of the evaluation. For this purpose, specific exposure scenarios for assessing substances during WEEE management have been developed for this manual;
  - Risks for the environment on WEEE management (Figure 3-1, step 4b);
  - Risks for workers during WEEE management (Figure 3-1, step 4c);
  - The availability of substitutes and of information on their hazardous properties (Figure 3-1, step 5);
  - Socio-economic impacts (Figure 3-1, step 6);
- Finally, a recommendation is to be included in the dossier and where relevant the rational for a restriction is to be detailed.

Figure 3-1 below provides an overview of the individual steps of the detailed assessment and illustrates flows of information and decisions.

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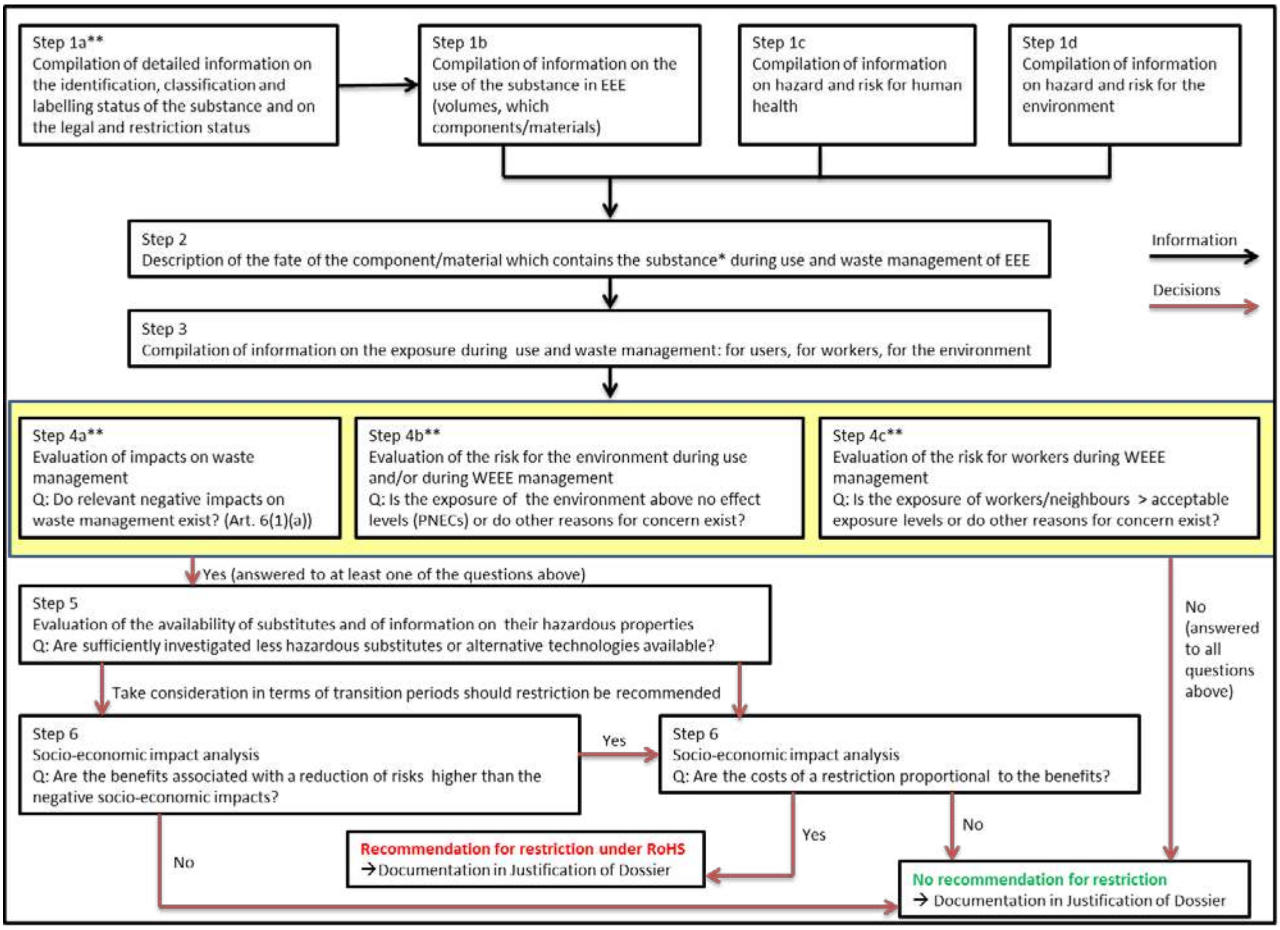
[73] See: http://echa.europa.eu/documents/10162/13632/nutshell_guidance_csa_en. pdf

[74] See: http://echa.europa.eu/support/guidance-on-reach-and-clp-implementation

Figure 3-1: Workflow of the detailed assessment



Source: Adapted and revised from AUBA (2013)

Notes: * The substance and/or its derivatives.

** , "Shortcuts" may be taken should the initial investigation of the substance indicate:

- In relation to step 1, that the level of protection of the environment and or of health achieved through a RoHS Restriction shall not be higher than the level achieved through other legislation under which restrictions exist (e.g. POPs Regulation, Ozone and F-gas Regulation). See 3.1P III Step 1a) Compilation of basic information on the identification, classification, labelling and legal status of the substance in this respect.
- in relation to step 4 that it is not expected to be present in EEE, seeing as impacts related to the presence of a substance in EEE would not be expected

See further detail in the following sections.

Article 6(1), last paragraph specifies that during a review of the list of substances in Annex II, the Commission shall consult interested parties, i.e. stakeholders of relevance to EEE.

- To comply with this stipulation, the process of substance assessment shall include as a minimum a stakeholder consultation of the complete draft dossiers of each substance under review, to allow stakeholders among others the possibility of contributing information where data gaps exist (no data or conflicting views). This consultation should be held according to the specifications of the EU guidelines for stakeholder consultations.[75]

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[75] The online stakeholder consultation shall be conducted following the minimum standards for consultation of interested parties set out in the Commission Communication COM (2002) 704 final of 11.12.2002, COM(2012) 746, COM(2012) 746, SWD(2012) 422, COM(2014) 368, and SWD(2015) 111.

- The assessment of substances could furthermore include a stakeholder consultation at the beginning of the process, calling stakeholders to prepare and submit information of relevance as to the use of the substances under review in EEE manufacture and their impacts on the environment and on health during the use phase and the waste phase. This consultation should also be held according to the specifications of the EU guidelines for stakeholder consultations. Such contributions are understood as an important source of information for the assessment, particularly where publicly available data is less recent and thus possibly not sufficiently reflecting the current status of use and presence of a substance in EEE.
- The assessment should also include direct consultation with targeted stakeholders, for example:
  - Manufacturers or suppliers of EEE and EEE components, in which each substance under review (or its derivatives) is expected to be used in manufacture and/or present in the final product;
  - Manufacturers of the substances under review;
  - End-users of relevant of EEE and EEE components that can provide information on impacts related to use - this may include both commercial users such as users of medical equipment, but also consumer organisations;
  - Representatives of Member States which have investigated the substances under review in the past or which have access to market surveillance data of relevance to the review;
  - Representatives of the waste management value chain (collection and treatment operators, etc.) that can provide data as to possible impacts on the waste phase.

The methodology is not a legally binding instrument. Article 6(1) of the Directive refers to proposals of Member States for the review and amendment of the list of restricted substances in Annex II, stating that these shall contain the information referred to in Article 6(2), i.e., the information specified above. In this sense, proposals submitted by Member States could consider the methodology to ensure compliance with the Article 6(2) information requirements but are not obliged to do so. A review and possible amendment of the list based on a Member States' proposal would follow the same assessment steps as review triggered by a Commission initiative.

3.1. P III Step 1a) Compilation of basic information on the identification, classification, labelling and legal status of the substance

The **aim** of this first step is to provide basic information on the substance.

Furthermore, information on regulatory measures to minimize health and environmental impacts caused by the substance of concern shall be provided.

Information required

The following information, structured as described below, is required:

- Identification of the substance
  - Name, other identifiers and composition of the substance
  - Physico-chemical properties
- Classification:

  - Harmonised classifications at community level shall be specified from Annex VI of Regulation 1272/2008(EC) where such classifications exist.
  - Self-classification(s) notified by industry according to the CLP-regulation are also to be taken into consideration. Self-classifications shall be specified in detail where harmonised classifications are lacking. Self-classifications may differ among notifiers as well as from harmonised classifications, referring to additional end-points in terms of risks or specifying a hazard at a different level. Should a significant share of self-classifications (10% of notifiers and above) address additional end-points of concern or classify higher levels of hazard than those specified in the respective harmonised classification, these should be summarised as well. This should allow consideration whether additional impacts of relevance to the Article 6(1) criteria may incur.

- Legal status and restrictions of use
  - International agreements
  - Regulation of the substance under REACH
  - Other legislative measures
  - Non-governmental initiatives
  - Voluntary restrictions by industry

For substance groups, including elements and their compounds, a list of known members of the group should be compiled to identify possible group members. In the case of organic chemicals, this could include theoretical structural members, for example where all members are to share a certain molecular structure. In cases where a structural and / or functional definition of members included in the group can be formulated so that it is clear, which substances are in the group and which are not, this may be applied to avoid the generation of extensive lists, provided that members of the group for which data is available are specified. The information related to the parameters above should be compiled for all group members for whom data is available.

Result/Expected Outcome: A clear documentation of substance specific information including the legal status and possible conflicting legislation shall be provided.

If information collected at this stage should show that the substance is already restricted by the POPs Regulation, by the Regulation on substances that deplete the ozone layer or by the F-gas Regulation covering the use in EEE, the assessment should take consideration of whether a restriction under RoHS would achieve the same or a higher level of environmental and health protection (for example through a stricter threshold). The assessment should only continue where a RoHS restriction can be expected to achieve a higher level of protection or where this cannot yet be concluded. This approach should also be followed where a restriction under one of these regulations is expected in the near future.

If information collected at this stage should show that the substance is listed in Annex XIV (Authorisation) or Annex XVII (Restriction) of the REACH Regulation, the assessment should take consideration of whether a restriction under RoHS would achieve the same or a higher level of environmental and health protection. In the case of an Annex XIV listing, granted authorisations should also be reviewed to understand implications for the transition period and for possible exemptions required should a RoHS restriction be recommended.

Sources of information

- Classification and Labelling Inventory (ECHA)[76]
- ECHA substance information system[77].
- European Union law and other documents considered to be public are provided on EUR-Lex homepage[78].
- Stockholm Convention website[79]
- Montreal Protocol website[80].

Further information sources:

- eChemPortal of the OECD[81].
- ChemIDplus of the U.S. National Library of Medicine[82]
- Subsport[83] (provides information on international agreements, EU regulatory, governmental and NGO, Trade Union and company lists)

This information will be documented in Chapter 1 of the Dossier.

3.2. P III Step 1b) Compilation of detailed information on the use of the substance in EEE

The **aim** of this step is to provide information on the substance use which is essential for P III Step 3 “Determination of the relevant waste streams and treatment processes and release estimation “ and P III Step 5 “Substitutes”.

Information required

- Compile information on EEE in which the substance is used: This information is needed in order to determine relevant waste streams (WEEE categories) (see P III Step 2). Information shall also be compiled in which main materials/components of EEE the substance is present.
- Compile information on the functions for which the substance is used: In order to evaluate substitutes, the information on the function of the substance (e.g. use as a plasticiser, stabiliser, flame retardant, solder, etc.) or the properties that it enables in EEE (e.g., conductivity, corrosive resistance, machinability, etc.) is also to be compiled.
- Compile information on the annual volumes of the substances used in/present in EEE placed on the global and on the EU market. If available, information should also be compiled on the distribution of these volumes in relation to the typical application sub-groups.

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[76] See: https://echa.europa.eu/information-on-chemicals/cl-inventory-database

[77] See: http://echa.europa.eu/information-on-chemicals

[78] See: https://eur-lex.europa.eu/homepage.html

[79] See: http://chm.pops.int/TheConvention/Overview/TextoftheConvention/tabid/2232/Default.aspx

[80] See: http://ozone.unep.org/montreal-protocol-substances-deplete-ozone-layer/32506

[81] See: https://www.echemportal.org/echemportal/index.action

[82] See: https://chem.nlm.nih.gov/chemidplus/

[83] See: www.subsport.eu

- Compile information, where available, on possible impacts of the substance and/or its derivatives on the environment and on health that are associated with the use phase. This should include both impacts expected during intended use (e.g. skin exposure to surface areas, inhalation of emissions of volatile substances) and during non-normal use (e.g. emissions during a fire, emissions of liquid or powder substances as a result of breakage). Where available, information should furthermore be specified regarding the likelihood of the various impacts to occur and the range of possible impacts (emissions) or to allow making assumptions as to the likelihood and range of possible impacts. Such data shall support the performance of exposure estimation in P III Step 3 (see Section 3.6).

For substance groups, including elements and their compounds, information related to the parameters above should be compiled for all group members for whom data is available. It is assumed that members shall have similar functions and uses as this is often the rational for group restriction, where one member may constitute a substitute for another. In such cases, the substitution of one member through another would constitute a regrettable substitution as impacts in the use and/or waste phase are expected to be of a similar order. Thus, where a high use or waste management relevance is identified, the most hazardous representative of the group is to be chosen for developing estimations to be included in the dossier (exposure estimations, risk assessment and socio-economic analysis).This shall allow determining the possible impacts related to hazardous properties (human health) of the substance group in the context of the assessment.

Possible sources of information

- Information from substance registration dossiers
- Studies and working papers
- Product and material databases (for details see P III Step 1a - Section 3.1, Sources of information)
- Websites of relevant companies and business associations
- Stakeholder consultation (both online consultation and direct correspondence with stakeholders)

Detailed information on uses of the substance in EEE will be compiled in Chapter 2 of the Dossier.

3.3. P III Step 1c) Compilation of information on human health hazards

The **aim** of this step is to describe the hazard of the substance and provide information on safe exposure levels.

Information required

- Compile **information** on hazards identified in relation to human health: The hazard of the substance and related effects on human health shall be described. The reliability, relevance and adequacy of information shall be assumed in case of recent assessments conducted by or on behalf of EU bodies (e.g. ECHA, JRC and the COM), but should be evaluated if any original literature is available. Specific attention shall be given to the respective endpoints of concern (the organs and/or organ systems of the human body which are assumed to be the most sensitive). Safe exposure threshold levels and other guidance values from European and international bodies will be listed.
- Results of hazard assessments if already available by a EU body

- Comprehensive risk profile of the substance
- Endpoints of concern and No Observable Adverse Effect Levels (NOAELs)
- Guidance values (AELs, DNELs, DMELs, OELs; Reference levels, etc.)
- Derivation of DNELs according to the ECHA guidance document in case no reliable DNEL is available

For substance groups, including elements and their compounds, information should be compiled for all group members for whom data is available. Differences in associated hazards and exposures should be addressed to allow concluding at later stages if the rational for a group restriction is justified (i.e. that impacts related to the Article 6(1) criteria are expected to be similar for all group substances or for a sub-set thereof). It is assumed that members shall have similar classifications as this is often the rational for group restriction, where one member may constitute a substitute for another. In such cases, the substitution of one member through another would constitute a regrettable substitution as impacts in the use and/or waste phase are expected to be of a similar order. Thus, where a high use or waste management relevance is identified, the most hazardous representative of the group is to be chosen for developing estimations to be included in the dossier (exposure estimations, risk assessment and socio-economic analysis).This shall allow determining the possible impacts related to hazardous properties (human health) of the substance group in the context of the assessment.

Result/Expected Outcome: A hazard assessment and threshold levels for exposure below which risks for human health are considered to be controlled shall be documented as basic requirements for risk characterisation. In case no threshold can be established, respective DMELs and unit risk levels shall be discussed.

Sources of information

For substances already under consideration within the REACH process, available Annex XV dossiers, risk assessment reports (RARs) gained from the Existing Substances Regulation (EEC) No 793/93) and documents provided by ECHA, including the Chemical Safety Reports, are considered as first-hand references.

- European Chemical Agency (ECHA), Annex XV dossiers: Registered Substances information, restriction proposals, risk assessment reports, guidance documents[84] (e.g. R7[85], R8[86])
- Opinions of the Scientific Committees of the European Commission (SCOEL, SCHER, SCENIHR, SCCP, SCCS, RAC, SEAC)

Examples of further relevant information sources:

Other EU sources:

- European Agency for Health and Safety at Work (OSHA)[87]
- Occupational exposure limits set-out in the Carcinogens and Mutagens Directive (CMD) and/or in the Chemical Agents Directive (CAD) for protecting workers against risks to their health and

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[84] See: https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment for list of ECHA guidance documents.

[85] Guidance on Information Requirements and Chemical Safety Assessment

[86] Characterisation of dose [concentration] - response for human health

[87] See: https://osha.europa.eu/en

safety arising, or likely to arise, from exposure to carcinogens and mutagens or to chemical agents at work[88].

- European Food Safety Authority (EFSA)[89]

International sources:

- eChem Portal of OECD[90]
- OECD QSAR toolbox[91]
- WHO Library information system (WHOLIS)[92]
- International Agency of Research on Cancer (IARC)[93]
- International Program of Chemical Safety (IPCS)[94]
- POPRC: Persistent Organic Pollutants Review Committee[95]
- UNEP United Nations Environmental Programme[96]
- UNECE United Nations Economic Commission for Europe[97]

Member States:

- Gefahrenstoffinformationssystem (GESTIS) der deutschen gesetzlichen Unfallversicherung[98],
- ANSES (French Agency for Food, Environmental and Occupational Health & Safety[99], INERIS (French National Institute for Industrial Environment and Risks[100] and INRS (French National Institute for Research and Occupational Health and Safety[101].
- RIVM (National Institute for Public Health and the Environment, Netherlands[102]

Non-EU countries and other sources:

- Agency of Toxic Substances and Disease Registry (ATSDR) of the U.S. Department of Health and Human Services[103]
- Chemical Carcinogenesis Research Information System (CCRIS) of the US National library of medicine[104]

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[88] See:

[89] See: http://www.efsa.europa.eu/

[90] See: http://www.oecd.org/

[91] See: http://www.qsartoolbox.org/

[92] See: http://www.who.int/library/en/

[93] See: http://www.iarc.fr/

[94] See: http://www.inchem.org/

[95] See: http://www.pops.int/TheConvention/POPsReviewCommittee/OverviewandMandate/tabid/2806/Default.aspx

[96] See: http://www.unep.org/

[97] See: http://www.unece.org/

[98] See: http://gestis.itrust.de/nxt/gateway.dll/gestis_de/000000.xml?f=templates$fn=default.htm$vid=gestisdeu:sdbdeu$3.0

[99] See: https://www.anses.fr/en

[100] See: https://www.ineris.fr/fr

[101] See: http://en.inrs.fr/

[102] See: https://www.rivm.nl/en/

[103] See: https://www.atsdr.cdc.gov/

[104] See: https://toxnet.nlm.nih.gov/newtoxnet/ccris.htm

- Integrated Risk Information System (IRIS) of the US National library of medicine[105]
- Toxicology Data Network (ToxNet) of the US National library of medicine[106]
- National Institute of Technology and Evaluation (NITE); Japan[107]
- Scientific literature (e.g., PubMed, Web of Knowledge)[108]
- European Centre for Ecotoxicology and Toxicology of Substances (ECETOC)[109]

This information will be compiled in Chapter 3 of the Dossier.

3.4. P III Step 1d) Compilation of information on hazard(s) for the environment

The **aim** of this step is to provide basic information to be used for identification of the environmental hazard, including bio-accumulation potential or secondary poisoning and the potential for long range transport.

Information required

- Compile **information** on hazards - identification of hazard(s) for the environment: The hazard of the substance and effects on the environment shall be described. The reliability, relevance and adequacy of information shall be assumed in case of recent assessments conducted by or on behalf of EU bodies (e.g. ECHA, JRC and the COM), but should be evaluated if any original literature is available. Specific attention shall be given to PBT properties of a substance.
- Predicted No Effect Concentration (PNEC) and guidance values from European and international bodies will be listed. The lowest PNEC for each environmental medium will be reported and be used for risk characterisation.
- PNECs and guidance values of European and international bodies
- NOAEC values for the aquatic compartment
- NOAEC values for the terrestrial compartment if available
- Half-life in air, soil, water, water-sediment
- LogK_{ow} as indicator for bio-accumulation
- Bio-concentration factor (BCF) values
- Risk of secondary poisoning and bio-accumulation

Hazard assessment and threshold levels for exposure below which risks for the environment are considered to be under control shall be documented as basic requirements for risk characterisation. PBT properties shall be documented.

For substance groups, including elements and their compounds, information should be compiled for all group members for whom data is available. Differences in associated hazards should be addressed to allow concluding at later stages if the rational for a group restriction is justified (i.e. that impacts related to the Article 6(1) criteria are expected to be similar for all group members or

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[105] See: https://www.epa.gov/iris

[106] See: https://toxnet.nlm.nih.gov/

[107] See: https://www.nite.go.jp/index-e.html

[108] See: https://www.ncbi.nlm.nih.gov/pubmed/

[109] See: http://www.ecetoc.org/

for a sub-set thereof).It is assumed that members shall have similar classifications as this is often the rational for group restriction, where one member may constitute a substitute for another. In such cases, the substitution of one member through another would constitute a regrettable substitution as impacts in the use and/or waste phase are expected to be of a similar order. Thus, where a high use or waste management relevance is identified, the most hazardous representative of the group is to be chosen for developing estimations to be included in the dossier (exposure estimations, risk assessment and socio-economic analysis).This shall allow determining the possible impacts related to hazardous properties (environmental) of the substance group in the context of the assessment.

Possible sources of information

See sources of information as listed in P III Step 1c (see Section 3.3).

Additional information sources:

- Syracuse Research Cooperation (SRC); Environmental fate database[110].
- ECHA guidance documents[111]:
  - Guidance on Information Requirements and Chemical Safety Assessment (R7)
  - PBT Assessment (R11)
  - Environmental exposure estimation (R16)

These facts will be documented in Chapter 4 of the Dossier.

3.5. P III Step 2 Determination of the relevant waste streams and treatment processes and release estimation

The **aim** of this step is to determine which steps of the overall WEEE management are relevant in terms of expected release of the substance and to generate information and data on the basis of which the relevant release estimations shall be evaluated. It is noted that the scope of the WEEE directive and the scope of the RoHS Directive are not completely aligned and there are differences related to the categorisation of EEE in the two Directives. For example, photo-voltaic panel systems benefit from an exclusion from scope under RoHS (Article 2(2)(i)) but are not excluded from the scope of WEEE. Detail of the EEE categories specified under the WEEE Directive and equipment considered to be covered therein is provided in the Appendix, Section A.4.

P III Step 2a) Determine which treatment processes does the equipment containing the substance undergo

Management of WEEE in many cases consists of several steps before individual material streams are re-used, recycled or disposed of. It includes collection, transport, storage and treatment of separately collected WEEE. Separation and recovery of the main materials/components is for most types of separately collected WEEE one of the initial treatment steps – performed either by manual dismantling or by automated shredding and subsequent sorting.

Treatment processes applied include manual dismantling (where also hazardous components may be removed), mechanical disintegration and crushing of the appliances (various types of shred-

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[110] https://www.srcinc.com/what-we-do/environmental/scientific-databases.html

[111] See https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment for list of ECHA guidance documents.

ding, grinding processes etc.) and manual or automated sorting of materials. Furthermore, thermal processes – such as, for example, for the stripping of hazardous fractions from gas discharge lamps, flat screens or cooling and freezing equipment – are applied.

Due to differences in the material composition, the treatment options for individual WEEE categories, respectively groups of appliances, differ too. It is thus necessary as a first step, to identify the waste streams in which the typical applications, containing a substance in question, are be found in and what types of treatment such waste stream undergoes.

A significant share of WEEE is not collected by the foreseen systems so that the average share of WEEE collected in 2016 out of the EEE "placed on the market" in 2013-15 was ca. 50% [112]. Furthermore, a considerable part of WEEE arising in Europe is shipped to third countries (for 2012, Huisman et al. (2015) estimated ≈ 1.5 million tonnes) and subjected to treatment under uncontrolled conditions[113]. Therefore, also processes applied in the treatment of waste streams, where the non-appropriately collected WEEE typically end up have to be considered, i.e. treatment of other waste fractions (e.g., municipal waste), incineration and mechanical treatment and sorting and in some cases also land-filling.

Information required

- The following information is needed to determine which treatment processes the substance undergoes:
  - information on the main materials in which the substance is present (see P III Step 1b "Information on the use of the substance")
  - information on the WEEE categories in which the substance is present, i.e. EEE applications in which it is present.

Information shall be compiled as to the main materials/components in which the substance is expected to be contained (or, in case of lack of data, assumed to be contained based on the typical applications addressed in P III Step 1b). Materials shall be specified based on the main materials/components usually resulting from treatment of WEEE. Where available, data should be specified as to the quantities/concentrations in which the substance is expected to be present. The following list details materials usually resulting from the treatment of WEEE:

- Ferrous metals (except those being part of electronic components)
- Non-ferrous metals (except those being part of electronic components)
- Plastics (except those being part of electronic components)
- Electronic components (those which are known to be separated to a large extent from WEEE as a separate fraction, including printed circuit boards, engines, motherboards connectors, etc.; the substance may be contained in metals, plastics, ceramics or any other material of the component)
- Cables
- Glass

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[112] Data is representative for EEE in scope of the WEEE Directive, which may differ from the scope of EEE in the scope of the RoHS Directive. Data is based on EUROSTAT data, online data code: env_waselee. See also https://ec.europa.eu/eurostat/statistics-explained/index.php/Waste_statistics_-_electrical_and_electronic_equipment#Collection_of_WEEE_by_country

[113] See: http://www.cwitproject.eu/wp-content/uploads/2015/09/CWIT-Final-Report.pdf

- Powders
- Fluids (except those being part of electronic components)
- Others (wood, concrete and ceramics, rubber, etc.)

As the next step, typical EEE containing the substance should be associated with the WEEE categories (see below) according to Annex III of the WEEE Directive (2012/19/EU). In case of lack of data, estimation shall be attempted based on existing knowledge acquired during the first parts of the assessment, i.e. based on the applications in which the substance is present and the EEE categories in which these are expected to be found. For this purpose, an alignment is provided in the Appendix, Section A.4. In cases where the scopes of the directives do not overlap, and equipment understood to be in the scope of RoHS is not under the scope of WEEE[114], information should be sought as to what waste stream such equipment (or its components) are treated with, how this is performed and possible impacts of relevance to the Article 6(1) criteria.

1. Temperature exchange equipment
2. Screens, monitors
3. Lamps
4. Large equipment
5. Small equipment
6. Small IT and telecommunication equipment

It is necessary to have knowledge about the presence of the substance in the individual WEEE categories for the following reasons:

- The rate of separate collection varies considerably between the WEEE categories (and types of appliances).
- The amount of shipments to third countries vary between WEEE categories.
- The treatment options vary between individual WEEE categories. Certain WEEE categories or product groups, such as gas discharge lamps, screens and cooling and freezing appliances, undergo dedicated treatment processes under special conditions as a first treatment step, whereas WEEE from certain product groups is treated together with other product groups.

The following table can be used to summarize the **initial treatment** processes, applied according to the WEEE category in which EEE containing the substance is to be found. This shall later allow specifying the relevant waste streams for which it is to be assessed if emissions occur that would fulfil the RoHS Article 6(1) criteria.

Table 3-1: Initial treatment processes for WEEE

	The substance is present in appliances belonging to					
Initial treatment process	Cat1	Cat2	Cat3	Cat4	Cat5	Cat6
For WEEE collected separately						
Collection and transport	x	x	x	x	x	x
Dedicated treatment processes for cooling & freezing appliances	x					
Dedicated treatment processes for screens		x				

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[114] For example, some medical devices, such as blood analyses equipment, include components exposed to bodily fluids during use. Such components are required to be treated as medical waste.

Dedicated treatment processes for lamps			x			
Manual dismantling	x	x		x	x	x
Shredding (and automated sorting)	x			x	x	x
For WEEE not collected separately						
Landfilling (of residual waste)		x	x		x	x
Mechanical treatment (of residual waste)		x	x		x	x
Incineration		x	x		x	x
Uncontrolled treatment in third countries	x	x		x	x	x

Source: Adapted from AUBA (2013)

Note - the indications in the table serves as an example. Where the table is to be used as described above, an x should be indicated where there is evidence that the substance (i.e. respective applications) is present in the relevant category and waste treatment. Specifying the x in brackets is to indicate that evidence is not available and that indication is based on suspicion. This should enable differentiating in later phases between differences in the level of certainty of specific results.

Treatment of secondary waste: The following table can be used to summarise intermediate and final treatment processes applied to secondary waste streams derived from WEEE treatment, for the main material/component in which the substance is present. This shall later allow specifying the relevant waste streams for which it is to be assessed if emissions occur that would fulfil the RoHS Article 6(1) criteria.

Table 3-2: Treatment processes for wastes derived from WEEE

Treatment process for wastes derived from WEEE treatment	The substance is present in the following main component/material								
	Ferrous metals	Non-ferrous metals	Plastics	Electronic components	Cables	Glass	Powders	Fluids	Others
Under current operational conditions in the EU									
Storage of secondary wastes	x	x	x	x	x	x	x	x	x
Shredding and automated sorting of secondary wastes	x	x	x	x	x	x			
Recycling of ferrous metals	x								
Recycling of NE metals		x			x				
Recycling of plastics			x		x				
Recycling of glass						x			
Recycling as building material						x			x
Landfilling of residues	(x)	x	x	x	x	x	x		
Incineration of residues		x	x	x	x		x		x
Co-incineration of residues			x	x					x
Dedicated processes for hazardous residues				x			x	x	
Under uncontrolled conditions									
Acid leaching				x					
Grilling/desoldering				x					
Uncontrolled combustion			x	x	x		x		x
Uncontrolled dumping of residues			x	x		x	x		x

Source: adapted from AUBA (2013)

Note - the indications in the table serves as an example. Where the table is to be used as described above, an x should be indicated where there is evidence that the substance (i.e. respective applications) is present in the relevant category and waste treatment. Specifying the x in brackets is to indicate that evidence is not available and that indication is based on suspicion. This should enable differentiating in later phases between differences in the level of certainty of specific results.

P III Step 2b) Determination of processes to undergo exposure assessments

The applied treatment processes can be divided into two types:

- Processes dedicated to WEEE or waste derived thereof
- Processes where WEEE and waste thereof are processed together with other waste

The table below provides guidance on which processes are dedicated specifically to WEEE or wastes derived thereof, and which are not.

Table 3-3: Overview of WEEE treatment processes

Processes dedicated to WEEE or wastes derived thereof	Co-processing with other wastes
Collection and transport of WEEE*	Landfilling of residual waste containing WEEE
Storage of secondary wastes*	Mechanical treatment of residual waste
Dedicated treatment processes for cooling & freezing appliances, screens, lamps	Incineration of residual waste
Manual dismantling of WEEE	Shredding/sorting of metals
Shredding (and automated sorting) of WEEE	Recycling of ferrous metals
Shredding/sorting of cables	Recycling of non-ferrous metals
Shredding/sorting of electronic components	Recycling of glass
Shredding/sorting of plastics	Recycling as construction material
Recycling of plastics	Landfilling of residues from WEEE treatment
Uncontrolled treatment in third countries**	(Co-)Incineration of residues
	Uncontrolled dumping of residues**
	Uncontrolled burning of residues**

Source: adapted from AUBA (2013)

Notes: * Collection, transport and storage should be assessed if the following criteria apply: the substance is used as (or in) a liquid (e.g. cooling agents, electrolytes), the substance is used as a gas, the substance is used in powders in components which can easily be damaged during the handling of WEEE, or the substance is (or is bound to) a solid or liquid under normal conditions of use but may easily evaporate at higher temperatures (e.g. in closed metal vessels exposed to sunlight).

** For uncontrolled treatment in third countries, uncontrolled dumping of residues or burning of wastes, caution is to be used as the data quality may be insufficient for quantitative release estimation.

Information required

A quantitative release estimation related to waste management operations shall be performed based on available information regarding the substance content in the typical waste processes and the amounts treated per annum. Depending on data availability and the waste management routes of typical EEE of relevance to the substance under assessment, the estimation shall take into account possible emissions from both dedicated and non-dedicated WEEE installations. Where data is not available as to the actual quantities, assumptions shall be made as to the amount of relevant WEEE treated per annum, respective volumes of the substance therein and respective shares of the substance to be emitted to the environment (air, water, soil as supported by available data). Such assumptions are to be made on the basis of existing evidence as far as possible. For example, the level of emissions may differ between various operators and data on total emissions associated with relevant EEE placed on the EU market will not always be available. In such cases, evidence on substance emissions at a certain WEEE management operator or an average where data from a few operators is available is to be used to estimate total emissions in relation to all relevant EEE placed on the market. On the basis of these assumptions, estimation shall be carried out, specifying how results have been derived and possible uncertainties.

Based on the collection rates for a particular WEEE category, the material composition of the relevant WEEE category and the distribution of such WEEE between specific application treatment operations, the overall amount of the substance treated in a particular process on EU level can be estimated.

Appendix A.5 (to be added) will provide values for separate collections of individual WEEE categories; average material composition of WEEE; the share of applied treatment processes; values for the number of installations and the operational hours of individual treatment processes; and examples of release factors for WEEE treatment processes. This data is provided to support assumptions for estimating the amount of substance treated and respective emissions.

The quantitative assessment of substance released from WEEE treatment processes should be based on:

- the amount of substance entering treatment;
- physico-chemical properties of the substance (volatility, water solubility, degradability and adsorption behaviour, etc.);
- formation of hazardous degradation/transformation products;
- conditions under which the treatment is performed.

The outcome of the qualitative assessment should include:

- a qualitative justification as to why release of the substance from a particular WEEE treatment process is to be expected (or why they are not expected where this is the case).
- a qualitative justification as to why the conditions in the specified treatment will result in release of the substance or in the generation of hazardous degradation products in the process (or why this shall not happen where this is the case).

- In cases where the assessment has established in P III Step 1b) Compilation of detailed information on the use of the substance in EEE or in this step that the substance under review does not remain in its specific form in EEE, it may be possible to conclude at early stages that impacts are not expected during use and/or in the waste phase.

  – Before such a conclusion is reached, it should also be considered if releases of possible derivatives may be expected in the waste phase. Derivatives to be considered shall include hazardous residues, transformation and/ degradation products of the substance. Should this be the case, the assessment of possible releases of the substance should be focused at releases of possible derivatives where these can be identified and where it can be established that impacts related to the Art. 6(1) criteria may be associated with such releases.

  Where releases of the substance and of its derivatives can be excluded, a “short-cut” may be taken in terms of assessing possible exposures and risks, seeing as these would not be expected where releases do not occur. In this case, the assessment documentation should specify that exposures, respectively risks are not expected as the substances and/or its derivatives do not remain in the EEE and thus releases, which could lead to exposures and to actual impacts, are not expected.

Sources of information (P III Steps 2a and 2b)

Information sources that can be used to obtain data on treatment and emissions for estimations:

- Information already collected in previous steps
- Chemical Safety Reports (if available und data appropriate for quantitative release) from ECHA or the registrant;
- Studies and research

- ECHA guidance documents[115]:
  - Environmental exposure estimation (R16)
  - Estimation of exposure from waste life (R18)
- Information and data from EUROSTAT;

Facts about relevant waste streams and treatment processes as well as the outcome of release estimations will be documented in Chapter 5 of the Dossier.

3.6. P III Step 3 Exposure estimation during use and/or WEEE treatment

The **aim** of this step is to determine human and environmental exposure to the substance during use and/or during the relevant WEEE treatment processes (see P III Step 1b and P III Step 2).

Approach: Existing information on human and environmental exposure related to the relevant WEEE treatment processes shall be used to estimate the range of possible exposures. Where data is available, exposure estimations shall be performed using suitable models (e.g. ECETOX-TRA, EUSES).

Examples of effects of substances used in EEE potentially leading to impacts on human health and/or the environment include (not exhaustive):

- Leaching of substances when the WEEE-components end up in landfills (e.g. metals and BFRs), leading to contamination of soil, surface water and ground water;
- Emissions of particle bound substances (e.g. Ba oxide; phosphor coatings; BFRs as TBBPA, HBCDD; metals such as Be, As or Ni) via fine dust during collection, transport, dismantling, shredding and mechanical treatment;
- Effects on humans caused by inhalation of dust or contaminated air during shredding and dismantling processes;
- Effects on humans caused by skin contact and/or inhalation of workers during manual dismantling of WEEE;
- Emissions of substances not being destroyed or immobilised during thermal processes (heavy metals, phthalates);
- Negative impacts may arise due to derivatives of a substance that are generated during waste treatment. For example, halogenated substances (e.g. PVC-plastics and BFRs) are dioxin precursors in thermal processes (considering that other substances such as Cu and Sb are very potent catalysts in the transformation reactions). These lead to risks for human health and the environment when WEEE materials are incinerated without using best available techniques, which is the case also in several countries within the EU; and
- Emissions of volatile substances (e.g. Hg) from broken components during collection, transport, dismantling, shredding and mechanical treatment.

Information required

Available and relevant data regarding exposure (e.g. monitoring data; population group, exposure time, exposure concentration) have to be collected. Literature on human and environmental expo-

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[115] See: https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment for list of ECHA guidance documents.

sure to a specific substance as a result of waste management should be summarised. On the basis of the release estimates calculated in P III Step 1b and P III Step 2, exposure concentrations for end-users for the environment and for workers shall be calculated.

In case the operational conditions vary considerably, different scenarios should be analysed. Existing risk reduction measures and their impact on possible exposure to the substance of concern will be described.

For substance groups, including elements and their compounds, possible differences in expected exposure severity should be discussed in relation to differences in associated hazards of group members. This is to allow concluding at later stages if the rational for a group restriction is justified (i.e. that impacts related to the Article 6(1) criteria are expected to be similar).

The following information, structured as described below, is required:

- Exposure of end-users (EEE during use)
- Occupational exposure of workers (EEE waste processing plants)
- Exposure of neighbouring residents (EEE waste processing plants)
- Exposure of adjacent environment (EEE during use, EEE waste processing plants)

Result/Expected Outcome: Exposure levels for the environment, workers and neighbouring residents shall be summarised.

Sources of information

- Information on releases of substances from waste management is available for some substances and elements under the European Release and Transfer Register (E-PRTR) on releases[116].
- Information on releases of substances is available from the European Information Platform for Chemical Monitoring (IPCHEM). This is “the European Commission’s reference access point for searching, accessing and retrieving chemical occurrence data collected and managed in Europe”. Data is available for four categories: Environmental monitoring, Human Bio-Monitoring, Food and Feed, Products and Indoor Air[117].
- European Centre for Ecotoxicology and Toxicology Chemicals[118]: provides a Targeted Risk Assessment (TRA) tool to determine the exposure of workers and consumers and environmental exposure, based on different exposure scenarios.
- EUSES for environmental exposure estimation[119]
- Further information sources which might provide relevant information are listed in P III Step 1c (information sources related to human health) and in P III Step 1d (information sources related to risks for the environment)
- Stakeholder consultation

This information (if measured data are available) will be documented in Chapter 6 of the Annex II Dossier and is part of the evaluation of exposures during use and during waste management operations.

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[116] See: https://prtr.eea.europa.eu/#/home

[117] See: https://ipchem.jrc.ec.europa.eu/RDSIdiscovery/ipchem/index.html

[118] See: http://www.ecetoc.org/tra

[119] See: https://ec.europa.eu/jrc/en/scientific-tool/european-union-system-evaluation-substances

3.7. P III Step 4 Evaluation of impacts

In addition to the negative impacts of the substances during use and during waste management operations of EEE (P III Step 4a), risks for workers (P III Step 4b) and for the environment (P III Step 4c) related to these life cycle phases should be assessed.

For substance groups, including elements and their compounds, possible differences in expected exposure severity should be discussed in relation to differences in associated hazards of group members. This is to allow concluding at later stages if the rational for a group restriction is justified (i.e. that impacts related to the Article 6(1) criteria are expected to be similar).

3.8. P III Step 4a) Evaluation of risks for end-users of EEE as specified by Article 6(1)(b) (first part)[120]

The **aim** of this step is to characterise the risks which might arise due to direct or indirect contact with the substance during the use of EEE.

Approach: The information collected in previous steps (e.g., evidence as to exposure during normal and non-normal use, threshold levels, toxicological reference values, endpoints of concern, exposure data) will be considered to describe the expected risk. Exposure levels above reference values indicate that there is cause of concern and that the risk is not controlled.

Objectives:

- A qualitative risk characterisation if no threshold level is available;
- If appropriate data are available, a quantitative assessment should be performed for each exposure pattern of a given exposure scenario (comparison of exposure with estimated safe exposure levels);
- If appropriate data are available, it will be examined if there is an unacceptable exposure of end-users to the substance during normal and non-normal use, also specifying the likelihood of occurrence of the exposure and its range.

Result/Expected Outcome: The risk characterisation for human health will determine if, in the defined exposure scenarios, risks to human health are to be expected for end-users of EEE. If monitoring data of sufficient quality (relevant and reliable) are available, the risk characterisation will be based on measured data. It should be assessed if there is a margin of safety which is considered to be sufficient. The data source for exposure assessment will be explained in order to identify uncertainties and underlying assumptions. For the purpose of the assessment it shall be considered if the substance/substance group is comparably easily releasable during use due to the following reasons:

- The substance is used in or as a liquid (under ambient conditions) in EEE
- The substance is in particulate form in EEE
- The substance is highly volatile (under ambient conditions) when used in EEE
- Evidence exists that the potential for release of the substance/substance group in the use phase is significant and that such release may result in adverse impacts on health and or on the

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[120] Article 6(1)(b)(first part): “could give rise, given its uses, to uncontrolled or diffuse release into the environment of the substance”;

environment. For example, the risk of breakage of mercury containing discharge lamps and of resulting emissions is considered to be significant.

Sources of information

- for details see P III Step 1a)-1c), 2 and 3
- ECHA guidance documents[121]:
  - Characterisation of dose [concentration] - response for human health (R8)
  - Consumer exposure assessment (R15)

The results of this step are documented in Chapter 7.1 of the Dossier.

3.9. P III Step 4b) Evaluation of negative impacts on WEEE management as specified by Article 6(1)a and 6(1)(b)(second part)[122]

The **aim** of this step is to assess whether a substance or group of substances could have a negative impact during WEEE management operations, e.g. on the possibilities for preparing for the reuse of WEEE or for the recycling of materials from WEEE.

Approach: The information collected in previous steps (e.g., evidence on exposure during WEEE management operations, evidence on obstacles for preparing WEEE for reuse or for recycling of materials from WEEE) will be considered to describe the expected impacts. Relevant negative impacts on any possible step within the overall treatment process of WEEE have to be considered.

Result/Expected Outcome:

The evaluation should assess whether a substance or group of substances could have negative impacts during WEEE management operations, e.g. on the possibilities for preparing for the reuse of WEEE or for the recycling of materials from WEEE. It shall be considered that relevant negative impacts on WEEE management exist, if at least one of the following **criteria** applies:

- Evidence exists that the presence of the substance in WEEE hinders recycling and/or recovery as it has adverse effects on recycling / recovery processes. For this purpose, lower recycling/recovery rates shall be considered where e.g. the presence of the substance makes recycling/recovery processes impossible or so expensive that a treatment option lower in the waste treatment hierarchy has to be chosen
- Evidence exists that large amounts of the substance are not eliminated or collected for safe disposal during treatment processes, but contaminate the recycled material (metals, plastics, glass) and thus remain in the recycling loop. As a consequence:
  - Use of respective recycled content (secondary materials) is limited to certain application areas or completely prohibited; or

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[121] See: https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment for list of ECHA guidance documents.

[122] Article 6(1)(a) could have a negative impact during EEE waste management operations, including on the possibilities for preparing for the reuse of waste EEE or for recycling of materials from waste EEE;
(b)(second part): “could give rise to hazardous residues, or transformation or degradation products through the preparation for reuse, recycling or other treatment of materials from waste EEE under current operational conditions;”

  - The hazardous substance / substance group may be distributed across various types of recycled materials such as metals, plastics, glass or building material and subsequently in the environment.

- Evidence exists that the presence of the substance in WEEE results in a large amount of material from the overall treatment process having to be treated as hazardous waste.
- Evidence exists that hazardous degradation/transformation products are formed during WEEE management (including thermal processes (combustion, milling), mechanical, chemical and biological processes (mechanical biological treatment, landfilling) and that these result in impacts on human and/or environmental health.

Sources of information

- Information on WEEE treatment (e.g. information available from the WEEE forum and in the context of ongoing activities on the standardisation of minimum treatment standards for WEEE treatment (CENELEC)).
- Information on any processes where WEEE or materials derived from WEEE are treated (in particular BREFs for waste treatment industries, glass production, storage and handling, non-ferrous metals industries, iron and steel production, waste incineration, polymers)
- Stakeholder consultation (waste treatment sector)

The findings/results of this step will be documented in Chapter 7.2 of the Dossier.

3.10. P III Step 4c) Evaluation of risks for workers (Article 6(1)(c)) and neighbouring residents (Article 6(1)(b))[123]

The **aim** of this step is to characterise the risks which might arise due to direct or indirect contact with the substance during the EEE waste management processes.

Approach: The information collected in previous steps (e.g., threshold levels, toxicological reference values, endpoints of concern, exposure data) will be considered to describe the expected risk. Exposure levels above reference values indicate that there is cause of concern and that the risk is not controlled.

Objectives:

- A qualitative risk characterisation if no threshold level is available
- If appropriate data are available, a quantitative assessment should be performed for each exposure pattern from a given exposure scenario (comparison of exposure with estimated safe exposure levels
- If appropriate data are available, it will be examined if there is an unacceptable exposure of workers involved in WEEE operations
- If appropriate data are available, it will be examined if neighbouring residents are at risk (e.g. due to persistent or volatile properties of substances)

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[123] Article 6(1)(b) could give rise, given its uses, to uncontrolled or diffuse release into the environment of the substance, or could give rise to hazardous residues, or transformation or degradation products through the preparation for reuse, recycling or other treatment of materials from waste EEE under current operational conditions;
Article 6(1)(c) could lead to unacceptable exposure of workers involved in the waste EEE collection or treatment processes;

Result/Expected Outcome: The risk characterisation for human health will determine if, in the defined exposure scenarios, risks to human health are to be expected for workers and neighbouring residents. If monitoring data of sufficient quality (relevant and reliable) are available, the risk characterisation will be based on measured data. It should be assessed if there is a margin of safety which is considered to be sufficient. The data source for exposure assessment will be explained in order to identify uncertainties and underlying assumptions. It shall be considered that negative impacts on workers or on neighbouring residents exist if at least one of the following **criteria** applies:

- Evidence exists of exposure of workers to substance or substance group and of subsequent negative impacts on worker health.
- Evidence that the substance/substance group was measured at significantly elevated levels in the environment (air, water, soil, biota) near WEEE treatment installations / locations. Evidence of elevated levels measured in the environment shall generally be considered significant when end-point related limit values are exceeded (i.e. DMELs, PNEC, etc.) and when this can be tied to emissions from the presence of the substance in WEEE. Consideration should determine if harm may occur or not as a result of elevated levels and so whether a restriction should be considered if control measures (such as workplace exposure limits, which are applicable at recycling sites) are not effective at preventing harm to humans or to the environment.

Sources of information

- for details see P III Step 1a)-1c), 2 and 3
- ECHA guidance documents[124]:
  - Characterisation of dose [concentration] - response for human health (R8)
  - Occupational exposure assessment (R14)

The results of this step are documented in Chapter 7.3 of the Dossier.

3.11. P III Step 4d) Evaluation of the risk for the environment (Article 6(1)(a) and/or b)[125]

The **aim** of this step is to assess the environmental risks associated with waste management operations.

Approach/Criteria: Environmental concentrations near EEE processing plants (if available) and Predicted Environmental Concentrations (PECs) as calculated and described in previous steps will be compared with Predicted No Effect Concentrations (PNECs) in order to evaluate the expected risk for the environment. If the PEC values are above PNECS a risk for the environment cannot be excluded. A qualitative assessment will be performed in case there are PBT and vPvB substances for which no PNEC can be derived.

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[124] See: https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment for list of ECHA guidance documents.

[125] Article 6(1)(a) could have a negative impact during EEE waste management operations, including on the possibilities for preparing for the reuse of waste EEE or for recycling of materials from waste EEE;
(b) could give rise, given its uses, to uncontrolled or diffuse release into the environment of the substance, or could give rise to hazardous residues, or transformation or degradation products through the preparation for reuse, recycling or other treatment of materials from waste EEE under current operational conditions;

Result/Expected Outcome: The risk characterisation for the environment will determine if any risks for the environment are to be expected in the defined exposure scenarios. The data source for exposure assessment will be detailed in order to identify and document uncertainties and underlying assumptions. It shall be considered that negative impacts on the environment from WEEE management locations exist if at least the following **criterion** applies:

- Evidence that the substance/substance group was measured at significantly elevated levels in the environment (air, water, soil, biota) near WEEE treatment installations / locations. Evidence of elevated levels measured in the environment shall generally be considered significant when end-point related limit values are exceeded (i.e. DMELs, PNEC, etc.) and when this can be tied to emissions from the presence of the substance in WEEE. Consideration should determine if harm to the environment may occur or not as a result of elevated levels and so whether a restriction should be considered if control measures (e.g. emission mitigation and end-of-pipe measures) are not effective at preventing harm to the environment.

Sources of information

- See sources given in 1d, 2, 3,
- ECHA guidance documents[126]: Characterisation of dose [concentration] – response for environment (R10).

The results of this step are documented in Chapter 7.4 of the Dossier.

- P III Step 5 Evaluation of the availability of substitutes and alternative technologies and information on their hazardous properties

If the results of P III Step 4 show that there is either a negative impact on WEEE management or a risk for human health or the environment during use or during WEEE management, it should be investigated if suitable[127] substitutes or alternative technologies are available.

Approach: Information should be compiled on possible alternatives for the substance under assessment (substitute substances or alternative technologies). Information should allow understanding the range of applicability of possible substitute substances/alternative technologies, the level of development of substitute substances/alternative technologies in terms of maturity for application as replacements and the potential of substitute substances/alternative technologies to themselves be associated with negative impacts on the environment.

For substance groups, including elements and their compounds, this chapter should include not just information on alternatives that are not part of the group, but also on the likelihood of group members to be applied as substitutes for each other, seeing as this is often the rational for group restriction, where one member may constitute a substitute for another. In such cases, the substitution of one member through another would constitute a regrettable substitution as impacts in the use and/or waste phase are expected to be of a similar order.

Information required

As a first step, a summary of available alternatives shall be compiled referring both to technological alternatives (elimination) and to substance alternatives (substitution). For each alternative, the

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[126] See: https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment for list of ECHA guidance documents.

[127] Technically feasible and commercially available within a certain time period

range of application for which it can be used as a replacement should be detailed to allow an understanding of the scope of applications for which alternatives exist or are in development stages. The stage of maturity as an alternative should further be specified (e.g. already applied in a certain application range; applied in certain cases; applied by certain manufacturers; in development stages), as well as the reliability of the alternative. Though in some cases it may become clear that an alternative does not provide sufficient reliability for a certain application, this may differ for other applications and could also be a focus for further research of the alternative. In this sense, the compilation should provide information as to the actual applicability of an alternative as a replacement, however not excluding information on alternatives found to be less suitable.

Information from this step should be documented in Chapter 8.1 of the Dossier.

As a second step, information on the hazardous properties of available substitute substances/alternative technologies is to be investigated. The hazardous properties of alternatives should be briefly described, including data availability and possible data gaps. Should a substance be determined to be persistent and bio-accumulative, but to lack classifications related to toxicity, available results of animal testing should be reviewed to consider if the substance could be toxic. This is of particular relevance for new substances where hazard classification is still in process. The considered alternative options have to be compared with each other and with the substance of concern in terms of their hazardous properties regarding the environment or human health.[128]

To establish the hazardousness of substitute substances/alternative technologies, information from the substance inventory developed in P I and P II is to be considered. In this respect it is important to note that a substance may have been given a low priority on the basis of it not being used in EEE. Should the substance have a hazard classification, this should be taken into consideration in order to derive if a restriction of the substance under assessment could motivate a phase-in of a substance also considered hazardous (regrettable substitution). Should this be the case, existing information on hazards and expected volumes of use should be documented to allow consideration in P III Step 7 whether an assessment of such potential alternatives is needed to allow simultaneous restriction of the substance and its potential alternatives that exhibit hazardous properties.

Where alternatives are themselves already subject to restrictions, they should also be specified as unsuitable replacements.

Information from this step should be documented in Chapter 8.2 of the Dossier.

Sources of information

- See sources given in P III Step 1c-d
- Support database
- Available studies on alternatives
- Stakeholder consultation
- Further information on how to assess alternatives is available on EPA's Design for the Environment (DfE) programme[129].

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[128] U.S, EPA Design for the Environment Programme Alternatives Assessment Criteria for Hazard Evaluation. Version 2.0. August 2011

[129] https://www.epa.gov/saferchoice/design-environment-alternatives-assessments

A summary of alternatives found to be mature and acceptable in terms of hazardous properties should be detailed in Section 8.3 of the Dossier. This section should also detail uncertainties of the results.

3.12. P III Step 6 Socio-economic impact analysis

The **aim** of this step is to assess whether the costs of a restriction scenario are proportionate to the benefits to the environment and to health expected thereof.

The **approach** presented here follows the recommendations of the ECHA guidance documents “Guidance on socio-economic analysis - Restrictions” and “on the preparation of socio-economic analysis as part of an application for authorisation”[130]. However, the analysis shall predominantly rely on information and data from available socio-economic analyses. Given the targeted approach of an assessment for a RoHS restriction, quantitative impacts shall be specified where data is available from prior studies or from stakeholders (monetary as also non-monetary as available). Estimations of additional impacts or analysis of the certainty of existing estimations shall be performed on a qualitative basis. Where relevant, it should be specified across what period economic impacts are expected to occur (one-time investments, operational costs, substitution in short term/long term, etc.).

Information required

The positive and negative socio-economic impacts of a restriction of the substance of concern shall be estimated by presenting the expected impacts of a RoHS restriction scenario. In cases where a restriction under REACH has been proposed, the differences between the RoHS and the REACH restriction scenarios in expected impacts should be analysed (costs for implementation versus benefits in terms of protection of the environment and of health) at least on a qualitative basis.

The following impact categories should be analysed (list is not exhaustive - further categories should be considered on a case-by-case basis):

- Impacts on manufacture of the substance (manufacture of the chemical sector in the EU and outside the EU), including impacts on
  - Costs of manufacture (of the substance and of substitutes);
  - Potential turnover);
  - Administration costs;
  - Unemployment and scar effects;
  - Impacts on SMEs;

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[130] See: ECHA guidance documents on SEA:

- General: https://echa.europa.eu/support/socio-economic-analysis-in-reach
- Restrictions:https://echa.europa.eu/documents/10162/23036412/sea_restrictions_en.pdf/2d7c8e06-b5dd-40fc-b646-3467b5082a9d
- Authorisations: https://echa.europa.eu/documents/10162/23036412/sea_authorisation_en.pdf/aadf96ec-fbfa-4bc7-9740-a3f6ceb68e6e

- Impacts on manufacture of EEE (manufacture of OEMs and the supply chain in the EU and outside the EU), including impacts on
  - Costs of manufacture (including benefits for manufacturers that have already substituted);
  - Impact on innovation;
  - Impact on raw material utilisation;
  - Potential turnover;
  - Administration costs;
  - Unemployment and scar effects;
  - Impact on trade, including international trade;
  - Impacts on SMEs;
  - Impacts on non-EEE manufacturers and users (in cases where equipment similar to EEE may be out of scope;

  Where relevant, supply stability of substitute materials (technologies), and raw material availability should be taken into consideration. Where substitutes are not sufficiently mature, the time required for R&D as well as possible costs should be estimated on the basis of available data.
- For industrial and private end-users of EEE:
  - estimation of increase/decrease in product costs;
  - effect on product lifetime, functionality and usability;
  - Impact on the quality of products;
  - Impact on safety of the public
  - For industrial consumers:
  - Estimation of consequences on competitiveness and jobs
- For waste management:
  - Impacts relating to the decrease of hazardous substances in generated WEEE;
  - Impact on amount of waste generated;
  - Necessity to adapt waste management processes;
  - Estimation of adaptation costs and cost savings (by less harmful alternatives);
  - Estimation of additional revenues from recycling, if a less harmful alternative allows more/easier recycling;
  - Effects on turnover;
  - Effects on employment.

All the individual categories over the life cycle, which may have an impact are summed up to provide the total socio-economic effect of a substance restriction in terms of:

- costs;
- competitiveness of the EU economy;

- employment;
- compatibility of EEE;
- impacts on environment and health.

Within the various categories, the distribution of costs and benefits between various actors (for example between different consumers, different manufactures, etc.) should also be considered and documented.

Sources of information

In addition to the **information** collected in previous steps, the following sources of information are suggested:

- Socio-economic assessment performed under REACH, RARs (if available and appropriate);
- Use of socio-economic assessment performed by other institutions;
- ECHA guidance: Guidance on the preparation of socio-economic analysis as part of an application for authorisation and for restriction proposals[131].
- Stakeholder consultation.

The results of the socio-economic impact analysis of a potential restriction are documented in Chapter 9 of the Dossier. This section should also detail uncertainties of the results.

3.13. P III Step 7 Decision on inclusion and rationale

The **aim** of this step is to decide whether a restriction of a substance/substance group under RoHS would be the most appropriate measure to combat negative impacts during use and during WEEE management operations on human health and the environment.

To reach this decision, a case-by-case **approach** has to be applied which shall consider the following aspects:

A recommendation for restricting a substance under RoHS should be considered where a risk for the environment or for human health during use or during WEEE treatment has been identified or can be assumed based on related estimates (see P III Step 4a - d). Where there is an uncertainty of data, the precautionary principle shall be taken into account. The application of the precautionary principle is related to whether or not the risk is managed, i.e., the range of possible impacts related to the use of a substance is acceptable. The precautionary principle is to be considered in the justification of a restriction if there are well-founded indications that a risk is not adequately managed but data gaps (e.g. regarding route and range of exposure) do not allow the estimation of impacts. If the lack of data does not allow estimating the nature of possible impacts (e.g., substance suspected of hazard but still under verification) a decision is to be postponed until such data gaps can be closed. For further guidance on data quality and dealing with data gaps see appendix A.7.

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[131] ECHA guidance documents on SEA:

- General: https://echa.europa.eu/support/socio-economic-analysis-in-reach
- Restrictions:https://echa.europa.eu/documents/10162/23036412/sea_restrictions_en.pdf/2d7c8e06-b5dd-40fc-b646-3467b5082a9d
- Authorisations: https://echa.europa.eu/documents/10162/23036412/sea_authorisation_en.pdf/aadf96ec-fbfa-4bc7-9740-a3f6ceb68e6e

The rationale behind an inclusion of the substance into Annex II of RoHS as an appropriate risk management option – or a justification why it is not - shall take into account the following aspects:

Hazardous potential

- The nature and reversibility of the adverse effect;

Identified Exposure

- The amount of substance released / the range of subsequent impacts;
  - The estimated number of exposed users or exposed workers;
  - The environment compartment to be exposed;
  - Expected exposure from WEEE that is not properly collected and treated;

Estimated risk

- The number of waste treatment processes from which the risks arise:

  For processes performed at a large number of installations/locations spread all over the EU (and third countries), restrictions under RoHS are appropriate. The same is true for waste treatment processes which can be carried out legally under a wide range of conditions, influencing the release rates of hazardous substances. For processes performed at only a small number of installations, other risk management measures at process or plant level should also be considered, including e.g. adaptations of waste legislation and occupational safety and health legislation, BAT definitions, enforcement actions.
- The severity and extent of the risk identified;
- Uncertainties within the risk assessment approach;

Impact on users and workers

The extent to which users/workers are exposed to emissions of the substance during use /during the waste phase respectively, resulting in negative impacts on their health.

Impact on the environment

The extent to which the environment is exposed to emissions of the substance as a result of its use in EEE, during the use and waste phase and the range of subsequent impacts.

Impact on waste management

- The extent to which material recycling/recovery rates are reduced[132];
- The extent to which recycled materials are contaminated with the hazardous substance / group of substances;
- The amount of hazardous waste which is generated in the course of processing WEEE;

Available Alternatives

- The availability of substitutes/alternatives with a less negative impact related to use and to WEEE management;

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[132] In particular if the recycling/recovery rate required under EU legislation is not achieved.

  - Technical feasibility of the alternative substance;
  - A less hazardous toxicological profile of the alternative substance.

- The availability of substitutes/alternatives with similar or higher impacts related to use and to WEEE management and their potential of leading to “regrettable” substitution;

Socio-economic impact analysis

- The socio-economic impacts (see P III Step 6, Section 3.12);
- The proportionality of costs of a restriction in comparison to the expected benefits of restriction;
- Uncertainties of the results and possible consequences of any wrong conclusions which are drawn from the assessment.

In the case of an assessment of a substance group, including elements and their compounds, the discussion of results should show that possible differences in expected impacts related to certain group members would not affect the fulfilment of the Article 6(1) criteria, i.e., the justification for restriction of the group. Should this not be the case, it should be considered if restriction of a sub-selection of the group members would be justified and subsequently the scope of the group to be restricted is to be adjusted.

The decision to recommend a substance or substance group for inclusion in Annex II of RoHS is to be documented in Chapter 9 of the RoHS-Dossier and shall include:

- The substance /substance group to be restricted (CAS number to be specified if relevant);
- Conditions of the restriction:
  - A recommendation on the threshold limit value (% by weight in the homogenous material) above which the substance/substance groups should not be present in the homogenous material once a restriction is in force. The limit value should be determined in relation to the level of presence in EEE and/or WEEE that could lead to negative impacts on the environment and/or health (i.e. exposures).
  - The scope of the restriction in terms of EEE Annex I categories and the transition period to be provided for different categories. The period recommended for transition should take into consideration:
    - the time needed for stakeholders to conclude on the presence of the substance in EEE relevant to them;
    - the time needed for stakeholders to verify the applicability of available substitutes; and
    - the time needed for stakeholders to request exemptions and for these to be processed by the Commission (decision) in cases justified as per Article 5 of the Directive.
  - It should also be detailed whether certain EEE is to be excluded from the scope of the restriction in light of parallel legislation with a more stringent restriction[133].
  - Whether EEE in scope of the RoHS Directive is to be excluded from the scope of other existing EU legislation (e.g. restrictions listed under Annex XVII of REACH, granted authorisations listed under Annex XIV of REACH).

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[133] As for example in Delegated Directive 2015/863: “*The restriction of DEHP, BBP and DBP shall not apply to toys which are already subject to the restriction of DEHP, BBP and DBP through entry 51 of Annex XVII to Regulation (EC) No 1907/2006.*’”

- Whether exemptions are to be granted for equipment benefiting from a REACH Annex XIV authorisation or whether such equipment should be granted a longer transition period.

APPENDIX

A.1 Information sources used for the 2013 inventory of substances in EEE" (PART I, Step 1)

This annex is reproduced from AUBA (2013). Links have been updated in a few cases.

For the inventory of substances used in EEE that has been established during the first review of RoHS Annex II in 2013, information from the following databases has been extracted:

- Substances listed in the IEC 62474 Database „Declarable Substances“ (IEC 62474 - Material Declaration for Products of and for the Electrotechnical Industry):
  http://std.iec.ch/iec62474
- ZVEI-Umbrella specifications: https://www.zvei.org/en/association/divisions/electronic-components-and-systems-division/material-data-declaration-on-product-level-and-the-umbrella-specification-based-on-product-families-as-an-efficient-example/

Information both on main components as well as on minor components of several components of EEE are available from product data sheets for product families, so-called "umbrella specifications". These data sheets were developed by manufacturers of components organised in the Electronic Components Division within the German Electrical and Electronic Manufacturers Association (ZVEI) and aim to comply with the request of customers for detailed material specifications on individual electronic components, semiconductors, passive components, printed circuit boards, and electromechanical components.

For this study, 60 product data sheets published at the ZVEI-website at December 2012 were used.

- Information on substance uses as available from registration dossiers: sub- stances with the use descriptor "SU16" "Manufacture of computer, electronic and optical products, electrical equipment" if available from ECHA
- Information on substance uses (Nace-codes C26 "Manufacture of computer, electronic and optical products" and C27 "Manufacture of computer, electronic and optical products"[134]) as available from the Nordic Product Register (SPIN – substances in preparations in nordic countries-register)- http://spin2000.net/

Information from the following studies was used:

- Inventory of Oeko-Institut (2008): Study on Hazardous Substances in Electrical and Electronic Equipment, not regulated by the RoHS Directive
- The inventory of potentially problematic substances contained in EEE comprises 64 substances, including hazardous substances as well as non-hazardous substances, which may cause problems in WEEE-management.
- Monitoring results of Umweltbundesamt (2011): Karzinogene, mutagene, reproduktionstoxische (CMR) und andere problematische Stoffe in Produkten. Identifikation relevanter Stoffe und

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[134] Relevant uses to be selected.

Erzeugnisse, Überprüfung durch Messungen, Regelungsbedarf im Chemikalienrecht. ISSN 1862-480

  - The study provides information on hazardous substances in products. Annex 4.B summarizes information on substances analysed in EEE (various information sources).

- Monitoring results SENS, SWICO & SLRS (2008): PCB in Kleinkondensatoren aus Elektro- und Elektronikaltgeräten. Schlussbericht.

About 15 hazardous substances were analysed in capacitors derived from small EEE.

- Review on hazardous substances in EEE provided by DANISH EPA (2012)

Greening of electronics – The list consists of 25 substances.

A.1.1 Data sources on use of nanomaterials

The following list of sources can be consulted:

- The Europa web-platform on nanomaterials provides general information: http://ec.europa.eu/research/industrial_technologies/nanoscience-and-technologies_en.html
- Second Regulatory Review on Nanomaterials {COM(2012) 572 final} The document covers nanomaterials within the scope of the Commission Recommendation 2011/696/EU on the definition of nanomaterial: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A52012DC0572
- Commission staff working paper on Types and uses of nanomaterials, including safety aspects accompanying the Communication from the Commission on the Second Regulatory Review on Nanomaterials https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52012SC0288

An EU project launched by the Commission in 2011 on occupational risks of nano-materials, and other recent research, including on the fate of nanomaterials in the environment and in waste, will provide more insight for further legislative guidance and risk assessment work[135],[136].

The International Organisation for Standardisation published a specific standard (ISO/TR 13121:2011) that offers guidance on the information needed to make sound risk evaluations and risk management decisions.

Current studies on nano-waste[137],[138].

- OECD: http://www.oecd.org/sti/sci-tech/oecdworkingpartyonnanotechnology.htm

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[135] Commission staff working paper. ´Types and uses of nanomaterials, including safety aspects Ac- companying the Communication from the Commission to the European Parliament, the Council and the European Economic and Social Committee on the Second Regulatory Review on Nanomaterials {COM(2012) 572 final}

[136] Communication from the commission to the European parliament, the council and the European economic and social committee. Second Regulatory Review on Nanomaterials. Brussels 03.10.2012

[137] Bio Intelligence Service (2011). Study on coherence of waste legislation, Final report prepared for the European Commission

[138] Musee, N.,2011, Nanowastes and the environment: Potential new waste management paradigm. Environment International. 37: 112-128

- ECHA: https://echa.europa.eu/regulations/nanomaterials
- France has implemented a national nanomaterial register to which nanomaterial producers, importers, distributers or formulators are obliged to register: https://www.r-nano.fr/

Furthermore, following databases from different institutions (e.g. consumer organisations) have been set up, but have major drawbacks to identify the use of nanomaterials in consumer products including EEE, because the information is often based on not verified producer declaration. On the other hand, many products containing nanomaterials might not be included in these databases, as the producers are not declaring the containment of nanomaterials:

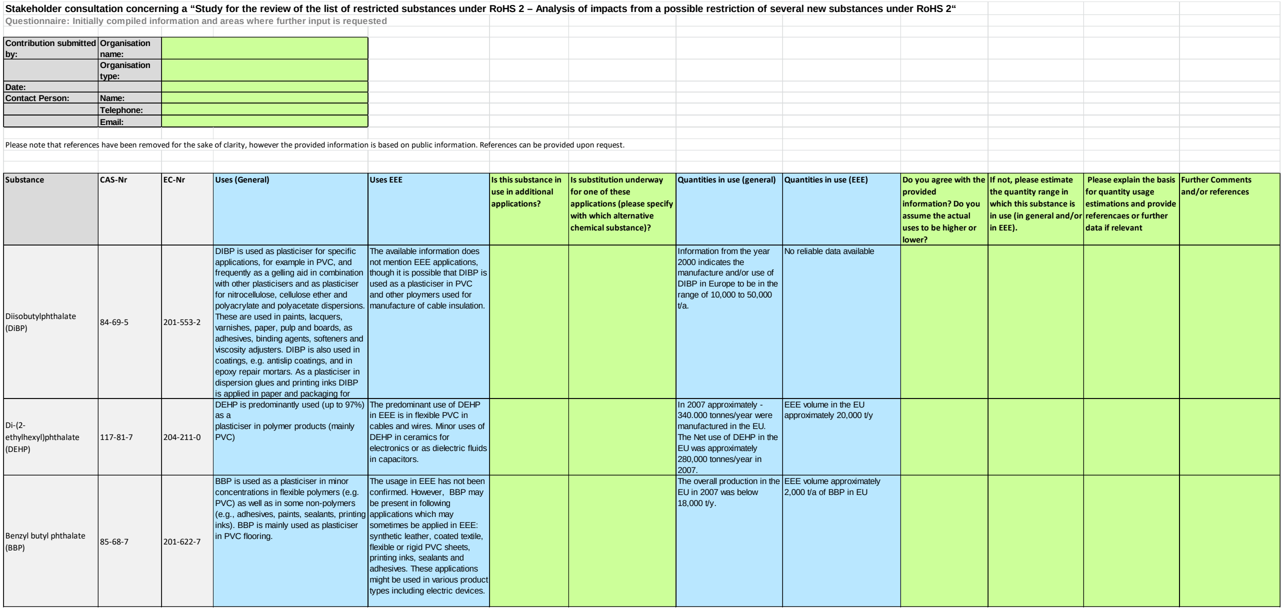
- The ANEC/BEUC 2010 inventory is an inventory of nanotechnology based consumer products established by European consumer organisations. The Microsoft Excel Table is available on the BEUC website (http://www.beuc.eu/safety/nanotechnology).
- The DTU Environment, the Danish Ecological Council and Danish Consumer Council have set up a nanomaterial data-base, including so far more than 3,000 products: http://nanodb.dk/en/about-us/
- A German inventory of nanotechnology based consumer products built up by BUND (Bund für Umwelt und Naturschutz Deutschland) is available online: https://www.bund.net/chemie/nanotechnologie/nanoprodukte-im-alltag/nanoproduktdatenbank/
- The Woodrow Wilson database is a U.S. inventory of nanotechnology based consumer products. Although the origin of the inventory is in the United States, it is applicable for global use. (http://www.nanotechproject.org/cpi/)
- Information on the application fields of nanomaterials, relevant health and environment aspects as well as facts on risk management and safety aspects can be found in the DaNa2.0 (Data and knowledge on Nanomaterials) database (https://www.nanopartikel.info/en/)

A.2 Template for collecting information of use of substances in EEE through stakeholder consultation in P1 Step 1b

Substance identity				**Uses in EEE**					**RoHS Status**	**Hazard group**	**Use relevance**	**REACh relevance**	**Overall priority**	**Previous comme**	**Estimated volume of use in EEE in the EU**									**Waste / use phase / comments**
CAS No	EC No	Name	Group (if applicable)	Please specify the known uses of the substance in EEE					Currently under assessment or previously assessed under RoHS	Based on evidence that the substance/ substance group has relevant hazard properties (Human health & environment)	Evidence for high volumes of use and/or used used as nanomaterial in EEE	Restriction under REACh Annex XVII including some EEE, or proposed + listed in Annex XIV or proposed		Stakeholder comments received in the previous stakeholder consultation	Please specify estimated range of use in EEE in the EU in tonnes per annum								Used as nanomaterial in EEE	Please provide information on possible use phase / waste management impacts acc. to RoHS Art. 6(1). Please also provide other relevant comments on specific substances here.
				Category	Main function / us	Additive use / Reactive use?	Presence in EEE plausible?	Substitute for another listed substance? Please specify.							0-1 t/a	1-10 t/a	10-100 t/a	100-1000 t/a	>1000 t/a	Phased-out	No knowledge	If you represent a manufacturer (OEM, supplier) please specify the range of your use related to EEE manufacture		
7440-02-0	231-111-4	Nickel (Ni)	Element	Metal compound	NA		Yes			Group I	WAHR	WAHR	**Group I**											
1304-56-9	215-133-1	Beryllium oxide		Metal compound	Ceramic capacitors		Yes		Yes	Group I	WAHR		**Group I**											
7440-41-7	231-150-7	Beryllium (Be)	Element	Metal compound	Alloys		Yes		Yes	Group I	WAHR		**Group I**											
1313-99-1	215-215-7	Nickel monoxide		Metal compound	NA		Yes			Group I	Nano		**Group I**											
1314-13-2	215-222-5	Zinc oxide		Metal compound	NA		Yes			Group I	Nano		**Group I**											

A.3 Template for collecting information from stakeholders for refined prioritisation of high priority substances as described in P II Step 2

The format below was developed in the course of a study prepared by Baron et al. (2014) and is provided here as an illustration. An example of the excel format can be viewed here: http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Substance_Review/Substance_Profiles/Questionaire_Background_Info_Substances_prioritisation.xlsx.



Stakeholder consultation concerning a “Study for the review of the list of restricted substances under RoHS 2 – Analysis of impacts from a possible restriction of several new substances under RoHS 2“

Questionnaire: Initially compiled information and areas where further input is requested

Contribution submitted by:	**Organisation name:**	
	Organisation type:	
Date:		
Contact Person:	**Name:**	
	Telephone:	
	Email:	

Please note that references have been removed for the sake of clarity, however the provided information is based on public information. References can be provided upon request.

Substance	**CAS-Nr**	**EC-Nr**	**Uses (General)**	**Uses EEE**	**Is this substance in use in additional applications?**	**Is substitution underway for one of these applications (please specify with which alternative chemical substance)?**	**Quantities in use (general)**	**Quantities in use (EEE)**	**Do you agree with the provided information? Do you assume the actual uses to be higher or lower?**	**If not, please estimate the quantity range in which this substance is in use (in general and/or in EEE).**	**Please explain the basis for quantity usage estimations and provide referencaes or further data if relevant**	**Further Comments and/or references**
Diisobutylphthalate (DiBP)	84-69-5	201-553-2	DIBP is used as plasticiser for specific applications, for example in PVC, and frequently as a gelling aid in combination with other plasticisers and as plasticiser for nitrocellulose, cellulose ether and polyacrylate and polyacetate dispersions. These are used in paints, lacquers, varnishes, paper, pulp and boards, as adhesives, binding agents, softeners and viscosity adjusters. DIBP is also used in coatings, e.g. antislip coatings, and in epoxy repair mortars. As a plasticiser in dispersion glues and printing inks DIBP is applied in paper and packaging for	The available information does not mention EEE applications, though it is possible that DIBP is used as a plasticiser in PVC and other ploymers used for manufacture of cable insulation.			Information from the year 2000 indicates the manufacture and/or use of DIBP in Europe to be in the range of 10,000 to 50,000 t/a.	No reliable data available				
Di-(2-ethylhexyl)phthalate (DEHP)	117-81-7	204-211-0	DEHP is predominantly used (up to 97%) as a plasticiser in polymer products (mainly PVC)	The predominant use of DEHP in EEE is in flexible PVC in cables and wires. Minor uses of DEHP in ceramics for electronics or as dielectric fluids in capacitors.			In 2007 approximately - 340.000 tonnes/year were manufactured in the EU. The Net use of DEHP in the EU was approximately 280,000 tonnes/year in 2007.	EEE volume in the EU approximately 20,000 t/y				
Benzyl butyl phthalate (BBP)	85-68-7	201-622-7	BBP is used as a plasticiser in minor concentrations in flexible polymers (e.g. PVC) as well as in some non-polymers (e.g., adhesives, paints, sealants, printing inks). BBP is mainly used as plasticiser in PVC flooring.	The usage in EEE has not been confirmed. However, BBP may be present in following applications which may sometimes be applied in EEE: synthetic leather, coated textile, flexible or rigid PVC sheets, printing inks, sealants and adhesives. These applications might be used in various product types including electric devices.			The overall production in the EU in 2007 was below 18,000 t/y.	EEE volume approximately 2,000 t/a of BBP in EU				

A.4 Alignment of electrical and electronic appliances to WEEE categories

Below the alignment of electrical and electronic appliances to the individual WEEE categories according to Annex III and Annex IV of the WEEE-Directive (2012/19/EU) is provided taking into account treatment options.

The listing in itself is neither exhaustive nor does it inform whether a particular appliance is in the scope of RoHS.

1. Temperature exchange equipment

Temperature exchange equipment/Cooling and freezing equipment: Refrigerators, Freezers, Equipment which automatically delivers cold products, Air conditioning equipment

Temperature exchange equipment/Others: Dehumidifying equipment, Heat pumps, Radiators containing oil and other temperature exchange equipment using fluids other than water for the temperature exchange

2. Screens, monitors, and equipment containing screens having a surface greater than 100 cm^2

Screens, Televisions, LCD photo frames, Monitors, Laptops, Notebooks.

3. Lamps

Straight fluorescent lamps, Compact fluorescent lamps, Fluorescent lamps, High intensity discharge lamps - including pressure sodium lamps and metal halide lamps, Low pressure sodium lamps, LED.

4. Large equipment

Large equipment household: Washing machines, Clothes dryers, Dish washing machines, Cookers, Electric stoves, Electric hot plates, Luminaires, Equipment reproducing sound or images, Musical equipment (excluding pipe organs in- stalled in churches), Appliances for knitting and weaving,

Large equipment/others: Large computer-mainframes, Large printing machines, Copying equipment, Large coin slot machines, Large medical devices, Large monitoring and control instruments, Large appliances which automatically deliver products and money, Photovoltaic panels.

5. Small equipment

Vacuum cleaners, Carpet sweepers, Appliances for sewing, Luminaires, Micro- waves, Ventilation equipment, Irons, Toasters, Electric knives, Electric kettles, Clocks and Watches, Electric shavers, Scales, Appliances for hair and body care, Calculators, Radio sets, Video cameras, Video recorders, Hi-fi equipment, Musical instruments, Equipment reproducing sound or images, Electrical and electronic toys, Sports equipment, Computers for biking, diving, running, rowing, etc., Smoke detectors, Heating regulators, Thermostats, Small Electrical and electronic tools, Small medical devices, Small Monitoring and control instruments, Small Appliances which automatically deliver products, Small equipment with integrated photovoltaic panels.

6. Small IT and telecommunication equipment (no external dimension more than 50 cm)

Mobile phones, GPS, Pocket calculators, Routers, Personal computers, Printers, Telephones.

To understand how the scopes of the directives align to the various EEE categories, the following list specifies the RoHS categories and under which WEEE categories they are understood to fall. This list is not exhaustive.

- RoHS Cat. 1: Large household appliances:
  - some of the equipment under this category is expected to fall under WEEE Cat. 1: temperature exchange equipment, such as refrigerators, freezers, equipment which automatically delivers cold products, air conditioning equipment.
  - some of the equipment under this category is expected to fall under WEEE Cat. 4: Large equipment, such as washing machines, clothes dryers, dish washing machines, cookers, electric stoves, electric hot plates,
- RoHS Cat. 2: Small household appliances.
  - some of the equipment under this category is expected to fall under WEEE Cat. 5. Small equipment, such as vacuum cleaners, carpet sweepers, appliances for sewing, microwaves, ventilation equipment, irons, toasters, electric knives, electric kettles, clocks and watches, electric shavers, sales, appliances for hair and body care, calculators, radio sets,
- RoHS Cat. 3: IT and telecommunications equipment -
  - some of the equipment under this category is expected to be covered under WEEE Cat. 2: screens, monitors, and equipment containing screens having a surface greater than 100 cm^{2,} such as screens, televisions, LCD photo frames, monitors, laptops, notebooks.
  - some of the equipment under this category is expected to fall under WEEE Cat. 4: Large equipment, such as large computer-mainframes, large printing machines, copying equipment.
  - some of the equipment under this category is expected to fall under WEEE Cat. 6. Small IT and telecommunication equipment (no external dimension more than 50 cm) such as mobile phones, GPS, pocket calculators, routers, personal computers, printers, telephones.
- RoHS Cat. 4: Consumer equipment -
  - some of the equipment under this category is expected to fall under WEEE Cat. 4: Large equipment, such as equipment reproducing sound or images, musical equipment.
- RoHS Cat. 5: Lighting equipment
  - light sources falling under this category fall under the WEEE Cat. 3: Lamps. According to Article 2(3)(c) of WEEE, the directive does not apply to filament bulbs.
  - luminaires under this category are expected to fall under WEEE Cat. 4: Large equipment or Cat. 5. Small equipment - depending on the size of the luminaire.
- RoHS Cat. 6: Electrical and electronic tools.
- RoHS Cat. 7: Toys, leisure and sports equipment -
  - some of the equipment under this category is expected to fall under WEEE Cat. 5. Small equipment, such as electrical and electronic toys, sports equipment, computers for biking, diving, running, rowing, etc.,
- RoHS Cat. 8: Medical devices -
  - some of the equipment under this category is expected to fall under WEEE Cat. 4: Large equipment, such as large medical devices.

  - some of the equipment under this category is expected to fall under WEEE Cat. 5. Small equipment, such as small medical devices.
  - according to WEEE Article 2(4)(g), “medical devices and in vitro diagnostic medical devices, where such devices are expected to be infective prior to end of life, and active implantable medical devices” are excluded from the scope of WEEE.
- RoHS Cat. 9: Monitoring and control instruments including industrial monitoring and control instruments -
  - some of the equipment under this category is expected to fall under WEEE Cat. 4: Large equipment, such large monitoring and control instruments.
  - some of the equipment under this category is expected to fall under WEEE Cat. 5. Small equipment, such as small monitoring and control instruments,
- RoHS Cat. 10. Automatic dispensers -
  - some of the equipment under this category is expected to fall under WEEE Cat. 4: Large equipment, such as large appliances which automatically deliver products and money.
  - some of the equipment under this category is expected to fall under WEEE Cat. 5. Small equipment, such as small appliances which automatically deliver products
- RoHS Cat. 11. Other EEE not covered by any of the categories above.

A.5 Information on WEEE management in the EU

The following section has been based on the AUBA 2013 methodology in structure and updated as far as new data were available.

The following information and sources have been compiled to assist the assessment of substance in relation to possible impacts of substances during the waste management of EEE.

A.5.1 Amounts of EEE put on the European market

Below the amounts of EEE put on the EU market divided by EEE categories according to WEEE Annex I (transitional period) in 2014 (last non-provisional data) and in 2016 (most recent provisional Eurostat estimation) according to Eurostat[139] are provided.

EEE category	**Products put on the market (t) for 2014**	**Products put on the market (t) 2016** - *provisional data, Eurostat estimate*
Automatic dispensers	72.404	71.655
Consumer equipment and photovoltaic panels	783.854	878.168
Electrical and electronic tools	555.788	624.977
Gas discharge lamps	84.613	71.333
IT and telecommunications equipment	1.250.096	1.148.155
Large household appliances	4.742.498	5.273.012
Lighting equipment	393.906	492.726
Medical devices	101.612	108.011
Monitoring and control instruments	142.959	179.233
Small household appliances	906.484	979.871
Toys, leisure and sports equip-	226.729	267.701
Total *…amounts collected / put on the market	9.260.943	10.094.842

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[139] See Waste electrical and electronic equipment (WEEE) by waste management operations [env_waselee], last update: 27-03-2019 under http://appsso.eurostat.ec.europa.eu/nui/submitViewTableAction.do

A.5.2 Information on material composition of WEEE

The following tables provide information on the material composition of individual categories/types of WEEE. Information has been taken from Tables 30-35 in the final report of the "Study on WEEE recovery targets, preparation for re-use targets and on the method for calculation of the recovery targets", prepared by BiPro, BIO by Deloitte (BIO) and the United Nations University (UNU) and published by the Commission in April 2015[140].

Material composition and compliance aspects for Category 1: Temperature exchange equipment

Materials	Percentage of total weight in %	Comments on compliance
Iron (Fe)	57.7%	
Copper (Cu)	5.2%	
Aluminium (Al)	2.7%	
Plastics	24.7%	Usually without Brominated Flame Retardants (BFRs)
Glass	0.0%	
Gold (Au)	0.000006%	
Silver (Au)	0.000002%	
Palladium (Pd)	0.0%	
Other	9.7%	CFC/HCFC as well as contaminated oil, PCB capacitors, PUR foam are the main hazardous substances to dispose of according to Annex VI

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[140] See study under: http://ec.europa.eu/environment/waste/weee/pdf/16.%20Final%20report_approved.pdf

Material composition and compliance aspects for Category 2: Screens, monitors, and equipment containing screens having a surface greater than 100 cm^2

Materials	Percentage of total weight in %	Comments on compliance
Iron (Fe)	25.8%	
Copper (Cu)	3%	
Aluminium (Al)	2.8%	
Plastics	24.5%	A share of the plastics fraction might contain BFRs and should be removed according to Annex VII requirements. BFR mainly contained in TV housing and monitor & TV sets (Wager et al, 2010).
Glass	29.6%	
Gold (Au)	0.005024%	
Silver (Au)	0.002150%	
Palladium (Pd)	0.000968%	
Other	14.29%	Hazardous components listed in Annex VII should be disposed of accordingly. For this category mercury contained in backlights and LCDs are main elements of concerns.

Material composition and compliance aspects for Category 3: Lamps

Materials	Percentage of total weight in %	Comments on compliance
Iron (Fe)	0%	
Copper (Cu)	0%	
Aluminium (Al)	12.5%	
Plastics	10.9%	Usually without Brominated Flame Retardants (BFRs)
Glass	66.70%	
Gold (Au)	0.0%	
Silver (Au)	0.0%	
Palladium (Pd)	0.0%	
Other	9.9%	Hazardous components listed in Annex VII should be disposed of accordingly. For this category, mercury and other heavy metals are the main elements of concern.

Material composition and compliance aspects for Category 4: Large equipment

Materials	Percentage of total weight in %	Comments on compliance
Iron (Fe)	53.6%	
Copper (Cu)	2%	
Aluminium (Al)	7.8%	
Plastics	10.4%	Usually without Brominated Flame Retardants (BFRs)
Glass	1.5%	Mainly from PV panels
Gold (Au)	0.005986%	
Silver (Au)	0.000003%	
Palladium (Pd)	0.0%	
Other	24.69%	Hazardous components listed in Annex VII should be disposed of accordingly.

Material composition and compliance aspects for Category 5: Small equipment

Materials	Percentage of total weight in %	Comments on compliance
Iron (Fe)	46%	
Copper (Cu)	8.8%	
Aluminium (Al)	4.3%	
Plastics	26.3%	Approximately 30% might contain BFRs. Particularly in IT housings [Waeger et al. 2010]. This fraction should be handled appropriately.
Glass	0.0%	Mainly from PV panels
Gold (Au)	0.001629%	
Silver (Au)	0.000368%	
Palladium (Pd)	0.000102%	
Other	14.6%	Hazardous components listed in Annex VII should be disposed of accordingly. Appliances of this category might include batteries, PCB containing and other capacitors and toner cartridges.

Material composition and compliance aspects for Category 6: Small IT and telecommunication equipment (no external dimension more than 50 cm)

Materials	Percentage of total weight in %	Comments on compliance
Iron (Fe)	39%	
Copper (Cu)	45.5%	
Aluminium (Al)	0%	
Plastics	35.8%	Might contain BFRs. Particularly in IT housings [Waeger et al. 2010].
Glass	12.89%	Mainly from PV panels
Gold (Au)	0.009017%	
Silver (Au)	0.002539%	
Palladium (Pd)	0.000678%	

Materials	Percentage of total weight in %	Comments on compliance
Other	2%	Hazardous components listed in Annex VII should be disposed of accordingly. For this category might include batteries, PCB containing and other capacitors and toner cartridges.

A.5.3 Information on treatment processes applied

Management of WEEE in many cases consists of several steps before individual material streams are re-used, recycled or disposed of.

For the initial treatment of particular WEEE categories including Cat 1 “Temperature exchange equipment”, Cat 2 “Screens, Monitors”, Cat 3 “Lamps”, Cat 6 “Small IT and telecommunication equipment” dedicated treatment processes are applied to a large extent.

Other WEEE categories, such as large household appliances and small appliances, are generically subjected to manual dismantling and treatment in shredder.

These initial processes aim at separation of different waste streams. Depollution measures lead to hazardous waste streams. Manual or mechanical separation and sorting steps result in waste streams for recycling and recovery and in residues for disposal (incineration or landfill).

When the substance is exclusively used in appliances belonging to a particular category these dedicated treatment processes should be considered.

Furthermore, the treatment processes applied to individual waste streams derived from initial WEEE treatment have to be considered. It is assumed, that several material streams, such as waste plastics, glass, metals, electronic components, etc. can be assessed generically for all types of WEEE. In addition to the final treatment process (recycling, recovery, incineration, landfilling) also intermediate treatment steps are possible.

In particular for substances which are widely used in EEE but connected with a particular material, such as substances used as flame retardants in plastics, the evaluation of individual material streams is recommended.

In addition, treatment operations for those waste streams (MSW, metal scrap) where WEEE, which is not separately collected, ends up, have to be considered.

Below, the main processes are described briefly including information on the fate of substances during the processes, information on installations and release factors, where available.

A.5.3.1 Collection and transport of WEEE and storage of WEEE and secondary wastes

It is assumed that collection, transport and storage of WEEE do not considerably differ for different types of appliances and respectively for WEEE-categories. Furthermore, differences between separate collection and collection as part of other waste streams (MSW or metal scrap) are considered to be of minor relevance.

Emissions to air:

Emissions to air may occur because of damaging of WEEE components containing volatile substances or because of evaporation of volatile components due to storage for longer periods under hotter conditions. Evaporations depend on the volatility of the substance.

Emissions to soil and water

Wastes stored outside may release substances, which are less bound to the materials, through rainwater run-off to water and soil. Of particular relevance are substances which are used as or in a liquid (e.g. compressor oils or electrolytes) or as powders.

A.5.3.2 Shredding and automated sorting of WEEE

Shredding and automated sorting is applied to all types of WEEE and many types of secondary wastes such as cables, electronic components, mixed plastics, etc. and diverse intermediate waste fractions.

Shredding may be performed in large ELV shredders, special shredders dedicated to particular types of WEEE or to secondary wastes (e.g. horizontal cross flow shredders or cable shredders) or encapsulated shredders.

Often shredding is combined with automated sorting techniques.

Emissions to air:

The substance contained in the shredded material can evaporate, if it is not firmly bound to the materials, or it can be emitted to air as part of dust particles. In most cases evaporation will be much less relevant than emission of dust.

Evaporations depend on the volatility of the substance; emissions with dust on the properties of the dust particles (particle size and density).

Emissions to soil and water are considered to be of minor relevance for most shredding processes.

Resulting waste streams include:

- Ferrous metals
- Non-ferrous metals
- Plastics
- Glass
- Powders
- Mixed shredder residues
- Residues from air treatment (filter dust)
- Particular intermediate waste fractions may be subjected to several shred- ding processes.

Number of installations:

Shredders of metal (mixed scrap) waste - About 350 mixed scrap shredders are operating in Europe in 2014. Mixed scrap shredders are generally capable of processing between 25 and 400 tonnes of metal waste per hour. Most of these shredders are located in the open air, not enclosed within buildings. (WASTE BREF Draft 2017[141])

WEEE shredders - various categories of WEEE are processed in shredders. For WEEE waste streams containing e.g. volatile fluorocarbons (VFCs), volatile hydrocarbons (VHCs), or mercury, closed shredders are in use. A majority of the WEEE shredders installed in the last years treat equipment such as cooling and refrigerating appliances containing hydrofluorocarbons and are generally capable of processing automatically 35 to 75 devices per hour in a two steps process: First cooling circuits of temperature exchange equipment are treated after which oils and VFCs are removed. Following the devices are shredded into smaller material components (ferrous scrap, mixed non-ferrous scrap, foam, and plastics) and VFC and VHC blowing agents are removed and treated separately. Specific WEEE shredders are also installed for large domestic appliances; cathode ray tube (CRT) equipment; flat panel displays; and lamps. (WASTE BREF Draft 2017)

ELV-shredders: 21037

Operation days:

(330 d)

Generic release factors for shredders

Parameter	Default	Reasoning
RF air	0.1	For materials with low weight, such as paper, plastics, minerals
	0.05	For materials with medium weight, such as rubber
	0.01	For materials with high weight, such as metals
RF water	minor	Mostly no water con- tact
RF soil	minor	Processing does not give rise to release to soil

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[141] Best Available Techniques (BAT) Reference Document for Waste Treatment, Industrial Emissions Directive 2010/75/EU (Integrated Pollution Prevention and Control) JOINT RESEARCH CENTRE Directorate Growth and Innovation Unit Circular Economy and Industrial Leadership European IPPC Bureau Final Draft (October 2017), European Integrated Pollution Prevention and Control Bureau (EIPPCB) at the European Commission's Joint Research Centre, available under: http://eippcb.jrc.ec.europa.eu/reference/BREF/WT/WT_Final_Draft1017.pdf

Specific transfer factors to dust (mechanical treatment of WEEE) (Source: BUWAL 2004)

TF	Substances
0.1	Al
0.14	Pb
0.01	Cr
0,01	Cu
0.01	Hg
0.07	Sb
0.13	Cd
0.01	Fe
0.02	Ni
0.25	Zn
0.12	Sn
0.08	Br
0.1	PentaBDE
0.04	HBCD
0.04	DecaBDE
0.03	Cl
0.04	P
0.03	TBBPA
0.03	OctaBDE
0.15	PCB Sum

Concentrations of substances in dust from mechanical treatment of WEEE (Source: BUWAL 2004)

Concentration (mg/kg)	Substance
20000	Al
5900	Pb
740	Cr
6000	Cu
1.7	Hg
1700	Sb
340	Cd

Concentration (mg/kg)	Substance
69000	Fe
2300	Ni
18700	Zn
4300	Sn
3400	Br
49	PentaBDE
10	HBCD
290	DecaBDE
4600	Cl
200	P
700	TBBPA
230	OctaBDE
27	PCB Sum

A.5.3.3 Manual dismantling

Manual dismantling is relevant for all types of WEEE except Cat 3 (lamps).

Emissions to air

The substance contained in components of the dismantled WEEE can evaporate, if they are not firmly bound to the materials. Where drillers, saws, etc. are used to support dismantling of appliances, also emissions with dust particles are relevant.

Emissions to soil and water are considered to be of minor relevance for most dismantling activities. Emissions, however, can occur, e.g. from leakage of waste oil etc.

For manual dismantling also skin contact of the workers with the substance is of relevance.

Resulting waste streams include:

- Ferrous metals
- Non-ferrous metals
- Plastics
- Glass
- Electronic components

A.6 Guidance on groups of similar substances

This guidance is based on discussions of the Commission expert group accompanying future substance reviews under Directive 2011/65/EU and a proposal prepared as guidance on the definition of groups of similar substances in which some adjustments have been made.

A.6.1 Introduction

Article 6(1) of the RoHS Directive (2011/65/EU) requires the European Commission to consider reviews and amendments of the list of restricted substances in Annex II. The directive gives the possibility to review and assess both single substances as well as groups of similar substances.

The term ‘grouping’ or ‘substance grouping’ is interpreted to describe the general approach for considering more than one substance at the same time in an assessment. Assessing a group of substances could in some cases provide an alternative to the individual assessment of substances, mainly in order to maximise efficiency.

This annex thus aims to provide implementing guidance, describing an approach that is to be applied in the grouping of substances under RoHS, to simplify where possible the assessment process. It is intended as an indicative list of guiding criteria for the selection of substances that can be better assessed together.

A.6.2 Grouping of substances under RoHS

Under RoHS, a group of substances subject to assessment for potential restriction in EEE should be composed of substances sharing one or a combination of the following similarities:

- Common structure, functional group(s) constituents or chemical classes;
- Common (eco-)toxicological effects, hazard classification or toxicokinetics;
- Common physico-chemical properties;
- Common mode or mechanism of action;
- Common adverse outcome pathway;
- Common environmental fate/behaviour;
- Likelihood of common precursors and/or breakdown products via physical or biological processes that result in similar substances;
- Constant pattern or trend across the group in the potency of the properties;
- Comparable type and duration of exposure due to either the use of the EEE or the management operations of the related WEEE;
- Similar or same purpose/use/function in specific applications
- Presence in EEE, or reasonable expectation of presence in EEE according to the substance’s characteristics, for the same purpose/use/function;

The above list is not exhaustive, but rather provides example criteria that can be used to group substances for assessment and potential restriction. The listed criteria can in some cases be used alone, but in general, the more criteria apply, the more robust the definition of the group. Selection of substances for grouped assessment depends on many criteria and each group needs to be considered on a case-by-case basis. Some general guidance is detailed below.

Table 3-4: Guidance on the application of substance grouping criteria

Criterion	Implications regarding the possibility for group assessment
Common structure, functional group(s), constituents or chemical classes	This alone will usually not be sufficient because typically in groups defined on the basis of common functionality, there will be too many substances with a very large variation in properties, behaviours and applications, so that the assessment as a group would be impractical. However, this can be used with other criteria to define a group.
Common (eco-)toxicological effects, hazard classification or toxicokinetics;	These are useful criteria as they limit a group assessment to substances that potentially have a similar negative health or environmental impact. Furthermore, in order to possibly establish a single threshold for the group, it should be considered if the concerned effects of the substances are additive or synergetic (for which case the threshold shall define the maximum total concentration of all members of the group of substance present in the homogenous material).
Similar physico-chemical properties	This criterion will usually not suffice for definition of a group on its own, but it could be useful in combination with other substance's properties, use or behaviours. For example, substances with similar vapour pressure may result in similar levels of exposure to workers.
Common mode or mechanism of action	This important criterion could contribute to a better definition of the group.
Common adverse outcome pathway	This important criterion could contribute to a better definition of the group.
Likelihood of common precursors and/or breakdown products via physical or biological processes that result in similar substances	If all substances in the group can be transformed to a similar extent at end of life into the same types of hazardous substances that are known to pose a risk to health or the environment, then they could be assessed as a group. However, substances that readily produce hazardous by-products should be assessed separately from substances that form these substances only under rare conditions.
Constant pattern or trend in the potency of the properties across the group	Predictable trends of properties that depend on structural features (e.g. alkyl chain length) within a group might be a way to determine which substances to include in a group.
Similar or same purpose/ use/function in specific applications	This criterion will usually not suffice for definition of a group on its own, but can be used to refine it. For example, if several similar substances could be used for the same application in EEE and are interchangeable and appear to be equally harmful, then it would seem sensible to consider them as a group.
Presence in EEE, or reasonable expectation of presence in EEE according to the substance's characteristics, for the same purpose/use/function	This criterion will usually not suffice for definition of a group on its own, but it could be useful in combination with other substance's properties, use or behaviours. For example, a substance not used in EEE, but similar to another one used in EEE can be assessed within the same group of the second substance if there is likelihood that the first substance is used to replace the second one in EEE.

One example of a grouping approach, is to look at the structural criterion in combination with other criteria, such as those related to the properties, effects, behaviour or mode of action of the grouped substances. In this case, groups of substances are selected based on the hypothesis that structural changes across the group will produce changes that would affect the whole spectrum of properties in consistent and coherent trends.

Another example is a group of substances having the same hazard classification (e.g. reproductive toxins), similar exposure levels (i.e. users and workers would be exposed to the same amount irrespective of which substance is used) and/or they are interchangeable in use so that one can be substituted for another. Substances with different hazard classifications or likely to have very different exposure levels may need to be assessed separately because their potential health and environmental impacts will be very different. However, some substances have not been fully tested so have not yet been classified. Therefore, substances with similar structure that are likely to have similar hazard classifications could be included in a group for assessment. Furthermore, substances that have similar but not identical classifications, such as reproductive toxins category 1A and 1B, and where exposure levels are not the same, might be considered for inclusion in one group for assessment if the effects of hazard classification and exposure result in similar negative health or environmental effects (i.e. also as a means of preventing regrettable substitution).

Before a group of substances can be assessed for potential restriction under RoHS, the following information should be documented to explain how the group of similar substances was derived:

- All members of the group are as far as possible[142], properly identified by a CAS name or number, an EC name and/or number, and/or one or more equivalent identifiers;
- All relevant criteria are considered, described, and documented, including assumption and/or information used to fill information gaps, as relevant;
- The applicability domain of the group is clearly defined (i.e. the similarity requirements to set the boundaries that are used as inclusion/exclusion criteria of the group) and justified, to allow substances to be considered in the future as members of the group.

It is of particular importance to describe and document the common elements of a group, together with the variation within the group. When differences between the members of the group exist so that the degree of similarity or commonality is challenged or appears less evident, such differences must be clearly described. Among possible example of such variations/differences, the following examples are worth mentioning:

- an effect which varies in intensity across the group, such that some members of the group meet the criteria for one hazard classification for the particular endpoint, whereas other members of the group meet the criteria for another;
- the presence of a breakpoint indicating a change in the mode of action or the effect of a consistent tendency across the group, e.g. a peak in activity or a breakpoint in a trend;
- a trend analysis that may apply to a subgroup but not to the whole group.

When the difference/variation does not negate the commonality for that criterion, then grouped assessment is confirmed as the right approach. On the contrary, when a difference/variation ne-

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[142] In some cases, for example where a grouping is based on similar structures, some members of a group may be theoretical (assumed not to have been synthesised) and thus to lack common identifiers, these shall be specified based on structure and other typical characteristics to allow understanding the justification for inclusion in the group.

gates the commonality for that criterion, then the grouped assessment may be determined as an inappropriate approach from the perspective of the criterion concerned.

Ultimately, decisions on whether to consider substances separately or as a group must be made on a case-by-case basis. It will be necessary to consider, whether the members of a group are sufficiently similar to determine if it will be beneficial to assess these as a group or separately.

If, for example, structure similarity is applied as a criterion, in practice it may be possible to identify the trends and changes for some but not all of the properties of potential interest in a given group. Likewise, significant differences in structure or composition, leading to significant changes in properties, inconsistent or incoherent trends, and/or different classifications, might indicate that the grouped approach is unlikely to be robust and efficient enough and that a substance-specific assessment is more appropriate.

Ideally, the robustness and validity of a group of substances should be confirmed or refuted as early as possible in the grouping exercise, in order to avoid an inefficient subsequent assessment.

A.6.3 Assessments of groups

Developing a group could be the result of an iterative process and subject to adjustment as more information becomes available on substances that could be added to the group or removed from the group, during the assessment of the group. Thus, during the assessment process, a given group of substances could be split into smaller groups, and substances could be added to it or removed from it in light of evidence obtained (e.g. if this shows that an included substance is very different to other members of the group and so requires separate assessment).

Where during an assessment one or more additional substances are scrutinised on the basis of the grouping criteria listed above and applicable to the group concerned, the substance could be:

- included in the group and in the related assessment; or
- kept out of the group, in which case the substance would need to be separately assessed.

If a substance is considered for inclusion in an existing group, it will be necessary to evaluate both the data for this substance in light of the group assessment, as well as the group assessment in light of the data for the additional substance. If the initial group assessment is sufficiently robust, the additional data is unlikely to alter the conclusions of the initial assessment.

The use of a group approach should, - as for the single substance approach, - identify and characterize (qualitatively or quantitatively) the negative impacts that should be tackled by a restriction under RoHS.

Grouping of substances has also been considered in other regulatory frameworks and international fora where further guidance is available:

- REACH: Section 1.5 of Annex XI;
- ECHA: Pages 65-71 of the ECHA Guidance on information requirements and substance safety assessment (Chapter R.6: QSARs and grouping of substances) (May 2008); and
- OECD: Pages 11-25 of the OECD Guidance on grouping of chemicals (Second edition, April 2014).

A.7 Guidance on data quality and dealing with data gaps

This guidance is based on discussions of the Commission expert group accompanying future substance reviews under Directive 2011/65/EU and a proposal prepared as guidance on data quality and dealing with data gaps, in which some revisions have been performed.

When do the recommended data quality requirements apply?

The methodology described in the manual consists of three parts. The first two parts (see Chapter 1 on Identification of substances and Chapter 2 on Prioritisation of substances) are aimed at the prioritisation of substances which will be assessed in the last part (see Chapter 3 on Detailed assessment of substances). The issue of data quality and data gaps is mainly relevant for the implementation of Part three. Therefore, the assessment in stage three is dealt with in this section.

Is there any additional guidance available?

Article 6(1) further specifies that the review shall use publicly available knowledge obtained from the application of chemical legislation such as REACH. Though this is not understood to mean that other sources should not be used, it suggests that the review is to be based on publicly available data. Additional guidance is available in Recital 10 of the RoHS directive, i.e. that measures should be based on an assessment of available scientific and technical information.

What is the main purpose to define data quality?

The most important reason is to avoid that poor-quality data are used to show that a restriction is justified or is not justified. The assessment should collect and review all available data and

- only base decisions on results that are non-controversial within the research community; and
- assess thoroughly research that gives unusual and inconsistent data compared to the non-controversial data and document such uncertainties within the assessment dossier.

Inconsistent data may be correct and usable, but it may also be wrong due to incorrect/unrealistic testing conditions. If certain data is controversial, but it cannot be proved wrong, it may be used to indicate the need for further research to allow the closing of a certain gap needed for coming to a decision.

How can “data quality” be defined?

Data quality for a certain parameter can be described by a set of meta-data (data about data) that can for instance be related to the data source (literature reference, date, place/region, experimental procedure, test method, standards, reproducibility, uncertainties, owner, author, etc.).

One fundamental requirement for data is the need for a clear and traceable source. Data should be used and documented in a transparent and reproducible way.

Documented use of meta-data includes an assessment as to whether the data are:

- adequate (useful, certain and accurate);
- relevant (fit for purpose);
- reliable (related to standardised methodology, experimental procedure or test method);

- subject to controversy within the scientific community.

What data can be used to fulfil the quality requirements?

Where available, data generated through other legislation related to chemicals and particularly through the REACH (Registration dossier, CORAP evaluation, Annex XV dossiers, authorisation dossiers, etc.) are recommended as a first choice. Relevant Risk Analysis Committee (RAC) opinions, Socio-Economic Analysis Committee (SEAC) opinions and the regulatory decision of the European Commission should be taken into account.

Other potential sources for relevant information can for instance be OECD reports, WHO reports, reports of EU governmental agencies, and also of non-EU governmental agencies (US EPA; etc.), statistics (EUROSTAT but also EU national), studies from recyclers, economic reports, market analysis from manufacturers and authorities, etc. Publicly available information should be preferred where possible.

Should data still be missing after the stakeholder consultation stage, it is recommended to widen the search for information, through requesting input from further / other stakeholders and to consider expanding the search beyond publicly available publications.

How should gaps be dealt with when collecting data?

Bearing in mind all uncertainties and difficulties with the data gathering and the fact that 100% sound data will never be available for the generation of all individual substance dossiers, the possibility of data gaps in the final dossiers has to be envisaged.

The lack of data may be due to the fact that it is not known, not compiled in a format that fits the intended purpose or that it is not made public by the data owners. Data owners might not be aware that their specific data input is requested, and it is therefore necessary during the working process to raise the awareness and motivation to make the information available. Sometimes data may be known, but still not possible to use in a dossier as it is regarded as business confidential information (BCI). Documentation of the fact that more data are available could be considered, but such data should not be used to justify a certain view.

In order to identify data gaps as early as possible in the substance dossier preparation, a 2-step approach is recommended. A first check should be carried out before a substance dossier is submitted for a stakeholder consultation. This will allow very specific information requests to be sent out to all stakeholders with the aim of filling identified data gaps during the consultation. A final sanity check would be carried out at the completion of the dossier in order to ensure that a potential proposal for an additional restriction in Annex II is fully substantiated by the best available relevant data.

Stakeholders who already use alternatives and have experience with substitution should be encouraged to make their voice heard during the public consultation phase. All data and meta-data collected through the process should be properly verified and documented.

The omission of concerned parties to share relevant and important information should not be a reason to not proceed with the assessment of a restriction proposal.

How should data gaps be documented?

In some cases where existing and important data gaps still exist, assumptions could be needed to complete the assessment. As a rule, the introduction of assumptions should be kept to an absolute minimum. In particular multiple assumptions could significantly increase the uncertainty of results and these should be noted and the consequence of uncertainties discussed. Each assumption needs to be logical, based on facts as well as transparently stated, documented and substantiated.

The dossier must be fully transparent and describe all results including uncertainties and shortcomings. Such open communication allows final decisions to be taken with full awareness of all uncertainties and possible consequences.

Furthermore, if the final assessment is inconclusive due to lack of data, it could be recommended to revisit the assessment within a few years, when such data has been generated (e.g. where the knowledge base is expected to expand through ongoing studies). Alternatively, areas requiring further research should be outlined, also specifying how such research can be expected to contribute to the conclusion of the assessment. On this basis, the Commission shall be able to determine the timing for a reassessment as well as to consider the preparation of relevant studies.

To ensure that data gaps and how they are dealt with is documented, the following aspects should be clearly presented within the assessment report (dossier):

all information that could be gathered,

- all information that had ultimately not been available,
- all assumptions used, and for each assumption its rationale,
- all conclusions that have been drawn **including the indication of uncertainties and possible consequences thereof**.

References:

RoHS Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment

Manual; Methodology for Identification and Assessment of Substances for Inclusion in the List of Restricted Substances (Annex II) under the RoHS2 Directive; Umweltbundesamt GmbH; January 2014.

A.8 Summary of Contribution submitted to Stakeholder Consultation on the RoHS Substance Methodology

A.8.1 List of contributing stakeholders:

A stakeholder consultation was held on the RoHS draft methodology for substance identification. Prioritisation and assessment between 26 October 2018 to 21 December 2018. The following stakeholders submitted (non-confidential) contributions to the stakeholder consultation:

> Contribution of **RINA Consulting** (formerly EdifERA and ERA Technology Ltd), submitted on 07.12.2018: PDF

> Contribution of **COCIR (European Association of the Radiological, Radiotherapy and Healthcare IT Industry)**, submitted on 14.12.2018: PDF

> Contribution of **ZVEI (Zentralverband Elektrotechnik- und Elektroindustrie**), submitted on 19.12.2018: PDF

> Contribution of **AmCham EU (American Chamber of Commerce to the European Union)**, submitted on 20.12.2018: PDF

> Contribution of **EUROMOT (the European Association of Internal Combustion Engine Manufacturers)** and **AEM (US Association of Equipment Manufacturers**), submitted on 20.12.2018: XLSX

> Contribution of **Digital Europe**, submitted on 20.12.2018: XLSX

> Contribution of **MedTech Europe**, submitted on 20.12.2018: PDF

> Contribution of **The European Semiconductor Industry Association (ESIA)**, submitted on 20.12.2018: PDF

> Contribution of **the Industry Associations DIGITALEUROPE, ESIA, IPC, JBCE, ITI, KEA, SEMI and ZVEI**, submitted on 21.12.2018: PDF

> Contribution of the **Beryllium Science and Technology Association (BeST)**, submitted on 21.12.2018: PDF

> Contribution of **the associations BeST, mmta, i2a, IMAT**, submitted on 21.12.2018: PDF

> Contribution of several **Industry Stakeholders**, submitted on 21.12.2018: PDF

> Contribution of **Japanese electric and electronic (E&E) industrial associations**, submitted on 21.12.2018:

>> General comments: PDF

>> Attachment 2 detailed comments on methodology: XLSX

>> Attachment 3 as draft Appendix on substitute: PDF

>> Attachment 4 as draft Appendix on group of substance: PDF

>> Attachment 5 as draft Appendix on data gap: PDF

> Contribution of **JBCE – Japan Business Council in Europe**, submitted on 21.12.2018: PDF

> Contribution of **Test and Measurement Coalition (TMC)**, submitted on 21.12.2018: PDF

> Contribution of **Campine**, submitted on 21.12.2018: PDF

> Contribution of the **Swedish Chemicals Agency (KEMI)**, submitted on 21.12.2018: PDF

> Contribution of the **European Chemical Industry Council - Cefic aisbl and Eurometaux,** submitted on 21.12.2018: XLSX

> Contribution of **Orgalime**, submitted on 21.12.2018: PDF

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A.2.0 Beryllium and its compounds

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ROHS Annex II Dossier for Beryllium and its compounds.

Restriction proposal for substances in electrical and electronic equipment under RoHS

Substance Name: Beryllium and its compounds 18/05/2020

EC Numbers: Beryllium metal: 231-150-7
Beryllium oxide (BeO): 215-133-1
and other Beryllium compounds

CAS Numbers: Beryllium metal: 7440-41-7
Beryllium oxide (BeO): 1304-56-9
and other beryllium compounds

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Abbreviations

BeS	Beryllium sensitisation
Be	Beryllium
BeO	Beryllium oxide
CAS number	A CAS Registry Number, also referred to as CASRN or CAS Number, is a unique numerical identifier assigned by Chemical Abstracts Service (CAS) to every chemical substance described in the open scientific literature
CBD	Chronic beryllium disease
ChemSec	The International Chemical Secretariat
CLP	Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (REACH)
CMR	Carcinogenic, Mutagenic, or Toxic for Reproduction
CORAP	Community Rolling Action Plan
CRM	Critical Raw Materials
CuBe	Copper-Beryllium alloy
EC number	The European Community number (EC Number) is a unique seven-digit identifier that was assigned to substances for regulatory purposes within the European Union by the European Commission.
EEE	Electrical and electronic equipment
EMC	Electromagnetic compatibility
MSDS	Material safety data sheet
n.d.	Not defined
OEL	Occupational Exposure Limits
OEM	Original Equipment Manufacturer
ppm	Parts per million
RMOA	Risk Management Option analysis
SCOEL	Scientific Committee on Occupational Exposure Limits
tpa	(metric) tonnes per annum
TWA	Time weighted average
WEEE	Waste electrical and electronic equipment

CONTEXT and SCOPE of the Substance Assessment

The substance assessment of beryllium and its compounds is being performed as part of the “Study on the review of the list of restricted substances and to assess a new exemption request under RoHS 2 – Pack 15”. With contract No. 07.0201/2017/772070/ENV.B.3 implementing Framework Contract No. ENV.A.2/FRA/2015/0008, a consortium led by Oeko-Institut for Applied Ecology, has been assigned by DG Environment of the European Commission to provide technical and scientific support for the review of the list of restricted substances and to assess a new exemption request under RoHS 2. This study includes an assessment of seven substances / group of substances[1] with a view to the review and amendment of the RoHS Annex II list of restricted substances. The seven substances have been pre-determined by the Commission for this task. The detailed assessment is being carried out for each of the seven substances in line with a uniform methodology which was developed as a part of this study[2].

In the course of the substance assessment, two stakeholder consultations were held to collect information and data for the seven substances under assessment. The first one was held from 20th April 2018 to 15th June 2018. The second one was held from 26th September to 7th November 2019 to provide specific data as to aspects on which data gaps still exist as well as to comment on the general interpretations made as to the current base of knowledge. Records of the consultations, including draft dossiers and stakeholder contributions, can be found at the Oeko-Institut’s project webpage at: https://rohs.exemptions.oeko.info/index.php?id=289.

For beryllium and its compounds, the 1st stakeholder consultation yielded a total of 18 contributions by different stakeholders. An overview of the contributions submitted during this consultation is provided in Appendix I. The contributions can be viewed at https://rohs.exemptions.oeko.info/index.php?id=294.

In the course of the 2nd stakeholder consultation, ten new stakeholder contributions were received. The stakeholders generally expressed their agreement to the recommendation for not proposing beryllium and beryllium oxide for a general restriction under RoHS, except a selective restriction proposal for the application of beryllium containing alloys in sliding brushes for electric motors. Following the consultation, several sections of the dossier have been amended based on new information provided. After the revision of the dossiers and their completion, a final stakeholder meeting was held on 27 April 2020 to allow stakeholders to comment on the dossiers and particularly on conclusions and recommendations.

This document represents the final version of the RoHS Annex II dossier for Beryllium and Beryllium oxide.

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[1] For the sake of better readability hereafter the term substance will be used for single substances as well as for group of substances.

[2] This methodology includes a dossier template for substance assessment which had been prepared by the Austrian Umweltbundesamt GmbH in the course of a previous study. The methodology for substance assessment has been revised based on various proposals from and discussions with stakeholders. Among others, revisions have been made to clarify when the Article 6(1) criteria are considered to be fulfilled and how the precautionary principle is to be applied. The methodology has also been updated in relation to coherence to REACH and other legislation and publicly available sources of relevance for the collection of information on substances have been updated and added. The methodology is available at https://rohs.exemptions.oeko.info/index.php?id=341

1 IDENTIFICATION, CLASSIFICATION AND LABELLING, LEGAL STATUS AND USE RESTRICTIONS

In past processes for identifying substances of relevance for possible restriction under RoHS, only beryllium metal and beryllium oxide were considered. The current assessment covers a broader scope of substances, namely elemental beryllium and its compounds and alloys.

1.1 Identification

The 'ECHA C&L inventory database' lists 13 beryllium compounds. Among them, only elemental beryllium and beryllium oxide are registered under REACH as of August 2019.[3]

The following table shows further beryllium compounds, including salts and silicates that are identifiable by a CAS code. The compilation is extracted from the recommendation from the Scientific Committee on Occupational Exposure Limits (SCOEL) that gave a recommendation on "beryllium and inorganic beryllium compounds".[4] In the following, this term will be used.

Table 1-1: Overview on beryllium and its inorganic compounds

Chemical name	CAS	Formula
Insoluble in water		
Beryllium	7440-41-7	Be
Beryllium acetylide	506-66-1	CBe_2
Beryllium carbonate (Basic beryllium carbonate (mixed salt)	66104-24-3	$Be_2CO_3(OH)_2$
Beryllium carbonate	13106-47-3	$BeCO_3$
Beryllium diboride	12228-40-9	B_2Be
Beryllium diboride	12536-51-5	BBe_2
Beryllium dibromide	7787-46-4	$BeBr_2$
Beryllium diiodide	7787-53-3	BeI_2
Beryllium hexaboride	12429-94-6	BeB_6
Beryllium orthosilicate	15191-85-2	Be_2SiO_4
Beryllium silicate (phenakite)	13598-00-0	Be_2SiO_4
Beryllium oxide	1304-56-9	BeO
Beryllium phosphide	58127-61-0	Be_3P_2
Beryllium selenide	12232-25-6	BeSe
Beryllium sulphide	13598-22-6	BeS
Beryllium telluride	12232-27-8	BeTe
Beryllium zinc silicate	25638-88-4	$BexH_4O_4Si.xZn$

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[3] ECHA Registered Substance Database: Entry for Beryllium (2018); https://echa.europa.eu/de/registration-dossier/-/registered-dossier/14917/1, last viewed 16.08.2019

[4] Scientific Committee on Occupational Exposure Limits SCOEL (2017): SCOEL/REC/175, Beryllium and Inorganic Beryllium Compounds, Recommendation from the Scientific Committee on Occupational Exposure Limits, Adopted 8th of February 2017; https://publications.europa.eu/en/publication-detail/-/publication/732b94b7-0a1b-11e7-8a35-01aa75ed71a1, last viewed 10.08.2019

Silicic acid, beryllium salt	58500-38-2	$BeSiO_3$
Tetraberyllium boride	12536-52-6	BBe_4
Triberyllium nitride	1304-54-7	Be_3N_2
Bertrandite	12161-82-9	$4\ BeO \times 2\ SiO_2 \times H_2O$
Beryl	1302-52-9	$3\ BeO \times Al_2O_3 \times 6\ SiO_2$
Soluble in water		
Beryllium chloride	7787-47-5	$BeCl_2$
Beryllium fluoride	7787-49-7	BeF_2
Beryllium diammonium tetrafluoride	14874-86-3	$BeF_4N_2H_8$
Beryllium hydroxide	13327-32-7	$Be(OH)_2$
Beryllium nitrate (anhydrous)	13597-99-4	Be(NO3)2
Beryllium nitrate tetrahydrate	13510-48-0	$Be(NO_3)_2 \times 4\ H_2O$
Beryllium phosphate	13598-26-0	$Be_3(PO_4)_2$
Phosphoric acid, beryllium salt	35089-00-0	$BexH_3O_4P$
Beryllium sulphate (anhydrous)	13510-49-1	$BeSO_4$
Beryllium sulphate (dihydrate)	14215-00-0	$BeSO_4 \times 2\ H_2O$
Beryllium sulphate (tetrahydrate)	7787-56-6	$BeSO_4 \times 4\ H_2O$

Source: Scientific Committee on Occupational Exposure Limits SCOEL (2017)

1.1.1 Name, other identifiers, and composition of the substance

As elemental beryllium and beryllium oxide are so far the only beryllium compounds that are registered under REACH, detailed data on their properties can be compiled.[5] For further beryllium compounds listed in Table 1-1, detailed data are not available at the ECHA databases.

Table 1-2: Substance identity and composition of beryllium metal and beryllium oxide

Chemical name	beryllium metal	beryllium oxide
EC number	231-150-7	215-133-1
CAS number	7440-41-7	1304-56-9
IUPAC name	beryllium	oxoberyllium
Index number in Annex VI of the CLP Regulation	004-001-00-7	004-003-00-8
Molecular formula	Be	BeO
Molecular weight (range)	9.01 g/mol	25.01 g/mol
Synonyms	beryllium	beryllium oxide
Structural formula	Be	Be = O
Degree of purity	No data	No data

Source: European Chemicals Agency ECHA, Brief Profile: Entries for beryllium and beryllium oxide (2018), https://echa.europa.eu

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[5] ECHA Brief Profile: Entry for Beryllium (2019); https://echa.europa.eu/de/brief-profile/-/briefprofile/100.028.318, last viewed 19.07.2019; ECHA Brief Profile: Entry for Beryllium oxide (2019); https://echa.europa.eu/de/brief-profile/-/briefprofile/100.013.758, last viewed 19.07.2019.

1.1.2 Physico-chemical properties

The physico-chemical properties of elemental beryllium and beryllium oxide are summarised in Table 1-3 below.[6]

Table 1-3: Overview of physico-chemical properties of beryllium metal and beryllium oxide

Property	beryllium metal	beryllium oxide
Physical state at 20°C and 101.3 kPa	100% (solid metal)	100% (solid, in compact or powder form)
Melting/freezing point	1,278°C	2,428 – 2,431°C
Boiling point	2,471°C	3,900°C [7]
Vapour pressure	13,332 hPa at 1 860°C	No data
Water solubility	500 ng/l at 20 °C and pH 6.11	1.39 - 200 µg/l at 18 - 23°C and pH 7
Partition coefficient n-octanol/ water (log KOW)	Not relevant	Not relevant
Dissociation constant	Not relevant	Not relevant
Relative density	1.848 - 1.850 at 20°C	3 g/cm³ at 20°C
Specific gravity	No data	No data

Source: European Chemicals Agency ECHA, Brief Profile: Entries for beryllium and beryllium oxide, https://echa.europa.eu

Information on physico-chemical properties for various inorganic beryllium compounds is shown in (Table 1-4), based on data compiled by SCOEL[8]

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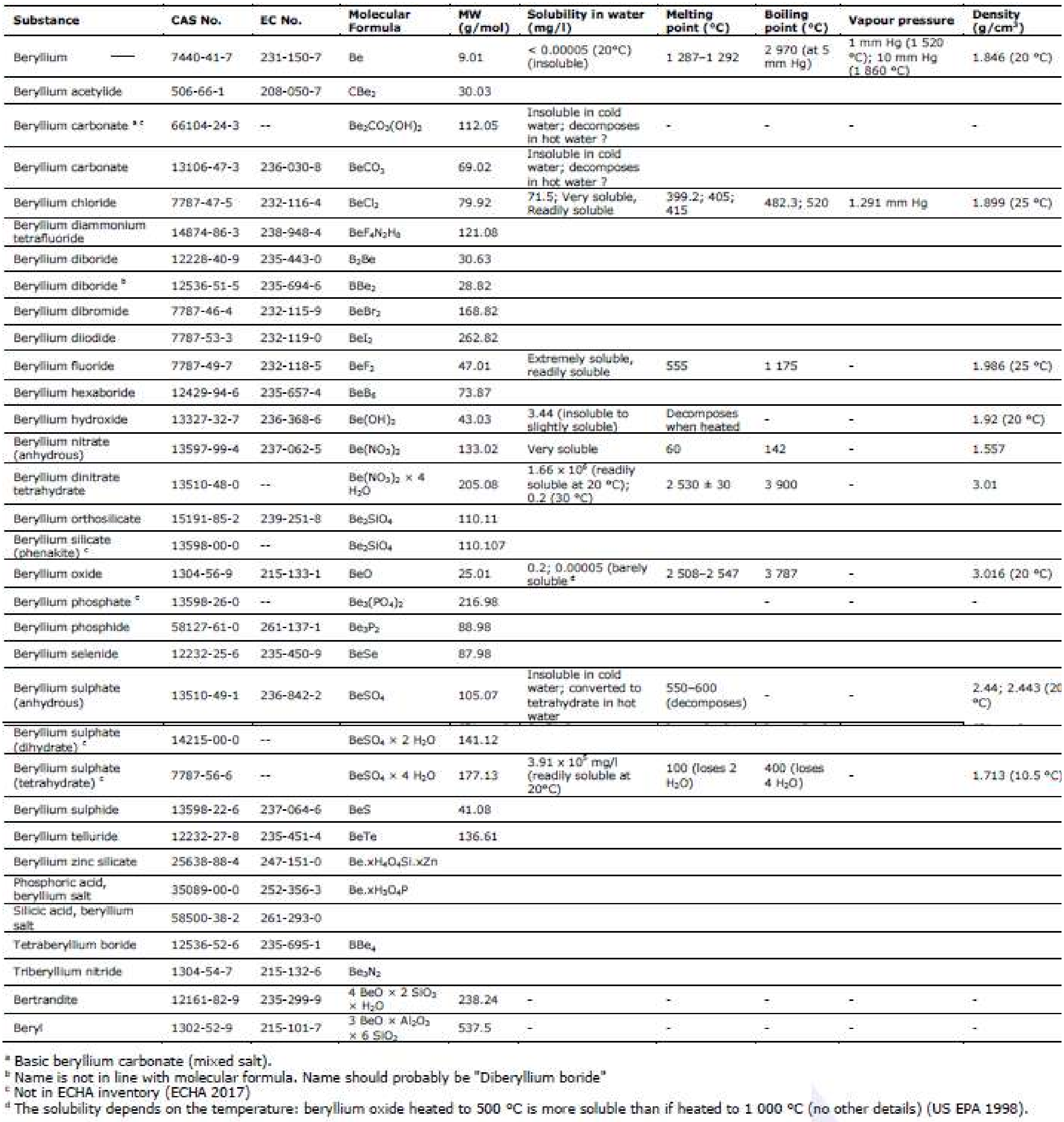
[6] Opt. cit. ECHA Brief Profile: Entry for Beryllium and Beryllium oxide (2018)

[7] GESTIS-Stoffdatenbank. http://gestis.itrust.de/nxt/gateway.dll/gestis_de/000000.xml?f=templates&fn=default.htm&vid=gestisdeu:sdbdeu, last viewed 19.07.2019

[8] Opt. cit. Scientific Committee on Occupational Exposure Limits SCOEL (2017)

Table 1-4: Physico-chemical data for inorganic beryllium compounds



Substance	CAS No.	EC No.	Molecular Formula	MW (g/mol)	Solubility in water (mg/l)	Melting point (°C)	Boiling point (°C)	Vapour pressure	Density (g/cm^3)
Beryllium	7440-41-7	231-150-7	Be	9.01	< 0.00005 (20°C) (insoluble)	1 287–1 292	2 970 (at 5 mm Hg)	1 mm Hg (1 520 °C); 10 mm Hg (1 860 °C)	1.846 (20 °C)
Beryllium acetylide	506-66-1	208-050-7	CBe_2	30.03					
Beryllium carbonate [a,c]	66104-24-3	--	$Be_2CO_3(OH)_2$	112.05	Insoluble in cold water; decomposes in hot water ?	-	-	-	-
Beryllium carbonate	13106-47-3	236-030-8	$BeCO_3$	69.02	Insoluble in cold water; decomposes in hot water ?				
Beryllium chloride	7787-47-5	232-116-4	$BeCl_2$	79.92	71.5; Very soluble, Readily soluble	399.2; 405; 415	482.3; 520	1.291 mm Hg	1.899 (25 °C)
Beryllium diammonium tetrafluoride	14874-86-3	238-948-4	$BeF_4N_2H_8$	121.08					
Beryllium diboride	12228-40-9	235-443-0	B_2Be	30.63					
Beryllium diboride [b]	12536-51-5	235-694-6	BBe_2	28.82					
Beryllium dibromide	7787-46-4	232-115-9	$BeBr_2$	168.82					
Beryllium diiodide	7787-53-3	232-119-0	BeI_2	262.82					
Beryllium fluoride	7787-49-7	232-118-5	BeF_2	47.01	Extremely soluble, readily soluble	555	1 175	-	1.986 (25 °C)
Beryllium hexaboride	12429-94-6	235-657-4	BeB_6	73.87					
Beryllium hydroxide	13327-32-7	236-368-6	$Be(OH)_2$	43.03	3.44 (insoluble to slightly soluble)	Decomposes when heated	-	-	1.92 (20 °C)
Beryllium nitrate (anhydrous)	13597-99-4	237-062-5	$Be(NO_3)_2$	133.02	Very soluble	60	142	-	1.557
Beryllium dinitrate tetrahydrate	13510-48-0	--	$Be(NO_3)_2 \times 4 H_2O$	205.08	1.66 x 10^6 (readily soluble at 20 °C); 0.2 (30 °C)	2 530 ± 30	3 900	-	3.01
Beryllium orthosilicate	15191-85-2	239-251-8	Be_2SiO_4	110.11					
Beryllium silicate (phenakite) [c]	13598-00-0	--	Be_2SiO_4	110.107					
Beryllium oxide	1304-56-9	215-133-1	BeO	25.01	0.2; 0.00005 (barely soluble [d]	2 508–2 547	3 787	-	3.016 (20 °C)
Beryllium phosphate [c]	13598-26-0	--	$Be_3(PO_4)_2$	216.98			-	-	-
Beryllium phosphide	58127-61-0	261-137-1	Be_3P_2	88.98					
Beryllium selenide	12232-25-6	235-450-9	BeSe	87.98					
Beryllium sulphate (anhydrous)	13510-49-1	236-842-2	$BeSO_4$	105.07	Insoluble in cold water; converted to tetrahydrate in hot water	550–600 (decomposes)	-	-	2.44; 2.443 (20 °C)
Beryllium sulphate (dihydrate) [c]	14215-00-0	--	$BeSO_4 \times 2 H_2O$	141.12					
Beryllium sulphate (tetrahydrate) [c]	7787-56-6	--	$BeSO_4 \times 4 H_2O$	177.13	3.91 x 10^5 mg/l (readily soluble at 20°C)	100 (loses 2 H_2O)	400 (loses 4 H_2O)	-	1.713 (10.5 °C)
Beryllium sulphide	13598-22-6	237-064-6	BeS	41.08					
Beryllium telluride	12232-27-8	235-451-4	BeTe	136.61					
Beryllium zinc silicate	25638-88-4	247-151-0	$Be.xH_4O_4Si.xZn$						
Phosphoric acid, beryllium salt	35089-00-0	252-356-3	$Be.xH_3O_4P$						
Silicic acid, beryllium salt	58500-38-2	261-293-0							
Tetraberyllium boride	12536-52-6	235-695-1	BBe_4						
Triberyllium nitride	1304-54-7	215-132-6	Be_3N_2						
Bertrandite	12161-82-9	235-299-9	$4 BeO \times 2 SiO_2 \times H_2O$	238.24	-	-	-	-	-
Beryl	1302-52-9	215-101-7	$3 BeO \times Al_2O_3 \times 6 SiO_2$	537.5	-	-	-	-	-

[a] Basic beryllium carbonate (mixed salt).
[b] Name is not in line with molecular formula. Name should probably be "Diberyllium boride"
[c] Not in ECHA inventory (ECHA 2017)
[d] The solubility depends on the temperature: beryllium oxide heated to 500 °C is more soluble than if heated to 1 000 °C (no other details) (US EPA 1998).

Source: Scientific Committee on Occupational Exposure Limits SCOEL (2017)

1.2 Classification and labelling status

The European regulation No 1272/2008 on Classification, Labelling and Packaging (CLP)[9] provides a framework for the communication of hazards of chemicals. Annex VI of the CLP Regulation lists substances where a harmonised classification exists, for instance in regard to human health concerns. However, suppliers often use different classification schemes for a substance, which is then referred to as 'self-classification' in the terminology of CLP.

1.2.1 Classification in Annex VI Regulation No 1272/2008

Elemental beryllium (metal) and beryllium oxide (BeO) are classified under the CLP regulation (Regulation (EC) No 1272/2008 on Classification, Labelling and Packaging). The harmonised classification according to Annex VI Regulation No 1272/2008 according to Table 3.1 of Annex VI is presented in Table 1-5.

Table 1-5: Classification according to part 3 of Annex VI, Table 3.1 (list of harmonised classification and labelling of hazardous substances) of Regulation (EC) No 1272/2008

Index No.	International Chemical ID	EC No.	CAS No.	Classification		Labelling			Spec. Conc. Limits, M-factors
				Hazard Class and Category Code(s)	Hazard statement code(s)	Pictogram, Signal Word Code(s)	Hazard statement code(s)	Suppl. Hazard statement code(s)	
004-001-00-7	beryllium	231-150-7	7440-41-7	Carc. 1B Acute Tox. 2 Acute Tox. 3 STOT SE 3 STOT RE 1 Skin Irrit. 2 Eye Irrit. 2 Skin Sens. 1	H350i H330 H301 H335 H372 H315 H319 H317	GHS06 GHS08 Dgr	H350i H330 H301 H372 H319 H335 H315 H317	-	-
004-003-00-8	beryllium oxide	215-133-1	1304-56-9	Carc. 1B Acute Tox. 2 Acute Tox. 3 STOT SE 3 STOT RE 1 Skin Irrit. 2 Eye Irrit. 2 Skin Sens. 1	H350i H330 H301 H335 H372 H315 H319 H317	GHS06 GHS08 Dgr	H350i H330 H301 H372 H319 H335 H315 H317	-	-
004-002-00-2	beryllium compounds with the exception of aluminium beryllium silicates, and with those specified elsewhere in this Annex	-	-	Carc. 1B Acute Tox. 2 Acute Tox. 3 STOT SE 3 STOT RE 1 Skin Irrit. 2 Eye Irrit. 2 Skin Sens. 1 Aquatic Chronic 2	H350i H330 H301 H335 H372 H315 H319 H317 H411	GHS06 GHS08 GHS09 Dgr	H350i H330 H301 H372 H319 H335 H315 H317 H411	-	-

Source: Annex VI Regulation No 1272/2008; https://echa.europa.eu/de/information-on-chemicals/annex-vi-to-clp, last viewed 19.04.2019

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[9] Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (REACH).

Moreover, one group entry exists for "beryllium compounds with the exception of aluminium beryllium silicates and with those specified elsewhere in this Annex" with the following entries:[10]

- Carc. 1B (Carcinogenicity) - H350i (May cause cancer by inhalation)
- Acute Tox. 2 (Acute toxicity, inhalation) - H330 (Fatal if inhaled)
- Acute Tox. 3 (Acute toxicity, oral) - H301 (Toxic if swallowed)
- STOT RE 1 (Specific Target Organ Toxicity Repeated Exposure) - H372 (Causes damage to organs through prolonged or repeated exposure).
- Eye Irrit. 2 (Serious eye damage/eye irritation)- H319 (Causes serious eye damage)
- STOT SE 3 (Specific target organ toxicity, single exposure; Respiratory tract irritation - H335 (May cause respiratory irritation
- Skin Irrit. 2 (Skin corrosion/irritation) - H315 (Causes skin irritation)
- Skin Sens. 1 (Sensitisation, skin) - H317 (May cause an allergic skin reaction)

The above-mentioned group entry additionally carries a harmonised classification for aquatic toxicity (H411 - 'Toxic to aquatic life with long lasting effects).

1.2.2 Self-classification(s)

Manufacturers, importers or downstream users must (self-)classify and label hazardous substances and mixtures to ensure a high level of protection of human health and the environment. If a harmonised classification is available, it should be applied by all manufacturers, importers or downstream users of such substances and of mixtures containing such substances.

However, mostly, suppliers decide independently as to the classification of a substance or mixture, which is then referred to as self-classification. Therefore, self-classification might indicate an e.g. additional hazard which is so far not reflected by the harmonised classification. The following assessment of the self-classification therefore emphasises cases where self-classifications differ and where additional hazards were notified in the self-classification.

According to ECHA's C&L inventory, which contains classification and labelling information on notified and registered substances received from manufacturers and importers, the total number of notifiers is as follows:

- 267 C&L notifications submitted to ECHA for beryllium metal[11]
- 31 C&L notifications submitted to ECHA for beryllium oxide[12]

As for **beryllium metal**, most notifiers follow the harmonised classification (253 of 267 notifications: 95%). Out of these, four notifiers did not list the Hazard Class STOT SE 3 but only provided the respective Hazard Statement (H 335 – May cause respiratory irritation). Four notifiers classified beryllium additionally to the harmonised classification for the physical hazard Flam Sol. 1 (H228 – Flammable solid) and the environmental hazard Aquatic Acute 1 (H400 – Very toxic to aquatic life).

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[10] ECHA (2019): Table of harmonised entries in Annex VI to CLP, https://echa.europa.eu/de/information-on-chemicals/annex-vi-to-clp, last viewed 19.04.2019

[11] ECHA CL Inventory: Entry for Beryllium (2018), https://echa.europa.eu/de/information-on-chemicals/cl-inventory-database/-/discli/details/47502, last viewed 11.06.2019

[12] ECHA CL Inventory: Entry for Beryllium oxide (2018), https://echa.europa.eu/de/information-on-chemicals/cl-inventory-database/-/discli/details/70014, last viewed 11.06.2019

A small part of the notifiers (11 notifiers) lacks classification such as e.g. the carcinogenic properties (7 notifiers) or provide only hazard statements.

As for **beryllium oxide**, most notifies follow the harmonised classification (29 out of 31 notifications: 94%). Out of these, two notifiers did not list the Hazard Class STOT SE 3 but only provided the respective Hazard Statement H 335 – May cause respiratory irritation. Two notifiers, among them a lead dossier of a REACH registration joint submission, do not classify for Skin Irritation 2, Skin Sensitation 1 and Acute Toxicity 3.

To summarize the various self-classifications, basically the same types of hazards are addressed as by the harmonised classification. Though in some cases the level of hazard may differ, or certain hazard types have been omitted and given that the harmonised classification is assumed to have a higher scrutiny the differences in the self-classification compared to the harmonised classification are not further considered.

1.3 Legal status and use restrictions

1.3.1 Regulation of the substance under REACH

- **Elemental beryllium metal** was taken up in the Community Rolling Action Plan (CoRAP) upon the demand of the German Federal Institute for Occupational Safety and Health (BAUA) in 2013. The inclusion was motivated with regard to the concern that occupational respiratory exposure of workers to airborne beryllium dust might cause health risks, particularly beryllium sensitisation (BeS) and chronic beryllium disease (CBD) or berylliosis due to long term exposure. With view at its classification as Carcinogen 1B, according to Annex VI of the CLP regulation, beryllium has been suspected to fulfil the Article 57(a) criteria for identification as a substance of very high concern (SVHC) and authorisation was recommended as the best way to regulate this hazard. Setting and enforcing an EU-wide binding occupational exposure limit was also regarded as an important step to enhance worker protection throughout the EU, next to the authorisation.
- For **beryllium oxide**, a risk management option analysis (RMOA) is under development since 03.10.2017 because of concerns about the carcinogenic properties of BeO.[13] The RMOA is carried out by the Netherland's National Institute for Public Health and the Environment and has not yet provided any suggestion on regulatory measures to be taken.
- Considering their classification as carcinogens, **entry 28 of REACH Annex XVII** applies to beryllium metal and beryllium oxide. The regulation prohibits the supply to the general public as a substance, as a mixture or as a constituent of other mixtures.

1.3.2 Occupational Exposure Limits (OEL)

The Directive **2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work** has recently been amended by Directive (EU) 2019/983, stipulating OEL for beryllium and its inorganic compounds as shown in Table 1-6. The regulation grants the industry a transition period of seven years for implementing occupational exposure controls for beryllium. Directive (EU) 2019/983 entered into force on 10 July 2019 and is due to be applicable in national law by 11 July 2021. As for beryllium and inorganic beryllium compounds, the Directive (EU) 2019/983 stipulates the following OEL:

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[13] https://echa.europa.eu/fr/rmoa/-/dislist/details/0b0236e1821a6f8c, last viewed 19.08.2019

Table 1-6: Occupational exposure limits for beryllium and its inorganic compounds

	SCOEL (2017)	Directive (EU) 2019/983 of 10 July 2019
8-hour TWA (Time weighted averages)	0.02 µg/m^3 beryllium (inhalable fraction)	- 0.2 µg/m^3 - A limit value of 0.6 µg/m^3 applies during a transitional period of 7 years until June 2026
15 min STEL (Short term exposure limit)	0.2 µg/m^3 beryllium (inhalable fraction)	No entry
Additional categorisation	Carcinogenicity group C (genotoxic carcinogen with a mode-of-action based threshold)	No entry
Notations	- Dermal and respiratory sensitisation - No notation on skin sensitisation	- dermal and respiratory sensitisation - carcinogenic properties mentioned

Source: Scientific Committee on Occupational Exposure Limits SCOEL (2017); Official Journal of the European Union L 164/23[14]

The DNEL value corresponds to the REACH registration dossier for beryllium (Table 1-7).[15]

Table 1-7: Guidance values for occupational exposure to beryllium

Population	Local / systemic effect	Effects	DNEL beryllium
Workers	Inhalation Exposure	Systemic long-term effects	0.2 µg/m^3

Source: ECHA Registered Substance Database: Entry for beryllium (2018)

1.3.3 Other legislative measures

Beryllium is listed on the 2017 catalogue of **Critical Raw Materials (CRM)** for the EU (COM (2017) 490 final).[16] Materials appearing on this list have been identified as critical for the EU due to a risk of supply shortage (scarcity) and their high importance for the economy. For beryllium, the supply risk scores at 2.4 and the economic importance scores at 3.9. These scores indicate that beryllium has a medium criticality as compared to other raw materials. Additional aspects (e.g. environmental, social) are not mentioned in the communication in this regard.

1.3.4 Non-governmental and non-regulatory initiatives

Beryllium metal and beryllium oxide are listed on several policies or codes of conducts for non-regulatory purposes. The “Be Responsible” voluntary product stewardship programme of BeST aims

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[14] DIRECTIVE (EU) 2019/983 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 June 2019 amending Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work, Official Journal of the European Union L 164/23

[15] Opt. cit. ECHA Registered Substance Database: Entry for Beryllium (2018)

[16] EU COM (2017): Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on the 2017 list of Critical Raw Materials for the EU, Brussels, 13.9.2017, COM(2017) 490 final, available under: http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=COM:2017:0490:FIN, last viewed 19.04.2018

at improving workers safety during the production and processing of beryllium-containing materials. The Global Automotive Declarable Substance List (GADSL) lists beryllium as a declarable (D) rather than restricted substance. Beryllium metal and beryllium oxide are listed in the SIN list as both substances are classified CMR according to Annex VI of the CLP Regulation. The entry on the SIN list does not stipulate a restriction of these substances but rather encourages efforts to substitute them with safer alternatives.[17]

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[17] http://sinlist.chemsec.org/search/search?query=beryllium, last viewed 24.07.2019

2 USE IN ELECTRICAL AND ELECTRONIC EQUIPMENT

2.1 Function of the substance

Beryllium is one of the most lightweight metals and at the same time very rigid with a good strength-to-weight ratio. Due to its unique combination of properties, beryllium is an essential material in the manufacture of various products and specific applications where lightweight structures are required which are resistant to deformation under high stresses or high temperatures. Thus, beryllium is considered a strategic material for many industry sectors. The important properties are summarised as follows, based on a variety of sources:[18]

As a pure metal:

- X-ray transparency and non-magnetic properties;
- Light weight metal with exceptional stiffness (Young's modulus);
- remains stable at high temperatures (melting point 1,284ºC) and it has good resistance to deformation at elevated temperatures;

As part of alloys:

- excellent electrical and thermal conductivity;
- good elastic modulus
- good corrosion and oxidation resistance;
- hardening agent in alloys with metals, especially copper, which produces a high strength alloy;
- about 50% greater rigidity than that of steel, while its density (1.84 g/cm^3) about 30% lower than that of aluminium;
- Excellent formability, machinability and joinability due to isotropic structures;
- Non-magnetic and non-sparking properties combined with high strength provide protection against fires and explosions.

Technical uses of beryllium and its compounds encompass the following technical forms:

- Pure beryllium metal and Be-rich alloys containing >30% beryllium;
- Copper beryllium alloys containing 0.10 – 2.0% beryllium;
- Al, Cu and Ni master/casting alloys containing 1 – 15% beryllium;
- Beryllium oxide (BeO) is mainly used in form of ceramics.

Because of the unique combinations of these individual properties of lightweight, strength, ductility, formability, machinability, electrical and thermal conductivity, fatigue resistance, resistance to loss of strength with long term exposure to heat, non-magnetic, non-sparking etc., BeST indicates that no other material can offer the same combinations of these properties like beryllium and beryllium alloys.

For the major part, beryllium is used as a component of alloys, especially in copper alloys. Only a few products contain pure beryllium metal or high beryllium containing composite parts. Beryllium metal is mainly used in form of alloys as it provides for long product service life, reliability and

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[18] http://beryllium.eu/about-beryllium/properties-of-pure-beryllium/; BeST (2018); ThermoFisher (2018), ZWEI (2018)

consistent electrical performance in moving/mating parts over the extended lifetime of RoHS category 9 industrial equipment (TMC 2018).[19]

As an alloying component in combination with copper, aluminium, or other metals, beryllium increases the alloys' rigidity, modulus of elasticity. Moreover, these alloys have a low density and better corrosion resistance in comparison with other light metals. For instance, high performance copper beryllium alloys (CuBe), containing 0.10 – 2.0% beryllium, offer the best possible combination of mechanical strength and electrical conductivity in EEE as well as thermal conductivity, resistance to corrosion and a high modulus of elasticity. Moreover, the alloy's properties enhance product performance, increase reliability, extend life products and facilitate miniaturisation of components and products in EEE.

Other alloys, e.g. aluminium beryllium alloys, are mainly used in the aerospace and space industries, however these application areas are outside of the scope of RoHS (AEM 2018).[20] Nickel beryllium alloys are used for springs that require need to retail high elastic modulus at elevated temperatures for a long product lifetime, such as thermostats and electric connectors (e.g. in plugs, sockets, and electromechanical switches etc.). According to the Association of Equipment Manufacturers AEM (2018),[21] nickel beryllium alloys are less common in the EEE sector than copper beryllium alloys.

Beryllium ceramics or powder, containing BeO in concentrations of 20% to 37% beryllium (BeST 2014)[22] has high heat conductivity and is therefore used for heat sinks in electronic appliances as well as an electrical insulator and thermal conductor for high-temperature equipment or in high technology ceramics. The Beryllium Science & Technology Association (BeST) asserts that beryllium oxide is typically applied to high-end products and rarely to consumer EEE. Beryllium oxide is one of the most expensive raw materials used in ceramics. The expense is linked in part to the precautions to avoid the toxic effects of the powder when handling during fabrication.[23] Beryllium ceramics is used in high power devices or high-density electronic circuits for high speed computers (ibid). Moreover, since BeO is transparent to microwaves, the material may be used as windows and antennas in microwave communication systems and microwave ovens (ibid).

Some power semiconductor devices have used beryllium oxide ceramic between the silicon chip and the metal mounting base of the package in order to achieve a lower value of thermal resistance

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[19] Test and Measurement Coalition TMC (2018): Contribution submitted on 15.06.2018 during the stakeholder consultation conducted from 20 April 2018 to 15 June 2018 in the course of the study to support the review of the list of restricted substances and to assess a new exemption request under RoHS 2 (Pack 15); http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Pack_15/1st_Consultation_Contributions/Contribution_TMC_7_Substances_response_20180615_fin.pdf

[20] Association of Equipment Manufacturers AEM (2018): Contribution submitted on 15.06.2018 during the stakeholder consultation conducted from 20 April 2018 to 15 June 2018 in the course of the study to support the review of the list of restricted substances and to assess a new exemption request under RoHS 2 (Pack 15); http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Pack_15/1st_Consultation_Contributions/Contribution_AEM_Beryllium_20180615_RoHS.PDF

[21] Opt. cit. AEM (2018)

[22] Beryllium Science & Technology Association BeST (2014): Contributions submitted during stakeholder consultation on 04.04.2014; documents to be retrieved at: http://rohs.exemptions.oeko.info/index.php?id=213

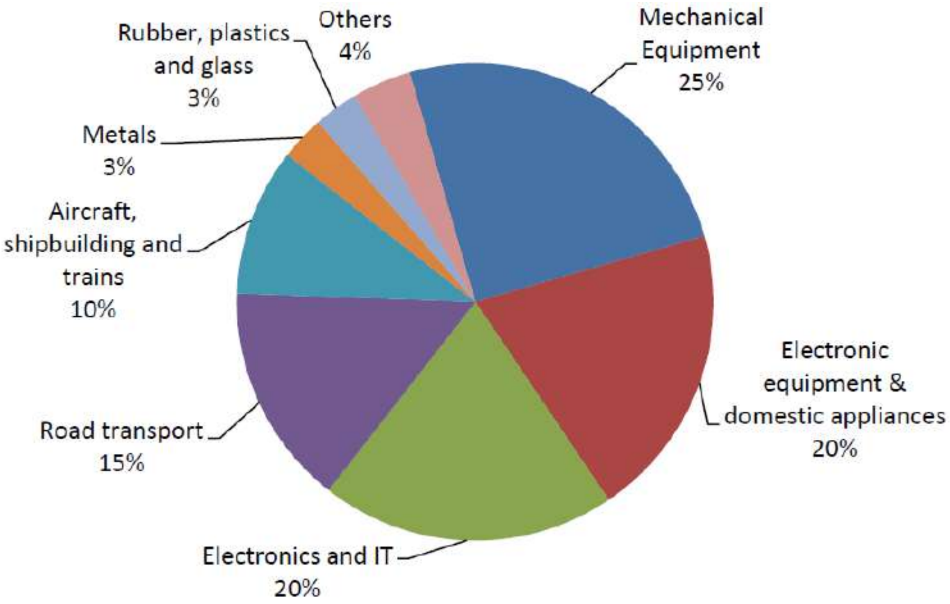
[23] AZoM (2001) Beryllium Oxide – Beryllia. https://www.azom.com/article.aspx?ArticleID=263 last viewed 26.08.2019

than for a similar construction made with alumina. It is also used as a structural ceramic for high-performance microwave devices, vacuum tubes, magnetrons, and gas lasers.[24]

2.2 Types of applications / types of materials

Beryllium is used across various industrial sectors as shown in Figure 2-1. EEE Applications that are within the scope of RoHS account for roughly 40% of the beryllium consumption.

Figure 2-1: End-use of beryllium in Europe in 2012 (by weight)



Source: BeST (2013) quoted by European Commission (2015)[25]

Table 2-1 shows relevant applications of beryllium as compiled by the German Federal Institute for Occupational Safety and Health (BAUA 2014) during its CORAP substance evaluation.[26]

Table 2-1: Overview of relevant application areas of beryllium and beryllium oxide

Sector	Applications examples
Aerospace (not under RoHS)	• Engines and rockets • Brakes and landing gear • Satellites and gyroscopes • Precision tools • Altimeters • Mirrors

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[24] Stanford Advanced Materials (SAM) https://www.samaterials.com/beryllia-/968-beryllium-oxide-beo-ceramic-heat-sinks.html last viewed 26.08.2019

[25] European Commission (2015): Report on critical raw materials for the EU - Critical raw materials

[26] The German Federal Institute for Occupational Safety and Health (BAUA) (2014) Substance evaluation report Beryllium; ZWEI (2018); AEM (2018); BeTS (2018); ESIA (2018); MedTech Europe (2018)

Sector	Applications examples
Energy and industrial equipment (not under RoHS)	• Heat exchanger tubes and heat sinks (BeO ceramics) • Electric motor brushes • Relays and Switches • Microelectronics and Microwave devices • Nuclear reactor components (Thermonuclear Experimental Reactor) • Oil field drilling devices
Telecommunications and ICT (RoHS categories 3, 4)	• Undersea repeater housings • Mobile phones; personal computers • RF-cable assemblies, • Transistor mountings on printed circuit boards • Substrate for integrated circuits, structural ceramics for ICs etc. • Electrical connectors, contacts, switches and springs • Lightweight housings and electromagnetic shielding
Components used in generic electrical and electronic equipment (EEE)[27] (including all RoHS categories except cat. 5)	• Electrical connectors and contacts, e.g. headers and wire housing; board-to-board connectors; RF-connectors; IC-sockets etc. • Thermal management components: dielectric heat sinks, thermal conductive paste, thermal grease (premium products may contain BeO based precision ceramic parts), • Circuit protection: fuse clips, • Test leads and test sockets, • Electromechanical DIP/SIP-switches, • Electric motors with sliding contact brushes • EMC (Electromagnetic Compatibility) gaskets, Fingerstock shields, • Different types of springs (spring clip, battery springs, contact springs); battery contacts and connectors
(Bio-)Medical and industrial devices (RoHS categories 8, 9)	• XRF/XRD spectrophotometric equipment: X-ray tube windows (Be-foil with typical size of 12x12 mm x 12.5 µm) • Magnetic Resonance Imaging, Scanning electron microscopes, • Medical & industrial laser and plasma generators • Elements of connectors; components in switches and attenuators; probe tips and contacts, HRF connectors, • BeO ceramic encapsulation of high-power semiconductors •
Defence (not under RoHS)	• Tank mirrors • Springs on submarine hatches • Mast mounted sights • Missile guidance • Nuclear triggers
Fire prevention	• Non-sparking tools • Sprinkler systems

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[27] https://eu.mouser.com/_/?Keyword=beryllium

Sector	Applications examples
Automotive (not under RoHS)	• Air-bag triggers • Anti-lock braking systems • Steering wheel connectors
Miscellaneous (non EEE applications - not under RoHS)	• Plastic moulds • Bellows • Jewellery (aquamarine and emerald mineral) • Golf clubs • Bicycle frames • Camera shutters • Fishing rods • Pen clips • Scrap metal recovery and recycling • Precision ceramics

Source: BAUA (2014) complement with data from various stakeholders to the consultation conducted from 20 April 2018 to 15 June 2018

Beryllium alloys are used in many specialised electronics applications, as they can be used to design miniaturised components (Foley et al. 2017). This is especially desirable for mobile consumer electronics such as smartphones with slim design. For a robust and reliable design (also for electromagnetic shielding), small gaps in the devices are sealed by a flexible mesh, so called finger stock. That mesh is often made of CuBe alloy because it is the strongest copper alloy. It retains about 22% to 28% of the conductivity of pure copper, and it has excellent shielding performance. The alloy contains 1.8% to 2.0% of beryllium and a minimum of 0.2% of nickel and cobalt but no more than 0.6% of nickel and cobalt and iron.[28]

Semiconductor devices that use beryllium oxide ceramics instead of aluminum oxide between the silicon chip and the metal mounting base tend to last longer because the beryllium oxide ceramics provide more heat resistance, efficient thermal management and effective heat dissipation (Foley et al. 2017). Beryllium oxide is specifically used in the ceramic encapsulation of high-power semiconductors to provide the best possible combination of thermal conductivity and dielectric property.

Table 2-2: Identified uses of beryllium and Be-compounds in electrical and electronic equipment

Beryllium and its compounds	Functions of Be	Examples on the component level	Examples of the EEE-relevant Applications	Concentration estimated
Beryllium-copper alloys	• A hardening agent in metal, high strength, electromagnetic shielding	Springs and spring-loaded electrical contacts and connectors	Used in telecommunication applications and high-conductivity alloys in automotive	• High-strength alloys contain typically
		• EMC (Electromagnetic	EEE devices, that need to be sealed against EMI (and	

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[28] https://www.evaluationengineering.com/home/article/13014317/emc-gaskets-sealing-against-emi-and-the-environment

Beryllium and its compounds	Functions of Be	Examples on the component level	Examples of the EEE-relevant Applications	Concentration estimated
		compatibility) gaskets[30]	dust), depending on their design	1.6%-2% Be [29]
	• High conductivity	• SMD (Surface mounted devices) contact springs; • Golden Brick contact • Wire clampers for PCB • Grounding contact • Conductive connectors, used to make contacts and connectors, relays, switches and shielding	• Antenna contacts (used in the smartphone)[31] • Battery contacts and electric clamps, used in almost all EEE devices, such as washing machines, clothes dryers, dish washers, microwaves, air con-ditioners, printed circuits boards, televisions, computers, etc.[32]	• High conductivity alloys containing 0.2%-0.6% Be
Beryllium-nickel alloys	• high strength and high temperature stability	• mechanically and thermally highly stressed springs, contacts, and connectors.	• “Test & Burn-in”[33] sockets for stress testing electronic devices (i.e. chips); • high temperature commercial lighting fixtures (e.g. halogen lamps)[34]	• Commoditi-sed NiBe alloys contain Be in the range of 2 wt%. e.g. “Alloy 360” contains 1.85%-2.05% Be in weight[35]

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[30] https://www.evaluationengineering.com/home/article/13014317/emc-gaskets-sealing-against-emi-and-the-environment

[29] http://www.ngk-alloys.com/NGK_Berylco_Design_Guide_En.pdf; http://beryllium.eu/wp-content/uploads/2016/07/Beryllium-Production-and-Outlook-Roskill-Mineral-Sevices.pdf

[31] https://www.ajato.com.tw/product/spring-contact/#Spring-contact-application

[32] Foley et al. 2017

[33] Test sockets and burn-in sockets are considered part of the electronic connector market, while wafer probes are designed to test bare die and wafers in the semiconductor equipment market. https://www.bce.it/wp-content/uploads/2013/10/BCE-Test-and-burn-in-sockets-_10-13_.pdf

[34] https://www.mill-max.com/products/new/high-temperature-beryllium-nickel-contacts

[35] https://materion.com/-/media/files/alloy/datasheets/other-alloy-products/ad0005_0615-alloy-360-nickel-beryllium-strip.pdf

Beryllium and its compounds	Functions of Be	Examples on the component level	Examples of the EEE-relevant Applications	Concentration estimated
Beryllium oxide ceramics	• Effective heat dissipation for small sized thermal manage-ment for EEE components,[36]	• Beryllium oxide (BeO) ceramic heat sinks, e.g. high-power semiconductors and power operational amplifiers	•	• Up to 99.9% beryllium oxide
Beryllium oxide ceramics	• (Be-bearing ceramic encapsulation provides an electric insulating material with excellent thermal conductivity).	• Radio Frequency (RF) power transistors; valve bases, some resistors[37]	• -Power amplifiers are used in aerospace & Hi-reliability communications, avionics & radar, Industrial & medical equipment.[38]	• containing 20% to 37% beryllium oxide (BeST 2014)[39]
		• other semiconductor components as a heat sink material,[40] e.g. transistor heat sinks[41]	• Generic EEE equipment	

Not all applications listed above are used for consumer EEE. Some specific uses of beryllium in industrial EEE, identified during the stakeholder consultation, include:

- Beryllium metal related to the use in X-Ray devices such as tubes and detectors[42], as its physical properties allow for maximum X-Ray transmission, excellent vacuum and thermal performance, and mechanical toughness;

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[36] Coherent (2018); TMC (2018)

[37] Greening of Electronics. Danish Ministry of the Environment, Environmental Project No. 1416, 2012, https://www2.mst.dk/Udgiv/publications/2012/07/978-87-92779-99-1.pdf

[38] ESIA (2018): ESIA submission Stakeholder Consultation on Be and its compounds - RoHS Substances Study Contribution, submitted on 15.06.2018

[39] Beryllium Science & Technology Association BeST (2014): Contributions submitted during stakeholder consultation on 04.04.2014; documents to be retrieved at: http://rohs.exemptions.oeko.info/index.php?id=213, last viewed 11.06.2018

[40] https://materion.com/-/media/files/beryllium/engineering-design/beryllium-as-a-heat-sink_materion.pdf

[41] http://www.delbertblinn.com/page_2frame.htm

[42] OLYMPUS OSSA (2018): Contribution submitted on 05.06.2018 during the stakeholder consultation conducted from 20 April 2018 to 15 June 2018 in the course of the study to support the review of the list of restricted substances and to assess a new exemption request under RoHS 2 (Pack 15); http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Pack_15/1st_Consultation_Contributions/OlympusOSSA_Submission-for-beryllium-and-its-compounds.pdf

- Beryllium metal or CuBe for use electron microscopes, spectrophotometers such as mass spectrometers, XRF/XRD equipment, surface analysis and micro analysis tooling;[43]
- Copper-Beryllium (CuBe) alloys are essential in the connectors of electrical cars, autonomous, vehicles, and solar panels;
- CuBe alloys in electrical contacts[44] (springs, contact springs, terminals connector) of industrial equipment;
- CuBe alloys for use in electrical connectors [45] and components in switches and attenuators; probe tips and contacts, HRF connectors, and springs and gaskets;
- BeO used as expansion matched submounts for the horizontal arrays;[46]
- BeO is specifically used in the ceramic encapsulation of high-power semiconductors to provide efficient thermal management and effective heat dissipation;[47]
- BeO use in high frequency high power integrated circuit packages. These are mainly used by the telecoms sector;[48]
- BeO, is an insulating material used in the construction of Radio Frequency (RF) Power transistors in power amplifiers.
- In its response to the stakeholder consultation, the Beryllium Science & Technology Association (BeST 2018)[49] states that the EEE manufacturers use beryllium only as a metal, mainly as alloying element in copper and as beryllium oxide ceramic. Beryllium salts or soluble compounds are not used in EEE. AEM (2018) states that *"Only beryllium metal, its alloys and beryllium oxide occur in*

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[43] Thermo Fisher (2018): Contribution submitted on 13.06.2018 during the stakeholder consultation conducted from 20 April 2018 to 15 June 2018 in the course of the study to support the review of the list of restricted substances and to assess a new exemption request under RoHS 2 (Pack 15); http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Pack_15/1st_Consultation_Contributions/Contribution_ThermoFischerScientific_Beryllium_RoHS_Consulation_public.pdf

[44] EDAX Inc. (2018): Contribution submitted on 11.06.2018 during the stakeholder consultation conducted from 20 April 2018 to 15 June 2018 in the course of the study to support the review of the list of restricted substances and to assess a new exemption request under RoHS 2 (Pack 15); http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Pack_15/1st_Consultation_Contributions/Contribution_EDAX_Inc_Beryllium_2ss180608.pdf

[45] MedTech Europe (2018): Contribution submitted on 15.06.2018 during the stakeholder consultation conducted from 20 April 2018 to 15 June 2018 in the course of the study to support the review of the list of restricted substances and to assess a new exemption request under RoHS 2 (Pack 15); http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Pack_15/1st_Consultation_Contributions/Contribution_MedTech_Europe_7_substance_contribution20180613_FINAL.PDF

[46] Coherent (2018b): Contribution submitted on 12.06.2018 during the stakeholder consultation conducted from 20 April 2018 to 15 June 2018 in the course of the study to support the review of the list of restricted substances and to assess a new exemption request under RoHS 2 (Pack 15); http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Pack_15/1st_Consultation_Contributions/Contribution_2_Coherent_Beryllium_Usage_Survey_at_Coherent_BUs_Ron_M_6-12-18_20180613.pdf

[47] Test and Measurement Coalition TMC (2018): Contribution submitted on 15.06.2018 during the stakeholder consultation conducted from 20 April 2018 to 15 June 2018 in the course of the study to support the review of the list of restricted substances and to assess a new exemption request under RoHS 2 (Pack 15); http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Pack_15/1st_Consultation_Contributions/Contribution_TMC_7_Substances_response_20180615_fin.pdf

[48] European Semiconductor Industry Association ESIA (2018): Contribution submitted on 15.06.2018 during the stakeholder consultation conducted from 20 April 2018 to 15 June 2018 in the course of the study to support the review of the list of restricted substances and to assess a new exemption request under RoHS 2 (Pack 15); http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Pack_15/1st_Consultation_Contributions/Contribution_ESIA_BeO_Final_15062018.pdf

[49] Opt. cit. BeST (2018)

electrical and electronic equipment (EEE). Other beryllium compounds such as the sulphate, chloride, nitrate, etc. have no known uses in EEE".[50] This statement is endorsed by BeST (2018), which confirms that the scope of the current substance evaluation, namely "beryllium metal and beryllium oxide" represents the only scope significant for the RoHS Directive. It is to be mentioned that the overview above omits possible applications of beryllium as intermediary material used in production processes in the course of EEE supply chains. EUROMOT (2019) remarks that "*all applications using Beryllium and its compounds are considered life of engine components meaning they are not intended to wear or be replaced as a maintenance item"*.[51]

2.3 Quantities of the substance used

The annual worldwide production of beryllium in 2014 was estimated at 300 metric tonnes, while imports of CuBe alloys (in form of strips & rods), pure Be and BeO into the EU were about 40 metric tonnes /year, according to BeST (2016; 2019).[52] USGS (2019) reports a global production volume for beryllium metal of 230 metric tonnes as of 2018. However, literature data from different sources on production and consumption of beryllium is contradictory to some degree. Knudson & Wilkins (2014) report that the worldwide beryllium consumption was about 400 metric tonnes per year and SCOEL (2017) quote (JRC 2012), that the future world consumption is expected to grow to 350 metric tonnes by 2020 and 425 metric tonnes by 2030, due to the application for fusion reactor power generator construction. The United States dominate the world's mine production of beryllium raw material. As illustrated by Figure 2-2, 73% of the world's primary beryllium supply is supplied to the world market by the United States, followed by China with 22%.

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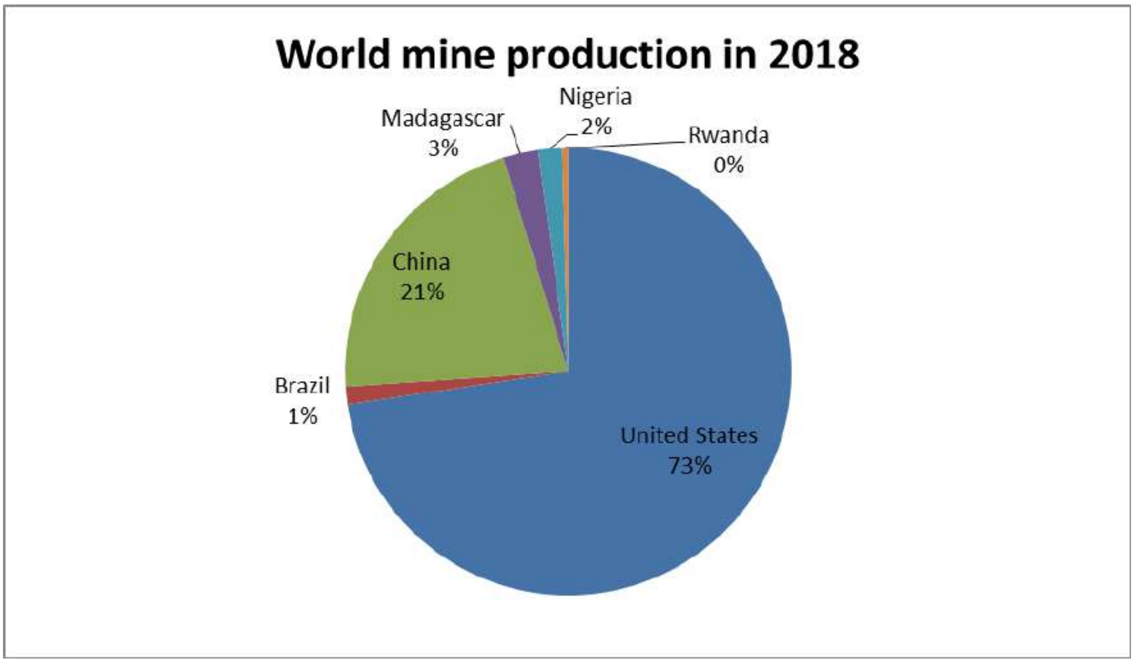
[50] Association of Equipment Manufacturers AEM (2018): Contribution submitted on 15.06.2018 during the stakeholder consultation conducted from 20 April 2018 to 15 June 2018 in the course of the study to support the review of the list of restricted substances and to assess a new exemption request under RoHS 2 (Pack 15);

[51] EUROMOT (2019): Contribution submitted on 7 November 2019 during the stakeholder consultation conducted from 26 September 2019 until 07 November 2019 in the course of the study to support the review of the list of restricted substances and to assess a new exemption request under RoHS 2 (Pack 15)

[52] BeST (2014): http://beryllium.eu/about-beryllium/facts-and-figures/ and BeST (2019): http://beryllium.eu/wp-content/uploads/2019/08/Beryllium-Infographics-Light-1.pdf , last viewed 09.03.2020

Figure 2-2: Country shares of primary beryllium production in 2018



Source: USGS (2019)

The most comprehensive consumption figures for beryllium commodities are available from the U.S. governmental organisation USGS. Figure 2-3, recited from the USGS report (2016), shows the beryllium flows in percent from mining to the end use stage. According to these figures, based on value-added sales revenues, 75% of the global beryllium production was used to make alloys, while the use of pure beryllium metal accounts for 20%. The remaining 5 percent of beryllium consumption are attributable to Be-bearing ceramics (USGS 2016[53]). The USGS report specifies that beryllium alloy strip and bulk products (the most common forms of processed beryllium) were used across all application areas mentioned. The majority of unalloyed beryllium metal and beryllium composite products were used in defence and scientific applications. Consumer electronics and telecommunications infrastructure, which are both included in the scope of RoHS, account for 26% of the total global beryllium consumption. In the EU, approximately 40% of beryllium commodities were used in telecommunications, electronics, automotive electronics (16%), aerospace components and general EEE (10%) and other (non EEE) end-use markets (34%) according to BeST (2018).

Figure 2-3: Beryllium flows from mining to end use stage (source: USGS 2016[53])

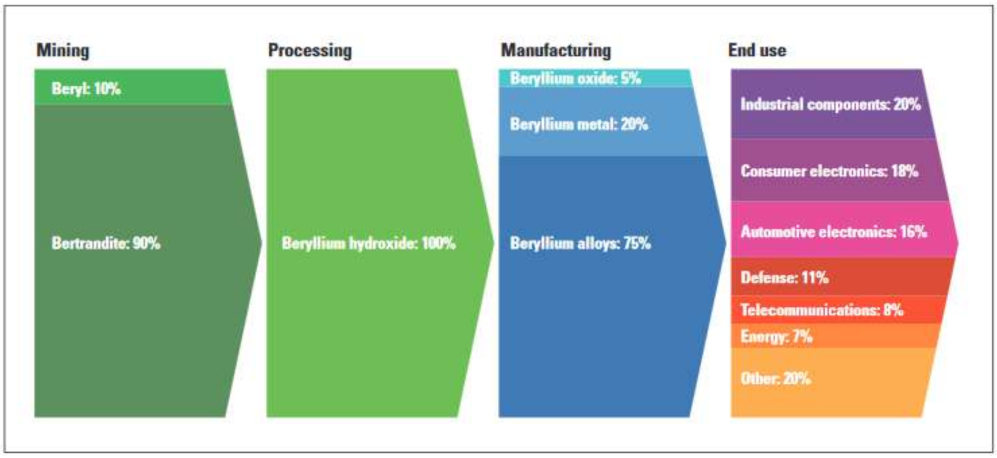


Figure 2. Simplified flow diagram of the beryllium industry. Percentages are relative to the total beryllium flow at each stage; flows between stages do not account for losses, changes in stocks, or recycling. End use category labelled "Other" includes 2 percent used in medical applications (Materion Corporation, 2016).

Source: USGS (2019)

The EU is a net importer of beryllium. Figure 2-4 demonstrates the simplified beryllium flow by weight in the EU. According to BeST (2018), the beryllium consumption in the EU is approximately 50 tonnes per year (about 14% of the worldwide consumption). 80% of the beryllium used in the EU goes into the production of beryllium alloys. Pure beryllium metal accounts for 16% of beryllium consumption in the EU, whereas beryllium oxide accounts for 4% approximately (extrapolated from the proxy estimation of the percentage distribution in the United States). In the EU, about 40% of beryllium is used in EEE and telecommunication equipment, which is included in the scope of the RoHS Directive (AEM 2018).[54] That amount equals about 23 tonnes per annum. However, a substantial amount of beryllium imports in the EU may be unaccounted for in raw material trade figures, as the substance is also contained in imported semi-finished products or finished consumer and industrial products. The quantities of beryllium used in other sectors are calculated based on the percentage distribution published by the 2015 report on critical raw materials for the EU.[55]

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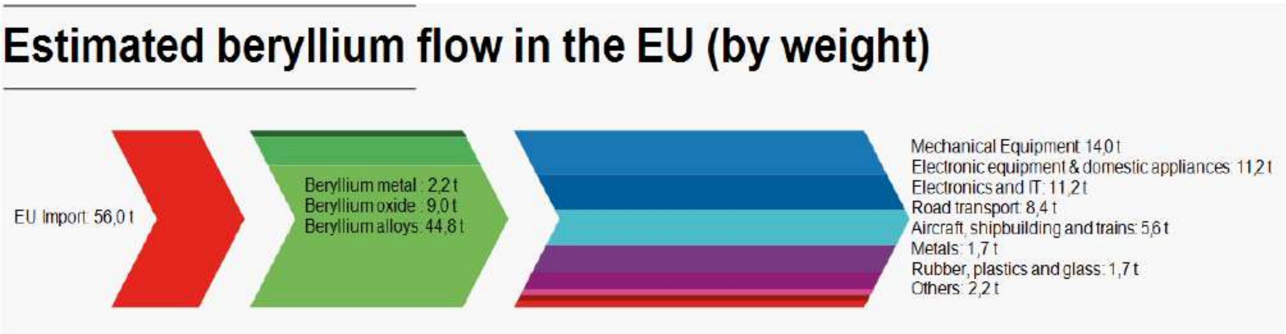
[53] USGS (2016) Beryllium—A Critical Mineral Commodity— Resources, Production, and Supply Chain https://pubs.usgs.gov/fs/2016/3081/fs20163081.pdf, last viewed 28.08.2019

[54] Association of Equipment Manufacturers AEM (2018): Contribution submitted on 15.06.2018 during the stakeholder consultation conducted from 20 April 2018 to 15 June 2018 in the course of the study to support the review of the list of restricted substances and to assess a new exemption request under RoHS 2 (Pack 15);

[55] European Commission (2015) Report on critical raw materials for the EU - Critical raw materials profiles. http://ec.europa.eu/DocsRoom/documents/11911/attachments/1/translations, last viewed 18.07.2019

Figure 2-4: Simplified beryllium flows in the EU to end use stage



Source: USGS (2019)

More detailed specification of the amounts of beryllium on the level of distinct products is not possible as numbers on beryllium contents in applications are not publicly available. Table 3-1 exemplary shows the extrapolated amount of beryllium used in EEE-products based on the available information. Knudson and Wilkins (2014) state that, among EEE applications that use beryllium-containing alloys, some models of cellular phones contain the highest amount of beryllium among WEEE items, reaching 40 ppm (parts per million). Strip-down analyses of electrical and electronic devices show that a typical smart phone such as an Apple I-Phone 5 contains 15.6 ppm beryllium.

Table 2-1: Estimation of the amount of beryllium used in exemplary EEE-products

Product types	Assumed beryllium concentration in products	Weight of reference products	Extrapolated amount of beryllium per product
Mobile phone	0.1% in weight[56]	Weight of an Apple iPhone 5: 112 g [57]	112 mg / Smartphone (=112g*0.1%*1,000)
Personal computer	0.0157% in weight[58]	Weight of a desktop PC[59]: 11.7 kg	1.84 g (=11.7 kg*0.0157%*1,000)
Computer Display	Alloy Cu-0.7Be: 0.3% in mass (HP, 2019[60])	Weight of a 27” HP display: 4.86 kg[61]	102 mg / Display (=4.86 kg*0.3%*0.7%*10^6)

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[56] Greening of Electronics. Danish Ministry of the Environment, Environmental Project No. 1416, 2012, https://www2.mst.dk/Udgiv/publications/2012/07/978-87-92779-99-1.pdf

[57] https://support.apple.com/kb/SP655?viewlocale=en_US&locale=de_DE

[58] http://web.mit.edu/ieee/sanjay/11.122/ewaste.htm

[59] https://www.eup-network.de/fileadmin/user_upload/Produktgruppen/Lots/Final_Documents/EuP_Lot3_PC_FinalReport.pdf; average weight of home desktops

[60] http://h20195.www2.hp.com/V2/getpdf.aspx/c05117791.pdf

[61] https://store.hp.com/GermanyStore/Merch/Product.aspx?id=4HZ38AA&opt=ABB&sel=MTO

3 HUMAN HEALTH HAZARD PROFILE

The following recites the harmonised hazard statements for human health hazards the CLP regulation that apply for beryllium metal, beryllium oxide (BeO) and beryllium compounds with the exception of aluminium beryllium silicates:

- Carc. 1B (Carcinogenicity) - H350i (May cause cancer by inhalation)
- Acute Tox. 2 (Acute toxicity, inhalation) - H330 (Fatal if inhaled)
- Acute Tox. 3 (Acute toxicity, oral) - H301 (Toxic if swallowed)
- STOT RE 1 (Specific Target Organ Toxicity Repeated Exposure) - H372 (Causes damage to organs through prolonged or repeated exposure).
- Eye Irrit. 2 (Serious eye damage/eye irritation)- H319 (Causes serious eye damage)
- STOT SE 3 (Specific target organ toxicity, single exposure; Respiratory tract irritation - H335 (May cause respiratory irritation)
- Skin Irrit. 2 (Skin corrosion/irritation) - H315 (Causes skin irritation)
- Skin Sens. 1 (Sensitisation, skin) - H317 (May cause an allergic skin reaction)

3.1 Critical endpoint

According to SCOEL (2017),[62] it is assumed that the toxicity of beryllium is attributable to particulate beryllium dust or fumes. Taylor et al (2003) recapitulate that "*exposure to certain beryllium compounds, particularly less soluble forms such as beryllium metal and oxides, appears to be correlated with a higher incidence of disease*." Such particulate matter can emerge from thermal and dry mechanical metal crafting processes. The toxicity hazard profile of such dust correlates with their respective beryllium content. For alloys, this refers to the content of elemental beryllium metal. SCOEL summarizes that "*The lung is the main target organ at inhalation exposure to beryllium and beryllium compounds. At relevant exposure concentrations, critical health effects comprise carcinogenicity, beryllium sensitisation (BeS) and chronic beryllium disease (CBD).*" "*Inhaled beryllium is deposited in the lung tissue, particularly in pulmonary lymph nodes. It is distributed from the lungs to the skeleton, after being very slowly absorbed into the blood. The skeleton is the ultimate site of beryllium storage. Trace amounts are distributed throughout the body. Less than 1% of orally administered beryllium is absorbed via the gastrointestinal tract.*"

The Substance Evaluation Conclusion Document, submitted by BAUA (2014),[63] explained that beryllium is classified as a non-threshold carcinogen known to provoke "Beryllium Sensitisation" (BeS) as an early health effect of respiratory exposure to beryllium that can result in Chronic Beryllium Disease (CBD) in case of long-term exposure. BeS refers to the activation of the body's immune response and is not necessarily associated with noticeable health symptoms. Upon long term exposure to non-soluble forms of beryllium (e.g. dust), BeS can develop into Chronic Beryllium Disease, "*a potentially disabling or even fatal respiratory disease*" (NIOSH, 2011).[64] Maier (2010)[65]

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[62] Opt. cit. Scientific Committee on Occupational Exposure Limits SCOEL (2017)

[63] German Federal Institute for Occupational Safety and Health BAUA (2014): Substance Evaluation Conclusion Document, https://echa.europa.eu/documents/10162/f76365ec-ce93-4422-bdf6-519517cc68be, last viewed 19.04.2018

[64] NIOSH (2011): Preventing Sensitization and Disease from Beryllium Exposure. National Institute for Occupational Safety and Health https://www.cdc.gov/niosh/docs/2011-107/pdfs/2011-107.pdf?id=10.26616/NIOSHPUB2011107 last viewed 21.1.2020

[65] Maier, L.A. (2010): Beryllium Health Effects in the Era of the Beryllium Lymphocyte Proliferation Test. Journal of Applied Occupational and Environmental Hygiene)16(5):514-520.

reports "*that BeS precedes CBD and develops after as little as 9 weeks of beryllium exposure. CBD occurs within 3 months and up to 30 years after initial beryllium exposure".*

According to Wambach and Laul (2008), are "acute health effects, primarily chemical pneumonitis caused by the more soluble forms of Be" whereas "CBD is caused by the immune system's continuing reaction to the less soluble forms of beryllium retained in the body".[66] Up to 4% of people that are exposed to beryllium bearing dust develop CBD (ibid). However, BeS and CBD seem to be related to an individual disposition of humans to immune-system response against beryllium exposure rather than general health hazards of beryllium. The authors assert, that existing data from the U.S. authority DOE did not exhibit a correlation of CDB cases to the length of employment of a worker in a beryllium facility (ibid). SCOEL (2017) provides an extensive review of existing toxicological studies (human and animal as well as in vitro studies) on the development mechanisms of BeS and CBD. In summary, SCOEL explains that "In humans, the primary target of beryllium toxicity following inhalation exposure is the respiratory tract, leading to BeS, acute and chronic beryllium disease and lung cancer as the principal effects. Regarding acute beryllium disease, high levels of exposure can result in inflammation of the upper and lower respiratory tract and airways, bronchiolitis, pulmonary edema, and chemical pneumonitis. Repeated inhalation exposure to low concentrations of beryllium or beryllium compounds can cause chronic beryllium disease (CBD) in humans. CBD is a cell-mediated immunological reaction of delayed type and is generally observed after a long latent period. BeS precedes chronic beryllium disease (CBD), but the progression from sensitisation to disease is not fully understood. The prevailing view is that most individuals must first be sensitised before beryllium in the lungs can cause the lung damage of CBD, based on studies showing that almost all individuals with CBD with positive BeLPT are also sensitised." In the case of beryllium, it appears to be extremely difficult to establish exposure dose – response relationship. Long term exposure to beryllium, even at low doses, seems to be able to inflict CBD in persons that have already been sensitised and have an individual genetic susceptibility.

Beryllium compounds have been shown to be skin sensitisers in animal experiments. Following skin contact, beryllium and beryllium compounds can cause allergic contact dermatitis or a granulomatous skin reaction in humans. It is suspected, that working clothes, shoes, and the workers' vehicles contaminated with beryllium bearing dust can affect (cause skin sensitisation) not only their owners but their family members if carried home and cleaned in private households (Taylor et al, 2003).

Single respiratory exposure events at high concentrations (> 100 µg/m³) of both soluble and insoluble beryllium compounds can cause Acute Beryllium Disease (ABD) in humans (WHO, 2001).[67] BeST (2019)[68] asserts that only soluble compounds may cause ABD whereas the US-OSHA (2017) has concluded that poorly soluble compounds cannot be ruled out to cause ABD.[69] Cummings et al., (2009) report case studies, which indicate that exposure soluble beryllium compounds can cause ABD at concentrations below 100 µg/m³.[70] Symptoms of ABD range from mild inflammation of the upper respiratory tract to tracheo-bronchitis and severe pneumonitis. As for systemic effects, after repeated inhalation, cardiovascular, renal, hepatic and haematological effects, and weight loss were

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[66] Wambach, P.F. and Laul, J.C. (2008): Beryllium health effects, exposure limits and regulatory requirements. Journal of Chemical Health and Safety. 15(4):5-12.

[67] WHO (2001): Concise International Chemical Assessment Document 32: Beryllium and beryllium compounds. World Health Organization https://www.who.int/ipcs/publications/cicad/en/cicad32.pdf last viewed 22.1.2020

[68] BeST (2019): Contribution submitted on 7 November 2019 during the stakeholder consultation conducted from 26 September 2019 until 07 November 2019 in the course of the study to support the review of the list of restricted substances and to assess a new exemption request under RoHS 2 (Pack 15)

[69] OSHA (2017): Occupational Exposure to Beryllium; Final Rule, US Occupational Safety and Health Administration, https://www.osha.gov/laws-regs/federalregister/2017-01-09 last viewed 22.1.2020

[70] Cummings, k.J.; Stefaniak, M. A.B.; Virji, A. and Kreis, K. (2009) A Reconsideration of Acute Beryllium Disease. Environmental Health Perspectives, 117(8):1250-1256

observed in humans, which may be a consequence of functional respiratory restrictions. The implementation of strict occupational exposure controls at workplaces have caused ABD to become extremely rare but not non-existent nowadays OSHA (2017).

As for carcinogenicity and genotoxicity, SCOEL concludes that even though the mechanism of action of the carcinogenicity of beryllium is not yet elucidated, it appears to involve indirect genotoxicity and cell transformation rather than direct genotoxicity. Therefore, beryllium and its inorganic compounds must be considered as human carcinogens and are categorised in SCOEL carcinogen group C (genotoxic carcinogen for which a practical threshold may exist). As for reproductive toxicity after respiratory exposure, no data could be found because human studies or animal studies were not available.

3.2 Existing Guidance values (DNELs, OELs)

In the EU, 65,000 workers are potentially exposed to beryllium. BeST (2019) estimates approximately 15,000 workers are potentially exposed to beryllium airborne particles in the EU, due to the intentional use of beryllium containing materials.[71] About 1,250 of them are employed in foundry or similar processes, most of them in Italy, France, Germany, the United Kingdom, Switzerland and Hungary. These workplaces are of particular concern as the highest exposure levels exceed 2 µg/m^3. Because of the trend to move foundry work to China, the number of workers in this sector in the EU may decrease in the future (IOM 2011).

In the EU, the Directive (EU) 2019/983, amending the Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work stipulates an OEL limit value of 0.2 µg/m^3 for beryllium and its inorganic compounds, coming in effect by July 2026. Currently, an OEL limit value of 0.6 µg/m3 applies during a transitional period of 7 years. On the level of EU member states, national regulations stipulate varying OEL limit values for beryllium and beryllium compounds (Table 3-1). Beyond the EU, various countries have also stipulated OEL limit values for beryllium and beryllium compounds (Table 3-2).

Table 3-1: Overview of existing OELs for beryllium and beryllium compounds in EU countries

EU	TWA (8hrs)		STEL (15min)		Remarks	References
	ppm	mg/m³	ppm	mg/m³		
Austria		0.002		0.008	TRK	AT GKV (2011)
Belgium		0.002		0.01	8 hrs TGG (TWA)	BE KB (2014)
Denmark		0.001				DK BEK (2011)
Germany (DFG)					BGV (BAR): 0.05 µg/l beryllium/L urine	Drexler and Hartwig (2012)
Finland		0.0001		0.0004	STEL = 15 min. average	FI MSAH (2012)
France (INRS)		0.002			VME = TWA 8 hrs	FR INRS (2012)
France (ANSES)		0.00001			(Recommendation only) Skin notation	FR ANSES (2010)
Ireland		0.0002				IE HSA (2011)
Sweden		0.002			Total dust	SE SWEA (2015)
UK		0.002			TWA	GB HSE (2011)

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[71] BeST (2019): Contribution submitted on 7 November 2019 during the stakeholder consultation conducted from 26 September 2019 until 07 November 2019 in the course of the study to support the review of the list of restricted substances and to assess a new exemption request under RoHS 2 (Pack 15)

- BAR [Biologischer Arbeitsstoff Referenzwert] = biological reference value
- TWA = Time-Weighted Average (usually 8 hours average).
- STEL = Short Term Exposure Limit (usually 15 minutes average).
- TGG [TijdGewogen Gemiddelde] = TWA.
- TRK [Technische RichtKonzentration] = indicative concentration.
- REL = Recommended Exposure Limit (NIOSH)
- TWAEV = Time-Weighted Average Exposure Value = TWA
- PEL = Permissible Exposure Level (OSHA)
- VME [Valeur Moyenne d'Exposition] = TWA.

Source: Scientific Committee on Occupational Exposure Limits SCOEL (2017); COM (2018) 171 final[72]

Table 3-2: Overview of existing OELs for beryllium and beryllium compounds in non-EU countries (expressed as Be)

EU	TWA (8hrs)		STEL (15min)		Remarks	References
	ppm	mg/m³	ppm	mg/m³		
Australia		0.002			TWAEV	AU SWA (2011)
CA (Ontario)		0.002		0.01	TWA	CA OML (2013)
CA (Québec)		0.002				Canada (2016)
Japan		0.002				JA JSOH (2015)
New Zealand		0.002				NZ HS (2013)
Norway		0.001				NO NLIA (2011)
Switzerland		0.002			inhalable aerosol	CH SUVA (2015)
USA (OSHA)		0.002		0.005	PEL	US OSHA (2006)
USA (NIOSH)		0.0005		0.0005	scientific opinion on REL	US NIOSH (2016)
USA (ACGIH)		0.00005			scientific opinion on TLV-TWA	US ACGIH (2012)

Source: Scientific Committee on Occupational Exposure Limits SCOEL (2017); COM(2018) 171 final

In the U.S., OSHA has established a permissible exposure limit (PEL) for beryllium of 0.2 µg/m^3 (8-Hr TWA) and 2.0 µg/m^3 as the short-term exposure limit, over a 15-minute sampling period.[73]

Internationally, the beryllium industry has launched the "Be Responsible" voluntary product stewardship programme in March 2017.[74] The Recommended Exposure Guideline (REG) endorses an exposure limit of 0.6 µg/m³ (inhalable), measured as an 8-hour time weighted average (TWA). The "Be Responsible" Programme seeks to continuously improve workers safety during the production and processing of beryllium-containing material and is continually evaluating its effectiveness.[75]

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[72] Opt. cit. Scientific Committee on Occupational Exposure Limits SCOEL (2017)

[73] Occupational Safety and Health Administration (OSHA) (2019): Final Rule to Protect Workers from Beryllium Exposure. https://www.osha.gov/berylliumrule last viewed 2.3.2020

[74] www.berylliumsafety.eu, last viewed 2.3.2020

[75] BeST (2019): Contribution submitted on 7 November 2019) during the stakeholder consultation conducted from 26 September 2019 until 07 November 2019 in the course of the study to support the review of the list of restricted substances and to assess a new exemption request under RoHS 2 (Pack 15)

4 ENVIRONMENTAL HAZARD PROFILE

Very few environmental assessments studies for beryllium or beryllium compounds could be found in the body of publicly available literature, nor were such studies mentioned by stakeholders during the consultation. BAUA (2014) did not assess environmental hazards during the CORAP substance evaluation for beryllium. The entries in the ECHA database on registered substances for beryllium and beryllium oxide do not contain eco-toxicological information.

Taylor et al (2003) report the results of a review study of beryllium in the environment. The authors state that “Beryllium contamination of soils, surface water, groundwater, and air in close proximity to facilities where beryllium has been manufactured, machined, and tested is not well documented” (neither in the U.S. nor outside the U.S.).

Geologic background concentrations of beryllium in water bodies vary depending on the occurrence of geochemically mobilised beryllium minerals. Acidic, organic-rich continental river waters exhibit a higher level of beryllium than ocean water and the beryllium concentration in groundwater tends to be higher than in surface waters. “*The beryllium content of ocean waters (*10^4 *to* 10^1 *mg/l for the Pacific Ocean) is approximately three orders-of-magnitude less than that of river waters*” (ibid). In soil, “*Natural beryllium concentrations range from a mean of 0.1 mg/kg to 40 mg/kg at locations around the world*” (ibid). Coal contains beryllium typically range from 1.46 to 1.52 mg/kg (data for the U.S.). The combustion of coal in power plants contributes to widespread environmental beryllium pollution if emission controls are insufficient. Taylor et al (2003) state that in the U.S. “*an estimated 80% of all beryllium emissions in the US originate from coal-fired vessels.*”

Data on the impacts of beryllium on biota is lacking. However, the substance may have effects on organisms in the aquatic environment. There are a few notifiers that classify beryllium for being hazardous to the aquatic environment (Aquatic Acute 1 - H400, Very toxic to aquatic life).

4.1.1 Endpoints of concern, NOAECs, acute, chronic

There are no data available.

4.2 Potential for secondary poisoning and bioaccumulation

There are no data available.

4.3 Guidance values (PNECs)

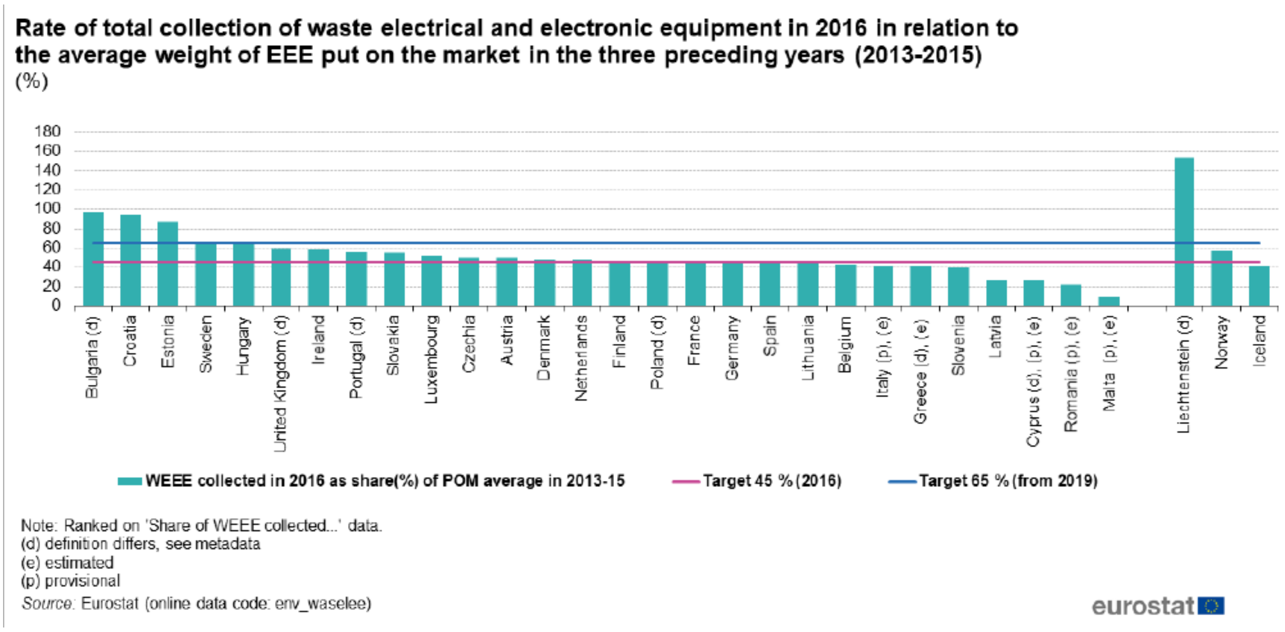
There are no data available.

5 WASTE MANAGEMENT OF ELECTRICAL AND ELECTRONIC EQUIPMENT

5.1 Description of waste streams

Waste electrical and electronic equipment (WEEE) is recycled or disposed of as solid waste. A certain amount of end of life EEE products are likely to be shipped outside the boundaries of the EU as second-hand goods. Between 2015 and 2016, the amount of EEE put on the EU market increased by 2.9% from 9.8 million tonnes to 10.1 million tonnes. The amount of collected WEEE varies across EU Member States. In 2016, eighteen EU Member States achieved or surpassed the 44.9% collection target for WEEE. Large household appliances accounted for 55.6% of the total collected WEEE. IT and telecommunications equipment (14.8%) and consumer equipment and photovoltaic panels (13.5%) are the second and third largest categories for WEEE collection in the EU, accounting for 669 thousand tonnes and 610 thousand tonnes respectively. Small household appliances contributed with 408 thousand tonnes, accounting for 9.0% to WEEE collection. The remaining seven categories together totalled about 325 thousand tonnes, or 7.2% of WEEE collected in the EU in 2016.[76]

Figure 5-1: Rates of WEEE collected per EU country in 2016



Rate of total collection of waste electrical and electronic equipment in 2016 in relation to the average weight of EEE put on the market in the three preceding years (2013-2015)
(%)

Note: Ranked on 'Share of WEEE collected...' data.
(d) definition differs, see metadata
(e) estimated
(p) provisional
Source: Eurostat (online data code: env_waselee)

Source: Eurostat (2019)

Hence, roughly 40% of the beryllium contained in the WEEE can be expected to enter a WEEE recycling process whereas the remaining 60% are disposed of together with WEEE as part of (municipal) solid waste. An unknown amount of beryllium is probably exported as second-hand EEE to non-EU countries. If disposed of as part of municipal solid waste, treatment in waste incineration plants (MSW) is the most likely disposal channel, whose endpoints are bottom ash and fly ashes from waste gas treatment. Beryllium and BeO that is liberated from WEEE during incineration may end up in both fractions. Some metal alloy parts (e.g. CuBe and NiBe) will likely pass the incineration process and could be recovered from the bottom ash. Fly ashes from MSWs are normally to be

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[76] Eurostat (2019) https://ec.europa.eu/eurostat/statistics-explained/index.php?title=Waste_statistics_-_electrical_and_electronic_equipment&oldid=445263#EEE_put_on_the_market_and_WEEE_collected_in_the_EU

disposed of as hazardous waste and this is a likely endpoint for the bulk of beryllium co-incinerated in MSW incinerators.

5.1.1 Main materials where the substance is contained

As reported in section 2.2, EEE contains metallic beryllium mostly in the form of copper-beryllium alloys, whose beryllium content is usually below 2 percent. Beryllium oxide and beryllium-bearing ceramics occur in minor amounts only. As established in section 2.3, the consumption of beryllium commodities in the EU is estimated to be approximately 50 tonnes per year. Additional amounts of beryllium are likely to be imported as part of end products but do not enter trade statistics for beryllium commodities. It can be assumed that a similar amount enters the total WEEE generated in the EU.[77] Thereof, roughly 40 percent are collected and subjected to sorting and recycling (see 5.1). A further distinction into different materials and WEEE categories is not possible due to non-existent data on many EEE applications of different generations and the WEEE that emerges thereof at the end of product life with a delay ranging from a few months to many years.

5.1.2 WEEE categories containing the substance

According to the Information provided by the stakeholders in the course of the consultation, no sufficient data on the uses of beryllium in individual EEE categories could be established. Hence, the data gap extends to the end of life of EEE products. As explained in section 2.2, beryllium may occur in many types of EEE devices in form of an alloy metal, beryllium oxide for ceramic parts and beryllium alloys combining beryllium with metals such as copper, nickel, or aluminium.

Table 5-1: WEEE categories susceptible containing beryllium metal, BeO, or Be-ceramics

WEEE Category	beryllium susceptible to be present in WEEE
Cat. 1. Thermal exchange equipment	x
Cat. 2. Screens, monitors and equipment containing screens	x
Cat. 3. Lamps	x
Cat. 4. Large equipment	x
Cat. 5. Small equipment	x
Cat. 6. Small IT and telecommunication equipment	x

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[77] Noteworthy to consider the possibility that present day WEEE may contain very old legacy devices with higher beryllium contents than modern EEE.

Table 5-2: Amounts and concentration of beryllium and BeO incorporated in specific EEE components

Application	Alloy	Weight CuBe (g)	Weight Be (g)
Relays	CuNi2Be	7	0.042
Switches./ Sensors	CuBe2	6	0.120
Connectors	CuBe2	18	0.360
Total for a 1000kg vehicle		31	0.522g/T (ppm)

Source: BeST (2019)[78]

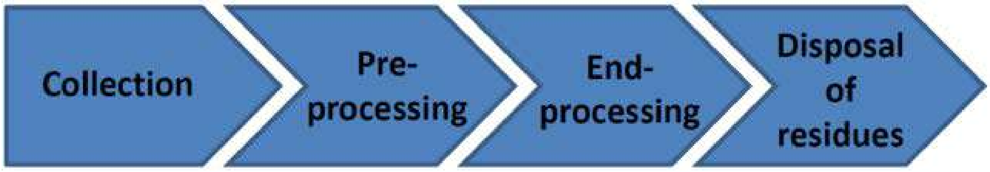
5.2 Applied waste treatment processes

The generic WEEE collection and recycling chain encompasses of four general steps, illustrated in Figure 5-2

1. Collection
2. Sorting/dismantling and pre-processing, incl. mechanical treatment such as shredding
3. End-processing, incl. refining of recycled materials
4. Disposal of residues

The recycling chain for end-of-life electrical and electronic equipment can be generically differentiated in the following steps:

Figure 5-2: Generic recycling chain for end-of-life EEE



Source: own illustration

WEEE collected for recycling is pre-sorted and then processed with the aim to recover valuable secondary materials and to separate hazardous materials. WEEE, which is separately collected, are either manually dismantled or shredded. This happens typically in large-scale metal shredders which can be combined with automated material sorting or specific shredders (e.g. horizontal cross-flow shredders, plants for treatment of screens etc.) (Knudson and Wilkins, 2014).[79]

Only a small amount, if any, of beryllium is recovered directly from post-consumer WEEE. Pure beryllium metal components used in technological applications have extremely long lifetimes (up to 30a), and, therefore, return to the recycle stream very slowly. TFS (2018) confirms the "*difficulty in separating Be containing metals from Electron Microscopes and X-Ray and Electron*

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[78] BeST (2019): Contribution submitted on 7 November 2019) during the stakeholder consultation conducted from 26 September 2019 until 07 November 2019 in the course of the study to support the review of the list of restricted substances and to assess a new exemption request under RoHS 2 (Pack 15)

[79] Knudson, T.L. and Wilkins, H. (2014): An Evaluation of Airborne Beryllium Exposures During Recycling of Waste Electrical and Electronic Equipment (WEEE). Proceeding of the 13th International Electronic Recycling Congress (IERC), Salzburg, Austria January 23, 2014

Spectrophotometers at end-of-life”. [80] The metallic beryllium components in WEEE are thus not specifically addressed by sorting and separation processes. The reason is the usually small size of the beryllium containing components in EEE products. Additionally, not all devices of a certain type contain beryllium bearing components so that the separation of beryllium containing WEEE by device type is no feasible option.

Co-processing with generic WEEE (usually done by shredding and then mechanical/physical separation) poses a difficulty for their identification beryllium bearing component among other metallic part and their separation under profitable circumstances. The low beryllium content in the alloys (beryllium-copper alloys contain 0.2% to 2.7% beryllium) poses little economic incentive for beryllium containing components in mass volume generic WEEE from post-consumer WEEE collection. The same applies for high concentrated beryllium components (e.g. X-ray windows). Such parts are usually small in size and would necessitate manual disassembly which cause too high labour costs compared to the recoverable value of beryllium scrap metal (the identification of beryllium within WEEE would require highly skilled workforce). The recycling of scrap metals from WEEE containing beryllium-copper alloy has been focusing on the economic profitable reclamation of the copper.

5.2.1 Initial treatment processes applied to the WEEE containing the substance of concern

Table 5-3: Initial WEEE treatment processes applied

Initial treatment processes	**Beryllium may be present in appliances belonging to:**					
	Cat1	**Cat2**	**Cat3**	**Cat4**	**Cat5**	**Cat6**
For WEEE collected separately						
Collection and transport	x	x	x	x	x	x
Dedicated treatment processes for cooling & freezing appliances	x					
Dedicated treatment processes for screens		x				
Dedicated treatment processes for lamps			x			
Manual dismantling	x	x		x	x	x
Shredding (and automated sorting)	x			x	x	x
For WEEE not collected separately						
Landfilling (of residual waste)		x	x		x	x
Mechanical treatment (of residual waste)		x	x		x	x
Incineration		x	x		x	x
Uncontrolled treatment in third countries	x	x		x	x	x

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[80] Thermo Fisher Scientific TFS (2018): Contribution submitted on 13.06.2018 during the stakeholder consultation conducted from 20 April 2018 to 15 June 2018 in the course of the study to support the review of the list of restricted substances and to assess a new exemption request under RoHS 2 (Pack 15)

5.2.2 Treatment processes applied to wastes derived from WEEE containing the substance of concern

Table 5-4: Treatment processes for wastes derived from WEEE

Treatment processes for wastes derived from WEEE treatment	**Beryllium may be present in the following main components/materials**								
	Ferrous metals	Non-ferrous metals	Plastics	Electronic components	Cables	Glass	Powders	Fluids	Others
Under current operational conditions in the EU									
Storage of secondary wastes	x	x	(x)*	x	x		x	x	
Shredding and automated sorting of secondary wastes	x	x	(x)*	x	x		x		x
Recycling of ferrous metals	x								
Recycling of NE metals		x							
Recycling of plastics			(x)*						
Recycling of glass									
Recycling as building material									
Landfilling of residues	x	x	x	x	x		x	x	x
Incineration of residues	x	x	x	x	x		x	x	x
Co-incineration of residues	x	x	x	x	x		x	x	x
Dedicated processes for hazardous residues							x	x	
Under uncontrolled conditions **									
Acid leaching		x		x	x			x	
Grilling/desoldering		x		x	x				
Uncontrolled combustion		x	(x)		x				
Uncontrolled dumping of residues			(x)	x	x		x	x	x

‘ Be/BeO might be present as a contaminant

** risk refers to disposal of second-hand EEE exported to developing countries

5.3 Waste treatment processes relevant for assessment under RoHS

5.4 Releases from WEEE treatment processes

Beryllium bearing alloys are assumed to enter primarily one of the metal fractions of mechanical recycling processes. These are typically ferrous metals, copper alloys, and aluminium. BeO and beryllium ceramics are likely to enter the non-metal residue, which is usually disposed of as solid waste. Transfer factors depend on process technologies applied as well as the processing regime. BeST (2019) states that *"Recovery of beryllium metal from beryllium-containing alloys in EEE (for example, the copper beryllium components included in end of life electronics) is not performed because of the small size of the components and the relatively low beryllium content per device (less than 40 ppm, even in devices with the highest beryllium alloy content)".*[81] Knudson and Wilkins (2014) analysed beryllium in the processed WEEE and found that *"concentrations were low ranging from <0.55 to 6.1ppm. Beryllium concentrations above the limit of detection were found in only 25% of the bulk samples".* However, mechanical-physical shredding and sorting under badly controlled operation regime could distribute traces of Be-alloys and BeO across several output fractions. This may also include fractions that are not usually expected to contain beryllium (such as separated plastics (ABS, PVC).

Beryllium contained in alloys and electrical circuits is recycled using metallurgic smelting processes. However, beryllium is usually not the primary target of metallurgic recycling due to its low concentration in alloys. AEM (2018) maintains, "*the concentration of beryllium in recovered secondary metals (mainly copper) is so low as to be undetectable"*. The alloy makes up approximately 0.15% of the copper used in electrical equipment which, during pre-processing of end-of-life equipment, is collected together with other copper scrap and diluted to lower than 2 ppm in the copper recycling stream (Knudson and Wilkins, 2014). Beryllium contained in secondary copper may therefore be co-processed in copper refining plants. Most of the beryllium content from the melt is thought to enter the slag (BeST 2019). Secondary copper usually undergoes electrometallurgical refinery where beryllium is likely to enrich in the electrolyte or be precipitated as constituent of anode sludge, depending on the pH. These residues are normally subjected to chemical processing aiming at extraction of precious metals. It could not be established whether beryllium recovery takes place in practice. Knudson and Wilkins (2014) state that recovery of beryllium from metallurgic copper slags was not economically feasible. As a result, for old scrap the recycling flow value is quite high (~75%), but the recycled content and particularly the end-of-life recycling rate material specific rate are very low. The fate of beryllium in the recycling processes of other alloys (e.g. aluminium, nickel) also remains unclear. Detailed data on the quantities of recycled beryllium in the EU are not available.

Beryllium oxide and beryllium-bearing ceramics occurring in WEEE are hardly accessible for recovery because industrialised recycling processes are not adjusted for the recovery of oxides or ceramics. Such components are likely to end up in solid shredding residue and dust and are eventually destined for final disposal. Beryllium contained in nuclear or medical apparatus is difficult to recycle due to a risk of scrap being contaminated with other hazardous materials.

Exposure of end-users to beryllium is presumably low for most EEE applications that contain beryllium bearing components. The CORAP substance evaluation (CORAP 2014) did not, based on

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[81] BeST (2019): Contribution submitted on 7 November 2019) during the stakeholder consultation conducted from 26 September 2019 until 07 November 2019 in the course of the study to support the review of the list of restricted substances and to assess a new exemption request under RoHS 2 (Pack 15).

the assessed data "*indicate a concern based on consumer exposure to beryllium via consumer uses*". Most EEE products contain beryllium alloys only within a casing and a release is unlikely under normal circumstances of use. Short term skin contact cannot be ruled out. However, the risk of contact allergy is limited as it occurs mostly due to long term exposure to beryllium.

One application area of **concern is electric motors with sliding contact brushes** used for instance in vacuum cleaners and electric tooling. According to Weiland et al (2011), "*a preferably used material for the construction of wires for sliding contacts are copper-beryllium alloys, in particular CuBe2, which are often used because of their good elastic properties*".[82] Such sliding contact brushes are likely to release airborne beryllium bearing dust due to abrasion during the use phase.[83] Argibay et al (2010) observe "*debris flakes forming on the fibre tips with characteristic widths in the range 10–100 µm and thickness on the order of 1 µm*". Consumer exposure to CuBe2 debris depends on the type of device (hand held) and frequency of use but might exceed Occupational Exposure Limits. Measurement data on exposure levels are not available.

5.5 Releases from WEEE treatment processes in developing countries

Old EEE products exported outside the EU in form of second-hand goods may end up in crude recycling processes. These may include manual crushing, open burning, open acid leaching and chemical precipitation as well as uncontrolled landfilling and dumping in the environment. Inappropriate and unsafe practices related to recycling and disposal of WEEE have been recognised as a cause of adverse health impacts for people living in the proximity of e-waste recycling sites (Grant et al. 2013).[84]

Acid leaching is often applied to extract precious metals from PWB. This process could dissolve metallic beryllium and BeO and form soluble beryllium compounds such as beryllium sulphate, beryllium chloride, or beryllium nitrate. Studies on informal recycling businesses in developing countries suggest that little if any safety precautions are usually taken. Workers are hardly protected against skin contact to chemicals and residues and airborne fumes. Thus, human and environmental exposure to soluble and insoluble beryllium compounds appears likely to occur. Specific information on quantities of WEEE processed under circumstances described above is not available nor is there any data on releases of beryllium and Be-compounds. It can be assumed that beryllium, among other hazardous chemicals emerging in the course of uncontrolled open burning and chemical leaching might be only a relatively small contributor to the serious health and environmental problems related to crude WEEE recycling.

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[82] Weiland et al (2011): Wire for sliding contacts and sliding contacts, Patent DE102011106518A1

[83] Argibay, Nicolas & A. Bares; Jason & H. Keith; James & Bourne, Gerald & Gregory Sawyer, W. (2010): Copper–beryllium metal fiber brushes in high current density sliding electrical contacts. Wear. 268. 1230-1236. 10.1016/j.wear.2010.01.014.

[84] Grant, K.; Goldizen, F.C.; Sly, P.D.; Brune, M-N.; Neira, M.; van den Berg, M.; and Norman R.E. (2013): Health consequences of exposure to e-waste: a systematic review. Lancet Glob Health 1: e350–61

6 EXPOSURE ESTIMATION DURING WEEE TREATMENT

Beryllium is a naturally occurring element and is ubiquitous throughout the environment. The substance is found in soils, rocks, coal, wood and foodstuffs. The general population is exposed to naturally occurring beryllium from ambient air, drinking water and diet on a daily basis. Additionally, beryllium is released from various technical processes, most notably combustion of coal but also from metal working processes. Although beryllium occurs in nature, the major source of its emission into the environment is through the combustion of fossil fuels (primarily coal), which releases beryllium-bearing dust and fly ash into the atmosphere. Most exposures to beryllium that cause human health effects are related to beryllium processing. The release occurs usually in form of airborne dust which can cause occupational exposure and environmental pollution of soil and water bodies. The average concentration of beryllium in outdoor air is < 0.03–0.07 ng/m³, with higher concentration in cities up to 6.7 ng/m³, and up to 100 ng/m³ near beryllium processing plants (ATSDR 2002,[85] WHO 2001[86]). The major route of human exposure is through airborne particles of beryllium metal, alloys, oxides, and ceramics. Beryllium particles are inhaled into the lungs and upper respiratory tract. Hand-to-mouth exposures and skin contact with ultrafine particles can also occur. Humans who live near sources of beryllium emissions are likely to be exposed to higher levels than the general population.

The contribution of WEEE recycling processes to beryllium-related environmental pollution and human exposure is unknown. BAUA estimated up to 65,000 workers being potentially exposed throughout the EU, though data did not allow estimating the actual workers in risk. The major exposure risk is likely to exist during the primary production processes of products that contain beryllium alloys. In 2016, BAUA concluded in its Risk Management Option analysis (RMOA) that further regulatory risk management activities are required for beryllium due to its hazard profile. With view at the DNEL for beryllium in dust of 60 ng/m³, "*a risk for workers exists at a lot of metal working processes"* whereas industry has thus far committed to a *"(voluntary) exposure limit of 200 ng/m³"* only".[87]

6.1 Basis of exposure estimation

Information specific to releases of beryllium bearing dust during the processing of WEEE is scarce, except one study (Knudson and Wilkins, 2014) on one WEEE shredding plant in the UK and one study on three WEEE recycling plants in Sweden (Julander et al, 2014). Therefore, several assumptions need to be made. The exposure risk to beryllium bearing debris differs between the general steps of WEEE treatment (see Figure 5-2):

Collection

Sorting/dismantling and pre-processing, incl. mechanical treatment such as shredding

End-processing, incl. refining of recycled materials

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[85] ATSDR, Agency for Toxic Substances and Disease Registry (2002): Toxicological profile for beryllium. U.S. Department of Health and Human Services, Public Health Service, Agency for Toxic Substances and Disease Registry, Atlanta, GA, USA. http://www.atsdr.cdc.gov/toxprofiles/tp4.pdf, last viewed 19.09.2019

[86] WHO, World Health Organization (2001): Concise International Chemical Assessment Document 32: Beryllium and Beryllium compounds, WHO, Geneva, Switzerland.

[87] BAUA (2016): Risk Management Option Analysis Conclusion Document, Substance Name: Beryllium

Disposal of residues

Assumption no 1: WEEE collection and pre-sorting is unlikely to cause elevated exposure levels above OEL because no abrasive forces occur.

Assumption no 2: mechanical treatment such as shredding is likely to cause elevated exposure levels due to the abrasive nature of the processes. The actual exposure risk depends on the feedstock materials (e.g. PWB and electric connectors), the type of processing equipment as well as safeguard measures.

Assumption no 3: End-processing of recycled materials is likely to pose a risk of occupational exposure to beryllium. However, the risk exists not exclusively due to RoHS-relevant recycling feedstock.

Assumption no 4: Disposal of residues from recycling as well as disposal of untreated WEEE in waste incinerators may lead to occupational exposure to beryllium. However, the risk exists not exclusively due to RoHS-relevant constituents of waste.

- Assumption no 5: Occupational Exposure Limits apply throughout the whole WEEE treatment processing chain but monitoring and implementation may not take places at each and every WEEE processing site. In particular, small recycling businesses may lack the instruments necessary for monitoring airborne beryllium dust. Absence of monitoring and occupational safeguard measures is to be assumed in WEEE processing sites in developing countries.

6.2 Human exposure estimation

Little has been published about the occupational exposures of workers to beryllium in the WEEE recycling industry. Therefore, estimates of the number of people exposed to beryllium at work in the WEEE recycling industry are not possible. Knudson and Wilkins (2014)[88] investigated the airborne beryllium exposure levels of workers processing WEEE in the UK. Results showed that "*All exposure measurements for airborne beryllium were below the level of analytical detection (<0.0069 µg/sample) and therefore below the […] OELs of 0.2 µg/m^3. Statistical analysis demonstrated that exposures are anticipated to be below this level greater than 95 percent of the time.*" In a peer reviewed study, Julander et al (2014)[89] report a geometric mean of 0.0018 µg/m^3 inhalable fraction of Be calculated from 75 samples taken at three formal WEEE recycling plants. The maximum detected value is an order of magnitude higher (0.017 µg/m^3), but still well below the *OELs of 0.2 µg/m^3*. However, both studies cited above fail to provide details on technical exposure controls implemented at the study sites. Thus, it cannot be judged whether the exposure situations encountered there are representative for other WEEE treatment plants in the EU.Based on the assumptions stated above, some potential hot spots of occupational exposures to beryllium bearing dust can be made: Workers and operators of mechanical and thermal WEEE treatment may be at risk to face peaks of exposure that exceed given Short Term Exposure Limits (STEL) if the feedstock currently processed contains legacy WEEE, which might contain higher than usual contents of

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[88] Knudson, T.L. and Wilkins, H. (2014): An Evaluation of Airborne Beryllium Exposures During Recycling of Waste Electrical and Electronic Equipment (WEEE). Proceeding of the 13th International Electronic Recycling Congress (IERC), Salzburg, Austria January 23, 2014

[89] Julander, A.; Lundgren, L.; Skare, L.; Grandér, M.; Palma, B.; Vahter, M. and Lidéna, C. (2014): Formal recycling of e-waste leads to increased exposure to toxic metals: An occupational exposure study from Sweden. Environment International 73: 243–251

beryllium compared to modern EEE products. Moreover, the occupational exposure at final disposal sites may exceed given STEL, if such legacy WEEE enters the disposal without proper pre-treatment. Workers in developing countries bear a high risk of occupational exposures to beryllium bearing dust.

As explained in 5.4, end consumers and professional users might be exposed to an unknown concentration of beryllium bearing dust released from electric motors with sliding contact brushes.

6.3 Environmental exposure estimation

Environmental exposure data specific to WEEE recycling processes are not available.

7 IMPACT AND RISK EVALUATION

The international risk-management standard ISO 31000 defines the term ‘risk’ as “the effect of uncertainty on objectives” (ISO 2011).[90] In the context of the RoHS Directive, Article 1 states its overarching objective as follows: “*contributing to the protection of human health and the environment, including the environmentally sound recovery and disposal of waste EEE*”. Thus, a risk can be regarded as a possible deviation from the objective to keep adverse impacts away from humans and the environment. To this end, the regulatory objective is to protect these safeguarded subjects against adverse impacts of hazardous substances contained in electrical and electronic equipment (EEE). The risk is considered as a function of a substance’s hazardous properties and the exposure of safeguard subjects to this substance. The risk evaluation provided in this section determines both aspects of risk in the case of beryllium oxide (BeO).

The hazard potentials of beryllium and beryllium oxide (BeO) are a result of the substances’ properties and their interaction with biota (human body and organisms). Section 3 provides information on the known hazard potential on human health. No data could be found about berylliums hazard potential to the environment.

In summary, it can be concluded that the health hazard potential of beryllium and BeO is significant. These substances are classified acute toxic by inhalation and oral ingestion and carcinogenic as well as skin irritating by dermal contact. Respiratory exposure does airborne beryllium is known to cause serious health impacts, “Beryllium Sensitisation” (BeS) as an early health effect and Chronic Beryllium Disease (CBD) due to long term exposure. However, uncertainty prevails regarding the dose-response relationship. The likelihood of adverse health impacts seems to be influenced not only by exposure levels but also due to a genetic predisposition of humans exposed to beryllium.

The possibilities of exposure at the working place and during the use phase of beryllium bearing EEE is outlined in section 6. In summary, it can be concluded that exposure to airborne beryllium might occur during the use phase of consumer EEE that contain high power electrical motors due to wear and tear of beryllium bearing sliding brushes. The resulting exposure levels are uncertain. Occupational exposure levels during the WEEE treatment are uncertain too. Is thought that the exposure at WEEE treatment plants remains below the OELs in force of 0.2 µg/m^3. However, short term exposure peaks cannot be ruled out and depend on the processing technology and safeguard measures applied. Concern regarding occupational exposure addresses mechanical shredding and hot-metallurgic recycling processes as well as final disposal of residues from recycling and untreated WEEE.

However, given the ubiquitous presence of beryllium and BeO in EEE products, there is reason to be alert of unexpected exposure hot spots. These might exist due to treatment of WEEE in incineration plants for MSW, uncontrolled disposal of concentrated residues, and crude WEEE recycling practices in developing countries.

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[90] ISO (2011). ISO 31000: Risk management - principles and guidelines.

8 ALTERNATIVES

8.1 Availability of substitutes / alternative technologies

- Due to its unique properties it is often recited that beryllium cannot easily be replaced by other materials without functional disadvantages, such as lower mechanical strength, elasticity and long-term reliability. However, industry has already undertaken to limit the use of beryllium for economic reasons (AEM 2018). Beryllium-rich materials are expensive and therefore only used when its unique and enabling properties are indispensable for the technical application purpose or product reliability. For example, pure beryllium metal and Al-Be (62% Be) alloys are only used in applications where demanding performance requirements cannot be met by beryllium free alloys. CuBe alloy is only used when high functional reliability is essential to ensure safe operation in the defence, transport or energy sector. High performance EEE products, which contain beryllium in form of alloys or ceramics, are usually designed to be lightweight and slim (e.g. electronic components on printed wiring boards, electric contacts and heat sinks). Other industrial EEE applications may be designed for heavy duty use and long-term reliability. Especially safety related applications contain beryllium alloys to ensure good performance and long-term reliability.
- The replacement of beryllium in alloys by other metals would in most cases be technically possible but would entail a decrease of the components' functional performance. Foley et al. (2017) state that "*In some less-demanding applications, copper alloyed with Ni-Si, Sn, Ti, or Sn-P may be substituted for high-cost beryllium-copper alloys, and aluminium nitride or boron nitride may be substituted for high-cost beryllium oxide with no loss in performance. The substitution of high-strength grades of aluminium metal, pyrolytic graphite (an ultra-thin graphite film with a thermal conductivity up to four times greater than that of copper), silicon carbide, steel, or titanium metal for beryllium metal or composites, however, can result in substantially reduced performance.*" JX Nippon states that the very high strength Cu-Ti alloy NKT322 has been already commercialised as a substitute to Cu-Be C172 (Be: 1.80-2.00 weight percent). However, ZVEI (2018) states that NKT322 GIGALLOY® achieves only about half of the conductivity of CuBe.[91] AEM (2018) provides a table (s. below) comparing the spring contact properties of copper beryllium with bronze alloys and also NKT322. The comparison given in Table 8-2 shows that copper beryllium with ca. 1.9% Be is superior overall, as it has higher electrical conductivity and the ratio of yield stress versus modulus of elasticity is higher than the other alloys.

Table 8-1: Copper beryllium alloys and substitutes: comparison of properties

Alloy	Yield stress N/mm²	Modulus of elasticity GPA	Ratio of Yield stress / Modulus of elasticity	Conductivity %IACS
Copper beryllium (1.8-2%Be)[3]	1120	127	8.82	25
NKT322[4]	800 to 1050	120	6.67 to 8.75	10-13
Bronze CuSn8	750	110	6.61	12
Posphor bronze CuSn9P	800	108	7.4	12

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[91] ZVEI (2018): Contribution submitted on 14.06.2018 during the stakeholder consultation conducted from 20 April 2018 to 15 June 2018 in the course of the study to support the review of the list of restricted substances and to assess a new exemption request under RoHS 2 (Pack 15)

Alloy	Yield stress N/mm²	Modulus of elasticity GPA	Ratio of Yield stress / Modulus of elasticity	Conductivity %IACS
Comments	Altered by heat treatment	Absolut value is less important than ratio	Highest values are best spring performance	Depends on heat treatment, but high conductivity is important to reduce oxidation caused by resistance heating

Source: (AEM, 2018)[92]

- Most of stakeholder responses from the 1st consultation state that substitution of beryllium in EEE leads to a loss of functional performance. BeST (2018) warns that "*it is not expected that any significant volume of beryllium usage can be substituted without an unacceptable loss of performance*".[93] For instance, the T&M Coalition states that "*there are no known alternatives that meet equivalent performance specifications or can assure the reliability of substitution required for of Category 9 industrial equipment*".[94] ESIA (2018) comments, "*An example of two materials exhaustively studied to replace BeO are diamond and Aluminum Nitride. However, these and other materials have various challenges inhibiting their adoption, especially for high power RF Power semiconductor packaging*".[95] Apex Microtechnology states that "*Alternative ceramic substrates"* such as Aluminium Nitride (AlN) *"lack the thermal conductivity and/or the thick film systems required for the manufacturing of these compact electronic microcircuits*."[96]
- Improper substitution of beryllium alloys, metals, or composites has resulted in higher risk of technical failure of certain components and thus reduced their product service life. Therefore, a substitution of beryllium in certain key components could entail an increase in failure rates of EEE products thus adding to the generation of WEEE.
- On the other hand, the electronics industry has been assessing the availability of substitutes for Be for economic reasons. As compared to potential substitutes, beryllium is a relatively expensive raw material and necessitates the implementation of expensive measures for occupational safety and pollution reduction throughout the production chain. Many EEE manufacturers have already reduced or even banned the use of beryllium bearing components in their products in order to improve end consumer acceptance Table 8-2. The overview shows that numerous EEE manufacturers have started to implement voluntary measures for phasing out beryllium from their products. Thus, it can be inferred that the unique and enabling properties of beryllium are less indispensable for the EEE industry than explained above. While engineering details are not

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[93] Beryllium Science & Technology Association BeST (2018): Contributions submitted during stakeholder consultation on 15 June.2018;

[94] T&M Coalition (2018): Contribution submitted on 15.06.2018 during the stakeholder consultation conducted from 20 April 2018 to 15 June 2018 in the course of the study to support the review of the list of restricted substances and to assess a new exemption request under RoHS 2 (Pack 15)

[95] European Semiconductor Industry Association (ESIA) Coalition (2018): Contribution submitted on 15.06.2018 during the stakeholder consultation conducted from 20 April 2018 to 15 June 2018 in the course of the study to support the review of the list of restricted substances and to assess a new exemption request under RoHS 2 (Pack 15)

[96] Apex Microtechnology (2019): Contribution submitted on 7 November 2019 during the stakeholder consultation conducted from 26 September 2019 until 07 November 2019 in the course of the study to support the review of the list of restricted substances and to assess a new exemption request under RoHS 2 (Pack 15)

publicly communicated there is a reason to assume that a reduction of beryllium in certain types of consumer EEE is not impossible after all. Also windows of Low Energy X-Ray detector instruments that do not require mechanical toughness "*can be made of thin Silicon Nitride (Si3N4)* and *have been successfully used; the benefits in are significant compared to Beryllium*".[97] TFS (2018) counters that "*Currently, there are no known material substitutions for Be or BeCu alloys in Electron Microscopy or X-ray or Electron Spectrophotometers*".

Table 8-2: Overview of various EEE manufacturers and their corporate policies regarding substitution of beryllium

EEE manufacturers	Substitution policy for beryllium
Apple	Self-commitment to eliminate beryllium in products down to < 1,000 ppm. As of 2019, beryllium-copper connectors and springs are eliminated from all new product designs
ASUS	Asus has shown progress on the elimination of beryllium
Dell	Dell monitors the use of beryllium but has not set elimination targets or threshold restrictions.
Google	Google has restricted the use of beryllium
HP	HP restricts the use of beryllium with a threshold limit of 1,000 ppm with the exemption of ceramics in electronic components and electrical bonding applications of beryllium copper, such as connectors, springs, or EMI gaskets. In 2019, HP states that they will restrict all remaining uses of beryllium in PCs and Displays.[98]
Huawei	Huawei has not published commitments to eliminate the use of beryllium and beryllium compounds in consumer products but reports it has restricted its use since 2016
Lenovo	Lenovo added phase-out target for beryllium and its compounds in 2019.[99] Suppliers are required to quantify and report the beryllium content for individual parts, thresholds for Be and BeO are between 1,000 ppm (e,g. heat sinks and insulator ceramics) and 200 ppm (IC substrates and housings alloys).
LG	Phasing out beryllium from mobile phones since 2011
Olympus OSSA	Olympus OSSA does not use EEE components containing Be compounds or Be alloys.[100]
Samsung	Since 2013, beryllium compounds phased out of all products
Sony	Sony has not published a timeline for phasing out beryllium but declares that today all Xperia™ products (smartphones) are beryllium-free.[101]

Sources: (Greenpeace, 2017)[102], various Engineering Specifications

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[97] EDAX, Inc. (2018): Contribution submitted on 06.08.2018 during the stakeholder consultation conducted from 20 April 2018 to 15 June 2018 in the course of the study to support the review of the list of restricted substances and to assess a new exemption request under RoHS 2 (Pack 15)

[98] HP (2019): General Specification for the Environment http://h20195.www2.hp.com/V2/getpdf.aspx/c05117791.pdf

[99] Lenovo (2019): Lenovo Engineering Specification 41A7731, Baseline Environmental Requirements for Lenovo Products, Materials and Parts. https://www.lenovo.com/us/en/pdf/41A7731.pdf

[100] OLYMPUS OSSA (2018): Contribution submitted on 05.06.2018 during the stakeholder consultation conducted from 20 April 2018 to 15 June 2018 in the course of the study to support the review of the list of restricted substances and to assess a new exemption request under RoHS 2 (Pack 15); http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Pack_15/1st_Consultation_Contributions/OlympusOSSA_Submission-for-beryllium-and-its-compounds.pdf

[101] https://blogs.sonymobile.com/about-us/sustainability/substance-control/substances-of-concern

[102] Greenpeace (2017): Guide to Greener Electronics 2017, Report Cards. https://www.greenpeace.org/usa/reports/greener-electronics-2017/

The following materials have been considered for substitution of beryllium and have presented the following issues Table 8-3:

Table 8-3: Possible substitute materials for beryllium in various application areas

Application Sector	Substitute materials	Issues with the substitute materials
Telecommunications electronic/automotive electronics/aerospace and defence electronics	Alloys of copper: e.g. CuZn brasses; CuSn bronzes, CuNiSi alloys etc.	Insufficient combination of strength/ formability/electrical conductivity/ stress relaxation resistance/failure to resist vibration/corrosion resistance
Aerospace/defence structural components	Titanium	Higher density / lower specific stiffness (modulus/density)
	Carbon fibre composites	Formability / high and low temperature properties / specific stiffness/ weldability / fracture toughness Impact resistance / specific heat
Aerospace/Defence industrial components	Alloys of copper: e.g. CuZn brasses; CuSn bronzes, CuNiSi alloys etc.	Insufficient combination of strength/ formability/thermal conductivity/ stress relaxation resistance/failure to resist vibration/corrosion resistance
Other: e.g. X-ray windows	Titanium / aluminium / polymers / glass	Reduced resolution of the X-ray or CT scan images leading to reduced detection of tumours and medical issues
Beryllium oxide laser bores	Aluminium oxide ceramic	Thermal conductivity
Nuclear facilities, e.g. ITER fusion reactor lining	Tungsten	Fail safe nuclear interaction of beryllium as a neutron reflector is lost, reducing safety margin in the event of loss of magnetic control of the hot gas plasma

Sources: Merchant Research & Consulting Ltd, London (2012): Beryllium Market Review. Quoted by (BeST, 2018)

8.2 Hazardous properties of substitutes

- BeST (2018) states that Cu-Ti alloy (e.g. NKT322) has a risk classification for work-related cancer similar to that of CuBe. ECHA has concluded[103] that titanium dioxide (TiO_2) meets the criteria to be classified as a Category 2 carcinogen. As TiO_2 is used in the production of copper titanium alloys, there is a risk of occupational exposure although the health impacts of TiO_2 differ from those of beryllium exposure (BES and CBD). However, the mechanisms of formation of airborne TiO_2 during technical processes differ from those of beryllium bearing dust. It is unlikely that airborne TiO_2 emerges from Cu-Ti alloys during WEEE processing and recycling operations.
- Other possible substitutes, as far as applicable, do not impose hazards that differ from those of general metal working industry.

8.3 Data basis for alternatives and uncertainties

The producers of beryllium free metal alloys assert that substitute materials are on the market for various applications. However, the available alternatives are not suitable for all applications of beryllium alloys. It is understood that substitution materials exist but their inferior technical performance limits their usefulness to almost all fields of application of beryllium. Also, alternative

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[103] https://echa.europa.eu/-/titanium-dioxide-proposed-to-be-classified-as-suspected-of-causingcancer-when-inhaled

technologies and product designs (e.g. more bulky physical design, wireless data transfer to eliminate pin contacts) can be considered but are either characterised to suffer significantly from reduced performance data, as well as higher energy consumption or are generally considered unsuitable in a given application context. Therefore, more efforts in development of tailored beryllium free metal alloys would be necessary if beryllium was restricted in EEE.

The information specified above regarding alternatives for beryllium and BeO originates from various documents generated also in the context of the REACH and CLP regulations. Such documents are understood to have been subject to review, stakeholder consultations as well as scrutiny of academic and professional expertise. Hence, these sources have to be granted a relatively high level of confidence.

9 DESCRIPTION OF SOCIO-ECONOMIC IMPACTS

The socio-economic impact analysis is inapplicable as the substance is not recommended for restriction in ANNEX II of ROHS.

10 RATIONALE FOR INCLUSION OF THE SUBSTANCE IN ANNEX II OF ROHS

There is currently little support in available data justifying a regulatory restriction of beryllium and BeO in EEE under RoHS. Industry stakeholders insist on the high technological importance of beryllium for the European EEE sector, as well as all possible end-application areas of EEE products. Since beryllium in alloys and in form of BeO in ceramics seems to be a very ubiquitous constituent of EEE, a regulatory restriction would entail massive shortcomings in functional performance of EEE products used in the EU. In particular, EEE of the RoHS categories 8 and 9 (bio-medical and industrial devices) would be affected because existing products are hard to redesign with beryllium free materials. Although some substitute materials are available, they do not match with the technical requirements in all respective application areas of beryllium. A reduction or substitution of beryllium and BeO necessitates research & innovation in alternative materials as well as product testing and certification, especially as it comes to medical and safety relevant products. Given the relatively high technical importance of the substances and based on the result of the risk evaluation that beryllium and BeO in EEE pose medium risks during WEEE treatment and disposal, the **inclusion of beryllium and BeO in ANNEX II of ROHS is currently not recommended.** This recommendation is in line with BAUA (2016), who expressed the opinion, that "*a general or even a partial ban will undoubtedly reduce risks, the societal impacts would be disproportionate*".[104] BAUA states that the health hazards of beryllium and BeO, in particular CBD and even beryllium sensitisation "can *be regulated through an OEL"* (occupational exposure limits). BAUA also indicates the "*high potential for risk reduction capacity and equivalent high health benefits for the workers. On the other hand, additional costs for the measures for exposure reduction may incur e.g. plants with encapsulated equipment. However, taking into account the investment for the continuous improvement, the additional costs would be proportional to the benefits arising from exposure reduction.*" The recommendation not to restrict beryllium under REACH implies that European WEEE recyclers make progress in implementing exposure controls in order to meet established OELs of 0.6/0.2 µg/m^3 for airborne beryllium at mechanical and thermal treatment plants throughout the EU. The implementation of exposure controls in WEEE treatment plants is beneficial beyond the prevention of BES and CBD since the same measures can reduce the release of other pollutants (e.g. heavy

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[104] BAUA (2016): Risk Management Option Analysis Conclusion Document, Substance Name: Beryllium (November 2016)

metal bearing dust) at the same time. Moreover, specific risk management measures should be implemented in the WEEE collection and recycling system in Europe. Specifically, domestic WEEE collection targets should be increased and the uncontrolled movement of WEEE (or second-hand EEE) towards recipients in developing countries should be stopped.

In addition, certain measures should be considered to cut the likelihood of exposure to beryllium:

A selective restriction of beryllium-containing CuBe alloys used as sliding contact brushes in electric motors, which form part of consumers and professional EEE, such as vacuum cleaners and tools. As a first measure, the prevalence of CuBe sliding contact brushes in the consumer applications should be further explored. Moreover, abrasion tests on CuBe sliding contact brushes should be conducted to determine the exposure of EEE-users to particulate CuBe debris and the effectiveness of exposure controls (e.g. protective boxes).

EEE manufacturers should commit to a voluntary reduction of beryllium in products. The beryllium content in many EEE products can be lowered to below 1,000 ppm as numerous large EEE manufacturer in the sector of consumer electronics have demonstrated (see Table 8-2). The voluntary measures should be adopted by the whole EEE sector, OEM should require their suppliers (components manufacturers) to indicate the concentrations of Be in weight of their intermediary products.

11 List of References

Baron et al (2014): Baron, Y.; Blepp, M.; Gensch, C.-O.; Moch, K. (Oeko-Institut e.V.); in collaboration with Hogg, D. (Eunomia Research & Consulting Ltd.); Study for the review of the list of restricted substances under RoHS 2 – Analysis of impacts from a possible restriction of several new substances under RoHS 2, 2014; commissioned by the EU Commission, DG Environment; available at: http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Substance_Review/20140806_Substance_Review_revised_version_final_plus_Dossier.pdf, last viewed 19.04.2018

Foley et al (2017): Foley, N.K., Jaskula, B.W., Piatak, N.M., and Schulte, R.F., 2017, Beryllium, chap. E of Schulz, K.J., DeYoung, J.H., Jr., Seal, R.R., II, and Bradley, D.C., eds., Critical mineral resources of the United States—Economic and environmental geology and prospects for future supply: U.S. Geological Survey Professional Paper 1802, p. E1– E32, https://doi.org/10.3133/pp1802E. available at: https://pubs.usgs.gov/pp/1802/e/pp1802e.pdf, last viewed 19.08.2019

Knudson & Wilkins (2014): Knudson T.; Wilkins, H.; An evaluation of airborne beryllium exposures during recycling of waste electrical and electronic equipment (WEEE), published in the Proceeding of the 13th International Electronic Recycling Congress (IERC), Salzburg, Austria, January 23, 2014

Taylor et al (2003): Taylor, T. P., Ding, M., Ehler, D. S., Foreman, T. M., Kaszuba, J. P., & Sauer, N. N. (2003). Beryllium in the Environment: A Review. Journal of Environmental Science and Health, Part A, 38(2), 439–469

12 Appendix I: Contribution to stakeholder consultation hold from 20 April 2018 to 15 June 2018

The following non-confidential contributions were submitted during the 1st stakeholder consultation (see also: https://rohs.exemptions.oeko.info/index.php?id=294)

> Contribution of the **JX Nippon Mining & Metals Corporation,** submitted on 30.04.2018: pdf

> Contribution of **Olympus OSSA,** submitted on 05.06.2018: pdf

> Contribution from **Amptek, Inc., a division of Ametek, Inc.**, submitted on 11.06.2018: pdf

> Contribution from **EDAX, Inc.,** submitted on 11.06.2018: pdf

> Contribution from **Coherent,** submitted on 12.06.2018:

>> Part1: pdf

>> Part 2: pdf

> Contribution from **Thermo Fisher Scientific,** submitted on 13.06.2018: pdf

> Contribution of the **Zentralverband Elektrotechnik- und Elektronikindustrie e. V. (ZVEI),** submitted on 14.06.2018: pdf

> Contribution of the **WSM Wirtschaftsverband Stahl-und Metallverarbeitung e.V.,** submitted on 15.06.2018: pdf

> Contribution of the **BeST - Beryllium Science & Technology Association, endorsed by ESIA,** submitted on 15.06.2018: pdf

> Contribution of **MedTech Europe** submitted on 15.06.2018: pdf

> Contribution of the **JBCE – Japan Business Council in Europe aisbl,** submitted on 15.06.2018: pdf

> Contribution of the **Test and Measurement Coalition (TMC)**, submitted on 15.06.2018: pdf

> Contribution of the **Association of Equipment Manufacturers (AEM),** submitted on 15.06.2018: pdf

> Contribution of the **European Semiconductor Industry Association (ESIA),** submitted on 15.06.2018: pdf

> Contribution of the **Japanese electric and electronic (E&E) industrial associations,** submitted on 14.06.2018: pdf

> Contribution of the **Coherent LaserSystems GmbH & Co. KG,** submitted on 15.06.2018: pdf

> Contribution of the **JX Nippon Mining & Metals Corporation,** submitted on 15.06.2018: pdf

> Contribution of the **AeroSpace and Defence Industries Association of Europe (ASD),** submitted on 14.06.2018: pdf

13 Appendix II: Contribution to stakeholder consultation hold from 6 September 2019 and until 07 November 2019

The following non-confidential contributions were submitted during the 2nd stakeholder consultation (see also: https://rohs.exemptions.oeko.info/index.php?id=336)

> Contribution of **COCIR (European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry),** submitted on 22.10.2019: PDF

> Contribution of the **EUROMOT (the European Association of Internal Combustion Engine Manufacturers)** and **AEM(US Association of Equipment Manufacturers**), submitted on 04.11.2019: XLSX

> Contribution of the **Japanese electric and electronic (E&E) industrial associations**, submitted on 06.11.2019: PDF

> Contribution of **JBCE – Japan Business Council in Europe**, submitted on 07.11.2019: PDF

> Contribution of the **Beryllium Science and Technology Association (BeST),** submitted on 07.11.2019: PDF

> Contribution of **Digital Europe**, submitted on 07.11.2019: PDF

> Contribution of **The European Semiconductor Industry Association (ESIA)**, submitted on 07.11.2019: PDF

> Contribution of the **Zentralverband Elektrotechnik- und Elektronikindustrie e. V. (ZVEI),** submitted on 07.11.2019: PDF

> Contribution of **Apex Microtechnology,** submitted on 07.11.2019: PDF

> Contribution of **Knowles Precision Devices**, submitted on 07.11.2019: PDF

A.3.0 Cobalt dichloride and cobalt sulphate

Öko-Institut e.V.
Institut für angewandte Ökologie
Institute for Applied Ecology

ROHS Annex II Dossier for Cobalt dichloride, cobalt sulphate, cobalt dinitrate, cobalt carbonate and cobalt di(acetate). Restriction proposal for substances in electrical and electronic equipment under RoHS

Substance Names: Cobalt dichloride, cobalt sulphate, cobalt dinitrate, cobalt carbonate and cobalt di(acetate)

15/05/2020

EC Number(s):	Cobalt dichloride 231-589-4 Cobalt sulphate 233-334-2 Cobalt dinitrate 233-402-1 Cobalt carbonate 208-169-4 Cobalt di(acetate) 200-755-8
CAS Number(s):	Cobalt dichloride 7646-79-9 Cobalt sulphate 10124-43-3 Cobalt dinitrate 10141-05-6 Cobalt carbonate 513-79-1 Cobalt di(acetate) 71-48-7

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Abbreviations

AEM	Association of Equipment Manufacturers
CDI	Cobalt Development Institute
CLP	Regulation (EC) No 1272/2008 on Classification, Labelling and Packaging
CMR	Carcinogenic, Mutagenic or Reprotoxic
DNEL	Derived No-Effect Level
ECHA	European Chemicals Agency
EEE	Electrical and Electronic Equipment
dw	Dry Weight
IC	Integrated Circuit
IED	Industrial Emission Directive
KEMI	Swedish Chemicals Agency
MCCP	Medium-Chain Chlorinated Paraffins
OEM	Original Equipment Manufacturer
Op. cit .	Opus citatum, the work cited
PCB	Printing Circuit Board
PNEC	Predicted No-Effect Concentration
REACH	Regulation (EU) No 1907/2006 on the Registration, Evaluation, Authorisation and restriction of Chemical substances.
RoHS	Directive 2011/65/EU (RoHS 2) on the restriction of the use of certain hazardous substances in electrical and electronic equipment
SIN	SIN (Substitute it Now!) List of the NGO ChemSec
SVHC	Substances of Very High Concern
WEEE	Waste of Electrical and Electronic Equipment
ZVO	Zentralverband Oberflächentechnik (Central Association of Surface Treatment Professionals Germany)
[explanation]	Editorial explanation by the authors of the substance assessment

CONTEXT and SCOPE of the DOSSIER / substance assessment

This substance assessment of cobalt salts is being performed as part of the "*Study on the review of the list of restricted substances and to assess a new exemption request under RoHS 2 – Pack 15*". With contract No. 07.0201/2017/772070/ENV.B.3 implementing Framework Contract No. ENV.A.2/FRA/2015/0008, a consortium led by Oeko-Institut for Applied Ecology, has been assigned by DG Environment of the European Commission to provide technical and scientific support for the review of the list of restricted substances and to assess a new exemption request under RoHS 2. This study includes an assessment of seven substances and group of substances[1] with a view to the review and amendment of the RoHS Annex II list of restricted substances. The seven substances have been pre-determined by the Commission for this task. The detailed assessment is being carried out for each of the seven substances in line with a uniform methodology[2].

According to the terms of references of the study the scope of the assessment concerns cobalt dichloride and cobalt sulphate. For this purpose, the evaluation has compiled relevant background information for understanding whether the two cobalt compounds are used in the manufacture of EEE and whether they remain present in final EEE articles placed on the EU market. However, the terms of reference of the study further points out that the *"grouping of substances (e.g. for cobalt or nickel compounds or for MCCPs) shall be possible by following the approach determined in the updated methodology, once agreed."* In the course of the assessment, it became apparent that the European Chemicals Agency (ECHA) was considering a restriction on the manufacturing, placing on the market and use of five cobalt salts as substances on their own or in mixtures. These five cobalt salts are: cobalt dichloride and cobalt sulphate together with cobalt dinitrate, cobalt carbonate and cobalt di(acetate). Therefore, it was recommended to the European Commission to extend the scope of this assessment under the RoHS Directive to the five cobalt salts as proposed by ECHA for a REACH Annex XVII restriction. The European Commission agreed in January 2019 to this scope adjustment. It should be noted that this adjustment was proposed because it was only possible to gather aggregated information with regards to EEE for the five cobalt salts, and not only for the two cobalt salts as initially foreseen.

However, further cobalt compounds including cobalt metal and cobalt alloys are not considered in this dossier. Their impact on human health and the environment during use or in the waste phase will not be assessed.

In the course of the substance assessment under RoHS, a 1st stakeholder consultation was held from 20 April 2018 to 15 June 2018 to collect information and data for the seven substances under assessment. Information on this consultation can be found at the Oeko-Institut's project webpage at: http://rohs.exemptions.oeko.info/index.php?id=289.

This consultation - as held before the scope adjustment - focused solely on cobalt dichloride and cobalt sulphate. For cobalt dichloride and cobalt sulphate, a total of seven contributions were

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[1] For the sake of better readability hereafter the term substance will be used for single substances as well as for group of substances.

[2] This methodology includes a dossier template for substance assessment which had been prepared by the Austrian Umweltbundesamt GmbH in the course of a previous study. The methodology for substance assessment has been revised based on various proposals from and discussions with stakeholders. Among others, revisions have been made to clarify when the Article 6(1) criteria are considered to be fulfilled and how the precautionary principle is to be applied. The methodology has also been updated in relation to coherence to REACH and other legislation and publicly available sources of relevance for the collection of information on substances have been updated and added. The methodology is available at https://rohs.exemptions.oeko.info/index.php?id=341

submitted by different stakeholders. An overview of the contributions submitted during this consultation is provided in Appendix I. The contributions can be viewed at: http://rohs.exemptions.oeko.info/index.php?id=296.

Based on the stakeholder input and publicly available information, a second version the dossier has been prepared, which was subject to a 2nd stakeholder consultation. An overview of the contributions submitted during this consultation is provided in Appendix I. The contributions can be viewed at https://rohs.exemptions.oeko.info/index.php?id=338.

The stakeholder contributions received during the 2nd stakeholder consultation[3] generally expressed agreement to the recommendation and confirmed that the substances do not occur in final products (JBCE 2019)[4], including finished medical devices (COCIR 2019)[5].

No specific information has been received during the 2nd stakeholder consultation on applications and quantities of the five cobalt salts. Thus, still no differentiation for the cobalt salts with regard to EEE could be done, which was the main reason to propose the scope extension. This is stressed here as the Cobalt Institute (2019)[6] in its contribution expressed some concerns about the process of grouping the cobalt salts.[7] However, industry did not contribute to specify the role of the initial cobalt salts with regards to EEE.

Concluding on the input of the 2nd stakeholder consultation, the dossier has not been revised. A final stakeholder meeting was held on 27 April 2020 to allow stakeholders to comment on the dossiers and particularly on conclusions and recommendations.

This document represents the final version of the RoHS Annex II dossier for cobalt dichloride, cobalt sulphate, cobalt dinitrate, cobalt carbonate and cobalt di(acetate).

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[3] See the list of contributions in Appendix II, section 13.

[4] JBCE – Japan Business Council in Europe (2019): Contribution submitted on 07.11.2019 during the stakeholder consultation conducted from 26 September 2019 to 07 November 2019 by Oeko-Institut in the course of the study to support the review of the list of restricted substances and to assess a new exemption request under RoHS 2 (Pack 15); https://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Pack_15/4th_Consultation/Contributions/contribution_JBCE_RoHS15_input_Assesment_Substance_Co_20191107.pdf

[5] COCIR (2019): Contribution submitted on 22.10.2019 during the stakeholder consultation conducted from 26 September 2019 to 07 November 2019 by Oeko-Institut in the course of the study to support the review of the list of restricted substances and to assess a new exemption request under RoHS 2 (Pack 15); https://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Pack_15/4th_Consultation/Contributions/contribution_COCIR_Cobalt_RoHS15_additional_7_substances_report_20191022.pdf

[6] Cobalt Institute (2019): Contribution submitted on 05.11.2019 during the stakeholder consultation conducted from 26 September 2019 to 07 November 2019 by Oeko-Institut in the course of the study to support the review of the list of restricted substances and to assess a new exemption request under RoHS 2 (Pack 15); https://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Pack_15/4th_Consultation/Contributions/contribution_CI_RoHS15_Response_Annex_II_Evaluation_5_Cobalt_20191105.pdf

[7] Cobalt Institute (2019): *"In particular, we are concerned by the unilateral grouping and extension of the evaluation beyond cobalt dichloride and cobalt sulphate to the other 3 salts. The grouping decision was made using a methodology which is not yet finalised nor agreed. Industry was not made aware of the changes and thus was unable to fully contribute to the analysis. These concerns are shared by the wider industry, it is not for the Commission's external consultants to make proposals or suggestions for decisions without due consultation with industry."*

1. IDENTIFICATION, CLASSIFICATION AND LABELLING, LEGAL STATUS AND USE RESTRICTIONS

1.1 Identification

1.1.1. Name, other identifiers, and composition of the substance

The following information on the substance identity of the five cobalt salts, cobalt dichloride[8],cobalt sulphate[9] cobalt dinitrate[10], cobalt carbonate[11] and cobalt di(acetate)[12] are extracted from the ECHA database on substances.

Table 1-1: Substance identity and composition of cobalt dichloride, cobalt sulphate, cobalt dinitrate, cobalt carbonate, cobalt di(acetate)

Chemical name	**Cobalt dichloride**	**Cobalt sulphate**	**Cobalt dinitrate**	**Cobalt carbonate**	**Cobalt di(acetate)**
EC number	231-589-4	233-334-2	233-402-1	208-169-4	200-755-8
CAS number	7646-79-9	10124-43-3	10141-05-6	513-79-1	71-48-7
IUPAC name	Cobalt(2+) dichloride	Cobalt (2+) Sulfate Cobalt Sulfate Cobalt Sulphate Cobalt sulphate heptahydrate cobalt(2+) sulfate Cobalt(II) sulfate cobalt(II) sulphate-1-water Cobalto(II) Sulfato 7-hidrato Cobaltsulfat CoSO4 λ²-cobalt(2+) ion sulfate	λ²-cobalt(2+) dinitrate	λ²-cobalt(2+) carbonate	λ²-cobalt(2+) diacetate
Index number in Annex VI of the CLP	027-004-00-5	027-005-00-0	027-009-00-2	027-010-00-8	027-006-00-6

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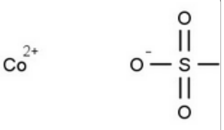
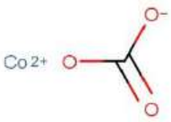
[8] ECHA Brief Profile: Entry for Cobalt dichloride; https://echa.europa.eu/de/brief-profile/-/briefprofile/100.028.718, last viewed 04.06.2018

[9] ECHA Brief Profile: Entry for Cobalt sulphate; https://echa.europa.eu/de/brief-profile/-/briefprofile/100.030.291, last viewed 04.06.2018

[10] ECHA Brief Profile: Entry for Cobalt dinitrate: https://echa.europa.eu/brief-profile/-/briefprofile/100.030.353, last viewed 22.02.2019

[11] ECHA Brief Profile: Entry for Cobalt carbonate: https://echa.europa.eu/brief-profile/-/briefprofile/100.007.428, last viewed 22.02.2019

[12] ECHA Brief Profile: Entry for Cobalt di(acetate): https://echa.europa.eu/brief-profile/-/briefprofile/100.000.687, last viewed 22.02.2019

Chemical name	**Cobalt dichloride**	**Cobalt sulphate**	**Cobalt dinitrate**	**Cobalt carbonate**	**Cobalt di(acetate)**
Regulation					
Molecular formula	$Cl_2 Co$	$Co H_2O_4S$	CoN2O6	CCoO3	C4H6CoO4
Molecular weight (range)	129.84 g/mol	154.99 g/mol	182.96 g/mol	118.94 g/mol	177.02 g/mol
Synonyms	cobalt (II) chloride Cobalt (II) chloride hexahydrate Cobalt Chloride Cobalt(2+) dichloride Cobalt(II) chloride Hexahydrate [for General Organic Chemistry] Cobaltdichlorid Cobalto(II) Cloruro 6-hidrato λ²-cobalt(2+) ion dichloride	cobalt sulfate Cobalt sulphate cobalt sulphate Cobalt(II) sulphate Cobalt (2+) Sulfate Cobaltsulfat Cobalto(II) Sulfato 7-hidrato cobalt(II) sulphate-1-water	Cobalt dinitrate Cobalt(II) dinitrate cobalt(2+) dinitrate cobalt(II) nitrate Cobaltdinitrat λ²-cobalt(2+) dinitrate Cobalt Dinitrate Cobalt Nitrate	Cobalt carbonate Cobalt(II) carbonate Cobalt Carbonate cobalt(2+) carbonate Cobalt(II)carbonic cobalte carbonate λ²-cobalt(2+) carbonate	Cobalt di(acetate) Cobalt(II) diacetate Acetic acid, cobalt(2+) salt (2:1) Bis(acetato)cobalt cobalt (II) ethanoate 4-water Cobalt Acetate Cobalt diacetate cobalt(2+) diacetate Cobalto(II) Acetato 4-hidrato λ²-cobalt(2+) diacetate
Structural formula	Co^{2+} Cl^- Cl^-				
Degree of purity	No data	No data	No data	No data	No data
Remarks	-	-	-	-	-

Source: European Chemicals Agency ECHA, Brief Profile: Entries for Cobalt dichloride, Cobalt sulphate, Cobalt dinitrate, Cobalt carbonate, Cobalt di(acetate)

1.1.2. Physico-chemical properties

Physico-chemical properties of cobalt dichloride, cobalt sulphate, cobalt dinitrate, cobalt carbonate and cobalt di(acetate) are summarised in Table 1-2 below and were extracted from the ECHA information database on chemicals as well as from the ECHA SVHC support documents.[13]

Table 1-2: Overview of physico-chemical properties of cobalt dichloride, cobalt sulphate, cobalt dinitrate, cobalt carbonate, cobalt di(acetate)

Property	Cobalt dichloride	Cobalt sulphate	Cobalt dinitrate	Cobalt carbonate	Cobalt di(acetate)
Physical state at 20°C and 101.3 k Pa	Solid (crystals)	Solid (crystals)	Pale-red powder	Red crystalline powder	Light-pink crystals
Melting/freezing point	736 °C 724 °C (ECHA 2011)	700 °C 735°C (ECHA 2010)	100-105 °C	No data	No data for anhydrous form, loses four H2O at 140°C for tetrahydrate form
Boiling point	1.049 °C	No data	74 °C	No data	No data
Vapour pressure	40 mmHg at 770°C	No data	No data	No data	No data
Water solubility	585.8 g/l at 20 °C	376.7 g/l at 20°C soluble 362 g/l at 20℃ 830 g/l at 100℃ (SVHC support document)	1338 g/l at 0°C soluble 2170 g/l at 80°C	Insoluble in water 0.18 g/100 g water	Readily soluble Soluble in water * The water solubility of cobalt(II) diacetate in the form of a numerical value or range is not available
Partition coefficient n-octanol/ water (log POW)	Not appropriate, inorganic substance	Not relevant	Not relevant	Not relevant	Not relevant
Dissociation constant	No data	No data	No data	No data	No data
Relative density	3.36 g/cm^3 at 20 °C	3.71 g/cm^3 at 20 °C	No data	No data	No data
Specific gravity	No data	No data	No data	No data	No data

Source: ECHA database on chemicals; ECHA (2010a,b,c,d and 2011)

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[13] ECHA (2010a): Support document for identification of cobalt (II) sulphate as a Substance of Very High Concern because of its CMR properties, Adopted on 2 December 2010; https://echa.europa.eu/documents/10162/5fa87d07-2872-4502-b07c-4186797aa442, last viewed 04.06.2018.

ECHA (2011): Support document for identification of cobalt dichloride as a Substance of Very High Concern because of its CMR properties, 20 June 2011;https://echa.europa.eu/documents/10162/7d541979-6f03-421b-91bb-039bfb326de1, last viewed 04.06.2018.

ECHA (2010b): Support document for identification of cobalt dinitrate as a Substance of Very High concern because of its CMR properties, Adopted on 2 December 2010; https://echa.europa.eu/documents/10162/a6ff4bdb-6aa3-48ff-b9b4-6f086d8f35fa, last viewed 22.02.2019.

ECHA (2010c): Support document for identification of cobalt carbonate as a Substance of Very High concern because of its CMR properties, Adopted 2 December 2010; https://echa.europa.eu/documents/10162/efdc02e9-f1e6-47c7-872b-7d6285457495, last viewed 22.02.2019.

ECHA (2010d): Support document for identification of cobald di(acetate) as a Substance of Very High concern because of its CMR properties, Adopted 2 December 2010; https://echa.europa.eu/documents/10162/f68e76b3-751d-48b4-a225-4a23c0ee6249, last viewed 22.02.2019.

1.2. Classification and labelling status

The Classification, Labelling and Packaging (CLP) regulation[14] ensures that the hazards presented by chemicals are clearly communicated to workers and consumers in the European Union through classification and labelling of chemicals. Annex VI of the CLP regulation No 1272/2008 lists substances where a harmonised classification exists based on e.g. human health concerns.

Annex VI of the CLP regulation is constantly adapted by engagement of Member State Competent Authorities and ECHA where new information becomes available, where existing data are re-evaluated or due to new scientific or technical developments or changes in the classification criteria. [15]

For an explanation on the human and environmental hazards, see section 2.4 and 4.

1.2.1. Classification in Annex VI Regulation No 1272/2008

The five cobalt salts all have the same classification under the CLP regulation (Regulation (EC) No 1272/2008 on Classification, Labelling and Packaging) with the following entries:[16]

- Acute Tox. 4 (Acute toxicity) - H302 (Harmful if swallowed);
- Skin Sens. 1 (Sensitisation of the skin) - H317 (May cause an allergic skin reaction);
- Resp. Sens. 1 (Sensitisation of the respiratory tract) - H334 (May cause allergy or asthma symptoms or breathing difficulties if inhaled;
- Muta. 2 (Germ cell mutagenicity) - H341 (Suspected of causing genetic defects);
- Carc. 1B (Carcinogenicity) - H350i (May cause cancer by inhalation);
- Repr. 1B (Reproductive Toxicity) - H360F (May damage fertility);
- Aquatic Acute 1 (Hazardous to the aquatic environment) - H400 (Very toxic to aquatic life); and
- Aquatic Chronic 1 (Hazardous to the aquatic environment) - H410 (Very toxic to aquatic life with long lasting effects).

The harmonised classification according to Table 3.1 of Annex VI Regulation No 1272/2008, for the five cobalt salts is presented in Table 1-3.

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[14] Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (REACH).

[15] For further information, see https://echa.europa.eu/regulations/clp/harmonised-classification-and-labelling, last viewed 19.04.2018

[16] https://echa.europa.eu/de/information-on-chemicals/annex-vi-to-clp, last viewed 19.04.2018

Table 1-3: Classification according to part 3 of Annex VI, Table 3.1 (list of harmonised classification and labelling of hazardous substances) of Regulation (EC) No 1272/2008 for the five cobalt salts

Index No.	International Chemical ID	EC No.	CAS No.	Classification		Labelling			Spec. Conc. Limits, M-factors
				Hazard Class and Category Code(s)	Hazard statement code	Pictogram Signal Word Code(s)	Hazard statement code(s)	Suppl. Hazard statement code(s)	
027-004-00-5	cobalt dichloride	231-589-4	7646-79-9	Carc. 1B Muta. 2 Repr. 1B Acute Tox. 4 Resp. Sens. 1 Skin Sens. 1 Aquatic Acute 1 Aquatic Chronic 1	H350i H341 H360F H302 H334 H317 H400 H410	GHS08 GHS07 GHS09 Dgr	H350i H341 H360F H302 H334 H317 H410	No data	Carc. 1B; H350i: C ≥ 0,01 % M=10
027-005-00-0	cobalt sulphate	233-334-2	10124-43-3						
027-006-00-6	cobalt di(acetate)	200-755-8	71-48-7						
027-009-00-2	cobalt dinitrate	233-402-1	10141-05-6						
027-010-00-8	cobalt carbonate	208-169-4	513-79-1						

Source: Annex VI Regulation No 1272/2008; https://echa.europa.eu/de/information-on-chemicals/annex-vi-to-clp, last viewed 15.04.2019

To summarize, it is understood based on the harmonised classification that all five cobalt salts are considered as CMR substances. This means that exposure to these substances could lead to severe impacts on human health and/or the health of other species, e.g., cancer, genetic defects and/or impacts on the reproductive system and organs. Given other hazards that have been classified, relevant pathways for such impacts include exposure through the respiratory system and through inhalation, through contact with skin and through oral exposure. The five cobalt compounds have further been classified for aquatic toxicity, meaning that exposure of aquatic organisms is also of potential concern.

1.2.2. Self-classification(s)

Manufacturers, importers or downstream users have to (self-)classify and label hazardous substances and mixtures to ensure a high level of protection of human health and the environment. If a harmonised classification is available, it should be applied by all manufacturers, importers or downstream users of such substances and of mixtures containing such substances.

However, mostly, suppliers decide independently as to the classification of a substance or mixture, which is then referred to as self-classification. Therefore, self-classification might indicate an e.g. additional hazard which is so far not reflected by the harmonised classification. The ECHA database C&L inventory contains classification and labelling information on notified and registered substances received from manufacturers and importers. The substance specific entries compile all hazards notified in self-classification.[17]

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[17] ECHA CL Inventory: Entry for cobalt dichloride; https://echa.europa.eu/de/information-on-chemicals/cl-inventory-database/-/discli/details/119523, last viewed 04 June 2018

To summarize the various self-classifications, basically the same types of hazards are addressed as by the harmonised classification. Though in some cases the level of hazard may differ or certain hazard types have been omitted and given that the harmonised classification is assumed to have a higher scrutiny the differences in the self-classification compared to the harmonised classification are not further considered. To conclude on the classification, the five cobalt salts are recognised CMR substances thus relevant for human health.

1.3. Legal status and use restrictions

1.3.1. Regulation of the substance under REACH

The five cobalt salts, cobalt dichloride, cobalt sulphate, cobalt dinitrate, cobalt carbonate and cobalt di(acetate) are all recognised as substances of very high concern and were all included in the REACH Candidate list in 2008 because of being carcinogenic and toxic for reproduction (Articles 57a and 57c).

On 20 December 2011, ECHA prioritised the five cobalt salts for inclusion in Annex XIV to the REACH Regulation.[18] In December 2012, the Commission requested ECHA[19] to investigate the uses of the five cobalt salts because at least one of the uses of the cobalt salts (e.g. surface treatment) was considered to pose a risk to human health that is not adequately controlled and might need to be addressed. The inclusion into Annex XIV of REACH was postponed until this investigation was to be completed.

Based on the outcomes of its investigation, compiled in a 2017[20] report, ECHA concluded that there is a need for a proposal for restriction of the five soluble cobalt salts. ECHA committed to make a proposal for a restriction of the substance and to submit a REACH Annex XV dossier for a restriction in 07/2018.[21]

Thus, for this restriction proposal under REACH, the five soluble cobalt salts are assessed as a group of substances.

ECHA CL Inventory: Entry for cobalt sulphate; https://echa.europa.eu/de/information-on-chemicals/cl-inventory-database/-/discli/details/79319, last viewed 04 June 2018

ECHA CL Inventory: Entry for cobalt di(acetate); https://echa.europa.eu/information-on-chemicals/cl-inventory-database/-/discli/details/126330, last viewed 18.02.2019

ECHA CL Inventory: Entry for cobalt dinitrate; https://echa.europa.eu/information-on-chemicals/cl-inventory-database/-/discli/details/242, last viewed 18.02.2019

ECHA CL Inventory: Entry for cobalt carbonate; https://echa.europa.eu/information-on-chemicals/cl-inventory-database/-/discli/details/72255, last viewed 18.02.2019

[18] ECHA (2011): Third Annex XIV recommendation - 20 December 2011; http://www.echa.europa.eu/documents/10162/13640/3rd_a_xiv_recommendation_20dec2011_en.pdf, last viewed 19.04.2018

[19] Recitals (11) and (12) of Commission Regulation (EU) No 348/2013 of 17 April 2013 amending Annex XIV to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH): http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32013R0348&qid=1493704087781&from=en, last viewed 04.06.2018

[20] ECHA (2017a): Study report on the conditions of use of five cobalt salts, Final report, May 2017, https://echa.europa.eu/documents/10162/13641/cobalts_salts_study_report_en.pdf/42f0947f-e7fe-7b14-fc97-cfda0c068e9d, last viewed 04.06.2018

[21] ECHA (2017b): Risk Management Option Analysis Conclusion Document, Substance Name: Soluble cobalt salts; 19/5/2017; https://echa.europa.eu/documents/10162/c362c44b-9470-a290-5ed7-c6c7a84989ae, last viewed 19.04.2018

The restriction proposal by ECHA has been posted in December 2018.[22] It is proposed that the cobalt salts cannot be manufactured, placed on the market or used unless a reference exposure value of 0.01 µg Co/m^3 ambient air is used by manufacturers and downstream users; they are required to implement a monitoring programme to demonstrate that all occupational exposures to the cobalt salts are below the reference exposure value of 0.01 µg Co/m^3.

The wording of the proposed restriction is shown in the following figure. The proposed restriction aims at reducing workers exposure levels and reducing the cancer risk and number of cancer cases resulting from occupational exposure to the cobalt salts.

As a number of national occupational exposure limits exists in the EU, the restriction proposal is further aimed at harmonizing EU-wide a high level of protection of human health across and besides minimizing the potential of market distortion.

The six-month public consultation under REACH ended on 19.06.2019. The comments submitted during the consultation as well as all ECHA documents (Information note on restriction report, restriction report and restriction report annexes) can be found on the ECHA webpage on submitted restrictions under consideration at: https://echa.europa.eu/restrictions-under-consideration/-/substance-rev/21805/term.

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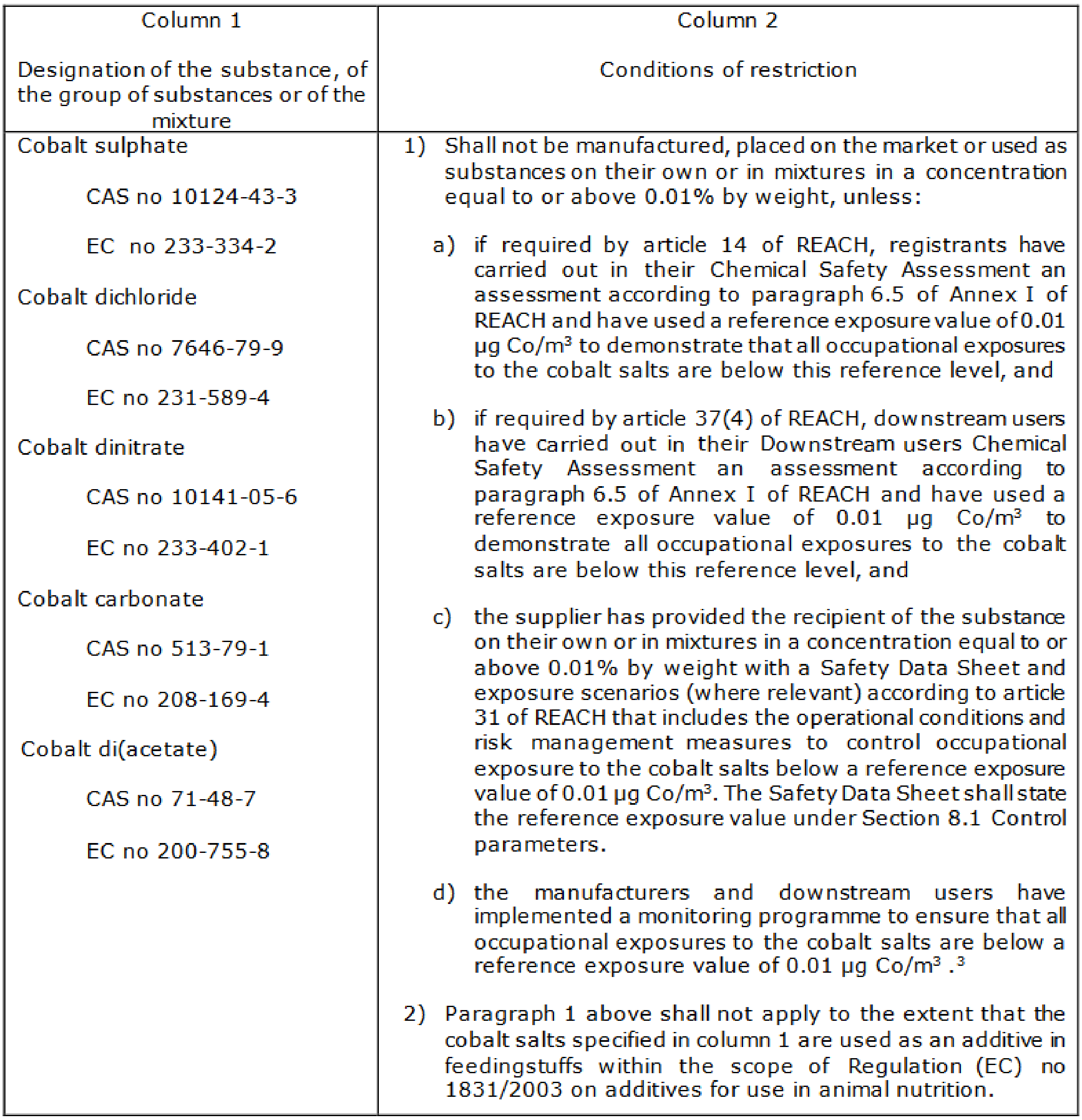
[22] ECHA (2018a): Annex XV Restriction Report, Proposal For A Restriction, Substance Names: cobalt sulphate cobalt dinitrate cobalt dichloride cobalt carbonate cobalt di(acetate); https://echa.europa.eu/documents/10162/0015c4ff-3036-9206-26ba-c6ff7ddf18e6, last viewed 18.02.2019

Figure 1-1: Proposed restriction according to Annex XV Restriction Report - Five cobalt salts



Column 1 Designation of the substance, of the group of substances or of the mixture	Column 2 Conditions of restriction
Cobalt sulphate CAS no 10124-43-3 EC no 233-334-2 Cobalt dichloride CAS no 7646-79-9 EC no 231-589-4 Cobalt dinitrate CAS no 10141-05-6 EC no 233-402-1 Cobalt carbonate CAS no 513-79-1 EC no 208-169-4 Cobalt di(acetate) CAS no 71-48-7 EC no 200-755-8	1) Shall not be manufactured, placed on the market or used as substances on their own or in mixtures in a concentration equal to or above 0.01% by weight, unless: a) if required by article 14 of REACH, registrants have carried out in their Chemical Safety Assessment an assessment according to paragraph 6.5 of Annex I of REACH and have used a reference exposure value of 0.01 µg Co/m^3 to demonstrate that all occupational exposures to the cobalt salts are below this reference level, and b) if required by article 37(4) of REACH, downstream users have carried out in their Downstream users Chemical Safety Assessment an assessment according to paragraph 6.5 of Annex I of REACH and have used a reference exposure value of 0.01 µg Co/m^3 to demonstrate all occupational exposures to the cobalt salts are below this reference level, and c) the supplier has provided the recipient of the substance on their own or in mixtures in a concentration equal to or above 0.01% by weight with a Safety Data Sheet and exposure scenarios (where relevant) according to article 31 of REACH that includes the operational conditions and risk management measures to control occupational exposure to the cobalt salts below a reference exposure value of 0.01 µg Co/m^3. The Safety Data Sheet shall state the reference exposure value under Section 8.1 Control parameters. d) the manufacturers and downstream users have implemented a monitoring programme to ensure that all occupational exposures to the cobalt salts are below a reference exposure value of 0.01 µg Co/m^3 .[3] 2) Paragraph 1 above shall not apply to the extent that the cobalt salts specified in column 1 are used as an additive in feedingstuffs within the scope of Regulation (EC) no 1831/2003 on additives for use in animal nutrition.

Source: ECHA (2018a)

It is expected that the outcome of the restriction proposal may have consequences as to the use of all cobalt salts and on surface treatment with cobalt in general. Should a restriction under the RoHS directive be recommended, the conditions of the restriction are to be evaluated in order to avoid double regulation and/or discrepancies. It is concluded that the REACH restriction process also applies to the manufacturing processes of EEE. Thus, risks arising at that stage are considered to be covered by the REACH Restriction, affording a high level of protection.

1.3.2. Other legislative measures

Cobalt and its compounds are subject to the other legal restrictions as follows:

- The IED Directive 2010/75/EU on industrial emissions (integrated pollution prevention and control) sets emission limit values for cobalt and its compounds at industrial sites.[23]
- In the Water Framework Directive 2006/11/EC on pollution caused by certain dangerous substances discharged into the aquatic environment of the Community, cobalt is listed as a substance for which water pollution has to be reduced; therefore, Member States are required to establish environmental quality standards for this purpose.
- Maximum air emission limit values for the incineration of waste are established in Directive 2000/76/EEC on the incineration of waste.[24]

Cobalt is listed on the 2017 list of Critical Raw Materials for the EU (COM(2017) 490 final)[25]. Materials appearing on this list have been identified as critical for the EU because possible risks of supply shortage (scarcity) and their impacts on the economy are higher than those of most of the other raw materials. Additional aspects (e.g. environmental, social) are not mentioned in the communication.

1.3.3. Non-governmental initiatives

The International Chemical Secretariat (ChemSec) has developed and regularly updates the so-called SIN List, which identifies potential substances of concern. The purpose of this list is to put pressure on legislators to assess and where relevant address substances identified therein in the future in respect to relevant chemical legislation.[26] Chemsec applies a number of categories for adding substances to the SIN List, including substances that can cause cancer, alter DNA or damage reproductive systems (CMR properties); substances that do not easily break down and accumulate in the food chain (PBT/vPvB substances); and substances of equivalent concern that give rise to an equivalent level of concern in terms of potential damage to health and environment (such as substances with endocrine disrupting properties).

All five cobalt salts[27] have been listed in the SIN List for the reason that they are *"classified CMR according to Annex VI of Regulation 1272/2008"*. Thus, the SIN List does not address further hazards then those already recognised by the harmonised classification.

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[23] Average emission limit values (mg/Nm^3) for the following heavy metals over a sampling period of a minimum of 30 minutes and a maximum of 8 hours for Cobalt and its compounds, expressed as cobalt (Co): 0,5 mg/Nm^3

[24] All average values over the sample period of a minimum of 30 minutes and a maximum of 8 hours: total 0,5 mg/m^3 and total 1 mg/m^3 for Cobalt and its compounds, expressed as cobalt (Co)

[25] EU COM (2017): Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on the 2017 list of Critical Raw Materials for the EU, Brussels, 13.9.2017, COM(2017) 490 final, available under: http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=COM:2017:0490:FIN, last viewed 19.04.2018

[26] http://chemsec.org/business-tool/sin-list/about-the-sin-list/, last viewed 24.07.2018

[27] https://sinlist.chemsec.org/search/search?query=cobalt, last viewed 20.02.2019

2. USE IN ELECTRICAL AND ELECTRONIC EQUIPMENT

All five cobalt salts (cobalt dichloride and cobalt sulphate, cobalt dinitrate, cobalt carbonate and cobalt diacetate) are used in surface treatment processes. The EEE specific uses in surface treatment processes are **electroplating** and **metal passivation**.

- In relation to **electroplating**, in the ECHA background documents of 2011[28] technical or decorative or magnetic plating is mentioned.

  According to the preliminary investigation regarding the conditions of use of the five soluble cobalt salts, ECHA (2013)[29] stated that the cobalt salts are used in **metal alloy plating processes**: *"The main process reported is gold-cobalt alloy electroplating, although other processes, such as zinc-cobalt, nickel-cobalt, nickel-cobalt-copper, tin-cobalt, etc., have also been identified. Cobalt sulphate appears to be the preferred cobalt salt for gold-cobalt electroplating, together with cobalt carbonate in very small amounts. Cobalt sulphate is also reportedly used in a large number of other cobalt alloy electroplating applications, while cobalt dichloride appears to be used for tin-cobalt and zinc-cobalt coatings specifically. Although no information has been provided regarding the interchangeability of the cobalt salts in electroplating applications, it might be inferred that, similar to the passivation processes, the choice of cobalt salt can affect the characteristics of the final coating. Specific surface characteristics such as ductility, grain size, etc. are referred to in the information supplied, which appear to be cobalt salt-specific."*

  According to ECHA (2018b)[30], *"metallic alloy coatings produced by electroplating are used for example in the jewellery and the watchmaking industry."*

- In **metal passivation**, an anti-corrosion layer/coating is achieved. According to Association of Equipment Manufacturers AEM:[31] *"some formulations also contain cobalt chloride (to give harder coatings)."*

  According to ECHA (2013), cobalt dichloride, cobalt sulphate, cobalt dinitrate and cobalt diacetate are used in the generation of **conversion layers in passivation** processes: *"Cobalt dinitrate appears to be the most commonly used cobalt salt for this application, accounting for more than half of the total use of cobalt salts in passivation. According to the information supplied in the consultation, each cobalt salt provides specific characteristics to the protective coating (colour, optical appearance, thermal and corrosion resistance, etc.) and can influence the speed of the passivation process. However, due to the limited information available, it is not possible to draw a firm conclusion as to whether the cobalt salts will be readily interchangeable from a technical or economic perspective in passivation applications."*

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[28] Op. cit. ECHA (2011 a and b)

[29] Op. cit. ECHA (2017a); from page 41 on as last part the following report is included: ECHA (2013): A preliminary investigation into the conditions of use of five cobalt salts final report July 2013, public version.

[30] ECHA (2018b): Restriction report Annexes; Annex XV Restriction Report, Proposal For A Restriction, Substance Names: cobalt sulphate cobalt dinitrate cobalt dichloride cobalt carbonate cobalt di(acetate); https://echa.europa.eu/restrictions-under-consideration/-/substance-rev/21805/term, last viewed 18.02.2019

[31] AEM Association of Equipment Manufacturers (2018): Contribution submitted on 15.06.2018 during the stakeholder consultation conducted from 20 April 2018 to 15 June 2018 by Oeko-Institut in the course of the study to support the review of the list of restricted substances and to assess a new exemption request under RoHS 2 (Pack 15); http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Pack_15/1st_Consultation_Contributions/Contribution_AEM_Cobalt_chloride_sulphate_20180615_RoHS.PDF, last viewed 16.07.2018

The Cobalt Institute[32] explains the processes in the course of this substance assessment at hand as follows; it should be noted that the statement focuses on cobalt dichloride and cobalt sulphate as the contribution had been submitted before the scope of this substance assessment was amended to the five cobalt salts:

> *"In these reaction processes the cobalt dichloride and/ or cobalt sulphate are combined with other metal salts and chemical constituents to prepare the formulation solutions (i.e. proprietary made-to-order mixtures). In solution the metal salts will dissolve and dissociate into their cationic and anionic components. Through the electrochemical deposition process or the passivation process, the cobalt ion is deposited onto the surface layers of the treated article; for example, in the form of metallic cobalt, as an alloyed metal layer, or as a metal oxide/hydroxide complex, or another cobalt-containing compound. The form and composition of the deposited layer will depend on the chemical constituents and technological processes selected by the DU* [downstream user] *company to achieve the required physical-chemical properties and technical functionality that has been specified by the end-user for the intended application."*

Thus, the cobalt salts are not present in the EEE, but transformed into a reaction product which is cobalt metal or a cobalt-containing compound (alloy) or e.g. in metal passivation apparently cobalt oxides. According to the ECHA background documents for e.g. cobalt dichloride and cobalt sulphate from 2011, the alloys could contain nickel, tungsten, iron, molybdenum, chromium, zinc, precious metals, etc.[33]

2.1. Function of the substance

As regards the function of the cobalt compounds in EEE, though the compounds are understood not to remain in the final product, their use affects the functional properties of the resulting plating layer, as also reflected in the following information:

- In relation to **electroplating**, ECHA (2018b) summarises that cobalt salts are used in metal or metal alloy plating (mainly gold-cobalt and tin-cobalt plating) for increased hardness and wear resistance and/or for metal colouring.

  In the ECHA background documents of 2011[34] technical or decorative or magnetic plating is mentioned: *"The function of the substance is to affect physical properties of surfaces, e.g. smoothness, hardness, brightness, ductility, resistance, porosity or the production of record and compact discs."*

  According to ECHA (2018b), *"one company […] estimates that around 45% of the components cobalt-coated by galvanising companies in Germany are used in the automotive sector. Cobalt*

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[32] Cobalt Institute (2018): Contribution submitted on 15.06.2018 during the stakeholder consultation conducted from 20 April 2018 to 15 June 2018 by Oeko-Institut in the course of the study to support the review of the list of restricted substances and to assess a new exemption request under RoHS 2 (Pack 15); http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Pack_15/1st_Consultation_Contributions/Contribution_Cobalt_Institute_Co_response_RoHS_15062018_CoCl2andCoSO4.pdf, last viewed 16.07.2018

[33] ECHA (2011a): Background document for cobalt dichloride; 20 December 2011; http://www.echa.europa.eu/documents/10162/a002b713-7e1a-46ba-ba54-13763c18fd82, last viewed 19.04.2018

ECHA (2011b): Background document for cobalt(II) sulphate, 20 December 2011; http://www.echa.europa.eu/documents/10162/ef958831-f28c-47f1-b159-ab4a32b53b2f, last viewed 19.04.2018

Both documents were developed in the context of ECHA's third Recommendation for the inclusion of substances in REACH Annex XIV.

[34] Op. cit. ECHA (2011 a and b)

salts also have important applications in the aerospace and defence sectors as well as in window construction".

- In **metal passivation**, an anti-corrosion conversion layer is achieved. According to ECHA (2018b) mainly used *"for improving the corrosion resistance of zinc plated metal, hence leading to longer service life and operating time of metal components."*

  According to the Association of Equipment Manufacturers AEM,[35] *"some formulations also contain cobalt chloride (to give harder coatings)."*

To summarise, the five cobalt salts are applied as process chemicals and do not remain in the final layer but rather react. The reaction product is cobalt metal, a cobalt-containing alloy or cobalt oxides.

It can be understood that cobalt / cobalt containing alloys or cobalt oxides provide properties such as resistance to wear and electricity, high temperature and corrosion. The exact properties can be understood to be a result of the compounds used in the various plating/passivation processes. ECHA (2013) states the function is a result of the process and thus understood to be (partly) affected by the specific cobalt compounds used even if it is no longer available in the coating in this previous form. It is further understood that detailed information for specific cobalt salts is not available. Interchangeability may be possible between cobalt salts in some cases, but it is not clear for which cobalt salt and whether this would have additional impacts on the process (amounts of used) or its outcomes (e.g. additional properties, plating thickness, etc.).

2.2. Types of applications / types of materials

The Cobalt Development Institute (CDI) stated in 2014[36] that "*in general Co is used in*

- *semi-conductors,*
- *component lead frames,*
- *contacts and connectors,*
- *printed circuit boards,*
- *processors and chipsets, and*
- *hard-disk drives.*

However, it is not known to the CDI yet which, and how much of each of the three cobalt substances [Cobalt dichloride, Cobalt sulphate, Cobalt metal] *are used in each of these applications.*"

On their website, the Cobalt Institute refers to EEE applications that contain cobalt as follows:

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[35] AEM Association of Equipment Manufacturers (2018): Contribution submitted on 15.06.2018 during the stakeholder consultation conducted from 20 April 2018 to 15 June 2018 by Oeko-Institut in the course of the study to support the review of the list of restricted substances and to assess a new exemption request under RoHS 2 (Pack 15); http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Pack_15/1st_Consultation_Contributions/Contribution_AEM_Cobalt_chloride_sulphate_20180615_RoHS.PDF, last viewed 16.07.2018

[36] Cobalt Development Institute (2014): Contribution submitted on 04.04.2014; http://rohs.exemptions.oeko.info/index.php?id=213, last viewed 19.04.2018

Integrated circuits[37]

- **Contacts:** *"The connections between different components of an integrated circuit (IC) are called contacts. Within these connections copper is generally used. The thickness and length of the connection causes gate resistance. Silicides such as CoSi2 can be used to reduce this resistance. The use of a cobalt silicide has the advantage of low resistance, good process compatibility (high duration of high temperatures) and little electro-migration (displacement of a substance by the electric current)."*
- **Metal leads**: *"Cobalt is also used in metal leads (a length of wire or a metal pad that comes from a device). Gold is commonly used for marking mechanical electrical contacts. By co-depositing the gold with 15% cobalt, the wear-resistance properties of the metal lead are greatly increased. When an electrical current passes through the IC cycling occurs, the friction produced can cause the IC to fail, the addition of cobalt prevents this."*
- **Packages**: *"Lastly, cobalt is used in the packaging of ICs. Cobalt can be used in printing circuit board materials (PCB). PCBs usually consist of an insulating support surrounded by layers of electrically resistive materials which are attached to highly conductive materials. Cobalt antimony, cobalt boron, cobalt geranium, cobalt indium, cobalt-molybdenum, cobalt phosphorous, cobalt rhenium, cobalt ruthenium, cobalt tungsten and cobalt vanadium can all be used as resistive materials."*

Semi-conductors[38]

"Cobalt is used in three main parts within a semi-conductor:

- *The trend of increasing power by increasing the electric current in copper metal wiring is leading to electro-migration (e.g. 'leaking') of the copper. Cobalt is currently the material being extensively researched for its ability to provide a* ***barrier to prevent the electro-migration of copper.***
- ***Magnet tunnel junction transistors.***
- ***Cobalt-silicon-germanium nanowires*** *can be used in optical electrical devices. Cobalt improves the contact interface and allows for a tuneable bandgap."*

Magnetic recording[39]

"Cobalt is an essential metal in data recording devices such as hard disk drives [...]. Cobalt is often found in the medium used in magnetic recording devices, usually in the form of iron-cobalt. When in contact with an electro-magnet field the metallic grains can be polarised in one direction. Eventually the medium will migrate back to the previous chaotic state however."

According to MedTech Europe,[40] also flow cytometer parts may contain cobalt sulphate. However, so far it was not specified whether cobalt sulphate is used as a material constituent, as an additive, as an intermediate or a reactant, etc. and what concentration of cobalt sulphate remains in the final

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[37] https://www.cobaltinstitute.org/integrated-circuits.html, last viewed 20.07.2018

[38] https://www.cobaltinstitute.org/semi-conductors.html, last viewed 20.07.2018

[39] https://www.cobaltinstitute.org/magnetic-recording.html, last viewed 20.07.2018

[40] MedTech Europe (2018): Contribution submitted on 15.06.2018 during the stakeholder consultation conducted from 20 April 2018 to 15 June 2018 by Oeko-Institut in the course of the study to support the review of the list of restricted substances and to assess a new exemption request under RoHS 2 (Pack 15); http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Pack_15/1st_Consultation_Contributions/Contribution_MedTech_Europe_7_substance_contribution20180613_FINAL.PDF, last viewed 16.07.2018

product; neither the function of cobalt sulphate in the flow cytometer parts nor quantities in which cobalt sulphate is applied in flow cytometer parts were specified by MedTech Europe. [41]

2.3. Quantities of the substance used

For quantities of cobalt salts used in surface treatment relevant for EEE, the Cobalt Institute[42] refers to recent information provided in the ECHA Call for Evidence (CfE)[43] in 2017 on the soluble cobalt salts. The Cobalt Institute[44] estimates the volumes as follows:

"Based on the survey results, less than 500 tonnes of cobalt salts were estimated to be used per year in the EU28 in the surface treatment sector, and survey responses indicated that this was primarily used for plating applications. […] The Secretariat notes that this volume (<500 tpa) is being used in the surface treatment sector, and the EEE-related applications represent a portion of this total volume."

Estimations as presented in ECHA (2013)[45] are based on the following information: *"The most comprehensive information regarding the volumes used in this sector has been provided by the Central Association of Surface Treatment Professionals Germany (ZVO). The volumes reported relate only to the German market and represent around 40 per cent of the total European market (ZVO). Based on these figures, the total volumes of cobalt salts used in the European surface treatment sector have been estimated and compared with the information made available by the Commission in its request to ECHA."*

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[41] MedTech Europe (2018): Information provided on request by Nathalie Buijs, MedTech Europe on 08.08.2018.

[42] Op. cit. Cobalt Institute (2018)

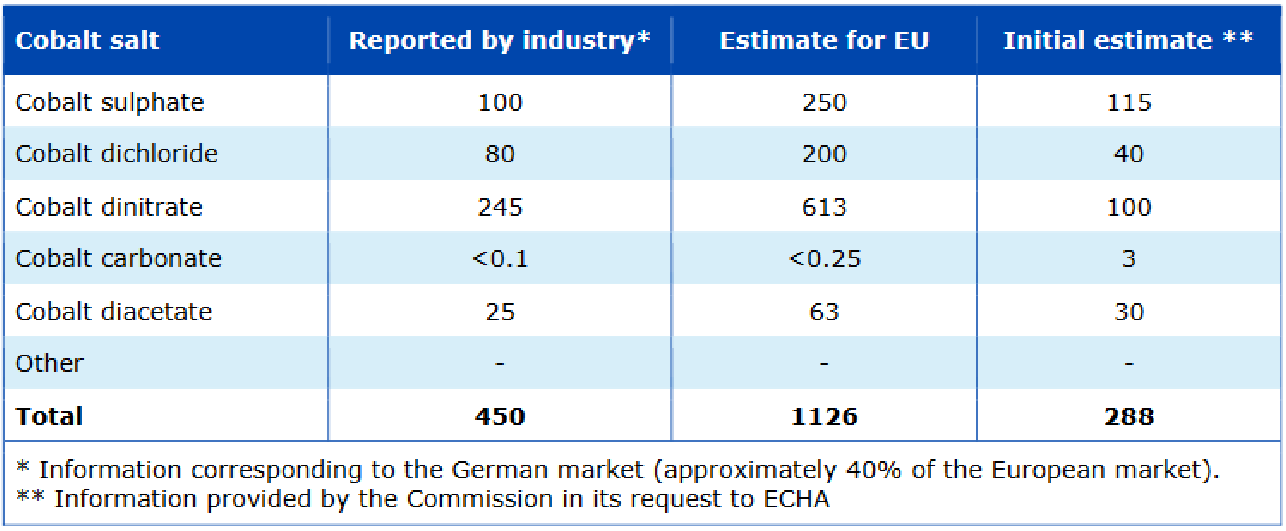
[43] https://echa.europa.eu/de/previous-calls-for-comments-and-evidence/-/substance-rev/17030/term, last viewed 16.07.2018

It should be noted here that contributions submitted during a call for evidence are not published by ECHA.

[44] Op. cit. Cobalt Institute (2018)

[45] Op. cit. ECHA (2017); from page 41 on as last part the following report is included: ECHA (2013): A preliminary investigation into the conditions of use of five cobalt salts final report July 2013, public version.

Figure 2-1: Reported and estimated volumes of cobalt salts used in surface treatment in 2012 (tonnes/year); the amounts of cobalt sulphate and cobalt dichloride are marked in yellow.



Cobalt salt	Reported by industry*	Estimate for EU	Initial estimate **
Cobalt sulphate	100	250	115
Cobalt dichloride	80	200	40
Cobalt dinitrate	245	613	100
Cobalt carbonate	<0.1	<0.25	3
Cobalt diacetate	25	63	30
Other	-	-	-
Total	**450**	**1126**	**288**

* Information corresponding to the German market (approximately 40% of the European market).
** Information provided by the Commission in its request to ECHA

Source: ECHA (2013): A preliminary investigation into the conditions of use of five cobalt salts final report July 2013, public version in ECHA (2017a)

To conclude, the estimates on the amounts of the five soluble cobalt salts in surface treatment ranged between 1,126 tonnes per year (ECHA 2013)[46] and 500 tonnes per year (Cobalt Institute 2017). The latest specifications of ECHA (2018b) agreed to a *"total volume of cobalt salts used in the surface treatment sector in the EU (2011-2013) was 500 tonnes, representing 1.5% of the total usage of cobalt salts in the EU."*

Information as to amounts of the cobalt salts used in the manufacture of imported EEE articles is currently not available.

There was no information received on the specific questions in the 2nd stakeholder consultation aimed to differentiate the use of the five cobalt salts in EEE. This confirms the decision on the change of scope, see introductory section of this dossier.

2.4. Potential for impacts of the substance on the environment and on health during the use of EEE

Seeing as the cobalt salts are understood not to be present in EEE, impacts would not be expected in relation to these substances in the use phase of such EEE. It is, however, noted that the application of these substances in plating processes applied in the manufacture of EEE components results in the presence of cobalt metal or cobalt alloys or cobalt oxide in EEE. Potential impacts on health and or the environment during the use phase of such equipment arising from other cobalt compounds than the five cobalt salts are considered being beyond the scope of this assessment.

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[46] Op. cit. ECHA (2017); from page 40 on as last part the following report is included: ECHA (2013): A preliminary investigation into the conditions of use of the five cobalt salts final report July 2013, public version.

3. HUMAN HEALTH HAZARD PROFILE

According to an ECHA report,[47] which was prepared to support the assessment of remaining cancer risks related to the industrial use of cobalt salts in the context of chemical risk management procedures under REACH, the divalent cobalt cation (Co^{2+}) moiety is considered to constitute the critical entity of the five cobalt salts and being responsible for systemic toxicity. In consequence, the classification of the five cobalt salts in Annex VI of the CLP regulation is identical.

As for the counter ions of the cobalt salts (i.e. sulphate, nitrate, chloride, acetate, and carbonate), ECHA (2018) summarises that the combination of released ions (i.e. both the cobalt (II) ion and the anion) is expected to be responsible for local toxicity by exposure to lungs or skin.

3.1. Critical endpoints

The cobalt salts are classified for the following human health hazards:

- CMR substances (carcinogenic and toxic for reproduction) and therefore recognised as substances of very high concern. Furthermore, they are recognised as being mutagenic (H341 - Suspected of causing genetic defects).
  The CMR properties are explained in more detail further below.
- They are recognised skin and respiratory sensitizing chemicals: H317 - May cause an allergic skin reaction and H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled.
- They are recognised as being acute toxic (category 4: H302 - Harmful if swallowed).

In the following, the consideration on carcinogenicity and mutagenicity are summarised from the ECHA report[48] as it is understood to be the most recent compilation on these critical endpoints of the five soluble cobalt salts:

Carcinogenicity

The carcinogenicity classification was allocated because the cobalt salts may cause cancer by inhalation.

According to ECHA (2017), uncertainties existed on the carcinogenic mode of action, whether the cobalt salts exhibit a threshold mode of action regarding their carcinogenicity effects - as claimed in the registration dossiers - or whether they should be considered as non-threshold carcinogens.

An assessment made by DHI[49] concluded that due to a lack of identified thresholds and due to remaining uncertainties regarding the mechanisms involved, the water-soluble cobalt salts are considered as genotoxic carcinogens and are to be assessed using a non-threshold approach.[50]

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[47] ECHA project SR 23 (no year): Support to the assessment of remaining cancer risks related to the industrial use of cobalt salts in the context of chemical risk management procedures under REACH, Poul Bo Larsen (DHI), Brian Svend Nielsen (DHI), Mona-Lise Binderup; https://echa.europa.eu/documents/10162/13563/echa_sr23_project_en.pdf, last viewed 16.07.2018

[48] ECHA project SR 23 (no year): Support to the assessment of remaining cancer risks related to the industrial use of cobalt salts in the context of chemical risk management procedures under REACH, Poul Bo Larsen (DHI), Brian Svend Nielsen (DHI), Mona-Lise Binderup; https://echa.europa.eu/documents/10162/13563/echa_sr23_project_en.pdf, last viewed 16.07.2018

According to ECHA (2018), the Risk Assessment Committee RAC agreed in 2016, that the cobalt salts should be considered as genotoxic carcinogens with a non-threshold mode of action and established a dose-response relationship for these substances, which is described below in section 3.2.

Mutagenicity

In vivo data indicate that cobalt salts may induce a variety of genotoxic alterations (DNA damage, gene mutations and chromosomal aberrations) in connection with intraperitoneal administration. Only very limited and non-conclusive human data are available with respect to the assessment of genotoxic effects from cobalt/ cobalt salt exposure.

The assessment made by DHI,[51] concluded that genotoxicity as a mode of action behind lung tumours cannot to be ruled out.

The assessment further stated that *“the underlying mechanisms for the genotoxic and carcinogenic effects of the cobalt salts have not been fully elucidated, but it is a general view that key mechanisms involved are:*

- *oxidative DNA damages due to cobalt(II) induced [*Reactive Oxygen Species*] ROS generation as Co(II) catalyses the generation of reactive oxygen species through a Fenton like mechanism;*
- *cobalt(II) induced impairment of DNA-repair mechanisms due to cobalt (II) binding to DNA-repair enzyme.”*

3.2. Existing Guidance values (DNELs, OELs)

ECHA (2018) summarises that a DNEL value of 40 µg Co/m^3 is used by the registrants in their Chemical Safety Assessments for the five cobalt salts. In the restriction proposal, ECHA (2018) criticises that the *“REACH registration dossiers […] presents the cobalt salts as non-genotoxic carcinogens with a threshold mode of action. The registration dossiers have not been updated to take into account the RAC agreement in 2016.”* As a result, they do not control or minimise the risks posed by the substances.

Instead in the restriction proposal, a dose-response relationship was derived for the respirable fraction. The exposure level for the surface treatment sector ranges at 4 µg Co/m^3 for passivation and at 7 µg Co/m^3 for plating operations. Based on the dose-response relationship as shown in the following figure and on the exposure levels for the surface treatment processes, individual excess lifetime cancer risk levels were derived which are e.g. among all uses highest ($\geq 10^{-2}$) for plating process in surface treatment.

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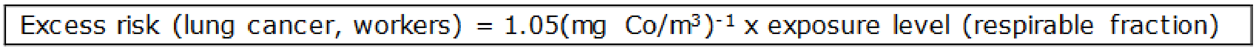
[49] Op. cit. ECHA project SR 23 (no year)

[50] OELs for non-threshold carcinogens are derived using a ‘cancer risk level’: the number of additional cases of cancer due to exposure to a carcinogenic, according to RIVM, the Dutch National Institute for Public Health and the Environment (2016): Difference in risk assessment of non-threshold carcinogens for workers; https://www.rivm.nl/en/Documents_and_publications/Common_and_Present/Newsmessages/2015/Difference_in_risk_assessment_of_non_threshold_carcinogens_for_workers, last viewed 24.07.2018

[51] Op. cit. ECHA project SR 23 (no year)

Figure 3-1: Dose-response relationship for the respirable fraction for the five cobalt salts



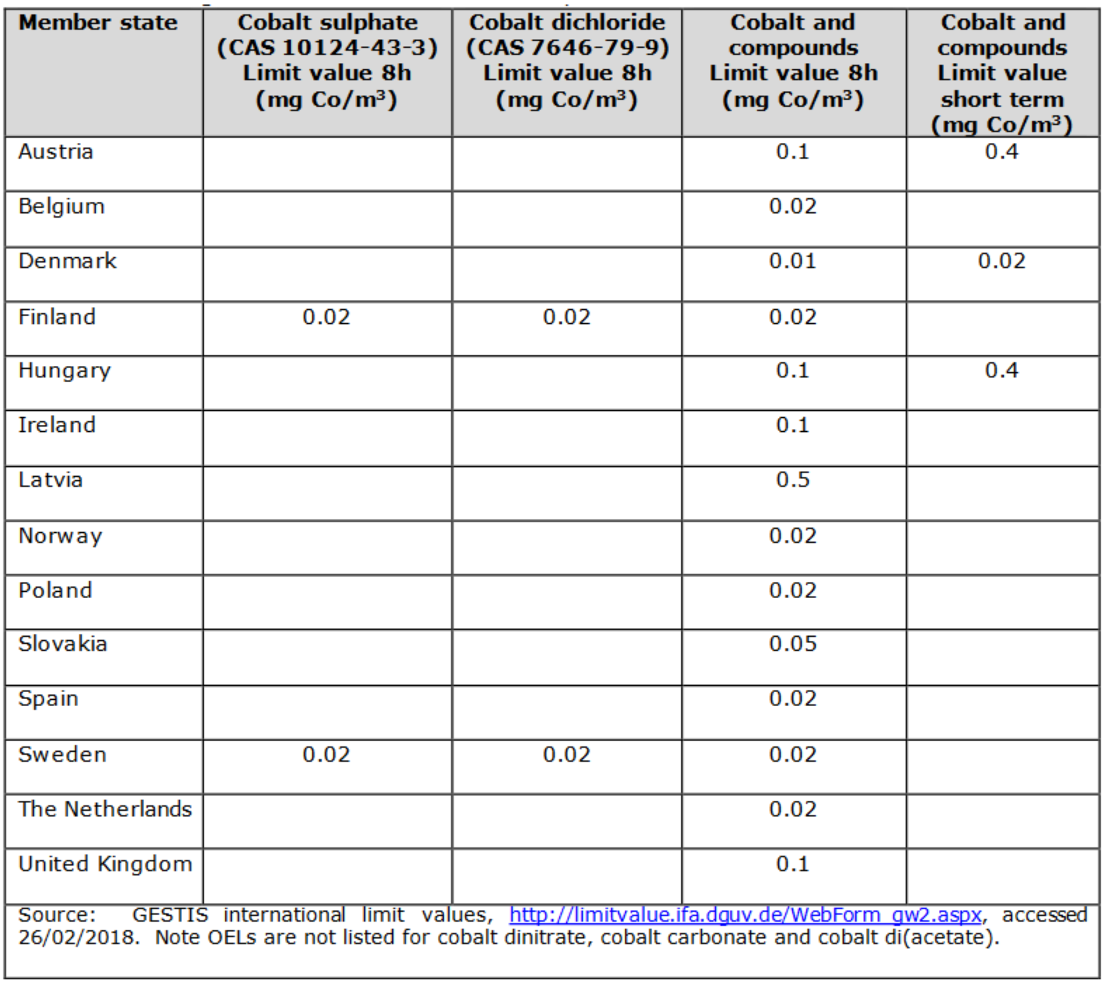
Excess risk (lung cancer, workers) = 1.05(mg Co/m^3)$^{-1}$ x exposure level (respirable fraction)

Source: ECHA (2018)

Based on a subsequent impact assessment, the conclusion is drawn in ECHA (2018a) that a reference exposure value of 0.01 µg Co/m^3 would be the most appropriate EU-wide measure to ensure a high level of protection of workers from the risk of developing cancer due to exposure to the cobalt salts.

According to ECHA (2018a), 15 member states have implemented regulatory measures to limit exposure of workers to the cobalt salts, which are shown in the following figure.

Figure 3-2: Existing national OELs for cobalt compounds



Member state	Cobalt sulphate (CAS 10124-43-3) Limit value 8h (mg Co/m^3)	Cobalt dichloride (CAS 7646-79-9) Limit value 8h (mg Co/m^3)	Cobalt and compounds Limit value 8h (mg Co/m^3)	Cobalt and compounds Limit value short term (mg Co/m^3)
Austria			0.1	0.4
Belgium			0.02	
Denmark			0.01	0.02
Finland	0.02	0.02	0.02	
Hungary			0.1	0.4
Ireland			0.1	
Latvia			0.5	
Norway			0.02	
Poland			0.02	
Slovakia			0.05	
Spain			0.02	
Sweden	0.02	0.02	0.02	
The Netherlands			0.02	
United Kingdom			0.1	

Source: GESTIS international limit values, http://limitvalue.ifa.dguv.de/WebForm_gw2.aspx, accessed 26/02/2018. Note OELs are not listed for cobalt dinitrate, cobalt carbonate and cobalt di(acetate).

Source: ECHA (2018a)

To conclude on the human health hazard, there are national occupational exposure limits in place in some Member States. The restriction proposal under REACH would provide an EU-wide harmonised protection level. Thereby, the manufacturing processes of EEE are covered (though only for the EU) and might substantially affect the uses and amounts of cobalt present in EEE.

Regarding the five cobalt salts, the divalent cobalt cation moiety is considered to constitute the critical entity being responsible for the human toxicity. However, the five cobalt compounds are converted during manufacture process and the resulting cobalt compounds might have an impact during use and waste phase. As pointed out in the section on the scope, such analysis is beyond the scope of this assessment.

4. ENVIRONMENTAL HAZARD PROFILE

The ECHA reports (2010a-d) supporting the identification of the five cobalt salts as Substances of Very High Concern did not consider environmental fate properties or hazards, since the dossiers were targeted at the identification of the five cobalt salts as CMR substances. There is no other environmental risk assessment available for the five cobalt salts. However, the European harmonised classification points out aquatic toxicity as environmental concern of the five cobalt salts. These substances are attributed the hazard statements H400 and H419 (Aquatic Acute 1 and Aquatic Chronic 1).[52]

4.1. Endpoints of concern

The five cobalt salts are toxic to aquatic organisms. The aquatic toxicity is acute and chronic as described by the hazard statements H400 – very toxic to aquatic life and H410 – very toxic to aquatic life with long lasting effects.

As the five cobalt salts are inorganic substances, degradation is not a relevant process. Due to the water solubility, the cobalt ion is the relevant compound in the environment. Therefore, in the following, bioaccumulation and the guidance values refer to cobalt.

4.2. Potential for secondary poisoning and bioaccumulation

Cobalt is considered not to bio-magnify through either freshwater or marine trophic food-webs according to the information of the ECHA database on registered substances:[53]

- In aquatic systems, cobalt accumulates from water to plants;
- In general, cobalt is not largely concentrated from soil into plant or soil into invertebrate or vertebrates.

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[52] ECHA (2019) Infocard on Cobalt dichloride https://echa.europa.eu/de/substance-information/-/substanceinfo/100.028.718, last viewed 12.09.2019. (similar hazard statements apply for other cobalt salts too)

[53] ECHA Registered Substance Database: Entry for Cobalt dichloride; https://echa.europa.eu/de/registration-dossier/-/registered-dossier/14346, last viewed 04.06.2018.

ECHA Registered Substance Database: Entry for Cobalt sulphate; https://echa.europa.eu/de/registration-dossier/-/registered-dossier/15094, last viewed 04.06.2018.

ECHA Registered Substance Database: Entry for Cobalt dinitrate; https://echa.europa.eu/registration-dossier/-/registered-dossier/14964; last viewed 18.02.2019.

ECHA Registered Substance Database: Entry for Cobalt carbonate; https://echa.europa.eu/registration-dossier/-/registered-dossier/14925, last viewed 18.02.2019.

ECHA Registered Substance Database: Entry for Cobalt di(acetate); https://echa.europa.eu/registration-dossier/-/registered-dossier/14769, last viewed 18.02.2019.

4.3. Guidance values (PNECs)

The predicted no effect concentration (PNEC) is the concentration below which exposure to a substance is not expected to cause adverse effects on species in the environment.

ECHA's registered substances database[54] provides guidance values on aquatic and terrestrial toxicity for cobalt. It should be noted that this information has been provided by the registrant and has not been subject to scrutiny by e.g. ECHA.

Table 4-1: PNECs values for cobalt

Fact	Compartment	PNEC values for cobalt
Hazard for aquatic organisms	Freshwater	0.6 µg/l
	Marine water	2.36 µg/l
	Sewage treatment plant (STP)	370 µg/l
	Sediment (freshwater)	9.5 mg/kg sediment dw
	Sediment (marine water)	9.5 mg/kg sediment dw
Hazard for terrestrial organism	Soil	10.9 mg/kg soil dw
Hazard for air	Air	No hazard identified
Hazard for predators	Secondary poisoning	No potential for bioaccumulation

Source: ECHA Registered Substance Database: Entries for the five cobalt salts

To conclude on the environmental hazards, the cobalt salts are not expected to remain in the environment but due to e.g. the water solubility, the cobalt ion is the relevant compound in the environment. As the cobalt salts are converted during EEE manufacture, a release of cobalt in the forms of cobalt alloys and cobalt oxide may appear in the waste phase. However, this release is not a release of the original cobalt salts that are in the scope of this RoHS assessment.

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[54] ECHA Registered Substance Database: Entries of the five cobalt salts

5. WASTE MANAGEMENT OF ELECTRICAL AND ELECTRONIC EQUIPMENT

The five cobalt salts are not present in original form in EEE and would thus also not be found in various EEE waste streams.

Though it is possible that the presence of such transformed cobalt compounds in EEE could have impacts on the environment and or on health, during the use phase or during waste management, such an assessment is beyond the scope of the study at hand.

Therefore, this section is not further detailed.

6. EXPOSURE ESTIMATION DURING USE AND DURING WEEE TREATMENT

As the five cobalt salts under consideration in this substance dossier are not present in the final EEE, it is concluded that there is no exposure to either of these substances during WEEE treatment.

7. IMPACT AND RISK EVALUATION

This section will not further be discussed as the available data indicate that the five cobalt salts are not present in EEE.

The restriction process under REACH is considered to sufficiently cover risks in the manufacturing process of EEE; thus, for coherence of the legislation, manufacturing is not considered.

8. ALTERNATIVES

No information has been provided on possible alternatives during the first stakeholder consultation on the grounds that cobalt dichloride and cobalt sulphate (as at this time, only these two cobalt compounds were addressed) are not present in EEE and therefore substitution does not need to be discussed.

Information on possible alternatives for cobalt dichloride and cobalt sulphate in the surface treatment processes is scarce. Some information is available as detailed below but does not indicate substitutes that can be considered to be practical in light of the hazardousness of such substitutes.

8.1. Availability of substitutes / alternative technologies

During ECHA's preliminary investigation into the conditions of use of the five cobalt salts summarised in 2013,[55] industry stated that *"no valid alternatives to the cobalt salts have been identified so far. In fact, it is remarked that the use of cobalt salts was developed by the automotive industry as an alternative to the use of chromium VI in passivation processes. No feasible alternatives are expected to be found in the near future."*

In the background document of ECHA in 2011, a cobalt-free passivation for zinc or zinc-alloy plating was mentioned. In the ECHA report in 2013, it was noted that *"one company did suggest that the replacement of cobalt salts with nickel compounds could be a viable option in the longer term, but no further information was provided on this."*

The (reverse) substitution by the following (more) hazardous substances is mentioned:[56]

- Substitution of zinc-cobalt plating by cadmium plating,
- Replacement of Cr(VI) in electroplating by Co(II); and though not mentioned in the ECHA report vice versa.

In the background document of ECHA in 2011,[57] with regards to alternatives, the interchangeability within different cobalt salts was also discussed, which is however considered as a substitution with an equally hazardous substance (see detail below). According to ECHA, industry argued that *"interchangeability between the cobalt salts included in ECHA's recommendation is not expected to occur at large-scale, and that case-by-case evaluation is deemed necessary."* ECHA acknowledged that cobalt dichloride or cobalt sulphate may in some of its uses hardly be replaceable by another cobalt(II) salt but concluded that *"considering scientific knowledge in chemistry and the principal chemical processes taking place it appears very improbable that it would technically not be possible to replace cobalt dichloride [or cobalt sulphate] in at least some of its uses by another cobalt salt or that cobalt dichloride [or cobalt sulphate] could not be used to replace other cobalt salts."* However, taking into account the comparable human health and environmental hazards of the five cobalt salts and the consequence that the five cobalt salts are grouped for a joint restriction proposal, the approach of substitution of one cobalt salt by another or by CR (VI) or cadmium does not seem to comprise a pragmatic solution as it is not expected to lead to environmental and or health benefits.

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[55] Op. cit. ECHA (2017); from page 40 on as last part the following report is included: ECHA (2013): A preliminary investigation into the conditions of use of five cobalt salts final report July 2013, public version.

[56] Op. cit. ECHA (2011a and b)

[57] Op. cit. ECHA (2011a and b)

8.2. Hazardous properties of substitutes

The various substitutes indicated above are all considered to have various hazardous properties that render their use as substitutes as problematic:

- Cadmium and hexavalent chromium are themselves restricted by the RoHS Directive and are thus not understood to be practical alternatives.
- Substituting one cobalt salt with another is also not considered to result in a benefit in terms of impacts on health and or environment as explained above. This is further supported by the understanding that a restriction on the use of the five cobalt salts is being considered under REACH (see Section 1.3.1).
- As for substitution with nickel compounds, two nickel compounds that are used in plating processes are being assessed in parallel for restriction under RoHS. Nickel sulphate and nickel sulphamate are both classified with comparable hazards, including among others being classified as CMR substances and as being toxic to the aquatic environment. Nickel and its compounds are furthermore subject to the restriction listed under entry 27 of REACH Annex XVII, which prohibits the use in post assemblies and articles coming into direct and prolonged contact with the skin. In this sense, substitution of the cobalt salts with a nickel compound is also not considered to result in a benefit in terms of impacts on health and or environment.

8.3. Data basis for alternatives and uncertainties

The information specified above regarding alternatives for the cobalt compounds and their hazardousness originates from various documents generated in the context of the REACH and CLP regulations. Such documents are understood to have been subject to scrutiny and to have a relatively high certainty.

9. DESCRIPTION OF SOCIO-ECONOMIC IMPACTS

9.1. Approach and assumptions

The scope of this assessment requires a review of possible socio-economic impacts related to a scenario in which the substances under assessment (five cobalt salts) were to be added to the list of restricted substances specified in Annex II of RoHS 2. This would restrict the presence of these substances in EEE to be placed on the market in the future.

However, as has been specified in the sections above, these compounds are used in plating processes of relevance to the manufacture of EEE, but do not remain in the final products in their compound form. These manufacturing processes are considered to be sufficiently covered by the restriction proposal under REACH affording a high level of protection.

In this sense, it is assumed that a restriction under RoHS of the five cobalt salts would not be effective: RoHS restricts the presence of substances present in EEE placed on the market and thus would not affect substances used in manufacture, assuming these do not remain present in the final product to be placed on the market. Against this background it is generally assumed that:

- Substitution would not take place, seeing as the applications do not contain these substances and would still be allowed on the market;
- The choice of related EEE available to consumers would not be expected to change, nor the properties and characteristics of such EEE;
- The amount of related EEE reaching end-of-life and subject to waste management would not be expected to change as a result of the restriction;
- Potential impacts of substitution on health and or environment during use and or the waste phase would thus not be expected.

9.2. Impact on chemicals industry

As the compounds do not remain present in the final product, it is assumed that manufacture could continue without change. In this sense the chemicals industry would continue manufacture as usual.

9.3. Impact on EEE producers (OEM[58] manufacturers and supply chain)

As the compounds do not remain present in the final product, it is assumed that manufacture, both of OEMs and the supply chain, could continue without change. In this sense EEE producers and their supply chain would continue manufacture as usual.

9.4. Impact on EEE users

As the compounds do not remain present in the final product, it is assumed that manufacture could continue without change and thus also the placing on the market of relevant products.

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[58] OEM: Original Equipment Manufacturer

9.5. Impact on waste management

As the compounds do not remain present in the final product, it is assumed that manufacture could continue without change and thus also the placing on the market of relevant products. The same EEE would reach the waste phase and require treatment and in this sense, any possible impacts at this stage related to the use of the five compounds in plating processes would not be expected to differ.

9.6. Impact on administration

As a restriction is not expected to affect EEE placed on the market, such ineffective listing of substances under RoHS should be avoided because compliance with the restriction would require provision of documentation and in some cases testing. This would result in an administrative burden for manufacturers and suppliers, and it can also be expected that a certain administrative burden would fall on regulators in relation to the implementation of the restriction in the RoHS Directive and in national legislation and its enforcement.

9.7. Total socio-economic impact

To summarise, a possible restriction can be expected to result in administrative costs for both, industry (e.g. EEE manufacturers, suppliers) and for regulators (e.g. legislators, market surveillance). However, the restriction is not expected to generate benefits for the environment or for health (in the form of prevention of possible impacts tied with the five cobalt salts in general and particularly during the use and waste phase of interest for RoHS 2 Article 6(1)). In terms of total socio-economic impacts this suggests that a restriction of the five substances would not be proportionate, given that its costs are not expected to generate benefits for the environment or for health.

10. RATIONALE FOR INCLUSION OF THE SUBSTANCE IN ANNEX II OF ROHS

The five cobalt salts cobalt sulphate, cobalt dichloride, cobalt dinitrate, cobalt carbonate, and cobalt diacetate are used in metal surface treatment processes, including electroplating and metal passivation. It can be understood that these substances are converted through the surface treatment processes and do not remain in their original form in the final produce, i.e, in relevant EEE and its parts. In the final coating, the cobalt salts are understood to be converted into metallic cobalt, as an alloyed metal layer, or as a metal oxide/hydroxide complex, or as another cobalt-containing compound.

Therefore, it is not recommended to include the five cobalt salts under consideration in this substance assessment to the list of restricted substances under RoHS. The reaction products are coatings or layers of cobalt metal or a cobalt-containing compound (alloy) or cobalt oxide/hydroxide complex. Thus, the cobalt salts are not present in the original form in the final EEE.

11. List of References

11.1. Databases

ECHA Brief Profile: Entry for Cobalt dichloride; https://echa.europa.eu/de/brief-profile/-/briefprofile/100.028.718, last viewed 04.06.2018

ECHA Brief Profile: Entry for Cobalt sulphate; https://echa.europa.eu/de/brief-profile/-/briefprofile/100.030.291, last viewed 04.06.2018

ECHA Brief Profile: Entry for Cobalt dinitrate: https://echa.europa.eu/brief-profile/-/briefprofile/100.030.353, last viewed 22.02.2019

ECHA Brief Profile: Entry for Cobalt carbonate: https://echa.europa.eu/brief-profile/-/briefprofile/100.007.428, last viewed 22.02.2019

ECHA Brief Profile: Entry for Cobalt di(acetate): https://echa.europa.eu/brief-profile/-/briefprofile/100.000.687, last viewed 22.02.2019

ECHA CL Inventory: Entry for cobalt dichloride; https://echa.europa.eu/de/information-on-chemicals/cl-inventory-database/-/discli/details/119523, last viewed 04 June 2018

ECHA CL Inventory: Entry for cobalt sulphate; https://echa.europa.eu/de/information-on-chemicals/cl-inventory-database/-/discli/details/79319, last viewed 04 June 2018

ECHA CL Inventory: Entry for cobalt di(acetate); https://echa.europa.eu/information-on-chemicals/cl-inventory-database/-/discli/details/126330, last viewed 18.02.2019

ECHA CL Inventory: Entry for cobalt dinitrate; https://echa.europa.eu/information-on-chemicals/cl-inventory-database/-/discli/details/242, last viewed 18.02.2019

ECHA CL Inventory: Entry for cobalt carbonate; https://echa.europa.eu/information-on-chemicals/cl-inventory-database/-/discli/details/72255, last viewed 18.02.2019

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ECHA Registered Substance Database: Entry for Cobalt sulphate; https://echa.europa.eu/de/registration-dossier/-/registered-dossier/15094, last viewed 04.06.2018.

ECHA Registered Substance Database: Entry for Cobalt dinitrate; https://echa.europa.eu/registration-dossier/-/registered-dossier/14964; last viewed 18.02.2019.

ECHA Registered Substance Database: Entry for Cobalt carbonate; https://echa.europa.eu/registration-dossier/-/registered-dossier/14925, last viewed 18.02.2019.

ECHA Registered Substance Database: Entry for Cobalt di(acetate); https://echa.europa.eu/registration-dossier/-/registered-dossier/14769, last viewed 18.02.2019.

11.2. Contributions, documents and reports

AEM Association of Equipment Manufacturers (2018): Contribution submitted on 15.06.2018 during the stakeholder consultation conducted from 20 April 2018 to 15 June 2018 by Oeko-Institut in the course of the study to support the review of the list of restricted substances and to assess a new exemption request under RoHS 2 (Pack 15); http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Pack_15/1st_Consultation_Contributions/Contribution_AEM_Cobalt_chloride_sulphate_20180615_RoHS.PDF, last viewed 16.07.2018

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ECHA (2010): Guidance on Intermediates, version 2, December 2010; https://echa.europa.eu/documents/10162/13632/intermediates_en.pdf/0386199a-bdc5-4bbc-9548-0d27ac222641, last viewed 19.04.2018

ECHA (2010a): Support document for identification of cobalt (II) sulphate as a Substance of Very High Concern because of its CMR properties, Adopted on 2 December 2010; https://echa.europa.eu/documents/10162/5fa87d07-2872-4502-b07c-4186797aa442, last viewed 04.06. June 2018.

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ECHA (2010c): Support document for identification of cobalt carbonate as a Substance of Very High concern because of its CMR properties, Adopted 2 December 2010; https://echa.europa.eu/documents/10162/efdc02e9-f1e6-47c7-872b-7d6285457495, last viewed 22.02.2019.

ECHA (2010d): Support document for identification of cobald di(acetate) as a Substance of Very High concern because of its CMR properties, Adopted 2 December 2010; https://echa.europa.eu/documents/10162/f68e76b3-751d-48b4-a225-4a23c0ee6249, last viewed 22.02.2019.

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ECHA (2013): A preliminary investigation into the conditions of use of five cobalt salts final report July 2013, public version; in ECHA (2017a)

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12. Appendix I: Contributions to 1st stakeholder consultation hold from 20 April 2018 to 15 June 2018

The following non-confidential contributions were submitted during the 1st stakeholder consultation (see also: http://rohs.exemptions.oeko.info/index.php?id=296):

> Contribution of **MedTech Europe** submitted on 15.06.2018: PDF

> Contribution of the **JBCE – Japan Business Council in Europe aisbl** submitted on 15.06.2018: PDF

> Contribution of the **Test and Measurement Coalition (TMC)** submitted on 15.06.2018: PDF

> Contribution of **Cobalt Institute** submitted on 15.06.2018: PDF

> Contribution of the **Association of Equipment Manufacturers (AEM)** submitted on 15.06.2018: PDF

> Contribution of the **Japanese electric and electronic (E&E) industrial associations** submitted on 14.06.2018: PDF

> Contribution of the **AeroSpace and Defence Industries Association of Europe (ASD)** submitted on 14.06.2018: PDF

13. Appendix II: Contributions to stakeholder consultation hold from 26 September 2019 to 07 November 2019

The following non-confidential contributions were submitted during the 2nd stakeholder consultation (see also: https://rohs.exemptions.oeko.info/index.php?id=338):

> Contribution of **COCIR (European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry),** submitted on 22.10.2019: PDF

> Contribution of **Cobalt Institute** submitted on 05.11.2019: PDF

> Contribution of the **Japanese electric and electronic (E&E) industrial associations** submitted on 06.11.2019: PDF

> Contribution of the **JBCE – Japan Business Council in Europe aisbl** submitted on 07.11.2019: PDF

> Contribution of **Digital Europe**, submitted on 07.11.2019: PDF

> Contribution of **The European Semiconductor Industry Association (ESIA)**, submitted on 07.11.2019: PDF

A.4.0 Diantimony trioxide

ROHS Annex II Dossier for Diantimony trioxide (flame retardant). Restriction proposal for substances in electrical and electronic equipment under RoHS

Substance Name: Diantimony trioxide (flame retardant)
EC Number: 215-175-0
CAS Number: 1309-64-4

20.05.2020

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Abbreviations

ABS	Acrylonitrile Butadiene Styrene copolymers
AEM	Association of Equipment Manufacturers
A-PPE	Thermoset Polyphenylenether
ASD	AeroSpace and Defence Industries Association of Europe
ATH	Aluminium Trihydroxide
ATO	Diantimony Trioxide
BAF	Bioaccumulation Factor
BAUA	Bundesanstalt für Arbeitsschutz und Arbeitsmedizin (German Federal Institute for Occupational Safety and Health)
BCF	Bioconcentration Factor
BDP	Bisphenol A bis(diphenyl Phosphate)
BFR	Brominated Flame Retardant
BT	Bismaleimide Triazine
C&L	Classification and Labelling
CMR	Carcinogenic, Mutagenic or Reprotoxic
Co	Cobalt
CoRAP	Community Rolling Action Plan
CTI	Comparative Tracking Index
DNEL	Derived No Effect Levels
DOPO	9,10-dihydro-9-oxa-10-phosphahenanthrene-10-oxide
ECHA	European Chemicals Agency
EDG	European Domestic Glass
EEE	Electrical and Electronic Equipment
ESGA	European Special Glass Association
ESIA	European Semiconductor Industry Association
EU RAR	European Risk Assessment Report
EVA	Polyethyl Co-Vinyl Acetate
FR	Flame Retardant
HBCDD	Hexabromocyclododecane

HFFR	Halogen Free Flame Retardant
Hg	Mercury
HIPS	High Impact Polystyrene
i2A	International Antimony Association
IEC	International Electrotechnical Commission
IED	Industrial Emissions Directive
IUPAC	International Union of Pure and Applied Chemistry
KEMI	Swedish Chemicals Agency
LCD	Liquid crystal display
LCP	Liquid crystal polymers
LIFT	Lateral Ignition and Flame spread Test
LOI	Limiting Oxygen Index
MC	Melamine Cyanurate
MDH	Magnesium (di)hydroxide
MPP	Melamine Polyphosphate
MSDS	Material safety data sheet
OEL	Occupational Exposure Limit
OEM	Original Equipment Manufacturer
PA	Polyamide
PBT	Persistent, Bioaccumulative, Toxic
PTMT	Polytetramethylterephthealate (=Poly Butylene Terephthalate)
PC	Polycarbonate
PWB	Printed Wiring Boards
PE	Polyethylene
PET	Poly Ethylene Terephthalate
PNEC	Predicted No Effect Concentration
PP	Polypropylene
PPE	Polyphenylenether
PPO	Polyphenylenoxide
PTFE	Poly(tetrafluoroethylene

PVC	Polyvinylchloride
RCR	Risk Characterisation Ratio
RDP	Resorcinol bis(diphenyl Phosphate)
SIN	SIN (Substitute it Now!) List of the NGO ChemSec
STOT RE	Specific target organ toxicity (repeated exposure)
SPIN	Substances in Preparations in Nordic Countries
TBBP-A	Tetrabrombisphenol A
TCP	Tricresyl Phosphate
TMC	Test and Measurement Coalition
TMF	Trophic Magnification Factor
TPP	Triphenyl Phosphates
UL	Underwriters Laboratories
US EPA	United States Environmental Protection Agency
vPvB	Very Persistent or Very Bioaccumulative
ZVEI	Zentralverband Elektrotechnik- und Elektronikindustrie e. V.

CONTEXT and SCOPE of the DOSSIER/ substance assessment

The substance assessment of diantimony trioxide is being performed as part of the "*Study on the review of the list of restricted substances and to assess a new exemption request under RoHS 2 – Pack 15*". With contract No. 07.0201/2017/772070/ENV.B.3 implementing Framework Contract No. ENV.A.2/FRA/2015/0008, a consortium led by Oeko-Institut for Applied Ecology has been assigned by DG Environment of the European Commission to provide technical and scientific support for the review of the list of restricted substances and to assess a new exemption request under RoHS 2. This study includes an assessment of seven substances and group of substances[1] with a view to the review and amendment of the RoHS Annex II list of restricted substances. The seven substances have been pre-determined by the Commission for this task. The detailed assessment is being carried out for each of the seven substances in line with a uniform methodology[2].

In the course of the substance assessment, a 1st stakeholder consultation was held from 20 April 2018 to 15 June 2018 to collect information and data for the seven substances under assessment. Information on this consultation can be found at Oeko-Institut's project webpage at: http://rohs.exemptions.oeko.info/index.php?id=289.

For diantimony trioxide, a total of 14 contributions were submitted by different stakeholders. An overview of the contributions submitted during this consultation is provided in Appendix I. The contributions can be viewed at: http://rohs.exemptions.oeko.info/index.php?id=290.

Based on stakeholder input and publicly available information, a second version of the dossier has been prepared, which was subject to a 2nd stakeholder consultation that was held from 05 December 2019 to 30 January 2020. The consultation period was prolonged for two weeks in order to compensate for any cooperation difficulties that might have arisen due to the holiday season and ended on 13 February 2020.

For diantimony trioxide, a total of 18 contributions were submitted by different stakeholders. An overview of the contributions submitted during this consultation is provided in Appendix I. The contributions can be viewed at: https://rohs.exemptions.oeko.info/index.php?id=332.

Additionally, there were confidential contributions submitted that contain concrete socio-economic information and cost estimates. As no restriction of ATO is proposed, it was decided not to process these data further.

Stakeholders mainly commented in the 2nd stakeholder consultation on the following issues:

- Uses and quantities, variety of formulations to achieve flame retardancy;
- Waste management and sorting techniques,
- The references on exposure data and the estimation of risks for workers,

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[1] For the sake of better readability hereafter substance will be used for single substances as well as group of substances.

[2] This methodology includes a dossier template for substance assessment which had been prepared by the Austrian Umweltbundesamt GmbH in the course of a previous study. The methodology for substance assessment has been revised based on various proposals from and discussions with stakeholders. Among others, revisions have been made to clarify when the Article 6(1) criteria are considered to be fulfilled and how the precautionary principle is to be applied. The methodology has also been updated in relation to coherence to REACH and other legislation and publicly available sources of relevance for the collection of information on substances have been updated and added. The methodology is available at https://rohs.exemptions.oeko.info/index.php?id=341

- The analysis of alternatives: the references for alternatives in the form of front runner companies and ecolabel schemes, the technical limitations and hazards of alternatives,
- The data basis of the socio-economic analysis,
- The recommendation to assess the substance group of ATO and halogenated flame retardants.

Based on the input from the 2nd stakeholder consultation, the dossier has been revised and completed to the version 3 at hand which represents the final version.

After the revision of the dossiers and their completion, a final stakeholder meeting was held on 27 April 2020 to allow stakeholders to comment on the dossiers and particularly on conclusions and recommendations.

This document represents the final version of the RoHS Annex II dossier for Diantimony trioxide (flame retardant).

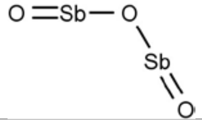
1 IDENTIFICATION, CLASSIFICATION AND LABELLING, LEGAL STATUS AND USE RESTRICTIONS

1.1 Identification

1.1.1 Name, other identifiers, and composition of the substance

The information compiled in the following table on the substance identity of diantimony trioxide originates from the ECHA information on substances database[3] and the European Risk Assessment Report (EU RAR) on diantimony trioxide from 2008.[4]

Table 1-1: Substance identity and composition of diantimony trioxide

Chemical name	Diantimony trioxide
EC number	215-175-0
CAS number	1309-64-4
Index number in Annex VI of the CLP Regulation	051-005-00-X
Molecular formula	Sb_2O_3
Molecular weight	291,49 g/mol
IUPAC name	oxostibanyl stibinate, dioxodistiboxane
Synonyms	Antimony (III) oxide Antimony (3+) oxide Antimony oxide (Sb2O3) Antimony peroxide Antimony trioxide Antimony oxide Antimony sesquioxide Antimony white Flowers of antimony Senarmontite Valentinite Sesquioxide C.I. Pigment White 11 C.I. 77052 ATO, PATOX
Structural formula	
Degree of purity	ECHA database of registered substances lists different compositions and indicates different impurities The EU RAR indicates the purity for diantimony trioxide at 99.3 to 99.5 % (with the exception of wetted forms, for which a lower specification limit of 95 % was given)
Remarks	None

Source: European Chemicals Agency ECHA, Brief Profile: Entry for Diantimony trioxide (2018), https://echa.europa.eu and EU RAR (2008)

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[3] ECHA Brief Profile: Entry for Diantimony trioxide; https://echa.europa.eu/de/brief-profile/-/briefprofile/100.013.796, last viewed 19.04.2018

[4] European Union Risk Assessment Report EU RAR (2008): Diantimony trioxide, November 2008; http://www.echa.europa.eu/documents/10162/553c71a9-5b5c-488b-9666-adc3af5cdf5f, last viewed 19.04.2018

1.1.2 Physico-chemical properties

The physico-chemical properties of diantimony trioxide are summarised in Table 1-2 below and were extracted from the ECHA's information on substances database,[5] comments from the International Antimony Association)[6] have been added.

Table 1-2: Overview of physico-chemical properties of diantimony trioxide

Property	Value
Physical state at 20°C and 101.3 kPa	Solid (100 %)
Melting/freezing point	656 °C
Boiling point	1,425 °C at 101.3 kPa
Vapour pressure	1.33 hPa at 574 °C
Water solubility	370 µg/L
Partition coefficient n-octanol/ water (log K_{OW})	No data available. i2a (2020) stated that this is because the study is technically not feasible. This study does not need to be conducted for inorganic substances (cf. Annex VII section 7.8 Column 2 of regulation 1907/2006; i2a 2020)
Dissociation constant	No data available. i2a (2020) stated that this is because the study is technically not feasible. The substance does not contain relevant functional groups for which an assessment of the dissociation behaviour would provide information for risk assessment purposes. Therefore, the determination of a dissociation constant is not considered to be required (Guidance on information requirements and chemical safety assessment Chapter R.7a: Endpoint specific guidance, section R.7.1.17.1; i2a 2020).

Source: ECHA Brief Profile: Entry for Diantimony trioxide; International Antimony Association i2a (2020)

1.2 Classification and labelling status

The Classification, Labelling and Packaging (CLP) regulation[7] ensures that the hazards presented by chemicals are clearly communicated to workers and consumers in the European Union through classification and labelling of chemicals. Annex VI of Regulation No 1272/2008 lists substances where a harmonised classification exists based on e.g. human health concerns.

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[5] Op. cit. ECHA Brief Profile: Entry for Diantimony trioxide

[6] International Antimony Association i2a (2020): Contribution submitted on 30.01.2020 during the stakeholder consultation conducted from 05 December 2019 to 13 February 2020 by Oeko-Institut in the course of the study to support the review of the list of restricted substances and to assess a new exemption request under RoHS 2 (Pack 15); https://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Pack_15/4th_Consultation_PartII/contribution_i2a_RoHS_15_Comments_on_ATO_Report_cover_letter_FINAL_20200130.pdf

[7] Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (REACH).

Annex VI of the CLP regulation is constantly adapted by engagement of Member State Competent Authorities and ECHA where new information becomes available, where existing data are re-evaluated or due to new scientific or technical developments or changes in the classification criteria.[8]

For an explanation on the human and environmental hazards, see section 0 and 4.

1.2.1 Classification in Annex VI Regulation No 1272/2008

For diantimony trioxide, there is a harmonised classification according to Regulation No 1272/2008, Table 3.1 of Annex VI for carcinogenicity Category 2, carrying the hazard statement code H351, i.e. suspected of causing cancer. For more details, see the following table.

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[8] For further information, see https://echa.europa.eu/regulations/clp/harmonised-classification-and-labelling, last viewed 19.04.2018

Table 1-3: Classification according to part 3 of Annex VI, Table 3.1 (list of harmonised classification and labelling of hazardous substances) of Regulation (EC) No 1272/2008

Index No.	International Chemical ID	EC No.	CAS No.	Classification		Labelling			Spec. Conc. Limits, M-factors	Notes
				Hazard Class and Category Code(s)	Hazard statement code(s)	Pictogram, Signal Word Code(s)	Hazard statement code(s)	Suppl. Hazard statement code(s)		
051-005-00-X	antimony trioxide	215-175-0	1309-64-4	Carc. 2	H351	GHS08 Wng	H351	-	-	-

Source: Annex VI Regulation No 1272/2008; https://echa.europa.eu/de/information-on-chemicals/annex-vi-to-clp, last viewed 19.04.2018

The human health concerns for ATO are detailed in section 3.

1.2.2 Self-classification(s)

Manufacturers, importers or downstream users have to (self-)classify and label hazardous substances and mixtures to ensure a high level of protection of human health and the environment. If a harmonised classification is available, it should be applied by all manufacturers, importers or downstream users of such substances and of mixtures containing such substances.

However, mostly, suppliers decide independently as to the classification of a substance or mixture, which is then referred to as self-classification. Therefore, self-classification might indicate an e.g. additional hazard which is so far not reflected by the harmonised classification. The following assessment of the self-classification therefore emphasises cases where self-classifications differ and where additional hazards were notified in the self-classification.

The ECHA database C&L Inventory contains classification and labelling information on notified and registered substances received from manufacturers and importers. With regard to diantimony trioxide, there is a total number of 1,680 notifications (as of July 2018).[9]

To summarise, the various self-classifications, basically the same types of hazards are addressed as by the harmonised classification. Though in some cases the level of hazard may differ, or certain hazard types have been omitted, and given that the harmonised classification is assumed to have a higher standard of scrutiny, the differences in the self-classification compared to the harmonised classification are not further considered.

1.3 Legal status and use restrictions

1.3.1 Regulation of the substance under REACH

Diantimony trioxide was included in the Community Rolling Action Plan (CoRAP) by the German Federal Institute for Occupational Safety and Health (BAUA). The substance evaluation is currently ongoing. As initial grounds for concern, the following short list is published at the ECHA website:[10]

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[9] ECHA CL Inventory: Entry for Diantimony trioxide (2018); https://echa.europa.eu/de/information-on-chemicals/cl-inventory-database/-/discli/details/16879, last viewed 10.08.2018

[10] https://echa.europa.eu/de/information-on-chemicals/evaluation/community-rolling-action-plan/corap-table/-/dislist/details/0b0236e180b91312

- Carcinogenic,
- Exposure of workers,
- High (aggregated) tonnage,
- High RCR (which is the Risk Characterisation Ratio which is a comparison of exposure levels to predicted no-effect concentrations (PNECs) or derived no-effect levels (DNELs)),
- Other exposure / risk-based concern,
- Wide dispersive use.

According to the Justification Document for the Selection of a CoRAP Substance (BAuA 2016)[11], diantimony trioxide is used as a reducing agent for Cr(VI) in cement, as a substitute for Fe(II)SO_4, a use that has not been addressed in the EU RAR (2008)[12]. The BAuA argues that "*it should be examined whether antimony(III) oxide is a suitable substitute for Fe(II)SO4. There are indications that the DNEL was not derived in accordance with the ECHA Guidance Chapter R.8 which gives rise to the concern of higher resulting RCRs [Risk Characterisation Ratios]*[13] *than those described by the registrants. Due to high tonnage and uses by professional workers, a high potential of exposure is anticipated.*"

1.3.2 Other legislative measures

Other legislative measures address antimony and its compounds as a group. As this also includes diantimony trioxide, these legal restrictions are compiled in the following:

- **Regarding human health issues,**
  - There was a proposal for community-wide measures to reduce risks, submitted by the Swedish Chemicals Agency KEMI in 2008.[14] The proposal recommended establishing occupational exposure limit values for antimony trioxide according to Directive 98/24/EEC.[15]
  - Occupational exposure limits of 0.5 mg/m³ antimony trioxide on average and lower have been established in several EU countries (see section 3.2).
  - A migration limit of antimony trioxide is set
    - for plastics used in contact with foodstuffs by Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food Text with EEA relevance relating to plastic materials and articles intended to come into contact with foodstuffs.[16]
    - for toys or components of toys by Directive 2009/48/EC on the safety of toys.[17]

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[11] BAUA German Federal Institute for Occupational Safety and Health (2016): Justification Document for the Selection of a CoRAP Substance; https://echa.europa.eu/documents/10162/44adc62e-ff48-4ce8-9c4f-58dd8b77253a

[12] Opt cit. EU RAR European Union Risk Assessment Report (2008): Diantimony trioxide, November 2008

[13] Risk Characterisation Ratios (RCRs) are derived by comparing exposure levels to suitable predicted no-effect concentrations (PNECs) or derived no-effect levels (DNELs).

[14] Swedish Chemicals Agency (2008): Proposal for Community-wide measures to reduce risks; Diantimony Trioxide; 2008-11-26; http://www.echa.europa.eu/documents/10162/13630/trd_sweden_diantimony_trioxide_en.pdf, last viewed 19.04.2018

[15] Council Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work

[16] Specific migration limit SML = 0,02 mg/kg (expressed as Antimonium and analytical tolerance included)

[17] Migration limits

- A maximum level for antimony is set for water intended for human consumption by the Council Directive 98/83/EC on the quality of water for human consumption.[18]

- **Regarding environmental issues:**
  - The so-called IED Directive 2010/75/EU[19] on industrial emissions (integrated pollution prevention and control) sets air emission limit values for waste incineration plants for antimony and its compounds. Accordingly, the average emission limit values for the following heavy metals over a sampling period of a minimum of 30 minutes and a maximum of 8 hours are set as concentrations in mass per cubic meter at 0,5 mg/m^3 for antimony and its compounds, expressed as antimony (Sb).
  - According to Commission Decision 2014/955/EU amending Decision 2000/532/EC on the list of waste pursuant to Directive 2008/98/EC, any compound of antimony is characterised as a "heavy metal" and leads to a classification as hazardous waste.
  - Limit values for antimony (as Sb) are set by "Council Decision of 19 December 2002 establishing criteria and procedures for the acceptance of waste at landfills pursuant to Article 16 of and Annex II of Directive 1999/31/EC (2003/33/EC)".[20]

Antimony is listed on the 2017 list of Critical Raw Materials of the EU (COM(2017) 490 final)[21]. Materials appearing on this list have been identified as critical for the EU. The criteria for criticality are possible risks of supply shortage (scarcity) and that their impacts on the economy are higher than those of most of the other raw materials. Additional aspects (e.g. environmental, social) are not mentioned in the communication in this regard.[22,23]

1.3.3 Non-governmental initiatives

The International Chemical secretariat (Chemsec) has specified and updates the SIN List, which identifies potential substances of concern. The purpose of this list is to put pressure on legislators to assess and where relevant address substances identified therein in the future in respect of relevant chemical legislation. Chemsec applies a number of categories for adding substances to the SIN List,

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- in dry, brittle, powder-like or pliable toy material: 45 mg/kg Antimony
- in liquid or sticky toy material: 11,3 mg/kg Antimony
- in scraped-off toy material: 560 mg/kg Antimony

[18] 5,0 µg/l Antimony

[19] Directive 2010/75/EU of the European Parliament and of the Council of 24 November 2010 on industrial emissions (integrated pollution prevention and control) (Recast); https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32010L0075&from=EN, last viewed 24.07.2018

[20] Council Decision of 19 December 2002 establishing criteria and procedures for the acceptance of waste at landfills pursuant to Article 16of and Annex II to Directive 1999/31/EC(2003/33/EC); http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2003:011:0027:0049:EN:PDF, last viewed 19.04.2018: See there "2.1.2.1. Leaching limit values" for waste acceptable at landfills for inert waste and limit values for non-hazardous waste"; antimony is abbreviated as Sb.

[21] EU COM (2017), Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on the 2017 list of Critical Raw Materials for the EU, Brussels, 13.9.2017, COM(2017) 490 final, available under: http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=COM:2017:0490:FIN, last viewed 19.04.2018

[22] As of March 2020, the most recent CRM list was published on the EU COM webpage in 2017.

[23] Campine (2020) noted that the study of the critical raw material listing indicates the importance of antimony trioxide in E&E applications. The study reviewed for that reason also found a lack of substitutes. Substitution of ATO in EEE will be addressed in section 8.

including substances that can cause cancer, alter DNA or damage reproductive systems (CMR properties); substances that do not easily break down and accumulate in the food chain (PBT/vPvB substances); and substances of equivalent concern that give rise to an equivalent level of concern in terms of potential damage to health and environment (such as substances with endocrine disrupting properties). The entry on the SIN list does not stipulate a restriction of these substances but intents to encourage efforts to substitute them with safer alternatives.

Diantimony trioxide is considered "carcinogen" according to the harmonised classification in the EU.[24] Furthermore, diantimony trioxide is added to the SIN List not only for this reason but also because "*reprotoxic effects have been reported*".[25]

i2a (2020) contested the inclusion of this information, arguing that it was "*misleading information on the reproductive toxicity of Sb, which is specific to some compounds, administered in doses beyond the concentrations used in EEE plastics, and administered via routes which are not relevant for the assessment of the safety of EEE (i.e. injection)*". Information in this section however is added to present non-governmental initiatives related to the toxicity and/or the future use of the substance, as is the case with the information from the SIN list. As to the reprotoxic characterisation, a third[26] of the data submitters consider this substance as Toxic to Reproduction, according to the ECHA Brief Profile on ATO. Of this minority indicating the property of concern, most indicate that it may relate to an impurity or additive rather than the substance itself.

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[24] https://echa.europa.eu/de/brief-profile/-/briefprofile/100.013.796 las visited 15.11.2019

[25] SIN list (2018): http://sinlist.chemsec.org/search/search?query=1309-64-4, last viewed 19.04.2018

[26] 33.33% of REACH registrations on ATO

2 USE IN ELECTRICAL AND ELECTRONIC EQUIPMENT

The terms of references define the scope of the assessment on the application of diantimony trioxide to the use as flame retardant. Thus, several applications mentioned by stakeholders during the 1st stakeholder consultation[27] are out of scope of the assessment and will not be considered here.

2.1 Function of the substance

The function of ATO is that of a synergist for halogenated flame retardants. The International Antimony Association (i2a) (2018)[28] and the European manufacturer Campine, lead registrant for diantimony trioxide,[29] describes the function as flame retardant synergist as follows:

> Diantimony trioxide (ATO) *"is an additive, which functions as a synergist with halogens, to confer high flame retardancy (and hence, fire safety) performance to plastic components used in EEE. Halogens provide flame retardancy via the so-called "Radical Trap Mechanism". This is a process where reactive radicals are fed to the decomposition gas, which in turn cuts the supply of fuel* [any substance that can combust, e.g. the plastic] *to the combustion region, to cease the combustion chain reaction. The halogens released by the plastic they are contained in, quench the chemical reaction occurring in the flame by isolating the various factors, preventing the material from reaching its ignition temperature.*
>
> *Whereas halogenated flame retardants are moderately effective on their own, they become twice more effective when combined with ATO (in a ratio of 1:3 or 1:4). ATO effectively enables a reduced use of halogens while increasing the flame retardancy of the plastics. […] The use of a combined halogen + ATO flame retardant solution provides flame retardancy via an additional "Gas phase (heat absorption and dilution) Mechanism" of flame retardancy. The halogens with the ATO act as heat-absorbing substances which i) trigger endothermic reactions and cool down the polymer, and ii) dilute the decomposition gas and cut the supply of fuel to the combustion region, thereby ceasing the combustion chain reaction."*

Fire safety standards

There are different fire safety standards with different tests worldwide and the requirements depend on the type of application / component.

Technical standards from the International Electrotechnical Commission (IEC) determine fire safety requirements; the IEC publications with the number 60695 ("IEC 60695 Series") cover fire hazard testing issues, e.g. guidance for assessing the fire hazard of electro-technical products, glowing/ hot-

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[27] Use as clarifying aid in certain glasses, use as opacifying agent in functional ceramics and use as catalyst in the production of PET; see Appendix I for further explanation.

[28] International Antimony Association (i2a) (2018): Contribution submitted on 15.06.2018 during the stakeholder consultation conducted from 20 April 2018 to 15 June 2018 by Oeko-Institut in the course of the study to support the review of the list of restricted substances and to assess a new exemption request under RoHS 2 (Pack 15); http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Pack_15/1st_Consultation_Contributions/Contribution_i2a_diantimony_Response_ATO_20180615_FINAL.pdf, last viewed 26.06.2018

[29] Campine (2018): Contribution submitted on 13.06.2018 during the stakeholder consultation conducted from 20 April 2018 to 15 June 2018 by Oeko-Institut in the course of the study to support the review of the list of restricted substances and to assess a new exemption request under RoHS 2 (Pack 15); http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Pack_15/1st_Consultation_Contributions/Contribution_Campine_diantimony_response_ATO_180615_non_confidential.pdf, last viewed 26.06.2018

wire based test methods, etc.[30] There are also IEC test methods on the finished component depending on the end application, e.g. fire hazard testing on cables.[31]

Besides the IEC standards, requirements from the American Underwriters Laboratories (UL) have been adopted in Europe and Asia as well. The UL-94 requirement is a test for flammability of materials; V-0 is the highest flammability rating.

Further standards according to i2a and Campine,[32] the *"Limiting Oxygen Index (LOI), which measures the minimum percentage of oxygen concentration it takes to support the candle-like or flaming combustion of plastics in an air-like gas mixture (ISO 4589 and ASTM D2863). Other methods include: Lateral Ignition and Flame spread Test (LIFT), upward flame spread tests (UL-94V and NASA 6001 test 1), cone calorimeter, Steiner Tunnel test (ASME E84)".* However, the stakeholders Campine (2018) and i2a (2018) stress that UL 94 V-O is the most commonly referenced test in the E&E sector and indicates the highest flame-retardant level.

I2a (2020) and Campine (2020) in their contributions for the 2nd stakeholder consultation stress that the ATO + halogen based-formulations offer the highest flame retardancy performance UL 94 V-0 with the lowest disruption of the polymer's original and/or desired technical and functional properties.

2.2 Types of applications / types of materials

Summarizing the stakeholder contributions, for the use of ATO as synergist for halogenated flame retardants in plastics, the following applications types can be differentiated in order to cover the waste stream of relevance:[33]

1. Plastics used for enclosures, and for components (e.g. corrugated pipes),
2. Cables and wires,
3. Semiconductor packaging, Printed Wiring Boards (PWBs) and connectors

2.2.1 Plastics, e,g. for EEE enclosures and corrugated pipes

ATO is used in plastics for enclosures such as e.g. for telephone handsets, for keyboards, for monitors, housings for computer or TVs and for connectors, plugs and switches. Campine (2018) states that *"ATO will be present in levels between 2 and 8 % in flame retardant plastics.*

According to i2a, Acrylonitrile Butadiene Styrene (ABS) is a typical polymer where ATO is applied for enclosures. ZVEI states that aside from ABS, diantimony trioxide is used in Polytetramethylterephthalate plastics (PTMT), polypropylene (PP)*"and other plastics"*, The combination of PP + ATO + halogenated FR is applied in *"corrugated plastic conduits with light and medium compressive and impact strength*".

To conclude, ATO is obviously used for enclosures in several types of plastics. The concentration of ATO is understood to vary. Campine (2020) stresses that there is no *"1 standard formulation"* but that there are multiple reasons to use different amounts of ATO in plastics. Campine (2020) and i2a (2020) both stress that *"The primary one [reason] is the nature of the polymer and its inherent flame*

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[30] See the IEC page of the Technical Committee TC 89 Fire hazard testing at https://www.iec.ch/dyn/www/f?p=103:7:12958917783846::::FSP_ORG_ID,FSP_LANG_ID:1283,25, last viewed 14.05.2019

[31] https://www.iec.ch/dyn/www/f?p=103:7:0::::FSP_ORG_ID:1214, last viewed 14.05.2019

[32] Op. cit. International Antimony Association (i2a) (2018) and Campine (2018)

[33] Op. cit. Campine (2018), International Antimony Association (i2a) (2018), Europacable (2018), ZVEI (2018)

retardancy. Following this, the intended application or use of the component, its potential for exposure to contact/erosion, the compatibility with technical and functional properties of the polymer, including color, weight, flexibility, etc., as well as price (these chemicals are costly and will not be added unless they are necessary).“ i2a (2020) adds that *“the EEE sector is very rich in terms of components and qualities. Different FR formulations can be used depending on a multitude of reasons. The statement in the report underestimates the complexity of the combined performance of the various criteria the EEE producers aim to meet and should be corrected.”*

The European Council of Vinyl Manufacturers ECVM (2020) [34] states that PVC is not used in EEE housing, enclosures and printing wiring boards.

2.2.2 Cables

Europacable (2018)[35] states that ATO is used in electric and optical cables for varying purposes, for different voltages and markets such as telecommunication, automation, construction, power networks, oil & gas, electrical appliances. As relevant for this assessment, Europacable (2018) mentions the low voltage cables for electrical appliances.

Europacable (2018) further explains that the concentration of ATO in the homogeneous materials used in cable applications, in particular in sheath, due to its flame-retardant property is higher than 0.1 %. Concentrations between 0.5 and 8 % have been identified. ECVM (2020)[36] reports that *“levels between 2 and 8% may be present in […] PVC cable insulation (these levels relate to the PVC part of these articles, not the entire article).”*

The Zentralverband Elektrotechnik- und Elektronikindustrie e. V. (ZVEI) (2020)[37] reports levels of 5-8% for all kind of polymers (see Figure 2-2).

As for polymers where ATO is added, Europacable (2018) lists polyvinyl chloride (PVC) or polyethylene (PE) or rubber whereas i2a (2018)[38] additionally lists polymethylpentane and polypropylene. PVC is still the predominating polymer used for cable insulation.[39]

As for PVC as halogen-containing polymers, KEMI (2015) notes that no flame retardants need to be added. It is understood that the halogen content present in the PVC polymer sufficiently provides halogen compounds for ATO to react as synergist, which is confirmed by ZVEI (2020) and ECVM (2020): *“Although medium chain chlorinated paraffins are used in some PVC cables as a secondary*

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[34] ECVM - European Council of Vinyl Manufacturers (2020): Contribution, submitted on 13.02.20 during the stakeholder consultation conducted from 05 December 2019 to 13 February 2020 by Oeko-Institut in the course of the study to support the review of the list of restricted substances and to assess a new exemption request under RoHS 2 (Pack 15); https://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Pack_15/4th_Consultation_PartII/contribution_ECVM_RoHS15_diantimony_Comments_on_ATO_Report_20200207.pdf

[35] Europacable (2018): Contribution submitted on 15.06.2018 during the stakeholder consultation conducted from 20 April 2018 to 15 June 2018 by Oeko-Institut in the course of the study to support the review of the list of restricted substances and to assess a new exemption request under RoHS 2 (Pack 15); http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Pack_15/1st_Consultation_Contributions/Contribution_EUROPA_CABLE_Sb2O3_consultation_1_20180615.pdf, last viewed 26.06.2018

[36] Op. cit. ECVM (2020)

[37] Zentralverband Elektrotechnik- und Elektronikindustrie e. V. (ZVEI) (2020): Contribution submitted on 28.01.2020 during the stakeholder consultation conducted from 05 December 2019 to 13 February 2020 by Oeko-Institut in the course of the study to support the review of the list of restricted substances and to assess a new exemption request under RoHS 2 (Pack 15);; https://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Pack_15/4th_Consultation_PartII/contribution_ZVEI_RoHS15_ATO_ZVEI_cons_3_dossiers_20200128_final.pdf

[38] Op. cit. International Antimony Association (i2a) (2018)

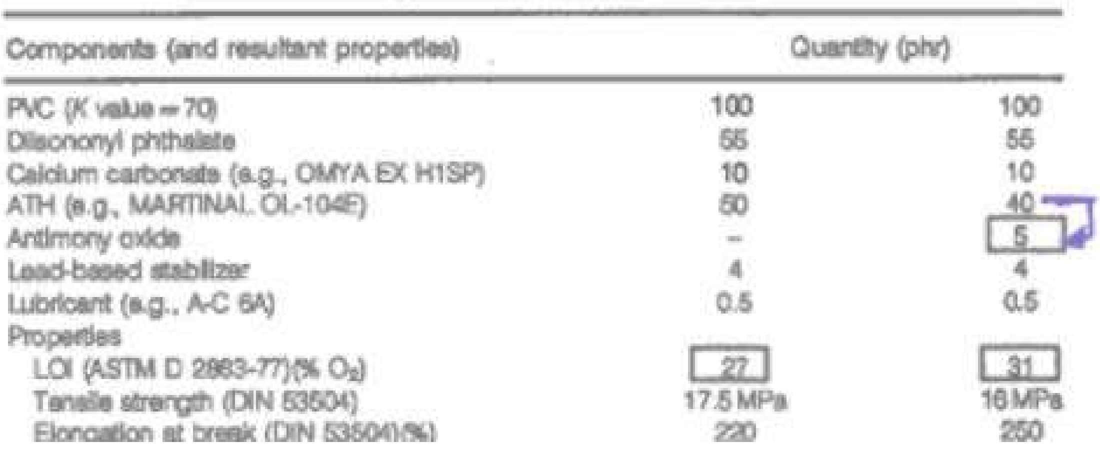
[39] https://www.pvc4cables.org/en/pvc-cables/market, last viewed 24.03.2020: “*In 2018, PVC accounted for 41.2% of the European cables market. PVC maintains its historical dominance in the low-voltage cables sector*.”

plasticizer and flame retardant, it is not necessarily in combination with ATO, as PVC contains enough chlorine for ATO to act as synergist."

However, ECVM (2020) as well as Campine (2020) still stress the need for flame retardants in soft PVC: "*Whereas for rigid PVC, indeed little or no flame-retardant synergists are needed, for flexible PVC, this is not the case. Indeed, the plasticizers added to soften the PVC decrease its inherent flame retardancy and in such cases, flame retardants need to be added to recover the lost flame retardancy.*"

Campine refers to one example of "KabelWerke Eupen dr. Beyer" which is depicted in the figure below: *"With ATH in the composition it is not possible to reach the needed LOI. When some of the [Aluminium Trihydroxide] ATH is exchanged by half of this amount with ATO, better flame-retardant performance is reached, with no significant impact on tensile strength/elongation at break. In some cases (low cost applications e.g.) partial substitution can be done as in this example is the case."*

Figure 2-1: Typical PVC-based cable formulations with Aluminium Trihydroxide (ATH)



Components (and resultant properties)	Quantity (phr)	
PVC (K value = 70)	100	100
Diisononyl phthalate	55	55
Calcium carbonate (e.g., OMYA EX H1SP)	10	10
ATH (e.g., MARTINAL OL-104E)	50	40
Antimony oxide	–	5
Lead-based stabilizer	4	4
Lubricant (e.g., A-C 6A)	0.5	0.5
Properties		
LOI (ASTM D 2863-77)(% O_2)	27	31
Tensile strength (DIN 53504)	17.5 MPa	16 MPa
Elongation at break (DIN 53504)(%)	220	250

Source: Campine (2020)

Note: The two right columns show differing compositions in relation to the compounds in the left column and their related properties.

MedTech Europe (2020)[40] reports as a high-performance grade PVC cable formulation 15 parts ATO per 100 parts PVC plus a total of 40 parts of halogenated flame retardants (all by weight).

To conclude, there is variety of cable formulations possible. As PVC is the mainly used polymer, concrete examples of formulations have been submitted here: As for PVC cables, stakeholders emphasize the need for use of FRs, however non-halogenated flame retardancy is possible as the PVC polymer provides the halogens for ATO to act as a synergist. In other polymers, ATO and halogenated flame retardants are used.

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[40] MedTech Europe (2020): Contribution submitted on 12.02.2020 during the stakeholder consultation conducted from 05 December 2019 to 13 February 2020 by Oeko-Institut in the course of the study to support the review of the list of restricted substances and to assess a new exemption request under RoHS 2 (Pack 15); https://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Pack_15/4th_Consultation_PartII/contribution_Medtech_RoHS_15_REG02864_Impact_Report_Issue_2.1_FINAL_20200130.pdf

2.2.3 Printed Wiring Boards (PWBs),[41] semiconductor packaging and connectors

According to the stakeholders, ATO is also used in PWBs together with brominated flame retardants (ZVEI 2018). According to Campine (2018), ATO is specifically used with tetrabromo bisphenol A (TBBP-A). As for the polymer matrix for PWBs, the use of ATO can be expected as well, according to i2a e.g. in polymethyl pentane. To conclude, it is understood that ATO is usually present in PWBs in the epoxy resins as well as potentially in other polymers.

The European Semiconductor Industry Association (ESIA) stressed the application in semiconductor packaging, where ATO is used in conjunction with halogen and other metal oxides. The materials are resins, these are mainly thermosets and not thermoplastics.[42]

Based on the polymers poly butylene terephthalate or polyamide, connectors with thin wall thicknesses or compact sizes incorporate a flame-retardant system based on BFRs plus ATO with 4 % to 7% of ATO. [43] The following figure summarizes for some of the applications the polymers and the flame-retardant systems used as well as the ATO concentration included. However, on corrugated pipes in the text explaining the table, ZVEI (2020) states that apart from HDPE – which is specified in the table, - also PP is used.

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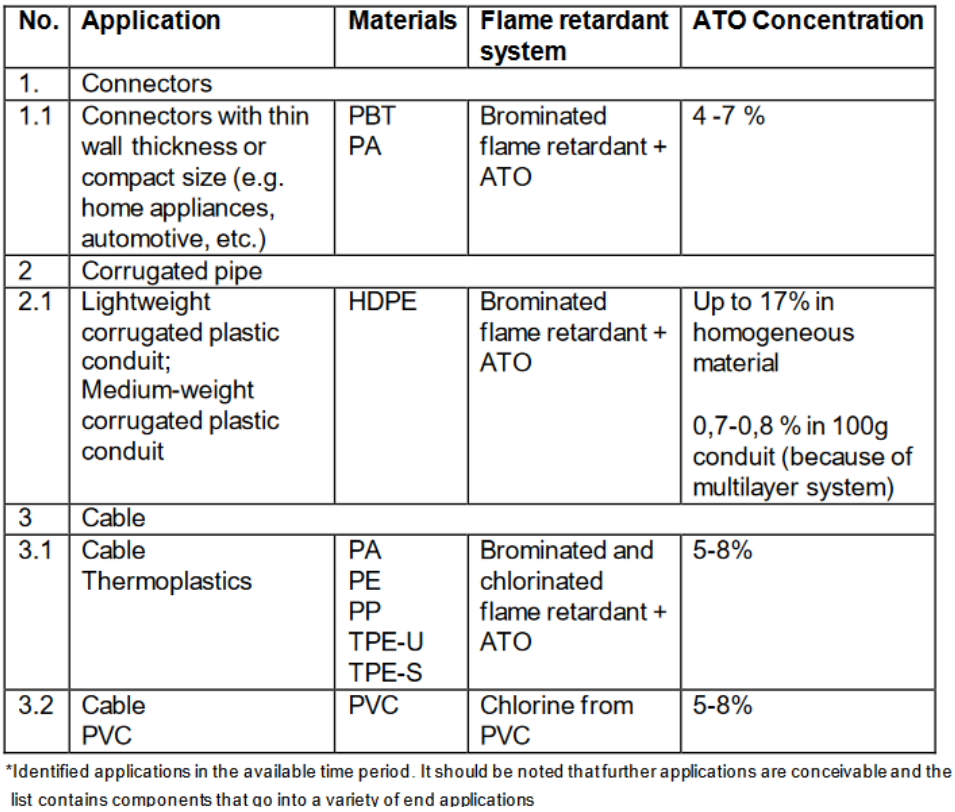
[41] I2a (2020) suggested to add the following definition for PWBs: “PCB refer to the completed circuits on a board, while PWB refers more to the board itself.”

[42] European Semiconductor Industry Association (ESIA) (2020): Contribution submitted on 13.02.2020 during the stakeholder consultation conducted from 05 December 2019 to 13 February 2020 by Oeko-Institut in the course of the study to support the review of the list of restricted substances and to assess a new exemption request under RoHS 2 (Pack 15); https://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Pack_15/4th_Consultation_PartII/contribution_ESIA_RoHS15_Diantimony_Trioxide_20200206.pdf

[43] Op. cit. ZVEI (2020)

Figure 2-2: Overview about the main applications (halogenated FR in combination with ATO)*



No.	Application	Materials	Flame retardant system	ATO Concentration
1.	Connectors			
1.1	Connectors with thin wall thickness or compact size (e.g. home appliances, automotive, etc.)	PBT PA	Brominated flame retardant + ATO	4 -7 %
2	Corrugated pipe			
2.1	Lightweight corrugated plastic conduit; Medium-weight corrugated plastic conduit	HDPE	Brominated flame retardant + ATO	Up to 17% in homogeneous material 0,7-0,8 % in 100g conduit (because of multilayer system)
3	Cable			
3.1	Cable Thermoplastics	PA PE PP TPE-U TPE-S	Brominated and chlorinated flame retardant + ATO	5-8%
3.2	Cable PVC	PVC	Chlorine from PVC	5-8%

*Identified applications in the available time period. It should be noted that further applications are conceivable and the list contains components that go into a variety of end applications

Source: ZVEI (2020)

There were specific applications mentioned for EEE of the categories 8, 9 and 11: E.g. EUROMOT (2020)[44] listed rubber tubes in heavy duty diesel engines to contain ATO (heat-shrink tubing with 10% ATO, fuel supply tube with 6.5 -9.5% ATO and fuel drain tube 6.5 –9.5% ATO). EUROMOT stresses the high temperature environment in EEE category 11 equipment and additional specific technical requirements.

As regards EEE Category 8 and 9 industrial, ATO is anticipated to be present in multiple components of all these, from board mountable components and cables, to plastic enclosures. Consequently, a restriction would affect the whole product portfolios and therefore require incremental effort comparable to that required to meet entry into scope of RoHS. This will necessitate a detailed supply chain investigation to gather information on substance presence, quantity and planned transition timeframes. From the experience of the industrial test & measurement sector, experience of the

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[44] EUROMOT (the European Association of Internal Combustion Engine Manufacturers), AEM (North American Association of Equipment Manufacturers)and EMA (US Engine Manufacturers Association): Contribution submitted 12.02.2020 during the stakeholder consultation conducted from 05 December 2019 to 13 February 2020 by Oeko-Institut in the course of the study to support the review of the list of restricted substances and to assess a new exemption request under RoHS 2 (Pack 15); https://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Pack_15/4th_Consultation_PartII/contribution_EUROMOT-AEM-EMA_RoHS15_Diantimony_trioxide_20200207.pdf

efforts and engagements necessary both to bring its portfolios into RoHS compliance, this will take years.[45]

2.3 Quantities of the substance used

In the EU RAR (2008), ATO in flame retardant plastic, resin and rubber that are placed on the EU market, was estimated to 20,000 tonnes. i2a (2018)[46] explained that single amounts can be allocated as follows:

- 70 % is used in EEE plastics
- 20 % in construction materials (insulation panels, insulation foamed films, film sheets and fabrics requiring flame retardancy, and cables) and
- 10 % is used in other applications (e.g. insulation tapes in automotive sector) which are also not relevant for EEE.

From the stakeholder inputs to the 2nd consultation, it cannot be concluded whether these shares still apply, e.g. ECVM (2020) stated that they cannot comment due to lack of reliable data.

I2a[47] reported more recent data: In 2018, 85,000 tonnes of ATO were produced globally for use in flame retardants. Therefrom, 27,000 tonnes (~ 32 %) were used in PVC, 43,000 tonnes in thermoplastics (~50 %), and 15,000 tonnes in different other applications e.g. rubber. According to this report 25,000 tonnes ATO are used in EEE in different materials. These are global consumption figures and the transfer to the European level is difficult.

One of EUROMOT's members[48] estimates that approximately 2,340 kg of ATO is used in products that this company places on the market in EEA area annually. It was not specified in the contribution which types of products were meant.

Estimations for the European market have been provided by the Phosphorus, Inorganic and Nitrogen Flame Retardants Association PINFA (2017)[49] and Campine (2018), one of the registrants of ATO; however, both estimations are not EEE-specific: PINFA (2017) estimates the ATO consumption for

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[45] Test and Measurement Coalition (TMC) (2020): Contribution the submitted on 12.02.2020 during the stakeholder consultation conducted from 05 December 2019 to 13 February 2020 by Oeko-Institut in the course of the study to support the review of the list of restricted substances and to assess a new exemption request under RoHS 2 (Pack 15); https://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Pack_15/4th_Consultation_PartII/contribution_TMCoalition_RoHS17_feedback_3_substances_20200212.pdf

European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry (COCIR) (2020): Contribution submitted on 28.01.2020 during the stakeholder consultation conducted from 05 December 2019 to 13 February 2020 by Oeko-Institut in the course of the study to support the review of the list of restricted substances and to assess a new exemption request under RoHS 2 (Pack 15); https://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Pack_15/4th_Consultation_PartII/contribution_COCIR_RoHS15_consultation_on_3_Substances_v2_20200128.pdf

[46] Op. cit. International Antimony Association (i2a) (2018)

[47] A report of the Roskill Consulting Group Ltd. Compiled on behalf of i2a in 2019. The report was submitted as a confidential Annex I to the i2a contribution to the 2nd stakeholder consultation

[48] Op. cit. EUROMOT (2020)

[49] Phosphorus, Inorganic and Nitrogren Flame Retardants Association PINFA (2017): Flame retardants in electric and electronic applications, non-halogenated phosphorus, inorganic and nitrogen (PIN) flame retardants; October 2017, 3rd edition; https://www.pinfa.eu/wp-content/uploads/2018/05/PINFA_EE_brochure_Edition_2017-11.pdf, last viewed 24.07.2018.

the European market at approximately 20,000 tonnes in 2015,[50] whereas Campine[51] estimates that 10,000 tonnes ATO are used in Europe per year.

As for cables, Europacable (2018) states that no exact volume of ATO can be consolidated due to various applications in several markets, it is estimated that quantities used for the EU cable market are in the range of 100 to 1000 tonnes of ATO.

In conclusion, it is understood from the information above that considerable amounts of ATO are used in EEE applications. There are recent estimations for the global amount of ATO consumption. However, it is not possible to state at this point the amount of ATO placed on the European market per year.

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[50] ZVEI (2018) cited amounts given by the Phosphorus, Inorganic and Nitrogen Flame Retardants Association PINFA at 20,000 tonnes in 2015.

[51] Op. cit. Campine (2018)

3 HUMAN HEALTH HAZARD PROFILE

3.1 Endpoints of concern

Diantimony trioxide is classified for carcinogenicity Category 2 (H351 - Suspected of causing cancer) according to Annex VI of the CLP Regulation.

The Swedish Chemicals Agency KEMI (2015) summarised in its assessment of the risk reduction potential of hazardous substances in electrical and electronic equipment on the EU market: *"It has been agreed* [this refers to e.g. the opinion of SCHER][52] *that the carcinogenic effects are most likely caused by particle overload and impaired lung clearance which leads to the formation of tumours (particle effect, no substance specific effect). ATO is considered a threshold carcinogen with an NOEL of 0.5 mg/m³ (with the critical concentration expected to be 10 times higher). The carcinogenic hazard by inhalation does not apply via dermal or oral exposure."*

This hazard based on particle effect is also described by Campine:[53] "*Fine dust inhalation leads to lung overload and lung toxicity, which has triggered a carcinogenic response in certain test animals through inflammation and hypoxia (NTP)"*

The Canadian Ministers of the Environment and of Health have conducted a screening assessment of diantimony trioxide in 2010 concluding that there is no evidence available to suggest carcinogenic potential for antimony trioxide via the oral route.

In the EU RAR[54], it was concluded that diantimony trioxide is of low acute toxicity via oral and dermal route. As for the repeated dose toxicity; the EU RAR stated that the studies *"indicate that repeated inhalation exposure to diantimony trioxide may cause pulmonary inflammation, lung emphysema and pneumoconiosis."*

As for mutagenicity, in the EU RAR it is explained that *"diantimony trioxide does not cause systemic mutagenicity in vivo after oral administration. However, it is not possible to conclude on mutagenicity in specific site of contact tissues (local mutagenicity) and thus, whether the result is relevant for the situation in the lung after inhalation exposure, which is the site where tumours have been found in the carcinogenicity studies. However, the in vivo data might suggest that a possible mutagenic potency of diantimony trioxide would be low and it is believed that a possible local genotoxic effect of diantimony trioxide would only be biologically relevant at concentration levels that also cause particle overload."*

Collective evidence from genotoxicity studies suggests that antimony trioxide is not likely to be mutagenic but may exert some clastogenic effects in vitro. (Canada 2010) noted the clastogenic effect in vitro and independently decided that no conclusive in vivo evidence of genotoxicity was available for antimony trioxide.

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[52] Scientific Committee on Health and Environmental Risks SCHER (2010/2011): Opinion on the Risk from the Use of Diantimony Trioxide in Toys; https://ec.europa.eu/health/scientific_committees/environmental_risks/docs/scher_o_125.pdf (last viewed 24.07.2019)

[53] Op. cit. Campine (2018) and Annex 1 of the contribution submitted by Campine (2018); http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Pack_15/1st_Consultation_Contributions/Contribution_Campine_diantimony_Annex_1.pdf, last viewed 28.06.2018

[54] Op. cit. EU RAR European Union Risk Assessment Report (2008): Diantimony trioxide, November 2008

According to the Swedish Chemical Agency KEMI (2015), also reprotoxic effects have been reported. However, the little number of studies suggesting reprotoxic effects are at least so far not substantial enough to for a further in-depth assessment and classification.

Additionally, one in vitro study on bacteria and mammal cells from 2009 indicated that ATO was genotoxic.[55]

To conclude, ATO is considered being suspected of causing cancer via inhalation; furthermore, the carcinogenic effect observed in the lung is considered a particle effect. Thus, inhalation is the exposure route where a focus should lie. In contrast, carcinogenicity is not considered to apply to dermal and oral exposure.

3.2 Existing Guidance values (DNELs, OELs)

3.2.1 Occupational exposure limits

There are occupational exposure limits established in several EU countries at 0.5 mg/m³ antimony trioxide, however some even lower. The table below shows the international limit values as compiled by IFA, the institute for occupational safety from the German Social Accident Insurance in the database GESTIS International Limit Values.[56] In Germany, the occupational limit value was lowered to 6 µg Sb/m³ for the respirable fraction in May 2018.[57]

The Swedish Chemicals Agency KEMI recommended in 2008[58] to establish occupational exposure limit values for antimony trioxide according to Directive 98/24/EEC on the protection of the health and safety of workers from the risks related to chemical agents at work. However, a European wide coherent OEL has not been set so far.

Table 3-1: International limit values for ATO provided

Country	Limit value - Eight hours, mg/m³
Australia	0,5 (inhalable aerosol)
Austria	0,1 (inhalable aerosol)
Canada - Québec	0,5 (inhalable aerosol)
Finland	0,5 (inhalable aerosol)
Germany (AGS)	0,006 (Respirable fraction)
Hungary	0,1 (inhalable aerosol)
Latvia	1 (inhalable aerosol)
New Zealand	0,5 (inhalable aerosol)
Singapore	0,5 (inhalable aerosol)
South Korea	0,5 (inhalable aerosol)

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[55] Op. cit. Swedish Chemical Agency KEMI (2015)

[56] IFA Institut für Arbeitsschutz der Deutschen Gesetzlichen Unfallversicherung; GESTIS International Limit Values: Entry for Antimony trioxide; https://limitvalue.ifa.dguv.de/WebForm_ueliste2.aspx

[57] Ausschuss für Gefahrstoffe – AGS, BAuA (2018): Begründung zu Antimontrioxid und Antimontrisulfid (A-Staub) in TRGS 900, Ausgabe: Mai 2018; https://www.baua.de/DE/Angebote/Rechtstexte-und-Technische-Regeln/Regelwerk/TRGS/pdf/900/900-antimontrioxid-antimontrisulfid.pdf?__blob=publicationFile&v=2

[58] Swedish Chemicals Agency (2008): Proposal for Community-wide measures to reduce risks; Diantimony Trioxide; 2008-11-26; http://www.echa.europa.eu/documents/10162/13630/trd_sweden_diantimony_trioxide_en.pdf, last viewed 19.04.2018

Sweden	0,25 (inhalable aerosol)
Switzerland	0,1 (inhalable aerosol)
United Kingdom	0,5 (Inhalable dust)

Source: IFA Institut für Arbeitsschutz der Deutschen Gesetzlichen Unfallversicherung in GESTIS: International Limit Values: Entry for Antimony trioxide

3.2.2 Values submitted during REACH registration

The following guidance values have been submitted by the industry as part of the REACH registration dossiers. These values are not verified by official authorities. The DNELs for diantimony trioxide as summarised on the ECHA information on chemical database which come from Registration dossiers (i.e. from industry) are compiled in Table 3-2. Exposure routes where no hazard was identified are not listed here.

Table 3-2: Guidance values for diantimony trioxide, bw = body weight

Population	Local / systemic effect	Effects	DNEL
Workers	Inhalation Exposure (inhalable fraction of the aerosol)	Local Effect - Long term	315 µg/m³
	Dermal Exposure	Systemic Effect - Long term	67 mg/kg bw/day
General Population	Inhalation Exposure (inhalable fraction of the aerosol)	Local Effect - Long term	95 µg/m³
	Dermal Exposure	Systemic Effect Long term	33.5 mg/kg bw/day
	Oral Exposure	Systemic Effect Long term	33.5 mg/kg bw/day

Source: ECHA Brief Profile: Entry for Diantimony trioxide

To conclude on the human health hazards, the carcinogenic hazard of ATO by inhalation is the exposure route that might be the most relevant in the waste phase due to waste management operations with size reduction. The occupational exposure limits will be taken as guiding values for inhalation. As for dermal exposure, the DNEL provided by the registrants will be taken into account. Both routes – besides the inhalation route also the dermal route – have so far always been considered in waste management operations with size reduction of plastics.

4 ENVIRONMENTAL HEALTH HAZARD PROFILE

The Canadian Ministries of the Environment and of Health conducted a screening assessment of diantimony trioxide in 2010. For environmental effects, the assessment is mainly based on information on the acute and chronic toxicity of dissolved antimony to a variety of aquatic, soil and sediment organisms compiled in the EU RAR (2008).

As for the environmental fate, the Canadian Ministries of the Environment and of Health[59] summarize that diantimony trioxide has some (though limited) solubility in water and will therefore dissolve in contact with moisture once in these ecosystems and yield a variety of dissolved antimony species, depending on the environmental conditions. Given its negligible vapour pressure and limited water solubility, antimony trioxide will tend to remain in soil rather than migrate into other environmental media, such as air or water.[60]

The transformation of diantimony trioxide in the different environmental compartments is rather complex as described in the EU RAR (2008)[61]. The appearance of different binding/speciation forms and oxidation states of antinomy depends on the pH, the presence of other metal ions or on oxic versus anoxic systems for sediments and soil.

Regarding potential PBT properties, the European approach as laid down in REACH Annex XIII defines that the PBT and vPvB criteria only apply to organic substances, including organo-metals. However, the Canadian Ministries of the Environment and of Health[62] consider the substance diantimony trioxide as being persistent because the trivalent antimony ions that are released into solution when it dissolves cannot be irreversibly degraded. Depending upon ambient conditions, e.g. pH, trivalent antimony can be oxidised to pentavalent antimony. This transformation is typically reversible. Therefore, the Canadian Ministers of the Environment and of Health[63] conclude that antimony trioxide meets the persistence criteria for all media (i.e., air, water, soil and sediment).

To conclude, potential releases of ATO from EEE manufacturing and use would dissolve, though limited, in the environment and would be part of dissolved antimony species found in the environment.

4.1 Endpoints of concern

The Canadian Ministries of the Environment and of Health[64] conclude that the data indicate that soluble forms of antimony generally have a moderate potential to cause harm to aquatic, soil and sediment organisms.

There are companies notifying self-classifications, so called notifiers, that classify diantimony trioxide for being hazardous to the aquatic environment (Aquatic Acute 3 - H412, Harmful to aquatic life with long lasting effect). It is noted that self-classification has a lower certainty than a classification of a joint submission.

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[59] Op. cit. Environment Canada, Health Canada (2010)

[60] Environment Canada, Health Canada (2010): Screening Assessment for the Challenge Antimony trioxide (Antimony oxide) Chemical Abstracts Service Registry Number 1309-64-4; September 2010; https://www.ec.gc.ca/ese-ees/9889ABB5-3396-435B-8428-F270074EA2A7/batch9_1309-64-4_en.pdf, last viewed 19.04.2018

[61] Op. cit. EU RAR European Union Risk Assessment Report (2008): Diantimony trioxide, November 2008

[62] Op. cit. Environment Canada, Health Canada (2010)

[63] Op. cit. Environment Canada, Health Canada (2010)

[64] Op. cit. Environment Canada, Health Canada (2010)

4.2 Potential for secondary poisoning and bioaccumulation

The Canadian assessment explains that for metals, bioaccumulation determined by a bioconcentration factor (BCF) or a bioaccumulation factor (BAF) is considered of little usefulness:

"For example, some metals may be highly accumulated from the surrounding medium because of their nutritional essentiality. Furthermore, both essential and non-essential metals may be regulated within relatively narrow margins by the homeostatic and detoxification mechanisms that many organisms possess. It follows that when ambient concentrations of metals are low, BCFs and BAFs often increase. Conversely, when ambient metal concentrations are high, BCFs and BAFs tend to decrease […]. Thus, inverse relationships may be observed between BCF and BAF values and metal exposure concentrations, and this complicates the interpretation of these values. Natural background concentrations in organisms may contribute to these negative trends. […]

Although field-based BAFs can give some indication of the biomagnification potential of a metal, a better approach is to derive a trophic transfer factor from prey to predator […] (also called trophic magnification factor or TMF), or to study changes in metal concentrations in biota making up natural food webs (i.e., trophic magnification)."

In the assessment of Environment Canada, Health Canada (2010), it is concluded that there are several lines of evidence to suggest that the bioaccumulation potential of antimony in natural ecosystems is low: *"very low BCFs and BAFs obtained from three laboratory (steady-state) studies and three field studies, three biota–soil accumulation factors well below 1, and two field investigations indicating the absence of biomagnification of antimony in natural food webs."*

In the EU RAR,[65] it is concluded for bioaccumulation that no fully reliable bioaccumulation studies are available and measured data from different aquatic organisms have been used to calculate tentative BCF-values:

- For marine fish the BCFs vary between 40 and 15,000 whereas for freshwater fish the BCF values are lower the highest being 14.
- For invertebrates tentative BCFs in the range of 4,000-5,000 have been calculated.

According to the EU RAR, there is a considerable uncertainty in these BCF-values. The risk characterization for secondary poisoning in the EU RAR was performed using two BCF values of 40 and of 15,000. In the EU RAR a $\text{PNEC}_{\text{sec posisoning}}$ was determined of 374.8 mg Sb/kg food and also for secondary poisoning in the marine environment.

Potential for secondary poisoning and bioaccumulation will not further be considered because as diantimony trioxide will solubilize in water and transform into antimony ions, it is considered that the allocation of the respective antimony compounds cannot be determined.

4.3 Guidance values (PNECs)

The predicted no effect concentration (PNEC) is the concentration below which exposure to a substance is not expected to cause adverse effects to species in the environment. Therefore, the determination of these values is important for further characterisation of possible risks.

The PNECs from the EU RAR are compared to the PNEC values extracted from the REACH registration dossiers as shown in the ECHA information on chemicals database.[66]

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[65] Op. cit. EU RAR European Union Risk Assessment Report (2008): Diantimony trioxide, November 2008

[66] https://echa.europa.eu/de/brief-profile/-/briefprofile/100.013.796

Table 4-1: PNECs of diantimony trioxide

	Compartment	**PNEC values EU RAR**	**PNEC value Registration dossiers**
Hazard for Aquatic Organisms	Freshwater	113 µg Sb/l	135 µg/L
	Marine water	11.3 µg Sb/l	13.5 µg/L
	Sewage treatment plant (STP)	2.55 mg Sb/l	3.05 mg/L
	Sediment (freshwater)	11.2 mg Sb/kg dw	13.4 mg/kg sediment dw
	Sediment (marine water)	2.24 mg Sb/kg dw	2.68 mg/kg sediment dw
Hazard for Terrestrial Organism	Soil	37 mg Sb/kg dw	44.3 mg/kg soil dw

Source: European Chemicals Agency ECHA, Brief Profile: Entry for Diantimony trioxide, https://echa.europa.eu, and EU RAR (2008)

If guidance values will be needed in the following assessment, the PNEC values from the EU RAR will be taken. The PNEC values provided in the registration dossier is considered not to have been subject to scrutiny by ECHA or any EU expert group.

5 WASTE MANAGEMENT OF ELECTRICAL AND ELECTRONIC EQUIPMENT

5.1 Description of waste streams

5.1.1 Enclosures: Plastics

The WEEE Directive[67] requires that plastics used in EEE containing brominated flame-retardants have to be removed from any separately collected WEEE according to Annex VII on the selective treatment for materials and components of waste electrical and electronic equipment referred to in Article 8(2).

ATO is stated to be used as synergist together with halogenated flame retardants and, specifically in plastics, with brominated flame retardants. The separation process of brominated flame retardants as applied in Europe is established on density-based sink-float sorting techniques after size reduction by shredding. Post-shredder sorting techniques separate plastics that contain a diantimony trioxide-based flame retardant combination with a high efficiency from other non-flame retardant plastic types, because of the high density of antimony trioxide ($\rho = 5{,}7\ g/cm^3$).[68] According to the KU Leuven,[69] X-ray fluorescent based optical sorting techniques are also used alternatively or in combination with density based sink-float sorting techniques after size reduction by shredding as state of the art recycling processes in Europe.

This fraction is as of today's state of the art not recycled but sent to incineration with energy recovery as there is no further post-shredder sorting of different plastic materials to obtain a required purity, e.g. to separate the plastic material ABS and HIPS containing brominated flame retardants.

As for the recovery of antimony from the ashes of the incinerated plastics, it is so far not common practice according to the KU Leuven. Campine (2018) also states that *"the recovery of antimony out of plastics is not yet implemented on a broader scale because the operation is not economically viable yet and rather complex (due to pop's in FR plastics)."* i2a (2018) explains that *"in a number of countries, bottom ash is used for road and other constructions, unless the concentration of ATO in the ash exceeds a particular limit, in which case it must be treated as a hazardous waste (i.e. landfilled)."*

The following aspects have been raised by stakeholders during the 2nd stakeholder consultation:

- Campine and i2a (2020) claim that there are several research projects that aim to increase the recyclability of this plastic fraction. The projects are listed in Appendix III (section 14). It is concluded that these projects are being launched and/or arriving at pilot plant stage. They are not at a technological readiness level that impacts current waste management practices.

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[67] Directive 2012/19/EU of the European Parliament and of the Council of 4 July 2012 on waste electrical and electronic equipment (WEEE) (recast); https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32012L0019&from=EN, last viewed 02.07.2018

[68] KU Leuven-University of Leuven (2018): Contribution submitted by Jef Peeters, Department of Mechanical Engineering, Faculty of Engineering & Engineering Technology, KU Leuven-University of Leuven on 15.06.2018 during the stakeholder consultation conducted from 20 April 2018 to 15 June 2018 by Oeko-Institut in the course of the study to support the review of the list of restricted substances and to assess a new exemption request under RoHS 2 (Pack 15);

http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Pack_15/1st_Consultation_Contributions/Contribution_KU_LEUVEN_Diantimony_Trioxide_20180615.pdf, last viewed 26.06.2018 and
Op. cit. ZVEI (2018)

[69] Op. cit. KU Leuven-University of Leuven (2018)

- The European Recycling Industries' Confederation EuRIC (2020)[70] raises concern whether XRF and density separation techniques can properly deal with phosphorus-based flame retardants which may be used to substitute ATO+BFR. It is explained that XRF sensors cannot detect phosphorus-based flame retardants and density-based separation may not allow the correct separation of plastics containing phosphorus-based flame retardants (PFR) from "clean" plastic fractions, because of the density overlap between PFR and non-PFR plastic fractions. EuRIC is concerned that a restriction could *"lead, via the substitution by PFRs, to a higher residual fraction of non-recycled plastics (if a restriction is implemented), and of lesser quality of recycled plastics, containing PFR"*.

  The consultant agrees that the waste management sector may be challenged by a growing use of phosphorus-based flame retardants in EEE polymer fractions. It should be noted here that ATO is not proposed for a restriction but that instead the functional group of ATO+FR should be assessed.

5.1.2 Printed Wiring Boards and their resins

Printed wiring boards that contain brominated flame retardants and diantimony trioxide are usually treated by copper smelters to recover the copper. The plastic material is sent to incineration with energy recovery.[71] ESIA (2020)[72] notes that the majority of the resins are thermosets and not thermoplastics, therefore having limited availability for recycling and Sb recovery.

The printed wiring boards are taken out before shredding, because there are typically established recycling routes for these, aimed to recover the precious and minor/rare metals they contain.[73]

5.1.3 Cables

PVC cables that might also contain diantimony trioxide are usually first separated from WEEE and then recycled separately.[74]

The cables can be stripped, or they can be shredded in whole. In both methods, the plastic mantle can be recuperated (e.g. by density sorting).[75]

Europacable specifies (2018):[76]

The usual process for cables treatment at end of life is

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[70] EuRIC – The European Recycling Industries' Confederation (EuRIC) (2020): Contribution submitted on 12.02.2020 during the stakeholder consultation conducted from 05 December 2019 to 13 February 2020 by Oeko-Institut in the course of the study to support the review of the list of restricted substances and to assess a new exemption request under RoHS 2 (Pack 15); https://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Pack_15/4th_Consultation_PartII/contribution_EuRIC_RoHS15_Review_list_restricted_substances_20200213.pdf

[71] Op. cit. ZVEI (2018)

[72] Op. cit. ESIA (2020)

[73] Op. cit. Campine (2018)

[74] Op. cit. ZVEI (2018)

[75] Op. cit. Campine (2018)

[76] Op. cit. Europacable (2018)

i. A sorting per cable type/materials (PVC or PE or rubber or...)

ii. Per cable lot (for instance PVC based), a grinding of the cable and a plastic/metal separation thanks to vibrating tables

The cables specifically containing ATO, for instance based on PVC, are not separated from the other PVC cables stream. They are all grinded together and the PVC obtained after treatment may most probably contain ATO at variable concentration. A recycling takes place at least in some front running companies,[77] however, the share of the recycling of cable insulation compared to the total amount of cable material / insulation has not been indicated by industry.

ECVM (2020) notes in this regard that in 2018, more than 150 kt of PVC waste from cables have been recycled in the EU by the VinylPlus Programme.[78]

5.1.4 Main materials in the waste stream where the substance is contained

From the above, it can be understood that ATO in the waste phase shall mainly be contained in polymer plastics from housings and cables (e.g., ABS, PVC, PE) as well as in PWB laminates.

5.1.5 WEEE categories containing the substance

ATO is used for the flame retardancy of plastics in housings, cables and electric installations as well as of laminates for PWB. These materials and components are found in almost all types of EEE: Plastic housings are also quite common, particularly but not exclusively in consumer products that do not require the robustness provided by metal housings. It is thus expected that relevant components and materials can be found in EEE of all categories.

5.2 Applied waste treatment processes

5.2.1 Initial treatment processes applied to the WEEE containing the substance of concern

The following table summarizes in which initial treatment processes ATO-containing materials of EEE can be found. Collection and transport are also relevant for all WEEE categories collected separately but is not considered for potential emission of ATO in this process. Whereas manual dismantling is not relevant for all (W)EEE categories, the treatment process shredding (and automated sorting) is relevant for all EEE categories. This process, where mechanical disintegration and crushing of the appliances (various types of shredding, grinding processes etc.) takes place, should be further assessed for potential emissions of ATO.

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[77] E.g. as mentioned by Campine (2018):

CABLO, a subsidiary of the Aurubis Group, is specialised in the separation of metals and plastics, in particular in the recycling of cable waste and cable scrap. In addition to recovering brass, aluminium, copper, iron and lead, CABLO re-uses the plastic components using an injection moulding technique which has been specially developed to recycle plastics (PVC, PE).

The Vinyloop© process developed by Solvay is a mechanical recycling process using an organic solvent to separate the PVC compound from other types of plastic waste or from the other materials in a PVC composite.

The tonnage of recycled cables is increasing due to direct reuse of PVC and recycling via the Vinyloop process. In 2016, 127 kTon of PVC cables were recycled (containing ATO).

[78] https://vinylplus.eu/documents/51/59/VinylPlus-Progress-Report-2019

Table 5-1: Initial treatment processes applied

Initial treatment processes	The substance is present in appliances belonging to:										
	Cat 1: Large household appliances	Cat 2: Small household appliances	Cat 3: IT an telecommunications	Cat 4: consumer equipment	Cat 5: Lighting equipment	Cat 6: Electrical and electronic tools	Cat 7: Toys leisure and sports equipment	Cat 8: Medical devices	Cat 9: Monitoring and control instruments	Cat 10: Automatic dispensers	Cat 11: Other EEE not covered by categories 1-10
For WEEE collected separately											
Collection and transport	X	x	x	x	X	x	x	x	x	x	x
Dedicated treatment processes for cooling & freezing appliances	X										
Dedicated treatment processes for screens	X	x	x			x	x	x	x		x
Dedicated treatment processes for lamps					X						
Manual dismantling (also for refurbishment)	X	x	x	x	X	x		x	x		
Shredding (and automated sorting)	X	x	x	x	X	x	x	x	x	x	x
For WEEE not collected separately											
Landfilling (of residual waste)		x	x		X	x					
Mechanical treatment (of residual waste)		x	x		X	x					
Incineration	X	x	x	x	X	x	x	x	x	x	x
Uncontrolled treatment in third countries	X	x	x	x	X	x	x	x	x	x	x

5.2.2 Treatment processes applied to wastes derived from WEEE containing the substance of concern

The following table summarises the treatment processes of secondary waste derived from WEEE treatment.

Table 5-2: Treatment processes for wastes derived from WEEE

Treatment processes for wastes derived from WEEE treatment	The substance is present in the following main component/material								
	Ferrous metals	Non-ferrous metals	Plastics	Electronic components	Cables	Glass	Powders	Fluids	Others
Under current operational conditions in the EU									
Storage of secondary wastes									

Shredding and automated sorting of secondary wastes			x	X	x				x
Recycling of ferrous metals									
Recycling of NF metals									
Recycling of plastics			x	X	x				x
Recycling of glass									
Recycling as building material									
Landfilling of residues			x	X	x				
Incineration of residues			x	X	x				x
Co-incineration of residues			x	X	x				x
Dedicated processes for hazardous residues			(x)	(x)	(x)				(x)
Under uncontrolled conditions									
Acid leaching									
Grilling/desoldering									
Uncontrolled combustion			x	X	x				
Uncontrolled dumping of residues			x	X	x				x

5.3 Waste treatment processes relevant for assessment under RoHS

As presented above, the main waste treatment processes in which ATO can be expected to be present include:

- All relevant materials/components: Collection and sorting of WEEE (PWBs and cables are sorted out and sent to separate treatment);
- Plastic casing: Shredding of WEEE followed by sorting of shredded fraction:
  - Density based sink-float sorting techniques, to separate plastics containing BFR from shredded fraction (more common);
  - Sorting techniques based on x-ray fluorescence which detects bromine content (BFRs), to separate plastics containing BFR from shredded fraction (less common);
- PWBs – Copper smelting is performed on PWBs to recover the copper, sending residual plastic including ATO as part of flame-retardant materials to incineration and thermal recovery;
- Cables are treated separately:
  - Cable types are sorted to various groups (PVC, PE, rubber, etc.);
  - Plastic and metal are separated through stripping/shredding grinding;
  - This is followed by sorting with vibration tables or density sorting so as to recuperate the plastic mantle (density sorting);
  - A mechanical separation process which is solvent-based has also been developed (Vinyloop©) to separate PVC compounds from other plastic waste and from other PVC composites to allow

reuse of PVC. This is understood to be a new process still implemented on small scale compared to the total amount of EEE cables placed on the market.

- Incineration with energy recovery of WEEE residues/separated fraction containing ATO as part of flame-retardant system;
- Recovery of antimony from the ashes of the incinerated plastics and other components is currently not common, but applied in some countries (where ATO concentration is above a certain limit, fraction is treated as hazardous waste, i.e. landfilled).[79]

5.4 Releases from (relevant) WEEE treatment processes

From the waste treatment processes mentioned above, the shredding processes are the most relevant concerning releases of substances incorporated in the shredded material. During shredding processes, the material is mechanically highly worked-up and dust is released. Substances like ATO may occur being bound to the airborne particles resulting from the shredding of the material. The emissions to air are considered rather relevant for human health (workers) and will therefore be further evaluated in the exposure estimations. Through the treatment of ATO-containing WEEE articles and the deposition of airborne particles, the substance evaluated here ends up in other environmental compartments like water and soil (waste water, …).

BFR-ATO loaded plastics that sorted out during gravimetric WEEE separation processes (e.g. swim/sink)[80], where the presence of ATO is used as an indicator for the presence of brominated FR. These plastic parts undergo waste treatment by incineration for the most part.

In relation to emissions, EERA (2020)[81] further states that *“the BAT/BREF requirements for shredder processes, ensure that the shredder dust is captured, and that this shredder dust is incinerated, hence the shredder processes do not pose a risk for human health or the environment. For CRT appliances a manual separation of the plastics is state of the art. At the workstations of the manual dismantling, dust extraction systems ensure the reduction of any human health and environmental risks to an absolute minimum”*.

Also, other stakeholders[82] stress that occupational exposure to dust has to be avoided in general, which is specified in (national) occupational limits or global specifications.[83]

5.4.1 Releases to air, water and soil from waste incineration plants

KEMI (2015) refers to possible emissions from incineration: “*Incineration of plastic waste from EEE products can produce discharges of antimony trioxide distributed among various output fractions, such as emissions, wastewater, ash and slag. Previous studies estimated concentrations of*

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[79] Campine (2020) noted here that “*industry is able to change the incineration processes into pyrolysis (ending up with removable Sb content) or into improved mono-incineration of WEEE plastics maximizing the Sb content in fly ashes (doctorate KULeuven) so that the recuperation is possible. Landfill can be avoided in 2 years.”* This is noted as however it is not current practice, this comment is not taken up.

[80] This plastic fraction does not comprise PVC cables waste, the great majority of which is recycled according to ECVM (2020).

[81] European Electronics Recyclers Association (EERA) (2020): Contribution submitted on 12.02.2020 during the stakeholder consultation conducted from 05 December 2019 to 13 February 2020 by Oeko-Institut in the course of the study to support the review of the list of restricted substances and to assess a new exemption request under RoHS 2 (Pack 15); https://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Pack_15/4th_Consultation_PartII/contribution_EERA_RoHS15__possible_Restriction_TBBPA_ATO_20200212.pdf

[82] Op. cit. i2a (2020), Campine (2020), ECVM (2020)

[83] https://www.who.int/occupational_health/publications/en/oehairbornedust3.pdf

antimony in municipal waste to approximately 10-60 ppm, with large variations. From EEE waste, the concentrations are reported to be in the range from several hundred up to thousands ppm."

In the EU RAR (2008), emission estimations for incineration are made for Municipal Solid Waste (MSW) assuming a concentration value of antimony of 40 mg Sb/kg waste (= 40 ppm). However, KEMI (2015) stated that from EEE waste, the concentrations are reported to range from several hundred up to thousands ppm.

Emissions from incineration plants are expected via air, wastewater, ash and slag.

The EU RAR rapporteur assumed 1 % emissions to air and 0.3 % emissions to water. 60 % of the antimony in the influent incinerator wastewater is removed as sludge and 40 % remains in the wastewater and will be released to the waste water treatment plant (WWTP). The sludge generated goes to a hazardous waste landfill.

Table 5-1: Total annual amount of antimony emissions to air, water and landfill due to 100 % incineration of MSW within the EU

Compartment	Released amount of antimony (t/y)	Continental (90 %; t/y)	Regional (10 %; t/y)
Air	4.5	4.0	0.4
Wastewater	5.4	4.9	0.5
Landfill (ash + sludge)	4,485	4,037	448

Quelle: EU RAR (2008)

As long as the activities related to a specific stage of the life-cycle of a substance can be assumed to take place within a region, as it is often the case for manufacture, formulation and industrial uses, 100 % of the whole registrant's tonnage at EU level is attributed to the regional scale. When activities are more widely distributed over the EU, as is assumed for wide dispersive uses or in this case incineration, only a fraction of the whole registrant's tonnage at EU level is attributed to the region (10 % by default) while most of it (90 % by default) is attributed to the continental scale.[84]

It is obvious that plastic waste containing halogenated flame retardants contains a higher amount of ATO. Therefore, these emission estimations are not comparable to WEEE ATO plastic waste. Nonetheless, not all WEEE is properly disposed of by consumers and thus collection rates in the EU are far from 100 %. WEEE that is not properly collected shall at least in part be sent to municipal treatment for which the values above are considered to be representative.

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[84] ECHA (2016): Guidance on information requirements and Chemical Safety Assessment Chapter R.16: Environmental exposure assessment; Version 3.0, February 2016; https://echa.europa.eu/documents/10162/13632/information_requirements_r16_en.pdf, last viewed 24.07.2018

6 EXPOSURE ESTIMATION DURING USE AND DURING WEEE TREATMENT

For exposure estimations, the following scenarios will be looked at:

- WEEE treatment and therein the shredding process of EEE plastics;
- Incineration of waste fractions;
- General release of ATO into the environment.

6.1 Human exposure estimation

6.1.1 Exposure of workers of EEE waste processing plants

From the description of the waste streams it is assumed that exposure of workers in WEEE waste processing plants to diantimony trioxide can occur during the processes of processing and shredding cable and plastic waste, where generation of dust from decomposing and shredding of EEE plastic is likely.

Exposure can occur through inhalation of dust and dermal uptake, whereas the exposure through inhalation is assumed to be the relevant exposure pathway.

Exposure estimation for workers was modelled by using the ECETOC's Targeted Risk Assessment (TRA)[85] tool to calculate the risk of exposure from chemicals to workers, consumers and the environment. The ECETOC TRA tool is intended for manufacturing and formulation processes. Hence, appropriate processes to describe the exposure conditions of waste treatment processes do not yet exist.

However, process category 24: "high (mechanical) energy work-up of substances bound in materials and/or articles" has been selected to calculate the exposure of workers of EEE waste processing plants.

This approach was first introduced by the Austrian Umweltbundesamt for the RoHS assessment of the phthalates DEHP, DBP and BBP[86] and has also been used by KEMI for the MCCP dossier[87] and the Fraunhofer Institutes for the assessment of TBBP-A that has been performed on behalf of the BSEF, aisbl – The International Bromine Council and was submitted as part of the contribution of BSEF on 23.04.2018 during the stakeholder consultation conducted from 20 April 2018 to 15 June 2018 in the course of this study.[88]

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[85] http://www.ecetoc.org/tools/targeted-risk-assessment-tra/

[86] https://www.umweltbundesamt.at/rohs2

[87] Swedish Chemicals Agency KEMI (2018): ROHS Annex II Dossier MCCP, Proposal for a restriction of a substance in electrical and electronic equipment under RoHS; https://www.kemi.se/global/rapporter/2018/report-4-18-rohs-annex-ii-dossier-mccp.pdf, last viewed 24.07.2018

[88] The following assessment was submitted as part of the contribution of BSEF, aisbl – The International Bromine Council: Contributions submitted on 23.04.2018 during the stakeholder consultation conducted from 20 April 2018 to 15 June 2018 by Oeko-Institut in the course of the study to support the review of the list of restricted substances and to assess a new exemption request under RoHS 2 (Pack 15); see PDF5 at: https://rohs.exemptions.oeko.info/index.php?id=291:

Fraunhofer Institute for Toxicology and Experimental Medicine (ITEM), Fraunhofer Institute for Manufacturing Engineering and Automation (IPA) (n.y.): Assessment of TBBPA (tetrabromobisphenol A) according to the "Methodology for Identification and Assessment of Substances for Inclusion in the List of Restricted Substances (Annex III) under the RoHS2 Directive"; submitted as contribution of the BSEF, aisbl – The International Bromine Council to the 1st stakeholder consultation, submitted on 23.04.2018; available at: https://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Pack_15/1st_Consultation_Contributions/TBBPA_under_RoHS_13102015_clean__2_.pdf

As ATO is a metalloid-containing inorganic substance, exposure estimation based on (the very low) vapour pressure is not applicable. Instead, the exposure estimation for ATO as a solid was modelled.

Further selected input parameters for the plastic and cable shredding were taken in accordance with other RoHS assessments (KEMI 2018, Austrian Umweltbundesamt and Fraunhofer Institute for Toxicology and Experimental Medicine (ITEM), Fraunhofer Institute for Manufacturing Engineering and Automation (FhG-IPA):

- professional setting,
- 8 hours activity (>than 4 hours),
- outdoors, since shredding equipment is assumed to be either completely outdoors or in large, partially open halls, therefore, local exhaust ventilation is not considered,
- no respiratory protection or gloves (dermal PPE - personal protective equipment).

As for the parameter in substance in the preparation, the range of 1 to 5 % was chosen based on the information on the applications of ATO in plastics and cables (see section 2.2).

Measurements in the plastic waste stream supports the assumption that this range is realistic: Morf and Taverna (2004)[89] measured in TV and PC enclosures a content of 1.6 % antimony, and a more recent measurement in plastic fraction of WEEE revealed a content of 1.4 % antimony.[90] [91]

The input parameters for the exposure estimation are compiled in Table 6-1.

Table 6-1: Input parameters used in ECETOC TRA for worker exposure

Scenario name	Shredding of WEEE plastic and cables
Treatment setting	Professional
Duration of activity	>4 hours/day
Use of ventilation	Outdoors
Respiratory protection	No
Substance in preparation	1-5 %

Source: Own compilation based on ECETOC TRA 3.1

In ECETOC TRA, the process category 24 (PROC 24) described as “high (mechanical) energy work-up of substances bound in materials and/or articles” and the subcategory assuming a low fugacity leads to the following exposure values, concentrations are given in mg/m^3:

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[89] Morf, L. & Taverna, R. (2004): Metallische und nichtmetallische Stoffe im Elektroschrott, Stoffflussanalyse.

[90] Taverna, R. et al. (2017): Stoffflüsse im Schweizer Elektronikschrott. Metalle, Nichtmetalle, Flammschutzmittel und polychlorierte Biphenyle in elektrischen und elektronischen Kleingeräten. Bundesamt für Umwelt, Bern. Umwelt-Zustand Nr.1717; https://www.bafu.admin.ch/bafu/de/home/themen/chemikalien/publikationen-studien/publikationen/stofffluesse-im-schweizer-elektronikschrott.html

[91] Both are measurements on specific plastic fractions are taken for justification for the substance in preparation of 1-5% in ECETOC. It is considered being justified to take these data as a worst-case scenario.

Table 6-2: Exposure estimates with ECETOC TRA for ATO in PROC 24a

Process Category (PROC)	Long-term Inhalative Exposure Estimate (mg/m^3) c= 1-5 %	Long-term Dermal Exposure Estimate (mg/kg/day) c= 1 – 5 %
PROC 24a	4,20E-01	5,66E-01

Source: Own compilation based on ECETOC TRA 3.1

The estimations yielded with ECETOC TRA are based on rather conservative assumptions. In order to further evaluate the estimates, workplace measurements have been investigated in other studies.

However, there are few measured values for ATO from workplaces in the waste management sector:

The institute for occupational safety from the German Social Accident Insurance[92] carried out a statistical evaluation for workplace measurements for antimony and its compounds other than hydrogen antimony in the period from January 2005 to May 2017. From this evaluation, it is understood that in the sector of “waste disposal and incineration, slag processing, electrical scrap recycling, wholesale with scrap material”, 43 measurements from the workplace are available; thereof 37 % were below the detection limit of 0,0075 mg/m^3 and 95 % of the measurements revealed levels below 0,011mg/m^3 (detection limit plus 0,00346). However, only two data points (values) refer to shredding and sorting processes. Thus, there is a great difference between the estimated and measured data from Germany.

The German Federal Institute for Occupational Safety and Health BAuA, as the member state authority for ATO in the CORAP list[93], was asked to provide more data.

One occupational exposure study in e-waste recycling plants in Sweden[94] examined the workers’ exposure to metals. Samples were taken for recycling workers by personal air samplers and for office workers by static sampling at three formal e-waste recycling plants in Sweden. The measured concentrations in the inhalable[95] as well as the OFC[96] fractions are compiled in the following table. In general, the data meets the expectation of a higher exposure for recycling workers than for office workers. The geometric mean concentration for antimony in the inhalable fraction was ~25 times and ~6 times higher for the recyclers than for the office workers, respectively.

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[92] IFA Institut für Arbeitsschutz der Deutschen Gesetzlichen Unfallversicherung (n.y.): MEGA-Auswertungen zur Erstellung von REACH-Expositionsszenarien für Diantimontrioxid sowie Antimon und seine Verbindungen, außer Antimonwasserstoff; https://www.dguv.de/medien/ifa/de/fac/reach/mega_auswertungen/antimon.pdf

[93] Op. cit. BAuA (2016)

[94] Julander, A; Lundgren, L.; Skare, L.; Grandér M.; Palma, B.; Vahter, M.; Lidéna, C. (2014): Formal recycling of e-waste leads to increased exposure to toxic metals: An occupational exposure study from Sweden; Environment International 73 (2014) 243–251.

[95] Inhalable fraction: “Mass of total airborne particles that is inhaled through the nose and mouth.” (International Organization for Standardization, 2012)

[96] Open face cassette (OFC) 37-mm cassette sampler for collecting airborne particles corresponding to OELV (occupational exposure limit values). Has been called total dust sampler.

Table 6-3: Antimony concentration (GM (GSD) & range) in the collected inhalable fraction and OFC fraction from personal air sampling (exposure data for recycling workers) and from static sampling (exposure data for office workers) at three e-waste recycling plants in Sweden

	Inhalable fraction (µg/m^3)		OFC fraction (µg/m^3)	
	Recycling workers (n=77)	**Office workers (n=3)**	**Recycling workers (n=65)**	**Office workers (n=3)**
GM (GSD) Range	0.21 (2.3) 0.0041–1.1	0.0085 (2.0) 0.0041–0.015	0.15 (2.5) 0.0042–0.88	0.023 (2.9) 0.011–0.049

Source: Julander et al. 2014

Note: GM – Geometric Mean, GSD – Geometric Standard Deviation

Julander et al. (2014) also analysed biomarkers from workers and found linear correlations for antimony between the inhalable fraction and exposure biomarkers (blood, plasma and urine) as for some other metals such as e.g. mercury and lead. Thus Julander et al. (2014) point out the occupational exposure to multiple metals for e-waste recycling work, even in modern plants with adequate protection routines, and claim that rare metals such as In and Sb, and not only Hg and Pb, must be monitored in these settings both in air and human samples. It has to be noted that the exposure by multiple toxic metals as a combined/cumulative exposure cannot be considered here.

I2a (2020)[97] noted that the ECETOC TRA model estimates represent substance-exposure (i.e. mg Sb_2O_3/m^3) whereas OELs are given as mass antimony per volume air (e.g. mg Sb/m^3); thus, estimates derived with ECETOC TRA cannot directly be compared with such OELs.

I2a (2020)[98] further notes that "*the fraction of dust (according to EN 481) is neither reported nor considered for the OELs. Since all reported exposure levels (i.e. ECETOC TRA, IFA, Julander et al.) refer to the inhalable fraction, they cannot directly be compared with OELs given for the respirable fraction as is the case for the German OEL, which is also the lowest OEL referenced. Vetter (2018) calculated factors for converting inhalable exposure levels into respirable levels relevant for the ATO industry. The suggested overall conversion factor was derived at 5.*" Taking this conversion factor into account, the maximum exposure level in Julander et al. (2014) would then be at a level of 0.22 µg/m^3 (converted to the respirable fraction), according to i2a (2020).

To conclude, the data from the working places indicate that the strictest occupational exposure limits in the EU of 6 µg/m^3 are not exceeded.

However, it is not known whether the workplaces examined by Julander et al. (2014) have different protection routines than other facilities in the EU.

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[97] Annex I of i2a contribution: EBRC Consulting GmbH (2020): Comments on the Exposure Assessment Part of RoHS Annex II, 16 January 2020; provided as Annex I to the contribution of i2a submitted on 30.01.2020; https://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Pack_15/4th_Consultation_PartII/contribution_i2a_RoHS_15_Comments_ATO_Report_FINAL_Annex_IV_20200130.pdf

[98] Op. cit. Annex I of i2a contribution

6.1.2 Exposure of neighbouring residents of EEE waste processing plants

From the EU, no data have been found on the exposure of neighbouring residents of EEE waste processing plants. It is understood that for the incineration of plastic waste from EEE products, the IED Directive 2010/75/EU[99] on industrial emissions (integrated pollution prevention and control) applies where the air emission limit values for waste incineration plants for antimony and its compounds are set at 0,5 mg/m^3 for antimony and its compounds, expressed as antimony (Sb). It is understood that the IED Directive covers the potentially relevant emissions from waste incineration plants. Thus, this exposure will not be further considered here.

6.1.3 Consumer exposure

According to the EU RAR,[100] diantimony trioxide is used in several products available to consumers which are PET, flat and pile upholstered furniture (residential and commercial furniture), cuddly toys, upholstery seatings and automobile interior textiles in private and public transportation, draperies, and wall coverings, electrical and electronic equipment e.g. distribution boxes for electrical lines and polyvinyl chloride wire, cable and textile coating.

The EU RAR states that *"the release of diantimony trioxide from the surface of products to atmospheres may be a potential way of exposure. Due to negligible volatility of diantimony trioxide, vapour release is not relevant. Instead, diantimony trioxide may be released as dust due to wear or abrasion. Direct dermal contact with products containing diantimony trioxide may give dermal exposure."*

Among the scenarios presented in the EU RAR ("drinking from a PET-bottle", "sucking on cuddly toys" (oral exposure), "indoor air" (inhalation and oral exposure) and "sitting on upholstery fabric" (dermal exposure)), the scenario on indoor air is the relevant one for EEE. Relating to inhalation exposure, the scenario based on values measured in a study on the ATO content in household dust conducted in the UK stated: *"Compared to naturally occurring amounts in soil of around 0.2 µg/g, house-dust contained relatively high amounts of antimony with median values of 13 µg/g, corresponding to 15.6 µg Sb_2O_3/g. The 90th percentile in the same publication was close to 50 µg/g, corresponding to 60 µg Sb_2O_3/g. When taking the CSOIL (parameter set for human exposure modelling) estimate for particulate matter (dust) in indoor air of 52.5 µg/m^3 into consideration (Otte et al., 2001), 15.6 µg Sb_2O_3g dust corresponds to 0.819 ng $_{Sb2O3}$/m^3. This is considered a typical value. A reasonable worst-case scenario of 60 µg Sb_2O_3/g corresponds to 3.15 ng Sb_2O_3/m^3."*

To conclude on consumer exposure, values that are available for indoor use suggest that the exposure is below the limit values as presented in section 0, also from a precautionary point of view, considering the occupational exposure limit of Germany at 6 µg/m^3.

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[99] Directive 2010/75/EU of the European Parliament and of the Council of 24 November 2010 on industrial emissions (integrated pollution prevention and control) (Recast); https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32010L0075&from=EN, last viewed 24.07.2018

[100] Op. cit. EU RAR (2008)

6.2 Environmental exposure estimation

According to the EU RAR,[101] diantimony trioxide is released to the environment through air effluents and waste water from manufacture, formulation, processing, use and disposal of diantimony trioxide. Further unintentional emission sources are production of non-ferrous metals, coal combustion and road traffic. Therefore, environmental exposure for diantimony trioxide cannot be associated specifically to the use in EEE.

Diantimony trioxide dissolves in the environment and is present as different antimony species, depending on the environmental conditions. Antimony can be found in all environmental compartments. In the Screening Assessment of the Canadian Ministries of the Environment and of Health,[102] it is noted that the soluble forms of antimony like ATO (though poorly soluble) generally have a moderate potential to cause harm to aquatic, soil and sediment organisms. It is concluded there that the substance is not entering the environment in a quantity or concentration or under conditions that have or may have an immediate or long-term harmful effect on the environment or its biological diversity or that constitute or may constitute a danger to the environment on which life depends.

6.2.1 Monitoring data: remote regions, biota

In the EU RAR[103], different background levels of antimony are defined as antimony occurs naturally: natural background concentration (a situation before any human activity), baseline background concentration (corresponding to very low anthropogenic pressure), ambient concentration (diffuse anthropogenic input in the past or present) and realistic worst-case ambient concentration.

According to the EU RAR, antimony concentration measured in air varies and mostly depends on the emissions by road traffic or metal smelting and manufacturing industries: *"The measured concentrations in European air normally range from background values of about 0.1 ng Sb/m^3 in remote areas of Norway, to several tenths of ng Sb/m^3 and above in areas with heavy traffic or in regions with metal smelting and manufacturing industries. The concentrations (from several thousand to several tens of thousands of ng Sb/m^3) of methylated antimony measured in sewage gas and landfill gas (see section 3.1.2.7.2 above) indicate that these kinds of sources may, at least at a local scale, be important."*

6.2.2 Monitoring data: waste management

No monitoring data were found that measure ATO released into the environment by WEEE treatment plants. The environmental exposure by WEEE treatment is not further elaborated.

It should be noted that there are legislative measures in place that set e.g. air emission limit values for waste incineration plants (IED Directive 2010/75/EU; see also section 1.3.2).

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[101] Op. cit. EU RAR European Union Risk Assessment Report (2008): Diantimony trioxide, November 2008

[102] Environment Canada, Health Canada (2010): Screening Assessment for the Challenge Antimony trioxide (Antimony oxide) Chemical Abstracts Service Registry Number 1309-64-4; September 2010; https://www.ec.gc.ca/ese-ees/9889ABB5-3396-435B-8428-F270074EA2A7/batch9_1309-64-4_en.pdf, last viewed 19.04.2018

[103] EU RAR European Union Risk Assessment Report (2008): Diantimony trioxide, November 2008

7 IMPACT AND RISK EVALUATION

It should be noted that for halogenated flame retardants applied with ATO, the use of the latter allows applying less halogenated flame retardants. From the human health and environmental perspective, the application of ATO should not be assessed alone but together with the halogenated flame retardant. However, as such a combined/cumulative assessment is not in scope of this dossier, these considerations cannot be further explored.

7.1 Impacts on WEEE management as specified by Article 6 (1)a

Article 6 (1)a of the RoHS Directive stipulates that specific account should be taken on whether a substance selected for a review *“could have a negative impact during EEE waste management operations, including on the possibilities for preparing for the reuse of waste EEE or for recycling of materials from waste EEE”.*

As diantimony trioxide is solely used in combination with halogenated flame retardants, diantimony trioxide is used in the plastic waste stream as one sound parameter to sort out plastic containing brominated flame retardant.[104] As described in the stakeholder contribution by KU Leuven,[105] the presence of ATO in plastics is commonly used to sort out the plastic for incineration. Post-shredder sorting techniques separate plastics containing diantimony trioxide-based flame-retardant systems with a high efficiency from other non-flame-retardant plastic types, because of the high density of antimony trioxide (ρ = 5,7 g/cm^3). According to the KU Leuven,[106] also X-ray fluorescent-based optical sorting techniques are used alternatively or in combination with density-based sink-float sorting techniques after size reduction by shredding as state-of-the-art recycling processes in Europe. This fraction is as of today’s state of the art not recycled but is sent to incineration with energy recovery. The reasons are that there is no further post-shredder sorting of different plastic materials to obtain a required purity, e.g. to separate the plastic material ABS and HIPS both containing brominated flame retardants.

To conclude, ATO used as synergist together with brominated flame retardants does not have a negative impact on the recycling of materials from waste EEE because ATO is used as a sound parameter to sort out plastic containing brominated flame retardants; ATO in this process has to be recognised as supporting the sorting technique based on sink-float that is the commonly applied process. In this sense, ATO supports to separate plastic fractions where the fraction not containing ATO might be recycled.

The plastic fraction containing ATO (and brominated flame retardants) is often not recycled but incinerated. The recovery of antimony from the ashes of the incinerated plastics is so far not common practice according to the KU Leuven. Campine (2018) also states that *“the recovery of antimony out of plastics is not yet implemented on a broader scale because the operation is not economically viable yet and rather complex (due to pop’s in FR plastics).”* i2a (2018) explains that *“in a number of countries, bottom ash is used for road and other constructions, unless the concentration of ATO in the ash exceeds a particular limit, in which case it must be treated as a hazardous waste (i.e. landfilled).”*

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[104] It has to be noted that here (soft) PVC containing ATO is excepted as PVC cable insulation containing ATO is partly recycled by e.g. industry initiatives as mentioned in section 5.

[105] Op. cit. KU Leuven-University of Leuven (2018)

[106] Op. cit. KU Leuven-University of Leuven (2018)

7.2 Risks for workers

The exposure estimation gained by ECETOC for the process of plastic shredding shows that there are potential risks for human health due to exposure to ATO that need to be managed. These results indicate that protection routines have to be established in waste recycling plants in Europe.

However, the measurements from occupational settings like in Julander et al. (2014) relativize the high exposure estimation provided by ECETOC TRA: The measured data are way below the estimates and also below the national occupational exposure limit (OEL) which is mostly set at 0.5 mg/m^3.

It has to be pointed out that the OEL in Germany was recently decreased to 0,006 mg/m^3. This divergence in national OEL for antimony and its compounds indicates that the risk for workers associated with the exposure to ATO has not been assessed according to uniform principles in Europe.

The consultant agrees to the input of i2a (Annex I of its contribution) that Julander et al (2014) "*because of the comprehensive and peer-reviewed nature of the dataset, as well as its specific relevance for recycling of e-waste, this study is considered as being highly relevant for exposure estimation for workers involved in recycling of EEE articles*." However, the following circumstances are considered difficult to assess: In Europe, it is a precondition that recycling plants are equipped with proper ventilation and that the protection of workers is ensured. While it has been established by Julander et al. (2014) that two of the three Swedish e-waste recycling plants participating in the survey had process ventilation, process ventilation did not cover all areas in one company. The reason for not using process ventilation given by the third company was that operations had been outsourced into a temporary building.

Therefore, it is difficult to assess whether workplace measurements are representative for European recycling plants or whether the estimates provided by ECETOC TRA are more appropriate.

It should be noted that the process parameters for plastic shredding, implemented in ECETOC, have been defined in the same way in other RoHS assessments, e.g. recently by the Swedish Chemicals Agency KEMI[107] as well as by two Fraunhofer Institutes.[108] We also do not assume this waste process model renders exactly to the process model as described in the EU RAR (e.g. in the Non-PVC production scenarios), as claimed by COCIR (Annex I of the contribution).

ECETOC TRA is considered to be a recognised tool to be used in this context. In the case of the phthalates DEHP, DBP and BBP[109], the estimates for workplace exposure provided by ECETOC TRA have been used to substantially support the decision to restrict the phthalates and add them to the RoHS Annex II. Thus, great importance has been attached to the exposure estimations derived

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[107] Swedish Chemicals Agency KEMI (2018): ROHS Annex II Dossier MCCP, Proposal for a restriction of a substance in electrical and electronic equipment under RoHS; https://www.kemi.se/global/rapporter/2018/report-4-18-rohs-annex-ii-dossier-mccp.pdf, last viewed 24.07.2018

[108] The following assessment was submitted as part of the contribution of BSEF, aisbl – The International Bromine Council: Contributions submitted on 23.04.2018 during the stakeholder consultation conducted from 20 April 2018 to 15 June 2018 by Oeko-Institut in the course of the study to support the review of the list of restricted substances and to assess a new exemption request under RoHS 2 (Pack 15); see PDF5 at: https://rohs.exemptions.oeko.info/index.php?id=291:

Fraunhofer Institute for Toxicology and Experimental Medicine (ITEM), Fraunhofer Institute for Manufacturing Engineering and Automation (IPA) (n.y.): Assessment of TBBPA (tetrabromobisphenol A) according to the "Methodology for Identification and Assessment of Substances for Inclusion in the List of Restricted Substances (Annex III) under the RoHS2 Directive"; submitted as contribution of the BSEF, aisbl – The International Bromine Council to the 1st stakeholder consultation, submitted on 23.04.2018; available at:

[109] AUBA Austrian Umweltbundesamt (2014): RoHS ANNEX II Dossier DEHP, Restriction proposal for hazardous substances in electrical and electronic equipment under RoHS, January 2014.

from ECETOC in the context of RoHS assessments as mentioned above. In the consultant's opinion, this was due to the fact that the precise conditions prevailing in the respective e-waste recycling facilities and the level of workers' protection were not known.

To conclude, there are reliable exposure data only from a few e-waste recycling plants available. These measurements indicate that exposures are below the lowest national OEL in the EU. Against the background of varying national OELs for ATO, the consultant recommends carrying out further monitoring at recycling plants to establish better evidence regarding the exposure to ATO.

7.3 Risks for consumers and neighbouring residents

The EU risk assessment[110] came to the conclusion for inhalation of indoor air that there was no concern for consumers. In addition, Campine (2020) states that the blooming of Sb at the surface of plastic parts is generally below detection level, i.e. negligible for consumers of EEE.

Indirect exposure via the environment, in addition to indoor air, exists from ambient air, drinking water and foodstuffs. The assessments in the EU RAR[111] and the Screening Assessment of the Canadian Ministries of the Environment and of Health[112] both came to the conclusion that the total exposure level to ATO resulting from environmental media is expected to be low.

KEMI (2015) summarizes the additional assessment of the United States Environment protection Agency (US EPA) as follows: *"Based on a review of the available data regarding antimony concentrations in food and environmental media, and biomonitoring data, EPA sets the conclusion that general population exposure to antimony is expected to be low. Because food and water are the primary sources of general population exposure, and the less toxic (i.e., pentavalent) form of antimony predominates in these media, significant human health risks are not anticipated."* This is also relevant for ATO, because it is expected to dissolve in contact with environmental compartments and to transform in other antimony forms.

7.4 Risks for the environment

There are no specific data on the release of diantimony trioxide from EEE or EEE waste management into the environment. Therefore, general results regarding ATO entering the environment are considered in the following.

The Screening Assessment of the Canadian Ministries of the Environment and of Health,[113] which is the most recent evaluation of ATO, concludes that diantimony trioxide is not entering the environment in a quantity or concentration or under conditions that have or may have an immediate or long-term harmful effect on the environment or its biological diversity, or that constitute or may constitute a danger to the environment on which life depends.

Against these findings it is concluded that the impact of ATO that is released during use and waste phase of EEE under the waste management conditions described in this dossier has a low potential to cause harm to the environment.

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[110] Op. cit. EU RAR (2008)

[111] Op. cit. EU RAR (2008)

[112] Op. cit. Environment Canada, Health Canada (2010)

[113] Op. cit. Environment Canada, Health Canada (2010)

8 ALTERNATIVES

ATO acts as a synergist for halogenated flame retardants. As the scope of this assessment addresses ATO on its own and in combination with the halogenated flame retardants included in this current review, this section on alternatives will cover the following possibilities for substituting ATO:

- Substituting ATO as a synergist, also referred to as mono-substitution;
- Substituting the halogenated flame retardant together with ATO as synergist ATO – hereafter referred to as co-substitution;
- Alternative technologies.

Alternatively, it was proposed by stakeholders during the 2nd consultation[114] to evaluate substitutes in relation to individual applications instead of a general assessment for EEE covered under RoHS. "*There is no way of performing a general assessment of alternatives, but rather this should be done for each application separately.*[115]" Such an assessment could take into account life cycle impact of alternatives, technical or cost impacts of substitution and substance-specific FR performance, recycling potential, recycled contents applicable in the polymers, environmental and human health "*at the same level*" as demanded in the contribution of i2a (2020) and Campine (2020). However, according to the methodology for substance assessment under RoHS, the assessment of possible substitutes and other alternatives should go as far as necessary to *"allow understanding, in which applications substitutes or alternative technologies are already applied and subsequently to what degree the substance (or substance group) has been phased-out. Where differences occur related to substitute or alternative technology implementation, such as between manufacturers of certain regions, product or component categories, etc., this should be specified. It should also be specified whether substitutes or alternative technologies can be considered to have less negative impacts (interpreted in comparison with the impacts of the substance in relation to the Article 6(1)(a-c) criteria)."* A detailed case-by-case examination (as requested by some stakeholders) of concrete applications that use substances restricted under RoHS not feasible here.

Various information sources have been used to gather information on alternatives and to compensate for missing information from stakeholders during the consultation. Besides information by manufacturers of alternatives, voluntary industry approaches have been reviewed. Furthermore, other studies have been investigated. Regarding costs, it should be noted that, generally speaking, data are hardly explorable in desktop research, and information on costs are vague.

8.1 Availability of substitutes / alternative technologies

8.1.1 Alternatives to ATO as synergist for flame retardants

Other substances acting as synergist can be used alternatively to ATO., However, even in the absence of "halogenated flame-retardants" ATO plays an important role in the flame retardancy of PVC cables. Alternatives for both cases are based on zinc, tin or other metal salts:

Tin compounds, so-called stannates: There are several stannate compounds on the market under the trade name "Flamtard"[116]; they are used as polymer additive providing the smoke supressing

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[114] Op. cit. ZVEI (2020), Campine (2020), and i2a (2020)

[115] Op. cit. i2a (2020)

[116] https://www.williamblythe.com/markets/polymer-additives/ last viewed 20.11.2019)

and flame-retardant synergist functions for polymer processing at temperatures below 220°C. They are used as a co-additive in phosphate-based flame retardants to optimise char formation.

Concrete examples are:

- Zinc (hydroxy)stannate (ZnSnO3.3H2O or ZnSn(OH)6, CAS: 12027-96-2) is available under the trade name Flamtard H;[117] and can be used in polyvinyl chloride and polymer materials containing halogenated and antimony additives. Thus, it is a synergist that can be used in combination with ATO, but also as a drop-in substitute to the application in halogen-free flame-retardant polymer materials.
- Zinc Stannate (ZnSnO3, CAS 12036-37-2; Flamtard S):[118] is described by the manufacturer for use in antimony-free applications in the electronic industry. Examples for host materials are indicated as follows: PVC systems for cable sheathing, epoxy resins for printed wiring boards, polyamides and surface coatings.
- **Zinc borate** is available e.g. under the tradename Firebrake and its flame retarding effect is based on the “co-work” of zinc and boron oxides with additional effects (water release). [119] According to the product descriptions, zinc borate can be used as a partial or complete replacement of ATO e.g. in flexible PVC.[120] Firebrake 415, zinc borate oxide (Zn4(BO2)6O, EC 420-340-7) is registered under REACH. However, the entry in the ECHA Registered Substances Database does not contain any further information and the tonnage data are confidential.[121] In halogen-free formulations, zinc borate is used as a synergist with ATH.[122] The combination with ATH is applicable in polymers such as several elastomers,[123] epoxy resins[124] and polyolefins.[125] A partial or complete substitution of ATO is indicated for elastomers and halogen-free epoxy resins, for example.

According to figures from the European Flame Retardants Association (EFRA) for 2005, borate and stannate make up a market share in the European flame retardant market based on tonnages of 3.2 %, which is comparable to the 3.4 % market share of ATO.[126] In contrast, the ZVEI[127] (2018) stated that *“while there might be also alternative synergists for brominated flame retardants, no use of such synergists is known to us. Therefore, possible alternatives to the system brominated flame retardant / antimony trioxide are usually halogen-free flame-retardant systems based on phosphorus or nitrogen.”* As this substitution is a co-substitution of halogenated FR and synergists, this will be discussed further under 8.1.2.

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[117] https://www.williamblythe.com/products/e-k/flamtard-h/, last viewed 20.11.2019.

[118] https://www.williamblythe.com/products/e-k/flamtard-s/, last viewed 20.11.2019.

[119] https://www.borax.com/products/firebrake

[120] Firebrake® ZB to replace antimony oxide at https://www.borax.com/BoraxCorp/media/Borax-Main/Resources/Brochures/firebrake-zb-antimony-oxide.pdf

[121] ECHA Registered Substance Database: Entry for FIREBRAKE 415; https://echa.europa.eu/registration-dossier/-/registered-dossier/4286, last viewed 17.07.2019

[122] Op. cit. Phosphorus, Inorganic and Nitrogren Flame Retardants Association PINFA (2017)

[123] https://www.borax.com/BoraxCorp/media/Borax-Main/Resources/Brochures/firebrake-zb-elastomers.pdf

[124] https://www.borax.com/BoraxCorp/media/Borax-Main/Resources/Brochures/firebrake-zb-epoxy.pdf

[125] https://www.borax.com/BoraxCorp/media/Borax-Main/Resources/Brochures/firebrake-zb-polyolefins.pdf

[126] The European Flame Retardants Association EFRA (2007): Flame Retardants, Frequently Asked Questions; EFRA - January 2007 at https://www.flameretardants-online.com/images/itempics/2/9/1/item_18192_pdf_1.pdf

[127] Op. cit. ZVEI (2018)

It can be concluded that there are alternative synergists available on the market; however, the mono-substitution of ATO - where the application of the halogenated FR remains – is understood to be applied to a lesser extent then the possibilities for substituting ATO+ halogenated FR.

8.1.2 Alternative flame retardants to the combination of halogenated flame retardants and ATO

It seems that some companies apply an approach to substitute both, halogenated FR and the synergist ATO.

Though the ZVEI (2018) states that *"the substitution of halogenated by halogen-free materials is a very big challenge due to several technical requirements especially for existing parts. In consequence no case of a successful substitution in existing parts is known.*" In contrast, KEMI[128] elaborates that *"ATO [as well as halogenated FR such as TBBP-A] is already included in 10 out of 13 examined companies' chemical lists of hazardous substances that should be limited or phased out, and there are examples of companies that already have phased out ATO."*

The companies' lists of some computer manufacturers confirm the restriction of ATO for all their materials: There are voluntary restrictions for ATO by Apple[129] and Dell[130].

Apple restricts ATO as well as both brominated and chlorinated compounds as flame-retardant in all materials. Here, the parallel phase-out of ATO and halogenated FR can be stated in the Apple product portfolio.[131]

Dell limits the use of ATO to mechanical plastic parts above 25 grams and for brominated/chlorinated flame-retardants as well to mechanical plastic parts; plastic parts greater than 25 grams and products designated as Halogen Free or BFR/CFR-Free. Thus, Dell restricts ATO and halogenated FR in the plastic parts and must therefore use other flame-retardants, e.g. for enclosures. However, Dell also refers to a product designation "*Halogen Free or BFR/CFR-Free*". Thus, it can be concluded that alternative flame retardants are also applicable in other components than mechanical plastic parts above 25 grams.

Samsung's[132] voluntary restriction applies to ATO in *"Mobile phones and Tablets (including accessories and chargers); MP3 players (including accessories); Digital cameras and Camcorders: Main PWB, case and internal wires; TVs: internal wires (except LCD/LED panel and PDP module); Notebooks (except power cord and adapter), Monitors: internal wires (except panel); Home theatres: internal wires."* The restrictions of brominated or chlorinated flame retardants do not cover the same list of applications as for ATO. Seemingly, a simultaneous phase out of different FR is not attempted.

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[128] Op. cit. KEMI (2015)

[129] Apple Regulated Substances Specification 069-0135-K, September 2018; https://www.apple.com/environment/pdf/Apple_Regulated_Substances_Specification_Sept2018.pdf

[130] Dell Specification, Materials Restricted for Use, Document Number: ENV0424 Revision:A03-00; https://i.dell.com/sites/doccontent/shared-content/solutions/en/Documents/ENV0424-A02.pdf

[131] Also Clariant (2020) states in its contribution: *"The transition to halogen free technologies is a challenge for the E&E industry, but it can be done as demonstrated by OEMs like e.g. Apple and Hewlett Packard."*

[132] Samsung Electronics, Standards for Control of Substances used in products (SEC Registration No. 0QA-2049), Revision 19, October 13, 2017; https://www.samsung.com/us/smg/content/dam/samsung/sg/aboutsamsung/2017/environment/pdf/standard-substances-products-en.pdf; Samsung's restriction on ATO includes various exceptions.

Clariant (2020)[133] confirms the conclusion from their experience with customers: "*Electronics brand owners (OEMs) in particular have made pledges and created roadmaps to transition to halogen free technologies. A restriction on ATO and is sole replacement is often not seen as worthwhile–if one has to re-formulate and possibly re-tool, why not go "all the way" to halogen free. An exception* [to voluntary substitution] *were periods in the last years where antimony surged in price and there was an economic incentive to substitute it"*

Furthermore, some ecolabel schemes restrict halogenated flame retardants, e.g. TCO Generation 8, for all-in-one PCs, desktops, notebooks and displays.[134] Some stakeholder argued that private organisations – such as e.g. TCO - cannot be considered as trend-setters. However, TCO as well as the European Commission (because of the EU Ecolabel) is a member of the Global Ecolabeling Network GEN that defines the ecolabel as follows: *"An ecolabel identifies products or services proven environmentally preferable overall, within a specific product or service category. […] In contrast to "green" symbols, or claim statements developed by manufacturers and service providers, the most credible labels are awarded by an impartial third party for specific products or services that have been independently determined to meet transparent environmental leadership criteria, based on life-cycle considerations."*

However, from the TCO mandate *"exempted are printed wiring board laminates, electronic components and all kinds of cable insulation."* With regard to further ecolabels that also ban halogenated substances as flame retardant and partly also as polymer, e.g. TÜV Green Product Mark Computers or EPEAT Computer & Display (IEEE); however, the formulation coverage varies. When halogenated polymers are also banned, there are exemptions e.g. for cable insulation.

The voluntary approaches mostly do not indicate the flame retardant by which ATO and the halogenated FR are substituted. The ecolabel scheme TCO Generation 8 that requires that "*non-halogenated flame retardants […] appear on the public.* The TCO Certified Accepted Substance List[135] lists ten flame retardants (Table 8-1).

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[133] Clariant (2020) Contribution submitted on 13.02.2020 during the stakeholder consultation conducted from 05 December 2019 to 13 February 2020 by Oeko-Institut in the course of the study to support the review of the list of restricted substances and to assess a new exemption request under RoHS 2 (Pack 15); https://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Pack_15/4th_Consultation_PartII/contribution_Clariant_RoHS15_ATO_20200212.pdf

[134] The Scheme requires that *"parts that weigh more than 25 grams (10 g for headsets and 5 g for smartphones) and are made mainly of plastics must not contain flame retardants or plasticizers with halogenated substances or intentionally added halogens as part of the polymer.";* TCO Generation 8 (as of 2018) for displays, notebooks, tablets, desktops, all-in-one PCs; https://tcocertified.com/certification-documents/

[135] TCO Certified Accepted Substance List, last updated: 27 May 2019: https://tcocertified.com/accepted-substance-list/

Table 8-1: Halogen-free (thus ATO-free) flame retardants according to the TCO Certified Accepted Substance List (further details on the substances in the following chapter)

Category	Entries from the TCO Certified Accepted Substance List
Metal hydroxides	• Aluminium hydroxide • Magnesium Hydroxide
Organic phosphorus- based FR	• Aluminium Diethylphosphinate • Bisphenol A diphosphate • Substituted Amine Phosphate mixture • Triphenyl phosphate • Tetrakis(2,6-dimethylphenyl)-m-phenylene biphosphate • Phenoxyphosphazene
Inorganic phosphorus-based FR	• Red Phosphorus
Siloxanes & silicones	• Siloxanes and silicones, di-Methyl, di-Phenyl, polymers with Phenylsilsesquioxanes (CAS 68648-59-9)

Source: TCO Certified Accepted Substance List, last updated: 27 May 2019: https://tcocertified.com/accepted-substance-list/

The table above shows alternatives such as halogen-free organo-phosphorus compounds (among others) as indirect alternatives to ATO which is not applied as synergist to these FR anymore. Especially for the TBBP-A/ATO combination, more alternatives are discussed in the TBBP-A dossier.

Clariant (2020)[136] states that its phosphinate based FRs are a halogen free solution and are in commercial use for:

- *“engineering plastics: standard and high temperature polyamides, polybutylene terephthalate (PBT), polyethylene terephthalate (PET), achieving Ul 94 V0 down to 0.4 mm thickness*
- *epoxy adhesive layers for flexible printed circuit boards (FCCL, base material is polyimide which does not need FR)*
- *FR4 printed circuit boards (epoxy resin base material), especially in consumer electronics these are commonly used (overall market share ca. 20%), with DOPO1and its derivatives being the dominant F epoxy adhesive layers for flexible printed circuit boards, FR4 printed circuit boards especially in consumer electronics these are commonly used (overall market share ca. 20%), with DOPO and its derivatives being the dominant FR.“*

Clariant further explains that “*Common flammability ratings are UL 94 V0 and the Glow Wire Ignition Temperature. Both are determined and defined for a certain sample thickness. Due to miniaturisation, the requested minimum thickness can go down to 0.4 mm (in some cases even 0.2 mm). Thinner parts are generally more difficult to flame retard.”* […] *We can only speak for our Clariant phosphinate product range which goes into connectors, switches etc. and flexible printed circuit boards diverse E&E end applications. Here, current stringent requirements down to 0.4 mm can be met.*”. Whereas ZVEI responses that “*up to twice as much flame-retardant additive is required to achieve* [flame retardancy according to the standards] *regarding thin wall thicknesses ≤ 0.4 mm*

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[136] Op. cit. Clariant (2020)

for halogen-free flame-retardants", which has "*considerable negative influences on the mechanical characteristics of the material*".

Clariant states that "*DuPont,*[137] *(one of the leading specialty materials companies) published a white paper on non-halogen flame retarded polymers for E&E, demonstrating the wide range of commercially available alternatives. All major other compounders like BASF, DSM, Solvay, Sabic, EMS, Lanxess, KingFa, and Changchun have similar or related offerings.*"

The above considerations allow for the conclusion, that halogen- and ATO-free FR are available and are already being applied commercially. Nevertheless, the substitution of conventional FR in EEE-parts might still be challenging, in particular for those, which are designed to support high energy loads, such as power cords and power adapters. However, in some products (e.g. display panels), economic considerations rather than technical feasibility might be the reason for not substituting FR.

Alternative technologies

An alternative technology would mean eliminating the use of both flame retardant and the synergist by e.g. the use of inherent flame-retardant materials. To this substitution possibility, Clariant (2020) stresses that "*The selection of a material for a certain part of E&E equipment starts with requirements like mechanical, electrical and appearance properties plus possibly a required flammability rating. These properties together with price determine the selection. Flame retardants are generally avoided where possible because they add cost, production complexity and a detrimental effect on e.g. mechanical properties due to the high loadings (10% ... 30% typically). Therefore, alternative technologies have only limited chances where other established solutions exist.*"[138]

Still, examples are:

Metal enclosures/housings for IT products, e.g. aluminium: This shift is done by some manufacturers especially where the application of metal enclosures has additional benefits such as higher durability in notebooks. There are notebooks with metal enclosures by e.g. Acer[139], Apple[140], Asus,[141] Dell,[142] and HP[143] with comparable prices compared to the latest developed laptops with plastic enclosures.

Inherently non-flammable polymers:

ZVEI[144] lists different inherently non-flammable polymers, such as Liquid crystal polymer (LCP), Polysulfone (PSU), Polyether sulfone (PES), Polyetherimide (PEI), Polyamide-imide (PAI). As they are all based on aromatic sub-structures, their inherent characteristics makes them difficult to combine to the requirements for the corresponding plastics, according to ZVEI.

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[137] https://www.dupont.com/knowledge/whitepaper-nhfr-polymers-for-electrical-and-electonic-components.html

[138] Op. cit. Clariant (2020)

[139] Acer Spin 5 Notebook; https://www.acer.com/ac/de/DE/content/model/NX.H62EG.001

[140] Apple MacBook Air Notebook; https://www.apple.com/de/shop/buy-mac/macbook-air
Apple Ipad (pro); https://www.apple.com/de/shop/buy-ipad/ipad-pro

[141] Asus ZenBook 14 UX431FA Notebook, https://www.asus.com/de/Laptops/ASUS-ZenBook-14-UX431FA/

[142] Dell Inspiron 13 7000 Laptop; https://www.dell.com/de-de/shop/laptops-2-in-1-pcs/inspiron-13-7000-laptop/spd/inspiron-13-7380-laptop

[143] HP SPECTRE NOTEBOOK; https://store.hp.com/GermanyStore/Merch/Offer.aspx?p=c-hp-spectre-notebook

[144] Op. cit. ZVEI (2020)

PINFA in its brochure from 2017[145] describes recent developments in the field of flame retarded thermoplastic elastomers, however, only for cable applications:

- Use of metal hydroxides in wire and cable applications, where the metal hydroxides ATH and MDH are used in polyethyl Co-vinyl Acetate (EVA)-based cable compounds that contain modified nanoclays (organoclays) so that the content of the traditional flame retardant in these compounds can be reduced.
- Thermoplastic elastomers (TPE) consist of a thermoplastic urethane as monomer and copolyesters and polyether block amide. There are different TPE types with different desired properties. *"Metal phosphinates can effectively balance mechanical properties and flame retardancy in TPEs. Polyphosphonates have also been found to perform well in TPE-E systems."*
- Thermoplastic urethanes consist of hydroxyl terminated polyesters or polyethers and diphenylmethane diisocyanate. By adding 12-15 % metal phosphinate in fine grades with nitrogen synergists or by adding formulations containing melamine cyanurate, the flame-retardant classification UL 94 V-0 is achieved. Polyphosphonates are also used in specific applications where e.g. transparency is desired, and also work synergistically with melamine cyanurate and metal phosphinate for improved flame retardancy and mechanical properties.

Other thermoplastics, e. g. polycarbonates and polyphenylenether:

The actual application of these polymers in cables is difficult to determine. The webpage of PVC4Cables, a platform of the European Council of Vinyl Manufacturers (ECVM), specifies the share of other polymer material according to a figure presented in the following. It has to be noted, however, that this covers all kinds of cables and not only low voltage cables as used in EEE. According to these figures, at least TPE is applied, though to the low percentage of 1.1 %.

ZVEI (2020) notes on their mechanical properties that due to their amorphousness, these plastics are much more susceptible to stress corrosion cracking. In addition, polycarbonates are unsuitable for thin-wall applications below 0.75mm as they do not meet flame-retardancy standards.

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[145] Pinfa (Phosphorus, Inorganic and Nitrogren Flame Retardants Association) (2017): Flame retardants in electric and electronic applications, non-halogenated phosphorus, inorganic and nitrogen (PIN) flame retardants; October 2017, 3rd edition; https://www.pinfa.eu/wp-content/uploads/2018/05/PINFA_EE_brochure_Edition_2017-11.pdf, last viewed 24.07.2018.

Figure 8-1: **Share of polymers used in cable sheeting and insulation on the European cable market 2016 according to ECVM**

PVC cables have a well-established cost/ performance track record. In 2016, PVC accounted for 46% of the EU cables market. PVC maintains its historical dominance in the low-voltage cables sector with a market share of around 70%.

Source: https://www.pvc4cables.org/en/pvc-cables/market, last viewed 17.07.2019

For plastics enclosures in EEE, the Swedish Chemicals Agency KEMI (2015) concludes that *“replacement by polymer alloys is possible, but this might lead to higher costs and still requires up to 0.5 % halogen addition (PTFE).”* UBA (2008) mentions that PC and PPE could be used as alternatives on the material level for ABS so as to eliminate the use of halogenated FR/ATO[146]. Another proposition is the substitution of currently applied housing polymers by liquid crystal polymers (LCP). As in general, also for this alternative, pros (“several very good properties”, ZVEI (2018)) and cons (“specific drawbacks” ZVEI (2018)) exist without further specification. For now, it is not yet clear to which extent housing materials used for other equipment could be suitable here.[147]

To conclude, there are alternatives on the market for some applications in EEE components based on a co-substitution of the halogenated FR with its synergist ATO.. The option of alternative technologies which basically means a substitution of the polymeric host material, though literature provides these alternatives, actual application in products recently placed on the market cannot be confirmed properly.

8.2 Hazardous properties of substitutes

In the following, the hazardous properties of the alternative synergists are depicted. Based on the information as provided in the ECHA Information on Chemicals database, the synergists zinc stannate and zinc (hydroxy)stannate are not classified as hazardous. However, there is not yet a harmonised classification.

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[146] UBA (2008) Bromierte Flammschutzmittel –Schutzengel mit schlechten Eigenschaften. (in German) https://www.umweltbundesamt.de/sites/default/files/medien/publikation/long/3521.pdf

[147] Op. cit. Morose 2006

On the contrary, zinc borate was assessed in the United States during the Green Screen Assessment of DecaBDE and alternatives and was assessed as being of high concern for genotoxicity (US EPA 2014).[148]

Table 8-2: Hazardous properties of substitutes for diantimony trioxide as a synergist

Substance (CAS)	Harmonised classification	Restrictions under REACH	Human Health and Environmental Concerns	Additional comments
Zinc stannate (12036-37-2)	None	None	According to the majority of notifications provided by companies to ECHA in CLP notifications, no hazards have been classified.	According to KEMI (2015), Zinc stannate is not classified as hazardous but the substance has been self-classified as H315 Skin Irrit. 2, Causes skin irritation, H319 Eye Irrit. 2, H335 STOT SE 3a.[149]
Zinc (hydroxy) stannate (12027-96-2)	None	None	According to the majority of notifications provided by companies to ECHA in CLP notifications, no hazards have been classified.	
Zinc borate (1332-07-6) e.g. “Firebrake”: Zinc borate oxide (Zn4(BO2)6O)	None	None	According to the classification provided by companies to ECHA in REACH registrations, this substance is very toxic to aquatic life, is toxic to aquatic life with long-lasting effects, is suspected of damaging fertility or the unborn child and causes serious eye irritation. No data available for the commercial “Firebrake”.	Under the IUPAC name zinc borate, there are several substances in the ECHA Information on Chemicals database. A green Screen Assessment by US EPA in 2014 points out a high concern for genotoxicity.

Source: ECHA Information on Chemicals database, KEMI (2015), US EPA (2014)

Stakeholders remark that the hazards of alternatives as compiled in the table above are not yet finally assessed, and that data is lacking in REACH registration dossiers for environmental and human health endpoints of concern for zinc stannate, zinc (hydroxo)stannate, and zinc borate (firebrake 415). It should be taken into account that Zinc and borate individually are known to have at least ecotoxicological properties, according to i2a.[150]

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[148] United States Environmental Protection Agency US EPA (2014): An alternatives assessment for the flame retardant Decabromodiphenyl ether (DecaBDE), Final Report, January 2014; https://www.epa.gov/sites/production/files/2014-05/documents/decabde_final.pdf, last viewed 24.07.2019

[149] i2a (2020) argues not to use references extracted from the ECHA Brief Profiles but only hazard/classification information reported in the REACH Registration Dossiers published on the ECHA website. The consultant agrees that the self-classification can also be due to e.g. impurities or additives. However in the absence of a harmonised classification, and data from a registration, reporting of self-classification is considered legitimate.

[150] Op. cit. i2a (2020)

The hazardous properties of the non-halogenated flame retardants as allowed by the TCO ecolabel scheme are compiled in the following table.

Table 8-3: Hazardous properties of alternatives to halogenated flame retardants according to TCO generation 8

Substance	CAS	Harmonised classification	Restriction under REACH	Human Health and Environmental Concerns
Aluminium Diethyl-phosphinate	225789-38-8	No harmonised classification	None	The European FP7 research project Enfiro (https://www.enfiro.eu) reached the following conclusion for this substance: low acute (eco-)toxicity and no bioaccumulation potential; limited degradation (persistence); moderate chronic aquatic toxicity According to Clariant (2020), DEPAL is the key ingredient in Clariant's Exolit OP products and has received a Green Screen Benchmark of 3, an independent, very positive rating for environmental and health profile.[151]
Aluminium hydroxide	21645-51-2	No harmonised classification	None	According to KEMI (2018), no risk to human health, data gaps concerning environmental hazards
Red Phosphorus	The CAS number does not distinguish between the white and red allotropes of elemental phosphorus	No harmonised classification	None	According to Clariant (2020) "*P4 is highly toxic [… however], red phosphorus is far less so. The Clariant product (Exolit RP 607) is labelled as: a.H228 Flammable solid.b.H317 May cause an allergic skin reaction.c.H412 Harmful to aquatic life with long lasting effects. In addition, in humid environments and at higher temperatures phosphine (PH3) gas may be formed which is toxic.*"
Bisphenol A diphosphate	181028-79-5; 5945-33-5	No harmonised classification	None	In 2012, ECHA RAC concluded to remove the harmonised classification of Aquatic Chronic 4 (May cause long-term adverse effects in the aquatic environment),[152] resulting in no classification for Bisphenol A diphosphate
Substituted Amine Phosphate mixture	66034-17-1	No harmonised classification	None	No further information found.

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[151] https://www.clariant.com/en/Corporate/Case-Studies/Flame-Retardants/Clariants-phos-phinate-flame-retardant-receives-excellent-GreenScreen-Benchmark-3-rating

[152] ECHA Risk Assessment Committee ECHA RAC (2012): Opinion proposing harmonised classification and labelling at EU level of (1-methylethylidene)di-4,1-phenylene tetraphenyl diphosphate; Bisphenol A Diphosphate; Bisphenol A Polyphosphate

https://echa.europa.eu/documents/10162/f414039f-a858-54ce-66fe-4919774e597b, last viewed 24.07.2019

Triphenyl phosphate	115-86-6	No harmonised classification	Added to CoRAP in 2013; Regulatory management option analysis (RMOA) submitted by France in 2017	According to CoRAP justification,[153] potential endocrine disruptor; RMOA due to concerns of endocrine disruption and skin sensitizer[154]
Tetrakis(2,6-dimethylphenyl)-m-phenylene biphosphate	139189-30-3	Skin Sens. 1 - H317	None	According to the harmonised classification, this substance may cause an allergic skin reaction. Additionally, the classification provided by companies to ECHA in CLP notifications identifies that this substance may cause long-lasting harmful effects to aquatic life (ECHA Brief Profile)
Siloxanes and silicones, di-Me, di-Ph, polymers with Ph silsesquioxanes	68648-59-9	No harmonised classification	None	No further information found
Magnesium Hydroxide	1309-42-8	No harmonised classification	None	According to the classification provided by companies to ECHA in CLP notifications, this substance causes serious eye irritation, causes skin irritation and may cause respiratory irritation (ECHA Brief Profile)
Phenoxyphosphazene	890525-36-7; 2791-22-2; 2791-23-3	No harmonised classification	None	No further information found

Source: KEMI (2018); European Chemicals Agency ECHA, https://echa.europa.eu

It should be highlighted that the human and environmental health hazards of the organophosphate esters differ depending on the side group of the phosphate:[155] Most non-chlorinated alkylated organophosphates are currently registered without restriction under REACH. However, some arylated organophosphates are suspected as being potential endocrine disruptors (e.g. triphenyl phosphate) and the potential to generate phosphorus sources for waste and surface water should be assessed. Moreover, Phosphorous and Phosphate-based FRs may release phosphine gas (PH3) when they are exposed to humidity and burning, which have their own high toxicity. Thus, current substance evaluations and listings of substances on the CoRAP list should carefully be considered when choosing substitutes.

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[153] UK CA (2013): Justification for the selection of a candidate CoRAP substance; https://echa.europa.eu/documents/10162/47fa7ee3-8323-4532-bb52-f1d8fe3b5ea4, last viewed 25.09.2018

[154] https://echa.europa.eu/de/rmoa/-/dislist/details/0b0236e181b00e8a

[155] Chlorinated organophosphates also belong to halogenated substances. Thus, they are not further considered.

As to be seen from the third and fourth column of Table 8-3, there are data lacking for human health and environmental implications for the other substances proposed as alternatives. Regrettable substitution should be avoided.

Campine (2020) notes in this regard, that in the Flanders Human Biomonitoring the test of 428 young people on the presence of 70 environment polluting substances showed the de decrease of harmful BFRs, whereas *"almost everybody's urine contained traces of the new generation organophosphate fire retardants, of which the effects on health is not yet investigated."*[156]

Polymers do not have to be registered under REACH; therefore no (eco-) toxicological data have to be submitted to ECHA before bringing the polymers onto the market. As a consequence, an assessment of hazardous properties of polymers mentioned in section 8.1.3 is not possible. Still, phasing out halogenated flame retardants including ATO as a synergist by using inherent inflammable polymers could be a step forward for several types of applications as far as a conclusion on the polymers' suitability is possible.

8.3 Data basis for alternatives and uncertainties

It is understood that alternatives exist and are applied in some cases. Especially the application of halogen-free enclosures – thus also ATO free – is assured because phosphorous-based flame retardants in EEE enclosures (e.g. LCD TVs) are reported to be found in the waste stream.[157] So-called front running companies or ecolabel schemes also ban halogenated substances commonly encountered in plastic parts greater than 25 grams. Still, it cannot fully be concluded whether exemptions self-set benchmarks of ecolabel schemes or companies are made due to difficulties in substitution or price considerations. As very few companies restrict halogenated substances for all materials like e.g. Apple or Dell, rather the price considerations might be the reason.

In their contributions, stakeholder specify the following applications of ATO in the field of the electrical installations for which a substitution is not possible. If diantimony trioxide were to be added to annex II, exemptions would be necessary in these areas, however, this is no exhaustive list:

- Electrical and electronic parts with thin walls, e.g. electrical and electronic connectors in home appliances, automotive etc.; ZVEI (2018 & 2020)
- Electrical and electronic parts with short distance between conductors, e.g. electrical or electronic connector with high density of pins; ZVEI (2018)
- Parts with mechanical connecting function due to the lower elongation at break, e.g. parts for installation in profile rail; ZVEI (2018)
- the hermetic sealing function needed on semi-conductors where no alternatives have been proven to be as technically performant as the ATO+BFR combination; i2a (2018).[158]
- PP-based corrugated plastic conduits; ZVEI (2020)
- some high-performance and high reliability semiconductor products with critical technology limits (e.g. networking and connectivity products); ESIA (2020)

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[156] http://www.milieu-en-gezondheid.be/sites/default/files/atoms/files/STP%20MG_Rapport%20jongerencampagne%202016-2020_gecomprimeerd.pdf (last accessed 27.03.2020) cited by op. cit. Campine (2020)

[157] Op. cit. KU Leuven (2018)

[158] i2a (Caroline Braibant) in personal communication, 18. July 2018

- ATO is used also in rubbers, paints, adhesives/sealants, and potting compounds for which exemptions may be needed for each type of use; MedTech (2020).

It needs to be taken into account that the substitution of flame-retardants may have implications on the process technologies used in the manufacturing of plastic parts: E.g. ZVEI (2020) specifies that the combination of recycled PP + non-halogenated organic FR can only be used in injection moulding technology but not in extrusion. For example, corrugated plastic conduits are manufactured by extrusion. Thus, with a change from the ATO plus halogenated FR to non-halogenated OFR, one may lose the possibility of using recycled PP for plastic components which entails impacts on the carbon footprints for such components. The same argument was also raised by Campine (2020).[159]

Especially with regard to so-called not-substitutional applications of ATO, stakeholder contributions are difficult to confirm without concrete knowledge on manufacturing processes, the way in which ATO is applied and the quantities used in this specific application. As earlier pointed out, uncertainties exist concerning the hazardous properties of polymers (and some non-halogenated alternatives) that, if they are inherently inflammable, this could entail a turning away from the need for BFR/ATO. Finally, while comprehensive search provided a list of substitutes, the actual application of these substitutes in products cannot be confirmed properly.

8.4 Conclusion on alternatives

The input provided by stakeholders illustrates application areas of ATO, where substitution is challenging. In case of a restriction of ATO, a high number of exemptions requests can be expected.

Possible alternatives for the use of ATO require a co-substitution of the halogenated flame-retardants to with which ATO is applied as a synergist. Another option would be a substitution of the polymer host material in order to avoid the use of halogenated flame-retardants in the first place. However, this option is limited to technical reasons because the properties of alternative polymers do seldomly match the technical specifications required for a given EEE application.

The actual application of substitutes in products placed on the market cannot be comprehensively recorded as the stakeholders did not provide concrete information on implemented alternatives. There are, however, evidences that substitutes are applied:

- The application of substitution is confirmed by waste stream analysis: Halogen-free enclosures – thus also ATO-free – is assured because phosphorous-based flame retardants in EEE enclosures (e.g. LCD TVs) are reported to be found in the waste stream.[160]
- Voluntary approaches phasing out ATO or explicitly halogenated flame retardants, e.g. certain ecolabel schemes or restricted substance lists of companies. Thus, they use other flame retardants in their product.

In addition to the claims by stakeholders for exemptions from a restriction, the following aspects provide a collection of hurdles for substitution according to industry contributions:

- Replacement of ATO can entail a necessity for using higher concentrations of other FR with effects on material properties, e. g. for PVC in cable insulation/ sheathing; ECVM (2020)
- Thin wall thicknesses of plastic parts require higher loadings of FR; Clariant (2020)

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[159] Campine (2020) refers to an investigation by Marc Leifert (ICL, supplier of the different flame-retardant systems, and in this regard able to compare the different solutions in detail) on the mechanical performance of the different options indicating that Brominated/ATO FR systems are ideal for reusing them in extrusion.

[160] Op. cit. KU Leuven (2018)

- In cases where fire safety is priority, “*ATO+halogen combination remains the preferred choice*” (i2a 2020); however, this might also be due to economic considerations (lower costs);
- A change to phosphorus-based compounds may have negative impact on sorting and recycling; EuRIC & EERA (both 2020)
- In addition, the number of possibilities to use recycled polymer decreases; ZVEI, Campine & i2a (all three 2020)
- Some applications allow little freedom of choice regarding the flame-retardant, for instance, in cases where the mechanical or thermal stability of the polymer depends on the flame-retardant system (i2a & MedTech, both 2020).

Regarding the substitution of the flame retardant to which ATO is a synergist, should be carefully decided on to avoid regrettable substitution.

9 DESCRIPTION OF SOCIO-ECONOMIC IMPACTS

9.1 Approach and assumptions

The scope of this assessment requires a review of possible socio-economic impacts related to a scenario in which antimony trioxide were to be added to the list of restricted substances specified in Annex II of RoHS 2. This would restrict the presence of ATO in EEE to be placed on the market in the future.

ATO is commonly used as a synergist together with halogenated flame retardants with the aim of enhancing flame retardant properties. An added value of the use of ATO in these cases is explained to be that lower quantities of the applied flame retardant can be used. In the case of a restriction, a number of substitution routes could be chosen, depending on the component in which ATO is being substituted and the level of required flame retardancy:

- Substitution of ATO with alternative synergists on the substance level;
- Phase-out of ATO at the cost of an increase in the amount of used flame retardant;
- Substitution through replacement of the applied flame retardant (elimination);

In this respect it is noted that some EEE will already be compliant with the new restriction, seeing that some OEMs already specify ATO as a restricted substance in components and materials purchased from the supply chain (see section 8.1.1) and have already completed the phase-out of ATO.

The impacts related to the phase-out of ATO depend on the substitution route as well as on the substitutes chosen. However, impacts related to ATO in use and waste management would be expected to decline (depending on the approval of possible temporary exemptions).

9.2 Impact on chemicals industry

Impacts on this industry depend on the route (see section 8.1) chosen:

- In the case of a substance substitution a parallel increase in sales of other synergists would be expected or of alternatives BFR free polymers, where the use of BFR-ATO is not required. Seeing that ATO enables a reduction in the amount of BFRs added to polymers, a restriction of ATO would entail a need to develop and test new flame retarded polymer systems. This is expected to take several years and may also necessitate considerable investments in material research.
- Should manufacturers of EEE decide to omit the use of ATO as a synergist, it is understood that larger quantities of BFRs would be necessary to establish the same levels of retardancy, increasing sales of such substances.
- Elimination of the need for ATO through the replacement of the BFR with other flame retardants shall result in an additional increase in sales of alternative flame retardants and a decrease in BFR sales. It is noted that halogenated flame retardants and non-halogenated flame retardants are not necessarily manufactured by the same producers and that this type of phase-out could lead to a shift of business between various manufacturers. In relation to BFRs it is also noted that there are only a few global locations where bromine is sourced. For example, both in Jordan and Israel, bromine is sourced from the Dead Sea. In both countries, these chemical industries provide a significant source of income and employment, while also having an impact on the surrounding

environment.[161] Therefore, reduction in the production of BFRs would also decrease such extraction.

- In the case of a substitution with inherently non-flammable polymers, ZVEI (2020) estimates the prices being at least three times as high and the availability as being limited. Another aspect is the different processing behaviour (e.g. shrinkage in plastic processing tools) so that existing tools would no longer be applicable.

9.3 Impact on EEE producers

A possible phase-out of ATO and possibly of certain halogenated flame retardants shall generate costs to the EEE industry and its suppliers. Such costs are related not only to the difference in costs between ATO and alternative synergists (or between the combination of ATO and BFRs with the replacement flame retardant), but rather also to costs of redesign, testing and implementation of relevant substitutes. As it is apparent that substitutes exist for ATO as well as for BFRs, it can be assumed that the phase-out would progress quickly in some areas, particularly where experience has been gained with alternatives through voluntary phase-out to have already taken place.

In any case, the general cost differences of such products also mean that OEMs shall view the burden of costs of a substitution differently, and this may differ between OEMs based in the more developed countries and OEMs based in less developed ones. In some areas phase-out may be more difficult. Stakeholders mention several applications of diantimony trioxide in the field of electrical installations, where it is expected that substitution is not possible. It is unclear how extensive the effort of substitution could be in these cases, however during this period, relevant industries shall need to pursue exemptions to allow further use, generating additional administrative costs in terms of requesting and accompanying the exemption evaluation process (possibly on a repeated basis, should substitution require a longer period of time). Additional administrative costs are attributed to the need to document compliance with the restriction and in some cases to test EEE for such compliance. In general, administrative costs are expected to be lower than the costs of substitution. This is based on the understanding that companies shall already have prepared similar compliance documentation in the past for parts where deca-BDE or octa-BDE were traditionally used as flame retardants.[162]

Campine (2020) note in this respect that the voluntary phase-out was initiated by some of the users because of the continuous uncertainty of the ATO status. I2a (2020) clarify that the meaning o "phase-out" refers to limiting the allowed levels of ATO in polymers to below 1000 ppm rather than a total absence of the synergist. This does not apply in many cases, which are recognised as exceptions by respective OEMs. The consultants assume however that where ATO has been phased-out, this was often also related to the decision of OEMs to phase-out brominated flame retardants. It can be assumed that if BFR were not applied, ATO would also not be needed as a synergist. I2a note that using less ATO will probably have a considerable impact on the production costs (cf. end of first paragraph of section 8.3).

Various stakeholder contributions are generally concerned of the expected increase in production costs if ATO was restricted. According to Clariant (2020) the transition to halogen free technologies is a challenge for the E&E industry. As there is no drop-in alternative, there are one-time costs for re-formulating and re-tooling. Clariant names OEMs like Apple and Hewlett Packard, that are on the

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[161] See Samuel Neaman (2007) Reclaiming the Dead Sea Alternatives for Action, available under: http://negev.ilbiz.co.il/upload_pics/English%20version%20300807%20_2_.pdf

[162] Op cit. Depa (2010)

transition path. "*Sufficient lead time is required for the industry value chain to adopt and build up the required production capacities for alternatives.*"[163]

Manufacturers from EEE Cat. 9 mention the need for a transition period of at least 10 years. TMC anticipates that the entire portfolio of products will be affected; the portfolio scale is between 2,000 to 3,000 products (average of members) with tens of thousands of products plus option combinations".[164]

As a reference to the possible costs of compliance for the medical industry, COCIR[165] specifies the costs for complying with RoHS based on past experiences. Between 2010 and 2014 costs were around 300 million euros and by 2021 they were up to 860 million euros. The cost is mostly related to labour time of skilled personnel, such as engineers, technicians and researchers. These human resources will have to be diverted from developing innovations in more valuable medical devices.

The results of MedTech Europe's survey of its members on the transition and on-going compliance costs of RoHS are estimated to be similar or possibly higher for diantimony trioxide: Transition costs for medical devices were between 0.7% and 10% of revenue/turnover, with an average of 8.4%. For IVD medical devices expenditure of revenue/turnover was between 0.1 and 0.6%, with an average of 0.42%. On-going compliance costs were calculated as between 0.01% and less than 1% of revenue/turnover for medical devices and an average of 0.007% of revenue/turnover for IVD medical devices. The cost may be higher because so many components contain this substance which are used in almost every medical electrical product.

9.4 Impact on EEE users

In many applications a phase-out of ATO can be expected to be easier on the background of a large range of substitutes already recognised. Consumers are not expected to be affected from such changes in terms of the choice of products available. As a substitution would only be expected in cases where a comparable level of flame retardancy is achieved (compliance with relevant standards) an impact is also not expected in relation to the services/properties provided to consumers from various EEE. In contrast, costs of substitution can be expected to be transferred by the EEE industry to consumers and to increase the costs or relevant EEE. As cables and PWBs are used in most EEE, such impacts cannot be expected to be focused in certain categories but to affect most EEE.

On impacts on EEE users, COCIR[166] warns of possible adverse impacts, such as:

- Medical device manufacturers may pass on compliance costs to their customers in form of higher prices;
- Redesign of products dur to ATO restriction will divert human resources from more promising medical innovations, which will delay the market readiness of new life saving technologies (see section 5.3);

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[163] Op. cit. Clariant (2020)

[164] Op. cit. TMC (2020)

[165] Op. cit. COCIR (2020)

[166] Op. cit. COCIR (2020)

- Some medical devices will have to be withdrawn from the EU market so that they are no longer available to EU hospitals and clinics. Patients would as a result have to be treated using less effective techniques (see section 5.6).

9.5 Impact on waste management

The assessment of the impact on the waste management if ATO is restricted is seen ambiguously:

- On the one hand, ATO due to its high specific density allows separating the plastic fractions obtained after shredding and sort out brominated flame-retardant plastic in the density-based sink-float sorting techniques. In this regard, ATO is considered to facilitate the recycling of WEEE by sorting out hazardous waste or waste that so far cannot be directed to recycling (see section 7.1). A restriction of ATO would also hamper this separation technique as the restriction of ATO does not necessarily lead to a non-use of brominated flame retardants; thus this waste fraction is understood to further exist and thus needs to be sorted out. This view has been supported by the waste management sector[167], who raises concerns as to whether current waste management techniques can properly deal with phosphorus-based flame retardant.
- On the other hand, BFR-ATO loaded plastics mostly undergo waste incineration, which causes a transfer of antimony, that is considered a critical raw material, in the incineration ash that is landfilled. A phase-out of ATO can be effective preventing such losses and in that sense have a positive impact in terms of resource efficiency and a shift towards a more circular economy, notwithstanding the fact that this policy strategy is not yet addressed by RoHS Article 6(1).

9.6 Impact on administration

Administrative costs for regulators can be expected on the EU as well as the national level. The EU can expect to incur one-time costs related to the amendment of Annex II with the new restriction of ATO. Additional costs may be relevant in the longer term, depending on whether exemptions would be requested and how long such exemptions would remain valid (frequency of revaluations). As for national regulators, costs related to the transition of the amendment into national legislation are also expected in the short term, while additional costs would be associated with the transposition of possible exemptions. Both I2a (2020) and Campine (2020) state that if ATO is restricted, it is very highly likely that exemptions will be requested and necessary, and that these will be necessary over a long period, with several re-evaluations.

Costs related to market surveillance can also be expected to occur on an annual basis to ensure compliance with the new regulations. The scope of such costs differs from country to country depending on the (possibly changing) level of activity of the MS in market surveillance.

9.7 Total socio-economic impact

Though various costs are associated with the phase-out of ATO, positive impacts in the waste phase, fulfilling the Article 6(1) criteria are also apparent concerning improved resource efficiency. It should also be noted that though a positive environmental impact could be expected in this respect, it needs to be evaluated whether the shift to various substitutes would not create a negative impact that would to some degree cancel such positive impacts. For example, in cases where the phase-out of ATO shall result in higher amounts of BFRs being used, a negative impact on the environment is to be expected. At present quantification of such aspects is not feasible due to lack of data, however such an analysis would assist in determining whether the possible benefits are proportional to costs.

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[167] Op. cit. EERA and EuRIC (both 2020)

Current substitute availability also suggests that in many applications, a phase-out is technically feasible, even if it is difficult to estimate the resource (time, financing) required for this change.

10 RATIONALE FOR INCLUSION OF THE SUBSTANCE IN ANNEX II OF ROHS

Diantimony trioxide is used as a synergist for halogenated flame retardants (FR), which means that the quantities of halogenated flame retardants applied in EEE can be reduced. The most relevant applications for ATO are plastics (e.g. for EEE enclosures), cable insulations and resin-based Printed Wiring Boards. Though stakeholders submitted additional information on some applications and overall quantities, there is still a lack of specific information on the current quantities of ATO placed on the European market as a constituent of EEE. It is recognised that this uncertainty is a consequence of the high variety of possible formulations following specific technical requirements.

Next to its primary function as a FR synergist, ATO is used as a gravimetric parameter in post-shredder sink-float sorting techniques during WEEE recycling. Owing to its high density, it aids the separation of plastic that contains halogenated flame retardants. It is therefore concluded that ATO facilitates WEEE management as it improves the detection and separate disposal of plastics containing halogenated FR.

With regard to risks for human health, it is concluded that workers in WEEE recycling plants are exposed to ATO especially in dismantling and shredding processes. However, the estimated potential exposure is put into perspective by measurements at operational e-recycling facilities. Although the sample size is limited in numbers, these workplace measurements are below the national occupational exposure limits. However, as ATO is suspected of being carcinogenic, there is reason to invoke the precautionary principle to intensify the monitoring of occupational exposure to ATO in recycling plants.

Although alternatives to ATO in its function as a FR-synergist are available, a mono-substitution (substituting only ATO as synergist) does not currently seem to be applied in EEE products on the market.

The application of alternatives to the combination ATO and halogenated flame retardants (co-substitution) is confirmed by waste stream analysis, which means that phosphorus-based flame-retardant plastics is found in the waste stream. Ecolabel schemes as well as voluntary industry policies demonstrate that a replacement of the system halogenated FR / synergist is feasible in some of the application areas, if not in all of them. A restriction of ATO alone could lead to so-called regrettable substitution, in other words, cause increased use of halogenated flame retardants. The increased use of halogenated FR is expected to be more harmful to human health and the environment than the net benefit of an ATO restriction. Furthermore, there are possible substitutes that are suspected to entail adverse human health impacts, e.g. some arylated organophosphates. Such regrettable substitution is to be avoided in co-substitution.

In summary, despite its suspected carcinogenic properties, **is not recommended to add diantimony trioxide to Annex II of the RoHS Directive**. The main reason is that occupational exposure limits can be met during WEEE recycling. A secondary reason is the function of ATO as a FR synergist that allows for a reduced use of halogenated FR in EEE.

10.1 Additional recommendation for a group assessment of FR-synergist systems

From the background of the aforementioned trade-offs in environmental and health effects, the consultant suggests undertaking a joint assessment of the system of halogenated flame retardants and the ATO synergist.

The group approach is supported by the RoHS methodology,[168] which states that *"a group of substances subject to assessment for potential restriction in EEE should be composed of substances sharing one or a combination of the following similarities:* […] *similar or same purpose/use/function in specific applications."* The recommended group assessment is based on the functional application purpose of these substance combinations, which is providing flame retardancy.

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[168] The methodology is available at https://rohs.exemptions.oeko.info/index.php?id=341

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12 Appendix I: Contributions to 1st stakeholder consultation held from 20 April 2018 to 15 June 2018

The following non-confidential contributions were submitted during the 1st stakeholder consultation (see also: http://rohs.exemptions.oeko.info/index.php?id=290):

> Contribution of the **Swedish Chemicals Agency (KEMI)** submitted on 11.06.2018:

>> Assessment of the risk reduction potential of hazardous substances in electrical and electronic equipment on the EU market: PDF

> Contribution of the **European Domestic Glass (EDG) and European Special Glass Association (ESGA)** submitted on 13.06.2018, PDF

> Contribution of the **Zentralverband Elektrotechnik- und Elektronikindustrie e. V. (ZVEI)** submitted on 14.06.2018: PDF

> Contribution of **MedTech Europe** submitted on 15.06.2018: PDF

> Contribution of **KU LEUVEN** submitted on 15.06.2018: PDF

> Contribution of **SPECTARIS** submitted on 15.06.2018: PDF

> Contribution of the **International Antimony Association (i2a)** submitted on 15.06.2018: PDF

> Contribution of the **Test and Measurement Coalition (TMC)** submitted on 15.06.2018: PDF

> Contribution of the **Association of Equipment Manufacturers (AEM)** submitted on 15.06.2018: PDF

> Contribution of **Europacable** submitted on 15.06.2018:

>> Part 1: PDF

>> Part 2: PDF

> Contribution of the **European Semiconductor Industry Association (ESIA)** submitted on 15.06.2018: PDF

> Contribution of the **Japanese electric and electronic (E&E) industrial associations** submitted on 14.06.2018: PDF

> Contribution of **Campine** submitted on 15.06.2018:

>> Contribution: PDF

>> Annex 1: PDF

>> Annex 2: PDF

> Contribution of the **AeroSpace and Defence Industries Association of Europe (ASD)** submitted on 14.06.2018: PDF

13 Appendix II: Contributions to 2nd stakeholder consultation hold from 05 December 2019 to 13 February 2020

The following non-confidential contributions were submitted during the 2nd stakeholder consultation (see also: https://rohs.exemptions.oeko.info/index.php?id=332):

> Contribution of the **Norwegian Environment Agency**, submitted on 27.01.2020: PDF

> Contribution of the **Japanese electric and electronic (E&E) industrial associations,** submitted on 27.01.2020: PDF

> Contribution of the **Zentralverband Elektrotechnik- und Elektronikindustrie e. V. (ZVEI),** submitted on 28.01.2020: PDF

> Contribution of **COCIR (European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry),** submitted on 28.01.2020:

>> Contribution: PDF

>> Annex 1: PDF

> Contribution of the **International Antimony Association (i2A),** submitted on 30.01.2020:

>> Cover Letter: PDF

>> Comments: PDF

> Contribution of the **Test and Measurement Coalition (TMC),** submitted on 12.02.2020: PDF

> Contribution of **MedTech Europe,** submitted on 12.02.2020: PDF

> Contribution of **EuRIC – The European Recycling Industries' Confederation,** submitted on 12.02.2020: PDF

> Contribution of **Meggitt,** submitted on 12.02.2020: PDF

> Contribution of **EUROMOT (the European Association of Internal Combustion Engine Manufacturers)** and **AEM(US Association of Equipment Manufacturers)**, submitted on 12.02.2020: PDF

> Contribution of **EERA – European Electronics Recyclers Association**, submitted on 12.02.2020: PDF

> Joint Contribution of **Digital Europe** and the **JBCE – Japan Business Council in Europe** , submitted on 13.02.2020: PDF

> Contribution of **ZEBRA Technologies,** submitted on 13.02.2020: PDF

> Contribution of the **ECVM - European Council of Vinyl Manufacturers,** submitted on 13.02.20: PDF

> Contribution of the **European Semiconductor Industry Association (ESIA),** submitted on 13.02.2020: PDF

> Contribution of **Clariant,** submitted on 13.02.2020: PDF

> Contribution of **Campine,** submitted on 13.02.2020: PDF

> Contribution of **APPLiA - Home Appliance Europe,** submitted on 13.02.2020: PDF

14 Appendix III: Research projects enabling recycling of plastic containing halogenated flame retardants and ATO

The input of Campine and i2a during the 2nd stakeholder consultation points out several research projects that aims to mechanically recycle plastics with the combination of ATO with halogens, e.g.

- Life PlasPLUS - Recycling of high-quality secondary thermoplastics and critical raw materials coming from mixed WEEE and EoL vehicles; a project in the EU funded LIFE programme: Life 18 ENV/BE/000368; https://ec.europa.eu/environment/life/project/Projects/index.cfm?fuseaction=search.dspPage&n_proj_id=7189

  The project aims to scale up a new froth flotation/triboelectricity prototype to sort flame retardant plastics and separate fibre-reinforced plastic at the Italian recycling plant of Comet Traitements plant into added-value thermoplastic streams by demonstration unit.
- A project “PLAST2bCLEANED” started recently in November 2019 (https://plast2bcleaned.eu/): The project is about chemical recycling of WEEE plastics with removal of Br and ATO.
- The “PolyStyreneLoop” targets EPS building waste contaminated with HBCD and target a chemical recycling of the polymer; the project tis funded in the EU LIFE programme and runs from 2017 until 2021; https://ec.europa.eu/environment/life/project/Projects/index.cfm?fuseaction=search.dspPage&n_proj_id=6263 and also at: https://www.ivv.fraunhofer.de/en/recycling-environment/recycling-of-contaminated-plastics/polystyreneloop.html.
- The project “CreaTor” targets to remove hazardous, already banned bromine- containing flame-retardants from waste streams using continuous purification technologies: supercritical CO2 and cost-effective solvent-based processes using natural deep eutectic solvents (NADES) in twin-screw extruders; https://www.creatorproject.eu/about/. The project is funded under the EU Horizon 2020 research and innovation programme under Grant Agreement no. 820477.
- According to Campine, there are also initiatives to alter the incineration process with energy recovering to optimise the recuperation of ATO and Br, e.g. by KULeuven.
- KULeuven (2018) on the NLPR project: Next Level Plastic recycling project funded by the Flemish government has demonstrated that: It is technically feasible to sort out plastic components based on the presence of bromine and antimony and to mechanically recycle these plastics maintaining both good mechanical and flame-retardant properties. Ongoing analysis are currently investigating the presence of deca brominated flame retardants in the waste stream of LCD TV plastics for which a pilot line to sort these plastics on a component level has recently been implemented.

15 Appendix IV: Applications mentioned by stakeholders that are not in scope of this assessment; the following uses are understood to be intermediate uses of diantimony trioxide:

- **Use as clarifying aid in certain glasses:** Contributions of European Domestic Glass (EDG) and the European Special Glass Association (ESGA)[169], of SPECTARIS[170] and of the International Antimony Association (i2a)[171] explain this to be an intermediate use in the synthesis of certain glasses with the purpose of providing specific characteristics to the glass. Accordingly, it is used to provide a specific glass with enhanced transparency by oxidizing the Iron (Fe) ions and thus prevents the color of Fe^{2+} ions. This increases the solar and light transmission. Besides the effect or optical transmission, the addition of Sb_2O_3 in the glass ingredients has an additional effect on the molten glasses in terms of improving turbidity and removing bubbles. It is also used to produce special glass inhibiting the reduction of solarisation effects. Sb ions are present, bound in the glass matrix.
- **Use as opacifying agent in functional ceramics:** According to the i2a[172] as well as the Zentralverband Elektrotechnik- und Elektronikindustrie e. V. (ZVEI)[173], diantimony trioxide is added to ceramic minerals at high temperature (800-1000°C). In the final product the antimony ions will be embedded in the ceramic matrix with ionic bonds/semi-covalent bonds to other atoms like oxygen, silicon etc., resulting in some kind of oligomeric or polymeric mixed antimony and silicon oxides. E.g. Meggitt PLC (2020)[174] uses ATO as a dopant in several different types of piezoceramics that are used in a wide variety of applications, including transducers for medical ultrasound, vibration sensors for the automotive and aerospace industry, under water acoustics and flowmeters.

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[169] European Domestic Glass (EDG) and European Special Glass Association (ESGA) (2018): Contribution submitted on 13.06.2018 during the stakeholder consultation conducted from 20 April 2018 to 15 June 2018 by Oeko-Institut in the course of the study to support the review of the list of restricted substances and to assess a new exemption request under RoHS 2 (Pack 15); http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Pack_15/1st_Consultation_Contributions/Contribution_EDG_ESGA_diantimony_trioxide_20180611_submission_on_Sb2O3.pdf, last viewed 26.06.2018

[170] SPECTARIS (2018): Contribution submitted on 15.06.2018 during the stakeholder consultation conducted from 20 April 2018 to 15 June 2018 by Oeko-Institut in the course of the study to support the review of the list of restricted substances and to assess a new exemption request under RoHS 2 (Pack 15); http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Pack_15/1st_Consultation_Contributions/Contribution_Spectaris_diantimony_180614StakeholderConsultations_Main.pdf, last viewed 26.06.2018

[171] International Antimony Association (i2a) (2018): Contribution submitted on 15.06.2018 during the stakeholder consultation conducted from 20 April 2018 to 15 June 2018 by Oeko-Institut in the course of the study to support the review of the list of restricted substances and to assess a new exemption request under RoHS 2 (Pack 15); http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Pack_15/1st_Consultation_Contributions/Contribution_i2a_diantimony_Response_ATO_20180615_FINAL.pdf, last viewed 26.06.2018

[172] Op. cit. International Antimony Association (i2a) (2018)

[173] Zentralverband Elektrotechnik- und Elektronikindustrie e. V. (ZVEI) (2018): Contribution submitted on 14.06.2018 during the stakeholder consultation conducted from 20 April 2018 to 15 June 2018 by Oeko-Institut in the course of the study to support the review of the list of restricted substances and to assess a new exemption request under RoHS 2 (Pack 15); http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Pack_15/1st_Consultation_Contributions/Contribution_diantimony_trioxide__ZVEI_Answers_RoHS_Pack_15_Fragebogen_ATO.pdf, last viewed 26.06.2018

[174] Meggitt PLC (2029): Contribution submitted on 12.02.2020 during the stakeholder consultation conducted from 05 December 2019 to 13 February 2020 by Oeko-Institut in the course of the study to support the review of the list of restricted substances and to assess a new exemption request under RoHS 2 (Pack 15); https://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Pack_15/4th_Consultation_PartII/contribution_Meggitt_RoHS15_Input_ATO_20200211.pdf

Use as catalyst in the production of PET: According to the i2a,[175] ATO is converted during the catalysis. Definitions of a catalyst usually assume that it makes a chemical reaction happen more quickly without itself being changed,[176] and the EU RAR (2008) states that the *"final concentration of diantimony trioxide in PET is typically around 180 to 220 ppm, but can be up to 550 ppm"*. However, i2a – in other press releases – refer to e.g. the study of Duh (2002)[177] that explains that *"in the commercial process, it is first dissolved in ethylene glycol (EG) at about 150°C under a nitrogen blanket to form antimony glycolate before being added to the polycondensation reactor. In small-scale lab polymerization experiments, dry* Sb_20_3 *can be directly added to the reactor at the beginning of the polycondensation stage. The* Sb_20_3 *added is readily dissolved because there is still ample free EG in the reaction mixture."* In the final PET, there remains residual Sb; according to i2a,[178] "*measurable levels of Sb would be typically present in very small (ppb or at worst in ppm*^{2}*) concentrations*".

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[175] Op. cit. International Antimony Association (i2a) (2018)

[176] See https://dictionary.cambridge.org/de/worterbuch/englisch/catalyst, last viewed at 09.05.2019

[177] Duh B. (2002): Effect of antimony catalyst on solid-state polycondensation of poly(ethylene terephthalate) Polymer. 2002; 43: 3147–3154.

[178] Op. cit. International Antimony Association (i2a) (2018)

A.5.0 Indium phosphide

Öko-Institut e.V.
Institut für angewandte Ökologie
Institute for Applied Ecology

ROHS Annex II Dossier for Indium phosphide. Restriction proposal for substances in electrical and electronic equipment under RoHS

Substance Name: Indium phosphide
EC Number: 244-959-5
CAS Number: 22398-80-7

19/05/2020

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Abbreviations

BATRRT	Best available treatment, recovery and recycling techniques
C	Concentration
CAS number	A CAS Registry Number, also referred to as CASRN or CAS Number, is a unique numerical identifier assigned by Chemical Abstracts Service (CAS) to every chemical substance described in the open scientific literature
CdSe	Cadmium Selenide
ChemSec	The International Chemical Secretariat
CLP	Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (REACH)
CMR	CMR substances are substances that are that are classified as carcinogenic, mutagenic or toxic for reproduction
CoRAP	Community Rolling Action Plan
CVD	Chemical Vapour Deposition
DNEL	Derived No Effect Levels
DWDM	Dense Wavelength Division Multiplexing
EC number	The European Community number (EC Number) is a unique seven-digit identifier that was assigned to substances for regulatory purposes within the European Union by the European Commission.
ECHA	European Chemical Agency
EEE	Electrical and electronic equipment
EWC	European Waste Catalogue
GaAs	Gallium Arsenide
HBT	Heterostructure Bipolar Transistors
HEMT	High Electron Mobility Transistors
IARC	International Agency for Research on Cancer
IMAT	Working group on Innovative Materials for Sustainable High-Tech Electronics, Photonics and Related Industries
InP	Indium Phosphide
IR	Infrared
ITO	Indium Tin Oxide
LCD	Liquid Crystal Display
LED	Light Emitting Diodes
LiDAR	Light Detection and Ranging
MMTA	Minor Metals Trade Association

MSDS	Material safety data sheet
n.d.	Not defined
OEL	Occupational Exposure Limit
OLED	Organic Light-Emitting Diode
PWB	printed wiring boards (also known as printed circuit boards)
PBT	PBT substances are substances that are Persistent, Bioaccumulative and Toxic
vPvB	vPvB substances are substances that are very Persistent and very Bio-accumulative (vPvB).
QD	quantum dots
RE	repeated exposure
REACH	Regulation (EU) No 1907/2006 on the Registration, Evaluation, Authorisation and restriction of Chemical substances
STOT	Specific target organ toxicity
Tb	Terabyte

1 CONTEXT and SCOPE of the DOSSIER / substance assessment

The substance assessment of indium phosphide is being performed as part of the "*Study on the review of the list of restricted substances and to assess a new exemption request under RoHS 2 – Pack 15*". With contract No. 07.0201/2017/772070/ENV.B.3 implementing Framework Contract No. ENV.A.2/FRA/2015/0008, a consortium led by Oeko-Institut for Applied Ecology, has been assigned by DG Environment of the European Commission to provide technical and scientific support for the review of the list of restricted substances and to assess a new exemption request under RoHS 2. This study includes an assessment of seven substances / group of substances[1] with a view to the review and amendment of the RoHS Annex II list of restricted substances. The seven substances have been pre-determined by the Commission for this task. The detailed assessment is being carried out for each of the seven substances in line with a uniform methodology which was developed as a part of this study[2].

In the course of the substance assessment, two stakeholder consultations were held to collect information and data for the seven substances under assessment. The first one was held from 20th April 2018 to 15th June 2018. The second one was held from 26th September to 7th November 2019 to provide specific data as to aspects on which data gaps still exist as well as to comment on the general interpretations made as to the current base of knowledge. Records of the consultations, including draft dossiers and stakeholder contributions, can be found at the Oeko-Institut's project webpage at: http://rohs.exemptions.oeko.info/index.php?id=289.

For indium phosphide, the 1st stakeholder consultation yielded a total of 16 contributions by different stakeholders. An overview of the contributions submitted during this consultation is provided in Appendix I. The contributions can be viewed at http://rohs.exemptions.oeko.info/index.php?id=292.

The 12 different stakeholder contributions[3] received during the 2nd stakeholder consultation, which was held from 26th September to 7th November 2019 generally expressed their agreement to the recommendation for not proposing InP for a restriction under RoHS. The contributions can be viewed at http://rohs.exemptions.oeko.info/index.php?id=334.

Several stakeholders provided information on volumes of InP that are expected to be placed on the market as part of various applications in the future. Also, an outlook on future quantum dot technologies was provided. Several sections of the dossier have been adjusted. In particular, section 2.3 on the quantities and section 6 where several references were included concerning exposure data with having implications on section 7, the risk evaluation, and 9, the socio-economic analysis. Slight changes were also undertaken in 5.3 on recycling practices and 8.1 on alternatives. The input finally led to a slightly modified Rationale in the sense of neither proposing the substance for restriction nor for a future revision of this assessment under the same scope.

A final stakeholder meeting was held on 27 April 2020 to allow stakeholders to comment on the dossiers and particularly on conclusions and recommendations. This document represents the final version of the RoHS Annex II dossier for Indium phosphide.

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[1] For the sake of better readability hereafter the term substance will be used for single substances as well as for group of substances.

[2] This methodology includes a dossier template for substance assessment which had been prepared by the Austrian Umweltbundesamt GmbH in the course of a previous study. The methodology for substance assessment has been revised based on various proposals from and discussions with stakeholders. Among others, revisions have been made to clarify when the Article 6(1) criteria are considered to be fulfilled and how the precautionary principle is to be applied. The methodology has also been updated in relation to coherence to REACH and other legislation and publicly available sources of relevance for the collection of information on substances have been updated and added. The methodology is available at https://rohs.exemptions.oeko.info/index.php?id=341

[3] Another six stakeholder provided the same report than already contributed by the working group of which they are members.

2 IDENTIFICATION, CLASSIFICATION AND LABELLING, LEGAL STATUS AND USE RESTRICTIONS

2.1 Identification

2.1.1 Name, other identifiers, and composition of the substance

Indium phosphide with its identifiers is summarised in the following table. The information was extracted from the Annex XV report on the proposal for harmonised classification and labelling of indium phosphide from France in 2009[4] and from the ECHA database information on substances.[5]

Table 2-1: Substance identity and composition of indium phosphide

Chemical name	Indium phosphide
EC number	244-959-5
CAS number	22398-80-7
IUPAC name	Indium phosphide indiganylidynephosphane phosphinidyneindium
Index number in Annex VI of the CLP Regulation	015-200-00-3
Molecular formula	InP
Molecular weight (range)	145.8 g/mol
Synonyms	See IUPAC names
Structural formula	$\mathrm{In} \equiv \mathrm{P}$
Degree of purity	No data
Remarks	-

Source: Annex XV report on the proposal for harmonised classification and labelling of indium phosphide from France (2009); ECHA information on chemicals database; https://echa.europa.eu/

2.1.2 Physico-chemical properties

Physico-chemical properties of indium phosphide are summarised in the table below and were extracted from the Annex XV report on the proposal for harmonised classification and labelling of indium phosphide from France in 2009.[6]

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[4] France (2009): Annex XV Dossier - Indium phosphide – CAS 22398-80-7; https://echa.europa.eu/documents/10162/7564f5ed-a09c-41a0-b8ee-7aebf4287c99; last viewed 25.05.2018

[5] ECHA Information on Chemicals Database: Entry for indium phosphide (2018); https://echa.europa.eu/substance-information/-/substanceinfo/100.040.856, last viewed 25.05.2018

[6] Op. cit. France (2009)

Table 2-2: Overview of physico-chemical properties of indium phosphide

Property	Value
Physical state at 20°C and 101.3 kPa	Black brittle crystals with metallic appearance
Melting/freezing point	1062°C
Boiling point	No data
Vapour pressure	No data
Water solubility	Insoluble in water (no value available). Slightly soluble in mineral acids.
Partition coefficient n-octanol/ water (log POW)	No data
Dissociation constant	No data
Vapour density relative to air	No data
Specific gravity	No data

Source: Annex XV report on the proposal for harmonised classification and labelling of indium phosphide from France (2009)

2.2 Classification and labelling status

Regulation (EC) No 1272/2008 on Classification, Labelling and Packaging (CLP)[7] ensures that the hazards presented by chemicals are clearly communicated to workers and consumers in the European Union through classification and labelling of chemicals. Annex VI of Regulation No 1272/2008 lists substances where a harmonised classification exists based on e.g. human health concerns.

Annex VI of the CLP regulation is constantly adapted by engagement of Member State Competent Authorities and ECHA where new information becomes available, where existing data are re-evaluated or due to new scientific or technical developments or changes in the classification criteria.[8]

For an explanation on the human and environmental hazards, see section 4 and 5.

2.2.1 Classification in Annex VI Regulation No 1272/2008

A harmonised classification according to Annex VI Regulation No 1272/2008 is available for indium phosphide, the classification according to Table 3.1 of Annex VI is presented in the following table. For indium phosphide, there is a harmonised classification and labelling for carcinogenicity Category 1B (H350: May cause cancer), reproductive toxicity Category 2 (H361f: Suspected of damaging fertility) and for specific target organ toxicity (repeated exposure) Category 1 (H372: Causes damage to organs through prolonged or repeated exposure. Indium phosphide induces severe effects in lungs).

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[7] Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (REACH).

[8] For further information, see https://echa.europa.eu/regulations/clp/harmonised-classification-and-labelling, last viewed 19.04.2018

Table 2-3: Classification according to part 3 of Annex VI, Table 3.1 (list of harmonised classification and labelling of hazardous substances) of Regulation (EC) No 1272/2008 for indium phosphide

Index No.	International Chemical ID	EC No.	CAS No.	Classification		Labelling			Spec. Conc. Limits, M-factors
				Hazard Class and Category Code(s)	**Hazard statement code(s)**	**Pictogram, Signal Word Code(s)**	**Hazard statement code(s)**	**Suppl. Hazard statement code(s)**	
015-200-00-3	indium phosphide	244-959-5	22398-80-7	Carc. 1B Repr. 2 STOT RE 1	H350 H361f H372 (lungs)	GHS08 Dgr	H350 H361f H372 (lungs)	-	Carc. 1B; H350: C ≥ 0.01% STOT RE 1; : C ≥ 0.1% STOT RE 2; H373: 0.01% ≤ C < 0.1%

Source: Annex VI Regulation No 1272/2008; https://echa.europa.eu/de/information-on-chemicals/annex-vi-to-clp, last viewed 19.04.2018

2.2.2 Self-classification(s)

Manufacturers, importers or downstream users have to (self-)classify and label hazardous substances and mixtures to ensure a high level of protection of human health and the environment. If a harmonised classification is available, it should be applied by all manufacturers, importers or downstream users of such substances and of mixtures containing such substances.

However, suppliers decide usually independently as to the classification of a substance or mixture, which is then referred to as self-classification. Therefore, self-classification might indicate an e.g. additional hazard, which is so far not reflected by the harmonised classification. The following assessment of the self-classification therefore only refers to cases where additional hazards were notified in the self-classification.

The ECHA database Classification and Labelling (C&L) inventory contains classification and labelling information on notified and registered substances received from manufacturers and importers. With regard to indium phosphide, there is a total number of 62 companies notifying self-classifications (so called notifiers) (as of May 2018).[9] Most notifications (60 notifiers) specify the harmonised classification of Carc. 1B (H350), STOT RE 1 (H372 (lungs)) and Repr. 2 (H361(f)). Two notifiers have a deviant classification specifying only H351 (Suspected of causing cancer).

To summarise, the various self-classifications address the same types of hazards as the harmonised classification. In some cases, the level of hazard may differ, or certain hazard types have been omitted. Given that the harmonised classification is assumed to have a higher scrutiny, the differences in the self-classification compared to the harmonised classification are not further considered.

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[9] ECHA CL Inventory: Entry for indium phosphide (2018); https://echa.europa.eu/de/information-on-chemicals/cl-inventory-database/-/discli/details/117665, last viewed 25.05.2018

2.3 Legal status and use restrictions

2.3.1 Regulation of the substance under REACH

Indium phosphide is not regulated under REACH.

Because of being classified as carcinogen category 1B, the restrictions for substances under entry 28 of REACH Annex XVII apply for indium phosphide and prohibit the supply to the general public as a substance, as mixtures or as a constituent of other mixtures. It is noted that use of the substance in EEE would generally not be considered as a supply of the substance to the general public (neither as a substance, as a mixture or as a constituent thereof).

2.3.2 Other legislative measures

Indium is listed on the 2017 list of Critical Raw Materials for the EU (COM(2017) 490 final).[10] Materials appearing on this list have been identified as critical for the EU because possible risks of supply shortage (scarcity) and their impacts on the economy are higher than those of most of the other raw materials. Additional aspects (e.g. environmental, social) are not mentioned in the communication.

2.3.3 Non-governmental initiatives

The International Chemical secretariat (ChemSec) has developed and updates the SIN List, which identifies potential substances of concern. The list is a way for putting pressure on legislators to assess and, where, relevant address substances identified therein in the future in respect to relevant chemical legislation.[11] There are a number of categories for adding substances to the SIN List, including substances that can cause cancer, alter DNA or damage reproductive systems (CMR properties); substances that do not easily break down and accumulate in the food chain (PBT/vPvB substances); and substances of equivalent concern that give rise to an equivalent level of concern in terms of potential damage to health and environment (such as substances with endocrine disrupting properties).

Indium phosphide is listed in the SIN List because it is "*classified CMR according to Annex VI of Regulation 1272/2008*."[12]

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[10] EU COM (2017), Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on the 2017 list of Critical Raw Materials for the EU, Brussels, 13.9.2017, COM(2017) 490 final, available under: http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=COM:2017:0490:FIN, last viewed 19.04.2018, last viewed 19.04.2018

[11] SIN List (2020a) What is the SIN List? https://sinlist.chemsec.org/what-is-the-sin-list/ , last viewed 26.02.2020

[12] SIN List (2020b) Entry for Indium Phosphide to finde under https://sinsearch.chemsec.org/chemical/22398-80-7, last viewed 26.02.2020

3 USE IN ELECTRICAL AND ELECTRONIC EQUIPMENT

Indium phosphide is employed in a wide variety of devices, products, and applications. Due to its semiconductor and photovoltaic properties, indium phosphide is used in a wide array of applications in optoelectronic devices, displays, high-speed electronics and photovoltaics. Typical applications of InP include e.g.:[13]

- Lasers, photo detectors and modulators used for global telecommunication networks;
- Spectroscopic analysers and LiDAR (Light Detection And Ranging) applications;
- High Electron Mobility Transistors (HEMT) and Heterostructure Bipolar Transistors (HBT) for high-speed electronic devices;
- Semiconductor quantum dots (QD) as a colour converting component of liquid crystal display backlit devices;
- Substrate for photovoltaic cells.

3.1 Function of the substance

As compared to other semiconductor materials such as silicon and gallium arsenide (GaAs), indium phosphide is generally characterised by superior electrical and thermal properties, higher electron mobility, higher frequency as well as higher thermal conductivity.

In optoelectronic appliances, InP-based active material produces light emission, detection, or modulation at wavelengths compatible with low dispersion or low loss in optical fibres, which enables much higher data rates (for a given distance) or much longer distances (for the same data rate) than can be achieved with other materials, like e.g. GaAs. Consequentially, the wafers have low power consumption and a low noise performance.[14]

With these functionalities, indium phosphide is considered to be the enabling semiconductor material for high power and/or high frequency performance electronic components and for various functionalities of optoelectronic devices. In these devices InP, as the gain medium[15] of generating infrared light, is responsible for the emission wavelength of laser chips and the detection wavelength of the photo-diodes at 1.30 µm or 1.50 µm ranges. The wavelength windows are determined by the minimum absorption windows of silica which is the key material of optical fibres used in telecommunications networks.[16] [17]

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[13] References are included in sections 2.1 and 2.2

[14] T&M Coalition (2018), Contribution of Test / Measurement Coalition submitted on 15.06.2018 during the stakeholder consultation conducted from 20 April 2018 to 15 June 2018 by Oeko-Institut in the course of the study to support the review of the list of restricted substances and to assess a new exemption request under RoHS 2 (Pack 15); http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Pack_15/1st_Consultation_Contributions/Contribution_TMC_7_Substances_response_20180615_fin.pdf, last viewed 20.12.2018

[15] A gain medium is a medium which can amplify the power of light (typically in the form of a light beam), which is needed in a laser in order to compensate for the resonator losses.

[16] Coherent (2018), Contribution of Coherent submitted on 12.06.2018 during the stakeholder consultation conducted from 20 April 2018 to 15 June 2018 by Oeko-Institut in the course of the study to support the review of the list of restricted substances and to assess a new exemption request under RoHS 2 (Pack 15); http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Pack_15/1st_Consultation_Contributions/Contribution_Coherent_Indium_phosphide_Stakeholder_Response_20180612.pdf, last viewed 20.12.2018;

[17] 3SPT (2018), Contribution of 3SPT submitted during the stakeholder consultation conducted from 20 April 2018 to 15 June 2018 by Oeko-Institut in the course of the study to support the review of the list of restricted substances and to assess a new exemption request under RoHS 2 (Pack 15); http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Pack_15/1st_Consultation_Contributions/Contribution_3SPT_Technologies_InP_1st_Stakeholder_Consultation_InP_3SPT_Participation.pdf, last viewed 20.12.2018

In the context of the RoHS directive, indium phosphide has been in the focus of discussions related to the application of quantum dot technologies in displays and in lighting. InP has been mentioned as a possible alternative for cadmium selenide in display lighting and in solid state lighting applications.[18] From past evaluations related to this application, it is further understood that the use of InP in quantum dot technologies in such products has increased.[19] In such applications, indium phosphide is used to enhance the colour gamut.[20]

3.2 Types of applications / types of materials

Basically, the application fields of indium phosphide can be classified into the following types of applications:

- Optoelectronics;
- High-speed electronics;
- Displays and lighting;
- Photovoltaic applications.

In the following these different types of applications will be briefly presented.

Optoelectronics

In optoelectronic devices indium phosphide is contained in lasers, photo detectors and modulators in the wavelength window (1550 nm) typically used for global **telecommunication networks**.[21]

These networks are operated at infrared (IR) wavelengths on the basis of dense wavelength division multiplexing (DWDM). Within this context, the properties of optical fibres are considered to be ideal for long-distance transmission with minimal loss and dispersion. The data rate of DWDM networks is in the order of terabytes/sec (Tb/s). The distance between the links may exceed 1000 km. Consequently, DWDM networks are employed world-wide for subsea and terrestrial communications

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[18] Further information is available in the evaluation report of RoHS exemption requests 2013-2 and 2013-5, available under: http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_IX/20140422_RoHS2_Evaluation_Ex_Requests_2013-1-5_final.pdf, last viewed 19.04.2018

[19] Oeko-Institut (2016), Assistance to the Commission on Technological Socio-Economic and Cost-Benefit Assessment Related to Exemptions from the Substance Restrictions in Electrical and Electronic Equipment: Pack 10 Final Report, prepared for the European Commission, DG Environment, available under: http://rohs.exemptions.oeko.info/fileadmin/user_upload/reports/20160602_Final_Report_RoHS_Pack_10_Cd_QDs_amended.pdf, last viewed 19.04.2018

[20] ANIE (2018), Contribution of ANIE submitted on 15.06.2018 during the stakeholder consultation conducted from 20 April 2018 to 15 June 2018 by Oeko-Institut in the course of the study to support the review of the list of restricted substances and to assess a new exemption request under RoHS 2 (Pack 15); http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Pack_15/1st_Consultation_Contributions/Contribution_ANIE_Federation_Indium_phosphide_20180615.pdf, last viewed 20.12.2018

[21] IMAT (2018), Contribution of IMAT submitted on 15.06.2018 during the stakeholder consultation conducted from 20 April 2018 to 15 June 2018 by Oeko-Institut in the course of the study to support the review of the list of restricted substances and to assess a new exemption request under RoHS 2 (Pack 15); http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Pack_15/1st_Consultation_Contributions/Contribution_IMAT_InP_RoHS_Consultation_20180615.pdf, last viewed 20.12.2018

networks.[22] In order to achieve the lowest attenuation available on optical fibre (about 0.26 dB/km), the light signals require a wavelength between 1510 nm and 1600 nm.[23]

Minor Metals Trade Association (MMTA) points out that telecommunication as well as data-communication systems based on InP outperform conventional systems (e.g. based on copper) in terms of energy efficiency by “several orders of magnitude”.[24]

According to IMAT,[25] concrete applications in the field of tele- and data-communication are:[26]

- Long-haul optical fibre connections over great distances up to 5000 km typically >1.25 Tb/s;
- Metro ring access networks;
- Company networks and data centre;
- Fibre optical network terminals at house connection points (so called last mile);
- Connections to wireless 3G, LTE and 5G base stations;
- Free space satellite communication.

Besides in tele- and data-communication, lasers with InP technology are also used for **sensing applications**. These refer to spectroscopic applications, where a specific wavelength is needed to interact with matter to detect certain objects, e.g. highly diluted gases. Furthermore, InP lasers are considered to be eye safe, since their radiation is absorbed in the vitreous body of the human eye and therefore cannot harm the retina. Taking this into account, another important sensing application based on InP lasers is considered to be in the field of LiDAR (Light Detection and Ranging) that may serve as the technological basis for future mobility functionalities (autonomous driving) and the automation industry.[27]

In summary, relevant examples for sensing applications are.[28]

- Gas spectroscopy for drive test equipment with real-time measurement of CO, CO_2 and NO_x;
- Stand-Off detection of traces of explosive substances on surfaces, e.g. for safety applications in airports;

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[22] Infinera (2018): Contribution of Infinera submitted on 11.06.2018 during the stakeholder consultation conducted from 20 April 2018 to 15 June 2018 by Oeko-Institut in the course of the study to support the review of the list of restricted substances and to assess a new exemption request under RoHS 2 (Pack 15); http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Pack_15/1st_Consultation_Contributions/Contribution_Infinera_InP_Questionnaire_submission_with_cover_letter_20180615.pdf, last viewed 15.07.2018

[23] Op. cit. IMAT (2018)

[24] MMTA (2018), Contribution of MMTA submitted on 15.06.2018 during the stakeholder consultation conducted from 20 April 2018 to 15 June 2018 by Oeko-Institut in the course of the study to support the review of the list of restricted substances and to assess a new exemption request under RoHS 2 (Pack 15); http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Pack_15/1st_Consultation_Contributions/Contribution_MMTA_InP_1st_Stakeholder_Consultation_Response_vf_20180615.pdf, last viewed 20.12.2018

[25] IMAT’s contribution was prepared by its Working Group on Innovative Materials for Sustainable High-Tech Electronics, Photonics and Related Industries. Several stakeholder participating in the consultation, e.g. UnitedMonolithic Semiconductors GmbH (UMS), VISHAY, AZURSpace Solar Power GmbH, Spectaris,Freiberger Compound Materials GmbH (FCM) and Fraunhofer HHI, are members of IMAT. In their individual contributions, these companies expressed their support for the comments submitted.

[26] Op. cit. IMAT (2018)

[27] Op. cit. MMTA (2018); Op. cit. IMAT (2018)

[28] Op. cit. MMTA (2018); Op. cit. IMAT (2018).

- Quick verification of traces of toxic substances in gases and liquids (including tap water) or surface contaminations with analysis capabilities at the ppb level;
- Thickness measurements of polymers;
- Spectroscopy for non-destructive product control of e.g. food (early detection of spoiled foodstuff); as well as
- LiDAR applications for autonomous driving and the automation industry.

In addition to this, MMTA considers the application of InP in professional monitoring and control equipment to be critical for the continued development, qualification and manufacture of both current and next generation communications optical/photonic fibre network applications.[29]

High-speed electronics

Devices containing InP are also used to realise high-speed microelectronics. In particular, this refers to High Electron Mobility Transistors (HEMT) or Heterostructure Bipolar Transistors (HBT), which are assembled into circuits and modules for – among others – the following applications:[30]

- Robotics: Robotic vision is essentially based on high resolution imaging radar systems at millimetre-waves;
- Radiometric sensing: Almost all air constituents and pollutions in the atmosphere show characteristic absorptions/emissions (fingerprints) in the microwave range. InP allows to fabricate small, lightweight and mobile systems to identify such substances;
- Wireless communications: High-speed 5G wireless communications will explore InP technology due to its superior performance. Such systems operate at frequencies beyond 100 GHz in order to support high data rates.

Displays and lighting

In the display industry, indium phosphide is currently applied as a possible technology for colour converting components of liquid crystal display (LCD) backlit devices, including televisions and monitors. This technology utilises semiconductor quantum dots (QD) as a colour converting material. Nanoco Technologies considers InP QDs to be a safer alternative to Cd-based (e.g. CdSe) QDs, which were the first QDs that reached the market. This assessment is substantiated by pointing out that “InP QDs are typically over-coated with one or more ‘shell’ layers of another semiconductor material, such as ZnS, then integrated into a resin matrix to form a film”.[31]

Besides display applications, Nanoco anticipates that the use of QDs in specialised LED lighting products will increase in the next few years.[32]

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[29] Op. cit. MMTA (2018)

[30] Op. cit. IMAT (2018)

[31] Nanoco (2018), Contribution of Nanoco submitted on 15.06.2018 during the stakeholder consultation conducted from 20 April 2018 to 15 June 2018 by Oeko-Institut in the course of the study to support the review of the list of restricted substances and to assess a new exemption request under RoHS 2 (Pack 15); http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Pack_15/1st_Consultation_Contributions/Contribution_Nanoco_InP_Consultation_20180615.pdf, last viewed 20.12.2018

[32] Nanoco (2019). Contribution of Nanoco submitted during the stakeholder consultation conducted from 26 Sept 2019 to 7 Nov 2019 by Oeko-Institut in the course of the study to support the review of the list of restricted substances and to assess a new exemption request under RoHS 2 (Pack 15), see the link in the annex

Photovoltaic applications

As described by IMAT, indium phosphide is also used in ultra-high performance photovoltaic cells. Modules with efficiencies of up to 46% contain InP substrates in order to achieve an optimal bandgap combination for the conversion of solar radiation into electrical energy. Also, concentrator photovoltaics (CPV) that feature lenses and curved mirrors to focus sunlight onto small, but highly efficient, multi-junction solar cells as well as solar cells for space applications use (Ga)InP and other III-V compound semiconductors[33] to achieve the required bandgap combinations. One way to significantly increase conversion efficiency also in terrestrial PV systems is the use of similar III-V solar cells in CPV systems where only about one-tenth of a percent of the area is covered by high-efficiency III-V solar cells.[34]

Based on a short literature review, the consultants assume that InP-based photovoltaic application are still in the research and development stage and have yet not reached the mass market, mainly due to cost restrictions.[35]

3.3 Quantities of the substance used

In this section, the quantities of Indium phosphide that are used in the application fields mentioned above are provided as far as available.

3.3.1 Wafers for optoelectronics and high-speed electronics

For the 1st stakeholder consultation, MMTA compiled an overview of the applications and quantities placed on the EU/EEA[36] market. The following figures were given for the annual EU/EEA consumption specified according to different application fields:[37]

- Photonic applications:
  - Fibre-optic networks, wireless base stations and satellite communications: **9-10 kg**
  - Other laser and sensor applications, LiDAR autonomous driving, vehicle emissions testing, spectroscopy analysis for food, chemical analysis: **6 kg**
- Electronic semiconductor applications:
  High speed (Terahertz) Hetero-junction Bipolar Transistors in measurement analysers and non-military radio frequency communications: **8 kg**

Based on these figures, MMTA estimates a total annual EU/EEA consumption of approximately **24 kg** of InP contained in the application clusters mentioned above. With the assumption that the EU/EEA market represents between 20-25% of the global market, a global consumption of between 96 and 120 kg per year is calculated accordingly.[38] In the second stakeholder consultation, Lumentum stated that it concurs with these numbers regarding the InP use in optical

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[33] III-V compound semiconductors are obtained by combining group III (Boron group) elements (essentially Al, Ga, In) with group V (Nitrogen group) elements (essentially N, P, As, Sb).

[34] Op. cit. IMAT (2018)

[35] https://photovoltaiksolarstrom.com/photovoltaiklexikon/indiumphosphid/ last viewed 26.02.2020

[36] As opposed to the EU market, the EEA (European Economic Area) includes the EU28 as well as Iceland, Liechtenstein and Norway. Since the quantities used in the latter counties are relatively small, the volume difference between EU28 and EEA is understood to be negligible.

[37] Op. cit. MMTA (2018)

[38] Op. cit. MMTA (2018)

communication.[39] Regarding spectroscopy analysis, Lynred indicated that "*In one year, the total mass of InP processed at Lynred is less than 2,5 kg and less than 150 g can finally be found in final products*".[40]

Additionally, MMTA points out that the amounts of InP used in military applications in laser guidance systems and THz HBT transistor semiconductors in communications and decision-making applications are considered to be far greater than uses in EEE products.[41]

Due to the lack of data from independent market research institutes or from associations related to indium phosphide (InP) the Fraunhofer Heinrich-Hertz-Institute[42] conducted a survey among all supplying manufacturers. Since nearly all manufacturers responding to the survey supplied confidential figures as to their own sales, IMAT considers the total figure of 75,000 Wafers to be a robust upper limit of the InP use at the global scale. Furthermore, IMAT estimates that 75,000 InP wafers with a 2" size equal to a total mass of 268 kg. This amount will be reduced by the process step of thinning, which is a required process to produce the individual components in a very small size. According to IMAT, in a typical product, the thickness of a wafer is reduced from ca. 375 µm to 50 – 300 µm. Moreover, the yield of marketable devices is considered to be in the dimension of less than 80%. Concerning EEE, this would result in an estimated amount of max. 134 kg of InP inside products that will come on to the global market per year. Since the share of the European market is estimated to be 25%, IMAT calculates an amount based on information provided by its members of less than **33 kg** of InP material in products in Europe. Concerning the breakdown in terms of application fields, IMAT assumes the largest portion of the total amount to go into industrial or infrastructure (telecom) applications with hardly anything reaching the consumer market.[43]

According to these numbers, currently, the opto- and high-speed electronic industry consumes ~ 24 to 33 kg InP in Europe annually.

3.3.2 Displays and lighting

Besides wafers, the use of InP in QDs for displays is currently considered to be one of the largest areas of use for this material in the EU.

Figures for the amount of InP used in this application filed is provided by Nanoco citing an IHS market research report,[44] that predicts 11.6 million Cd-free displays to be sold in 2018, resulting in sales of 10.9 million m^2 of display area of QD displays. Based on an analysis carried out by Nanoco concerning commercially available InP-based display products, the amount of InP per m^2 of display area is estimated to be up to 0.03 g. Assuming that worldwide 100% of all sold QD displays were based on InP technology, approximately 0.3 tonnes of InP would be required per year for this application. According to forecasts for 2018 that predict around 20% of global 4K TV sales to be in Europe, Nanoco estimates a total of around **60 kg** per year for Europe.[45]

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[39] Lumentum (2019). Contribution of Lumentum submitted during the stakeholder consultation conducted from 26 Sept 2019 to 7 Nov 2019 by Oeko-Institut in the course of the study to support the review of the list of restricted substances and to assess a new exemption request under RoHS 2 (Pack 15); see the link in the annex

[40] Lynred (2019). Contribution of Lynred submitted during the stakeholder consultation conducted from 26 Sept 2019 to 7 Nov 2019 by Oeko-Institut in the course of the study to support the review of the list of restricted substances and to assess a new exemption request under RoHS 2 (Pack 15); see the link in the annex

[41] Op. cit. MMTA (2018)

[42] Refered to in. IMAT (2018) as non-public. The Fraunhofer Heinrich-Hertz-Institute is member of the Working Group IMAT that submitted the contribution.

[43] Op. cit. IMAT (2018)

[44] IHS Wide Color Gamut & Quantum Dot Display Market Tracker – H1 2017, https://technology.ihs.com/api/binary/578908?attachment=true last viewed 26.02.2020

[45] Op. cit. Nanoco (2018)

Concerning future requirements, Nanoco assumes that the InP QD technology will become more mature and applicable to different display formats (e.g. mobile phones, etc.). Against this background, the number of sold display units employing this technology is said to increase (with 23.7 million units in 2021, which roughly means a doubling within only three years). Based on information provided during the 2nd stakeholder consultation, it is estimated that:

1. The current growth rate of InP QD technology with a doubling of sold units every three years will continue over the next 10 years;
2. As further assumption, the specific amount of InP required per display will not decrease;
3. This resulted in approx. **600 kg** (= 60 kg * $2^{10/3}$) of InP used in display applications per year **in Europe in 2028.**
4. No practical direct use of InP in lighting in Europe, according to OSRAM.

With the technology becoming more mature, Nanoco further expects the specific material demand to decrease in the long-term: Micro-LED technology, for example, which applies QDs “on-chip”, could potentially reduce the amount of QDs required per display by an order of magnitude. Overall, the assessments by Nanoco come to the conclusion that material usage of InP in QD display applications will increase in the short-term (3-5 years), but then decrease thereafter.[46] In the 2nd stakeholder consultation, Nanoco indicates that the firm finds the ~600 kg/annum in 2028 “a fair estimate” for InP QD use “on-layer”. Nanosys forecasts EU InP volumes will peak at approximately **190 kilograms/annum in 2027** and shall begin to decline rapidly from there, as new, ultra-efficient, quantum dot technologies are commercialised.

The use of QDs in specialised LED lighting products is expected to increase in the next few years.[47] Besides this qualitative statement by Nanoco, however, at the time of publishing of the interim report, no data was available that estimate future volumes for such applications. Therefore, the consultant assumed the following: The market share of Cd-based QDs in lighting applications which was estimated to be 5% in 2015 and causes a CdSe consumption of 8 kg, was taken as a starting point. As a further assumption, the specific amount of InP was assumed double the amount of CdSe. By 2028, the market share for Cd-based QDs in all lighting applications is estimated to reach 80 %. Subsequently, for InP this would result in approx. **265 kg** (=8 kg * 2 * 80/5) of InP used in lighting applications per year in Europe. For these market estimations, there are at least four contributions to the 2nd stakeholder consultation (Fraunhofer IAP, OSRAM, Nanoco, Nanosys) that explain why the assumption is an overestimation and that the amounts for lighting will be much lower. Contributions by Nanoco, Nanosys and OSRAM forecast the lighting market to consume very little to zero InP in the EU over the next five to ten years due to the low InP content of lighting products that are likely to be commercialised. No further quantitative data was contributed. The consultants assume that these forecasts are more representative, seeing as the contributors are acquainted with the current status of InP QD applications and its expected future developments.

In the 2nd consultation, stakeholders were asked to provide estimations to the development of the distribution of different display configurations (“on-layer”, “on-edge” and “on-chip”). Nanosys reported the “on-edge” to have been discontinued and expect the “on-chip” configuration to never be commercialised using InP QD. Also, Nanoco believes that “on-chip” technologies would be unlikely to be adopted for displays in the near future. Thus, the current and future configuration according to Nanosys is and will be “on-layer”/ ”on-surface”.

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[46] Op. cit. Nanoco (2018)

[47] Op. cit. Nanoco (2018)

To this, Nanoco and Nanosys add that new technologies can be expected: QD-OLED and QD-µLED that would have a similar configuration to “on-chip” applications with little differences (lower light density requirements and “*far higher volume of QDs will be used for colour conversion per display*”). As the QD-OLED and QD-µLED market grow, the share of “on-layer” QD displays may decrease.[48] [49] OSRAM supports “*that “on-chip” QD-LED are suitable and acceptable for the market from our current point of view. This is due to disadvantages regarding energy and material efficiency, costs and design obstacles of “on layer” and “on edge” configurations*.” According to Fraunhofer IAP, QD-OLEDs will first be ready for market from around 2021. Others are QDEF and QDEL (quantum dot Electroluminescent).[50] Nanosys sees QD-OLEDs as a bridge technology in the premium segment until QDEL would be fully commercialised. Fraunhofer IAP indicates that the commercialisation of QD-OLED and QDEL displays will strongly depend on the level of technology developments of InP-based QDs, since there are still several challenges remaining for those technologies.[51]

In its contribution, Nanoco makes a forecast for projected figures for QD-OLED/QD-µLED screens sold with corresponding QD masses used up to 2028 and thereof derives numbers for InP used in 2028: The figure of 2 tonnes was found to be a maximum amount estimate, assuming that all QD-OLED and QD-µLED displays on the EU market between 2019 – 2028 utilise InP-based QDs. However, a figure of **1.3 tonnes in 2028** may be a more realistic maximum amount estimate, again assuming that all QD-OLED and QD-µLED displays on the EU market utilise InP-based QDs. The consumption of InP would decrease if such displays did not consist only of InP-based QD but also of other types.[52] The assumption of all QD-OLED and QD-µLED displays using InP-based QDs is challenged by a statement of Nanosys[53] which forecast CdSe-based quantum dots to continue to maintain approximately 35% market share worldwide for QDEF applications.

Nanoco[54] predicts the specific amount of InP needed for lighting compared to CdSe to be lower if the industry swaps to InP-based materials. This is due to the possibility of lower material usage in the “on-chip” technology, Nanoco believes that even with an increased market share, the overall amount of QDs used in lighting applications would decrease.

3.3.3 Photovoltaic applications

Three contributions to the 2nd stakeholder consultation provided appraisals on the quantity of InP used in photovoltaic applications all attributing only little to no relevance to InP use in photovoltaic applications.[55] [56] However, no further attention will be given to these contributions as PV is not covered by the scope of the RoHS directive at the time of writing this report.

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[48] It is clear from the contributions of several stakeholders that the share of these technologies in which QD are applied shall increase on the market, However, how divided is the market between different types of QD (CeSe, InP, other …) is uncertain at present.

[49] Op. cit. Nanoco (2019)

[50] Nanosys (2019). Contribution of Nanosys submitted during the stakeholder consultation conducted from 26 Sept 2019 to 7 Nov 2019 by Oeko-Institut in the course of the study to support the review of the list of restricted substances and to assess a new exemption request under RoHS 2 (Pack 15), see the link in the annex

[51] As cited by Fraunhofer IAP (2019): Donghyo Hahm, Donghyun Ko, Byeong Guk Jeong, Sohee Jeong, Jaehoon Lim, Wan Ki Bae, Changhee Lee & Kookheon Char (2019) Environmentally benign nanocrystals: challenges and future directions, Journal of Information Display, 20:2, 61-72

[52] Op. cit. Nanoco (2019)

[53] Op. cit. Nanosys (2019)

[54] Op. cit. Nanoco (2019)

[55] Op. cit. Nanosys (2019), op. cit. Lumentum (2019)

[56] IMAT (2019), Contribution of six members of IMAT e.V (Fraunhofer HHI; UnitedMonolithic Semi-conductors GmbH (UMS); Vishay Semiconductor GmbH; AZURSpace Solar Power GmbH; Freiberger Compound Materials GmbH (FCM); Spectaris) submitted during the stakeholder consultation conducted from 26 Sept 2019 to 7 Nov 2019 by Oeko-Institut

3.3.4 Conclusion on InP quantities in total

The **total amount** of InP, entering the **European market** as a constituent of various EEE applications, is currently estimated to be **below 100 kg p.a.** For the further assessment within this report, an amount of 100 kg InP per annum in the EU is taken as a basis.

In general, from the four application areas, the quantum dots seem to be the application of InP with the most relevance for the next ten years while IMAT expect the consumption of InP in optoelectronics and in highspeed electronics “only” to double or to triple. InP applications in PV seem to be of nearly no relevance (though also not in scope of the RoHS Directive). In light of the expected developments in InP QD technologies, the consumption of InP could increase in the future. Data reported to the consultant within the 2nd Stakeholder Consultation ranges from below 200 kg p.a. to up to 2,000 kg p.a. An average of the range represented by the reported data, would account for **1100 kg p.a. in 2028.**

3.4 Potential for impacts of the substance on the environment and on health during the use of EEE

Concerning potential impacts on the environment and on human health during the use of InP applications, almost no information was provided by stakeholders.

However, MMTA points out that the InP applied in optical communication devices is being managed by professional users in large facilities, e.g. data-centres. Therefore, MMTA considers any risks during use to be managed proficiently. MMTA is confident that only negligible amounts would come into contact with consumers. If glass fibre in residential applications would become more widespread, domestic premises might contain miniscule amounts (approximately 1 mg) of InP, but the telecommunications box would remain the property of the provider and would, therefore, be managed by them.[57] Lumentum supports MMTA’s contribution.[58]

In the case of displays and lighting applications, the consumption takes place not only at the level of professional users, but also private end users. In the view of the consultant, this opens up potential impacts on a large number of consumers.

Concerning the possibility of InP emissions during the use phase of EEE, no information has been provided by stakeholders. However, since InP is not considered to be volatile it can be assumed that hardly any emission occurs due to intended use. Furthermore, InP is usually encapsulated in wafers and quantum dot substrate. Under these circumstances, the potential for emissions during the intended use of EEE appears to be negligible.

On the other hand, based on past evaluation of exemptions related to QD technologies, it can be understood that potential emissions can be expected during fire.

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in the course of the study to support the review of the list of restricted substances and to assess a new exemption request under RoHS 2 (Pack 15); see the link in the annex

[57] Op. cit. MMTA (2018)

[58] Op. cit. Lumentum (2019)

4 HUMAN HEALTH HAZARD PROFILE

The human health hazard of indium phosphide has been reviewed for the purpose of the harmonised classification. In the following the main results from the Annex XV dossier proposing the harmonised classification for indium phosphide prepared by France in 2009[59] are briefly summarised.

4.1 Critical endpoints

The substance has CMR properties as follows:[60]

Carcinogenicity: In the dossier, two cohort studies in the semiconductor industry are described: One study reports an excess of risk of melanoma and rectum cancer whereas the other study reports a significant excess of lung cancer in women and non-significant excess of stomach and breast cancer in women. Due to the limited size of the two cohorts, the limited information on exposure history and co-exposures and the lack of consistency of results between the two cohorts, it is not possible to draw a conclusion on the carcinogenic effect of indium phosphide in humans.

In animal studies, tumours of lungs, adrenal gland and other less significant tumours are induced by indium phosphide in mice, rats and hamsters. Development of tumours outside lungs after inhalation exposure suggests that the mechanism does not only rely on a local inflammatory and proliferative effect.

France (2009) concluded that indium phosphide may cause cancer, which is in line with the conclusion of the International Agency for Research on Cancer (IARC)[61] that considered indium phosphide as probably carcinogenic to humans (Group 2A) because of inadequate evidence in humans and sufficient evidence in experimental animals.

Reproductive toxicity: In an animal study, a decrease in reproductive organs is observed that was more important than the general decrease of body weight. The study provides evidence that indium phosphide induces toxic effects on the male reproductive system. Interpretation of the study is however limited by the single dose used and the absence of direct assessment of fertility function. Toxicokinetic data shows that indium can accumulate in testes after inhalation and raises a concern on potential accumulation of high concentrations due to chronic exposure. Therefore, indium phosphide was concluded as suspected of damaging fertility.

Besides the CMR properties, acute and repeated toxicity data were also reported in the dossier. The data on **repeated dose toxicity** indicated that indium phosphide causes damage to lungs by prolonged exposure through inhalation: Studies, using inhalation or intratracheal instillation, show that indium phosphide induces severe inflammation in lungs. Particles accumulate in lungs but can also be found in bronchial and mediastinal lymph nodes. Modification of the anti-oxidative potential of the cells by indium phosphide could lead to different lesions and to hyperproliferation. The proportion of the substance which passes into systemic circulation is unknown, but at higher doses, other organs can be reached, such as liver, where necrosis is observed. Severe effects (death, moribund condition and hepatic necrosis) are found in animal studies.

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[59] Op. cit. France (2009)

[60] Op. cit. France (2009)

[61] IARC International Agency for Research on Cancer (2006), to be found under http://publications.iarc.fr/104 (last accessed 10.01.2020)

4.2 Existing Guidance values (DNELs, OELs)

The Annex XV dossier does not address DNELs because of not being relevant for this type of dossier. The following occupational exposure limits for indium and indium compounds in workplace air are extracted from the IARC's Monographs on the Evaluation of Carcinogenic Risks to Humans.[62]

Table 4-1: Occupational exposure limits and guidelines for indium and indium compounds

EU country	Concentration (mg/m^3) (as indium)	Interpretation
Belgium; Finland; Netherlands; Spain Sweden	0.1	TWA (Time Weighted Average: threshold limit value based on a 8-hour workday and a 40-hour workweek)
Ireland	0.1	TWA
	0.3	STEL (Short Term Exposure Limit: threshold value based on a 15-minute average)

Source: IARC (2006)

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[62] Op. cit. IARC International Agency for Research on Cancer (2006)

5 ENVIRONMENTAL HAZARD PROFILE

There is no environmental hazard assessment available for indium phosphide. The Annex XV dossier (France 2009) did not consider environmental fate properties or hazards, since the dossier was targeted at the identification of indium phosphide as a CMR substance. As indium phosphide is not regulated under REACH, there is no information via ECHA databases available.

Additional desktop research did not reveal substantial information on environmental hazards. The database of the PubChem of the US National Library of Medicine[63] provided the following information on environmental fate: "*Monovalent and bivalent indium compounds tend to disproportionate into the trivalent compounds and indium metal; the trivalent compounds are most stable. Due to the ionic nature of indium salts, volatilization from soil surfaces will not be important.*"

Against the lack of information, further aspects (identification of hazard potential, endpoints of concern, potential for secondary poisoning and bioaccumulation, and guidance values [PNECs]) are omitted in the dossier at hand.

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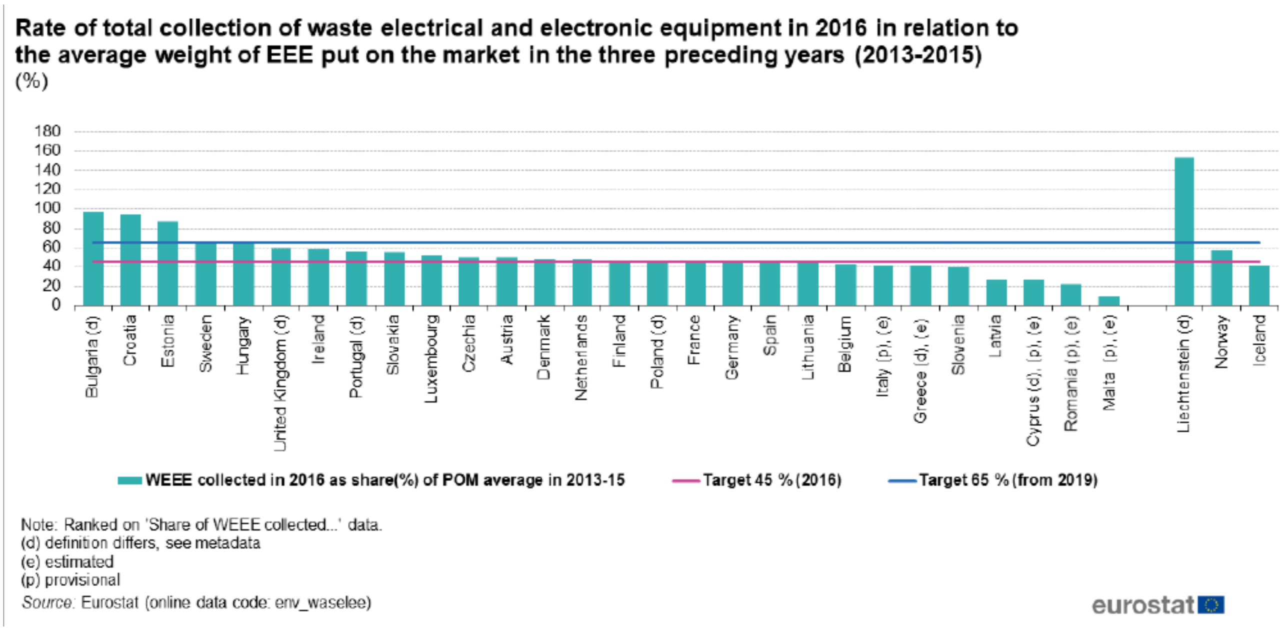
[63] PubChem of the US National Library of Medicine (2020) https://pubchem.ncbi.nlm.nih.gov/compound/Indium-phosphide, last viewed 26.02.2020

6 WASTE MANAGEMENT OF ELECTRICAL AND ELECTRONIC EQUIPMENT

As described above, within the scope of RoHS, indium phosphide is used for various applications in optoelectronics, displays and high-speed electronics. The WEEE Directive requires the separate collection and treatment of all waste EEE falling in scope of the WEEE Directive. However, not all WEEE is collected and the WEEE Directive specific target rates regarding collection only require Member States to achieve a collection rate of 55% from 2016 and of 65% by 2019.[64] Despite these targets, current data suggests that these rates are still not achieved in most Member States; on the contrary, as can be seen in Figure 6-1, in most Member States, the collection rate is considered to be below 50%.

Figure 6-1: **Total collection rate for Waste electrical and electronic equipment in 2015 as a percentage of the average weight of EEE put on the market in the three preceding years (%)**



Note: Ranked on 'Share of WEEE collected...' data.
(d) definition differs, see metadata
(e) estimated
(p) provisional
Source: Eurostat (online data code: env_waselee)

Source: Eurostat (2019)[65]

Against this background, two main scenarios have to be assessed - emissions from waste during waste treatment and emissions of waste that is not correctly disposed of. Moreover, in the last case, it also needs to be taken into account that incorrect disposal can occur in the form of municipal waste, but possibly also in the open environment including uncontrolled or diffuse release into the environment of the substance.

6.1 Description of waste streams

Indium phosphide may be contained in the following WEEE categories:

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[64] WEEE Directive, Article 7(1) further specifies: "*From 2019, the minimum collection rate to be achieved annually shall be 65% of the average weight of EEE placed on the market in the three preceding years in the Member State concerned, or alternatively 85% of WEEE generated on the territory of that Member State*".

[65] Eurostat (2019) https://ec.europa.eu/eurostat/statistics-explained/index.php?title=Waste_statistics_-_electrical_and_electronic_equipment&oldid=445263#EEE_put_on_the_market_and_WEEE_collected_in_the_EU, last viewed 26.02.2020

- Cat. 2. Screens, monitors and equipment containing screens having a surface greater than 100 cm^2, for example televisions, LCD photo frames, monitors, laptops, notebooks;
- Cat. 3. Lamps
- Cat. 4. Large equipment (any external dimension more than 50 cm), for example IT and telecommunication equipment; equipment reproducing sound or images; medical devices; monitoring and control instruments;
- Cat. 5. Small equipment (no external dimension more than 50 cm), for example equipment reproducing sound or images, medical devices; monitoring and control instruments;
- Cat. 6. Small IT and telecommunication equipment, for example mobile phones.

6.2 Applied waste treatment processes

6.2.1 Initial treatment processes applied to the WEEE containing the substance of concern

Table 6-1: Initial treatment processes applied

Initial treatment processes	**The substance is present in appliances belonging to:**					
	Cat1	Cat2	Cat3	Cat4	Cat5	Cat6
For WEEE collected separately						
Collection and transport		x	x	x	x	x
Dedicated treatment processes for cooling & freezing appliances						
Dedicated treatment processes for screens		x				
Dedicated treatment processes for lamps			x			
Manual dismantling		x		x	x	x
Shredding (and automated sorting)		x	x	x	x	x
For WEEE not collected separately						
Landfilling (of residual waste)		x	x	x	x	x
Mechanical treatment (of residual waste)		x	x	x	x	x
Incineration		x	x	x	x	x
Uncontrolled treatment in third countries		x	x	x	x	x

6.2.2 Treatment processes applied to wastes derived from WEEE containing the substance of concern

Table 6-2: Treatment processes for wastes derived from WEEE

Treatment processes for wastes derived from WEEE treatment	**The substance is present in the following main component/material**								
	Ferrous metals	Non-ferrous metals	Plastics	Electronic components	Cables	Glass	Powders	Fluids	Others
Under current operational conditions in the EU									
Storage of secondary wastes			x	x					
Shredding and automated sorting of secondary wastes			x	x					
Recycling of ferrous metals									
Recycling of NF metals				x					
Recycling of plastics			x						
Recycling of glass									
Recycling as building material									
Landfilling of residues			x	x					
Incineration of residues			x	x					
Co-incineration of residues			(x)	(x)					
Dedicated processes for hazardous residues			x	x					
Under uncontrolled conditions									
Acid leaching									
Grilling/desoldering									
Uncontrolled combustion			x	x					
Uncontrolled dumping of residues			x	x					

6.3 Waste treatment processes relevant for assessment under RoHS

In **optoelectronic and high-speed electronic applications**, most[66] InP based components are located on the populated printed wiring boards (PWB). The standard WEEE recovery process involves disassembling the hardware to where the PWB is separated from the chassis.[67]

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[66] An exemption may be QD applications besides “on-chip” technology, such as “on layer” and “on edge” configurations.

[67] Op. cit. Infinera (2018)

The WEEE Directive and implementing regulations require treatment facilities to safely recycle/dispose of WEEE hazardous wastes. Member States provide further guidance on methods to employ safe WEEE disposal.[68] Since InP components are not specifically identified in this guidance or in waste classifications of the European Waste Catalogue (EWC), Oclaro assumes that these are not removed from WEEE during pre-treatment. As a result, InP chips are expected to remain on PWB or in WEEE residues after pre-treatment.[69]

The PWBs are then shredded to recover precious metals like gold, palladium and platinum and other usable materials. According to the Lumentum company, this material is treated by specialised refiners which may apply different recovery methods:[70]

- Chemical strip of surface metals;
- Smelting to separate precious metals;
- Ball-milling and smelting to separate and recover precious metals.

In order to clarify the InP material stream during waste processing, Lumentum reached out to one of its main refiners in the USA. The inquiry came to the conclusion that the refiner was not measuring the indium content in its mixed materials nor was the refiner aware of any smelter measuring indium content or recovering indium from its material. The reason is, according to Lumentum, the relatively low market price for indium (approx. $0.30 per gram of indium versus approx. $40 per gram of gold).[71] This seems to make the indium a low priority in the eyes of a metal refiner so that specific measurements are not undertaken for the element.

Besides missing economic incentives, IMAT highlights the following reasons for low recycling possibilities of InP from WEEE:[72]

- Minor concentrations in final products;
- No specialised collection system of InP containing WEEE established;
- Lack of appropriate recycling technology;
- Moreover, indium-specific detection and separation is currently not implemented in recycling processes of secondary metal fractions from WEEE.

COCIR[73] further specifies, "*Indium is a very scarce element so that its concentration in WEEE is too low for it to be economically recovered. Most indium in WEEE is available as indium tin oxide (ITO), a transparent electrically conducting coating on displays. The quantity of indium phosphide in WEEE*

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[68] As pointed out by Oclaro Inc., for instance in the UK, the 'Best available treatment, recovery and recycling techniques' (BATRRT) needs to be considered.

[69] Oclaro (2018), Contribution of Oclaro submitted on 15.06.2018 during the stakeholder consultation conducted from 20 April 2018 to 15 June 2018 by Oeko-Institut in the course of the study to support the review of the list of restricted substances and to assess a new exemption request under RoHS 2 (Pack 15); http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Pack_15/1st_Consultation_Contributions/Contribution_Oclaro_Indium_phosphide_CAC_15062018.pdf, last viewed 20.12.2018

[70] Lumentum (2018), Contribution of Lumentum submitted on 14.06.2018 during the stakeholder consultation conducted from 20 April 2018 to 15 June 2018 by Oeko-Institut in the course of the study to support the review of the list of restricted substances and to assess a new exemption request under RoHS 2 (Pack 15); http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Pack_15/1st_Consultation_Contributions/Contribution_1_Lumentum_Indium_phosphide_Questionnaire_1st_Cons_20180615.pdf, last viewed 20.12.2018

[71] Op. cit. Lumentum (2018)

[72] Op. cit. IMAT (2018)

[73] COCIR (2019): Contribution of COCIR submitted during the 2nd stakeholder consultation conducted from 26.09.2019 to 07.11.2019 by Oeko-Institut in the course of the study to support the review of the list of restricted substances under RoHS (Pack 15). See the link in Annex II

will be much less than the amount of ITO so that it has no effect on WEEE processes and is not recoverable."

Display screens containing InP QDs are considered to be collected as consumer equipment (for TVs) or as IT and telecommunications equipment (for monitors). For the plastic components, including the QD film, Nanoco expects them to most likely either be shredded and incinerated, or to be disposed of in landfills.[74]

According to the database of the Toxicology Data Network (ToxNet) of the US National library of medicine, the US EPA stipulates solid waste containing indium phosphide may become characterised as a hazardous waste when subjected to testing for reactivity as stipulated in the Code of Federal Regulations for the identification and listing of hazardous waste (40 CFR 261.23), and if so characterised, must be managed as a hazardous waste.

Contrary to high-speed and opto-electric application, Nanosys believes that InP QDs „*would make an excellent candidate for recycling with sufficient incentives to set-up a recycling program to recycle indium content form QD displays as indium was added to the EU Critical Raw Materials list in 2017*".[75]

For **lighting equipment,** containing InP QDs information on the relevant waste treatment processes was not provided by the stakeholders. The consultant therefore assumes that roughly the same waste treatment approach as for the screens is applicable.

6.4 Releases from (relevant) WEEE treatment processes

During the **shredding process**, particulates are generated. Within this context, Infinera mentions a publication[76] by Oliveira and Margarido, whose measurements have shown the smallest particle size to be at about 0.04 mm (40 µm). Although there are exposure risks at the WEEE processing stage, Infinera assumes that this risk can be adequately managed through engineering controls and proper use of respiratory personal protection equipment. Standard respirators (e.g. N95) with HEPA[77] filters would help to reduce the wearer's inhalation exposure to airborne particulates. These respiratory filters have been tested and certified by NIOSH to be at least 95% efficient when tested against very "small" particles that are the most difficult size to filter (approximately 0.3 µm).[78] Hence, Infinera expects respiratory exposure of InP to be adequately controlled.[79]

Furthermore, Infinera points out that on-site audits conducted by its selected WEEE collection and processing company RENE AG confirm that the health and safety program at each recycler location is properly managed and maintained.[80] Furthermore, none of the particles from PWB shredding are considered to be in the nanoscale (<100 nm) intrinsic to quantum dots that are used in display technology. Since no nanoparticles are generated, Infinera argues that there is understood to be no

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[74] Op. cit. Nanoco (2018)

[75] Op. cit. Nanosys (2019)

[76] Oliveira, Paula & Taborda, Filipa & Nogueira, Carlos & Margarido, Fernanda. (2012). The Effect of Shredding and Particle Size in Physical and Chemical Processing of Printed Circuit Boards Waste. Materials Science Forum. 730-732. 653-658. 10.4028 to find under www.scientific.net/MSF.730-732.653. last viewed 26.02.2020

[77] HEPA is the abbreviation for "High Efficiency Particulate Air"

[78] US Food and Drug Administration. Masks and N95 Respirators. To find under https://www.fda.gov/medical-devices/personal-protective-equipment-infection-control/masks-and-n95-respirators last viewed 26.02.2020

[79] Op. cit. Infinera (2018)

[80] RENE AG is a German company and it is thus assumed that its statements covers recyclers in Germany and in the region.

risk of exposure to InP nanoparticles in the WEEE recovery stage attributable to PWB shredding and disassembly.[81]

When InP-based quantum dots are **burned or dissolved**, Nanoco assumes that indium and phosphorus are separated and form different compounds, such as indium oxide and phosphates, which are not classified as carcinogenic.[82]

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[81] Op. cit. Infinera (2018)

[82] Op. cit. Nanoco (2018)

7 EXPOSURE ESTIMATION DURING USE AND/OR DURING WEEE TREATMENT

7.1 Basis of exposure estimation

According to the available figures for the different application fields, the **total volume** of indium phosphide placed on the **European market** through InP applications is estimated to be **~ 100 kg p.a.** It is understood that this amount includes both applications produced within the EU as well as imported amounts of InP (see section 3.3 for more details).

In the light of its physico-chemical properties, indium phosphide is not considered to be volatile. Furthermore, based on the available information, it is not applied as a surface material, but encapsulated in wafers and quantum dots. Even though specific information regarding release rates are not available, the potential for emissions during the use of the substance appears to be very limited (see section 3.4).

7.2 Human exposure estimation

7.2.1 Exposure of workers

7.2.1.1.1 Workers in the production of InP containing EEE

Nanosys refers in its contribution to the 2nd stakeholder consultation to the exposure of workers in quantum dot manufacturing. The company explains that InP would not be an input to the InP/ZnS QD manufacturing process. Furthermore, manufacturing InP/ZnS quantum dots would not involve transporting quantities of pre-made InP through communities where there may be some risk of spillage. In the InP QD manufacturing process the InP cores would be made and encapsulated in a shell in situ before it is ultimately incorporated into a film or device.[83]

In the IARC monograph on InP [84], some exposure data is presented for workers in the semiconductor and microelectronics industry "*where workers are involved in the production of indium phosphide crystals, ingots and wafers, in grinding and sawing operations, in device fabrication and in clean-up activities.*"

7.2.1.1.2 Workers of EEE waste processing plants

In this dossier, only the possible exposure of humans related to the handling, treatment and disposal of WEEE with contents of InP is addressed. Against this background, waste from three different product types is considered:

- Waste from use in printed wiring boards of optoelectronic and high-speed electronic applications;
- Waste from display screens containing InP QDs, and
- Waste from lighting equipment containing InP QDs.

As appears from section 6.1, the total amount of InP available for potential exposure of humans in the WEEE phase are small, in the worst case a maximum of 100 kg p.a. for the applications mentioned above. Printed wiring boards of **optoelectronic and high-speed electronic applications** contain various rare and precious metals that to a large extent can be recovered at the

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[83] Op. cit. Nanosys (2019)

[84] See footnote 61

end-of-life of the products. There seems to be two main technical ways to extract the metals from the matrix:[85]

- Pyrolysis at high temperature (>1,200 ˚C) by which all the organic material will disappear leaving the metals to be extracted from the ashes, slags and possibly also collected vapour condensates;
- Shredding of the laminate from the printed wiring boards followed by extraction of the metals from the boards and disposal by incineration of the shredded laminate.

Both types of processes could lead to release to air and thereby inhalation exposure of workers. However, the potential exposure levels are assumed to be low considering that:

- The major part of InP in the EEE products is considered not to be released to the air during shredding but will remain in the product matrix until combustion / pyrolysis takes place at high temperature that destroys InP in the process (see section 7.2.3 for more details);
- Emissions of particulates can be adequately managed through engineering controls and proper use of respiratory personal protection equipment.

During shredding of **display and lighting equipment,** emissions of particulate matter are not considered to be in the nanoscale (<100 nm) intrinsic to quantum dots that are used in display technology (see section 6.4).

However, one occupational exposure study in e-waste recycling plants in Sweden[86] measured the inhalable fraction from personal air sampling of recycling workers and from static sampling representing office workers at three e-waste recycling plants in Sweden. Julander et al. (2014) analysed biomarkers from the workers and found a linear correlation between the presence of indium in the inhalable fraction and between the presence of indium in exposure biomarkers (blood, plasma and urine) as well as for other metals such as mercury, lead and also antimony. Thus, Julander et al. (2014) points out the occupational exposure to multiple metals at e-waste recycling works, even in modern plants with adequate protection routines and claims that rare metals, such as In and Sb, and not only Hg and Pb, must be monitored in these settings both in air and human samples.

7.2.2 Exposure of neighbouring residents of EEE waste processing plants

Following the considerations made above, it is concluded that the exposure levels for neighbouring residents will also be very low.

7.2.3 Consumer exposure

Due to the fact that InP is not applied as a surface material in its applications, but encapsulated in wafers and quantum dots, consumer exposure can be excluded. This is supported by a contribution of Nanosys.[87]

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[85] ECB (2006), European Union Risk Assessment Report. CAS: 79-94-7, Tetrabromobisphenol-A or TBBP-A. Part II: Human Health. European Chemicals Bureau (ECB), 2006; https://echa.europa.eu/documents/10162/32b000fe-b4fe-4828-b3d3-93c24c1cdd51 last viewed 26.02.2020

US EPA (2015), Flame retardants in printed circuit boards. Final Report, August 2015. United States Environmental Protection Agency (US EPA). Publication 744-R-15-001 under the Design for the Environment programme, available under: https://www.epa.gov/sites/production/files/2015-08/documents/pcb_final_report.pdf last viewed 26.02.2020

[86] Julander, A; Lundgren, L.; Skare, L.; Grandér M.; Palma, B.; Vahter, M.; Lidéna, C. (2014): Formal recycling of e-waste leads to increased exposure to toxic metals: An occupational exposure study from Sweden; Environment International 73 (2014) 243–251.

[87] Op. cit. Nanosys (2019)

According to COCIR[88], exposure data of consumers to indium exists but the association further explains that there are many natural and anthropogenic sources of indium so that these do not provide indication as to the exposure to InP in particular.

7.3 Environmental exposure estimation

The environmental exposure resulting from handling, treatment and disposal of WEEE from **optoelectronic and high-speed electronic materials** containing InP is considered to be low, partly because the total amount available for exposure in the WEEE phase is low (total lower that 100 kg p.a.), and partly because most of the relevant waste materials will be treated either by pyrolysis at re-cycling plants or by incineration at large municipal waste incineration plants (see previous section).

When heated to decomposition, InP may emit toxic fumes of phosphorous oxides (POx)[89] that can be removed with water. With a decomposition temperature of 380°C,[90] it is considered to be very unlikely that InP will survive pyrolysis at >1,200˚C during which printed wiring boards are destroyed by pyrolysis with the aim to recover rare / precious metals. The same is applicable for the incineration at municipal waste incineration plants where the combustion temperature reaches 850˚C.

Waste water from the cleaning of gases at municipal waste incineration plants must be treated properly to avoid pollution prior to release into the aquatic environment or pre-treated prior to discharge to the public sewerage system. In the consultants' view, the amounts of InP potentially ending up in waste water are assessed to be small as the major part will be destroyed thermally prior to cleaning of the combustion gases.

As pointed out in section 6.3, waste from **display and lighting equipment** is expected either to be shredded and incinerated, or to be disposed of in landfills. Since in most Member States, the collection rate is considered to be below 50% (see section 6), landfilling is understood to be still very relevant in many cases. Against this background, as a worst-case assumption, 60% of waste from display and lighting equipment may end up in landfilling. With InP inventories of 100 kg / year (see section 3.3), a total of 60 kg / year can be estimated for this pathway.

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[88] Op. cit. COCIR (2019)

[89] Op. cit. France (2009)

[90] Sun et al (2005); Optimised cleaning method for producing device quality InP(100) surfaces; http://www.slac.stanford.edu/pubs/slacpubs/11000/slac-pub-11018.pdf, last viewed 26.07.2019

8 IMPACT AND RISK EVALUATION

The estimated worst-case amounts of InP used for EEE applications in the EU that potentially could be released in the waste phase to the external environment in an untransformed form are assessed to be in the range 100 kg / annum, see sections 6.2 and 6.3. Consequently, the possible local occupational, residential or environmental concentrations will be very low.

Nanosys points out that because of their core-shell structure, manufactured InP/ZnS quantum dots pose a very low risk of toxicity to humans. Studies have shown that such core-shell InP/ZnS quantum dots are well-suited for in vivo use in humans. A recent study by the Center for Bio-Molecular Nanotechnologies and McGill University found that core-shell InP/ZnS posed a “very low” toxicity risk to humans and offered “good bio-compatibility”.[91]

Based on worst case exposure scenario assumptions, it is not found meaningful to try to establish specific risk assessment scenarios or perform risk evaluations for these scenarios. Based on the available information and the described worst-case assumptions, the overall assessment is that, if evaluated, the risk to humans and the environment would turn out to be very low / negligible.

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[91] Cited by Nanosys (2019): Virgilio Brunetti et al, “InP/ZnS as a safer alternative to CdSe/ZnS core/shell quantum dots: in vitro and in vivo toxicity assessment,” Nanoscale, 2013,5, 307-317

9 ALTERNATIVES

9.1 Availability of substitutes / alternative technologies

Optoelectronics

Indium phosphide, and alloys of indium phosphide with related compounds such as InGaAsP or InGaAlAs, are considered to be unparalleled for use within transmitters or receivers in fibre optic communications systems at 1.3 µm or 1.55 µm wavelength ranges.[92]

According to SMART Photonics, InP is the only direct bandgap semiconductor with a bandgap that can be tuned to emit at a wavelength range between 1,200 and 1,700 nm. This functionality is considered to be needed for optical communications > 1km to 10,000km with no substitute available for reliable lasers in this wavelength range.[93]

At some wavelengths, however, substitution of InP by other semiconductor materials appears to be possible, but according to Coherent, this would be associated with reduced performance, higher production cost, unknown reliability, etc. Gallium arsenide could be an alternative for InP in some applications that are not sensitive to the emission wavelength of the laser.[94]

As pointed out by Infinera, early in the development of optoelectronic devices for fibre-optic communications, gallium arsenide (GaAs)-based devices, which are ideally suited to 0.85 µm transmission, were tested at 1.3 or 1.5 µm. These efforts, however, ultimately failed due to high-defect density that is inherent to highly-strained or lattice-mismatched, indium-containing alloys grown on GaAs substrates. Based on these results, indium phosphide was established as the substitute for GaAs devices and apparently offered better technical performance. In the early history of optoelectronic device development, suggestions to use devices based on II-VI semiconductors[95] (such as CdZnSe) were also made but were abandoned in the 1990s due to high defect density and poor mechanical stability inherent in these materials.[96]

Moreover, Infinera mentions that some commercial suppliers of optoelectronic components operating at 1.5 µm employ a silicon-based photonics technology. However, in Si photonics, the active devices are fabricated from InP and placed on a Si substrate for integration with other optical functions. Therefore, Infinera considers Si photonics to be a viable integration technology for InP-based devices, but not to represent a substitution path for InP. The rationale for this conclusion is that silicon by itself cannot be used for lasers or direct amplification. For Infinera, silicon appears to be ideal only for simpler, single wavelength applications, and for co-packaging with active devices in the “pluggable” market for client optics and metro transponders. Likewise, optoelectronic devices emitting at other wavelengths (IR, visible, and UV) may be fabricated from other III-V materials and may find other commercial applications. Infinera concludes however, that there is no alternative available to InP for high-capacity, long-haul networks based on DWDM technology.[97]

Photodetection devices could provide the best opportunities for substitution. According to Lumentum, for this application field, germanium would be a suitable substitute when integrated with

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[92] Op. cit. Lumentum (2018)

[93] Smart Photonics (2018), Contribution of Smart Photonics submitted on 15.06.2018 during the stakeholder consultation conducted from 20 April 2018 to 15 June 2018 by Oeko-Institut in the course of the study to support the review of the list of restricted substances and to assess a new exemption request under RoHS 2 (Pack 15); find the link in the annex

[94] Op. cit. Coherent (2018)

[95] II-VI compound semiconductors are obtained by combining group II elements with group VI elements.

[96] Op. cit. Infinera (2018)

[97] Op. cit. Infinera (2018)

silicon nanowire waveguides on silicon substrates, because its lower absorption coefficient can be compensated by increased device length. However, substitution is considered to be limited to optical component architectures that edge-couple light from optical fibre to the waveguide. In contrast, normal incidence photodiode geometries, which are the most common solution at lower bitrates and which provide advantages in alignment tolerance, power handling capability, and polarisation independence, are not considered to be compatible with substitution by Ge-on-Si waveguide photodiodes.[98]

For **modulators**, Lumentum assumes that in limited cases, an alternative exists in silicon, but its application would be associated with performance limitations on bandwidth and insertion loss. This would limit substitution to applications where either the symbol rate is low (25 Gbaud), or where erbium-doped fibre amplifiers can be added in line to boost the signal, which increases the power dissipation and limits the compactness of the transceiver.[99]

Also in the **data centre** applications, silicon germanium technology has some limited functions according to MMTA, however, it is considered to be unsuccessful where there are greater distances between individual data centres.[100]

As **alternative technology**, gas lasers and solid-state lasers could be considered. As pointed out by IMAT, these alternatives would suffer significantly from performance data, such as output power, weight, size, energy consumption, life span, cooling requirements, and cost. Therefore, they could not be used in applications mentioned in section 3.2.[101]

High-speed electronics

For high-frequency electronics, InP is considered to be necessary because of its very high electron velocity. For limited applications InP, however, IMAT presumes replacement by GaAs based technologies or Silicon based technologies such as CMOS or SiGe technology.[102]

Displays and lighting

As pointed out by Nanoco, InP QD technology has been investigated and developed over a number of years as a safer alternative to Cd-based QDs. Hence, it would be difficult to substitute InP for a Cd-free material of the same functionality. One possible alternative could be CFQD® quantum dot material produced by Nanoco, which is an alloy of indium and other elements. According to Nanoco, alternative materials (e.g. $CuInS_2$ and halide perovskite QDs) are currently being investigated, but these materials do not provide the required performance for commercial applications. Nanosys also referred to such materials, pointing out that prototype displays with green halide perovskite quantum dots were presented recently.[103] Gallium arsenide would have a similar band gap to InP and has been developed as a possible substitute for some applications where the material is formed in a layer using chemical vapour deposition (CVD) or similar processes. However, the formation of colloidal QDs using GaAs has proved to be more difficult than using InP and the optical performance characteristics turned out to be significantly inferior. Nanoco expects it might be possible to develop

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[98] Op. cit. Lumentum (2018)

[99] Op. cit. Lumentum (2018)

[100] Op. cit. MMTA (2018)

[101] Op. cit. IMAT (2018)

[102] Op. cit. IMAT (2018)

[103] Op. cit. Nanosys (2019)

GaAs QDs in future, but it would take many years of research, which is currently considered not to be a significant area of focus for either academic or commercial research teams.[104]

Another option for LCDs could be inorganic phosphors. Although inorganic phosphors are considered to be cheap and relatively efficient, Nanoco assumes that they are not able to give the enhanced colour reproduction increasingly demanded by consumers. Furthermore, the increased colour filtration to improve their colour performance would lead to significantly greater energy consumption.[105]

When considering alternative display **technologies**, it needs to be considered that OLED (organic light-emitting diode) displays are well established, but they are considered to be much more expensive to manufacture in large sizes, tend to have higher power consumption and are expected not to achieve the same brightness as LCD displays.[106] Nanosys summarises that OLED provide several "unique benefits" – particularly in relation to thin form factors, low black levels and good refresh rates – but OLEDs would be "*unable to meet all of the market demands for display performance*".[107]

Concerning lighting, no explicit information concerning possible substitutes was provided by the stakeholders. However, in the view of the consultant, it appears to be reasonable that the same substitutes as for displays could also apply for lighting.

Photovoltaic applications

Also concerning lighting, no explicit information concerning possible substitutes was provided by the stakeholders. Based on a short literature review, the consultant comes to the assessment that the most relevant substitute for InP in ultra-efficient photovoltaic applications is a substrate based on GaAs.

In general

IMAT explains, that worldwide InP quantities would be so low that prices remain high: "*InP wafers are five times more expensive than GaAs wafers of the same size. […] Worldwide companies and research institutes have been looking for viable alternatives to InP for more than 30 years now. If the future brings cost-saving alternatives, industry would make use of them*."

9.2 Hazardous properties of substitutes

According to ECHA InfoCard, GaAs is classified as a Carcinogen and Reproductive toxin. Therefore, Oclaro considers GaAs to be at least as hazardous as InP.[108] IMAT agrees with this statement.[109]

Nanoco states that studies on the toxicity of InP-based QDs have concluded the material to be a safer alternative to Cd-based QDs[110]. Within this context, it is mentioned that a study performed by Brunetti et al.[111] compared the cytotoxicity of CdSe/ZnS and InP/ZnS QDs in vitro and in vivo

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[104] Op. cit. Nanoco (2018)

[105] Op. cit. Nanoco (2018)

[106] Op. cit. Nanoco (2018)

[107] Op. Cit Nanosys (2019)

[108] Op. cit. Oclaro (2018)

[109] Op. cit. IMAT (2019)

[110] Op. cit. Nanoco (2018)

[111] Quoted by Nanoco (2018) and Nanosys (2019) as: V. Brunetti, H. Chibli, R. Fiammengo, A. Galcone, M.A. Malvindi, G. Vecchio, R. Cingolani, J.N. Nadeau and P.P. Pompa, Nanoscale, 2013, 5, 307

(Drosophila). It was concluded in this study that InP/ZnS core/shell QDs provided a “safer alternative” to CdSe/ZnS QDs for biological applications. Cd^{2+} ions were shown to leach from the core of the QDs, despite a two-monolayer ZnS shell. The CdSe/ZnS QDs were observed to induce cell membrane damage, conditions of oxidative stress in the cells, damage of the genetic material and interference with Ca^{2+} homeostasis, which can be mainly ascribed to the presence of Cd^{2+}. Since an almost identical amount of In^{3+} ions leached from the InP/ZnS QDs, the results suggest that In-based QDs have a much lower intrinsic toxicity than Cd-based QDs.[112]

Taking into account the information of the hazardous properties given above as well as the CLP classification[113] of GaAs, the consultants can follow the assessment of Oclaro and Nanoco that GaAs is at least as hazardous as InP.

9.3 Data basis for alternatives and uncertainties

It is understood that material alternatives do exist, but they appear to be very limited to certain fields of application. For example, germanium-based substitutes are mentioned to be feasible in photo detection devices[114]. Also alternative technologies (e.g. gas lasers / solid state lasers in optoelectronics and OLED in displays / lighting application) can be considered, but are characterised to suffer significantly from reduced performance data, as well as higher energy consumption.[115]

The information specified above regarding alternatives for indium phosphide originates from various documents generated also in the context of the REACH and CLP regulations. Such documents are understood to have been subject to scrutiny and to have a relatively high certainty.

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[112] See footnote 111

[113] The CLP classification of GaAs includes: ‘Carc. 1B’, ‘Repr. 1B’, STOT RE 1 (respiratory and haematopoietic systems); ‘Repr. 1B’ is higher (‘danger, may cause...’) than ‘Repr. 2’ (‘warning, suspected of...’); furthermore, the specific target organ toxicity of GaAS has also has a wider scope than just lungs.

[114] Op. cit. Lumentum (2018)

[115] Op. cit. IMAT (2018); Op. cit. Nanoco (2018)

10 DESCRIPTION OF SOCIO-ECONOMIC IMPACTS

10.1 Approach and assumptions

The scope of this assessment requires a review of possible socio-economic impacts related to a scenario in which indium phosphide as the substances under assessment was to be added to the list of restricted substances specified in Annex II of RoHS 2. This would restrict the presence of these substances in EEE to be placed on the market in the future.

In lack of quantitative data in many areas of the assessment, the following sections provide mostly provide a qualitative estimation as to possible impacts.

10.2 Impact on chemicals industry

As pointed out by IMAT, InP is produced and sold as a wafer by a very small number of companies worldwide representing at least 90% of the market. Producers of InP wafers are e.g.:[116]

- AXT, USA/China
- InPACT, France
- JX Nippon Mining and Metals Corporation, Japan
- PamXiam, China
- Sumitomo, Japan
- Vital Materials, China
- Wafer Technology, United Kingdom

InPACT, for example, according to own data the “largest Western producer” of InP substrates, is dedicated exclusively to InP.[117] Due to this specialisation, it can be assumed that a restriction of InP would have a significant impact on the continued existence of this company and, if applicable, the entire industry.

10.3 Impact on EEE producers

It is understood that InP is used as an enabling material in products with high value creation, such as global telecommunication networks (see section 3.2 for more details).

As pointed out by MMAT, European companies contribute to a global market volume of 25 billion Euros in the field of optical networking equipment and components, which supports a nearly 3 trillion Euros global industry in telecommunications services.[118]

According to SMART Photonics, the market for InP transceivers alone is estimated to be close to 10 billion Euros p.a., of which “a significant part” is produced in Europe.[119] Concerning InP based high-speed and optoelectronic hardware, IMAT estimates the market share of European manufactures to reach approximately 25% of the world market.[120]

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[116] Op. cit. IMAT (2018)

[117] See http://www.inpactsemicon.com/companyoverview.php, last viewed 26.02.2020

[118] Op. cit. MMAT (2018)

[119] Op. cit. Smart Photonics (2018)

[120] Op. cit. IMAT (2018)

On the level of individual enterprises, Oclaro states that "the majority" of the company's income is reliant on InP technology. In particular, the growth of the company and the related employment depends on the use of InP.[121]

3SPT states that the company would have to discontinue its semiconductor laser diode manufacturing activity in the range between 1.3 - 1.5 µm if indium phosphide would be restricted under RoHS; this would affect a turnover of more than 10 million Euros.[122]

Lynred, which explained that InP is used in its manufacturing process of InGaAs infrared detectors, a significant part of the company turnover, stated that "*40 jobs are full or partially directly concerned by InP-based activities (excluding subcontractors and suppliers)*". It is assumed that this statement refers only to jobs of employees within the company.[123]

In general, as pointed out by Nanoco, a restriction of InP entails the development of QD based on non-regulated material or new (non-QD) technologies, both involving "*significant investment of time and cost*".[124]

10.4 Impact on EEE users

Regarding the impact on EEE users, it is pointed out by Infinera[125] that elimination of InP would have serious consequences regarding the costs for long-haul (>100 km) communications networks. Alternative network technologies and architectures would be required that are expected to cause a substantial increase in the number of network nodes in a terrestrial network, with each node consisting of short-haul optical transmission equipment (GaAs-based optoelectronic devices communicating over linkages of <10 km) operating with plastic optical fibre (to be installed between nodes).

With information provided by Infinera[126], alternative laser technologies (e.g. based on GaAs) additional lasers will be required to provide the current network capabilities. The purchase of these GaAs lasers as well as the associated modules is considered to be more expensive. Additionally, these components will cause higher power consumption and the resulting hardware will also require more rack space in data centres. Based on Infinera's calculations, a network using GaAs technology will be five times more expensive than current networks with InP lasers. Furthermore, this technology would cause five times more energy demand that InP based networks and it would require five times more rack space in data-centres.

Moreover, IMAT assumes that in case of a restriction of InP the quality of infrastructure for data communication would be influenced drastically both for industry and private consumers.[127] Data market studies cited by LUMENTUM illustrate "*socio-economic losses by preventing the digital economy from growing if InP use was banned*." According to these figures, the losses in the big data market – where the supporting optical communication technology relies on InP based components – ranges from 27 to 107 billion Euro in the EU 27 by 2025.[128]

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[121] Op. cit. Oclaro (2018)

[122] Op. cit. 3SPT (2018)

[123] Op. cit. Lynred (2019)

[124] Op. cit. Nanoco (2019)

[125] Op. cit. Infinera (2018)

[126] Op. cit. Infinera (2018)

[127] Op. cit. IMAT (2018)

[128] Op. cit. Lumentrum (2019)

Regarding the maintenance and repair of existing equipment IMAT further points out that replaced components should have the same properties in order to guarantee the functionality of a device. However, if adequate spare parts would no longer be available due to a restriction of InP the entire device had to be scrapped.[129]

Concerning display applications, Nanoco expects the risk of a market gap if QD manufacturers are no longer able to use InP. Until new materials or technologies become market-ready, display technology would not deliver the expected performance for the consumers. This may require higher operating costs if the device efficiency is reduced. The alternative QD material options, Cd-based and Pb-based material, have the potential for being released, e.g. in case of a house fire, so that consumers could be exposed to Cd or Pb.[130]

10.5 Impact on waste management

The various methods for treating relevant EEE waste are not understood to be a result of the use of InP. Hence it is assumed that for the most part, substitutes of InP would be similar in relation to the risk of exposure, and thus it is assumed that the waste management practices would not change. However, if Cd- or Pb-based alternatives are allowed via exemptions, "*these may have additional disposal considerations compared to InP, in order to ensure that these metals do not leach into the environment*".[131] Similarly, the main motivation for waste treatment of PWBs is understood to be the recovery of various metals. Here too the change in the use of InP is not expected to change the waste management methods. EEE containing alternative material QDs is likely to be recycled the same way as those currently used for InP QD.

10.6 Impact on administration

A change in regulation always results in a certain burden of compliance, in terms of administration of the legal change of the Directive and its transposition to national law of EU countries. If the transition period provided for the regulation change would not suffice to accompany the phase-out, it is possible that some exemptions may be requested from the substance restrictions and that these would have a further administrative burden.

In the case of a restriction of a chemical substance, further administrative costs can be expected to incur in relation to enforcement of the new restrictions and the need to adapt and to operate market surveillance of compliance.

10.7 Total socio-economic impact

As explained at the onset of this chapter, the small amounts of InP potentially present in EEE products raises doubt as to the effectiveness of a possible restriction and thus as to the incurrence of actual impacts. Should a restriction be introduced, significant cost-related impacts could be expected, especially for EEE manufacturers and users. Due to the fundamental role of InP especially in the area of telecommunication, these impacts could also not be softened by longer transition period for a restriction of InP.

In addition, a restriction of InP is also not expected to generate benefits for the environment or for health (in the form of prevention of possible impacts tied with InP as a substance in general and particularly during the use and waste phase of interest for RoHS 2 Article 6(1)). The main reason for

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[129] Op. cit. IMAT (2018)

[130] Op. cit. Nanoco (2018) & (2019)

[131] Op. cit. Nanoco (2019)

this assessment can be seen in the fact that in terms of total socio-economic impacts, the potential alternatives (GaAS for optoelectronic devices and Cd-based QD for displays / lighting) are not expected to have a better environmental performance than InP (see section 9.2). This suggests that a restriction of the two substances would not be proportionate, given that its costs are not expected to generate benefits for the environment or for health.

11 RATIONALE FOR INCLUSION OF THE SUBSTANCE IN ANNEX II OF ROHS

Based on the available information, it can be expected that the quantities of indium phosphide used in its main areas of application (optoelectronics, high-speed electronics, displays and lighting as well as photovoltaic applications) currently do not exceed 100 kg / year. For the time being, the estimated worst-case amounts of InP used for EEE applications in the EU that potentially could be released in the waste phase to the external environment in an untransformed form are estimated to be below 100 kg / year.

With regard to the currently available substitutes, a restriction of InP is not expected to generate substantial benefits for the environment or for health, since potential alternatives (especially GaAS for optoelectronic devices and Cd-based QD for displays / lighting) are not considered to have a better environmental performance than InP.

Should a restriction be introduced, however, significant cost-related impacts could be expected, especially for EEE manufacturers and users. Due to the fundamental role of InP especially in the area of data transfer and telecommunication, these impacts could have a substantial negative impact on Europe´s economy as a whole.

Against this background, it is **currently not recommended to pursue a restriction under the RoHS Directive of indium phosphide**.

However, there are relevant hints that the consumption of InP may increase significantly in the future. Especially the use of InP-based QD technology in displays and LED lighting equipment is expected to become a major driver in this respect. Taking into account worst case assumptions, total quantities of use of up to 2,000 kg / year cannot be excluded by 2028 (see section 3.3 for more details).

InP is at least as hazardous as GaAs and has a comparable use and toxicological profile. Based on the 10-100 tons REACH dossier of GaAs, which concluded that risks to human health and environment are irrelevant, the consultants assume that this applies also to the use of InP, even if the quantities of InP would increase up to the maximum estimate for 2028.

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13 Appendix I: Contribution to stakeholder consultation hold from 20 April 2018 to 15 June 2018

The following non-confidential contributions were submitted during the 1st stakeholder consultation (see also: https://rohs.exemptions.oeko.info/index.php?id=292)

> Contribution of **Coherent,** submitted on 12.06.2018: pdf

> Contribution of the **3SPT Technologies,** submitted on 14.06.2018: pdf

> Contribution of **Infinera,** submitted on 11.06.2018: pdf

> Contribution of **Lumentum,** submitted on 15.06.2018:

>> Contribution: pdf

>> Annex: pdf

> Contribution of the **Minor Metals Trade Association (MMTA),** submitted on 15.06.2018: pdf

> Contribution of **OCLARO,** submitted on 15.06.2018: pdf

> Contribution of **MedTech Europe,** submitted on 15.06.2018: pdf

> Contribution of **Freiberger Compound Materials GmbH (IMAT),** submitted on 15.06.2018: pdf

> Contribution of **Nanoco Technologies Ltd,** submitted on 15.06.2018: pdf

> Contribution of the **SMART Photonics,** submitted on 15.06.2018: pdf

> Contribution of the **Test and Measurement Coalition (TMC),** submitted on 15.06.2018: pdf

> Contribution of **ANIE Federazione,** submitted on 15.06.2018: pdf

> Contribution of the **Association of Equipment Manufacturers (AEM),** submitted on 15.06.2018: pdf

> Contribution of the **Japanese electric and electronic (E&E) industrial associations,** submitted on 14.06.2018: pdf

> Contribution of the **AeroSpace and Defence Industries Association of Europe (ASD),** submitted on 14.06.2018: pdf

> Contribution of the **Institute of Photonic Integration Technical University Eindhoven (TUE),** submitted on 15.06.2018: pdf

14 Appendix II: Contributions to stakeholder consultation hold from 26 September 2019 to 07 November 2019

The following non-confidential contributions were submitted during the 2nd stakeholder consultation (see also https://rohs.exemptions.oeko.info/index.php?id=334):

> Contribution of **COCIR (European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry),** submitted on 22.10.2019: PDF

> Contribution of **Nanoco Technologies Ltd,** submitted on 01.11.2019: PDF

> Contribution of the **Japanese electric and electronic (E&E) industrial associations** submitted on 06.11.2019: PDF

> Contribution of **Nanosys**, submitted on 06.11.2019: PDF

> Contribution of **IMAT e.V.**, submitted on 07.11.2019: Cover letter: PDF; Contribution: PDF

> Contribution of **Fraunhofer IAP**, submitted on 07.11.2019: PDF

> Contribution of **Fraunhofer HHI**, submitted on 07.11.2019: PDF

> Contribution of **UnitedMonolithic Semiconductors GmbH (UMS**), submitted on 07.11.2019: Cover letter: PDF; Contribution: PDF

> Contribution of **Digital Europe**, submitted on 07.11.2019: PDF

> Contribution of **The European Semiconductor Industry Association (ESIA)**, submitted on 07.11.2019: PDF

> Contribution of **Vishay Semiconductor GmbH**, submitted on 07.11.2019: PDF

> Contribution of **Lumentum,** submitted on 07.11.2019: PDF

> Contribution of **LYNRED by Sofradir and ULIS**, submitted on 07.11.2019: PDF

> Contribution of **OSRAM**, submitted on 07.11.2019: Cover letter: PDF; Contribution: PDF

> Contribution of the **AZURSpace Solar Power GmbH**, submitted on 07.11.2019: Cover letter: PDF; Contribution: PDF

> Contribution of the **Zentralverband Elektrotechnik- und Elektronikindustrie e. V. (ZVEI),** submitted on 07.11.2019: PDF

> Contribution of **Spectaris**, submitted on 07.11.2019: PDF

> Contribution of **Freiberger Compound Materials GmbH (FCM)**, submitted on 07.11.2019: Cover letter: PDF; Contribution: PDF

A.6.0 Medium chain chlorinated paraffins (MCCPs) - Alkanes, 04-17, chloro

ROHS Annex II Dossier MCCPs.

Restriction proposal for substances in electrical and electronic substances equipment under RoHS

Medium- chained chlorinated paraffins (MCCPs)
Alkanes, C14-17, chloro
EC Number(s): 287-477-0
CAS Number(s): 85535-85-9

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Abbreviations

CAS number	A CAS Registry Number, also referred to as CASNR or CAS Number, is a unique numerical identifier assigned by Chemical Abstracts Service (CAS) to every chemical substance described in the open scientific literature
CLP	Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (REACh)
CoRAP	Community Rolling Action Plan
DINP and DIDP	Diisononyl phthalate
DNELs	Derived No Effect Level
EC number	The European Community number (EC Number) is a unique seven-digit identifier that was assigned to substances for regulatory purposes within the European Union by the European Commission.
ECETOC TRA model	European Centre for Ecotoxicology and Toxicology of Chemicals’ Targeted Risk Assessment
EEE	Electrical and Electronic Equipment
EINECS	European Inventory of Existing Commercial Chemical Substances
EPA	Environmental Protection Agency
EU RAR	EU Risk Assessment Report
KEMI	Swedish Chemicals Agency
LCCPs	Long-chained chlorinated paraffins
LOAEL	Lowest Observed Adverse Effect Level
MCCPs	Medium-chained chlorinated paraffins
MSDS	Material safety data sheet
NOAEL	No Observed Adverse Effect Level
NOEC	No Observed Effect Concentration
OEL	Occupational exposure limits
OH radicals	Hydroxyl radical
P & B properties	Physico-chemical properties
PBT	Persistent, bioaccumulative and toxic substances
PE, HDPE	Polyethylene, High density polyethylene
PEC	predicted environmental concentrations
PNEC	Predicted No Effect Concentrations
POP	Persistent organic pollutant
PVC	Poly vinyl chloride
RCR	Risk Characterisation Ratios

REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
SCCPs	Short-chained chlorinated paraffins
SVHC	Substances of Very High Concern
STOT SE	Specific target organ toxicity - single exposure
t/y	Metric tonnes per year
U.S. NTP	U.S. National Toxicology Program
UK	United Kingdom
UVCB	Substance of Unknown or Variable Composition, Complex reaction products or Biological materials
VPE	Vinylethoxysiloxane-propylethoxysiloxane copolymer
vPvB	Very persistent and very bioaccumulative
WEEE	Waste Electrical and Electronic Equipment

CONTEXT and SCOPE of the substance assessment

The substance assessment of medium chain chlorinated paraffins (MCCPs) – Alkanes, C14-17, chloro[1] is being performed as part of the "*Study on the review of the list of restricted substances and to assess a new exemption request under RoHS 2 – Pack 15*". With contract No. 07.0201/ 2017/772070/ENV.B.3 implementing Framework Contract No. ENV.A.2/FRA/2015/0008, a consortium led by Oeko-Institut for Applied Ecology has been assigned by DG Environment of the European Commission to provide technical and scientific support for the review of the list of restricted substances and to assess a new exemption request under RoHS 2. This study includes an assessment of seven substances / group of substances[2] with a view to the review and amendment of the RoHS Annex II list of restricted substances. The seven substances have been pre-determined by the Commission for this task. The detailed assessment is being carried out for each of the seven substances in line with a uniform methodology which was developed as a part of this study.[3]

In the course of the substance assessment, two stakeholder consultations were held to collect information and data for the seven substances under assessment. The first one was held from 20 April 2018 to 15 June 2018. The second one was held from 05 December 2019 to 13 February 2020 to provide specific data as to aspects on which data gaps still exist as well as to comment on the general interpretations made as to the current base of knowledge. Records of the consultations, including draft dossiers and stakeholder contributions, can be found at the Oeko-Institut's project webpage at: https://rohs.exemptions.oeko.info/index.php?id=289.

For MCCPs, the 1st stakeholder consultation yielded a total of eight contributions by different stakeholders. An overview of the contributions submitted during this consultation is provided in Appendix I. The contributions can be viewed at http://rohs.exemptions.oeko.info/index.php?id=293.

In the course of the 1st stakeholder consultation, a dossier on MCCPs was submitted by the Swedish Chemicals Agency KEMI proposing to add Medium-Chained Chlorinated Paraffins to the list of restricted substances.[4] This document was submitted to the Commission in June 2018 as the first restriction proposal by a Member State.[5] The proposal follows the (former) RoHS Dossier template (see footnote 3) and serves as an essential foundation for the dossier at hand, whereby additional and new information from stakeholders including a position paper submitted by the industry association EuroChlor[6] have been taken into account.

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[1] Hereafter „MCCPs"

[2] For the sake of better readability hereafter the term substance will be used for single substances as well as for group of substances.

[3] This methodology includes a dossier template for substance assessment which had been prepared by the Austrian Umweltbundesamt GmbH in the course of a previous study. The methodology for substance assessment has been revised based on various proposals from and discussions with stakeholders. Among others, revisions have been made to clarify when the Article 6(1) criteria are considered to be fulfilled and how the precautionary principle is to be applied. The methodology has also been updated in relation to coherence to REACH and other legislation and publicly available sources of relevance for the collection of information on substances that have been updated and added. The methodology is available at https://rohs.exemptions.oeko.info/index.php?id=341

[4] Swedish Chemicals Agency KEMI (2018): ROHS Annex II Dossier MCCP, Proposal for a restriction of a substance in electrical and electronic equipment under RoHS; https://www.kemi.se/global/rapporter/2018/report-4-18-rohs-annex-ii-dossier-mccp.pdf, last viewed 24.07.2018

[5] European Commission Environment DG at http://ec.europa.eu/environment/waste/rohs_eee/substances_en.htm, last viewed 24.07.2018.

[6] EuroChlor (2018): Euro Chlor views on the proposal to add medium-chain chlorinated paraffins (MCCP) to Annex II of the Restriction of Hazardous Substances Directive (RoHS); Position Paper, July 2018.

In the course of the 2nd stakeholder consultation, ten new stakeholder contributions were received. The stakeholders generally expressed concern regarding the allocation of chlorinated paraffins with chain lengths of C13 and below as SCCP, that form part of the mixture in commercial MCCP. Regarding the impacts of a restriction under REACH, several stakeholders warned about long lasting phase-out periods due to the need for new material development, testing and certification, in particular in the sector of medical appliances.

In the aftermath of the 2nd stakeholder consultation, the UK Environment Agency has concluded the substance evaluation of MCCPs in the framework of the Community rolling action plan (CoRAP). The conclusion is that MCCP fulfil PBT and vPvB criteria of REACH Annex XIII and are thus suggested as a candidate for a Substance of Very High Concern (SVHC).[7] In addition it has been concluded in the Art. 48 report that restrictions are required for this group of substances. The dossier at hand has been updated accordingly. Moreover, several chapters of the dossier have been revised based on new information provided by stakeholders. The version 3 of the dossier represents the final version of the RoHS Annex II dossier for MCCP.

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[7] UK Environment Agency (2019) Substance Evaluation Conclusion EC No 287-477-0 as required by REACH Article 48 and Evaluation report for Medium-chain chlorinated paraffins, available online: https://echa.europa.eu/documents/10162/f684ca0c-072b-a60e-100b-825439aa8429

1. IDENTIFICATION, CLASSIFICATION AND LABELLING, LEGAL STATUS AND USE RESTRICTIONS

1.1 Identification and physico-chemical properties of the substance

Medium-chained chlorinated paraffins (MCCPs), also known as chloro-paraffin, refer to a range of compositions/constituents rather than a single one. Commercially available MCCP products generally contain a range of compositions/constituents of linear chloro-alkanes with a medium carbon chain length in the range of C14-17, (EC No: 287-477-0, CAS No: 85535-85-9) Technical-grade MCCPs for industrial applications contain a broad range of combinations of carbon chain length and degree of chlorination between *20-70 % by weight*.[8] The chlorination levels of commoditised products are usually in the range of 40-70 % by weight mass as shown in Table 1-1 (EU RAR 2005).[9] Under the REACH and CLP regulations, MCCPs are classified as substances from the UVCB category (Unknown or Variable Composition, Complex Reaction Products or Biological Materials).

1.1.1. Name, other identifiers, and composition of the substance

Table 1-1: Substance identity and composition of medium-chained chlorinated paraffins (MCCPs)

Chemical name	Medium-chained chlorinated paraffins (MCCPs)
EC number	287-477-0
CAS number	85535-85-9
IUPAC name	Alkanes, C14-17, chloro
Index number in Annex VI of the CLP Regulation	602-095-00-X
Molecular formula	The substance group includes a range of chlorinated isomers of C14 to C17 paraffin. $C_xH_{(2x-y+2)}Cl_y$, where x = 14-17 and y=1-17
Molecular weight (range)	233 - 827 g/mole
Synonyms	Chlorinated paraffin (C14-17); chloroalkanes, C14-17; chloroparaffin; chloroparaffine, C14-17; medium-chained chlorinated paraffins
Structural formula	ECHA provides the following general chemical formula:

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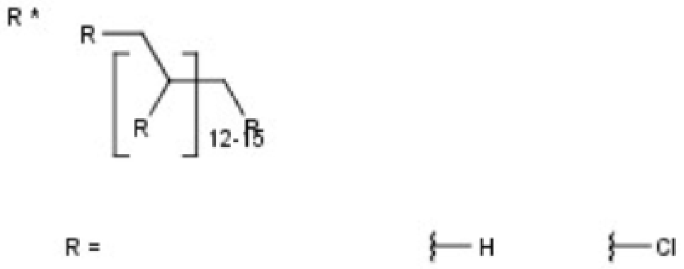
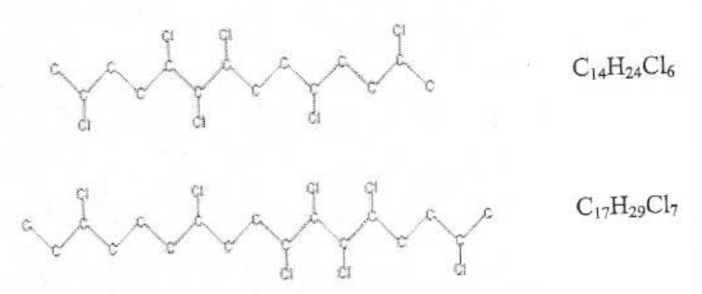
[8] European Union Risk Assessment Report EU RAR (2008): Alkanes, C14-17, chloro (MCCP) - Part II Human Health, European Commission, Joint Research Centre, Institute for Health and Consumer Protection ; http://publications.jrc.ec.europa.eu/repository/bitstream/111111111/15069/1/lbna24589enn.pdf, last viewed 24.07.2018

[9] European Union Risk Assessment Report EU RAR (2005): Alkanes, C14-17, chloro (MCCP) - Part I - environment, Luxembourg: European Commission; https://echa.europa.eu/documents/10162/ad6eebf1-49b2-4a7b-9f73-a2c11109ff0c, last viewed 24.07.2018

Chemical name	**Medium-chained chlorinated paraffins (MCCPs)**
	 Structure of two MCCP compounds according: 
Degree of purity	≥99 % (technical grade MCCPs traded in the EU)
Remarks	UVCB substance Commoditised MCCPs traded in the EU contain less than 1 % of LCCPs (long-chain) or SCCPs (short-chain) whereas commoditised MCCPs available in other world regions (e.g. China) may contain higher concentrations of SCCP/LCCPs

Sources: (ECHA, 2018; EU RAR, 2005; KEMI, 2018)

Commercial MCCPs consist of a mixture of isomers, where the unwanted content of short- or long-chained paraffin congeners depends on the purity of the paraffin feedstock used in production. According to KEMI (2018), MCCPs traded in the EU are thought to contain less than 1 % of short- or long-chained congeners, which is a result of the manufacturers' dedicated quality policies. However, the categorisation of MCCPs by CAS number is not consistent with the product specifications in markets outside the EU. Commercial products such as "CP-52", which is traded in China under the label of MCCP and which accounts for 80 % of the market volume, are marketed with regard to their chlorination level rather than the carbon chain length of their constituents. Claigan Environmental Inc. asserts that "*MCCP is normally marketed in the form of Chlorinated Paraffins 52% (CP52), which contains both SCCPs and MCCPs*". *"The chlorinated paraffin content in a typical formulation, such as CP52 is controlled completely by chlorine content, which explains the common presence of SCCPs*".[10]

Technical-grade chlorinated paraffins such as CP-52 have been shown to contain higher amounts of short-chained congeners (KEMI, 2018). Figure 1-1 shows the analytically derived congener profile of carbon and chlorine found in various samples of CP-52 (Yin 2016)[11]. The results suggest that commercial products labelled as CP-52 contain varying amounts of chained paraffin congeners with

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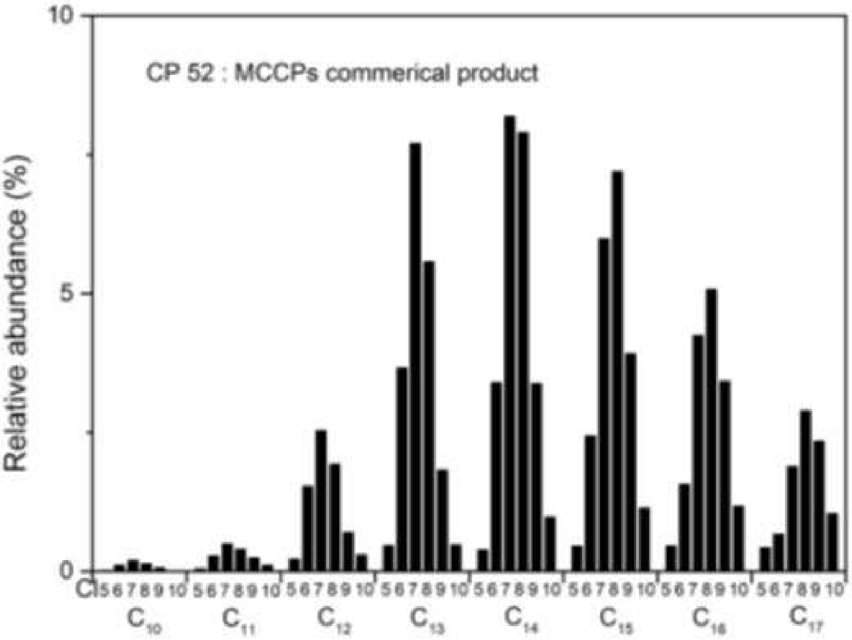
[10] Claigan Environmental Inc. (2019) Contribution submitted on 7 November 2019 during the stakeholder consultation conducted from 26 September 2019 until 07 November 2019 in the course of the study to support the review of the list of restricted substances and to assess a new exemption request under RoHS 2 (Pack 15)

[11] https://pdfs.semanticscholar.org/41b2/847fe723787a863568f1376aa840042fc8b6.pdf (accessed on 11.11.2019)

chain lengths outside the range of C14 to C17 that are attributed to the CAS number of MCCPs. For instance, sample “7” contains 2.5 % C12 and 7.5 % C13 paraffins, which are allotted to the group of short-chained chlorinated paraffins (SCCPs). A study of 253 flexible PVC in various consumer products purchased in 2019 in both Canada and the EU showed that 29 % of them contained SCCPs above 1,500 ppm (Claigan Environmental Inc., 2019). To this end, EuroChlor (2018) remarks “*it would be incorrect to assume that any <C14 chlorinated alkanes found in such imported products are SCCPs, as defined by the above CAS and EINECS numbers*”.

Figure 1-1: Congener profile of carbon and chlorine in technical chlorinated paraffins traded on the Chinese market under the name “CP-52”



Source: (Yin 2016)[12]

EuroChlor (2018) explains the occurrence of short-chained parrafins in technical MCCPs as follows: The classification of chloro paraffins in form of UVCB substances that are identifiable by CAS and EINECS numbers originates from market practices in the past. The distinction between SCCPs, MCCPs and LCCPs was introduced in the early 1980s to describe mixtures of chloro paraffins with similar properties. Thus, the “grouping” of these substances was motivated by technical considerations rather than their respective hazard profiles. The assignment of hazards profiles to these different UVCBs is considered to be misleading as the substance “groups” have not been defined for the purpose of applying regulatory restrictions based on their individual hazard profiles.

Referring to the distinction between SCCPs and MCCPs, EuroChlor (2018) further argues that each substance group is likely to contain congeners that are assigned to the other group. These constituents are not considered as impurities. For instance, the MCCP group (C14-17) contains paraffins with C13 or C18 carbon chain length, which are assigned to the SCCP or LCCP groups. However, since the groups were not defined for the purpose of hazard classification, it is considered pointless

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[12] https://pdfs.semanticscholar.org/41b2/847fe723787a863568f1376aa840042fc8b6.pdf (accessed on 11.11.2019)

to treat these congeners as impurities of the MCCP group in the context of regulatory risk assessments.

Against this background it is important to note that a large portion of EEE products placed on the European market is imported from China. Those products may contain chlorinated paraffins that do not match with the classification of MCCPs in the EU. EEE products containing commercial CPs such as CP-52 may contain certain amounts of chloro-paraffins of a wide carbon chain length distribution (such as C10-20 or C10-21).

1.1.2. Physico-chemical properties

Table 1-2 summarises the physico-chemical properties of MCCPs as compiled by KEMI (2018). It has to be born in mind that the physico-chemical properties of this substance group *cannot be described as one "true value but rather a range of values." Glüge et al. (2018).*[13] In other words, the properties of a commercial MCCP product may differ depending on its chain length and chlorination degree.

Table 1-2: Overview of physico-chemical properties of MCCPs

Property	Chlorine content (% wt)	Value	Remarks
Physical state at 20°C and 101.3 kPa	40-63	Liquid	
Melting / freezing point	Not specified (up to 63 %)	-50 to 25 °C	Commercial MCCP mixtures do not have a specific melting point, but they gradually soften when heated over a certain range of temperature levels.
Boiling point	Not specified	>200 °C	Decomposition with release of HCl
Vapour pressure	45	2.27 x10^{-3} Pa at 40 °C	A value of 2.7x10^{-4} Pa at 20 °C is used for environmental assessment.
		0.16 Pa at 80 °C	
	52	1.3 x10^{-4} –2.7 x10-4 Pa at 20 °C	
Water solubility	51	0.005-0.027 mg/L at 20 °C	Water solubility varies with both carbon chain length and degree of chlorination (EU RAR 2008)
Partition coefficient n-octanol / water (log POW)	45	5.52-8.21 Log P_{ow}	
	52	5.47-8.01 Log P_{ow}	
Density	41	1.095 g/cm3 at 20 °C	Density increases with increasing degree of chlorination.
	56	1.315 g/cm3 at 20 °C	
	40-58	1.1-1.4 g/cm3 at 25 °C	
	56	1.28-1.31 g/cm3 at 60 °C	

Source: KEMI (2018)

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[13] Glüge, J.; Schinkel, L.; Hungerbühler, K.; Cariou, R.; Bogdal, C. (2018): Environmental risks of medium-chain chlorinated paraffins (MCCPs) - A review. Environ. Sci. Technol. (52):12, pp 6743-6760

1.2. Classification and labelling status

Regulation (EC) No 1272/2008 on Classification, Labelling and Packaging (CLP)[14] provides for a unified means of communicating the hazards presented by chemicals to workers through classification and labelling. Annex VI of the Regulation lists substances where a harmonised classification exists based on e.g. human health concerns. That substance list is regularly adapted by engagement of Member State Competent Authorities and ECHA.[15]

For an explanation on the human and environmental hazards, see section 3.

Classification in Annex VI of Regulation No 1272/2008 (CLP)

Table 1-3: Classification according to Annex VI, Table 3.1 (list of harmonised classification and labelling of hazardous substances) of Regulation (EC) No 1272/2008

Index No.	International Chemical ID	EC No.	CAS No.	Classification		Labelling			Spec. Conc. Limits, M-factors	Notes
				Hazard Class and Category Code(s)	Hazard statement code(s)	Pictogram, Signal Word Code(s)	Hazard statement code(s)	Suppl. Hazard statement code(s)		
602-095-00-X	alkanes, C14-17, chloro; chlorinated paraffins, C14-17	287-477-0	85535-85-9	Lact. Aquatic Acute 1 Aquatic Chronic 1	H362 H400 H410	GHS09 Wng	H362 H410	EUH066		

Source: Annex VI Regulation No 1272/2008; https://echa.europa.eu/de/information-on-chemicals/annex-vi-to-clp, last viewed 19.04.2018

In summary, the CLP classification for MCCPs flags the following hazards:

- Reproductive toxicity on or via lactation of breast-fed children (H362), and
- Very high acute and chronic toxicity to aquatic life (H400).

Self-classification(s)

Manufacturers, importers or downstream users have to apply a harmonised classification (if available) and have also the possibility to (self)classify and label hazardous substances and mixtures containing such substances. Self-classification can indicate an additional hazard, for example, which, so far has not been adequately reflected by the harmonised classification. The following provides an overview of additional hazards based on self-classifications.

The ECHA database's Classification and Labelling Inventory contains information on notified and registered substances received from manufacturers and importers. With regard to MCCPs, as of November 2019, there are a total number of 378 companies notifying self-classification (so-called notifiers).[16] Most notifiers follow the harmonised classification (332 of 378 notifications: ~ 88 %). So

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[14] Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (REACH).

[15] For further information, see https://echa.europa.eu/regulations/clp/harmonised-classification-and-labelling, last viewed 19.04.2018

[16] ECHA CL Inventory: Entry for Alkanes, C14-17, chloro (2019); https://echa.europa.eu/de/information-on-chemicals/cl-inventory-database/-/discli/details/94445, last viewed 11.11.2019

far, not a single case is known where a more severe classification was notified. A minority (46 notifiers) differs from the harmonised classification by e.g. notifying only the classification of chronic aquatic toxicity or by not classifying acute aquatic toxicity (~ 6 %) at all. Thereof, 19 notifiers (5 %) provided a completely different classification by notifying skin irritation (H315 – causes skin irritation), eye irritation (H319 – causes serious eye irritation) and specific target organ toxicity by single exposure (STOT SE 3; H335 – may cause respiratory irritation); 3 notifiers (< 1 %) do not provide any classification at all.

Against this background, it can be concluded that for MCCPs, the currently available self-classifications do not indicate an additional hazard that is not reflected by the harmonised classification.

1.3. Legal status and use restrictions

1.3.1. Regulation of the substance under REACH

Since they are suspected of being PBT substances, MCCPs are on the Community Rolling Action Plan (CoRAP). They are also subject of concern regarding (environmental) exposure due to their wide dispersive use and high aggregated tonnage.[17] The UK evaluated MCCPs and acquired details on the exact composition of different MCCP products so as to verify the PBT status of different formulations. In 2014, the ECHA decided that further information on the relevant compositions of different commercial MCCP types is required.[18]

As of December 2019, the UK Environment Agency has published the CoRAP substance evaluation conclusion document. It is concluded that MCCPs require EU wide regulatory actions. MCCPs fulfil the criteria of REACH Annex XIII for PBT and vPvB substances and therefore should be included as SVHC on the REACH Candidate List as the first step for the authorisation process. In addition, a restriction of MCCPs under REACH is suggested as *“the most appropriate regulatory risk management measure*”.[19] This conclusion is assumed to apply to all MCCP product types because they will contain shared constituents with PBT/vPvB properties above 0.1 % w/w.

With this Conclusion document, the substance evaluation process is finished and the Commission, the Registrant(s) of the substance and the Competent Authorities of the other Member States are informed of the considerations of the evaluating Member State. The next steps of the regulatory process under REACH will encompass the development of an official Annex XV dossier for SVHC identification as well as an official Annex XV restriction dossier. Both dossiers will then be subject to public consultation before the Member State Committee takes a decision on the SVHC status of MCCPs.

1.3.2. Other legislative measures

While other EU legislation does not explicitly restrict the use of MCCPs, some risk management obligations are assigned:

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[17] http://www.echa.europa.eu/web/guest/information-on-chemicals/evaluation/community-rolling-action-plan/corap-table?search_criteria=85535-85-9, last viewed 15.10.2019

[18] ECHA (2014): Decision on Substance Evaluation Pursuant to Article 46(1) of Regulation (EC) No 1907/2006 for alkanes, C14-17, chloro (MCCP, medium-chain chlorinated paraffins); CAS No 85535-85-9 (EC No 287-477-0); case no. A-004-2014; https://echa.europa.eu/about-us/who-we-are/board-of-appeal/decisions, last viewed 19.04.2018

[19] UK Environment Agency (2019) Substance Evaluation Conclusion EC No 287-477-0 as required by REACH Article 48 and Evaluation report for Medium-chain chlorinated paraffins, available online: https://echa.europa.eu/documents/10162/f684ca0c-072b-a60e-100b-825439aa8429

- Pregnant workers (Directive 92/85/EEC): As MCCPs are classified as having hazardous effects via lactation, employers should conduct risk assessments for any pregnant or breastfeeding workers and decide on the measures to be taken.
- Via its classification, MCCPs is covered by:
  - EU Ecolabel Regulation 66/2010 that stipulates that the EU Ecolabel cannot be awarded to goods containing substances or preparations / mixtures meeting the criteria for classification as toxic, hazardous to the environment, carcinogenic, mutagenic or toxic for reproduction (CMR), in accordance with Regulation (EC) No 1272/2008 nor to goods containing substances referred to in Article 57 of Regulation (EC) No 1907/2006 (REACH).
  - SEVESO III Directive 2012/18/EU, according to which substances classified as Aquatic Acute 1 and Aquatic Chronic 1 have to follow requirements for holding at least 100 t (lower tier) or 200 t (upper tier).
- The Basel Convention applies to MCCPs because it includes a waste category for organo-halogen compounds in general.
- The Helsinki Convention on the Protection of the Marine Environment of the Baltic Sea Area (HELCOM) considered MCCPs as a substance of specific concern to the Baltic Sea, according to the final report of the HAZARDOUS project in 2009.[20]
- Commercial grade MCCPs may also contain components with chain lengths below C14, typically C13, and components above C17, typically C18. Carbon chain lengths between 10 and 13 are part of the typical composition of commercial grade MCCPs and were always present during MCCP assessment and testing.
- Carbon chain lengths between 10 and 13 are recognised as POPs and are restricted by the Stockholm Convention since 2017 and in the UNECE/LRTAP POPs-protocol since 2009. As a global pollutant, MCCPs are currently discussed as a candidate to be nominated to the Stockholm Convention for global phase-out of production and consumption.[21]

1.3.3. Non-governmental initiatives

The International Chemical Secretariat (Chemsec) specifies and updates the SIN List, which identifies potential substances of concern. The list is a measure for putting pressure on legislators to assess and, where relevant, address substances identified therein in the future in respect of relevant chemical legislation.[22] There are a number of reasons why substances are added to the SIN List, including carcinogenic properties, DNA-altering or -reproductive systems damage (CMR properties) and substances that do not easily break down and accumulate in the food chain (PBT / vPvB substances) or substances that give rise to an equivalent level of concern in terms of potential damage to health and environment (such as substances with endocrine disrupting properties).

ChemSec's SIN List does not contain an entry specified as MCCP (EC No: 287-477-0, CAS No: 85535-85-9). The entry named “Paraffin waxes and Hydrocarbon waxes, chloro” (EC No: 264-150-0, CAS No: 63449-39-8) refers to a different family of chloro-paraffins. The latter substance exhibits

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[20] Helsinki Commission, Baltic Marine Environment Protection Commission (2009): Hazardous substances of specific concern to the Baltic Sea, Final report of the HAZARDOUS project; Baltic Sea Environment Proceedings No. 119; http://www.helcom.fi/Lists/Publications/BSEP119.pdf, last viewed 24.07.2018

[21] https://echa.europa.eu/sv/information-on-chemicals/evaluation/community-rolling-action-plan/corap-table/-/dislist/details/0b0236e1807e3841

[22] http://chemsec.org/business-tool/sin-list/about-the-sin-list/, last viewed 24.07.2018

PBT and/or endocrine disruptor properties.[23] Additionally, the SIN List also includes SCCPs due to their PBT properties.[24] This indicates a confusion with nomenclature.

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[23] http://sinlist.chemsec.org/search/search?query=SCCP, last viewed 24.07.2018

[24] http://sinlist.chemsec.org/search/search?query=63449-39-8, last viewed 24.07.2018

2. USE IN ELECTRICAL AND ELECTRONIC EQUIPMENT

2.1. Function of the substance

The main function of MCCPs is that of a **secondary plasticiser** (extender) in PVC. While *a primary* plasticiser (mainly phthalates but also phosphate esters) can be used alone, its effectiveness is enhanced if combined with a secondary plasticiser. MCCPs are thus improving the functional performance and are also significantly cheaper than primary plasticisers. In fact, the low price seems to be one of the main reasons that they are used in a wide variety of PVC applications, including cables, according to KEMI (2018). It is understood that the use of MCCPs as secondary plasticiser or extender lowers the amount of (the more expensive) primary plasticisers needed. Low cost parts (including such embodied in higher value products) commonly contain a blend of plasticizer with DEHP and chlorinated paraffins (CP52) because the latter is roughly half the cost of DEHP plasticizer alone. Due to the use of technical grade MCCPs (such as CP52), SCCPs can be found in virtually any flexible PVC with DEHP, according to Claigan Environmental Inc. (2019).[25] MCCPs are used frequently as an extender for DEHP with concentrations generally well over 50,000 ppm of either DEHP or DINP, according to Claigan Environmental Inc. (ibid)

Moreover, MCCPs provide flame retardant properties that are harnessed on top of its function as a plasticiser extender. MCCPs are used as such in PVC, rubber and other polymers, including polyurethane, polysulphide, acrylic and butyl sealants and adhesives.

It should be noted that MCCPs were used as a substitute for short-chain chlorinated paraffins (SCCPs) in applications such as rubber and sealants. The Persistent Organic Pollutants Review Committee (POPRC) noted that MCCPs are listed as *“Potential Alternatives to SCCPs in Polyvinyl Chloride Processing”*:[26] Hence, the – previously assumed - lower hazard potential in comparison to SCCPs, which are however currently under scrutiny, has so far constituted one of the functions of MCCPs in technical applications.

2.2. Types of applications / types of materials

MCCPs are used in electrical and electronic equipment (EEE) mostly as constituents of PVC insulations for electric cables and wires and other soft plastic or rubber components, including polyurethane, polysulphide, acrylic and butyl sealants.

In the following, the typical chlorine content of the MCCPs is mentioned (if available) for the respective uses. This is done against the background that MCCP compounds with a higher degree of chlorination (chlorine content of 50−52 % by weight and of 55−60 % by weight) are under REACH scrutiny for PBT properties (for further details, see section 1.3.1).

2.2.1. Cable and wire sheathing and insulation

MCCPs are used as secondary plasticisers in flexible PVC that functions as sheathing and insulation jackets for cables and wires with rated voltage of less than 250 Volt (KEMI, 2018).

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[25] Claigan Environmental Inc. (2019) Contribution submitted on 7 November 2019 during the stakeholder consultation conducted from 26 September 2019 until 07 November 2019 in the course of the study to support the review of the list of restricted substances and to assess a new exemption request under RoHS 2 (Pack 15)

[26] http://chm.pops.int/Implementation/Alternatives/AlternativestoPOPs/ChemicalslistedinAnnexA/Shortchainchlorinatedparaffins(SCCPs)/tabid/5986/Default.aspx, last viewed 24.07.2018

The majority of secondary plasticisers used in PVC applications are medium-chain chlorinated paraffins with chlorine contents around 45 % by weight or 50-52 % by weight, with only very small amounts (<1% of total sales) of medium-chain chlorinated paraffins with higher (e.g. 56-58 % by weight) or lower (e.g. ~40 % by weight) chlorine contents (EU RAR, 2005).

For cable sheathing and insulation, MCCPs with chlorination degrees of typically around 50-52% wt. Cl are preferably used as they are more compatible with PVC and have a lower volatility than lower chlorinated analogues (EU RAR, 2008). The degree of chlorination and the preferred carbon chain length also depends on which primary plasticiser is used in PVC applications and which product function is required. Increasing chlorination increases the compatibility of chlorinated paraffins with PVC and the primary plasticiser. That way, the potential for migration is reduced, but at the cost of lower mechanical flexibility of the final product.

According to KEMI (2018), MCCPs are typically added to PVC at 10-15 % w/w of the total plastic but can reach up to 20 % of the polymer compound for sheathing or insulation of electric cables. In contrast, the MCCPs concentration in rubbers is comparatively low and does not exceed 3.8 %. EuroChlor indicates the typical MCCP-content (specified as CERECLOR™ S52) of PVC-P cable insulation to be 8.1 wt% and 7.8 wt% for PVC sheathing. The concentration limit is governed by well-established compatibility rules.[27] The application of PVC containing MCCPs for flexible cables insulation is predominant. This means that many EEE used in EU households may contain MCCPs. Taking into account that cables are used in more or less any kind of electrical and electronic equipment, MCCPs could be expected in any category of WEEE as well. Given its low volatility, it can be inferred that WEEE items contain almost the same concentration of MCCPs as new products.

2.2.2. Coatings, adhesives and sealants

The application of MCCPs in coatings, sealants, and adhesives is far less common than in PVC wire sheathing and insulation. MCCPs may be applied in certain polysulphide, acrylic and butyl sealants and adhesives, but the actual applications are not as frequent or as uniform as compared to the use in PVC. KEMI (2018) notes that *"it is difficult to obtain information on their market share"* for MCCP-containing sealants and adhesives in cable sheaths. While MCCPs may be applied in polyurethanes, the actual occurrence of that material in EEE could not be established.

MCCPs used in sealants as plasticisers with flame retardant properties generally have a chlorine content of 50–58 % wt. Cl. As for coatings, paints and varnishes, the actual use of MCCPs on/in EEE products hinges around *a chlorine content of 50–60 % as part of certain paints, varnishes and other coatings* (KEMI, 2018). *Resin-based, rubber or copolymer paints in EEE may also contain MCCPs as a plasticiser but "it is difficult to estimate how frequently these paints and varnishes are applied to EEE" (ibid).*

2.3. Quantities of the substance used

According to KEMI (2018), the most recent estimation from industry on the quantities of MCCPs used in EEE applications originates from INEOS Vinyl, one of the major MCCP manufacturers in the EU. Data were submitted as a stakeholder contribution during a consultation under RoHS, held in 2014.[28] The company estimated the total EU market for MCCPs at around 40,000 tonnes per year

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[27] Alan S Wilson (1995) Plasticisers, Principle and Practice, Institute of Materials. page 77, ISBN 0 901716 76 6,

[28] INEOS ChlorVinyls (2014): Contribution submitted 24.03.2014 during stakeholder consultation; http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Substance_Review/Substance_Profiles/20140324_INEOS_Contribution_RoHS_SC_Substance_Review_MCCP.pdf, last viewed 19.04.2018

and the amount of MCCPs used in PVC cable formulations at roughly 15,000 t/y. Information provided by stakeholders in the course of the present dossier preparation did not yield concrete data on more recent quantities:

- Europacable indicated *"quantities in the range of 1,000 to 10,000 t per year for the cable applications"* in the EU,[29] further explaining this to be *"a very approximate estimation, as it is not possible, for competition law reasons, to collect quantities of substances used at Europacable level. Any quantitative information on manufacturers' purchase of raw materials is considered confidential."*[30]
- EuroChlor (2018) stated on amounts that *"data on production levels cannot be legally provided due to the small size of the market here. This is restricted by EU competition law on the provision of production data."*

The quantities of MCCPs as specified in the past were summarised by KEMI (2018) as follows:

Figure 2-1: Estimation on amonts of MCCP contained in EEE, manufactured in EU 28

Source	MCCP demand (t/y)	MCCP use in EEE (t/y)	Reference Year (assumed)
EU RAR (ECB, 2005) Öko-Institut (2008)	45,000 - 160,000	>9,200	1997
Entec (2008)	63,691	Unknown	2006
REACH Registration*	10,000 – 100,000	Unknown	2019
INEOS Vinyl's comments on Öko-Institut study (2014)	40,000	15,000	2013

Source: KEMI (2018) * (most recent update: January 2020)

Comparing the data of the EU RAR (2008) and the amounts provided by INEOS ChlorVinyls (2014), the conclusion could be drawn that the total market volume of MCCPs in the EU decreases: In 2006, approximately 64,000 tonnes of MCCPs were used in total in the EU 25 and around 34,676 tonnes thereof were used in PVC. In 2014, the total amount of MCCPs was indicated at about 40,000 tonnes. The MCCP amount used for PVC cable formulations was estimated to account for about 15,000 tonnes. The general trend towards a declining consumption of MCCPs in the EU can be explained in part by the declining use of PVC compounds in European cable manufacturing industry. On the other hand, the amount of MCCP contained in finished EEE that are imported into the EU 28 is assumed to increase. KEMI (2017)[31] suggests that significant volumes of MCCPs enter the EU as part of cable insulation that is incorporated in imported EEE goods.

KEMI (2018) assumes that imports and exports of MCCPs in PVC and/or EEE are largely equivalent. Many of the imported semi-finished products that contain MCCPs are thought to be re-exported,

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[29] EuropaCable (2018a): Contribution submitted on 15.06.2018 during the stakeholder consultation conducted from 20 April 2018 to 15 June 2018 by Oeko-Institut in the course of the study to support the review of the list of restricted substances and to assess a new exemption request under RoHS 2 (Pack 15); http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Pack_15/1st_Consultation_Contributions/Contribution_EUROPA_CABLE_MCCP_consultation_1_20180615.pdf, last viewed 24.07.2018

[30] EuropaCable (2018b): Information provided to Questionnaire for Clarification, submitted 09.07.2018

[31] Swedish Chemicals Agency KEMI (2017): Study of a possible restriction of MCCP in electrical and electronic equipment regulated under RoHS, PM 2/17, May 2017; https://www.kemi.se/global/pm/2017/pm-2-17-study-of-a-possible-restriction-of-mccp-in-electrical-and-electronic-equipment-regulated-under-rohs.pdf, last viewed 19.04.2018

notably in form of industrial EEE. Although data are insufficient to specify mass flows in detail, the 2017 assessment estimated the amount of 15,000 tonnes per year for calculating emissions. This amount is presumably an underestimation, because *"according to Eurostat the import is 2.6 times bigger than the export for certain groups of EEE."* (ibid)

As for the import of MCCPs as part of finished EEE goods, Glüge et al (2018)[32] point to the fact that manufacturers in Asia indicate the content of chlorinated paraffins in products in regard to the chlorine content rather than specifying the MCCPs according to the carbon chain length or CAS numbers. In an attempt to estimate the amounts of chlorinated paraffins contained in EEE that is imported in the EU from China, Glüge et al. (2018) refer to the latest available production figure from China are from 2013 and indicate an amount of 1,050,000 tons; the International Chlorinated Alkanes Industry Association (ICAIA) stated that nearly 90 % of the chlorinated paraffins produced in China in 2012 were CP-52 (with a chlorine content of 52 %). Glüge et al. (2018) estimates conservatively that "*MCCPs might have been produced in the order of 600 000 t in China in 2013. This number is much larger than any of the production amounts reported in literature for North America, Russia, or the EU and indicates that."* The International Chloralkanes symposia in Beijing (2015) and New Delhi (2018) recorded Chinese capacity for CPs to be approximately 1.3 Million tonnes and that of India to be between 600,000 and 800,000 tonnes per year with a growth rate of 12-14%.[33] A recent estimate of the global production of chlorinated paraffins is about 2 million tonnes/year, with China and India as the main producers.[34]

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[32] Glüge, J.; Schinkel, L. et al (2018): Environmental risks of medium-chain chlorinated paraffins (MCCPs) - A review. Environ. Sci. Technol. (52):12, pp 6743-6760

[33] CEFIC (2020): Contribution submitted on 13.02.2020 during the stakeholder consultation conducted from 05 December 2019 until 13 February 2020 in the course of the study to support the review of the list of restricted substances and to assess a new exemption request under RoHS 2 (Pack 15)

[34] Jacob de Boer (2019), Oral presentation at Dioxin 2019 Conference, Kyoto, Japan).

2.4. Potential impacts of the substance on the environment and on health during the use of EEE

Potential impacts from MCCPs during the use of EEE can arise by a release of MCCP compounds from finished EEE products containing PVC and soft PVC cable insulation in households. Such a release may occur in form of migration and affects volatile compounds rather than non-volatile substances. Higher degrees of chlorination (typically around 50-52 % wt. Cl), which are often found in PVC, result in lower volatility (EU RAR, 2008). This is one of the reasons why MCCPs has so far been considered a less hazardous substitute for SCCPs. Section 6 discusses monitoring results for indoor air and indoor dust samples.

3. HUMAN HEALTH HAZARD PROFILE

The hazard characterisation of UVCB substances is generally challenging and this is true for MCCPs, since the group encompasses a plethora of distinct heterogeneous substances. MCCPs are characterised by molecules of four chain lengths (C14-17) and variable chlorination percentages. KEMI (2018) states, that *"it is not reasonable to expect full toxicological datasets to cover each possibility and, where data are not available on one particular MCCP substance, it may be possible to read across information available from other MCCP substances. In the absence of human epidemiology studies, in vivo animal studies have been considered in the reproductive and developmental toxicity evaluations of MCCPs."*

3.1. Critical endpoint

There is some evidence in the available literature that MCCPs are **not acutely toxic** for humans. As for **repeated dose toxicity**, kidney effects ('chronic nephritis' and tubular pigmentation) were reported as well as effects on the liver and thyroid after dietary exposure. Repeated dermal exposure may cause defatting to a certain degree. Repeated dose toxicity has a NOAEL of 23 mg/kg/day, based upon effects seen in rat kidney. Exposure to a MCCP (40 % chlorination) has been shown to lead to thyroid effects (follicular cell hypertrophy and hyperplasia). The thyroid effects were concluded to be secondary to changes in liver enzyme activity and of no real significance for humans (KEMI 2018).

As for skin and eye **irritation and sensitisation** potentials, MCCPs seem to be **rather non-problematic.** Human skin exposure to C15 chlorinated paraffin for 24 hours leads to a dermal absorption value of 1 % (KEMI 2018). Nevertheless, concerns regarding **unknown long-term effects** remain, for example the tendency of strongly lipophilic substances like MCCPs to enter breast milk.

As **for reproductive and developmental effect**s, an overall NOAEL of 47 mg/kg/day (600 ppm) MCCP as a maternal dose can be identified for these effects mediated via lactation. However, KEMI noted that the effects (11 % reduction in pup survival and related haemorrhaging) observed at the LOAEL (74 mg/kg/day; 1000 ppm) were not statistically significant but were supported by a dose-response relationship at higher exposure levels. MCCPs were proposed for endocrine disruption according to the Endocrine Disruptors Database[35] in 2007.

As for **mutagenicity and carcinogenicity,** MCCPs (C14-17 of 40–52% chlorination) were not found to be mutagenic. None of the usually applied test methods such as the Ames test,[36] gene mutation assays or in-vivo bone marrow tests, have provided any evidence on elevated risk levels. Epidemiological data on carcinogenicity from exposed human populations or toxicology studies are not available.

The Substance Evaluation Conclusion on MCCPs states that MCCPs are "*generally unreactive and not mutagenic*" although "*no carcinogenicity studies have been conducted*. In absence of directly

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[35] http://ec.europa.eu/environment/endocrine/strategy/substances_en.htm#report3: MCCPs are assigned endocrine disruption Cat. 1. This implies that at least one in-vivo study provides clear evidence for endocrine disruption in an intact organism

[36] The Ames test uses bacteria to test whether a given chemical can cause mutations in the DNA of the test organism.

applicable data, the carcinogenic potential of MCCPs "*is expected to be similar – at least in qualitative terms – to that of SCCPs, although direct read across is not appropriate*".[37]

Toxicokinetics: Chlorinated paraffins are widely distributed throughout the liver, kidney, intestine, bone marrow, adipose tissue and ovary. Whilst the metabolic pathways are uncertain, MCCPs may be excreted via the renal, biliary and pulmonary routes (as CO2). In addition, lactation in nursing mothers (IPCS, 1996) could be a pathway of elimination (KEMI, 2018).

3.2. Existing Guidance values (DNELs, OELs)

Derived No Effect Levels (DNEL) for MCCPs are shown in Table 3-1; they have been extracted from the publicly available ECHA databases, which are based on information from the REACH registration dossiers. It should be stressed that information provided by registrants has been subject to scrutiny by ECHA and the UK Environment Agency, acting as rapporteur, under the REACH Substance Evaluation programme (CoRAP).

It should be noted that the evaluation conclusion of MCCPs as a PBT substance can result in a repeal of these DNELs.

Table 3-1: Guidance DNEL values for worker DNEL systemic effects

Population	Local / systemic effect	Effects	DNEL*	UK (2008): Annex XV Restriction Report*
Workers	Inhalation Exposure	Systemic effects Long term	6.7 mg/m^3	1.6 mg/m^3 Inhalation route for kidney effects/carcinogenicity
	Dermal Exposure	Systemic effects Long term	47.9 mg/kg bw/day	11.5 mg/kg bw/day
	Eye Exposure	-	Low hazard No threshold derived	
General Population	Inhalation Exposure	Systemic effects Long term	2 mg/m^3	
	Dermal Exposure	Systemic effects Long term	28.75 mg/kg bw/day	
	Oral Exposure	Systemic Effect Long term	580 µg/kg bw/day	
	Eye Exposure	-	Low hazard No threshold derived	

Source: UK chemicals agency (2008) cited in KEMI (2018) * bw=body weight

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[37] UK Environment Agency (2019) Substance Evaluation Conclusion EC No 287-477-0 as required by REACH Article 48 and Evaluation report for Medium-chain chlorinated paraffins, available online: https://echa.europa.eu/documents/10162/f684ca0c-072b-a60e-100b-825439aa8429

4. ENVIRONMENTAL HAZARD PROFILE

MCCPs are UVCBs and the properties depend on the chain length and the chlorination degree of the numerous possible congeners. There is a relationship between biodegradation and both chain length and degree of chlorination which has been subject to detailed review under REACH.

The Substance Evaluation Conclusion for MCCPs summarises results from calculated prediction on the persistence of C14 to C17 MCCPs in water, which depends on the chlorine content of all of the structures. Almost all of the structures are predicted to be persistent, although the predictions may not all be reliable. Summarising from a variety of biodegradation tests, it is concluded that C14 chlorinated n-alkane, 41.3% and 45.5% Cl wt. meet the criteria for aquatic biodegradation, whereas "*the overall level of degradation appears to decline with increasing numbers of chlorine atoms.*"[38] The eMSCA concludes that many constituents of commercial chlorinated paraffin products exceed half-lives of 120 days in sediment at 12 °C.

4.1. Potential for secondary poisoning and bioaccumulation

The bioaccumulation potential of MCCPs is considered to decrease with increasing carbon chain length and chlorine content, according to Glüge et al. (2018). ECHA suspects C14 chlorinated n-alkane with a chlorine content of 50−52 % and of 55−60 % as potentially bioaccumulative and therefore requested further testing under REACH, The Substance Evaluation Conclusion for MCCPs underpins their relatively long elimination or depuration half-lives in fish and mammals, which is interpreted as a characteristic of a bioaccumulative substance (UK Environment Agency, 2019, p82)).

Glüge et al. (2018) note that besides the requested aqueous and dietary exposure tests by ECHA from the registrant, manufacturers tests for MCCPs with other carbon chain lengths and chlorination degrees will most probably be necessary to conclude whether MCCPs (or single congener groups of the MCCPs) should finally be considered as bioaccumulative.

The following Figure 4-1 shows that technical chlorinated paraffins (containing SCCP, MCCP and LCCP at various concentrations) have similar bioconcentration potential (log BCF) and bioaccumulation potential (log BAF) in aquatic organisms (daphnia magna).[39] The different substance groups appear to bioaccumulate to a similar extent in terrestrial birds and mammals (UK Environment Agency, 2019). Chlorination degree and chain length affect these properties, but the overall result indicates that all chlorinated paraffins can be environmentally problematic.

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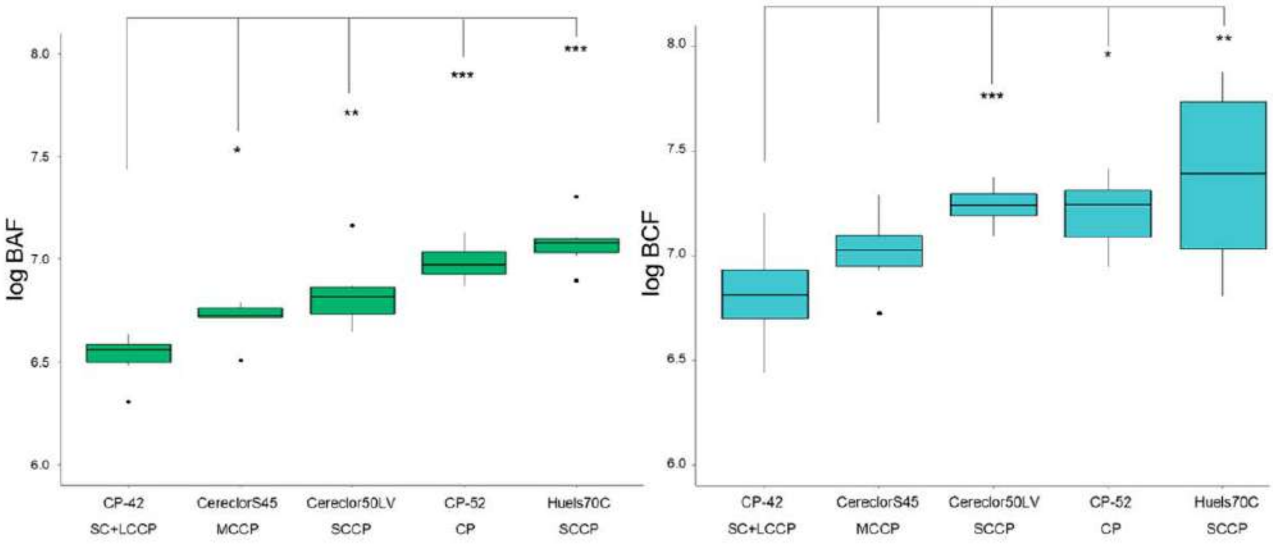
[38] UK Environment Agency (2019) Substance Evaluation Conclusion EC No 287-477-0 as required by REACH Article 48 and Evaluation report for Medium-chain chlorinated paraffins, available online: https://echa.europa.eu/documents/10162/f684ca0c-072b-a60e-100b-825439aa8429

[39] Castro M, Sobek A, Yuan B, Breitholtz M. (2019) Bioaccumulation Potential of CPs in Aquatic Organisms: Uptake and Depuration in Daphnia magna. Environ Sci Technol. 53(16): 9533-9541.

Figure 4-1: **Bioaccumulation and bioconcentration factors in aquatic organisms for five different technical CPs**



Source: Castro et al, (2019)

4.2. Endpoints of concern

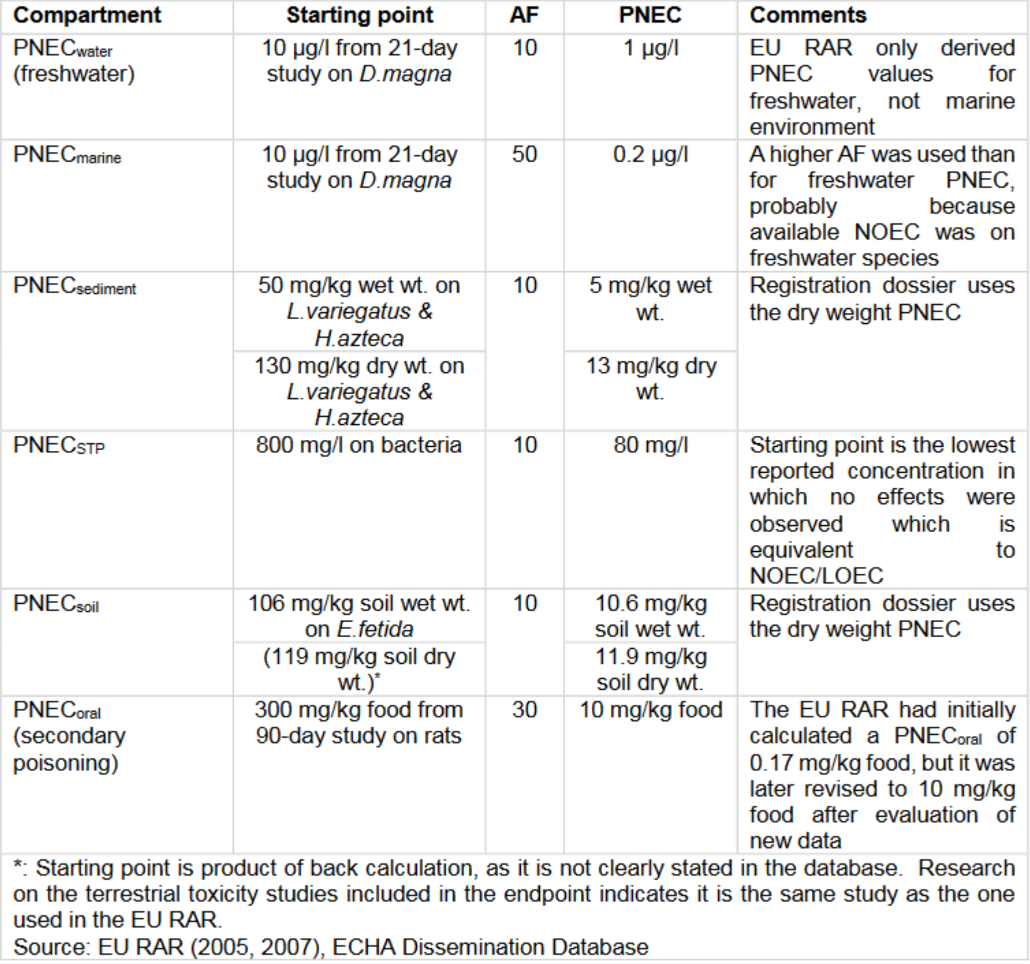
CLP Regulation classifies MCCPs as acute and chronic toxic to the aquatic environment (H400 - Very toxic to aquatic life and H410 - Very toxic to aquatic life with long lasting effects).

4.3. Guidance values (PNECs)

KEMI (2018) compared the Predicted No Effect Concentrations (PNEC) for MCCPs calculated in the EU RAR where the NOECs value was determined for the registration information in the ECHA database and found that the registrants used the same starting points to derive the PNECs.

The PNEC values as compiled by KEMI (2018) are presented in the following figure.

Figure 4-2: PNEC values for MCCPs



Compartment	Starting point	AF	PNEC	Comments
PNEC_{water} (freshwater)	10 µg/l from 21-day study on *D.magna*	10	1 µg/l	EU RAR only derived PNEC values for freshwater, not marine environment
PNEC_{marine}	10 µg/l from 21-day study on *D.magna*	50	0.2 µg/l	A higher AF was used than for freshwater PNEC, probably because available NOEC was on freshwater species
$\text{PNEC}_{sediment}$	50 mg/kg wet wt. on *L.variegatus & H.azteca*	10	5 mg/kg wet wt.	Registration dossier uses the dry weight PNEC
	130 mg/kg dry wt. on *L.variegatus & H.azteca*		13 mg/kg dry wt.	
PNEC_{STP}	800 mg/l on bacteria	10	80 mg/l	Starting point is the lowest reported concentration in which no effects were observed which is equivalent to NOEC/LOEC
PNEC_{soil}	106 mg/kg soil wet wt. on *E.fetida*	10	10.6 mg/kg soil wet wt.	Registration dossier uses the dry weight PNEC
	(119 mg/kg soil dry wt.)*		11.9 mg/kg soil dry wt.	
PNEC_{oral} (secondary poisoning)	300 mg/kg food from 90-day study on rats	30	10 mg/kg food	The EU RAR had initially calculated a PNEC_{oral} of 0.17 mg/kg food, but it was later revised to 10 mg/kg food after evaluation of new data

*: Starting point is product of back calculation, as it is not clearly stated in the database. Research on the terrestrial toxicity studies included in the endpoint indicates it is the same study as the one used in the EU RAR.

Source: EU RAR (2005, 2007), ECHA Dissemination Database

Source: KEMI (2018)

Conclusions on health and environmental hazard

First, it should be noted that with respect to the environmental and human health hazards MCCPs are understood to pose a lower risk than the short-chained chlorinated paraffins. While toxic effects seem to play a role, carcinogenicity cannot either be confirmed or be excluded. There are warnings regarding human health risks in terms of their endocrine disrupting properties and possible harm via lactation (H362). MCCPs however have to be considered as highly relevant for the environment especially taken into account the substance evaluation conclusion for PBT properties as well as their toxicity to aquatic organisms (H400 + H410).

5. WASTE MANAGEMENT OF ELECTRICAL AND ELECTRONIC EQUIPMENT

5.1. Description of waste streams

5.1.1. Main materials where the substance is contained

MCCPs are used as secondary plasticisers in flexible plastics, rubbers and other polymers that are applied in a multitude of application areas. Out of the total MCCP consumption in the EU, 54 % is used in PVC products, 11 % in rubber and 35 % in other polymers. Out of these, EEE products represent the largest application area. KEMI (2018) assumes that within the EEE sector, 83 % of MCCPs are used in PVC and 17 % in other polymers. The following considerations focus on the fate of MCCPs in the end of life treatment of PVC insulated cable and wires that are constituents of WEEE. Other MCCP-containing plastic parts and coatings found in WEEE are not thought to undergo specific treatment in regard to their MCCP content.

5.1.2. WEEE categories containing the substance

Cables and wires meet the definition of EEE as set out in Article 3(1)(a) of the WEEE Directive 2012/19/EU. Cables that are components of another EEE (internal – permanently attached – or externally connected and removable but sold together or marketed/shipped for use with the EEE), fall within the scope of the recast WEEE Directive (coming into force in 2018). Individual cables, that are not part of another EEE, are considered as EEE themselves and hence fall within the scope of WEEE. Only non-finished cables i.e. cable reels without plugs would be out of the scope of WEEE.

PVC insulated cables and wires principally occur in almost all EEE products although highly integrated products, such as smart phones, may barley contain discrete internal wires. The following lists EEE categories (Annex III of the WEEE Directive), which are likely to contain PVC insulated cables that contain MCCPs:

- Category 1: Temperature exchange equipment (e.g. refrigerators);
- Category 2: Screens, monitors and equipment containing screens having a surface > 100 cm^2;
- Category 4: Large equipment (any external dimension more than 50 cm);
- Category 5: Small equipment (no external dimension more than 50 cm); and
- Category 6: Small IT and telecommunication equipment (external dimension more than 50 cm).

Lamps (category 3) are not thought to contain PVC insulated cables or wires in relevant quantities, according to KEMI (2018). However, the authors of the dossier at hand remind on the fact that LED (Light Emitting Diodes) strips, which are nowadays widely incorporated in luminaires and in other products, contains flexible insulation and electrical wiring, as demonstrated by Figure 5-1.

Figure 5-1: Flexible LED-stripe (Light Emitting Diodes) containing internal wiring and insulation based on flexible polymers

Source: Oeko-Institut

5.2. Applied waste treatment processes

WEEE shall be collected separately from household waste, according to the collection targets specified WEEE Directive, and then recycled. In the EU, collection and recycling of WEEE, containing MCCPs, shall be implemented according to the following standards:

- EN 50625-1: Collection, logistics & treatment requirements for WEEE - Part 1: General treatment requirements
- TS 50625-5: Collection, logistics & treatment requirements for WEEE -- Part 5: Specification for the end-processing of WEEE fractions- copper and precious metals

However, collection rates of WEEE in the EU have been below 50 % (as of 2016), according to Eurostat (see Figure 5-2).[40] A collection target of 65 % applies since the beginning of 2019. This means approximately half of the generated amounts of WEEE are currently not collected and treated separately. The fate of not collected WEEE is uncertain, possibly old EEE products are incinerated together with household waste. A certain amount of end of life EEE might be exported abroad. According to the Countering WEEE Illegal Trade (CWIT) project in Europe in 2012, WEEE which is not part of the officially reported amounts of collection and recycling systems, was exported and recycled under crude conditions outside Europe. It is to be assumed that MCCPs contained in these waste flows does not undergo controlled end of life treatment.

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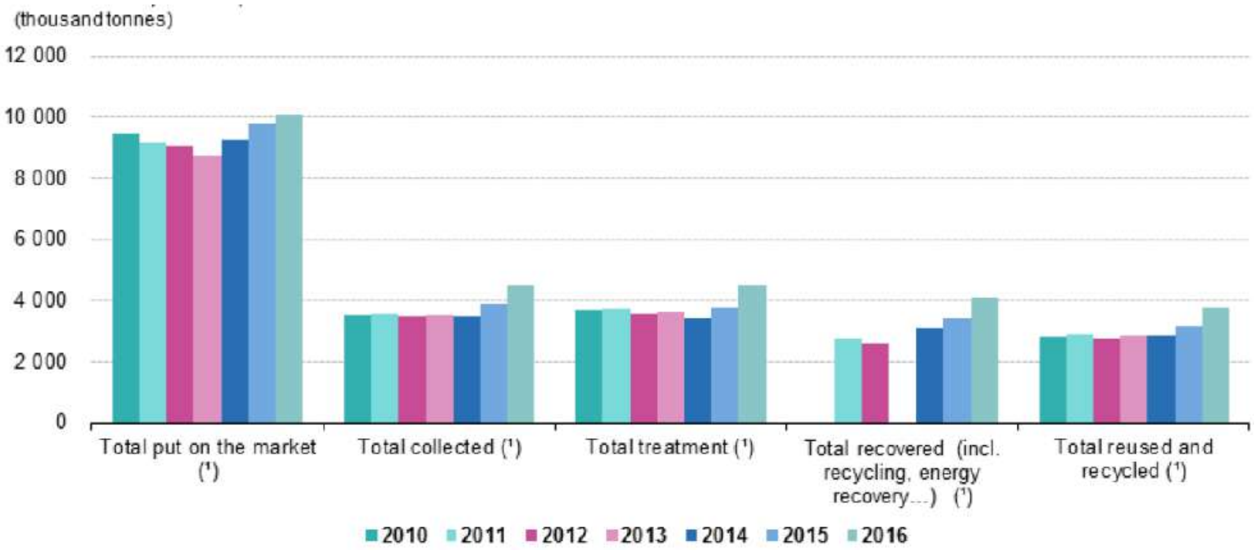
[40] Eurostat (2019): Waste statistics -electrical and electronic equipment. https://ec.europa.eu/eurostat/statistics-explained/pdfscache/32212.pdf. last viewed: 12.11.2019

Figure 5-2: Total EEE put on the market and WEEE collected and recycled in the EU (2010-2016)



Source: Eurostat (2019)

Collected WEEE undergoes manual dismantling or mechanical shredding, typically in large metal shredders, which can be combined with automated material sorting. External cables adhering to WEEE items must be removed and this can be performed before or after the manual dismantling or mechanical shredding processes. While manually dismantled cable scrap is usually a mono-fraction, consisting of cables and connectors with undamaged plastic insulation, the shredding products are usually mixtures of granulated metals and plastics. These granules need to be separated by means of physical or gravimetric separation processes. From these sorting processes, MCCPs are likely to end up in mixed plastic enriched fractions but partly in PVC residue that remains in the copper enriched fraction.

5.2.1. Initial treatment processes applied to the WEEE containing the substance of concern

Table 5-1: Initial treatment processes applied to different categories of WEEE

Initial treatment processes	The substance is present in appliances belonging to:					
	Cat1	Cat2	Cat3	Cat4	Cat5	Cat6
For WEEE collected separately						
Collection and transport	x	x	x	x	x	x
Dedicated treatment processes for cooling & freezing appliances	x					
Dedicated treatment processes for screens		x				
Dedicated treatment processes for lamps			x			

Initial treatment processes	The substance is present in appliances belonging to:					
	Cat1	Cat2	Cat3	Cat4	Cat5	Cat6
Manual dismantling	x	x		x	x	x
Shredding (and automated sorting)	x			x	x	x
For WEEE not collected separately						
Landfilling (of residual waste)		x	x		x	x
Mechanical treatment (of residual waste)		x	x		x	x
Incineration		x	x		x	x
Uncontrolled treatment in third countries	x	x		x	x	x

5.2.2. Treatment processes applied to wastes derived from WEEE containing the substance of concern

Recyclables and residues separated from WEEE normally undergo further treatment processes. Cables derived from dismantling of WEEE are sent to cable shredders. These are usually cutting mills combined with a sorting technique, including air separation, sieving, vibration desks or wet density separation. While the metal enriched fraction is sent to copper smelters and refiners, the MCCP-relevant fractions encompass different concentrates of plastics (PVC and others) as well as electronic components, depending on the process technologies applied:

Cables:

- Transports and storage of WEEE and intermediate recycling fractions and wastes
- Shredding and automated sorting of metals and plastic insulation material
- Recycling of non-ferrous metals in copper smelting and refining plants
- Recycling of pre-sorted PVC
- Incineration of plastic-rich residues in dedicated waste incinerators
- Landfilling of incineration residues

Electronic components (additional to the above):

- Shredding and automated sorting
- Recycling of non-ferrous metals in copper smelters
- Co-incineration of non-metallic residues in copper smelters

The economic driver of cable recycling is recovery of copper. The non-metal fraction is composed of the various polymers used in cable insulations i.e. PVC, PE, HDPE, VPE and rubber, as well as metals residues. The plastics fraction is usually incinerated. Plastics recycling technologies for PVC cables do exist (e.g. Vinyloop®) but the focus will be on mechanical recycling. About 100 kt of PVC cables are recycled annually. PVC from cable insulation is typically recycled into massive road traffic management products such as traffic cones and road bumps to slow down traffic. The MCCPs do not impede PVC cable recycling.[41] In 2015, over 100,000 tonnes of PVC cable waste were collected and in 2016, around 150,000 tonnes of PVC cable waste recycled.[42]

PVC from cable recycling that is not recoverable is usually incinerated in waste incineration plants. The combustion of PVC and MCCP bears the risk of a formation of dibenzo-p-dioxins and furans. In the EU, the Industrial Emissions Directive imposes strict limits on the emission of all harmful pollutants from waste incineration plants. . It is assumed, that municipal waste incinerator plants and metal smelters in the EU, run at sufficiently high temperatures (>900°C) so to prevent the formation/reformation of dioxins and are equipped with state-of-the-art waste gas treatment so that emissions of these pollutants into the environment are below the allowed thresholds.

5.3. Waste treatment processes relevant for assessment under RoHS

Releases of MCCPs during WEEE treatment are to be expected above all during the **shredding of PVC cables as well as for mixed WEEE,** which takes place at a large number of installations for disposal as well as for the recycling. During shredding residues that contain polymers (mainly PVC) are likely to contain MCCPs bound to the surface of the polymers. Such residues occur as dust and swirls of material enable MCCPs also to enter into the vapour phase.

The conversion of PVC recyclate may contain calendering as a process step. Although, this is not an inherent waste treatment process, it is of relevance as recycling and initial conversion of recyclate may occur in the same manufacturing site. If higher temperatures (> ambient temperature) are used for the calendering, releases through evaporation are more likely although such loss will be subject to risk management measures also employed in the first life manufacture.

The importance of the treatment processes for the assessment under RoHS will be commented on in the following sections.

The other WEEE treatment processes are considered of low relevance regarding MCCPs for different reasons: either they do not operate in a temperature range that is relevant for MCCP evaporation (above the ambient temperature but lower than the 900°C incineration temperature) or a process involves material parts that are too big to play a role for inhalation. In general, but especially for incineration and disposal, it is assumed that appropriate measures are taken and suitable to prevent releases, e.g. the appropriate construction of landfills so that leachate does not play a significant role.

5.4. Releases from (relevant) WEEE treatment processes

The figures below are generally based on the assumption of an annual MCCP consumption of 15,000 t in EEE in the EU (KEMI 2018, p34). This figure is almost certainly an underestimate as it solely takes into account the MCCPs used in manufacturing inside the EU but not the MCCP that has been imported as a constituent of final EEE goods (see section 2.3). Thus, it is very likely that more than 15,000 t/a of MCCP is contained in all EEE, including products manufactured as well as imported into the EU.

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[41] ECVM (2020): Contribution submitted on 13.02.2020 during the stakeholder consultation conducted from 05 December 2019 until 13 February 2020 in the course of the study to support the review of the list of restricted substances and to assess a new exemption request under RoHS 2 (Pack 15)

[42] VinylPlus, available at https://vinylplus.eu/uploads/Modules/Bannersreport/vinylplus-progress-report-2017.pdf, accessed on 30 July 2018.

It should be noted that KEMI (2018) lacked information regarding the MCCPs contained in imported EEE. Since the amount of MCCPs co-imported in EEE goods is unknown, the estimation presented below indicates that data gap with the term “plus X”.

There are four principal endpoints for WEEE, each having specific implications on the fate of the MCCPs contained in PVC-based cable and wire insulation materials.

- **WEEE collected separately:**

  Under the assumption that 49 % of EEE put on the market is collected as WEEE in the following years (Eurostat, 2019), this means[43] that approximately **half of the annual MCCP-inputs** to the European EEE market finally **end up in the dedicated WEEE treatment** channel.

  In terms of weight, 4.5 million tonnes of WEEE are collected per year (as of 2016) in the EU-28 (Eurostat, 2019). The quantity of MCCP in WEEE is the same as the MCCP content in EEE placed on the European market (i.e. 15,000 plus X t/a) since there is no significant release of MCCPs during the use phase of EEE. Thus, based on a 49 % collection rate, it can be estimated that the MCCP input to WEEE treatment channel is 7,350 plus X t/a (= 49 % × 15,000 plus X t/a).

  This amount enters subsequent cable recycling processes, including manual dismantling and mechanical shredding / separation processes. The MCCPs contained in the separated PVC fraction will be destroyed in the process of incineration in state-of-the-art waste incinerators (i.e. at temperatures >900°C). The highest MCCP releases are expected during shredding for recycling and mixed waste of and electronic products (WEEE) as outlined earlier in the preceded section.

  Now looking at MCCP in end-of-life EEE, another uncertainty exists. Concerning the amount of WEEE that enters separate collection and disposal routes (i.e.), this leaves 51 % of EEE that ends up in municipal waste incineration, landfilling, exports and remains unaccounted for. Another ~50 % (i.e. 7,650 plus X t/a) of MCCPs end up in one of the following three disposal routes:

- **Reused WEEE:**

  A small percentage (ca. 1 % according to Eurostat data for 2012) of WEEE may be reused.[44] The MCCPs contained therein remain in the second-hand products and re-enter the WEEE at the end of the second life phase.

- **WEEE collected as municipal solid waste**:

  The amounts of WEEE entering this disposal route are uncertain. However, experiences from WEEE collection suggest that a large share of end-of-life EEE is neither turned in as WEEE nor disposed of as household waste but rather stockpiled in the consumers` households for a longer period of time. While the MCCPs contained in stockpiled end-of-life EEE remains therein until it eventually is considered WEEE and disposed of, the MCCPs will be destroyed in the process of incineration in state-of-the-art municipal waste incinerators (i.e. at temperatures >900°C).

- **WEEE exported to third countries or remains unaccounted for**:

  A large fraction of the total flow of end-of-life EEE is not disposed of as household waste nor as WEEE but traded as second hand EEE. The fate of MCCPs contained in exported WEEE is

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[43] Assuming that the amount of end-of-life EEE generated in a given year roughly equals that of EEE products being placed on the EU market in the preceding years.

[44] It needs to be born in mind that old EEE (i.e. second hand goods) destined for reuse do not enter the WEEE collection as long as they circulate on the second hand market. Thus, re-used EEE (and the materials contained therein) are technically not subject to WEEE accounting. As for the domestic second-hand market, this results merely in delay of WEEE generation whereas second-hand EEE exported outside the EU drops out of the European WEEE accounting.

unclear but a release into the environment (air) cannot be ruled out if cable scrap is subjected to open burning at uncontrolled temperatures (further elaborated in section 5.5).

To conclude on the MCCP releases from WEEE treatment inside EU, first of all it should be noted that, from WEEE that is incinerated conformal, no releases should be expected. However, during recycling, releases are possible. From WEEE that is collected and treated as municipal solid waste also no releases are expected as this waste is incinerated as well even though this is not the correct way of disposal. If ever, EEE are reused, after their second (or more) re-use phases, EEE end up in either the WEEE disposal route or the municipal solid waste. No releases are expected during the use phase. Finally, non-EU disposal routes (export & open burning) are the sources for most of the MCCPs emissions globally, as elaborated in the next section.

Other release routes are formulation, conversion, and re-use of PVC recyclate, however releases from re-use can be neglected.

5.5. Collection and treatment of electrical and electronic equipment outside EU

In the discussion on end-of-life management of products containing hazardous substances, it is often argued that recycling and disposal of WEEE is conducted under controlled conditions in the EU with no significant emissions of hazardous substances to the environment.

Nevertheless, it needs to be recognised that a significant share of WEEE is not collected and rather traded outside the EU. The transboundary trade is understood to be not transparent and partly illegal. Old EEE that is traded as second- hand goods or products for repair and reuse does not fall under the WEEE directive because they are not considered waste. Even products that are damaged beyond repair are often not declared as waste and rather exported as second-hand goods. Since the average WEEE collection rates have been below 50 % in the EU average in 2016 (see Figure 5-2), one must assume that the legal trade of second-hand EEE as well as illegal exports of WEEE towards receiving countries outside the EU occurs.

According to the outcomes of an EU financed research study on illegal WEEE trade (Huisman et al. 2015), only 35 % of WEEE generated in the EU28 plus Norway and Switzerland was collected and recycled under controlled conditions in 2012. Although another 23 % was also collected, subsequent treatment was considered to be non-compliant with the European WEEE-Directive. 750,000 tonnes (8 %) were estimated to have been disposed via the general household waste bin and treated as MSW. From the undocumented 3.2 million tonnes (34 % of total), it was estimated that 1.7 million tonnes have been processed within the EU and 1.5 million tonnes exported from the EU (see Table 5-2 and Table 5-3).

Table 5-2: Management pathways of WEEE in the EU28 plus Norway and Switzerland in 2012

Management path	Volumes [Million t]	Volumes [% of total]
Collected and recycled	3.3	35 %
Disposed with household waste	0.75	8 %
Collected and processed under non-compliant conditions	2.2	23 %
Undocumented	3.2	34 %
Total	9.45	100 %

Source: (Huisman et al. 2015)[45]

Table 5-3: Pathways of undocumented WEEE generated in the EU28 plus Norway and Switzerland in 2012

Pathway of undocumented WEEE	Volumes [Mio t]	Volumes [% of total]	Sub-pathways of undocumented WEEE	Volumes [Mio t]	Volumes [% of total]
Processed in the EU	1.7 Mio. t	18 %	Non-compliant processing	0.95 Mio. t	10 %
			Scavenged and stolen parts	0.75 Mio t	8 %
Exported from the EU	1.5 Mio. t	16 %	Documented exports of used equipment	0.2 Mio t	2 %
			Undocumented exports of used equipment	0.9 Mio t	10 %
			Undocumented export of WEEE	0.4 Mio t	4 %

Source: (Huisman et al. 2015)

These figures indicate that a significant share of WEEE – including cables and other components with contents of MCCPs – ends up in countries where WEEE is treated and disposed of by means of very crude technologies that entail environment and human health damage.

With regards to cables, this of particular concern because it is usually performed by open burning of cables in order to liberate the metal wires (mostly copper) from their insulation material. The practice of open cable burning has been observed in many countries, but in particular in countries with a strong dominance of an unregulated recycling sector such as Ghana and Nigeria (Manhart et al.

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[45] Huisman, J.; Botezatu, I.; Herreras, L.; Liddane, M.; Hintsa, J.; Di Luda Cortemiglia, V. et al. (2015): Countering WEEE Illegal Trade (CWIT) Summary Report, Market Assessment, Legal Analysis, Crime Analysis and Recommendations Roadmap. Lyon. Online verfügbar unter http://www.cwitproject.eu/wp-content/uploads/2015/09/CWIT-Final-Report.pdf, last viewed: 17.07.2018.

2011[46]; Prakash und Manhart 2010[47]; Atiemo et al. 2016[48]). At the same time, West-African countries are also known to be major destinations for used EEE and WEEE exports from the EU. According to (Odeyingbo et al. 2017[49]) 77 % (around 56,000 t/a) of all imports of used equipment into Lagos (Nigeria) originated from EU countries (Amoyaw-Osei et al. 2011)[50] estimated that open cable fires in five West-African countries (Nigeria, Benin, Ghana, Côte d'Ivoire, Liberia) cause total dioxin (PCDD/F) emission equivalent to 3 %-7 % of total EU dioxin emissions to air in 2005.

Regarding the applied practices, recent research and co-operation projects – and in particular the Swiss funded SRI project[51] – found out that cable burning is mostly applied for waste cables with one or more of the following criteria:

- Short cables
- Thin cables
- Cables with no massive core
- Dirty cables
- Twisted cables

For such cables, mechanical liberation of metal wires (so called stripping) is economically unattractive as this would either demand quite significant labour input, or investments and running costs for recycling machines such as cable granulators. In this situation, open burning is – from an economic perspective – more attractive to recyclers (Buchert et al. 2016).[52] Thus, in many developing countries, mechanical cable stripping is only applied for long and quite thick cables with massive cores (e.g. overland power cables). Cables from EEE mostly fulfil the above listed criteria and are likely to be burned in informal sector settings.

In conclusion, the MCCP contained in WEEE or second-hand EEE that is traded outside the EU in amounts unaccounted for, is possible to undergo open burning under crude conditions (no emission controls applied, absence of occupational health protection, inadequate disposal of residues). Uncontrolled heating and burning of MCCP bearing plastics at low temperatures (<900°C) can lead to the formation of dibenzo-p-dioxins and furans, in particular in the presence of copper. Another combustion product is hydrochloric acid (HCl), a highly acidic fume that causes respiratory problems if inhaled without protective gear. However, this pollution potential is not specific to MCCP but also

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[46] Manhart, A.; Osibanjo, O.; Aderinto, A.; Prakash, S. (2011): Informal e-waste management in Lagos, Nigeria - socio-economic impacts and feasibility of international recycling co-operations. Final report of component 3 of the UNEP SBC E-waste Africa Project. Lagos & Freiburg.

[47] Prakash, S.; Manhart, A. (2010): Socio-economic assessment and feasibility study on sustainable e-waste management in Ghana. Öko-Institut e.V. Freiburg. Online verfügbar unter http://www.oeko.de/oekodoc/1057/2010-105-en.pdf, last viewed: 12.11.2015.

[48] Atiemo, S.; Faabeluon, L.; Manhart, A.; Nyaaba, L.; Schleicher, T. (2016): Baseline Assessment on E-waste Management in Ghana. Accra.

[49] Odeyingbo, O.; Nnorom, I.; Deubzer, O. (2017): Person in the Port Project - Assessing Import of Used Electrical and Electronic Equipment into Nigeria. Bonn. Online verfügbar unter http://collections.unu.edu/eserv/UNU:6349/PiP_Report.pdf, last viewed: 17.07.2018.

[50] Amoyaw-Osei, Y.; Agyekum, O. O.; Pwamang, J. A.; Mueller, E.; Fasko, R.; Schluep, M. (2011): Ghana e-Waste Country Assessmen. Accra. Online verfügbar unter http://ewasteguide.info/files/Amoyaw-Osei_2011_GreenAd-Empa.pdf, last viewed: 10.12.2015

[51] See: https://www.sustainable-recycling.org/

[52] Buchert, M.; Manhart, A.; Mehlhart, G.; Degreif, S.; Bleher, D.; Schleicher, T. et al. (2016): Transition to sound recycling of e-waste and car waste in developing countries - Lessons learned from implementing the Best-of-two-Worlds concept in Ghana and Egypt. Freiburg. Online verfügbar unter https://www.oeko.de/oekodoc/2533/2016-060-en.pdf, last viewed: 17.07.2018.

occurs for PVC as such, because the polymer consists of chlorine too. However, the presence of MCCPs in PVC cable insulation increases the chlorine content and adds to the problem.

In more recent data from EUROSTAT (2019), the collection rate of WEEE was found to be 49 % of the EEE put on the market. A detailed breakdown of numbers to the categories presented in Huisman et al. (2015) was not carried out since then. However, the share of WEEE and EEE second hand goods exported to non-European countries is still considered to be a significant number.

6. EXPOSURE ESTIMATION DURING USE AND/OR DURING WEEE TREATMENT

For the exposure estimation applying modelling tools, the estimations made by KEMI (2018) have been reviewed and can be followed. Beyond that, this section on exposure puts effort into the compilation of additional data that has not been brought into the discussion so far.

6.1. Human exposure estimation

6.1.1. Exposure of workers of WEEE processing plants

The following WEEE treatment activities are relevant for estimating the exposure to MCCPs at the working place:

- Shredding of WEEE that is collected separately; shredding of PVC cable waste,
- Formulation of PVC recyclate; and conversion of PVC recyclate into new PVC articles.

Incineration plants are not considered for the exposure of workers to MCCPs, as the substances are destroyed during incineration under controlled conditions.

Exposure estimation for workers was modelled by KEMI (2018) in the course of the preparation of the dossier at hand by using the ECETOC's Targeted Risk Assessment (TRA)[53] tool. It helps calculating the risk of exposure from chemicals to workers, consumers and the environment. The ECETOC TRA tool is intended for manufacturing and formulation processes, appropriate processes to describe the exposure conditions of waste treatment processes are available so far. The process category 24: "*high (mechanical) energy work-up of substances bound in materials and/or articles*" has been selected to calculate the exposure of workers of EEE waste processing plants. This approach was first introduced by the Austrian Umweltbundesamt for the RoHS assessment of the phthalates DEHP, DBP and BBP; it has also been used by the Fraunhofer ITEM IPA for TBBP-A.[54]

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[53] European Centre for Ecotoxicology and Toxicology of Chemicals' Targeted Risk Assessment 3; http://www.ecetoc.org/tools/targeted-risk-assessment-tra/

[54] Fraunhofer ITEM IPA, Wibbertmann and Hahn (2018): Assessment of TBBP-A (tetrabromopisphenol-A) according to the "Methodology for Identification and Assessment of Substances for Inclusion in the List of Restricted Substances (Annex III) under the RoHS2 Directive". Update August 2018. Fraunhofer ITEM, Fraunhofer IPA, Stuttgart.

Table 6-1: Input parameters used in ECETOC TRA modelling

Scenario name	**Shredding of separately collected WEEE and PVC cable waste**	**Formulation and conversion of PVC recyclate**
Process categories	24a, b, c	2, 3, 4, 8a, 8b, 14 (for both); plus 1 and 15 for formulation; plus 6 and 21 for conversion
Treatment setting	Professional	Industrial
Duration of activity	>4 hours/day	>4 hours/day
Use of ventilation	Outdoors	Indoor with LEV
Respiratory protection	No	No
Substance in preparation	<1 % (WEEE) 1-5 % (PVC cable waste)	1-5 % (formulation) 5-25 % (conversion into new material)

Source: KEMI (2018)

The consultants of this review study can follow the estimations of KEMI (2018) [55] both in relation to the methodology applied and the scenarios and parameters used. In the figure below, the long-term exposure estimates are copied for inhalative and dermal exposure because for these scenarios corresponding DNELs exist that can be compared with.

The highest exposure estimations incur for the following scenarios:

- For Long-term Inhalative Exposure, the shredding processes resulted in the highest estimates:
  - Shredding of WEEE collected separately (24c): 1.40 mg/m^3
  - Shredding of PVC cable waste (24c): 2.80 mg/m^3

  It was assumed that the substance was a solid with medium dustiness. It should however be noted, that the subcategory “c” assumes a high fugacity, which means that the process temperature is higher than the melting point of the substance; as MCCPs are a UVCB there is no distinct melting point but commercial MCCP mixtures gradually soften when heated over a certain range of temperature levels. Thus, the subcategory assuming a high fugacity could result in an overestimation.
- For Long-Term Dermal exposure, Conversion of PVC recyclate (6) resulted in a high estimate of 16.5 mg/kg/day.

In order to further evaluate the estimates, workplace measurements have been investigated. However, no workplace measurements in WEEE processing plants has of yet been available.

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[55] Op. cit. KEMI 2018, table 44 in Annex I

Figure 6-1: Exposure estimates by ECETOC TRA as performed by KEMI

Scenario name (PROC #)	Long-term Inhalative Exposure Estimate (mg/m^3)	Long-term Dermal Exposure Estimate (mg/kg/day)
Shredding of WEEE collected separately (24a)	2.10E-01	2.83E-01
Shredding of WEEE collected separately (24b)	3.50E-01	2.83E-01
Shredding of WEEE collected separately (24c)	1.40E+00	2.83E-01
Shredding of PVC cable waste (24a)	4.20E-01	5.66E-01
Shredding of PVC cable waste (24b)	7.00E-01	5.66E-01
Shredding of PVC cable waste (24c)	2.80E+00	5.66E-01
Formulation of PVC recyclate (1)	2.00E-03	6.86E-03
Formulation of PVC recyclate (2)	2.00E-04	2.74E-01
Formulation of PVC recyclate (3)	2.00E-03	1.37E-01
Formulation of PVC recyclate (4)	5.00E-01	1.37E+00
Formulation of PVC recyclate (8a)	1.00E+00	2.74E+00
Formulation of PVC recyclate (8b)	2.50E-01	2.74E+00
Formulation of PVC recyclate (14)	2.00E-01	6.86E-01
Formulation of PVC recyclate (15)	1.00E-01	6.86E-02
Conversion of PVC recyclate (2)	6.00E-04	8.23E-01
Conversion of PVC recyclate (3)	6.00E-03	4.11E-01
Conversion of PVC recyclate (4)	3.00E-02	4.11E+00
Conversion of PVC recyclate (6)	6.00E-03	1.65E+01
Conversion of PVC recyclate (8a)	3.00E-02	8.23E+00
Conversion of PVC recyclate (8b)	3.00E-03	8.23E+00
Conversion of PVC recyclate (14)	6.00E-03	2.06E+00
Conversion of PVC recyclate (21)	6.00E-02	1.70E+00

Source: KEMI (2018)

6.1.2. Exposure of neighbouring residents of EEE waste processing plants

Monitoring data for air would be necessary in order to estimate local exposure of neighbouring residents of EEE waste processing plants. However, there was no such data found during the preparation of this dossier.

6.1.3. Consumer exposure

KEMI (2018) does not consider consumer exposure to MCCPs as currently being relevant in this case, but points out that this might need to be evaluated in the future. For the current assessment, a number of analysis of indoor air and indoor dust have been found and reviewed:

- Wong et al (2017)[56] analysed selected dust samples from offices, homes and non-residential buildings in several countries. The highest concentration of chlorinated paraffins was measured in dust from China with a mean of 3044 µg/g. According to the authors, this may be due to the fact that China is the biggest producer of chlorinated paraffins. Chlorinated paraffins in dust in samples from Australia, the United Kingdom, Canada and Sweden ranged from 280 to 1330 µg/g. The pattern of congeners measured in the dust samples differ. In the dust from Australia, Canada and UK, C14 congeners were predominant and C15 congeners were the second most predominant.
- Dust analysis from private homes in Stockholm from 2018[57] showed that MCCPs with a median concentration of 31 µg/g dust was found; thus MCCPs were detected in higher concentrations compared to other chlorinated paraffins LCCPs and SCCPs (with a median concentration of 20 and 13 µg/g dust).
- A review on “chlorinated paraffins in indoor dust samples” (Coelhan and Hilger 2014)[58] reported data from Hamburg and Munich: Accordingly, MCCPs were detected in concentrations of 36 and 400 µg/g dust.
- As for indoor air measurements, Coelhan and Hilger (2014) report one study that measured MCCPs in indoor air at a median concentration of 69 ng/m^3 and a range from <5 to 210 ng/m^3.

The data presented here underlines that consumers, especially children, are exposed to MCCPs that are released from articles. The impact arising from this exposure is discussed in section 7.3. There is also extensive data on the occurrence of chlorinated paraffins in human breast milk, showing that exposure occurs.[59]

6.2. Environmental exposure estimation

KEMI (2018) uses the EUSES tool[60] to estimate the predicted environmental concentrations (PECs); the evaluation was carried out for all relevant waste management processes, i.e. shredding, formulation and compounding, incineration and landfilling, which will be summarised. Additionally, to the exposures from models as performed by KEMI (2018), environmental monitoring data for MCCPs are compiled from information provided by the Norwegian Environment Agency[61] and from information specified in Glüge et al. (2018).

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[56] Wong, F.; Suzuki, G.; Michinaka, C.; Yuan, B.; Takigami, H.; de Wit, C.A. (2017): Dioxin-like activities, halogenated flame retardants, organophosphate esters and chlorinated paraffins in dust from Australia, the United Kingdom, Canada, Sweden and China, Chemosphere, 168 (1248).

[57] WSP Environmental Sverige (2018): Indoor Pollutants In Dust From NonHazCity Pilot Families In Stockholm, Test Report On Dust Campaign, Report from Work in GoA 5.4 ”Test your environment”.

[58] Coelhan, M.; Hilger, B. (2014): Chlorinated Paraffins in Indoor Dust Samples: A Review; Current Organic Chemistry 2014, 18, 2209- 2217.

[59] EFSA Panel on Contaminants in the Food Chain (CONTAM) (2020): Scientific opinion on the risk for animal and human health related to the presence of chlorinated paraffins in feed and food. EFSA Journal;18(3):5991, available online: https://efsa.onlinelibrary.wiley.com/doi/pdf/10.2903/j.efsa.2020.5991

[60] European Union System for the Evaluation of Substances

[61] Norwegian Environment Agency (2018): Contribution submitted on 15.06.2018 during the stakeholder consultation conducted from 20 April 2018 to 15 June 2018 by Oeko-Institut in the course of the study to support the review of the list of restricted substances and to assess a new exemption request under RoHS 2 (Pack 15);

KEMI (2018) performed EUSES estimations for releases of MCCPs during WEEE treatment on the local and regional scale. The estimations for the regional PEC, which aggregates the releases from different WEEE processes, are shown in the table below.

Direct releases occur initially to air and water, but due to the MCCPs persistence and the environmental distribution of emissions, it is estimated to be found in all environmental compartments.

Table 6-2: PEC values for MCCP releases as estimate by EUSES on the regional scale

Regional PEC according to EUSES calculations	Value
Regional PEC in surface water (total)	6.37×10^{-5} mg/l
Regional PEC in seawater (total)	5.91×10^{-6} mg/l
Regional PEC in surface water (dissolved)	3.38×10^{-5} mg/l
Regional PEC in seawater (dissolved)	4.56×10^{-6} mg/l
Regional PEC in air (total)	1.21×10^{-6} mg/m^3
Regional PEC in agricultural soil (total)	0.872 mg/kg ww
Regional PEC in pore water of agricultural soil (total)	8.39×10^{-5} mg/kg ww
Regional PEC in natural soil (total)	0.108 mg/kg ww
Regional PEC in industrial soil (total)	0.182 mg/kg ww
Regional PEC in sediment (total)	0.864 mg/kg ww
Regional PEC in seawater sediment (total)	0.116 mg/kg ww

Source: KEMI (2018)

For the estimations in environmental compartments, no corresponding monitoring data are available. There are some environmental monitoring data for MCCPs that are compiled from information provided by the Norwegian Environment Agency.[62] The monitoring data target to a lesser extent different environmental compartments - besides air – but rather biota. These data show that MCCPs have been detected in the air and different biota (see the following Table 6-3).

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http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Pack_15/1st_Consultation_Contributions/Contribution_Norwegian_Environment_Agency_TBBPA_MCCPS_20180614.pdf, last viewed 24.07.2018

[62] Norwegian Environment Agency (2018): Contribution submitted on 15.06.2018 during the stakeholder consultation conducted from 20 April 2018 to 15 June 2018 by Oeko-Institut in the course of the study to support the review of the list of restricted substances and to assess a new exemption request under RoHS 2 (Pack 15); http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Pack_15/1st_Consultation_Contributions/Contribution_Norwegian_Environment_Agency_TBBPA_MCCPS_20180614.pdf, last viewed 24.07.2018

Table 6-3: Monitoring data from Norway

Env. compartment / biota	MCCP levels	Source
Air	30 – 130 pg/m^3	Monitoring of environmental contaminants in air and precipitation 2014; http://www.miljodirektoratet.no/Documents/publikasjoner/M368/M368.pdf Monitoring of environmental contaminants in air and precipitation 2015; http://www.miljodirektoratet.no/Documents/publikasjoner/M579/M579.pdf Monitoring of environmental contaminants in air and precipitation 2016; http://www.miljodirektoratet.no/Documents/publikasjoner/M757/M757.pdf
Trout	<0.5 – 1.8 ng/g	Environmental pollutants in large Norwegian lakes, 2016; http://www.miljodirektoratet.no/Documents/publikasjoner/M807/M807.pdf
Perch	<0.5 – 3.1 ng/g	
Cod liver	32.3 - 131.0 (931.5) µg/kg ww (2012) 292 - 1202 µg/kg ww (2015) 154 - 1850 µg/kg ww (2016)	Contaminants in coastal waters of Norway (Milkys) 2012; http://www.miljodirektoratet.no/Documents/publikasjoner/M69/M69.pdf Contaminants in coastal waters of Norway (Milkys) 2015; http://www.miljodirektoratet.no/Documents/publikasjoner/M618/M618.pdf Contaminants in coastal waters of Norway (Milkys) 2016; http://www.miljodirektoratet.no/Documents/publikasjoner/M856/M856.pdf
Blue mussel	2.4 - 17.9 µg/kg ww (2012) 11.1 – 115 µg/kg ww (2015) 24.2 – 114 µg/kg ww (2016)	

Source: Norwegian Environment Agency (2018)

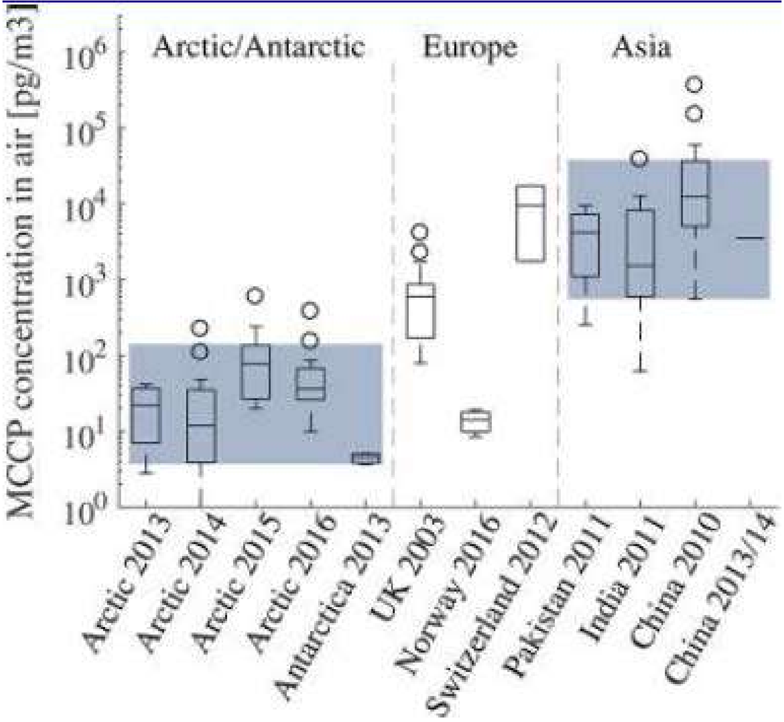
For cod liver and blue mussels, there are measurements for the years 2012, 2015 and 2016. The Norwegian Environment Agency itself has not evaluated the trends over the time of the MCCPs concentrations in the biota. Though in the current assessment, a statistical evaluation was not performed, it can be observed that that the ranges of the MCCPs concentrations measured increased over the years cod liver as well as blue mussel. Under the understanding that mussels would be at a lower level within the food chain than cod further suggests that the concentrations of MCCPs accumulate throughout the food chain.

Not all MCCPs in the environment derives from EEE but also from other applications, however an increasing MCCPs contamination in biota can be concluded from the Norwegian monitoring data.

6.2.1. Monitoring data: remote regions, biota

In contrast to the findings of KEMI (2018) that there has been no monitoring data of MCCPs in remote regions, the review of Glüge et al. (2018) summarizes several findings of MCCPs in remote areas. MCCPs concentration in the air measured in the Arctic and Antarctic region, in comparison to e.g. concentrations measured in Europe, are shown in the following figure.

Figure 6-2: MCCPs concentrations in air



Source: Glüge et al. (2018); the blue rectangles indicate the MCCP concentration ranges in the specific regions. The data from the Arctic are only semi quantitative.

As for biota, Glüge et al. (2018) reported findings in fish and birds where measurements are also available from the Arctic. Glüge et al. (2018) concluded that the relatively high MCCP concentrations found in Arctic fish show once more that MCCPs are able to undergo long-range atmospheric transport, and that the MCCP concentrations in bird eggs and bird tissue were in the same range or slightly lower than the SCCP concentrations measured in the same animals and at the same points in time. Although old analytical methods were uncertain, recent optimised methods in principle support old monitoring data, showing wide-spread contamination of the environment with chlorinated paraffins (Yuan et al 2019 Accumulation of short-, medium-, and long chain chlorinated paraffins in marine and terrestrial animals from Scandinavia (Yuan et al, 2019).[63] A new finding is the unexpected and high concentrations of chlorinated paraffins (including MCCP) in terrestrial species (e.g., predatory birds), both in Sweden (ibid) and China (Zhou et al 2016).[64]

In their position paper[65], EuroChlor questioned the monitoring results stating that *“several of the studies, relied upon as part of the proposal, are also questionable. These studies utilise old methods that cannot effectively distinguish between Short Chain Chlorinated Paraffins (SCCP, a controlled substance in the EU) and MCCP. These older methods relied on laboratory produced technical standards that bear little chemical resemblance to any products ever placed on the market, adding to their inconclusive findings. Only by applying modern methods (see van Mourik et al. 2015) can such molecules be accurately quantified in biological or environmental samples.”* These issues were

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[63] Yuan, B.; Vorkamp, K.; Anna Roosm, A.M. et al. (2019): Accumulation of Short-, Medium-, and Long-Chain Chlorinated Paraffins in Marine and Terrestrial Animals from Scandinavia. Environ Sci Technol. 53(7): 3526−3537

[64] Zhou et al (2016): Extensive organo-halogen contamination in wildlife from a site in the Yangtze river delta. Sci. Total Environ. 554-555: 320-8)

[65] Opt. cit. EuroChlor (2018)

reviewed in a EuroChlor sponsored symposium with academics and regulators on analytical methods for chlorinated paraffins in Amsterdam in February 2019, which showed the variability of results and the problems encountered with analysing environmental samples.

Glüge et al. (2018)[66] discussed the sources of errors in the measurements for occurrence of MCCPs in the environment, biota, and humans. They summarised the studies *"Taking all the other possible error sources into account", "we have to assume that most of the reported concentrations might not be very accurate. We believe, however, that the overall picture from the whole set of measurements and studies is (at least at the order of magnitude) correct and will give valuable insights into the environmental contamination with MCCPs."* Glüge et al. (2018) concluded: *"If we look at the obtained overall picture of the environmental contamination with MCCPs, we see that MCCPs have been detected in all environmental compartments as well as in fish, birds, mammals, and human tissues, and they are often measured in higher concentrations than SCCPs. Most alarming to us are the sediment concentrations that reach or exceed the PNEC in sediment, as well as the increasing time trends observed for the MCCPs in various locations worldwide. We also observe the potential of the MCCPs to undergo long-range atmospheric transport and their high potential for chronic toxicity to aquatic invertebrates."*

In the consultants view the data uncertainties have been sufficiently taken into consideration in the Glüge et al. (2018)[67] data. The increase in sampling data for biota provided in the Norwegian data also strengthens the concerns raised by Glüge in relation to the increasing time trends observed for MCCPs worldwide. Though it may be argued what the range of impact is, the understanding that MCCPs may be classified as vPvB[68] suggests that a precautionary approach may be relevant here.

6.3. Exposure under uncontrolled disposal

If incineration does not take place under controlled conditions, the presence of chlorinated paraffins can give rise to hazardous reaction products. In case of uncontrolled fires (accidental fire) and at co-combustion at lower temperatures or not well functioning incinerators, chlorinated paraffins can be a source of chlorine, subsequently leading to the formation of polychlorinated dioxins and furans. Furthermore, unsaturated hydrocarbon products, including aromatic products such as polychlorinated biphenyls and polychlorinated naphthalene, can also be formed under certain circumstances, such as under heat or in contact with alkaline substances (Oeko-Institut, 2008).[69]

The informal cable treatment (open cable burning), though not common in the EU, is a massive human health issue for the workers and the local population. Furthermore, this will also be addressed in the impact and risk evaluation section under risk for the environment.

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[66] Opt. cit. Glüge et al. (2018)

[67] Opt. cit. Glüge et al. (2018)

[68] See footnote **Fehler! Textmarke nicht definiert.**.

[69] Oeko-Institut (2008): Study on Hazardous Substances in Electrical and Electronic Equipment, not Regulated by the RoHS Directive

7. IMPACT AND RISK EVALUATION

The CORAP substance evaluation of the human health and environment hazards of MCCPs has concluded that MCCP are very persistent and very bioaccumulative (vPvB) and therefore qualify as SVHC and POP (UK Environment Agency, 2019). This conclusion affects the impact and risk evaluation here at hand because as a result of both properties, the current DNELs and PNEC would no longer be applicable.

7.1. Impacts on WEEE management as specified by Article 6 (1)a

There is information lacking especially on actual amounts of MCCPs entering the European market through the import of articles. Thus, the actual amount entering the waste cannot properly be estimated. The assessment in section 5 is generally based on the assumption of an annual MCCP consumption of 15,000 t in EEE in the EU plus an amount X entering the EU through imported EEE articles.

However, there are no evidences found that the actual MCCP content in WEEE plays any role for the treatment processes, respectively there were no interferences found in WEEE processes related to the presence of MCCPs. MCCP neither enhances nor hinders the recycling process of flexible PVC. PVC recycling is possible and increasingly applied independent of the MCCP content in the polymer as can be understood from the claims of industry, e.g. projects like VinylPlus.

Informal recycling and its problems associated with MCCPs are subsumed to risks to the environment.

7.2. Risks for workers

Based on the estimations derived from ECETOC and in order to derive a risk characterisation ratio (RCR), KEMI (2018) compared the exposure estimation values to the most stringent DNEL values that have been given in the EU RAR (2008) and not to those DNELs that have been provided by the REACH registrants (see section 3.2).

The findings lead to two relevant scenarios (with RCRs >1) where risks are not adequately controlled, that are:

- The shredding of PVC cable waste (PROC 24c), taking a DNEL for inhalative exposure at 1.6 mg/m^3, the inhalation RCR is at 1.75; no respiratory protection equipment or gloves were considered in the assessment by KEMI (2018) as these are not used uniformly; and
- the conversion of PVC recyclate (PROC 6) through dermal exposure during calendering operations with temperatures higher than the ambient; the RCR – assuming a DNEL for long term dermal exposure at 11.5 mg/kg bw/day – is at 1.43.

The findings from KEMI (2018) differ from the EU RAR as the latter did not identify an unacceptable risk to workers' health under all PVC-related scenarios examined (formulation/manufacture, calendering, compounding, extrusion/moulding).

Generally, estimations gained by ECETOC are rather used for workplace management and for concluding whether protection measures have to be established. Thus, the results indicate that an exposure by MCCPs in WEEE recalling plants occurs and protection routines in the waste recycling plants in Europe have to be installed.

It should however be noted that a classification of MCCPs as vPvB would also affect the DNEL for human health; thus the risk for workers arising from shredding of PVC cable waste and conversion of PVC recyclate expected under the current classification may need to be revised in the case of a classification as future DNELs cannot anticipated here.

7.3. Risks for consumers and neighbouring residents

The data show that MCCPs are ubiquitously present in indoor air and indoor dust. The indoor dust can be inhaled. House dust itself may also lead to dermal exposure and in small children to oral exposure due to mouthing behaviour.[70] A conservative estimate of 100 mg/day has been proposed for house dust intake for children (Oomen, et al., 2008).[71] The uptake can then be calculated by multiplying the measured concentrations with dust uptake defaults. As body weight for children, 10 kg is assumed (body weight assumption in ECETOC TRA v.3 model according to Wibbertmann and Hahn 2018).[72] The DNEL for the general population for long term oral exposure has been indicated at 580 µg/kg bw/day by the REACH registrants. Taking this current DNEL, no risk for children by MCCPs in house dust can be derived (see results in the table below).

Table 7-1: MCCPs concentrations in house dust in Europe and the derived long-term oral exposure of children

Range in dust measurements	Long-term oral exposure of children assuming 10 kg body weight
31 – 464 µg/g	0.031 – 0.464 µg/kg/day

Source: Own compilation; dust measurements from WSP Environmental Sverige (2018) and Wong et al. (2017) for the UK

However, as the substance evaluation of MCCPs is currently not finished, the general exposure of consumers by house dust is to be considered to raise some concern: the vPvB properties can lead to accumulation where current values are exceeded. Even more as for the human health hazard, there is a harmonised classification for MCCPs indicating “May cause harm to breast-fed children”. Thus, a general risk that MCCPs may affect the human health cannot be ruled out.

7.4. Risks for the environment

From the regional predicted environmental exposure estimations gained by EUSES, there are some processes that indicate an environmental risk: PVC formulation and conversion, as well as landfilling of WEEE and PVC waste and incineration leads to MCCPs releases that exceeds the PNECs of some environmental compartments:

According to KEMI (2018) risks are identified;

- By formulation of PVC for the sediment, marine water and for secondary poisoning via the earthworm food chain;

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[70] European Chemicals Agency ECHA (2015): Guidance on Information Requirements and Chemical Safety AssessmentChapterR.15: Consumer exposure estimation; Draft (Public)Version 3.0 October 2015; https://echa.europa.eu/documents/10162/23047722/draft_201510_r15_peg_infreq_uses_en.pdf/4c52b39e-ca5e-4cb2-a6e3-b8020dc8d047, last viewed 20.11.2019

[71] Oomen, A.G.; Janssen, P.J.C.M.; Dusseldorp, A.; Noorlander, C.W. (2008): Exposure to chemicals via house dust; https://www.rivm.nl/bibliotheek/rapporten/609021064.html

[72] Fraunhofer ITEM IPA, Wibbertmann and Hahn (2018): Assessment of TBBP-A (tetrabromopisphenol-A) according to the “Methodology for Identification and Assessment of Substances for Inclusion in the List of Restricted Substances (Annex III) under the RoHS2 Directive”. Update August 2018. Fraunhofer ITEM, Fraunhofer IPA, Stuttgart.

- By conversion of PVC for freshwater, sediment, marine water and for secondary poisoning via the earthworm food chain (4.10);
- By landfilling of WEEE and PVC waste for sediment and for secondary poisoning via the earthworm food chain; and
- By incineration of WEEE and PVC waste: secondary poisoning via the earthworm food chain.

To conclude, WEEE treatment as performed in Europe results in risks for the environment despite the conclusion not taking into account the vPvB properties recently established by the UK Environmental agency as a conclusion from the CORAP process.

Additionally, the collection and treatment of electrical and electronic equipment outside EU with regards to cables has a special human health and environmental risk aspect. In the context of PVC cables, uncontrolled burning - in order to liberate the metal wires (mostly from copper) from their insulation material - and thus releases of halogenated compounds entail the formation of halogenated dioxins and furans with health implications for workers. In addition, the applied storage and treatment practice result in a release of chemicals incorporated in the WEEE. This is of utmost interest in the case of (potential) PBT/vPvB substances as is the case for MCCP. The practice of open cable burning has been observed in particular in West-African countries with a strong dominance of informal sector recycling. There are estimates that open cable fires in five West-African countries (Nigeria, Benin, Ghana, Côte d'Ivoire, Liberia) cause total dioxin (PCDD/F) emission equivalent to 3 %-7 % of total EU dioxin emissions to air in 2005 (see section 5.5). This number shows that there is a considerable contribution of dioxin emissions.

Against the background, that MCCPs have recently been considered for being vPvB in the ECHA PBT expert group, these releases have to be considered.

Hence, there is evidence that MCCPs can be considered as a global pollutant as it can be measured in various environmental compartments and also in organisms at high trophic levels.

The findings of MCCPs concentrations in remote regions far from emission sources support the presumption of MCCPs or at least certain compounds with a high chlorine content being very persistent substances. The bio-accumulative property is based on MCCPs measurements in various environmental compartments and also in organisms at high trophic levels. In light of global supply chains and the potential for long-range transport, releases of PBT/vPvB substances are not only of relevance if occurring locally. They are also to be considered as bioaccumulation takes place mainly in the food chain and various produce is imported to the EU from countries where WEEE and second hand EEE is exported to. It is not the focus of this work to quantify this exposure route and consequential risks. Though the emissions of MCCPs are not only due to the use in EEE under the scope of the RoHS directive, the monitoring data support the general concern on MCCPs.

8. ALTERNATIVES

8.1. Availability of substitutes / alternative technologies

Former studies came to the conclusion that there would be currently no one-to-one alternatives to MCCPs available on the market.[73] This is due to the fact that several requested properties can be attributed to MCCPs, which are flame retardancy, improved water and chemical resistance, enhanced viscosity, ageing stability, and finally, reduced formulation costs. In this light, alternatives should be based on product specific reformulations. However, PVC cable formulations have already undergone several phases where reformulations were necessary e.g.

- the phase out of heavy metals (Pb and Cd) as thermal stabilizer and PBDEs due to the introduction of the first RoHS Directive,
- the European ban of the four phthalates under REACH and RoHS 2 and
- the listing of SCCPs in the UNECE/LRTAP POPs-protocol and listing as a POP for global phase-out in the Stockholm Convention (respectively ban in the EU POP regulation).

These changes all happened consecutively. It is therefore understood that PVC formulation and the use of additives is constantly under development to take into account restrictions. Industry itself describes a continuous adaptation of stabilizers[74] and plasticizers.

For the two main functions of MCCP, the plasticising as well as the flame-retardant effect, alternatives are available. This may entail that more than one substance is needed to replace MCCPs in order to achieve desired material characteristics.

The following table lists main potential alternatives for the plasticising or flame-retardant properties of MCCPs that can be used in soft PVC, besides long chain chlorinated paraffins (LCCPs), certain phthalates (e.g. DINP) and several phosphate esters as well as diantimony trioxide and metal hydroxides such as aluminium hydroxide and magnesium hydroxide.

Table 8-1: Plasticising and/or flame-retardant properties and production/import volume of alternatives

Substance	CAS	Plasticiser	Flame retardant	Production and import volume in the EU
Long-chain chlorinated paraffins (LCCPs)	63449-39-8	Yes	Yes	High registered tonnage 10,000-100,000 tpa
Phthalates, e.g. DINP	28553-12-0	Yes	No	High registered tonnage of 100,000-1,000,000 tpa; *used as direct substitute of phthalates under pressure, e.g. DEHP*

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[73] Op. cit. KEMI (2018)

[74] “Stabilisers formulations are being continuously adapted to anticipate on the regulatory context and with sustainability in the visor”; Cavallero, A. (2017): About PVC stabilisers and Sustainability, Dr. Alain Cavallero, European Stabiliser Producers Association, ESPA; 1st PVC4CABLES conference, 26 October 2017; https://www.pvc4cables.org/images/Cavallero.pdf, last viewed 25.09.2018

Substance	CAS	Plasticiser	Flame retardant	Production and import volume in the EU
Phthalates, e.g. DIDP	68515-49-1	Yes	No	High registered tonnage of 100,000-1,000,000 tpa; *used as direct substitute of phthalates under pressure, e.g. DEHP*
Adipates, e.g. Bis(2-ethylhexyl) adipate (DEHA, DOA)	103-23-1	Yes	No	Low registered tonnage of 1,000 – 10,000 tpa
Citrates, e.g. Acetyl tri-n-butylcitrate (ATBC)	77-90-7	Yes	No	High registered tonnage of 10,000 – 100,000 tpa
Trimellitates, e.g, Tris(2-ethylhexyl) trimellitate (TOTM)	3319-31-1	Yes	No	High registered tonnage of 10,000 – 100,000 tpa, Tonnage is expected to increase in the future given that the substance has been highlighted as a substitute to a number of phthalates under regulatory pressure.
Cresyl diphenyl phosphate	26444-49-5	Yes	Yes	Substance not registered
Tricresyl phosphate	1330-78-5	Yes	Yes	Substance not registered
Trixylyl phosphate	25155-23-1	Yes	Yes	Low registered tonnage of 1,000 – 10,000 tpa
Triphenyl phosphate	115-86-6	Yes	Yes	Low registered tonnage of 1,000 – 10,000 tpa
Isodecyl diphenyl phosphate	29761-21-5	Yes	Yes	Low registered tonnage of 1,000 – 10,000 tpa e.g. Phosflex 390 by ICL
2-ethylhexyl diphenyl phosphate	1241-94-7	Yes	Yes	Low registered tonnage of 1,000 – 10,000 tpa
Bisphenol-A bisphosphate (BDP)	5945-33-5	Yes	Yes	Low registered tonnage of 1,000 – 10,000 tpa
Aluminium hydroxide	21645-51-2	No	Yes	High registered tonnage of 1,000,000 – 10,000,000 tpa
Magnesium hydroxide	1309-42-8	No	Yes	High registered tonnage 100,000 – 1,000,000 tpa e.g. FR-20 by ICL
Antimony trioxide	1309-64-4	No	Yes	Usually used as a synergist in combination with halogenated flame retardants; supports the inherent flame retardancy of PVC.

Source: KEMI (2018) and own additions

The following table summarises halogen-free flame retardants used in cable compounds as compiled in the Oeko-Institut report of 2008 updated with more current information gained from stakeholder contributions. [75]

Table 8-2: Halogen-free flame retardants used in cable compounds

Flame retardant	Polymers	Flame retardancy effectiveness	Applications
Metal hydroxides, e.g. Aluminium trihydroxide (**ATH**) Magnesium dihydroxide (**MDH**) (Aluminium-oxide-hydroxide (**AOH**, boehmite)	**Polyolefins:** Low-density polyethylene (LDPE) Polyethylene vinyl acetate copolymer (EVA) Polyethylen-co-butene Polyethylen-co-octene **Elastomers:** Natural Rubber (NR) Poly-ethylene-Diene Rubbers (EPDM) Poly-Styrene-Butadiene Rubbers (SBR) Silicone rubbers (SiR) **Thermoplastic Elastomers (TPE)**	In fire, these mineral FRs decompose, absorbing energy, releasing water (reducing fire intensity and diluting fire gases), and creating an oxide fire barrier against heat from the flame and to prevent burnable polymer decomposition products from reaching the flame	Electrical cables - Low voltage - Medium voltage - Photovoltaic (PV) cables - Emergency lighting Control cables - Fire alarm cables Information cables - LAN cables - Telephone cables
Zinc borate	See above	Synergist with ATH Zinc borate is a smoke suppressant that works in the condensed phase by forming a glass-like char.	See above
Zinc stannate and zinc hydroxystannates	See above	Synergist with ATH Zinc (hydroxy-)stannate works both in the gas phase (flame) and in the condensed phase (smoke) simultaneously	See above
Phosphorus based flame retardants			
Metal phosphinates, e.g. **Aluminium diethylphosphinate (Alpi)** and polyphosphonates	**Used in fire-resistant coatings for cables** - Polyolefins	Flame inhibition and charring properties of phosphorus-based materials reduce the flammability of	Electrical cables - Photovoltaic (PV) cables Control cables

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[75] Op. cit. Pinfa (2017) last viewed 24.07.2018.; op. cit. Kemi (2018)

Flame retardant	Polymers	Flame retardancy effectiveness	Applications
	- Polypropylene (PP) **Elastomers:** - Thermoplastic Elastomers (TPE) - Thermoplastic Poly Urethanes - Thermoplastic Polyesters	polymers. A char on the surface prevents heat transfer and protects the polymer below	- Lift cables - Fire alarm cables
Red phosphorus		See above	
Phosphate esters (e. g. Tricresyl Phosphate TCP)		See above	
Ammonium polyphosphate (APP)		With loading of 15–30 % new developed products can achieve highest fire safety standards (UL 94 V0) by formation of an insulating fire barrier me retardants used in HFFR cable compounds.	
Nitrogen flame retardants			
Melamine Derivatives (e.g. melamine cyanurate, melamine (poly)phosphate)	**Used in fire-resistant coatings for cables** - Polyolefins - Polypropylene (PP) **Elastomers:** - Thermoplastic Elastomers (TPE) - Thermoplastic Poly Urethanes - - Thermoplastic Polyesters	A low dosing between 7–15 % results in polymer decomposing (PA) without flaming	

Source: KEMI (2018); Oeko-Institut (2008); Pinfa (2017)

Furthermore, in case of a restriction of MCCPs, the development of substitutes for cable and wire insulation may be extended beyond its combination with PVC. Instead of finding a substitute flame retardant and plasticiser for PVC, the search for alternative insulation materials could be extended to polymers other than PVC. This would bring the additional advantage of phasing-out halogenated polymers in EEE products altogether. However, PVC is used in cables because it provides excellent flexibility, is cost-effective and can be recycled. Without further innovation, other polymers may not match these advantages of PCV to the same extent. Thus, this approach may apply to a set of substances that are already restricted by the RoHS Directive (such as PBDEs) as well as further substances that are also discussed for a possible restriction under RoHS such as diantimony trioxide which is used as synergist for halogenated flame retardants. Pinfa (2017) describes the following (MCCP-free) flame retarded thermoplastic elastomers for cable applications:

- Thermoplastic elastomers (TPE) consist of a thermoplastic urethane as monomer and copolyesters and polyether block amide. There are different TPE types with different desired properties.

"Metal phosphinates can effectively balance mechanical properties and flame retardancy in TPEs. Polyphosphonates have also been found to perform well in TPE-E systems."

- Copolyester elastomers are based on polybutylene terephthalate and polyether groups. Metal phosphinates finely grained provides flame retardancy with an addition of polyphosphonates or nitrogen synergists in some cases.
- Thermoplastic urethanes consist of hydroxyl terminated polyesters or polyethers and diphenylmethane diisocyanate. By adding 12-15 % metal phosphinate in fine grades with nitrogen synergists or by adding formulations containing melamine cyanurate, the classification UL 94 V-0 is achieved. Polyphosphonates are also used in specific applications where e.g. transparency is desired and also work synergistically with melamine cyanurate and metal phosphinate for improved flame retardancy and mechanical properties.

The webpage of PVC4Cables, a platform of the European Council of Vinyl Manufacturers (ECVM) specifies the shares of polymer material used in cable sheeting and insulation on the European cable market as to see from Figure 8-2; however, it should be noted that these statistics cover all kind of cables not only the low voltage cables as used in EEE (and addressed here). In 2016, PVC held a share of just under 50 % while the former mentioned TPE only accounts for ~1 %. With ~15 %, HFFR-LSFOH is on the third position. These *"Halogen-Free Flame Retardant - Low Smoke and Fume, Zero Halogen Compounds"* can be based on poly-olefins (PP, PE)[76] and thermoplastic elastomers (e.g. PU). Here, flame retardancy is facilitated through Magnesium and Aluminium hydroxides.[77] With respect to this material, other stakeholders speak of a trend, e.g. Pinfa (2017) describes further developments in the field of metal hydroxides for the use in wire and cable applications.[78]

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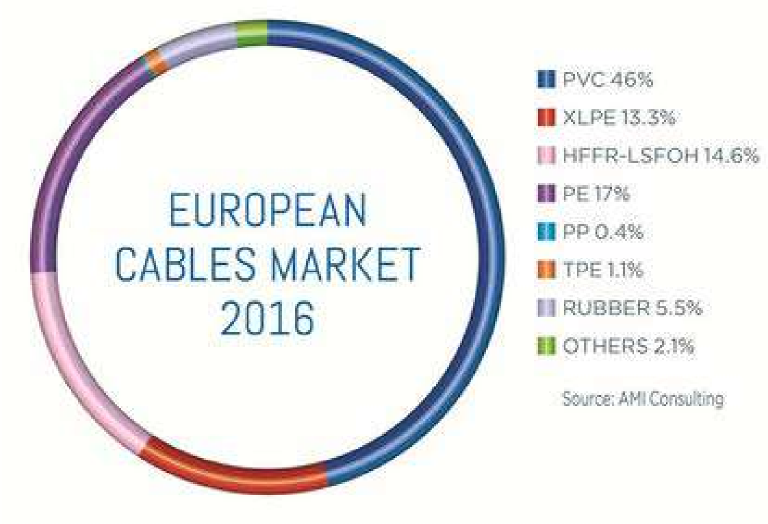
[76] https://www.polyone.com/files/resources//EM_LSFOH_BU_Overview___75360.pdf (assessed 21.11.2019)

[77] Anixter (2012) LOW SMOKE ZERO HALOGEN WIRE AND CABLE BEST PRACTICES https://www.anixter.com/content/dam/Anixter/White%20Papers/12F0003X00-Anixter-LSZH-WP-W%26C-EN-US.pdf (assessed 21.11.2019)

[78] Pinfa (Phosphorus, Inorganic and Nitrogren Flame Retardants Association) (2017): Flame retardants in electric and electronic applications, non-halogenated phosphorus, inorganic and nitrogen (PIN) flame retardants; October 2017, 3rd edition; https://www.pinfa.eu/wp-content/uploads/2018/05/PINFA_EE_brochure_Edition_2017-11.pdf, last viewed 24.07.2018.

Figure 8-1: Share of polymers used in cable sheeting and insulation on the European cable market 2016 according to the European Council of Vinyl Manufacturers (ECVM)



Source: https://www.pvc4cables.org/en/pvc-cables/market

Abbreviations:

PVC – Polyvinylchloride; XLPE – Cross-linked polyethylene; HFFR-LSFOH – Halogen-Free Flame Retardant - Low Smoke and Fume, Zero Halogen Compounds (often olefins); PE – polyethylene; PP – polypropylene; TPE – thermoplastic elastomers

KEMI (2018) concludes that, overall, the use of alternatives would be likely to be *“associated with more specific, product-by-product reformulations, tailor-made in order to ensure optimised results for end-products.”* The following table shows such concrete examples for MCCP-free PVC formulation with a set of the above-mentioned plasticizers and flame retardants.

Table 8-3: MCCP-free PVC formulation for cable and wire

	Product / supplier
Plasticizer DINP; Stabilizer & Process Aid; Ecopiren 3.5C (magnesium hydroxide); Antimony Oxide or Antimony Oxide Replacement	Europiren
ESO (Drapex 6.8, epoxidised soybean oil), Stabilizer BaZn (Mark 6731, barium zinc), Plasticizer DIDP, ATH (Hydral 710), Calcium Carbonate (Atomite Whiting), Elvaloy® HP441 (ethylene/n-butyl acrylate), Antioxident (Irganox 1010, pentaerythritol tetrakis(3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate)), Antioxident (DLTDP, dilauryl thiodipropionate), TiPure® R960 (titanium dioxide)	DuPont

Source: Europiren: https://www.europiren.com/flame-retardants/ecopiren-pvc-wire-and-cable-formulations/, last viewed 25.09.2018;
DuPont: http://www2.dupont.com/Elvaloy/en_US/tech_info/elvaloy_pvc_wire_and_cable.html#start, last viewed 25.09.2018

Certain companies restrict the use of MCCPs

The availability of alternatives becomes apparent by the fact that so-called frontrunner companies where environmental management and health and safety are of strategic importance restrict the use of MCCPs, e.g.:

- Dell in its Specification on "Materials Restricted for Use",[79] Alkanes C14-C17, chloro, Medium Chain Chlorinated Paraffins (MCCPs) are restricted with a threshold limit of 1000ppm which is clearly below the concentration of the substance in preparation.

  It has to be noted however that Dell refers to the CAS number as specified for this dossier, which means that other chlorinated paraffins specified by different CAS numbers might be used.
- According to the Apple Regulated Substances Specification,[80] "Chlorinated Paraffins, Short and Medium Chain (SCCP and MCCP)" and as well "Chlorine and its compounds" and consequently "Polyvinyl Chloride (PVC)" are restricted substances in homogeneous materials used in Apple products with a limit threshold of 900 ppm Cl.

8.2. Hazardous properties of substitutes

As it was outlined earlier, two strategies are possible in terms of the substitution of MCCPs in EEE: first, substitution of MCCP in the existing polymer matrix for one or more other substances with flame retardant and plasticising properties; second, application of alternative polymer materials, other than PVC, in which desired properties can achieved without MCCPs.

Substances that fall under the category of the first substitution strategy are assessed in Table 8-4; other assessments are discussed in further detail thereafter. The assessment of the hazardousness of alternative polymer materials is not as easy as for concrete substances that are subject to registration under REACH as polymers do not have to be registered. Therefore no (eco-) toxicological data have to be submitted to ECHA before bringing the polymers onto the market. As a consequence, an assessment of hazardous properties of polymers mentioned in section 8.1 is not possible. Still a conclusion is drawn under 8.4.

The entries of Table 8-4 can be categorised to four groups due to structural similarities: (1) Long-chain chlorinated paraffins; (2) Alkyl-substituted carboxylic esters (phthalates, DEHA, ATBC, TOTM); (3) Organophosphate esters (OPE); (4) Inorganic FR (ATH, MTH, ATO). However, none of the inorganic substances listed in Table 8-4 can provide plasticising properties. Human and environmental risk can differ within a group and cannot be generalised. LCCPs are suspected of low human health risk; though, PBT properties cannot be excluded. Of the second category, ATBC seems to be the most promising candidate as the others are suspected of having several undesirable properties. For OPEs, the determining factor for an environmental or human health risk seems to be whether phenyl, cresyl and/or xylyl substituents are side chains to the phosphate. For a tri-substituted compound, there is a wide variety of substitution patterns; individual assessment of compounds leads to the conclusions that simplifications by grouping may not lead to a misleading picture. Discussing the inorganic FR, the hydroxides shall be preferred to diantimony trioxide.

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[79] Dell (2018): Specification Materials Restricted for Use Revision: A03-00, Document Number: ENV0424; https://www.dell.com/learn/us/en/05/shared-content~solutions~en/documents~env0424-a02.pdf, last viewed at 24.07.2018

[80] Apple (2016): Apple Regulated Substances Specification 069-0135-J; https://www.apple.com/supplier-responsibility/pdf/Apple-Regulated-Substance-Specification.pdf, last viewed 24.07.2018

Table 8-4: Hazardous properties of substitutes for MCCPs

Substance	CAS	Harmonised classification	Restrictions under REACH	Human Health Concerns	Environmental Concerns
Long-chain chlorinated paraffins (LCCPs)	63449-39-8	No harmonised classification	None	Low toxicity	Potentially persistent and bioaccumulative (but past assessments reach different conclusions)
Di-'isononyl' phthalate DINP	28553-12-0	No harmonised classification	Entry 52 Annex XVII: Restrictions to use in toys and childcare articles that can be placed in the mouth by children	Significant increases of incidence of spongiosis hepatis together with other signs of hepatotoxicity in rats. Disagreement regarding relevance of spongiosis hepatis in humans. Concerns over endocrine disruption potential (anti-androgenic effects)	No toxic effects towards fish, invertebrates or algae
Di-'isodecyl' phthalate DIDP	68515-49-1	No harmonised classification		Significant increases of incidence of spongiosis hepatis together with other signs of hepatotoxicity in rats. Disagreement regarding relevance of spongiosis hepatis in humans. Reprotoxic effects. Decrease in survival incidences (NOAEL: 33 mg/kg bw/day)	Low bioaccumulation properties
Acetyl tri-n-butyl-citrate (ATBC)	77-90-7	No harmonised classification	None	low acute toxicity, low or slight sensitising, no mutagenic activity and no reproductive effects;	readily biodegradable as well as ultimately biodegradable. Indications for bioaccumulation potential and potential for aquatic toxicity
Tris(2-ethylhexyl) trimellitate (TOTM)	3319-31-1	No harmonised classification	Added to CoRAP in 2012		According to substance evaluation decision, potential PBT/vPvB; tonnages and exposure are expected to increase in the near future.[81]
Cresyl diphenyl phosphate	26444-49-5	No harmonised classification	None	Chronic toxicant with effects on liver, kidney and blood. Effects on fertility	Readily biodegradable; toxic to aquatic organisms

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[81] ECHA (2014): Decision on Substance Evaluation for tris(2-ethylhexyl)benzene-1,2,4-tricarboxylate; https://echa.europa.eu/information-on-chemicals/evaluation/community-rolling-action-plan/corap-table/-/dislist/details/0b0236e1807e4cae, last viewed 25.09.2018

Substance	CAS	Harmonised classification	Restrictions under REACH	Human Health Concerns	Environmental Concerns
Tricresyl phosphate	1330-78-5	No harmonised classification	Added to CoRAP in 2014	According to CoRAP justification, potential neurotoxic effects of (isomers of) TCP	According to CoRAP justification, (suspected) PBT[82]
Trixylyl phosphate	25155-23-1	Repr. 1B	SVHC included in Candidate list Added to CoRAP in 2014	According to substance evaluation decision, potential risk for secondary poisoning	According to substance evaluation decision,[83] suspected PBT/vPvB, high Risk Characterisation Ratio, potential risk for soil compartment and
Triphenyl phosphate	115-86-6	No harmonised classification	Added to CoRAP in 2013	According to CoRAP justification,[84] potential endocrine disruptor	
Isodecyl diphenyl phosphate	29761-21-5	No harmonised classification	None	there were several risks identified, which are however not further specified	
2-ethylhexyl diphenyl phosphate	1241-94-7	No harmonised classification	None	no risk identified	
Aluminium hydroxide	21645-51-2	No harmonised classification	None	no risk to human health	data gaps concerning environmental hazards
Magnesium hydroxide	1309-42-8	No harmonised classification	None	No further information	
Antimony trioxide	1309-64-4	Carc 2	None Added to CoRAP in 2018	According to CoRAP justification,[85] suspected CMR (reclassification for carcinogenicity may be necessary) and high Risk Characterisation Ratio	

Source: Op. cit. KEMI (2018) if not indicated differently; European Chemicals Agency ECHA, https://echa.europa.eu

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[82] ECHA (2016): Decisions on Substance Evaluation for Tris(methylphenyl) phosphate; see the different decisions for all Registrant(s) and separate decisions to individual Registrants at https://echa.europa.eu/de/information-on-chemicals/evaluation/community-rolling-action-plan/corap-table/-/dislist/details/0b0236e180694747, last viewed 25.09.2018

[83] ECHA (2016): Decisions on Substance Evaluation for Trixylyl Phosphate; https://echa.europa.eu/documents/10162/94e8d9c9-be37-6349-92ba-dddfac4122b5, last viewed 25.09.2018

[84] UK CA (2013): Justification for the selection of a candidate CoRAP substance; https://echa.europa.eu/documents/10162/47fa7ee3-8323-4532-bb52-f1d8fe3b5ea4, last viewed 25.09.2018

[85] DE MSCA (2016): Justification Document for the Selection of a CoRAP Substance; https://echa.europa.eu/documents/10162/44adc62e-ff48-4ce8-9c4f-58dd8b77253a, last viewed 25.09.2018

In earlier works from other stakeholders, there have been different methodological assessment approaches. Two of those will be summarised in the following focussing on their overall conclusions. However, it should be noted, that both concentrate on flame retardants rather than on plasticisers, still, implicit, to some of the flame retarding substances here plasticising effects are additionally attributed:

The **European ENFIRO project**[86] funded by the European Framework Programme compared the flame retardant and application performances as well as hazards and exposure. As for injection moulded products which covers cables and wires, 13 products of alternative flame retarding systems were tested for their mechanical properties and application performance; these 13 products have passed the highest flame retardancy level of UL-94 V-0 that are requirements from the American Underwriters Laboratories (UL) and have been adopted in Europe and Asia as well; the UL-94 requirement is a test for flammability of materials; V-0 is the highest flammability rating.

In 2015, Clariant presented the results of ENFIRO according to different level of concern.[87] The evaluation recommends the metal hydroxide ATH; the phosphorus based flame retardants aluminium diethylphosphinate (Alpi), ammonium polyphosphate (APP) and Dihydrooxaphospha-phenanthrene (DOPO); as the nitrogen based flame retardant melamine polyphosphate (MPP); and finally the synergist zinc (hydroxy)stannate as to see from Figure 8-2.

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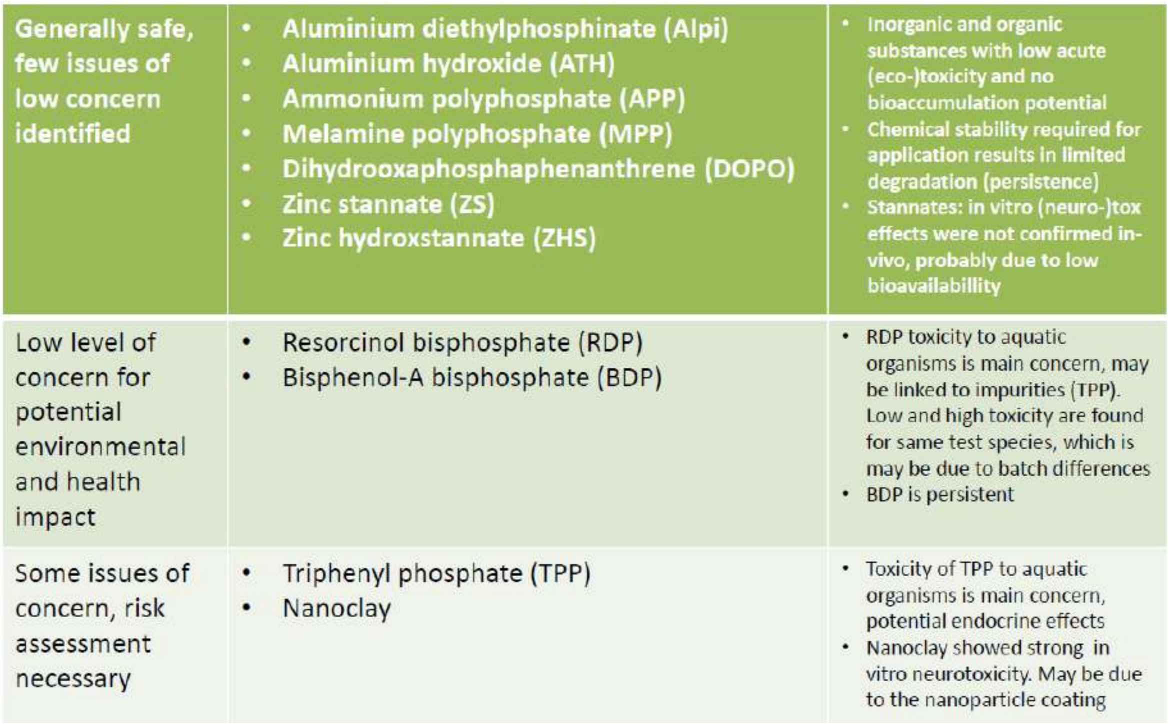
[86] ENFIRO project: Life Cycle Assessment of Environment-Compatible Flame Retardants (Prototypical Case Study); running from 2009-2012, https://cordis.europa.eu/project/rcn/92068_en.html, last viewed 25.09.2018

[87] Clariant (2015): SCI Fire and Materials Group, Overview of non-halogen flame retardants; Adrian Beard Clariant Flame Retardants, pinfa.org, 05.11.2015; https://www.soci.org/general-pages/search#q=flame%20retardant%20Beard, last viewed 25.09.2018

Figure 8-2: Evaluation of halogen-free flame retardants according to the ENFIRO approach of different level of concerns



Generally safe, few issues of low concern identified	• Aluminium diethylphosphinate (Alpi) • Aluminium hydroxide (ATH) • Ammonium polyphosphate (APP) • Melamine polyphosphate (MPP) • Dihydrooxaphosphaphenanthrene (DOPO) • Zinc stannate (ZS) • Zinc hydroxstannate (ZHS)	• Inorganic and organic substances with low acute (eco-)toxicity and no bioaccumulation potential • Chemical stability required for application results in limited degradation (persistence) • Stannates: in vitro (neuro-)tox effects were not confirmed in-vivo, probably due to low bioavailabillity
Low level of concern for potential environmental and health impact	• Resorcinol bisphosphate (RDP) • Bisphenol-A bisphosphate (BDP)	• RDP toxicity to aquatic organisms is main concern, may be linked to impurities (TPP). Low and high toxicity are found for same test species, which is may be due to batch differences • BDP is persistent
Some issues of concern, risk assessment necessary	• Triphenyl phosphate (TPP) • Nanoclay	• Toxicity of TPP to aquatic organisms is main concern, potential endocrine effects • Nanoclay showed strong in vitro neurotoxicity. May be due to the nanoparticle coating

Source: Clariant (2015)

As a second, the outcomes of an assessment with the **GreenScreen® for Safer Chemicals**[88] approach are presented in the following. This approach explains itself being *“a method of comparative Chemical Hazard Assessment (CHA) that can be used for identifying chemicals of high concern and safer alternatives.”*

The Green Screen approach was used by the US EPA[89] in order to compare flame retardants in printed circuit boards. The summary of five additively used and halogen-free flame retardants is shown in Table 8-5. Measured data for human health and environmental risk properties (coloured letters in table below) were mainly found to be low (category 2 of 5) or very low (category 1/5); a few times, moderate hazard classification (3 of 5) was derived from empirical data. Once, high hazard could be attributed to human health hazard through repeated doses or silicon dioxide. In terms of the modelled data, the high environmental persistence (category 4 of 5) calculated for all reviewed substances is based on the fact that “substances are comprised of metallic species that will not degrade but may change oxidation stare or undergo complex processes under environmental conditions” (except for melamine polyphosphate). Estimated low and medium hazard for aluminium diethylphosphinate and aluminium hydroxide (categories 2/3 of 5) is “based on analogy to experimental data from a structurally similar compound”.

Of those five compounds examined here, melamine polyphosphate is considered to be the less favourable in the over-all perspective.

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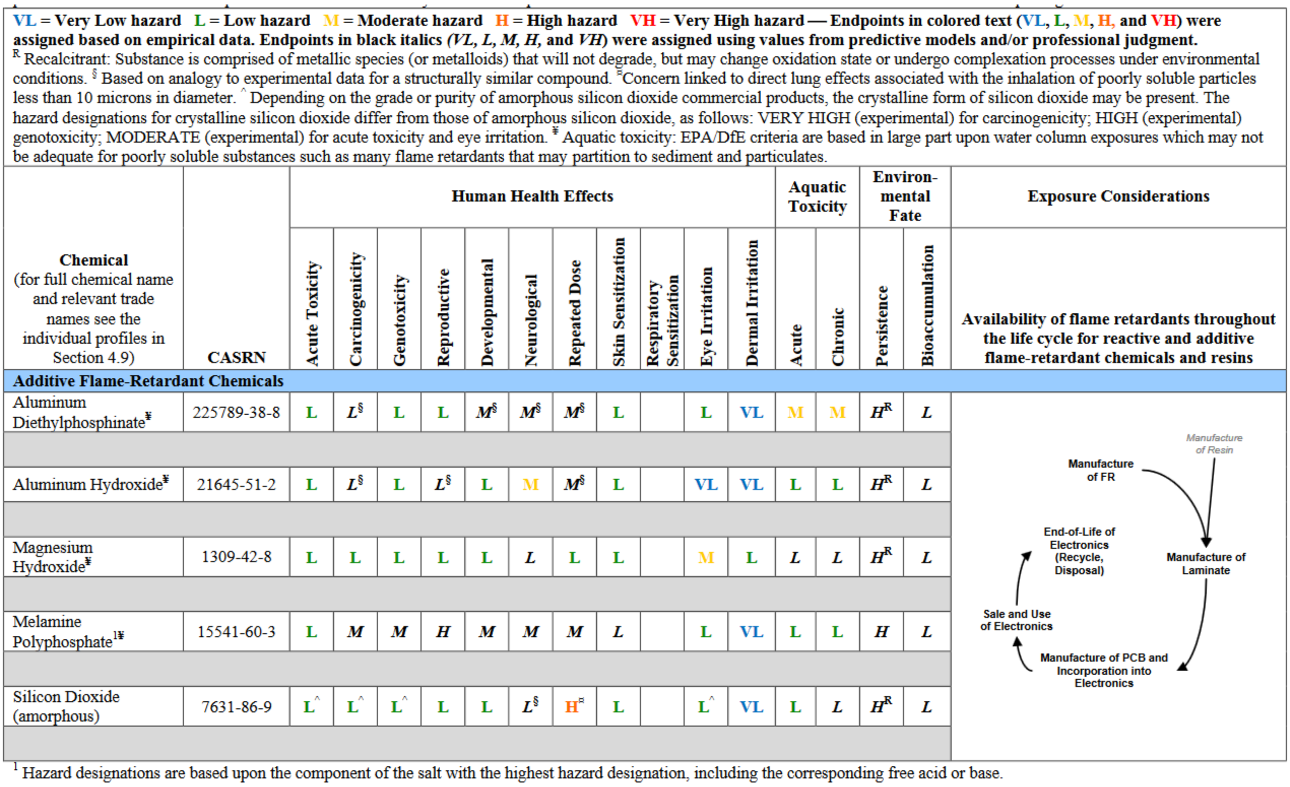
[88] https://www.greenscreenchemicals.org/method/full-greenscreen-method, last viewed 25.09.2018

[89] US EPA (2015): Flame retardants in printed circuit boards. Final Report, August 2015. United States Environmental Protection Agency (US EPA). Publication 744-R-15-001 under the Design for the Environment programme, available under: https://www.epa.gov/sites/production/files/2015-08/documents/pcb_final_report.pdf

Table 8-5: Screening Level Hazard Summary for Additive Flame-Retardant Chemicals



VL = Very Low hazard L = Low hazard M = Moderate hazard H = High hazard VH = Very High hazard — Endpoints in colored text (VL, L, M, H, and VH) were assigned based on empirical data. Endpoints in black italics *(VL, L, M, H, and VH)* were assigned using values from predictive models and/or professional judgment.
^{R} Recalcitrant: Substance is comprised of metallic species (or metalloids) that will not degrade, but may change oxidation state or undergo complexation processes under environmental conditions. § Based on analogy to experimental data for a structurally similar compound. ¤Concern linked to direct lung effects associated with the inhalation of poorly soluble particles less than 10 microns in diameter. ^ Depending on the grade or purity of amorphous silicon dioxide commercial products, the crystalline form of silicon dioxide may be present. The hazard designations for crystalline silicon dioxide differ from those of amorphous silicon dioxide, as follows: VERY HIGH (experimental) for carcinogenicity; HIGH (experimental) genotoxicity; MODERATE (experimental) for acute toxicity and eye irritation. ¥ Aquatic toxicity: EPA/DfE criteria are based in large part upon water column exposures which may not be adequate for poorly soluble substances such as many flame retardants that may partition to sediment and particulates.

Chemical (for full chemical name and relevant trade names see the individual profiles in Section 4.9)	CASRN	Human Health Effects											Aquatic Toxicity		Environmental Fate		Exposure Considerations
		Acute Toxicity	Carcinogenicity	Genotoxicity	Reproductive	Developmental	Neurological	Repeated Dose	Skin Sensitization	Respiratory Sensitization	Eye Irritation	Dermal Irritation	Acute	Chronic	Persistence	Bioaccumulation	Availability of flame retardants throughout the life cycle for reactive and additive flame-retardant chemicals and resins
Additive Flame-Retardant Chemicals																	
Aluminum Diethylphosphinate¥	225789-38-8	L	$L^{\S}$	L	L	$M^{\S}$	$M^{\S}$	$M^{\S}$	L		L	VL	M	M	H^{R}	*L*	
Aluminum Hydroxide¥	21645-51-2	L	$L^{\S}$	L	$L^{\S}$	L	M	$M^{\S}$	L		VL	VL	L	L	H^{R}	*L*	
Magnesium Hydroxide¥	1309-42-8	L	L	L	L	L	*L*	L	L		M	L	*L*	*L*	H^{R}	*L*	
Melamine Polyphosphate1¥	15541-60-3	L	*M*	*M*	*H*	*M*	*M*	*M*	*L*		L	VL	L	L	*H*	*L*	
Silicon Dioxide (amorphous)	7631-86-9	L^	L^	L^	L	L	$L^{\S}$	H¤	L		L^	VL	L	*L*	H^{R}	*L*	

[1] Hazard designations are based upon the component of the salt with the highest hazard designation, including the corresponding free acid or base.

Note: This table contains hazard information for each chemical; evaluation of risk considers both hazard and exposure. Variations in end-of-life processes or degradation and combustion by-products are discussed in the US EPA (2015) report but not addressed directly in the hazard profiles. The caveats listed above must be taken into account when interpreting the information in the table.

Source: US EPA (2015)

8.3. Data basis for alternatives and uncertainties

There is certainty to the point that there is no substitution of MCCPs possible through one substance: As MCCPs perform as secondary plasticizer and as flame retardant, substitution has to be achieved through at least two other substances.

Thus, a lot of substitution combinations will be possible that can greatly vary in their health and environmental hazards. Some groups of existing substitutes need further assessment before being used right away, e.g. the tri-substituted organophosphorus esters, such as e.g. tricresyl phosphate. KEMI (2018) additionally states that potential substitutes, e.g. phosphate esters, are not immediately available on the market in the required quantity because they have not been registered under REACH or have been registered only in small tonnages. However, a restriction of a substance under RoHS always includes a transition period that also allows an adaption of production capacities.

Uncertainties concern also the (eco-)toxicological profile of alternative polymer material; no respective information is available. There is evidence for the application of halogen-free polymer material applied on the market given through the industry-based statistics of the European Council of Vinyl Manufacturers.

8.4. Conclusion on alternatives

Alternatives for MCCPs for the plasticising as well as the flame retarding effects are commercially available on the market. A one-fits-all substitution is not probable, rather soft PVC formulation for cable and wire without MCCPs will be reached with a different set of plasticizers and with a varying set of flame retardants.

Addressing direct substitutions of MCCP by one or rather more substances, the following conclusion is drawn based on the former outlined availabilities and their hazard profiles: Some potential alternatives (e.g. ATO, Trixylylphosphate, Triphenylphosphat) have undesirable characteristics in their human health profile; LCCP, the most structurally similar alternative to MCCP, perform better in the human health assessment but raises concern with regards to PBT properties, thus, is unfavourable for the environment.

Preferable options are the metal hydroxide (ATH, MTH), the synergist zinc (hydroxy)stannate as well as some of the phosphorus-based flame retardants (case-by-case decision), and finally nitrogen-based flame retardants. This conclusion is in line with other assessments.[90]

On the side of the alternative polymer materials, HFFR-LSFOH compounds are a welcomed trend as halogenated flame retardants as well as halogenated polymer material (PVC, PFCs) are avoided. The variety of alternative materials enlarges the possibilities for substitution; these alternative materials and their compatibility with flame retardants were not assessed for their hazardous properties as explained above. But, in these materials, Mg and Al hydroxide are the main flame retarding substances (if no inherently inflammable material is used) which are considered environmentally friendly and without human health hazards.

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[90] Op. cit. KEMI (2018); ENFIRO (2009-2012) & Green Screen Assessement by US EPA (2015)

9. DESCRIPTION OF SOCIO-ECONOMIC IMPACTS

9.1. Approach and assumptions

The socio-economic analysis is based on the comparison of two scenarios.

- The **business-as-usual** scenario, that serves as a baseline for comparison, in which MCCPS are not restricted and can be applied further in EEE to be placed on the EU market.
- The **restriction scenario**, in contrast assumes that MCCPs are added to Annex II of the RoHS Directive, prohibiting their use in EEE once the restriction comes into force.

The analysis focusses on the differences between these two scenarios in terms of expected economic, environmental and social impacts.

For the analysis, it is assumed, that the substitution of MCCPs in PVC cable-insulation does not have an effect on the lifetime of the EEE nor on its usability in its intended use. It is assumed that 15,000 t/a of MCCPs are placed on the market in the EU as part of EEE.

It is furthermore clarified that cables with a rated voltage of more than 250 Volts do not fall under the RoHS 2 Directive and would thus not be affected by a restriction, i.e. differences in impact are not expected for such cables. Impacts related to such cables are therefore not discussed in the following sections.

9.2. Impact on chemicals industry

MCCP manufacturers

KEMI (2018) explains that in the REACH registration data that twelve registrants, three of which are only representatives have compiled and submitted information on MCCPs. As it is not clear from this data how many of the registrants are EU companies and how many represent manufacturers of imported volumes, KEMI assumes that there are <12 MCCP manufacturers in the EU. Cefic indicates the number of manufacturers in the EU is more likely in the range of six to ten. The number of employees of such manufacturers is not known. KEMI further note that four of the registrants of MCCPs have also provided data for the registration of LCCPs.

Under the restriction scenario, the revenues of chemical manufacturers from MCCP-sales would be lost (aside from MCCP for manufacture of PVC cables with a rated voltage above 250 Volts). Assuming a volume of MCCPs of 15,000 t/a in EEE, and the average market price of 850E/t, KEMI (2018) estimates the value of the affected market to be a maximum of ca. €12.8 million.

On the other side, should MCCPs be phased-out, an increase in sales of possible substitutes would be expected, particularly from outside the EU. In this sense, revenues of manufacturers of substitutes, such as LCCPs, are expected to increase under the restriction scenario and would compensate at least partially the MCCP-related revenue losses for non-EU businesses. This would provide a direct set-off of losses for those manufacturers who place both MCCPs and LCCPs on the market (four of the MCCP registrants) and may also lead to a shift in market share from manufacturers who only produce MCCPs (8 registrants) to those producing both (4 registrants) or to manufacturers of other alternatives (see below). The price of LCCPs per tonne is stated by KEMI (2018) to be ca. 24 % higher than MCCPs, or €1050 (LCCPs) vs. €850 (MCCPs) per tonne. In this sense, the shift towards this alternative would be expected to cover the losses of the respectively reduced MCCP production volumes. Aside from LCCPs, there is a wide variety of alternatives that current users of MCCPs could apply, both in terms of alternative substances (and combinations thereof) and alternative materials (i.e. substituting PVC). The benefits for the manufacturers of alternative substances cannot be reliably quantified. However, here too it is to be expected that revenues of increased sales of alternatives would set-off losses of decreased MCCP sales. It is also expected that EU companies would be among the beneficiaries as most of the identified alternative substances have been registered under the REACH Regulation and it is thus expected that at least some of these will be manufactured in the EU.

Manufacturers of PVC and alternative polymers

Under a restriction scenario, PVC manufacturers will have to bear the costs of switching to alternative materials and reformulating the PVC production. In some cases, the formulation of PVC could be changed, using substance alternatives for MCCPs. In such cases, the phase-out would entail an initial investment in the reformulation of PVC for relevant applications. Depending on the cost differences between MCCP and its substance alternatives, losses of PVC based MCCP formulations may be set-off to some degree by PVC based on other additives. KEMI (2018) refer to a publication by Weil et al (2006)[91] explaining "*how a PVC formulation that contains MCCPs and a phthalate can be replaced by a combination of higher phthalate loading and higher antimony trioxide loading. Similarly, a PVC formulation that is based on MCCPs and a phosphate plasticiser can be replaced by a combination of a phthalate and a higher loading of the phosphate plasticiser*". This would suggest that substance substitutes may lead to the use of higher volumes of other substances in the formulation of PVC, though it is difficult to conclude from this as to the differences in production costs.

In other cases, it can be expected that users will decide to replace PVC with other polymers, eliminating the need for MCCP. In such cases, manufacturers of other polymers would have increased revenues that would also partially set-off the losses related to the MCCP phase-out.

As it can be understood that the volumes of PVC manufacture are decreasing, it can be assumed that in some cases, alternative formulations shall already be available, reducing the initial investment costs in reformulation of PVC or of alternative polymers. In these cases, the difference between the business-as-usual scenario and the restriction scenario shall depend on the differences in volumes of use and costs of the alternative polymers and additives applied. Where the phase-out of MCCPs shall result in higher volumes of use of other substances, it is difficult to say if this shall also result in higher formulation costs, though it is understood that MCCP was commonly used in the past as it was relatively inexpensive and enhanced the qualities of other additives used in PVC.

The distribution of revenue losses and revenue gains between PVC manufacturers and manufacturers of other polymers shall depend on the rout of replacement chosen as well as on whether some of the manufacturers also manufacture alternatives.

It is possible that the reduction in demand for MCCPs could affect employment in enterprises manufacturing MCCPs. KEMI (2018) refer to data from VinylPlus from 2016[92] as to five companies representing 70 % of the total EU PVC market, which operate 41 production plants located in 21 different sites. These operations have a total of 7,000 employees, though not all of these can be connected to PVC containing MCCPs.

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[91] Cited by KEMI (2018) as Weil, E. D., Levchik, S., & Moy, P. (2006): Flame and Smoke Retardants in Vinyl Chloride Polymers – Commercial Usage and Current Developments. Journal of Fire Sciences, 24, 211-236.

[92] Cited by KEMI (2018) as VinylPlus. (2016): Progress Report 2015. Retrieved from http://www.vinylplus.eu/uploads/Modules/Bannersreport/160826_vinyplus_2016_web_ps_singlepage-version.pdf, the 10 October 2016

In parallel, however, it would also be expected that the increase in demand of MCCP alternatives shall lead to a contra-affect in relation to employment in enterprises manufacturing PVC applying substitutes or alternative polymers. In this sense, it is expected that the total impacts on employment in this respect shall not be high but rather that the distribution of employees between manufacturers of MCCP and its alternatives may change. Though numbers as to such manufacturers were not available, it is assumed that four of the MCCP manufacturers also manufacture LCCPs and for such manufacturers it is assumed that a shift from MCCPs to LCCPs shall compensate losses related with a restriction and thus also possible impacts on employment.

The various impacts cannot be quantified with the information currently available.

9.3. Impact on EEE producers

Three cost elements can be envisaged: the change in the cost of components and EEE through the change in plasticiser/flame retardant cost; the cost of process and equipment adaptations to the chosen alternative; and the cost of re-qualification of the new products.

Cable manufacturers

Cable manufacturers may face increased costs due to the higher market price of alternative plasticisers and flame retardants. For instance, KEMI (2018) refer to information form UK CA (2008) that the use of LCCPs is expected to result in a cost increase of 20-160 % and for the phthalates DINP and DIDP, this cost increase is expected to be in the region of 40-60 %. Phosphate esters have up to four times the cost of MCCPs. Only aluminium hydroxide appears to be less costly than MCCPs. KEMI (2018) estimates the total increased annual cost per year for cable manufacturers at a maximum of € 27 million, when replacing half of the 15,000 tonnes of MCCP with LCCP (accounting for ca. € 1.5 million additional costs) and the other half with a combination of DINP and 2-Ethylhexyl diphenyl phosphate (accounting for ca. € 25.4 million additional costs). It is explained that if a higher share of MCCP would be replaced with LCCP, the total costs would be lower.

The substitution of alternative plastic materials (e.g. polyethylene, polypropylene, fluoroplastics) for PVC is likely to increase production costs by 50-200 %. Consequently, the production of PVC-free electrical insulation is associated with 10-20 % higher costs.

Technically, the cost of process and equipment adaptations might not be significant. Necessary process and equipment adaptation specific to MCCPs and PVC cables are estimated to reach ca. € 1.1 million per year.

The cost of development, re-qualification, and approval of reformulated products cannot be quantified. However, the approval of medium and high voltage cables can take up to two years of testing, indicating that this may be an important parameter to consider in terms of the transition period needed for a restriction.

EEE producers

Estimating the magnitude of costs of EEE manufacturers is difficult. The relevant cost elements include technical costs and compliance costs. KEMI (2018) assumes that cable manufacturers might pass on the costs for research into suitable alternatives for MCCPs to the EEE manufacturers. The part of this additional cost can sum up to be € 28.1 million/a for the first five years and € 27 million/a thereafter, seeing as process and investments in equipment modifications would only be expected in the transition period.

On the basis of domestic production representing 59 % of overall EEE consumption in the EU, KEMI (2018) assumes that the economic burden on EU-based manufacturers of EEE would be at least €16.6 million/a over the first five years and € 16 million/a thereafter, with the rest being borne by non-EU manufacturers of EEE.

Compliance costs are estimated to be marginal, seeing as most manufacturers have already established a system for ensuring compliance with the RoHS Directive (i.e. administrative costs of compliance). In conclusion, the overall cost increase would be very small in comparison to the actual size of the EEE market.

COCIR reminds that the possibilities of a substitution of MCCPs should be assessed in conjunction with a possible restriction of diantimony trioxide (ATO) since the substitution of MCCP is more difficult if ATO-related flame retardants cannot be used. It should also be noted that industrial innovation cycles are time dependent. Time is needed to identify numerous EEE parts and components that become subject to a substance restriction, then qualify alternatives to MCCP, redesign and test products, acquire necessary certificates and finally upscale production. In particular, extended lead time to substitute a RoHS substance is expected in the sector of medical devices. This is due to the limited availability of qualified engineers who are capable of redesigning complex apparatus. MRI and CT will probably require one of the longest transition time for substitution, possibly between 5 to 7 years.[93]

9.4. Impact on EEE users

It can be envisaged that cable manufacturers would aim to pass at least part of their costs to their customers (EEE producers), which in turn may pass them on in the form of increased EEE retail prices. However, the amount per piece of equipment is expected to be very small, seeing as in the total composition, the amount of MCCP used in a EEE product and the respective amounts of substances used for its substitutions have a very small impact in the product price.

KEMI (2018 provide the following calculation to illustrate the range of impact for consumers on the base of a single product:

- *„A (large) item of EEE contains 2 kg of PVC sheathing which contains MCCPs;*
- *A PVC cable contains 10 % wt. MCCPs, thus the EEE article contains 0.2 kg of MCCPs;*
- *MCCPs are replaced by a combination of alternatives with a higher raw material cost. The cost increase is estimated at +€3,400/t or €3.4/kg62;*
- *The additional cost for this item of EEE due to the replacement of MCCPs would be 0.2 × €3.4 = €0.68.*“

9.5. Impact on waste management

Citing the Recovinyl website[94], KEMI (2018) estimates a total of 52 companies involved in PVC cable waste recycling in the EU. Assuming each of these employs between 5-15 workers, KEMI estimates

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[93] COCIR (2019): Contribution submitted on 7 November 2019 during the stakeholder consultation conducted from 26 September 2019 until 07 November 2019 in the course of the study to support the review of the list of restricted substances and to assess a new exemption request under RoHS 2 (Pack 15)

[94] Specified in KEMI (2018) as Recovinyl recyclers, available at: http://www.recovinyl.com/all-recyclers?field_cert_recylers_country2_tid=All&field_materials_tid=66 (accessed on 27 July 2016).

that 250-780 individuals are involved in PVC recycling in the EU, however, it is not assumed that the restriction scenario would affect the employment of these individuals.

As for impacts on waste management, KEMI (2018 estimate that the presence of MCCPs does not impact on the management of PVC cable waste at present and their substitutes would likely not impede the continued recycling or other end-of-life management of WEEE and PVC cable waste.

9.6. Impact on administration

Based on available information, it can be understood that the common testing methods for MCCPs are cost effective, but not always accurate in detecting and quantifying MCCPs whereas newer and more accurate methods are still expensive (KEMI (2018)).

Under a restriction scenario, compliance monitoring may impose additional testing-related costs for manufacturers and importers. Moreover, costs may occur due to the need to update the supply chain data through an in-depth investigation, assessment of suitability of substitutions with additional testing and new application to third party certification for specific components.[95] Moreover, competent authorities may also need to determine the presence of MCCPs in PVC cables in order to ensure compliance of EEE. These resources could be used for other purposes, thus additional testing brings opportunity costs. Lacking other information, a reasonable approximation of the size of these opportunity costs is the unit market price for the required tests multiplied by the expected number of tests. KEMI (2018) refer to an estimation of the Austrian Federal Environment Agency (Umweltbundesamt, 2014) that had assumed 7,000 tests per year to be conducted in the EU. Cost estimations were not available.

9.7. Impact on Human health

KEMI (2018) has summarised estimated impacts on health expected under a restriction scenario. Stakeholder categories related to the use and end-of-life phase (of relevance to the RoHS Article 6(1) criteria) are reproduced in Table 9-1. Details for additional categories can be found in KEMI (2018).

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[95] Test & Measurement Coalition (2019): Contribution submitted on 7 November 2019 during the stakeholder consultation conducted from 26 September 2019 until 07 November 2019 in the course of the study to support the review of the list of restricted substances and to assess a new exemption request under RoHS 2 (Pack 15)

Table 9-1: Summary of human health impacts along the supply chain under the Restriction scenario

Supply chain stakeholder category	Number of EU companies	Number of potentially exposed workers	Impacts on human health	Comments
WEEE treatment installations (shredding)	450	2,250-6,750	Low benefit	Modelling undertaken by KEMI shows a maximum long-term inhalative exposure of workers of 1.40 mg/m^3 for PROC 24c (High (mechanical) energy work-up of substances bound in materials and/or articles - pt > mp - High Fugacity. The risk characterisation has not raised any.
PVC waste recyclers (shredders)	52	250-780	Benefit	Modelling by KEMI shows a maximum long-term inhalative exposure of workers of 2.80 mg/m^3 (High (mechanical) energy work-up of substances bound in materials and/or articles - pt > mp - High Fugacity. The risk characterisation has raised some concern over inhalation exposure. Actual risk will depend on RMMs and operating conditions. The EU RAR did not identify an unacceptable risk to workers' health under all PVC-related scenarios examined
PVC compounders*	<50	<1,250	Benefit	Modelling by KEMI shows a maximum local dermal exposure of workers of 1.2 mg/cm^2 (calendering operations). The risk characterisation has raised some concern over inhalation exposure. Actual risk will depend on RMMs and operating conditions. The EU RAR did not identify an unacceptable risk to workers' health under all PVC-related scenarios examined
Landfills	8,400	Unknown	Unknown	No discernible exposure is expected. An assessment of exposure and risk was not undertaken by KEMI (2018)
Incinerators	715	Unknown	Unknown	No discernible exposure is expected. An assessment of exposure and risk was not undertaken by KEMI (2018)
Consumers/ general public	-	500 million citizens	Unknown	An assessment of exposure and risk has not been undertaken by KEMI (2018). The EU RAR established that there was no unacceptable risk for consumers or for humans exposed via the environment

Source: Adopted from KEMI (2018) Table 40

Note: *PVC compounders can be considered part of the manufacturing value chain, however, seeing as they combine recyclate PVC in their processing which is a result of the waste phase (PVC recycling) this category has been included here.

Kemi (2018) summarise that under the restriction scenario, benefits would generally be limited to the shredding of PVC cable waste and the compounding of PVC with MCCP-containing recyclate, though the calculated Risk Characterisation Ratios that give rise to concern are only marginally higher than 1. In absence of an exposure-risk relationship for MCCPs, it is not possible to monetise the benefits arising for workers under the Restriction Scenario. The key beneficiaries are explained to be a group of an estimated max. 2,000 workers in the EU PVC industry.

The consultants cannot follow the last statement seeing as for all stakeholder categories related to PVC manufacture (aside from compounders) impacts are of unknown or uncertain range and seeing as some of the benefits are expected in the waste phase (shredding at WEEE and PVC recycling installations).

Furthermore, in the course of this evaluation, additional risks have been investigated. Information as to elevated dust levels derived from samples taken from private homes are detailed in Section 6.1.3 and suggest that MCCPs emit from articles in which they are contained. Impacts related to these emissions are discussed in Section 7.3. Based on the sample data, at present a risk cannot be determined, given that MCCP has been concluded to fulfil the PBT and vPvB criteria[96] of REACH and the harmonised classification that MCCPs “May cause harm to breast-fed children”, it cannot be ruled out that this shall not change in the future. This has to do both with the assumption that a vPvB classification of MCCPs would result in the determination of stricter DNELs and PNECs for this substance, but also with the general understanding that continued use of a vPvB substance results in its accumulation in the environment, i.e. in this case in households and could increase the risk over time.

9.8. Impact on the environment

KEMI (2018) has summarised estimated impacts on the environment expected under a restriction scenario. Stakeholder categories related to the use and end-of-life phase (of relevance to the RoHS Article 6(1) criteria) are reproduced in Table 9-1. Details for additional categories can be found in KEMI (2018).

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[96] UK Environment Agency (2019): Substance Evaluation Conclusion EC No 287-477-0 as required by REACH Article 48 and Evaluation report for Medium-chain chlorinated paraffins, available online: https://echa.europa.eu/documents/10162/f684ca0c-072b-a60e-100b-825439aa8429

Table 9-2: Summary of human health impacts along the supply chain under the Restriction scenario

Supply chain stakeholder category	Number of EU companies	Impacts on the environment	Comments
WEEE treatment installations (shredding)	450	Benefit	Risk Characterisation Ratios calculated by KEMI (2018) do not show an unacceptable risk with MCCP. However, an estimated 0.75 tonnes of MCCPs are expected to be released to air each year and in this sense a restriction would lead to **a decrease of 0.75 tonnes of MCCP to air**.
PVC waste recyclers (shredders)	52	Benefit	Risk Characterisation Ratios calculated by KEMI (2018) do not show an unacceptable risk. However, an estimated 1.09 tonnes of MCCPs are expected to be released to air each year and in this sense, a restriction would result in **a decrease of 1.09 tonnes of MCCP to air**.
PVC compounders*: PVC formulation	<50	Benefit	Risk Characterisation Ratios calculated by KEMI (2018) show a concern for marine water and sediment. An estimated 0.36 and 0.12 tonnes of MCCPs are expected to be released to air and water respectively each year and in this sense, a restriction would result in **a decrease of 0.36 and 0.12 tonnes of MCCP to air and water**.
PVC Conversion		Benefit	Risk Characterisation Ratios calculated by KEMI (2018) show a concern for freshwater, marine water and sediment. An estimated 0.9 and 0.9 tonnes of MCCPs are expected to be released to air and water respectively each year and in this sense, a restriction would result in **a decrease of 0.09 and 0.09 tonnes of MCCP to air and water**.
Landfills	8,400	Neutral - Benefit	Under normal operating conditions, releases of MCCPs to the environment should be adequately controlled. However, in the opposite situation there might be release of MCCPs to the environment and therefore a benefit.in the form of **a decrease of 0 to 6.2 and 0 to 21.1 tonnes of MCCP to air and water**. (Modelling results suggest that 6.2 tonnes of MCCPs are released to air and 21.1 tonnes are released to water each year)
Incinerators	715	Neutral**	No benefit in the restriction scenario**. Under normal operating conditions, releases of MCCPs to the environment should be adequately controlled. Modelling results suggest that **0.12 tonnes of MCCPs are released to air and 0.06 tonnes are released to water each year**).

Source: Adopted from KEMI (2018) Table 41

Note: *PVC compounders can be considered part of the manufacturing value chain, however, seeing as they combine recyclate PVC in their processing which is a result of the waste phase (PVC recycling) this category has been included here.

** It is not clear why KEMI specify that now benefits are expected in the restriction scenario while also stating that modelling results suggest that releases to air and water occur. Possibly, a benefit would be expected here as well in the form of decreased releases, though this may depend on the performance of the specific incinerator and would thus translate to a neutral-beneficial impact.

KEMI (2018) summarize their results, expecting that overall, benefits to the environment would be focused on the elimination of releases of MCCPs during the shredding of waste (WEEE and PVC cable waste) and the formulation and compounding of PVC. A distinction is made in this respect between well operated landfills and incinerators under the strict conditions prescribed by regulation where releases of MCCPs from the PVC matrix should be low and between not well operated landfills and incinerators where possible releases have been calculated and cannot be neglected. The overall releases of MCCPs that would be eliminated are estimated to amount to 4-27 tonnes per year if taking into account emissions from not well operated landfills and incinerators. It is further noted that elimination of releases of MCCPs from these activities would also mean the elimination of releases of SCCPs which are to be found in imported commercial MCCPs products.

Further data provided by the Norwegian Environment Agency (see Section 6.2) shows MCCP levels detected in various biota. Among others, samples were taken from cod liver and blue mussels on a repeated basis in 2012, 2015 and 2016 and suggest that the levels of MCCP in the environment are increasing. This gives more weight to the benefit of reduced emissions concluded for the restriction scenario by KEMI.

Additional findings reported on by Glüge et al. (2018) show relatively high MCCP concentrations found in Arctic fish and so suggest that MCCPs are able to undergo long-range atmospheric transport. Though a level of uncertainty is discussed in relation to these results in Section 6.2.1, seeing that the increased time trends are also reported through the Norwegian data suggests that they are not to be neglected. This would also support the benefit related to emissions prevention that would result from a restriction scenario.

Considering these results against the assessment of MCCPs being very persistent and very bio accumulative (vPvB)[97] and in light of their potential for “high chronic toxicity to aquatic invertebrates” suggests that the benefit to the environment of a restriction scenario is to be considered significant. The understanding that a substance is persistent, bio accumulative and may have chronic effects on the environment gives more weight to the benefit of preventing possible releases to the environment in the future.

9.9. Total socio-economic impact

In relation to the differences in impacts between the businesses as usual scenario and the restriction scenario, the possible costs of a restriction are to be compared with its possible benefit.

Though it is expected that the restriction shall result in costs for MCCP manufacturers (up to €12.8 million which is the value of the affected market) possibly also affecting the number of employees of such enterprises, these are expected to be set-off at least to some degree by benefits expected for manufacturers of alternatives and subsequent increases in employment. This is of particular relevance for four manufacturers of MCCPs that are understood to also manufacture the alternative LCCPs.

As for PVC manufacturers, it is unclear to what degree actual costs can be expected here. Though a shift is expected from PVC containing MCCPs to PVC containing alternatives to MCCPs and possibly also towards alternative polymers, a decrease in PVC manufacture is already observed and it is possible that costs related to the need to reformulate and ensure the performance of alternatives have already incurred in the past, at least for some applications, and are thus of a low magnitude. As for costs related to alternative materials, here it can be seen that alternatives are often costlier than MCCPs, however these costs are to be shifted to component (e.g., cables) and EEE producers and subsequently to consumers.

Regarding manufacturers of related components (e.g., cables) and EEE, KEMI (2018) estimate that the quantifiable costs associated with a restriction on the use of MCCPs accounts for € 28.1 million per year over the first five years and € 27 million/y thereafter. KEMI notes that this estimate does not include costs of testing and other administrative costs, such as the cost of re-qualification and re-certification of MCCP-free cables.

It is expected that these costs would be transferred to the consumer, i.e. in the form of an increase in the costs of products in which MCCP containing cables are currently in use. In this respect, KEMI has estimated a cost increase of € 0.003 per kilogram of EEE or less than €1 for a single large appliance sold to the consumer. The consultants regard this difference as an acceptable cost difference, assuming that it would be countered with a positive impact on the environment and/or on health.

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[97] UK Environment Agency (2019) Substance Evaluation Conclusion EC No 287-477-0 as required by REACH Article 48 and Evaluation report for Medium-chain chlorinated paraffins, available online: https://echa.europa.eu/documents/10162/f684ca0c-072b-a60e-100b-825439aa8429

The benefits of a substance restriction are related to the decrease in worker exposures to MCCPs along the supply chain as well as to the decrease in emissions to the environment. A decrease in emissions in household dust may also be of relevance in light of the classification of MCCPs as a vPvB substance[98].

Based on the estimations of KEMI (2018), under the restriction scenario, worker exposures to MCCPs will be eliminated along the supply chain and a total of at least 4.12 tonnes of MCCPs per year would no longer be released to air and water. Calculating the monetised costs in relation to the amounts of emissions to be prevented per year after the 5th year of the restriction suggests that the cost of eliminating one tonne of MCCP emissions is: *"€27 million ÷ 4.12 tonnes = ca. €6,600 per kilogram of MCCPs released (without discounting)*". Though this gives indication as to the cost of preventing MCCP emissions, it is not to be interpreted as the benefit of the reduction.

It is not straightforward to estimate the benefit of the prevention of MCCP emissions in monetary terms. Nonetheless, the observed increase in the presence of MCCPs in biota contributes to the weight of such benefits, particularly given the classification of MCCPs as a vPvB substance.

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[98] See footnote 82.

10. RATIONALE FOR INCLUSION OF THE SUBSTANCE IN ANNEX II OF ROHS

MCCPs are a UVCB substance due to their unknown or variable composition that varies in chain length and in degree of chlorination. The harmonised classification of MCCPs of being reprotoxic via lactation of breast-fed children (H362), and of having very high acute and chronic toxic effects to aquatic life (H400 and H410), only partly reflects the hazardous potential that is caused by MCCPs:

- MCCPs have been assessed of being PBT as a conclusion of the CORAP substance evaluation programme under REACH: it has been generally recognised for meeting vPvB and PBT criteria.[99]

MCCPs manufactured in Europe contain congeners that are very likely vPvB, while MCCPs manufactured in Asia contain varying amounts of species with shorter than C13 carbon chain lengths (SCCP). Thus, as regards a classical risk assessment applying e.g. to the environment, a ratio of PEC/PNEC is not sufficient for assessing the risk.

The function of MCCPs is described as being a secondary plasticiser (extender) with flame retardant properties; the use in PVC and in rubber products, in particular electric cables, is confirmed. For the quantities of MCCPs, data provided by stakeholders do not suffice to map the amounts of MCCP imported in the EU as part of EEE-products. It can, however, reliably be assumed that MCCPs are used in relevant quantities in EEE mostly as constituents of PVC insulations for electric cables, wires and other soft plastic or rubber components, including polyurethane, polysulphide, acrylic and butyl sealants.

The risk evaluation is summarised as follows:

- Risks for workers: The MCCPs' application areas are likely to result in MCCP releases during recycling and disposal treatment of waste electric and electronic products (WEEE): A release of MCCPs in the form of vapours and dust can typically occur when shredding PVC cable waste and other WEEE. Other release routes are formulation, conversion, and re-use of PVC recyclate as well as final disposal. The processing of such recycling materials subsequently entails inhalative exposure of workers.
- Risks to the environment: The release of MCCPs from WEEE waste management has to be emphasised: This risk has been determined at present only by considering the current PNECs, which are in view of the vPvB properties a severe underestimation of the risk. In other words, though a risk is already apparent, it is possible that the actual risk is more severe, given the potential of being a vPvB substance.

  Environmental exposure has manifested in precipitation in soil and aquatic sediments, where secondary poisoning of organisms is likely to occur following uptake of MCCPs into the food chain. Unacceptable risks to human health and the environment have in particular been identified for treatment and final disposal of WEEE, but also in reformulation and use of recycled PVC. Given the widespread use of PVC insulated cables, the implementation of adequate risk management measures cannot be guaranteed in all possible points of release.
- Risks for consumers: There are studies detecting MCCPs in house dust. Applying the current DNELs, no risk for consumers can be determined. However, taking into account the draft

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[99] UK Environment Agency (2019) Substance Evaluation Conclusion EC No 287-477-0 as required by REACH Article 48 and Evaluation report for Medium-chain chlorinated paraffins, available online: https://echa.europa.eu/documents/10162/f684ca0c-072b-a60e-100b-825439aa8429

conclusion of the PBT expert group on the vPvB properties, it is likely that this conclusion is an underestimation.

The socio-economic analysis points to costs to be transferred to the consumer in a range that are perceived to be acceptable in light of the expected benefit in the form of elimination of exposure risks for workers and for the environment (prevention of emissions and subsequently risks to biota).

The restriction proposal by KEMI (2018) is supported by this assessment. KEMI (2018) proposes 0.1 % by weight as a maximum tolerable MCCP concentration in homogenous EEE material. Regarding the global differences to the nomenclature and CAS numbers used in various regions, a restriction of chlorinated paraffins should rather use a definition of chlorine content in relation to a chain length within a certain range instead of referencing to CAS numbers. It is therefore **recommended to restrict MCCPs** and add an explanation that this entry covers chlorinated paraffins containing paraffins **with a chain length of C14-17 – linear or branched**.

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Appendix I: Contribution to stakeholder consultation hold from 20 April 2018 to 15 June 2018

The following non-confidential contributions were submitted during the 1st stakeholder consultation (see also: http://rohs.exemptions.oeko.info/index.php?id=293):

> Contribution of the **Swedish Chemicals Agency (KEMI)** submitted on 11.06.2018:

>> Proposal for restriction of MCCP under RoHS submitted to the European Commission on 11.06.2018: PDF

>> Assessment of the risk reduction potential of hazardous substances in electrical and electronic equipment on the EU market: PDF

> Contribution of the **Norwegian Environment Agency** submitted on 14.06.2018: PDF

> Contribution of **MedTech Europe** submitted on 15.06.2018: PDF

> Contribution of the **Test and Measurement Coalition (TMC)** submitted on 15.06.2018: PDF

> Contribution of the **Association of Equipment Manufacturers (AEM)** submitted on 15.06.2018: PDF

> Contribution of **Europacable** submitted on 15.06.2018:

>> Part 1: PDF

>> Part 2: PDF

> Contribution of the **Japanese electric and electronic (E&E) industrial associations** submitted on 14.06.2018:

>> Part 1: PDF

>> Part 2: PDF

> Contribution of the **AeroSpace and Defence Industries Association of Europe (ASD)** submitted on 14.06.2018: PDF

Appendix II: Contribution to stakeholder consultation hold from 05 December 2019 and until 13 February 2020

The following non-confidential contributions were submitted during the 1st stakeholder consultation (see also: https://rohs.exemptions.oeko.info/index.php?id=335)

> Contribution of **COCIR (European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry),** submitted on 28.01.2020:

>> Contribution: PDF

>> Annex 1: PDF

> Contribution of the **Test and Measurement Coalition (TMC),** submitted on 12.02.2020: PDF

> Contribution of **MedTech Europe,** submitted on 12.02.2020: PDF

> Contribution of **EuRIC – The European Recycling Industries' Confederation,** submitted on 12.02.2020: PDF

> Joint Contribution of **Digital Europe** and the **JBCE – Japan Business Council in Europe** , submitted on 13.02.2020: PDF

> Contribution of the **Swedish Chemicals Agency (KEMI),** submitted on 13.02.20: PDF

> Contribution of **ZEBRA Technologies,** submitted on 13.02.2020: PDF

> Contribution of the **ECVM - European Council of Vinyl Manufacturers,** submitted on 13.02.20: XLSX

> Contribution of the **Cefic - European Chemical Industry Council,** submitted on 13.02.20: XLSX

> Contribution of the **Claigan,** submitted on 13.02.20: PDF

A.7.0 Nickel sulphate and nickel sulfamate

Öko-Institut e.V.
Institut für angewandte Ökologie
Institute for Applied Ecology

ROHS Annex II Dossier for Nickel sulphate and Nickel sulfamate. Restriction proposal for substances in electrical and electronic equipment under RoHS

Substance Name: Nickel sulphate, Nickel sulfamate

26/05/2020

EC Number(s):	Nickel sulphate: 232-104-9 Nickel sulfamate: 237-396-1
CAS Number(s):	Nickel sulphate: 7786-81-4, 10101-97-0, 10101-98-1 Nickel sulfamate: 13770-89-3

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Abbreviations

ABS	Acrylonitrile Butadiene Styrene
ACSIEL	Alliance Elektronique
BOELV	Binding Occupational Exposure Limit Value
bw	body weight
CAS	Chemical Abstracts Service
ChemSec	International Chemical secretariat
CLP	Regulation (EC) No 1272/2008 on Classification, Labelling and Packaging
CMR	Carcinogenic, Mutagenic, or toxic for Reproduction
DEPA	Danish Environmental Protection Agency
DNEL	Derived No-Effect Level
dw	Dry weight
EC	European Commission
ECHA	European Chemicals Agency
EEE	Electrical and Electronic Equipment
EQS	Environmental Quality Standards
EU RAR	European Risk Assessment Report
IED	Directive 2010/75/EU of the European Parliament and of the Council of 24 November 2010 on Industrial Emissions (integrated pollution prevention and control)
IUPAC	International Union of Pure and Applied Chemistry
MCCP	Medium-Chain Chlorinated Paraffins
OEL	Occupational Exposure Limit
OEM	Original Equipment Manufacturer
Op. cit .	Opus citatum, the work cited
PACT	Public Activities Coordination Tool
PBT	Persistent, Bioaccumulative and Toxic
PNEC	Predicted No-effect Concentration
PTFE	Polytetrafluoroethylene
RAC	Risk Assessment Committee

REACH	Regulation (EU) No 1907/2006 on the Registration, Evaluation, Authorisation and restriction of Chemical substances
RMOA	Regulatory Management Option Analysis
RoHS	Directive 2011/65/EU (RoHS 2) on the restriction of the use of certain hazardous substances in electrical and electronic equipment
SIN	Substitute It Now
SVHC	Substances of Very High Concern
STOT RE	Specific target organ toxicity (repeated exposure)
SME	Small and Medium-sized Enterprises
TWA	Time Weighted Averages
WEEE	Regulation (EU) No 2012/19 on Waste of Electrical and Electronic Equipment
WFD	Water Framework Directive
vPvB	Very Persistent and very Bioaccumulative

CONTEXT and SCOPE of the DOSSIER / substance assessment

The substance assessment of nickel sulphate and nickel sulfamate is being performed as part of the "*Study on the review of the list of restricted substances and to assess a new exemption request under RoHS 2 – Pack 15*". With contract No. 07.0201/2017/772070/ENV.B.3 implementing Framework Contract No. ENV.A.2/FRA/2015/0008, a consortium led by Oeko-Institut for Applied Ecology, has been assigned by DG Environment of the European Commission to provide technical and scientific support for the review of the list of restricted substances and to assess a new exemption request under RoHS 2. This study includes an assessment of seven substances / group of substances[1] with a view to the review and amendment of the RoHS Annex II list of restricted substances. The seven substances have been pre-determined by the Commission for this task. The detailed assessment is being carried out for each of the seven substances in line with a uniform methodology which was developed as a part of this study[2].

According to the terms of references of the study, the scope of the assessment concerns nickel sulphate and nickel sulfamate. For this purpose, the evaluation has compiled relevant background information for understanding whether the two nickel compounds are used in the manufacture of EEE and whether they remain present in final EEE articles placed on the EU market. Such information is the basis for assessing possible impacts on the environment and on health associated with the presence of these compounds in EEE and expected to incur during the use phase and/or during the waste phase (end-of-life). Assessment of possible impacts to arise from the presence of other nickel compounds in EEE to be placed on the EU market is beyond the scope of this assessment.

The specific terms of reference of the study points out that the *"grouping of substances (e.g. for cobalt or nickel compounds or for MCCPs) shall be possible by following the approach determined in the updated methodology, once agreed."* Though an aggregation of substances in a group entry, such as "nickel and its compounds", appears in the regulatory context, e.g. in the context of the scientific evaluation of occupational exposure limits, a group assessment of nickel and its compounds was not proposed for this assessment for the following reasons:

- The nickel salts under considerations here are solely used in metal surface treatment processes, including electrolytic plating and electroless technologies. It can be understood that these substances are transformed through the surface treatment processes and do not remain in their original form in the final produce, i.e. in relevant EEE and its parts. In the final coating, the nickel salts are understood to be converted into nickel metal or nickel^{2+} ions, depending on the process.
- To this extent, the assessment of "nickel and its compounds" would require an extension of the scope of this study to additional applications of nickel and its compounds, e.g. nickel as a derivative from surface treatment processes. This would go beyond the original scope of the study.

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[1] For the sake of better readability, hereafter the term "substance" will be used for single substances as well as for the group entry of substances, which ECHA lists on the same "Substance Infocard".

[2] This methodology includes a dossier template for substance assessment which had been prepared by the Austrian Umweltbundesamt GmbH in the course of a previous study. The methodology for substance assessment has been revised based on various proposals from and discussions with stakeholders. Among others, revisions have been made to clarify when the Article 6(1) criteria are considered to be fulfilled and how the precautionary principle is to be applied. The methodology has also been updated in relation to coherence to REACH and other legislation and publicly available sources of relevance for the collection of information on substances have been updated and added. The methodology is available at https://rohs.exemptions.oeko.info/index.php?id=341

In the course of the substance assessment, the 1st stakeholder consultation was held from 20 April 2018 to 15 June 2018 to collect information and data for the seven substances under assessment. Information on this consultation can be found at the Oeko-Institut's project webpage at: http://rohs.exemptions.oeko.info/index.php?id=289.

For nickel sulphate and nickel sulfamate, a total of eleven contributions were submitted by different stakeholders. An overview of the contributions submitted during this consultation is provided in Appendix I. The contributions can be viewed at http://rohs.exemptions.oeko.info/index.php?id=295.

Based on stakeholder input and publicly available information and stakeholder input, a second version of the dossier has been prepared, which was subject to a 2nd stakeholder consultation that was held from 26 September 2019 to 07 November 2019. For nickel sulphate and nickel sulfamate, a total of seven contributions were submitted by different stakeholders. An overview of the contributions submitted during this consultation is provided in Appendix II. The contributions can be viewed at: https://rohs.exemptions.oeko.info/index.php?id=337.

Mostly, stakeholders expressed agreement with the recommendation. The Nickel Institute (2019)[3] provided some valuable corrections and constructive suggestions for editions that were mostly taken up in this version of the dossier. For the controversial point on a further assessment of "nickel and its compounds", the indications for the recommendation are compiled in section 5.

Based on the input from the 2nd stakeholder consultation, the dossier has been revised and completed to the version 3 at hand which represents the final version.

After the revision of the dossiers and their completion, a final stakeholder meeting was held on 27 April 2020 to allow stakeholders to comment on the dossiers and particularly on conclusions and recommendations.

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[3] Nickel Institute (2019): Contribution submitted on 07.11.2019 during the stakeholder consultation conducted from 26 September 2019 to 07 November 2019 by Oeko-Institut in the course of the study to support the review of the list of restricted substances and to assess a new exemption request under RoHS 2 (Pack 15); https://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Pack_15/4th_Consultation/Contributions/contribution_NI_RoHS15_Comments_dossier_Ni_20191107.pdf, last viewed 30.01.2020

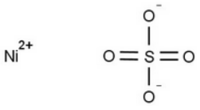
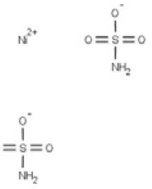
1. IDENTIFICATION, CLASSIFICATION AND LABELLING, LEGAL STATUS AND USE RESTRICTIONS

1.1 Identification

1.1.1. Name, other identifiers, and composition of the substance

The following information on the substance identity of nickel sulphate[4] and nickel sulfamate[5] are extracted from the ECHA database on substances.

Table 1-1: Substance identity and composition of nickel sulphate and nickel sulfamate

Chemical name	**Nickel sulphate**	**Nickel sulfamate (Nickel bis(sulphamidate))**
EC number	232-104-9	237-396-1
CAS number	7786-81-4, 10101-97-0, 10101-98-1	13770-89-3
IUPAC name	nickel(2+) ion sulfate	nickel(2+) ion disulfamate
Index number in Annex VI of the CLP Regulation	028-009-00-5	028-018-00-4
Molecular formula	NiO_4S	$H_4N_2NiO_6S_2$
Molecular weight (range)	154.756 g/mol	250.853 g/mol
Synonyms	Nickel (2+) Sulfate Nickel (ii) sulphate Nickel sulfate Nickel Sulphate Nickel Sulphate (slime) Nickel sulphate hexahydrate nickel(2+) ion sulfate Nickel(2+) sulfate nickel(2+);sulfate Nickel(II) sulfate Nickel(II) sulfate heptahydrate nickel(II) sulphate Sulfuric acid, nickel(2+) salt (1:1)	amidosulphuric acid Nickel (2+) Disulfamate nickel bis(sulfamidate) Nickel bis(sulphamidate) Nickel sulfamate Nickel sulphamate nickel(2+) disulfamate nickel(2+) ion disulfamate
Structural formula		

Source: ECHA, Brief Profile: Entries for Nickel sulphate and Nickel bis(sulphamidate); https://echa.europa.eu

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[4] ECHA Brief Profile: Entry for Nickel sulphate, https://echa.europa.eu/de/brief-profile/-/briefprofile/100.029.186, last viewed 11.06.2018

[5] ECHA Brief Profile: Entry for Nickel bis(sulphamidate), https://echa.europa.eu/de/brief-profile/-/briefprofile/100.033.982, last viewed 11.06.2018

1.1.2. Physico-chemical properties

Physico-chemical properties of nickel sulphate and nickel sulfamate are summarised in Table 1-2 below and were extracted from the ECHA Registered Substance Database.[6]

Table 1-2: Overview of physico-chemical properties of nickel sulphate and nickel sulfamate

Property	Nickel sulphate	Nickel sulfamate
Physical state at 20°C and 101.3 kPa	Solid (crystalline material)	Solid (crystalline material)
Melting/freezing point	53 °C for hexahydrate form; loss of water of crystallisation on heating; 840 °C for anhydrous form, decomposition temperature	decomposes at 141.63 °C
Boiling point	Not relevant	Not relevant
Vapour pressure	Not relevant	Not relevant
Water solubility	> 625 g/l at 0 °C and pH 6 - 8	in the range of 49.9 to 60.0% w/w of solution at 20.0 ± 0.5°C,
Partition coefficient n-octanol/ water (log K_{OW})	Not relevant	Not relevant
Dissociation constant	Not relevant	Not relevant
Relative density	2.07 g/cm³ at 20 °C for hexahydrate form 3.68 g/cm³ at 20 °C for anhydrous form	2.25 at 20 °C

Source: ECHA Registered Substance Database: Entry for Nickel sulphate and Nickel bis(sulphamidate)

1.2. Classification and labelling status

The Regulation No 1272/2008 on Classification, Labelling and Packaging (CLP)[7] ensures that the hazards presented by chemicals are clearly communicated to workers and consumers in the EU through classification and labelling of chemicals. Annex VI of this Regulation lists substances where a harmonised classification exists based on e.g. human health concerns.

Annex VI of the CLP Regulation is continuously adapted by Member State Competent Authorities and ECHA when new information becomes available, when existing data are re-evaluated, or due to new scientific or technical developments or changes in the classification criteria.[8]

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[6] ECHA Registered Substance Database: Entry for Nickel sulphate, https://echa.europa.eu/registration-dossier/-/registered-dossier/15304, last viewed 11.06.2018

ECHA Registered Substance Database: Entry for Nickel bis(sulphamidate), https://echa.europa.eu/de/registration-dossier/-/registered-dossier/14782/4/1, last viewed 11.06.2018

[7] Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (REACH).

[8] For further information, see https://echa.europa.eu/regulations/clp/harmonised-classification-and-labelling, last viewed 19.04.2018

Based on the conclusions of the ECHA RAC and the EU RAR the human and environmental hazards are further explained in section 3 and 4.

To summarize the table shown below, it is understood based on the harmonised classification that both nickel sulphate and nickel sulfamate are considered as CMR substances. This means that exposure to these substances above a certain threshold could lead to impacts on human health and/or the health of other species, e.g., cancer, genetic defects and/or impacts on the reproductive system and organs. Given other hazards that have been classified, relevant pathways for such impacts include exposure through the respiratory system and inhalation, through contact with skin and through oral exposure. Both compounds have further been classified for aquatic toxicity, meaning that exposure of aquatic organisms is also of potential concern.

1.2.1. Classification in Annex VI of CLP Regulation

Nickel sulphate and nickel sulfamate, are classified under the CLP regulation as follows: [9]

Table 1-3: Classification according to part 3 of Annex VI, Table 3.1 (list of harmonised classification and labelling of hazardous substances) of Regulation (EC) No 1272/2008

Index No.	International Chemical ID	EC No.	CAS No.	Classification		Labelling			Spec. Conc. Limits, M-factors
				Hazard Class and Category Code(s)	Hazard statement code(s)	Pictogram, Signal Word Code(s)	Hazard statement code(s)	Suppl. Hazard statement code(s)	
028-009-00-5	nickel sulfate	232-104-9	7786-81-4	Carc. 1A Muta. 2 Repr. 1B Acute Tox. 4 * Acute Tox. 4 * STOT RE 1 Skin Irrit. 2 Resp. Sens. 1 Skin Sens. 1 Aquatic Acute 1 Aquatic Chronic 1	H350i H341 H360D *** H332 H302 H372 ** H315 H334 H317 H400 H410	GHS08 GHS07 GHS09 Dgr	H302 H332 H315 H334 H317 H341 H350i H360D *** H372 ** H410	-	STOT RE 1; H372: C ≥ 1 % STOT RE 2; H373: 0,1 % ≤ C < 1 % Skin Irrit. 2; H315: C ≥ 20 % Skin Sens. 1; H317: C ≥ 0,01 % M=1
028-018-00-4	nickel bis(sulfamidate); nickel sulfamate	237-396-1	13770-89-3	Carc. 1A Muta. 2 Repr. 1B STOT RE 1 Resp. Sens. 1 Skin Sens. 1 Aquatic Acute 1 Aquatic Chronic 1	H350i H341 H360D *** H372 ** H334 H317 H400 H410	GHS08 GHS09 Dgr	H350i H341 H360D *** H372 ** H334 H317 H410	-	STOT RE 1; H372: C ≥ 1 % STOT RE 2; H373: 0,1 % ≤ C < 1 % Skin Sens. 1; H317: C ≥ 0,01 % M=1

Source: Annex VI Regulation No 1272/2008; https://echa.europa.eu/de/information-on-chemicals/annex-vi-to-clp, last viewed 19.04.2018

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[9] Annex VI Regulation No 1272/2008; https://echa.europa.eu/de/information-on-chemicals/annex-vi-to-clp, last viewed 19.04.2018

1.2.2. Self-classification(s)

In line with the CLP Regulation Article 4 (1), manufacturers, importers or downstream users have to (self-)classify and label hazardous substances and mixtures to ensure a high level of protection of human health and the environment. If a harmonised classification is available, it should be applied by all manufacturers, importers or downstream users of such substances and of mixtures containing such substances.

However, the majority of suppliers decide independently on the classification of a substance or mixture, which is then referred to as self-classification. Therefore, self-classification might indicate an e.g. additional hazard, which is so far not reflected by the harmonised classification. The following assessment of the self-classification therefore only refers to cases where additional hazards were notified in the self-classification.

According to the ECHA`s “classification and labelling” inventory (C&L) that contains classification and labelling information on notified and registered substances received from manufacturers and importers, the total number of notifiers is as follows:

- For nickel sulphate: 1,496 C&L notifications (as of June 2018);[10]
- for nickel sulfamate: 105 C&L notifications submitted to ECHA (as of June 2018).[11]

The higher number of notifications for nickel sulphate might reflect the higher usage amount also indicated by a higher tonnage band for nickel sulphate registered under REACH.

As for **nickel sulphate**, most notifiers follow the harmonised classification (1,407 of 1,496 notifications: 94%). Among them, 1,407 notifiers chose to state the carcinogenicity classification 1B instead of 1A but used the same hazard statement (H350i). Category 1A indicates that the substance is known to have carcinogenic potential for humans and this classification is largely based on human evidence. Category 1B specifies that the substance is presumed to have carcinogenic potential for humans and this classification is largely based on animal evidence. 84 notifiers additionally classify nickel sulphate for the human health hazard Eye irritation 2 (H319 – causes serious eye irritation). A minority of notifiers (5 notifiers) lacks certain classifications such as CMR properties (3 notifiers).

As for **nickel sulfamate**, most notifiers follow the harmonised classification (73 out of 105 notifications: 69%). 30 notifiers additionally classify for Acute Toxicity 4: 23 for H 302-Harmful if swallowed and 7 for H 302 and H332-Harmful if inhaled. A small minority (2 notifiers) lacks the Class and Category codes, only providing Hazard Statement Codes.

To summarise the various self-classifications, most notifiers follow the harmonised classification. In some cases, the level of hazard may differ, or certain hazard types have been omitted, and given that the harmonised classification is assumed to have a higher standard of scrutiny, the differences in the self-classification compared to the harmonised classification are not further considered. Furthermore, the ECHA website indicates that the self-classifications are affected by the presence of impurities or additives in the substance.

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[10] ECHA CL Inventory: Entry for Nickel sulphate, https://echa.europa.eu/de/information-on-chemicals/cl-inventory-database/-/discli/details/9597, last viewed 11.06.2018

[11] ECHA CL Inventory: Entry for Nickel bis(sulphamidate), https://echa.europa.eu/de/information-on-chemicals/cl-inventory-database/-/discli/details/16141, last viewed 11.06.2018

1.3. Legal status and use restrictions

In the following, legal restrictions for nickel sulphate and nickel sulfamate are described. It has to be noted that existing legal restrictions often address nickel and nickel compounds as a group of substances.

1.3.1. Regulation of the substance under REACH

Nickel and its compounds are subject to the restriction listed under entry 27 of REACH Annex XVII, which prohibits the use in post assemblies and articles coming into direct and prolonged contact with the skin.[12]

Entry 28 and entry 30 of REACH Annex XVII each applies to a list of specified substances. Both entries list nickel sulphate and nickel sulfamate. The listing of these substances prohibits the supply to the general public: as a substance, as a mixtures or as a constituent of other mixtures.

Nickel sulphate was subject to further scrutiny under REACH by the means of the so-called risk management option analysis (RMOA[13]). France, as the authority carrying out the RMOA, stated that 6 nickel compounds have been selected for further assessment. These are nickel sulphate, hydroxycarbonate, dichloride, dinitrate, bis(hydrogen)phosphate and monoxide. The RMOA has been carried out for nickel sulphate and nickel oxide because these two nickel salts cover the majority of the uses reported for nickel compounds. The French competent authority concludes that the conclusions of the RMOA are also valid for the other nickel compounds. Based on the RMOA, a binding occupational exposure limit value (BOELV) was proposed by the French authorities at 0.01 mg/m^3 for nickel compounds.[14]

In the further course of this process, the ECHA Committee for Risk Assessment (ECHA RAC 2018)[15] recommended an occupational exposure limit (OEL) of 0.005 mg/m^3 for respirable dust and 0.03 mg/m^3 for inhalable dust (for further information see section 3.1). ECHA RAC (2018) defines the group entry “Nickel and its compounds” as nickel metal and inorganic nickel compounds.

In the further process, the European Commission is expected to present a legislative proposal setting binding OEL values for nickel compounds and other substances in 2019, under the upcoming 4th revision of Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work. The Nickel Institute (2019) noted that the OEL for inorganic nickel compounds (classified as CMR 1A-1B) under the next revision of Directive 2004/37/EC is expected in 2020.

A number of Member States have already set OELs for nickel and nickel compounds.[16] The proposal of ECHA RAC (2018) serves as a preparation for the amendment of the Directive

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[12] E.g. earrings, necklaces, bracelets and chains, anklets, finger rings, wrist-watch cases, watch straps and tighteners, rivet buttons, rivets, zippers and metal marks, when these are used in garments restricting the rate of nickel release from those parts of such articles coming into direct and prolonged contact with the skin stating that a release of 0.5 µg/cm²/week for a period of at least two years of normal use of the article shall not be exceeded.

[13] In the meantime, the wording has been changed into Regulatory Management Option Analysis.

[14] France (2016): Risk management option analysis, Conclusion document for nickel sulphate, August 2016; https://www.echa.europa.eu/documents/10162/770bbde2-29f0-b09c-2682-4c1614f7e12c, last viewed 19.04.2018

[15] ECHA RAC (2018): Committee for Risk Assessment RAC, Opinion on scientific evaluation of occupational exposure limits for Nickel and its compounds, ECHA/RAC/A77-O-0000001412-86-189/F, Adopted 9 March 2018; https://echa.europa.eu/documents/10162/13641/nickel_opinion_en.pdf; last viewed 18.06.2018

[16] See an overview in: https://echa.europa.eu/documents/10162/026d40c4-7b36-4b8d-910c-bd036af685bf, last viewed 19.04.2018

2004/37/EC which constitutes a binding occupational exposure limit value which has to be then transposed by the Member States.

The RMOA documentation includes an analysis on the environmental impact, performed by Denmark. According to the RMOA, additional data for sediment compartment were collected in 2012, on the basis of which chronic effects and hazard for freshwater organisms were identified. Based on this data, the RMOA concluded that present risk management measures are not considered appropriate. The need for community-wide measures is expressed.[17] So far, no further steps were taken according to the publicly available information at the ECHA webpage.

1.3.2. Other legislative measures

Other legislative measures also address “nickel and its compounds” as a substance group entry. As this group entry also includes nickel sulphate and nickel sulfamate, these legal restrictions are compiled in the following:

- The IED Directive 2010/75/EU on industrial emissions (integrated pollution prevention and control) sets emission limit values for nickel and its compounds:[18]
  - Air emission limit values for waste incineration plants with an average emission limit values of 0,5 mg/Nm^3 over a sampling period of a minimum of 30 minutes and a maximum of 8 hours for nickel and its compounds, expressed as nickel (Ni), and
  - Emission limit values for discharges of waste water from the cleaning of waste gases for unfiltered samples at 0,5 mg/l.
  - According to the Nickel Institute (2019), there is an upcoming revision of the “Surface treatment of metals and plastics BREF” under the Industrial Emissions Directive.
- A daughter Directive to the WFD, Directive 2013/39/EU[19], sets environmental quality standards (EQS) for nickel in freshwater at 4 µg/l (bioavailable) and the marine water 8.6 µg/l.
- Directive 98/83/EC on the quality of water for human consumption sets a maximum level of 20 µg/l for nickel in water intended for human consumption.[20]
- Any nickel-containing compound (including the metals in metallic form, as far as these are classified as dangerous substances[21]) can lead to the classification of hazardous waste according to the Commission Decision 2000/532/EC establishing a list of hazardous waste pursuant to Article 1(4) of Council Directive 91/689/EEC on hazardous waste.

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[17] France and Anses (2014): Draft analysis of the most appropriate risk management option for nickel sulphate, April 2014; http://www.consultations-publiques.developpement-durable.gouv.fr/IMG/pdf/RMOA_NiSO4_PUBLIC.pdf, last viewed 22.02.2019

[18] Directive 2010/75/EU of the European Parliament and of the Council of 24 November 2010 on industrial emissions (integrated pollution prevention and control); https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32010L0075, last viewed 19.04.2018

[19] Directive 2013/39/EU of the European Parliament and of the Council of 12 August 2013 amending Directives 2000/60/EC and 2008/105/EC as regards priority substances in the field of water policy; https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32013L0039&from=EN, last viewed 18.06.2018

[20] The value applies to a sample of water intended for human consumption obtained by an adequate sampling method at the tap and taken so as to be representative of a weekly average value ingested by consumers. Where appropriate, the sampling and monitoring methods must be applied in a harmonised fashion to be drawn up in accordance with Article 7(4) of that Directive. Member States must take account of the occurrence of peak levels that may cause adverse effects on human health.

[21] Except pure metal alloys in their massive form according to Commission Decision 2014/995/EU

- Limit values are specified for nickel by Council Decision establishing criteria and procedures for the acceptance of waste at landfills pursuant to Article 16 of and Annex II to Directive 1999/31/EC (2003/33/EC).[22] The leaching limit value for waste that is acceptable at landfills for inert waste is calculated at liquid to solid ratios (L/S) of 2 l/kg and 10 l/kg for total release. For Nickel, leaching limit value is 0,2 mg/kg and 0,4 mg/kg dry substance in of 2 l/kg and 10 l/kg samples respectively. In percolation test, the limit value C_0 is 0,12 mg/l.
- Maximum limit values for airborne emission of Nickel and its compounds are established in the Industrial Emissions Directive (Directive 2010/75/EU).[23] The average emission limit value is 0,5 mg/Nm^3 over a sampling period of a minimum of 30 minutes and a maximum of 8 hours (Annex VI, part 3). The same legislation stipulates an emission limit value for discharges of Nickel in waste water from the cleaning of waste gases. For Nickel and its compounds, the limit values for Nickel in unfiltered samples is 0,5 mg/l (Annex VI, part 5).

1.3.3. Non-governmental initiatives

The International Chemical Secretariat (ChemSec) has developed and regularly updates the so-called SIN List, which identifies potential substances of concern. The list is a measure for putting pressure on legislators to assess and where relevant address substances identified therein in the future in respect to relevant chemical legislation.[24] ChemSec applies a number of categories for adding substances to the SIN List, including substances that can cause cancer, alter DNA or damage reproductive systems (CMR properties); substances that do not easily break down and accumulate in the food chain (PBT/vPvB substances); and substances of equivalent concern that give rise to an equivalent level of concern in terms of potential damage to health and environment (such as substances with endocrine disrupting properties).

Nickel sulphate[25] and nickel sulfamate[26] are both listed on the SIN List for the reason that they are *“classified CMR according to Annex VI of Regulation 1272/2008”*.

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[22] Leaching limit values for waste acceptable at landfills for inert waste and limit values for non-hazardous waste.

[23] https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2010:334:0017:0119:en:PDF; last viewed 12.09.2019

[24] http://chemsec.org/business-tool/sin-list/about-the-sin-list/, last viewed 24.07.2018

[25] http://sinlist.chemsec.org/search/search?query=Nickel+sulphate, last viewed 11.06.2018

[26] http://sinlist.chemsec.org/search/search?query=nickel+sulfamate, last viewed 11.06.2018

2. USE IN ELECTRICAL AND ELECTRONIC EQUIPMENT

Description of processes

The EEE specific uses of nickel sulphate and nickel sulfamate are in metal surface treatment in electrolytic plating as well as electroless technologies. Within these plating processes, the use of both nickel salts is explained to be an intermediate use resulting in inclusion into or onto a matrix. The function and applications of the nickel layer is further explained below.

Nickel sulphate and nickel sulfamate are converted into nickel metal during the electrolytic processes in surface treatment. The Nickel Institute[27] describes the plating process as follows:

> *"Nickel sulfate and nickel sulfamate are soluble nickel salts. During the electrolytic process in metal surface treatment, these nickel salts are dissolved in the electrolytic bath into nickel $^{2+}$ions and a salt complex (e.g. SO_4^{2-}). The nickel ions migrate to the cathode where the nickel ions are deposited as nickel metal on the surface of relevant parts that have to be plated. Electroless nickel plating is an auto-catalytic reaction. Similar to electrolytic plating, nickel salts are dissolved and form nickel $^{2+}$ions and a salt complex (e.g. SO_4^{2-}). Unlike the electrolytic process, it is not necessary to pass an electric current through the solution to form a deposit of nickel on the substrate. Electroless nickel plating provides an even deposit regardless of the shape and form of the workpiece. It is used as alternative process especially for non-conductive surfaces."*

As for the question on possible residues in the layer, the Carl Zeiss Jena GmbH in its stakeholder contribution[28] provided own measurements performed with energy dispersive X-ray spectroscopy, which is used to test for impurities. The data includes measurements of an electroless plated nickel layer, showing no residual nickel sulphate in the deposit, and of an electrolytically plated nickel layer put of nickel sulfamate, also showing no nickel sulfamate in the deposit. The measurements show that no residues remain after the treatment processes.

During the 2nd stakeholder consultation, Lynred (2019),[29] a manufacturer of infrared imaging detectors, stated that their suppliers communicate on the concentration of nickel sulfamate on the items that *"probably >0.1% on electroformed nickel screens and < 0,1% on the coatings of the concerned components of cold fingers"*. Lynred (2019) concluded that less than 100 g of nickel sulfamate might be found in final products of a year. Thus, there are uncertainties as to residues in the final product. However, this estimation will not further be taken into account.

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[27] Nickel Institute (2018): Contribution submitted on 15.06.2018 during the stakeholder consultation conducted from 20 April 2018 to 15 June 2018 by Oeko-Institut in the course of the study to support the review of the list of restricted substances and to assess a new exemption request under RoHS 2 (Pack 15); http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Pack_15/1st_Consultation_Contributions/Contribution_Nickel_Institute_Ni_20180608ROHS_Stakeholder_Consultation_FINAL_Comments.pdf, last viewed 18.06.2018

[28] Carl Zeiss Jena GmbH (2018): Contribution submitted on 07.06.2018 during the stakeholder consultation conducted from 20 April 2018 to 15 June 2018 by Oeko-Institut in the course of the study to support the review of the list of restricted substances and to assess a new exemption request under RoHS 2 (Pack 15); http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Pack_15/1st_Consultation_Contributions/RoHS-Pack15_Statement-CZJ_Ni-Compounds_final_signed_01062018.pdf, last viewed 18.06.2018

[29] LYNRED (2019): Contribution submitted on 07.11.2019 during the stakeholder consultation conducted from 26 September 2019 to 07 November 2019 by Oeko-Institut in the course of the study to support the review of the list of restricted substances and to assess a new exemption request under RoHS 2 (Pack 15); https://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Pack_15/4th_Consultation/Contributions/contribution_LYNRED_RoHS15_comments_Ni_20191107.pdf, last viewed 30.01.2020

In the following, the term **process chemical** will be used for the applications of nickel sulphate and nickel sulfamate, which means that they are applied in the production process and are chemically converted. The starting substance used in the process is not present in the final product.

The term process chemical rather than "intermediate" is proposed as under REACH, reduced registration requirements apply to intermediates, depending on the conditions of manufacture and use. The REACH Regulation defines an intermediate as a "*substance that is manufactured for and consumed in or used for chemical processing to be transformed into another substance*" (Article 3 (15)). However, ECHA states in its "Guidance on Intermediates" that surface treating agents are not regarded as intermediates.[30] As nickel sulphate and nickel sulfamate used as surface treating agents are exempted from intermediates according to ECHA, the full registration requirements under REACH are applicable.

2.1. Function of the substance

The functions of the metallic nickel layer in electronic parts, provided by nickel plating are summarised from the information given in the contribution by stakeholders (e.g. Nickel Institute, Carl Zeiss Jena GmbH, Alliance Elektronique – ACSIEL[31], Lynred). According to the contributions, the metallic nickel layer:

- acts as a diffusion barrier. France and Anses (2014) explain that the diffusion barrier prevents gold, tin and copper from diffusing into each other, leading to failure of chips, connections and circuit boards;
- provides corrosion resistance;
- provides wear resistance due to good hardness properties;
- provides strong adhesive properties to the substrate surface and to subsequent coating layers as it may be used as a finish layer or as underlayer;
- builds up homogenously and can be applied in a wide range of layer thicknesses; and
- has electrical conductivity.

The plating of plastic is also applied for decorative applications "*where bright or satin coatings are required*".[32]

2.2. Types of applications / types of materials

As mentioned before, nickel sulphate as well as nickel sulfamate are applied as process chemicals and do not remain in final components and products. The resulting metallic nickel plating is widely used in EEE products, e.g. for electrical connectors and contacts, microprocessors and other chip assemblies, integrated circuits, and printed circuit boards.

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[30] ECHA (2010): Guidance on Intermediates, version 2, December 2010; https://echa.europa.eu/documents/10162/13632/intermediates_en.pdf/0386199a-bdc5-4bbc-9548-0d27ac222641, last viewed 19.04.2018

[31] Alliance Electronique - ACSIEL (2018): Contribution submitted on 15.06.2018 during the stakeholder consultation conducted from 20 April 2018 to 15 June 2018 by Oeko-Institut in the course of the study to support the review of the list of restricted substances and to assess a new exemption request under RoHS 2 (Pack 15); http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Pack_15/1st_Consultation_Contributions/Contribution_ACSIEL_Nickel_CMG_Ni_Salts_20180615.pdf, last viewed 18.06.2018

[32] https://www.nickelinstitute.org/about-nickel/plating/, last viewed 19.02.2020

According to the Nickel Institute, the largest application of electroless nickel plating is for hard disc drives for computers.

The use of nickel plating on plastics is applied for ABS plastic mouldings of electronic products (i.e. in plastic housings). The plastic plating is according to the website of the Nickel Institute a recent development. Applications in terms of plastic parts cannot be specified based on the information assessed for the dossier here at hand. As the plating of plastic parts is also performed for decorative reasons, it is understood that this is also applied to “larger”[33] plastic parts.

2.3. Quantities of the substance used

According to the Nickel Institute (2018), “*for Europe, the total amount of nickel salts used in plating during electrical and electronic equipment manufacturing processes are estimated to be less than 5,000 t. ‘Nickel salts’ include nickel sulfate and nickel sulfamate, as well as other nickel compounds used for plating. No further information is available with regard to the specific use of nickel sulfate and nickel sulfamate.*”

Further nickel compounds for surface treatment are nickel chloride, nickel hydroxy carbonate, nickel nitrate, nickel diacetate and nickel hydroxide.

According to France and Anses (2014), there are three water-soluble salts used predominantly in electrolytic (and also electroless) nickel plating: nickel sulphate, nickel chloride and nickel sulfamate. Nickel sulphate is stated to be the most used salt; it is the least expensive nickel source and the related sulphate anion has little effect on the deposit properties contrary to anions from other salts. For surface treatment, France and Anses (2014) indicate an amount for nickel sulphate of 12,000 t/y. However, this includes also electroplating used in other sectors, especially aerospace and automotive. It was not feasible to single out the nickel consumption of the EEE sector since available statistical data are not sector specific in this regard.

2.4. Potential for impacts of the substance on the environment and on health during the use of EEE

Seeing that both nickel sulphate and nickel sulfamate are understood not to be present in EEE, impacts would not be expected in relation to these substances in the use phase of such EEE. It is, however, noted that the application of these substances in plating processes used in the manufacture of EEE components results in the presence of nickel or other nickel compounds in the relevant EEE. It is possible that the presence of these compounds may result in impacts on health and/or the environment during the use phase of such equipment. However, the investigation of the potential for such impacts is beyond the scope of this assessment.[34]

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[33] No definition of large can be given here. In the context of marking of plastic parts to facilitate recycling processes, different ecolabel schemes such es TCO or IEEE relate their requirements for marking to plastic parts with a weight greater than 25 grams

[34] There were additions to this paragraph proposed by Nickel Institute (2019) that concerned the OEL and the BREF which has been added in section 1.3. on legal status and use restrictions. The proposed additions are considered not to be linked to potential impact in the use phase but concern the manufacturing phase.

3. HUMAN HEALTH HAZARD PROFILE

The toxicological summary in the registration dossier provided in the ECHA database[35] show the same results for nickel sulphate and nickel sulfamate (the guidance values are given in terms of mg nickel and not as mg substance). It is therefore assumed that the nickel ion is the entity being mostly relevant for the human health hazards. In the regulatory context, it is commonly referred to a group “nickel and its compounds”.[36]

The Nickel Institute in its contribution 2019 pointed out that it should be noted here that nickel metal has a different and lower hazard classification than inorganic nickel compounds.

Nickel metal as nickel (CAS 7440-02-0) has a lower carcinogenic classification of category 2 by inhalation (Carc. 2 – H351 Suspected of causing cancer) compared to the inorganic compounds such as nickel sulphate and nickel sulfamate being harmonised classified for Carc. 1A (H350 May cause cancer) by inhalation; however, nickel is also classified for specific organ toxicity STOT RE 1 (H372 Causes damage to organs through prolonged or repeated exposure) and skin sensitation (Skin Sens. 1: H317 May cause an allergic skin reaction). Critical endpoint

The opinion of ECHA RAC (ECHA RAC 2018) is the most recent evaluation of the critical endpoints of nickel and its compounds. The following conclusions are relevant for the human health hazard of nickel sulphate and nickel sulfamate:

- The main hazard of nickel compounds is their carcinogenicity in the respiratory tract. Exposures to mixed nickel compounds have resulted in increased lung cancer risk. In some studies, cancer risk has correlated best with the exposure to soluble nickel. In addition, an increased risk for nasal cancer has been demonstrated.
- Differences in lung clearance and local cellular uptake between different nickel species are assumed to explain the variability in their carcinogenic potency.
- In humans, exposure to nickel is often via a mixture of soluble and poorly soluble nickel compounds.
- Nickel compounds are not directly mutagenic but have been shown to induce genotoxic effects via different indirect mechanisms.
- Chronic inflammation in the respiratory tract is also likely to play a significant role in nickel-induced carcinogenicity together with indirect genotoxicity.
- The available information on the mechanisms of genotoxicity and cancer support a mode-of-action based threshold for carcinogenic effects.
- The proposed OEL therefore relies on a mode of action-based threshold for the carcinogenicity of nickel compounds. In addition to the mechanistic data reviewed by RAC, data on the lack of genotoxicity in animals at inhalation doses below the levels causing inflammation and cytotoxicity support this conclusion.
- At exposures below the proposed limit value, no significant residual cancer risk is expected for workers.

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[35] Op. cit. ECHA Registered Substance Database: Entries for Nickel sulphate and Nickel bis(sulphamidate)

[36] https://echa.europa.eu/de/substance-information/-/substanceinfo/100.239.198

- Nickel compounds have also been shown to exert reproductive effects (effects on both fertility and developmental) in animal studies. The OELs proposed are also considered to be protective for reproductive effects.

Besides the relevant pathway by exposure through the respiratory system and inhalation, contact with skin and through oral exposure is also of relevance reflected by the harmonised classification and legislative measures as well as derived no effect levels as outlined in the next section.

3.1. Existing Guidance values (DNELs, OELs)

There are legal guidance values for the general population for dermal and oral exposure, which cover the group of nickel and its compounds:

- According to entry 27 of REACH Annex XVII: The direct exposure of consumers to products containing nickel and nickel compounds restricts the rate of nickel release ions in jewellery and other objects with skin contact 0.5 µg/cm²/week for a period of at least two years of normal use of the article coming into direct and prolonged contact with the skin.
- The Drinking Water Directive (98/83/EC sets parametric value for the quality of water intended for human consumption for chemicals, among them for nickel at 20 µg/l.

As for the risk of workers, it has already been mentioned that the ECHA RAC (ECHA RAC 2018)[37] concluded in March 2018 on occupational exposure limits (OELs) for nickel and its compounds, which includes metal nickel and nickel powder as well as a wide range of inorganic nickel compounds, including nickel sulphate and nickel sulfamate. This is due to exposure to nickel in occupational settings almost always being a mixture of different nickel species (mixture of soluble and poorly soluble nickel compounds) and therefore it was considered as not practicable to give different values for different nickel compounds.

The OEL proposed by ECHA RAC (2018) is shown in the following table. At exposures below the proposed limit value, it is concluded that workers are protected from nickel-induced carcinogenicity.

Table 3-1: OEL for the respirable fraction of both nickel metal and nickel compounds

	Limit value
OEL as 8-hour TWA	0.005 mg/m^3 for respirable dust
	0.03 mg/m^3 for inhalable dust

Note: Respirable dust is the fraction that can penetrate beyond the terminal bronchioles into the gas-exchange region of the lungs. Inhalable dust is the fraction of a dust cloud that can be breathed into the nose or mouth.

Source: ECHA RAC (2018); TWA - Total Weighted Average

The following table presents the guidance values submitted by the industry as part of the REACH registration dossier. These values are not verified by authorities.

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[37] Op. cit. ECHA RAC (2018)

Table 3-2: Guidance DNEL values for nickel sulphate and nickel sulfamate according to the registration dossiers

Population	Exposure route	Effects	Exposure	DNEL	Most sensitive endpoint
Workers	Inhalation	Systemic	Long term	0.05 mg/m^3	repeated dose toxicity (lung inflammation)
			Acute/short term	104 mg/m^3	acute toxicity
		Local	Long term	0.05 mg/m^3	carcinogenicity and repeated toxicity
			Acute/short term	1.6 mg/m^3	repeated dose toxicity (lung inflammation)
	Dermal	Local	Long term	0.44 $\mu g/cm^2$	sensitisation (skin)
General Population	Inhalation	Systemic	Long term	60 ng/m^3	developmental toxicity / teratogenicity
			Acute/short term	8.8 mg/m^3	acute toxicity
	Inhalation	Local	Long term	60 ng/m^3	developmental toxicity / teratogenicity
			Acute/short term	0.1 mg/m^3	repeated dose toxicity
	Oral	Systemic	Long term	0.011 mg/kg bw/day	developmental toxicity / teratogenicity
			Acute/short term	0.37 mg/kg bw/day	acute toxicity

Note: bw=body weight

Source: ECHA Registered Substance Database: Entries for Nickel sulphate and Nickel bis(sulphamidate)

To conclude on human health, as the two nickel salts are not present in the final EEE, there is not risk arising from these substances. Any potential risk for workers e.g. in shredding processes may result from the presence of nickel or nickel compounds others than the two nickel salts in scope of this assessment.

4. ENVIRONMENTAL HAZARD PROFILE

The 2008 EU RAR on the environment addressed nickel together with other nickel compounds, among them nickel sulphate. The EU RAR (2008) concludes that nickel ion is responsible for the toxic action of nickel in the environment. An environmental assessment of nickel metal, compiled in a DEPA report (DEPA 2015),[38] explains that the nickel ion is highly toxic in the environment. The actual toxicity of a nickel compound depends on the solubility of the nickel substance and the bioavailability of nickel ion in the environment.

4.1. Endpoints of concern

Due to the aquatic toxicity of the nickel ion, an environmental quality standard (EQS) for nickel in freshwater is set at 4 µg Ni/l (bioavailable) and the marine water 8.6 µg Ni/l, adopted through Directive 2013/39/EU.

The aquatic toxicity is also reflected by the harmonised classification of the CLP Regulation, which classifies nickel sulphate and nickel sulfamate as acute and chronic toxic to the aquatic environment (H400 - Very toxic to aquatic life and H410 - Very toxic to aquatic life with long lasting effects).

According to the background document for the RMOA for nickel sulphate,[39] an assessment has been completed in 2012 by DEPA on the chronic effects (and potential risks) on freshwater sediment organisms completing the existing environmental risk assessment for nickel compounds.

DEPA considered no risk management measure to be appropriate under the REACH Regulation, but expressed the need for other community-wide measures, such as:

- the establishment of an environmental quality standard for freshwater sediment under the WFD Directive;
- the need for a revision of the Best Available Techniques (BAT) reference documents (so-called BREF) in relation to nickel plating to protect specifically the freshwater sediment compartment also through the Industrial Emission Directive.

4.2. Potential for secondary poisoning and bioaccumulation

The EU RAR (2008) on nickel and its compounds summarises that nickel does bioaccumulate in aquatic biota but that the bioaccumulation factors are generally low and do not appear to biomagnify. Furthermore, the EU RAR (2008) concludes that the risk for secondary poisoning is considered as being low.

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[38] Danish Environmental Protection Agency (2015): Survey of nickel metal, Part of the LOUS review, Environmental project No. 1723, 2015; https://www2.mst.dk/Udgiv/publications/2015/06/978-87-93352-36-0.pdf, last viewed 18.06.2018

[39] Op. cit. France and Anses (2014)

4.3. Guidance values (PNECs)

The predicted no effect concentration (PNEC) is the concentration below which exposure to a substance is not expected to cause adverse effects on species in the environment.

ECHA's registered substances database provides guidance values on aquatic and terrestrial toxicity for nickel. The following guidance values are based on REACH registration dossiers data available on the ECHA database[40]. The information provided by the registrants has not been subject to scrutiny by ECHA or any EU expert group, or by the authors of this report.

Table 4-1: PNECs values for nickel

Fact	**Compartment**	**PNEC values for nickel** **Registration dossiers**
Hazard for aquatic organisms	Freshwater	7.1 µg/l
	Marine water	8.6 µg/l
	Sewage treatment plant (STP)	0.33 mg/l
	Sediment (freshwater)	109 mg/kg sediment dw
	Sediment (marine water)	109 mg/kg sediment dw
Hazard for terrestrial organism	Soil	29.9 mg/kg soil dw
Hazard for air	Air	No hazard identified
Hazard for predators	Secondary poisoning	0.12 mg/kg food

Source: ECHA Registered Substance Database: Entries for Nickel sulphate and Nickel bis(sulphamidate)

To conclude on the environmental hazards, the nickel salts are not expected to remain undissociated in the environment but due to e.g. the water solubility, the nickel ion is the relevant compound in the environment. As the nickel salts are converted during EEE manufacture, a release of nickel as an element may appear in the waste phase. This release does not a result from the nickel salts subject to this study and is therefore beyond the scope of this assessment.

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[40] Op. cit. ECHA Registered Substance Database: Entries for Nickel sulphate and Nickel bis(sulphamidate)

5. WASTE MANAGEMENT OF ELECTRICAL AND ELECTRONIC EQUIPMENT

As discussed above (see section 2), nickel sulphate and nickel sulfamate are used in plating technologies based on electrodeposition und electroless deposition for a broad range of electrical and electronic components, including ABS plastic mouldings. Nickel sulphate and nickel sulfamate are solely used as process chemicals which are converted into nickel metal during the electrolytic surface processes. Thus, the available data indicates that nickel sulphate and nickel sulfamate are not found in electrical and electronic equipment (EEE), not even as an impurity.

Due to the fact that these nickel salts are not present in the final EEE product, an evaluation on their impact on waste treatment processes is not further developed.

The evaluation of the waste stream processes would rather have to be conducted for the substance group "nickel and its compounds". Nickel is generally present in many forms in EEE waste (see EU RAR 2008), mostly as nickel compounds – e.g. nickel oxide or nickel hydroxide. Nickel metal and Ni^{2+} can be expected to be present in almost all EEE and thus in all WEEE categories. Nickel plating of plastics housings can be expected to be more common in consumer products which often have shorter lifetimes and do not need to be as robust as equipment with metal housings.

Already the Swedish Chemicals Agency KEMI concluded in it “Assessment of the risk reduction potential of hazardous substances in electrical and electronic equipment on the EU market” in 2015[41] that *“nickel compounds are hazardous to human and environment and are found to a great extent in EEE products, it is of interest to analyse them more extensively in order to make an assessment of their risks in EEE products.”*

This evaluation is however beyond the scope of this review.

The Nickel Institute (2019) claims in this regard that “*it should be noted, however, that no risks were identified for shredding processes in the REACH chemical safety assessment of the waste life-cycle stage (documented in the joint Chemical Safety Report), which is based on the Best Available Techniques (BAT) Reference Document (BREF) for Waste Treatment (JRC, 2018). Moreover, it should be acknowledged that nickel metal and inorganic nickel compounds have different hazard classifications.”*

The Joint Chemical Safety Report is not publicly available but submitted to the ECHA; results are extracted and made available in the ECHA Registered Substance database.[42] Thus, the claim of Nickel Institute cannot be scrutinised here. However, the consideration that nickel-plated plastics end up in waste stream processes where processing and shredding of plastic waste generates dust from decomposing and shredding of EEE plastic supports the conclusion as taken by KEMI (2015). No further information on nickel plated plastics in EEE especially on amounts have been provided by stakeholders. These considerations form the basis for the recommendation to assess the substance groups nickel and its compounds in the future.

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[41] Swedish Chemicals Agency KEMI (2015): Assessment of the risk reduction potential of hazardous substances in electrical and electronic equipment on the EU market; https://www.kemi.se/global/pm/2015/pm-7-15.pdf, last viewed 19.04.2018

[42] E.g. for nickel at: https://echa.europa.eu/de/registration-dossier/-/registered-dossier/15544/1; see there under toxicological information.

6. EXPOSURE ESTIMATION DURING WEEE TREATMENT

As nickel sulphate and nickel sulfamate are process chemicals and do not remain in the final EEE, it is concluded that there is no exposure to either of these substances during WEEE treatment.

7. IMPACT AND RISK EVALUATION

An impact and risk evaluation is not carried out as the available data indicate that nickel sulphate and nickel sulfamate are not present in EEE.

8. ALTERNATIVES

Information on possible alternatives are extracted from the following two reports that already reviewed substitution possibilities:

- Draft analysis of the most appropriate risk management option for nickel sulphate (France and Anses 2014);[43] and
- Survey of nickel metal, Part of the LOUS review by DEPA (2015).[44]

Further information from the stakeholder contributions submitted during the 1st stakeholder consultation is taken into consideration in the relevant sections.

8.1. Availability of substitutes / alternative technologies

France and Anses (2014) discussed the following possibilities for substitution:

- 'Drop-in' substances that directly replace nickel sulphate in the same production process without change (except minor changes) with other soluble nickel salts;
- the use of alternative substances; and
- alternative technologies.

According to France and Anses (2014), a **substitution** of nickel sulphate is possible **with other soluble nickel salts** (e.g. nickel chloride) as highly dissociated solution of the divalent nickel cation and the appropriate anion are reached. A number of other nickel salts have been used as intermediates in specialised electroless and electrolytic applications such as nickel acetate, nickel fluoborate, nickel hypophosphite and nickel methanesulphonate. The contribution by Coherent[45] submitted in the 1st stakeholder consultation in 2018 stated that "*in the future, this may change, as electroless nickel appears to be replacing sulfamate nickel in electronics applications (apparently the reliability data finally exists). This may be what prompted the RoHS proposal […]*". In electroless nickel plating, nickel acetate and hydroxycarbonate are used.

However, France and Anses (2014) conclude that the substitution between nickel salts is technically not feasible in all situations, e.g. nickel sulphate has no substitutes for the so called "diamond adhesion phase" which is however understood not to be relevant for EEE production. Additionally, France and Anses (2014) points out that other soluble nickel salts show the same hazard profile and that therefore no risk reduction benefit is reached.

As for **alternative substances,** France and Anses (2014) list that besides nickel, chromium, copper, zinc and tin are commonly electrodeposited commercially in large quantities. Nine other metals have been deposited on a commercial scale, however in much smaller quantities:

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[43] France and Anses (French Mandated National Institute) (2014): Draft analysis of the most appropriate risk management option for nickel sulphate, April 2014; http://www.consultations-publiques.developpement-durable.gouv.fr/IMG/pdf/RMOA_NiSO4_PUBLIC.pdf, last viewed 18.06.2018

[44] Danish Environmental Protection Agency DEPA (2015): Survey of nickel metal, Part of the LOUS review; Environmental project No. 1723, 2015; https://www2.mst.dk/Udgiv/publications/2015/06/978-87-93352-36-0.pdf, last viewed 18.06.2018

[45] Coherent (2018): Contribution submitted on 12.06.2018 during the stakeholder consultation conducted from 20 April 2018 to 15 June 2018 by Oeko-Institut in the course of the study to support the review of the list of re-stricted substances and to assess a new exemption request under RoHS 2 (Pack 15); http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Pack_15/1st_Consultation_Contributions/Contribution_Coherent_Nickel_Sulphate_Stakeholder_Response_20180612.pdf, last viewed 18.06.2018

cadmium, cobalt, iron, lead, manganese, indium, gold, silver and platinum (France and Anses 2014). France and Anses (2014) further note:

- Of these metals, only nickel and copper can be deposited by electroless processes. Iron and tin can in certain specific cases be considered to be potential substitutes, but nickel is always necessary when the above-mentioned technical characteristics, such as durability, hardness, high corrosion resistance and capability to withstand high temperatures are required.
- Alternatives such as chromium, cobalt or cadmium have been ruled out because of their hazard profile. Instead, it is understood that nickel plating processes are applied to replace cadmium and lead. According to France and Anses (2014), "*some electrical connector companies are now attempting to eliminate the use of cadmium, and are replacing it with either electroless nickel-PTFE or with zinc-nickel electroplate*" and furthermore "*the use of nickel diffusion barriers has grown with the advent of lead-free solders because the solders have higher melting points, which greatly increases inter-diffusion between copper and gold during wave soldering*".

As for noble metals that are alternatives for some specific uses, DEPA (2015) concluded that these are, however, *"more expensive than nickel and the economic feasibility of thus depends also on the implication the plating cost has to the overall cost of the product.*"

The substitution by noble metals is also noted in the contribution by Carl Zeiss Jena GmbH[46] which mentions the possibility to use layers of silver, gold or tantalum on the base of uncoated substrate. Carl Zeiss Jena GmbH[47] rules out this option because of more negative environmental impacts due to a higher demand of the critical raw materials silver, tantalum and gold.

Other possibilities mentioned by e.g. Carl Zeiss Jena GmbH[48] such as layers of nitride (titanium or chromium nitride) are explained not to reach the technical requirements and specifications. This is in line with the conclusion in the report of DEPA (2015) that states "*nickel used for plating can be replaced only in areas where there are no specific technical requirements regarding corrosion, or wear resistance. In functional plating in the car and aerospace industry no alternatives seem to be able to compete with nickel. Only where less stringent requirements are specified e.g. for decorative plating on indoor other surface treatments or technical solutions would be suitable.*" The conclusion was based on investigations of the Nickel Institute and documented in several reports covering uses of a range of nickel substances, which are however not publicly available.

Alternative processes/technologies like vacuum surface treatments (e.g. evaporation, spraying or chemical / physical vapour deposition) according to France and Anses (2014) can at this stage, only be implemented by larger companies: "*The costs are considered prohibitive for SMEs. In addition, while these processes are considered to be safe in use, clean-up and maintenance must take place in extremely strict conditions because of the fume hazard. These processes are not always appropriate for parts with particularly sophisticated shapes.*"

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[46] Op. cit. Carl Zeiss Jena GmbH (2018)

[47] Op. cit. Carl Zeiss Jena GmbH (2018)

[48] Op. cit. Carl Zeiss Jena GmbH (2018)

8.2. Hazardous properties of substitutes

There are various substitutes that are considered to have various hazardous properties that render their use as substitutes as problematic:

- Cadmium itself is restricted by the RoHS Directive and is thus not understood to be a practical alternative. In the report of France and Anses (2014) alternatives such as chromium, cobalt or cadmium have been ruled out because of their hazard profile.
- The substitution with other soluble nickel salts can be substituted for each other but present the same hazard profile. This would be a regrettable substitution which is not considered to result in a benefit in terms of impacts on health and or environment.
- As for the noble metals, Carl Zeiss Jena GmbH claims that silver, tantalum and gold are associated with a higher environmental impact; however, this statement is not substantiated further.

8.3. Data basis for alternatives and uncertainties

The information specified above regarding alternatives for nickel sulphate and nickel sulfamate originates from various documents generated in the context of the REACH Regulation and the setting for an occupational exposure limit. Such documents are understood to have been subject to scrutiny and to have a relatively high certainty. However, France and Anses (2014) point out that *“the analysis of alternatives […] has been carried out by the Nickel Institute in the framework of a socioeconomic analysis (SEA) based on internal reviews and reports as well as available literature. Again, this information has not been peer-reviewed or challenged and shall thus be considered as the Industry point of view; it has been aggregated, interpreted and summarized by Anses.”*

9. DESCRIPTION OF SOCIO-ECONOMIC IMPACTS

9.1. Approach and assumptions

The scope of this assessment requires a review of possible socio-economic impacts related to a scenario in which the substances under assessment (nickel sulphate and nickel sulfamate) were to be added to the list of restricted substances specified in Annex II of RoHS 2. This would restrict the presence of these substances in EEE to be placed on the market in the future.

However, as has been specified in the sections above, these compounds are used in plating processes of relevance to the manufacture of EEE, but do not remain in the final products in their compound form. In this sense, it is assumed that a restriction of the two substances would not be effective: RoHS restricts the presence of substances present in EEE placed on the market and thus would not affect substances used in manufacture, assuming these do not remain present in the final product to be placed on the market.

Against this background it is generally assumed that:

- Substitution would not take place, seeing as the applications do not contain these substances and would still be allowed on the market;
- the choice of related EEE available to consumers would not be expected to change, nor the properties and characteristics of such EEE;
- the amount of related EEE reaching end-of-life and subject to waste management would not be expected to change as a result of the restriction;
- potential impacts of substitution on health and or environment during use and or the waste phase would thus not be expected.

9.2. Impact on chemicals industry

As the compounds do not remain present in the final product, it is assumed that manufacture could continue without change. In this sense, the chemicals industry would continue manufacture as usual.

9.3. Impact on EEE producers

As the compounds do not remain present in the final product, it is assumed that manufacture could continue without change. In this sense, EEE producers and their supply chain would continue manufacture as usual.

The only aspect that might change is related to the administrative burden of the restriction of a new substance and the need to document its possible presence in products in order to comply with legislation. This impact is expected to be short termed, mainly occurring following the introduction of the restriction. Its essence would include the preparation of relevant documentation and in some cases, it can be expected that manufacturers and/or their suppliers would increase possible testing of the presence of the two Ni compounds in final components and products to ensure compliance with the restriction. Such activities may be initiated by suppliers that want to prove to Original Equipment Manufacturers (OEMs) that their materials and components are free from the restricted compounds, by OEMs with the same intention in mind as well as by OEMs as a means of controlling compliance of suppliers with OEM requirements related to the presence of the compounds.

It is noted that most OEMs have supply chain specifications related to the use and presence of hazardous chemicals in components and products purchased from the supply chain. The consultants are aware of a few OEMs that restrict the presence of Ni and its compounds components and products purchased from the supply chain, meaning that to a limited degree, the preparation of documentation and the performance of testing is already performed[49].

9.4. Impact on EEE users

As the compounds do not remain present in the final product, it is assumed that manufacture could continue without change and thus also the placing on the market of relevant products. A slight increase in prices may occur to support the administrative costs specified in Section 0, but these are only expected to result in a minor impact on prices (if at all).

9.5. Impact on waste management

As the compounds do not remain present in the final product, it is assumed that manufacture could continue without change and thus also the placing on the market of relevant products. The same EEE would reach the waste phase and require treatment and in this sense, any possible impacts in his stage related to the use of the two compounds in plating processes would not be expected to differ.

9.6. Impact on administration

As stated in Section 0, though the restriction is not expected to affect EEE placed on the market, compliance with the restriction would still require provision of documentation and in some cases EEE or its components would be tested to ensure that the two compounds are not present. This would result in an administrative burden for manufacturers and suppliers, and it can also be expected that a certain administrative burden would fall on regulators in the relation to the implementation of the restriction in the RoHS Directive and national legislation and its enforcement. This includes the burden of amending the RoHS Directive, of transposing new provisions into national legislation as well as burdens related to enforcement. Though market surveillance activities can be expected to some degree, the understanding that the compounds do not remain in the EEE would probably mean that market surveillance would occur on a small scale if at all (i.e. focus shall remain on substances for which continued illegal presence is expected).

9.7. Total socio-economic impact

To summarise, a possible restriction can be expected to result in administrative costs for both, industry (e.g. EEE manufacturers, suppliers) and for regulators (e.g. legislators, market surveillance). However, the restriction is not expected to generate benefits for the environment or for health (in the form of prevention of possible impacts tied with nickel sulphate and nickel

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[49] For example, Apple in its Regulated Substances Specification 069-0135-J, effective from 21 March, 2016, restricts nickel and its compounds in “all homogeneous materials used in Apple products, accessories, and packaging”. The specification refers the scope of this restriction as “Parts with direct and prolonged skin contact” and specifies “Metal alloys with nickel, plating material, anti-corrosive alloy” as examples. See https://www.apple.com/supplier-responsibility/pdf/Apple-Regulated-Substance-Specification.pdf for further detail.

sulfamate in general and particularly during the use and waste phase of interest for RoHS 2 Article 6(1)). In terms of total socio-economic impacts, this suggests that a restriction of the two substances would not be proportionate, given that its costs are not expected to generate benefits for the environment or for health.

It is noted that a possible restriction of nickel and its compounds can be expected to be more effective in terms of preventing possible impacts on environment and health in the use and waste phase of products, that are related to nickel plating of components using nickel sulphate and nickel sulfamate.[50] Nonetheless, before such an analysis is to be carried out, an assessment of the use of these compounds in EEE would need to be performed to clarify the range and nature of possible impacts related to the presence of Ni and its compounds in EEE in the use and waste phases.

An investigation of the socio-economic impacts of such a restriction is however beyond the scope of this review.

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[50] The Nickel Institute (2019) commented here that *“this statement is not supported by any evidence or data in the dossier. How can this assumption be made if an analysis has not been performed? There is no information in the draft report on the socio-economic impacts (potential impacts for the European industrial value chain; feasibility; competitiveness of manufacturers and SMEs, etc.) or potential benefits.”*

However, the next sentence explains that an assessment of the use of these compounds in EEE would need to be performed to clarify the range and nature of possible impacts related to the presence of Ni and its compounds in EEE in the use and waste phases.

10. RATIONALE FOR INCLUSION OF THE SUBSTANCE IN ANNEX II OF ROHS

The two nickel salts nickel sulphate and nickel sulfamate are used in metal surface treatment processes, including electrolytic plating and electroless technologies. It can be understood that these substances are transformed through the surface treatment processes and do not remain in their original form in the final product, i.e. in relevant EEE and its parts. In the final coating, the nickel salts are understood to be converted into nickel metal. It is therefore expected that a restriction of these compounds in EEE would not necessarily be effective in preventing their use in the processes. It is therefore not recommended to restrict the two substances, as benefits on health and environment would not be expected to incur as a result of such a restriction.

In parallel, the assessment would recommend a future assessment under RoHS of nickel and its compounds in order to clarify the range of expected impacts of nickel metal and nickel^{2+} ions during use and/or waste management to clarify the range and nature of possible impacts related to the presence of Ni and its compounds in EEE in the use and waste phases and whether a RoHS restriction of this group would allow preventing such impacts.[51]

It should be noted in this regard that the Swedish Chemical Agency KEMI (2015)[52] in its assessment of the risk reduction potential of hazardous substances in electrical and electronic equipment on the EU market concluded that nickel sulphate and nickel sulfamate as process chemicals for electroplating are not relevant for inclusion in RoHS. It should further be noted that during the substance prioritisation that is also performed in one task of this project, nickel and nickel monoxide have been included in the shortlisted substances.[53] The outcome of the substance prioritisation was based on the application of an algorithm to the substances in the EEE Inventory and the inclusion of nickel and nickel monoxide in the shortlist does not presume a recommendation for the inclusion in Annex II of the RoHS Directive. From the background that nickel, nickel alloys and various individual Ni compounds occur at different life cycle stages of EEE and pose different hazards, is recommended to undertake an aggregated assessment of the whole group entry “nickel and its compounds”, rather than specific Ni salts (scope of the current service request).

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[51] The Nickel Institute (2019) stated on this paragraph that *“this conclusive statement is not supported by any evidence in the draft Report. In addition, it should be acknowledged clearly that nickel metal has a different and lower hazard classification than nickel compounds. This aspect is not mentioned anywhere in the draft Report. It is an important point which should be acknowledged.”* The addition on the different hazard classification are made in section 3.

[52] Opt cit. Swedish Chemicals Agency KEMI (2015)

[53] The entry of nickel and its compounds in REACH Annex XVII based on the classification as skin sensitizer is one reason for this inclusion.

11. List of References

11.1. Databases

ECHA Brief Profile: Entry for Nickel sulphate, https://echa.europa.eu/de/brief-profile/-/briefprofile/100.029.186, last viewed 11.06.2018

ECHA Brief Profile: Entry for Nickel bis(sulphamidate), https://echa.europa.eu/de/brief-profile/-/briefprofile/100.033.982, last viewed 11.06.2018

ECHA Registered Substance Database: Entry for Nickel sulphate, https://echa.europa.eu/registration-dossier/-/registered-dossier/15304, last viewed 11.06.2018

ECHA Registered Substance Database: Entry for Nickel bis(sulphamidate), https://echa.europa.eu/de/registration-dossier/-/registered-dossier/14782/4/1, last viewed 11.06.2018

ECHA CL Inventory: Entry for Nickel sulphate, https://echa.europa.eu/de/information-on-chemicals/cl-inventory-database/-/discli/details/9597, last viewed 11.06.2018

ECHA CL Inventory: Entry for Nickel bis(sulphamidate), https://echa.europa.eu/de/information-on-chemicals/cl-inventory-database/-/discli/details/16141, last viewed 11.06.2018

11.2. Contributions, documents and reports

France (2016): Risk management option analysis, Conclusion document for nickel sulphate, August 2016; https://echa.europa.eu/documents/10162/026d40c4-7b36-4b8d-910c-bd036af685bf, last viewed 19.04.2018

ECHA RAC (2018): Committee for Risk Assessment RAC, Opinion on scientific evaluation of occupational exposure limits for Nickel and its compounds, ECHA/RAC/A77-O-0000001412-86-189/F, Adopted 9 March 2018;https://echa.europa.eu/documents/10162/13641/nickel_opinion_en.pdf; last viewed 18.06.2018

France and Anses (2014): Draft analysis of the most appropriate risk management option for nickel sulphate, April 2014; http://www.consultations-publiques.developpement-durable.gouv.fr/IMG/pdf/RMOA_NiSO4_PUBLIC.pdf , last viewed 22.02.2019

Carl Zeiss Jena GmbH (2018): Contribution submitted on 07.06.2018 during the stakeholder consultation conducted from 20 April 2018 to 15 June 2018 by Oeko-Institut in the course of the study to support the review of the list of restricted substances and to assess a new exemption request under RoHS 2 (Pack 15); http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Pack_15/1st_Consultation_Contributions/RoHS-Pack15_Statement-CZJ_Ni-Compounds_final_signed_01062018.pdf, last viewed 18.06.2018

Coherent (2018): Contribution submitted on 12.06.2018 during the stakeholder consultation conducted from 20 April 2018 to 15 June 2018 by Oeko-Institut in the course of the study to support the review of the list of restricted substances and to assess a new exemption request under RoHS 2 (Pack 15); http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Pack_15/1st_Consultation_Contributions/Contribution_Coherent_Nickel_Sulphate_Stakeholder_Response_20180612.pdf, last viewed 18.06.2018

ECHA (2010): Guidance on Intermediates, version 2, December 2010; https://echa.europa.eu/documents/10162/13632/intermediates_en.pdf/0386199a-bdc5-4bbc-9548-0d27ac222641, last viewed 19.04.2018

Alliance Elektronique - ACSIEL (2018): Contribution submitted on 15.06.2018 during the stakeholder consultation conducted from 20 April 2018 to 15 June 2018 by Oeko-Institut in the course of the study to support the review of the list of restricted substances and to assess a new exemption request under RoHS 2 (Pack 15); http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Pack_15/1st_Consultation_Contributions/Contribution_ACSIEL_Nickel_CMG_Ni_Salts_20180615.pdf, last viewed 18.06.2018

France and Anses (French Mandated National Institute) (2014): Draft analysis of the most appropriate risk management option for nickel sulphate, April 2014; http://www.consultations-publiques.developpement-durable.gouv.fr/IMG/pdf/RMOA_NiSO4_PUBLIC.pdf, last viewed 18.06.2018

Danish Environmental Protection Agency DEPA (2015): Survey of nickel metal, Part of the LOUS review; Environmental project No. 1723, 2015; https://www2.mst.dk/Udgiv/publications/2015/06/978-87-93352-36-0.pdf , last viewed 18.06.2018

LYNRED (2019): Contribution submitted on 07.11.2019 during the stakeholder consultation conducted from 26 September 2019 to 07 November 2019 by Oeko-Institut in the course of the study to support the review of the list of restricted substances and to assess a new exemption request under RoHS 2 (Pack 15); https://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Pack_15/4th_Consultation/Contributions/contribution_LYNRED_RoHS15_comments_Ni_20191107.pdf, last viewed 30.01.2020

Nickel Institute (2018): Contribution submitted on 15.06.2018 during the stakeholder consultation conducted from 20 April 2018 to 15 June 2018 by Oeko-Institut in the course of the study to support the review of the list of restricted substances and to assess a new exemption request under RoHS 2 (Pack 15); http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Pack_15/1st_Consultation_Contributions/Contribution_Nickel_Institute_Ni_20180608ROHS_Stakeholder_Consultation_FINAL_Comments.pdf, last viewed 18.06.2018

Nickel Institute (2019): Contribution submitted on 07.11.2019 during the stakeholder consultation conducted from 26 September 2019 to 07 November 2019 by Oeko-Institut in the course of the study to support the review of the list of restricted substances and to assess a new exemption request under RoHS 2 (Pack 15); https://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Pack_15/4th_Consultation/Contributions/contribution_NI_RoHS15_Comments_dossier_Ni_20191107.pdf, last viewed 30.01.2020

Swedish Chemicals Agency KEMI (2015): Assessment of the risk reduction potential of hazardous substances in electrical and electronic equipment on the EU market; https://www.kemi.se/global/pm/2015/pm-7-15.pdf, last viewed 19.04.2018

Appendix I: Contribution to stakeholder consultation hold from 20 April 2018 to 15 June 2018

The following non-confidential contributions were submitted during the 1st stakeholder consultation (see also: http://rohs.exemptions.oeko.info/index.php?id=295):

> Contribution of the **Carl Zeiss Jena GmbH** submitted on 07.06.2018: pdf

> Contribution of the **Swedish Chemicals Agency (KEMI)** submitted on 11.06.2018:

>> Assessment of the risk reduction potential of hazardous substances in electrical and electronic equipment on the EU market: pdf

> Contribution of **Coherent** submitted on 12.06.2018: pdf

> Contribution of **MedTech Europe** submitted on 15.06.2018: pdf

> Contribution of the **JBCE – Japan Business Council in Europe aisbl** submitted on 15.06.2018: pdf

> Contribution of the **Test and Measurement Coalition (TMC)**submitted on 15.06.2018: pdf

> Contribution of the **Nickel Institute** submitted on 15.06.2018: pdf

> Contribution of the **Association of Equipment Manufacturers (AEM)** submitted on 15.06.2018: pdf

> Contribution of the **Japanese electric and electronic (E&E) industrial associations** submitted on 14.06.2018: pdf

> Contribution of the **Alliance Elektronique - ACSIEL** submitted on 15.06.2018: pdf

> Contribution of the **AeroSpace and Defence Industries Association of Europe (ASD)** submitted on 14.06.2018: pdf

Appendix II: Contributions to stakeholder consultation hold from 26 September 2019 to 07 November 2019

The following non-confidential contributions were submitted during the 2nd stakeholder consultation (see also: https://rohs.exemptions.oeko.info/index.php?id=337):

> Contribution of **COCIR (European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry),** submitted on 22.10.2019: PDF

> Contribution of the **Japanese electric and electronic (E&E) industrial associations,** submitted on 06.11.2019: PDF

> Contribution of the **JBCE – Japan Business Council in Europe aisbl**, submitted on 07.11.2019: PDF

> Contribution of the **Nickel Institute,** submitted on 07.11.2019: PDF

> Contribution of **Digital Europe**, submitted on 07.11.2019: PDF

> Contribution of **The European Semiconductor Industry Association (ESIA)**, submitted on 07.11.2019: PDF

> Contribution of **LYNRED by Sofradir and ULIS**, submitted on 07.11.2019: PDF

A.8.0 Tetrabromobisphenol A (TBBP-A, flame retardant)

ROHS Annex II Dossier for TBBP-A Restriction proposal for substances in electrical and electronic equipment under RoHS

Substance Name: Tetrabromobisphenol A
(TBBP-A, flame retardant)
(2,2',6,6'-tetrabromo-4,4'-isopropylidenediphenol)
EC Number: 201-236-9
CAS Number: 79-94-7

10/06/2020

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Abbreviations

ABS	Acrylonitrile Butadiene Styrene
BAUA	German Federal Institute for Occupational Safety and Health
bw	Body Weight
C&L	Classification and Labelling inventory
CAS number	A CAS Registry Number, also referred to as CASRN or CAS Number, is a unique numerical identifier assigned by Chemical Abstracts Service (CAS) to every chemical substance described in the open scientific literature
CLP	Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (REACH)
CoRAP	Community Rolling Action Plan
DecaBDE	Decabromdiphenylether
DEPA	Danish Environmental Protection Agency
DNEL	Derived No Effect Levels
EC number	The European Community number (EC Number) is a unique seven-digit identifier that was assigned to substances for regulatory purposes within the European Union by the European Commission
ECETOC	European Centre for Ecotoxicology and Toxicology of Chemicals
ECETOC TRA	ECETOC’s Targeted Risk Assessment
ECHA	European Chemical Agency
ED	Endocrine Disruption
EEE	Electrical and Electronic Equipment
EFRA	European Flame Retardants Association
EFSA	European Food Safety Authority
ESIA	European Semiconductor Industry Association
EU RAR	EU Risk Assessment Report
FR4	Flame resistant epoxy resin binder for glass-reinforced epoxy laminate materials used in rigid printed wiring boards
GADSL	Global Automotive Declarable Substance List
HBCDD	Hexabromocyclododecane
HIPS	High Impact Polystyrene
IARC	International Agency for Research on Cancer
IPA	Fraunhofer-Institute for Manufacturing Engineering and Automatisation

ITEM	Fraunhofer-Institute for Toxicology and Experimental Medicine
Koc	Soil Adsorption Coefficient: Concentration of chemical in soil/Concentration of chemical substance in water * 100/ % organic carbon
MSDS	Material safety data sheet
n.d.	Not defined
OctaBDE	Octabromdiphenylether
OEL	Occupational Exposure Limit
OSPAR	Oslo and Paris Conventions; to protect the marine environment of the North-East Atlantic
PBT	Persistent, bioaccumulative and toxic (properties of a chemical)
PC	Polycarbonate
PET	Poly Ethylene Terephthalate
PNEC	Predicted no effect concentration
PWB	Printed Wiring Board (=printed circuit boards)
REACH	Regulation (EU) No 1907/2006 on the Registration, Evaluation, Authorisation and restriction of Chemical substances
SIN	SIN (Substitute it Now!) List of the NGO ChemSec
TBBP-A / TBBPA	Tetrabrombisphenol A
UBA	German Umweltbundesamt (Federal Environment Agency)
UK	United Kingdom
US EPA	United States Environmental Protection Agency
VECAP	Voluntary Emissions Control Action Programme
WEEE	Waste of Electrical and Electronic Equipment

CONTEXT and SCOPE of the Substance Assessment

The substance assessment of 2,2',6,6'-tetrabromo-4,4'-isopropylidenediphenol or tetrabromobisphenol A (TBBP-A, flame retardant), respectively, is being performed as part of the "*Study on the review of the list of restricted substances and to assess a new exemption request under RoHS 2 – Pack 15*". With contract No. 07.0201/2017/772070/ENV.B.3 implementing Framework Contract No. ENV.A.2/FRA/ 2015/0008, a consortium led by Oeko-Institut for Applied Ecology has been assigned by DG Environment of the European Commission to provide technical and scientific support for the review of the list of restricted substances and to assess a new exemption request under RoHS 2. This study includes an assessment of seven substances with a view to the review and amendment of the RoHS Annex II list of restricted substances. The seven substances have been pre-determined by the Commission for this task. The detailed assessment is being carried out for each of the seven substances in line with a uniform methodology.[1]

In the course of the substance assessment, the 1st stakeholder consultation was held from 20 April 2018 to 15 June 2018 to collect information and data for the seven substances under assessment. Information on this consultation can be found at Oeko-Institut's project webpage at:
http://rohs.exemptions.oeko.info/index.php?id=289.

For TBBP-A, a total of 11 contributions were submitted by different stakeholders. An overview of the contributions submitted during this consultation is provided in Appendix I. The contributions can be viewed at http://rohs.exemptions.oeko.info/index.php?id=295.

Among these contributions, a study from the Fraunhofer Institutes ITEM and IPA has been submitted, which is an assessment of TBBP-A performed according to the "Methodology for Identification and Assessment of Substances for Inclusion in the List of Restricted Substances (Annex III) under the RoHS 2 Directive, thus in the format of a RoHS dossier which was mandated and funded by BSEF, the Bromine Science and Environmental Forum.[2] Though no date on when the study was conducted is indicated, it is understood as a very recent data compilation. In August 2018, after the stakeholder consultation was closed, the BSEF provided an updated version of this assessment. It is understood that the update overall covers the DNELs retrieved from the ECHA Registered Substance Database that has been lowered in the last years. In the following, this updated assessment is referred to as Fraunhofer ITEM IPA, Wibbertmann and Hahn (2018).[3]

Nine different stakeholder contributions were received during the 2nd stakeholder consultation which was held from 05th December 2019 to 13th February 2020. The contributions can be viewed at http://rohs.exemptions.oeko.info/index.php?id=333.

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[1] This methodology includes a dossier template for substance assessment which had been prepared by the Austrian Umweltbundesamt GmbH in the course of a previous study. The methodology for substance assessment has been revised based on various proposals from and discussions with stakeholders. Among others, revisions have been made to clarify when the Article 6(1) criteria are considered to be fulfilled and how the precautionary principle is to be applied. The methodology has also been updated in relation to coherence to REACH and other legislation and publicly available sources of relevance for the collection of information on substances have been updated and added. The methodology is available at https://rohs.exemptions.oeko.info/index.php?id=341

[2] Frauenhofer ITEM & IPA, Hesse, Susanne; Wibbertmann, Axel; Hahn, Stefan; Miehe, Robert; Müller, Sebastian (no year): Assessment of TBBP-A (tetrabromopisphenol-A) according to the "Methodology for Identification and Assessment of Substances for Inclusion in the List of Restricted Substances (Annex III) under the RoHS2 Directive". Update August 2018. Fraunhofer ITEM, Fraunhofer IPA, Stuttgart; submitted as part of the contribution submitted by BSEF, aisbl – The International Bromine Council during the TBBP-A stakeholder consultation conducted from 20 April 2018 to 15 June 2018

[3] Fraunhofer ITEM IPA, Wibbertmann and Hahn (2018): Assessment of TBBP-A (tetrabromopisphenol-A) according to the "Methodology for Identification and Assessment of Substances for Inclusion in the List of Restricted Substances (Annex III) under the RoHS2 Directive". Update August 2018. Fraunhofer ITEM, Fraunhofer IPA, Stuttgart.

Areas on which stakeholders commented during the second stakeholder consultations are summarised in the order in which these issues are addressed in the dossier and include:

- The conclusions drawn from the structural comparison of BPA and TBBP-A;
- DEPA conclusions on PBT and endocrine disrupting properties are used as a basis;
- The presentation of waste management and sorting techniques;
- The references on exposure data;
- The analysis of hazards of alternatives proposed;
- The data basis of the socio-economic analysis;

A number of stakeholders have criticised the consideration in the assessment of possible impacts that the presence of a substance in EEE may have on WEEE management that takes place outside the EU, in cases where second hand EEE is exported from the EU and in cases of illegal waste exports. Recital 7 of the RoHS Directive states that despite the measures implemented through the WEEE Directive, "*significant parts of waste EEE will continue to be found in the current disposal routes inside or outside the Union*" and that even were such waste collected separately and submitted to recycling processes its contents of certain substances "*would be likely to pose risks to health or the environment, especially when treated in less than optimal conditions*". Consideration of adverse impacts of WEEE management that take place outside the EU are thus considered to be of relevance to this review, particularly when there is evidence that EEE originally placed on the European market may be handled at end-of-life outside the EU. One contribution explicitly stated its general agreement with the dossier and its recommendations.

After the revision of the dossiers and their completion, a final stakeholder meeting was held on 27 April 2020 to allow stakeholders to comment on the dossiers and particularly on conclusions and recommendations.

This document represents the final version of the RoHS Annex II dossier for TBBP-A.

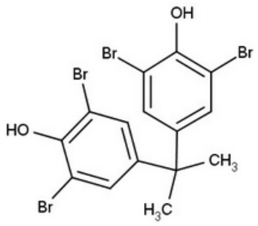
1. IDENTIFICATION, CLASSIFICATION AND LABELLING, LEGAL STATUS AND USE RESTRICTIONS

1.1 Identification

1.1.1. Name, other identifiers, and composition of the substance

The ‘ECHA information on substances database’ lists Tetrabromobisphenol-A (TBBP-A) and its synonymous names. The following Table 1-1 shows information on the substance identity of TBBP-A as listed in the ECHA database information on substances[4] and the European Risk Assessment Report (EU RAR).[5]

Table 1-1: Substance identity and composition of TBBP-A and its derivatives

Chemical name	**2,2',6,6'-tetrabromo-4,4'-isopropylidenediphenol**
EC number	201-236-9
CAS number	79-94-7
IUPAC name	2,6-dibromo-4-[2-(3,5-dibromo-4-hydroxyphenyl)propan-2-yl]phenol
Index number in Annex VI of the CLP Regulation	604-074-00-0
Molecular formula	$C_{15}H_{12}Br_4O_2$
Bromine content	58.8 % by weight
Molecular weight (range)	543.9 g/mole
Synonyms	2,2',6,6',-tetrabromo-4,4'-isopropylidenediphenol 2,2',6,6'-tetrabromo-4,4'-isopropylidenediphenol 2,2’,6,6’-tetrabromo-4,4’-isopropylidenediphenol 2,6-dibromo-4-[2-(3,5-dibromo-4-hydroxyphenyl)propan-2-yl]phenol 4,4'-Isopropylylidenebis(2,6-dibromophenol) 4,4'-propane-2,2-diylbis(2,6-dibromophenol) FR-1524 Tetrabromobisphenol A, TBBP-A, TBBP-A, TBBA
Structural formula	
Degree of purity	98.5 %
Remarks	-
Derivates	Tetrabromobisphenol-A dimethyl ether: CAS No. 37853-61-5 Tetrabromobisphenol-A dibromopropyl ether: CAS No. 21850-44-2 Tetrabromobisphenol-A bis(allyl ether): CAS No. 25327-89-3 Tetrabromobisphenol-A bis(2-hydroxyethyl ether): CAS No. 4162-45-2 Tetrabromobisphenol-A brominated epoxy oligomer: CAS No. 68928-70-1 Tetrabromobisphenol-A carbonate oligomers: CAS No. 94334-64-2 and 71342-77-3

Source: EU RAR 2008

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[4] ECHA Brief Profile: Entry for 2,2',6,6'-tetrabromo-4,4'-isopropylidenediphenol (2019); https://echa.europa.eu/de/brief-profile/-/briefprofile/100.001.125, last viewed 19.04.2018

[5] EU RAR – European Risk Assessment Report (2008): 2,2’,6,6’-tetrabromo-4,4’-isopropylidenediphenol (tetrabromo-bisphenol-A or TBBP-A). Final Environmental RAR of February 2008;

1.1.2. Physico-chemical properties

Physico-chemical properties of TBBP-A are summarised in Table 1-2 below and were extracted from the ECHA database information on substances[6] and from the EU RAR.

Table 1-2: Overview of physico-chemical properties of TBBP-A

Property	Value
Physical state at 20°C and 101.3 kPa	Solid (white crystalline powder)
Melting/freezing point	178°C; 181-182°C
Boiling point	316°C (decomposes at 200-300°C)
Vapour pressure	<1.19*10^{-5} Pa at 20°C
Water solubility	0.148 mg/l at 25°C (pH 5) 1.26 mg/l at 25°C (pH 7) 2.34 mg/l at 25°C (pH 9)
Partition coefficient n-octanol/ water (log KOW)	5.90 at 25°C
Dissociation constant	9.37 - 9.43 at 20°C
Relative density	2.17
Specific gravity	-

Source: ECHA Brief Profile: Entry for 2,2',6,6'-tetrabromo-4,4'-isopropylidenediphenol (2018) and https://echa.europa.eu/de/brief-profile/-/briefprofile/100.001.125; RAR (2006)

1.2. Classification and labelling status

The Classification, Labelling and Packaging (CLP) regulation[7] ensures that the hazards presented by chemicals are clearly communicated to workers and consumers in the European Union through classification and labelling of chemicals. Annex VI of Regulation No 1272/2008 lists substances where a harmonised classification exists based on e.g. human health concerns.

Annex VI of the CLP regulation is continuously adapted by engagement of Member State Competent Authorities and ECHA as far as new information becomes available, where existing data are re-evaluated or due to new scientific or technical developments or changes in the classification criteria.[8]

Further explanation on the human and environmental hazards is provided in sections 3 and 3.3.

Classification in Annex VI Regulation No 1272/2008

The harmonised classification according to Annex VI Regulation No 1272/2008 of tetrabromobisphenol A attributes the following environmental hazards to TBBP-A (see Table 1-3):

- Aquatic Acute 1 (Hazardous to the aquatic environment) – H400 (very toxic to aquatic life)
- Aquatic Chronic 1 (Hazardous to the aquatic environment) – H410 (very toxic to aquatic life with long lasting effects)

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[6] Opt. cit. ECHA Brief Profile for TBBP-A (2019)

[7] Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (REACH).

[8] For further information, see https://echa.europa.eu/regulations/clp/harmonised-classification-and-labelling, last viewed 19.04.2018

Table 1-3: Classification according to part 3 of Annex VI, Table 3.1 (list of harmonised classification and labelling of hazardous substances) of Regulation (EC) No 1272/2008

Index No.	International Chemical ID	EC No.	CAS No.	Classification		Labelling			Spec. Conc. Limits, M-factors	Notes
				Hazard Class and Category Code(s)	Hazard statement code(s)	Pictogram, Signal Word Code(s)	Hazard statement code(s)	Suppl. Hazard statement code(s)		
604-074-00-0	Tetrabromo-bisphenol-A; 2,2',6,6'-tetrabromo-4,4'-isopropyli-denediphenol	201-236-9	79-94-7	Aquatic Acute 1 Aquatic Chronic 1	H400 H410	GHS09 Wng	H410	-	-	-

Source: Annex VI Regulation No 1272/2008; https://echa.europa.eu/de/information-on-chemicals/annex-vi-to-clp, last viewed 19.04.2018

Self-classification(s)

Manufacturers, importers or downstream users are obliged to (self-)classify and label hazardous substances and mixtures to ensure a high level of protection of human health and the environment. If a harmonised classification is available, it should be applied by all manufacturers, importers or downstream users of such substances and of mixtures containing such substances.

However, mostly, suppliers decide independently as to the classification of a substance or mixture, which is then referred to as self-classification. Therefore, self-classification might indicate an e.g. additional hazard which is so far not reflected by the harmonised classification. The following assessment of the self-classification therefore emphasises cases where self-classifications differ and where additional hazards were notified in the self-classification.

According to the ECHA database ‘C&L Inventory’, which contains classification and labelling information on notified and registered substances received from manufacturers and importers, there is a total number of 501 notifications for tetrabromobisphenol A (as of September 2019).[9] Most notifycations refer to the harmonised classification and specify TBBP-A as very toxic to aquatic life (Aquatic Acute 1, H400) and as very toxic to aquatic life with long lasting effects (Aquatic Chronic 1, H410). The joint classification (16 notifiers) and an additional 29 notifiers also refer to TBBP-A as suspected of causing cancer (Carc. 2, H351).

1.3. Legal status and use restrictions

1.3.1. Regulation of the substance under REACH

TBBP-A was included in the Community Rolling Action Plan (CoRAP) by the Danish EPA (Danish Ministry of the Environment). The inclusion was motivated by the following concerns:[10]

- Suspected reprotoxicity;
- Potential endocrine disruptor;
- Suspected persistent, bioaccumulative and toxic (PBT/vPvB);

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[9] ECHA Registered Substances Database (2019): Entry for 2,2',6,6'-tetrabromo-4,4'-isopropylidenediphenol; https://echa.europa.eu/de/substance-information/-/substanceinfo/100.001.125 (visited on 10.10.2019)

[10] ECHA Substance Evaluation CoRAP (2019): Entry for TBBP-A (last viewed 10.10.2019)

- Use in large amounts of consumer products;
- Exposure of environment;
- Exposure of workers;
- High (aggregated) tonnage; and
- Wide dispersive use.

In March 2017, the ECHA requested the provision of further information concerning the endocrine disruptive properties of TBBP-A and the exposure and PBT properties (particularly persistency / environmental fate of methylated transformation products of TBBP-A (e.g. bismethyl ether TBBP-A and monomethyl ether TBBP-A)). The requested information is to be provided until 4 January 2021 (ECHA 2017).[11]

1.3.2. Other legislative measures

WEEE shall be collected separately from household waste, according to the collection targets specified WEEE Directive, and then recycled. Directive 2012/19/EU (WEEE Directive) stipulates that plastics-containing brominated flame retardants have to be removed from separately collected WEEE. That plastic fraction shall be disposed of or recovered in compliance with Waste Framework Directive 2008/98/EC. In the EU, collection and recycling of WEEE, containing TBBP-A, shall be implemented according to the following standards:

- EN 50625-1: Collection, logistics & treatment requirements for WEEE - Part 1: General treatment requirements;
- TS 50625-5: Collection, logistics & treatment requirements for WEEE -- Part 5: Specification for the end-processing of WEEE fractions- copper and precious metals.
- TS 50625-3-3: Collection, logistics & treatment requirements for WEEE - Part 3-3: Specification for de-pollution - WEEE containing CRTs and flat panel displays

1.3.3. Non-governmental initiatives

The OSPAR Convention of 1992 sets out to prevent and eliminate pollution and to take necessary measures to protect the maritime environment against the adverse effects of human activities. It aims to safeguard human health and to conserve marine ecosystems and, when practicable, to restore marine areas which have been adversely affected. TBBP-A was included in the OSPAR List of Chemicals for Priority Action in 2000. TBBP-A is considered to meet all three of the OSPAR criteria for the PBT (persistent, bioaccumulative and toxic) assessment, though it is noted that TBBP-A is a borderline case regarding the bioaccumulation criterion (OSPAR 2011).[12] Despite the OSPAR listing, TBBP-A does not meet the criteria for a PBT or a vPvB substance under REACH.

Another compilation of potential substances of concern – the so-called "SIN List" – has been developed and regularly updated by the independent non-profit organisation Chemsec (International Chemical Secretariat). The SIN list is meant to put pressure on legislators to assess substances listed therein and enact chemical legislation where necessary. TBBP-A was added to the SIN List for the reason that it is potentially persistent and bioaccumulative and that endocrine effects have been reported. It has been frequently found in humans and the environment."[13]

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[11] ECHA Substance Evaluation Decision (2017)

[12] OSPAR (2011): Background Document on tetrabromobisphenol-A.

[13] ChemSec (2019)

Various eco-label schemes address the substance group of halogenated flame retardants. The voluntary application of eco-labels requires their users to comply with the environmental safety precautions prescribed in the respective award criteria. TBBP-A is not allowed in products under the following eco-label schemes: The German Blue Angel label for hair dryers and TV sets requires that "*halogenated polymers shall not be permitted. Neither may halogenated organic compounds be added as flame retardants. Moreover, no flame retardants may be added which are classified pursuant to Table 3.1 or 3.2 in Annex VI to Regulation (EC) 1272/2008 as very toxic to aquatic organisms with long-term adverse effect and labelled with Hazard Statement H 410 or Risk Statement R 50/53.*" Process-related, technically unavoidable impurities; fluoroorganic additives used to improve the physical properties of plastics (provided that they do not exceed 0.5 percent weight) and plastic parts less than 25 grams in mass are exempt from this rule (DE-UZ 145 and DE-UZ 175). The Nordic Swan requires that a variety of organic halogenated flame retardants and other flame retardants that are assigned one or more hazard statements (H340–360) must not be added to products (Oeko-Institut 2014a).[14]

The harmonised classification of TBBP-A does not include any of these hazard classifications (i.e. H340–360), however, TBBP-A has been specified in self-classifications as suspected of causing cancer.

In 2009, the International Electronics Manufacturing Initiative (iNEMI) published a position statement proposing a threshold for the presence of bromine in EEE components specified to be "low halogen."[15] The position paper supports the following definition of "low halogen" (BFR-/CFR-/ PVC-free) electronics: "*A component* must meet all of the following requirements to be Low Halogen ("BFR/CFR/PVC-Free"):*

- *All printed board (PB) and substrate laminates shall meet Br and Cl requirements for low halogen as defined in IEC 61249-2-21 and IPC-4101B (refer to International Electrochemical Commission's (IEC) and Association Connecting Electronics Industries (IPC) standards for actual requirements) saying that for non-halogenated epoxide with a glass transition temperature of 120°C degree minimum, the maximum total halogens contained in the resin plus reinforcement matrix is 1,500 ppm with a maximum chlorine of 900 ppm and maximum bromine being 900 ppm.*
- *For components* other than printed board and substrate laminates: Each plastic within the component contains < 1,000 ppm (0.1 %) of bromine [if the Br source is from BFRs] and < 1,000 ppm (0.1 %) of chlorine [if the Cl source is from CFRs or PVC or PVC copolymers].*"

iNEMI member companies endorsing this position statement are: Cisco, Dell Inc., Doosan Corporation, HP, Intel Corporation, Lenovo, Nan Ya Plastics Corporation, Senju Comtek Corp. Sun Microsystems, Inc. and Tyco Electronics.

Moreover, TBBP-A is on several other substance lists (e.g. at member state level the List of Undesirable Substances of the Danish EPA[16] and at industry level on the Global Automotive Declarable Substance List (GADSL)).[17] The International Bromine Council, BSEF includes TBBP-A in its Voluntary Emissions Control Action Programme (VECAP) which is a voluntary product stewardship

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[14] Oeko-Institut (2014a): Osmani, D.; Dodd, N.; Wolf, O.; Graulich, K.; Bunke, D.; Groß, R.; Liu, R.; Manhart, A.; Prakash, S.; Development of European Ecolabel and Green Public Procurement Criteria for Desktop and Notebook Computers and Televisions, prepared by JRC-IPTS and Oeko-Institut e.V. – Institute for Applied Ecology for the Joint Research Centre (JRC) — Institute for Prospective Technological Studies (IPTS), Sevilla

[15] iNEMI (2009), iNEMI Position Statement on the Definition of "Low-Halogen" Electronics (BFR/CFR/PVC-Free)

[16] Danish Ministry of the Environment (DEPA) (2011): List of Undesirable Substances 2009

[17] GADSL (2018) Global Automotive Declarable Substance list

scheme.[18] The VECAP progress report of 2017 declares that 90 % of TBBP-A was handled according to the best practices as specified by VECAP "gold standard".[19] That code of conduct aims to control emissions during handling and use of brominated flame retardants.

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[18] https://www.vecap.info, last viewed 04.09.2019

[19] The European brominated flame-retardant industry (2017) The European Progress Report VECAP; referred to as VECAP (2017)

2. USE IN ELECTRICAL AND ELECTRONIC EQUIPMENT

2.1. Function of the substance

The primary use of TBBP-A is as a precursor in the production of brominated epoxy resins that function as reactively flame-retarded substrate in printed wiring boards (PWB). It is also used as an additive flame retardant in thermoplastic EEE components, for example housings that consist of ABS plastic. The most recent available data (2014) on proportions for the different types of application indicate that ~90 of TBBP-A are used for the production of FR4 PWB in form of a reactive flame retardant, while only 10 % are used as an additive flame retardant.[20] However, according to Fraunhofer ITEM IPA, Wibbertmann & Hahn (2018), the available literature data on uses varies widely (~70-90 % reactive use).[21]

The following sections outline the two different forms of use in EEE products.

2.2. Types of applications / types of materials

Reactive flame retardant

As outlined in earlier works (Oeko-Institut, 2014b)[22] and confirmed by stakeholders (e.g. AEM 2018; ZVEI, 2018)[23] [24] more recently, the primary use of TBBP-A is as a reactive intermediate in the manufacture of flame-retarded epoxy and polycarbonate resins.

In almost all epoxy-based PWBs of the FR4 type, TBBP-A – together with an epoxy-group containing di-carboxylated monomer – is a precursor for the epoxy resin material. After the polymerisation, this structure of the epoxy resin alternatingly consists of the two former monomers covalently linked via ester or ether bonds. Therefore, reacted TBBP-A lacks its original chemical signature and the substance is unlikely to be liberated from PWBs in its original substance identity. In these uses, the substance is chemically bound to the polymer and becomes thus an integrate part of the polymer matrix. Hence, the chemical identity of TBBP-A is altered during the production process of EEE components.

Regarding the chemical transformation of TBBP-A within the epoxy or polycarbonate resin formation, it is understood from stakeholder contributions as well as from other literature that the formation of these polymers requires (beside the epoxides and carbonates) a di-hydroxyl substituted counterpart as a reacting agent. By default, bisphenol-A (BPA) is used as a precursor, but TBBP-A can partly substitute the BPA in order to act as a carrier of bromine which provides the resin with flame retardant

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[20] Oeko-Institut (2014b): Study for the Review of the List of Restricted Substances under RoHS 2. Analysis of Impacts from a Possible Restriction of Several New Substances under RoHS 2 by Gensch, C.-O., Baron, Y. Blepp, M., Bunke, D., Moch, K.

[21] Op. cit. Frauenhofer ITEM IPA, Wibbertmann and Hahn (2018)

[22] Op cit. Oeko-Institut 2014b

[23] Association of Equipment Manufacturers (AEM; 2018): Contribution submitted during the TBBP-A stakeholder consultation conducted from 20 April 2018 to 15 June 2018 by Oeko-Institut in the course of the study to support the review of the list of restricted substances and to assess a new exemption request under RoHS 2 (Pack 15); see the link to the contribution in the Annex

[24] Zentralverband Elektrotechnik- und Elektroindustrie e.V. (ZVEI; 2018) –Contribution submitted during the TBBP-A stakeholder consultation conducted from 20 April 2018 to 15 June 2018 by Oeko-Institut in the course of the study to support the review of the list of restricted substances and to assess a new exemption request under RoHS 2 (Pack 15); see the link to the contribution in the Annex

properties. As mentioned above, the intrinsic substance characteristics of TBBP-A no longer exist in these polymers as the functional OH-groups are changed into C-O-C-ether or ester-bonds firmly fixed in the polymer matrix.[25] [26] [27]

As a reactive flame retardant, TBBP-A is applied in printed wiring boards (PWBs), but also in epoxy resin sealants, adhesives and encapsulations. Thus, the two main applications for epoxy resins that contain reacted TBBP-A as a flame retardant in EEE are:

- Laminated printed wiring boards PWB (designated FR4-type): rigid FR4-PWBs are used in nearly all types of EEE. It can be understood from Rakotomalala et al. (2010) that PWB containing reacted TBBP-A in form of epoxy resins have been used widely in the past and up to now. At present, FR4-PWBs are still the most common type of printed wiring board in the EEE sector. Industry stakeholders such as TMC report that TBBP-A-based FR4-PWBs are used in "*the entire portfolio of products*"[28]. Though market surveillance data provided by DEPA shows that TBBP-A concentrations are found mainly in polymer or composite product parts, in a few cases they have also been found in PWBs of commercial products.[29]

  These uses have also been mentioned by stakeholders in the 1st consultation of this substance evaluation program (BSEF, ZVEI, TMC, MedTech, JEITA, ASD and AEM, all 2018, as can be seen from concrete contributions linked in the Appendix).

- Epoxy resins are also used to encapsulate certain electronic components mounted directly on printed wiring boards. Examples are: plastic / paper capacitors, integrated circuits (e.g. microprocessors), bipolar power transistors, IGBT (Integrated Gate Bipolar Transistor) power modules, ASICs (Application Specific Integrated Circuits) and metal oxide varistors. This use of TBBP-A has been described by Oeko-Institut (2008), but has not been confirmed recently by any of the stakeholder contributions.

Additive flame retardant

TBBP-A is also used as an additive flame retardant in thermoplastic EEE components. The substance is non-covalently included in the polymer matrix. Non-covalent bonds are generally weaker than chemically reacted bonds, and therefore TBBP-A remains principally unchanged during the normal product use phase and enters the WEEE treatment processes in its original form. Where used as an additive flame retardant, TBBP-A is reported to be used in combination with antimony oxide for maximum performance.[30] [31] According to Fraunhofer ITEM IPA, Wibbertmann & Hahn

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[25] Test and Measurement Coalition (TCM) (2018): Contribution submitted during the TBBP-A stakeholder consultation conducted from 20 April 2018 to 15 June 2018 by Oeko-Institut in the course of the study to support the review of the list of restricted substances and to assess a new exemption request under RoHS 2 (Pack 15); see the link to the contribution in the Annex

[26] Alaee, M.; Arias, P.; Sjödin, A.; Bergman, Å. (2003): An overview of commercially used brominated flame retardants, their applications, their use patterns in different countries/regions and possible modes of release. Environ. Int. 29, 683-689.

[27] Buekens A. and Yang J.: Recycling of WEEE plastics: A Review in J Mater Cycles Waste Manag (2014): 16:415–434

[28] Op. cit. TCM (2018)

[29] Danish Environmental Protection Agency (DEPA; 2018): Contribution submitted (Part II) during the TBBP-A stakeholder consultation conducted from 20 April 2018 to 15 June 2018 by Oeko-Institut in the course of the study to support the review of the list of restricted substances and to assess a new exemption request under RoHS 2 (Pack 15); see the link to the contribution in the Annex

[30] Op. cit. TMC 2018

[31] MedTech Europe (2018): Contribution submitted during the TBBP-A stakeholder consultation conducted from 20 April 2018 to 15 June 2018 by Oeko-Institut in the course of the study to support the review of the list of restricted

(2018),[32] the thermoplastic which is of relevance concerning additive use of TBBP-A is acrylonitrile-butadiene-styrene (ABS). The material is considered to be the predominant plastic type in EEE products housings and packaging of electronic components. TBBP-A levels in ABS are usually 12 % to 16 % with a maximum of up to 22 %. Levels of ~14 % have been reported for HIPS which is the other polymer material that TBBP-A is used with (but to a lesser extent).[33]

As an additive flame retardant, TBBP-A is applied in EEE products. Examples of RoHS-relevant EEE products are computer monitors, tablets, notebook computers, printers, office machines, TV sets, other consumer electronics (electric toothbrush and straightener), medical and industrial electronics and small household appliances (electric plugs). Computer housings seem to be the most relevant application area.[34] [35] According to EMPA (2010),[36] ~30 % of housings of IT-appliances made of ABS are treated with TBBP-A, while the remaining housings use different flame retardants.

In their contributions to the 1st consultation, the stakeholders mention additive use of TBBP-A e.g. that "*relatively small amounts of TBBP-A [are] added to ABS (and possibly other polymers)".*[37] JEITA (2018) summarise that "*TBBPA may be contained in EEE when it is used as additive flame retardant*", however, they "*don't have exact information of resulted compounds*"[38] According to ZVEI (2018), any additive use of TBBP-A as flame retardant in Electric and Electronic equipment, e.g. in housing, is not known in Europe. In imported articles, however, the use of TBBP-A as an additive flame retardant needs to be further taken into account.

It is noteworthy that TBBP-A can also be found in a wide range of non-EEE applications that do not fall in the scope of RoHS, presumably building materials (e.g. PUR foam) (Morf et al 2003). However, recent innovation trends point towards an integration of smart electronic functions in all sorts of technical artefacts and formerly non-EEE products. This poses concern over a possible growth in numbers of goods and mass flow of additively flame retarded materials falling newly under the scope of RoHS due to the integration of EEE parts into these products. However, the issue is not specific to TBBP-A.

Intermediate (e.g. for the production of other flame retardants)

In the EU RAR (2008), the use of TBBP-A in the manufacture of derivatives is mentioned; however, it is also mentioned as being a less relevant type of application. The main derivatives are TBBP-A dimethyl ether, TBBP-A dibromopropyl ether, TBBP-A bis(allyl ether), TBBP-A bis(2-hydroxyethyl ether), TBBP-A brominated epoxy oligomer, and TBBP-A carbonate oligomers. The main use of these derivatives is also as flame retardants, usually for the purpose of tuning the reactive properties

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substances and to assess a new exemption request under RoHS 2 (Pack 15); see the link to the contribution in the Annex

[32] Op. cit. Fraunhofer ITEM IPA, Wibbertmann and Hahn (2018)

[33] BSEF (2020): Contribution submitted during the TBBP-A stakeholder consultation conducted from 5 Dec 2019 to 13 Feb 2020 by Oeko-Institut in the course of the study to support the review of the list of restricted substances and to assess a new exemption request under RoHS (Pack 15); see the link to the contribution in the Annex.

[34] Op. cit. Oeko-Institut (2014b)

[35] Op. Cit. DEPA 2018, Part II: Six of the tested components containing both TBP (tribromophenol) and TBBP-A had concentrations above 1000 ppm.

[36] Wäger, P., et al. (2010) RoHS Substances in Mixed Plastics from Waste Electrical and Electronic Equipment. Swiss Federal Laboratories for Materials Science and Technology (EMPA). September 17, 2010.

[37] Op. cit. AEM (2018)

[38] Japan Electronics and Information Technology Industries Association (JEITA; 2018) : Contribution submitted during the TBBP-A stakeholder consultation conducted from 20 April 2018 to 15 June 2018 by Oeko-Institut in the course of the study to support the review of the list of restricted substances and to assess a new exemption request under RoHS 2 (Pack 15); see the link to the contribution in the Annex

of the flame retardant according to special desired properties of the polymer matrix.[39] In this case, TBBP-A is used as an intermediate chemical and will not be present in final products.

2.3. Quantities of the substance used

Different data on TBBP-A tonnages have been published, but the most recent data, as cited by e.g. Fraunhofer Institute ITEM and IPA (2018),[40] originate from already five years ago (Oeko-Institut 2014b) except for the ECHA Registered Substance Database. The stakeholder consultation did not yield more contemporary information on amounts.

The information from the joint submission of the TBBP-A registration at ECHA indicates a total tonnage band of 1,000 to 10,000 tonnes per annum for manufactured and/or imported TBBP-A.[41] The quantities for the use of TBBP-A as reactive flame retardant were indicated to be approximately 5,850 tonnes per year.[42] Compared to earlier research, this seems to be a clear decrease. Data for 2003/2005 indicated ~ 40,000 tonnes of TPPB-A per year found in WEEE in the EU.[43] [44] However, it remains unclear whether the reported tonnage also accounts for the reacted TBBP-A that are part of flame retarded epoxy resins. Additionally, to the basic chemical, the import of TBBP-A-containing articles or half-finished products to the EU is most likely to happen in relevant quantities and needs to be taken into account as in such cases quantities would not be covered in the ECHA registration data.

An overall increasing trend of the global market volume of TBBP-A was reported since the 1990s.[45] Based on data from 2001, the EU RAR[46] refers to a global consumption of ~ 120,000 t/a. A very similar estimation was independently reached by Morose (2006),[47] who estimated a worldwide market demand for TBBP-A of 119,700 t/a in 2001. Covaci et al.[48] reported 170,000 t/a in 2004 globally of which ~ 18 % were used to produce derivates and oligomers, the other 82 % went into ABS or laminates for PWBs. According to a report by the German Umweltbundesamt from 2008,[49] 145,000t/a TBBP-A were used globally (with 7,000 t/a being used in the EU).

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[39] Op. Cit. EU RAR (2008)

[40] Op. Cit. Fraunhofer ITEM IPA, Wibbertmann and Hahn (2018)

[41] Op. Cit. ECHA Registered Substances Database (2019)

[42] Op. Cit. Oeko-Institut (2008)

[43] Op. Cit. Oeko-Institut (2008)

[44] Thereof, 6,600 t/a in form of a basic chemical, 6,000 t/a as partly finished products (in the form of master batch, epoxy resins etc.-) and 27,500 t/a in form of finished products and components).

[45] International Agency for Research on Cancer IARC (2015): Some Industrial Chemicals. IARC Monographs on the evaluation of carcinogenic risks to human. Section on tetrabromobisphenol A, p. 247 – 290.

[46] Op. cit. EU RAR on TBBP-A (2008)

[47] Morose, G., An Overview of Alternatives to Tetrabromobisphenol A (TBBP-A) and Hexabromocyclododecane (HBCD) (2006): Lowell, MA, USA

[48] Cited by Fraunhofer ITEM IPA, Wibbertmann and Hahn (2018)

[49] UBA (2008): Bromierte Flammschutzmittel –Schutzengel mit schlechten Eigenschaften.

Table 2-1: Summary of reported annual amounts of TBBP-A used in the EU

Application	Different specifications of the use amounts
Epoxy resins in printed wiring boards (reactive component)	• 900 – 2,250 t/a (90 % of the EU sales numbers of TBBP-A according to a stakeholder contribution of the European Flame Retardants Association EFRA in 2014)[50] • 5,850 t/a (Oeko-Institut, 2008)
Others • Epoxy resins to encapsulate certain electronic components (reactive component)[51] • Polycarbonate and unsaturated polyester resins (reactive component) • ABS thermoplastic (additive flame retardant)	• 100 – 250 t/a (10 % of the EU sales numbers of TBBP-A according to a stakeholder contribution of the European Flame Retardants Association EFRA in 2014)
Total	• 1,000 to 10,000 t/a (ECHA Registered Substance Database, 2019) • 1,000 – 2,500 t/a (EU sales volume of TPPBA according to a stakeholder contribution of the European Flame Retardants Association EFRA in 2014) • 7,000 t/a (German UBA, 2008) • 40,000 t/a (Oeko-Institut, 2008)

Source: ECHA Registered Substances Database: Entry for 2,2',6,6'-tetrabromo-4,4'-isopropylidenediphenol (2018); EFRA 2014, Oeko-Institut 2008, Oeko-Institut 2014b, UBA (2008).

Aside from the use of TBBP-A in the manufacture of flame retarded printed wiring boards, there is a lack of detailed data for any other applications. The European brominated flame retardant industry (2017) states that only 90 % of TBBP-A traded on the EU market could be accounted for while the rest end up in unknown destinations.[52] This may create the impression that the demand of TBBP-A used in Europe has recently decreased down to between 1,000 to 2,500 tonnes (EFRA 2014),[53] compared to the quantity reported by Oeko-Institut in 2008 and the submitted data to the ECHA registration system. Thus, these data as well as sales numbers of EFRA must also be viewed with caution, as these numbers only represent TBBP-A manufactured or imported for use in manufacture taking place in the EU. However, the amount of TBBP-A being incorporated in imported goods that are placed on the EU market is unknown. For example, it remains unclear whether the use of TBBP-A as additive flame retardant is more usual in the manufacturing of housings and enclosures outside the EU, and thus EEE with additive TBBP-A enter the market in imported articles. The majority of such goods containing PWBs and flame retarded ABS housings are imported from China. Hence,

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[50] Op. Cit. Oeko-Institut (2014b)

[51] Plastic/paper capacitors, microprocessors: used in plastic/paper capacitors, microprocessors, bipolar power transistors, IGBT (Integrated Gate Bipolar Transistor) power modules, ASICs (Application Specific Integrated Circuits) and metal oxide varistors)

[52] Op. cit. VECAP (2017)

[53] European Flame Retardants Association EFRA (2014): Contribution submitted during stakeholder consultation on 04.04.2014 by Oeko-Institut in the course of the study for the Review of the List of Restricted Substances under RoHS 2. Analysis of Impacts from a Possible Restriction of Several New Substances under RoHS 2 (Oeko-Institut 2014)

an unknown quantity of TBBP-A may enter the EU in form of imported final goods as well as intermediate products and components (e.g. master-batch plastic granulate, epoxy resins).[54] This means that the figures mentioned in Table 2-1 are most likely an underestimation.

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[54] Op. cit. Oeko-Institut (2014b)

3. HUMAN HEALTH HAZARD PROFILE

According to the harmonised classification in Annex VI of the CLP Regulation, TBBP-A is not classified for human health hazards. However, 13 notifiers, among them a joint submission of a REACH registration dossier, classify TBBP-A as carcinogenic Category 2 (H351 - Suspected of causing cancer). In summary, the C&L brief for TBBP-A, provided by ECHA, states that **“***this substance is suspected of causing cancer*”.[55]

The most recent report of DEPA (2015),[56] which was prepared for the purpose of justifying the selection of TBBP-A for CoRAP inclusion, summarised that there is potential for endocrine disrupting effects and toxic effects on reproduction and development (see explanation in the following section).

Concerns raised about TBBP-A, being suspected PBT, are summarised in the section on environmental hazards (section 3.3).

3.1. Endpoints of concern

On the potential endocrine disrupting effect of TBBP-A, DEPA[57] summarises the following:

“In vitro studies have demonstrated that TBBP-A has a high potency in competing with T4 for binding to transthyretin (TTR) in animals, however no firm conclusions regarding the affinity of TBBP-A for TTR in vivo can be drawn from the limited data available. The main target for TBBP-A human toxicity is thyroid hormone homeostasis, and most of the studies indicated a decrease in serum T4. In addition, weak estrogenic potency has been found, but TBBP-A did not induce CYP1, CYP2B1 or CYP3A mRNA, protein and respective monooxygenase activities. The BMDL$_{10}$ *of 16 mg/kg bw for changes in circulating thyroid hormone levels could, in principle, be used as the basis to derive a human health-based guidance value.*

Furthermore, Environment Canada/Health Canada reported that there is some recent evidence to suggest that TBBP-A may be capable of disrupting normal functioning of the thyroid system in amphibians and fish, and enhancing immune system activity in marine bivalves. This may further support the findings already described.”

The acute toxicity of TBBP-A is reportedly rather low by all routes of exposure (oral, dermal, inhalation) as well as for repeated dose toxicity. Information on effects is not available. Furthermore, the EU RAR (2008) stated that there was no data on carcinogenicity nor information that indicated toxicologically significant effects on fertility or reproductive performance at doses of up to 1,000 mg/kg.

The consultants note however that the EU RAR is older (2008) and based on data generated prior to its publication. It thus needs to be assumed that the statements of Environment Canada/Health Canada cited by DEPA (2015) regarding human toxicity and endocrine properties may be based on more recent data. The current substance evaluation under REACH based on DEPA (2015) anyhow aims to generate current data regarding endocrine disruption and PBT properties.

In its contribution to the 2nd stakeholder consultation, the Norwegian Environment Agency indicated their notification to ECHA´s Registry of Intention (RoI) that it will develop a proposal for classification

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[55] Opt. cit. ECHA Brief Profile: Entry for TBBPA (2019)

[56] Danish Environmental Protection Agency DEPA (2015): Justification for the selection of a substance for CoRAP inclusion, 2,2',6,6'-tetrabromo-4,4'-isopropylidenediphenol

[57] Opt. cit. DEPA (2015)

with Denmark. The foreseen classification is “Carc 1B” (H350 “May cause cancer”) and is to be submitted on 1 June 2020.[58] Here too, the consultants assume that the last efforts of DEPA and the Norwegian Environment Agency have allowed gathering more recent test results that support a classification of TBBP-A as “Carc 1B” (H350 “May cause cancer”).

3.2. Existing Guidance values (DNELs, OELs)

Information regarding existing guidance values in the form of derived no effect levels (DNELs) and occupational exposure levels have been extracted from the publicly available ECHA databases, which are based on information from the REACH registration dossiers. It should be stressed that information provided by registrants has not been subject to scrutiny by ECHA or any EU expert group. It should be further noted that if the pending evaluation of TBBP-A leads to identification as a potential endocrine disrupter, this would result in a repeal of these DNELs.

The DNELs for TBBP-A extracted from the ECHA Brief Profile are summarised in the table below.

Table 3-1: Derived no effect levels (DNELs) for TBBP-A

Population	Local / systemic effect	Effects	Threshold: DNEL
Workers	Inhalation Exposure	Systemic Effect Long term	17.6 mg/m³
	Dermal Exposure	Systemic Effect Long term	250 mg/kg bw/day
General Population	Inhalation Exposure	Systemic Effect Long term	4.3 mg/m³
	Dermal Exposure	Systemic Effect Long term	125 mg/kg bw/day
	Oral Exposure	Systemic Effect Long term	2.5 mg/kg bw/day

Source: ECHA Brief Profile: Entry for 2,2',6,6'-tetrabromo-4,4'-isopropylidenediphenol (2018)

3.3. Non-testing information opposing existing DNELs

TBBP-A molecules exhibit a notable structural similarity to bisphenol A (BPA) molecules and furthermore there is “*some evidence that TBBP-A can degrade to give bisphenol A under certain anaerobic conditions*[59]*, and that bisphenol-A is stable under these same conditions”,* according to the EU RAR (2008). Bisphenol A has been identified as a substance of very high concern (SVHC) because of its endocrine disrupting properties (article 57(f)). BPA causes probable serious effects to the environment, which give rise to an equivalent level of concern to those of CMR and PBT/vPvB

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[58] Norwegian Environment Agency (2020), Contribution of the Norwegian Environment Agency submitted during the stakeholder consultation conducted from 05 Dec 2019 to 13 Feb 2020 by Oeko-Institut in the course of the study to support the review of the list of restricted substances and to assess a new exemption request under RoHS 2 (Pack 15), see the link to the contribution in the annex; Link to the Registry of Intent: https://echa.europa.eu/registry-of-clh-intentions-until-outcome/-/dislist/details/0b0236e184330ec8 (last accessed 17.03.2020)

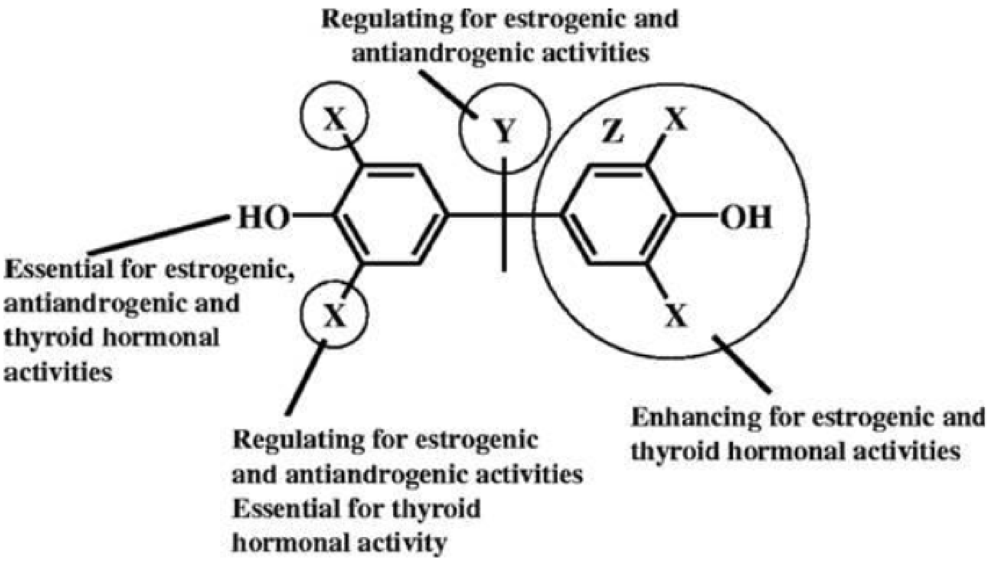
[59] This is among others confirmed by Ronen and Abeliovich 2002, Voordeckers et. al. (2002), Arbeli and Ronen (2003), Chu et al. (2005), Ravit et al. (2005), and Liu et al. (2013). For further details see TBBP-A Registration data under: https://echa.europa.eu/de/registration-dossier/-/registered-dossier/14760/2/3, last viewed 8.6.2020.

properties.[60] The SVHC identification of bisphenol A (and other structurally derived compounds) signals structural alerts that call for different modes of necessary actions to be taken. They are summarised as follows (structural abbreviations correspond to Figure 3-1):

"*To exert estrogenic activity, an unhindered hydroxyl group (OH-) on an aryl ring and a hydrophobic group on the para-position to the hydroxyl group (-C(-Y)$_2$-) is required. The hydroxyl group on one phenyl ring is also essential for an anti-androgenic activity of bisphenols. […] Kitamura et al. (2005)*[61] *demonstrated that a 4-hydroxyl group and double substitution by a halogen or methyl group at the 3,5-positions (X) of the A-phenyl group are essential for thyroid hormone activity of bisphenol.*"

As shown in Table 1-1, TBBP-A has the chemical structure presented in Figure 3-1 with the substituent X being bromine atoms and Y being methyl groups. Given the structural similarity of TBBP-A with BPA, it can be inferred that TBBP-A exhibits similar endocrine disrupting properties.

Figure 3-1: Structural alerts in phenols important to exert different hormonal activities



Source: Kitamura et al. (2005) cited by European Chemicals Agency ECHA (2017)

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[60] European Chemicals Agency ECHA (2017): SVHC SUPPORT DOCUMENT - 4,4'-ISOPROPYLIDENEDIPHENOL

[61] Kitamura et al. (2005). Comparative study of the endocrine-disrupting activity of bisphenol A and 19 related compounds. Toxicological sciences: an official journal of the Society of Toxicology 84, 249-259.

According to Alaee et al (2003), "*the key concern with TBBPA is its similarity in chemical structure to thyroxine (T4). It was shown that in in vitro T4-TTR assay TBBPA has stronger affinity for binding with the thyroid hormone transport protein transthyretin (TTR) than the natural ligand T4*". Since then, several peer-review studies report endocrine disrupting properties of TBBP-A such as Fini et al. (2007) or Shaw et al. (2010).[62] [63] Although, opposing studies exist such as a review by Colnot et al. (2014) that state "*adverse effects might be considered to be related to disturbances in the endocrine system. Therefore, in accordance with internationally accepted definitions, TBBPA should not be considered an "endocrine disruptor*".[64]

The following thresholds for the DNELs for BPA have been published in its ECHA brief profile. Comparing the DNELs of BPA (Table 3-2) with those of TBBP-A in Table 3-1 leads to the conclusion that thresholds are much lower for BPA. With regard to the structural similarity of BPA and TBBP-A, it can be anticipated that both substances show similar PBT & ED properties. Thus, DNELs of BPA might be applied for TBBP-A ad interim until the results of the ongoing substance evaluation led by the Danish EPA (Danish Ministry of the Environment) (see section 1.3.1) are available; requested test results for the endocrine disruptive property of TBBP-A should become available presumably in 2021. Since the ED expert group of ECHA is currently reviewing TBBP-A concerning its possible endocrine disrupting properties, the upcoming results of that assessment should be heeded for in the RoHS substance evaluation.[65]

Table 3-2: Derived no effect levels (DNELs) for BPA

Population	Local / systemic effect	Effects	Threshold: DNEL
Workers	Inhalation Exposure	Systemic Effect Long term	2 mg/m³
	Dermal Exposure	Systemic Effect Long term	31 µg/kg bw/day
General Population	Inhalation Exposure	Systemic Effect Long term	1 mg/m³
	Dermal Exposure	Systemic Effect Long term	1.9 µg/kg bw/day
	Oral Exposure	Systemic Effect Long term	4 µg/kg bw/day

Source: ECHA Brief Profile: Entry for 4,4'-isopropylidenediphenol (2019)

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[62] Fini, J.-B., Le Mével, S., Turque, N., Palmier, K., Zalko, D., Cravedi, J.-P., and Demeneix, B.A. (2007). An In Vivo Multiwell-Based Fluorescent Screen for Monitoring Vertebrate Thyroid Hormone Disruption. Environmental Science & Technology 41, 5908-5914.

[63] Shaw, S.; Blum, A.; Weber, R.; Kannan, K.; Rich, D.; Lucas, D.; Koshland, C.; Dobraca, D.; Hanson, S.; Birnbaum, L. (2010). "Halogenated flame retardants: do the fire safety benefits justify the risks?". Reviews on Environmental Health. 25 (4): 261–305.

[64] Colnot, T., Kacew, S. & Dekant, W. Mammalian toxicology and human exposures to the flame retardant 2,2′,6,6′-tetrabromo-4,4′-isopropylidenediphenol (TBBPA): implications for risk assessment; Arch Toxicol (2014) 88: 553

[65] Endocrine disruptor assessment list: https://echa.europa.eu/de/ed-assessment/-/dislist/details/0b0236e180932f8a (last viewed on 29.10.2019)

4. ENVIRONMENTAL HAZARD PROFILE

According to the harmonised classification and labelling, TBBP-A is very toxic to aquatic life and is very toxic to aquatic life with long lasting effects.

The environmental hazard evaluation process for TBBP-A, which concerns the endocrine disruptive as well as the PBT properties, is still ongoing[66] and will be pending until at least 2021.[67]

Nevertheless, some preliminary information on adverse impacts on biota has been gathered as a result of various studies:

- The endocrine disruptive properties of TBBP-A may cause effects on the thyroid hormone system of aquatic organisms by possible interference with oestrogen signalling. This concern was expressed by the Danish EPA and is based on various studies including both *in vitro* and *in vivo* assays. This concern is currently being analysed by means of a Larval Amphibian Growth and Development Assay (LAGDA) (test method: OECD 241).
- The persistency of one transformation product of TBBP-A, monomethyl ether TBBP-A (Phenol, 4,4 -(1-methylethylidene)-bis[2,6-dibromo-) is under evaluation. Further information will be requested in respect to the bioaccumulation potential and potentially hereafter on the chronic toxicity towards aquatic organism and/or mammalian species.

The following sections on the environmental properties are based on data of the EU RAR (2008)[68] and from the ECHA Registered Substance Database.[69]

4.1. Environmental fate properties

The EU RAR (2008) concludes that TBBP-A is persistent or potentially very persistent according to the criteria used under REACH. It is understood that primary biodegradation occurs only under specific environmental circumstances, e.g. under anaerobic conditions. The main degradation product found was bisphenol-A (BPA), which is persistent under anaerobic conditions (EU RAR 2008). BPA is recognised as SVHC for endocrine disrupting properties for the environment as well as for human health.

According to the ECHA Decision on Substance Evaluation (2017), TBBP-A transforms in natural sediments to monomethyl ether TBBP-A, a substance that is also suspected of meeting PBT criteria.

McCormick et al. (2010)[70] examined the relative toxicity of TBBP-A and it's two known degradations products BPA and TBBP-A DME using the exposure model of embryonic zebrafish. Their data showed "*an increase in embryo or larval mortality following developmental exposure to TBBP-A or BPA. TBBP-A DME exposure, however, did not result in death as compared to control embryos after one-week post-fertilization. TBBP-A proved to be 10 times more potent than BPA or TBBPA DME exposure.*"

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[66] Op. cit. ECHA Substance Evaluation Decision (2017)

[67] The test results have to be submitted by 04.01.2021; thereafter the MSCA have to review the submission.

[68] Op. cit. EU RAR 2008

[69] Op. cit. ECHA Registered Substances Database: Entry for 2,2',6,6'-tetrabromo-4,4'-isopropylidenediphenol (2019)

[70] McCormick et al. Embryonic exposure to tetrabromobisphenol A and its metabolites, bisphenol A and tetrabromobisphenol A dimethyl ether disrupts normal zebrafish (Danio rerio) development and matrix metalloproteinase expression Aquatic Toxicology100 (2010) 255–262

4.2. Endpoints of concern

The US EPA (2015) estimated the distribution of TBBP-A in the environment as follows: Air = 0 %, Water = 1.4 %; Soil = 64 %; and Sediment = 35 % (Estimated with Level III Fugacity Model).

In soil, TBBP-A is attributed a low mobility based on its calculated soil adsorption coefficient Koc. Therefore, leaching of TBBP-A from soil into groundwater is not expected to be an important transport mechanism. Estimated volatilization half-lives for a model river and lake indicate that it will have low potential to volatilise from surface water. In the atmosphere, TBBP-A is expected to exist primarily in a particulate phase (dust). Particulate TBBP-A will be removed from air by wet or dry deposition.

According to the EU RAR (2008), TBBP-A may cause long-term adverse effects to organisms in the aquatic environment. This conclusion is based on the toxic effects seen in acute toxicity assays with fish and daphnia (L(EC)50 <1 mg/l), the lack of biodegradation seen in standard ready biodegradation tests and the high bioconcentration factors (BCF>100) measured in fish (ibid).

It is noted that stakeholders argued that a BCF > 100 is not high and this is correct in relation to fulfilment of the bioaccumulation-criterion according to REACH, which requires a BCF above 2,000. However, the EU RAR perceived the BCF as being high at that time and TBBP-A is still under assessment for being bioaccumulative. See also discussion in the following section 4.3.

4.3. Potential for secondary poisoning and bioaccumulation

Secondary poisoning is a phenomenon related to toxic effects, which might occur in higher members of the food chain. It results from ingestion of organisms from lower trophic levels in which substances of concern have bio-accumulated. Chemicals which have bioaccumulation and bio-magnification properties within the food chain may particularly pose a danger to predatory species.

As for bioaccumulation, the highest measured bioconcentration factor (BCF) value for (freshwater) fish with TBBP-A is around 1,234 l/kg according to the EU RAR (2008), which is below the cut-off value for the REACH criterion for bioaccumulation at BCF >2,000 l/kg. It should be noted here, that according to the ECHA Registered Substances Database (2018), in the registration dossier a much lower BCF in aquatic species (fish) was indicated: "*The BCF of the parent TBBP-A molecule was approximately 150. The majority of the 14C-activity detected in fish tissue was not associated with the parent molecule. The whole-body half-life of 14C-activity was < 24 hours.*"

Monitoring data as presented in the EU RAR (2008) are available in a limited amount from remote regions, including the Arctic. However, a more extensive database of monitoring data in aquatic organisms exists. "*The data show that tetrabromobisphenol-A has been detected at low levels in a number of aquatic species, including some top predators such as harbour porpoise, but most of these data were collected from sites that may be influenced by local or regional sources of emission and so are difficult to interpret in terms of the PBT assessment. In addition, it should be noted that there are a significant number of samples analysed where tetrabromobisphenol-A was not detectable. Tetrabromobisphenol-A has been detected in a single sample of human breast milk from the Faroe Islands.*" (ibid)

DEPA (2015) states that there is no sufficient evidence to conclude that TBBP-A meets the bioaccumulation criteria for B or vB but that it is possible that it fulfils Article 57(f) as quasi PBT on the basis of its environmental toxicity and persistency.

4.4. Guidance values (PNECs)

The predicted no effect concentration (PNEC) is the concentration below which exposure to a substance is not expected to cause adverse effects to species in the environment. Therefore, the knowledge of these values is important for further characterisation of possible risks.

The following PNEC values for TBBP-A for different compartments are extracted from the EU RAR (2008), the ECHA Registered Substances Database: Entry for 2,2',6,6'-tetrabromo-4,4'-isopropylidenediphenol (2018) as well as values compiled in a collection of references provided by the Norwegian Environmental Agency as a contribution to the first stakeholder consultation.[71]

Table 4-1: Predicted No-Effect Concentration (PNEC) for TBBP-A

Fact	**Compartment**	**PNEC value ECHA Registered Substances Database 2018**	**PNEC value EU RAR 2008**	**PNEC value Norwegian Environment Agency 2014**
Hazard for Aquatic Organisms	Freshwater	16 µg/l	1.3 µg/l	6.6 µg/l
	Marine water	0.34 µg/l	0.25 µg/l	0.05 µg/l
	Sewage treatment plant (STP)	1.5 mg/l	-	-
	Sediment (freshwater)	9 mg/kg sediment dw	2.7 mg/kg wet weight In some cases, a higher PNEC is applied for a sediment where TBBP-A may show a stronger adsorption.	0.24 dw
	Sediment (marine water)	1.8 mg/kg sediment dw	0.54 mg/kg wet weight	0.063 dw
Hazard for Air	Air	No hazard identified	long-range transport to the Arctic could occur	-
Hazard for Terrestrial Organism	Soil	0.031 mg/kg soil dw	0.012 mg/kg wet weight	-
Hazard for Predators	Secondary poisoning	222.22 mg/kg food	>667 mg/kg food	-

Source: EU RAR (2008), ECHA Registered Substances Database: Entry for 2,2',6,6'-tetrabromo-4,4'-isopropylidenediphenol (2018), Norwegian Environment Agency (2018)

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[71] Norwegian Environment Agency (2018): Contribution submitted during the TBBP-A stakeholder consultation conducted from 20 April 2018 to 15 June 2018 by Oeko-Institut in the course of the study to support the review of the list of restricted substances and to assess a new exemption request under RoHS 2 (Pack 15); see the link to the contribution in the Annex

5. WASTE MANAGEMENT OF ELECTRICAL AND ELECTRONIC EQUIPMENT

5.1. Description of waste streams

According to BSEF, TBBP-A is produced mainly in Israel, the United States, Jordan, Japan and PR China.[72] Thus, releases of the substance from primary production processes are not expected to occur in Europe. Certain amounts of TBBP-A are imported as a commoditised intermediate chemical (see 2.3), which is used for the manufacturing of various EEE products. Notably, TBBP-A is used as a reactant in the manufacturing of FR4 printed wiring boards (PWB). However, wastes emerging during the PWB production do not fall under the scope of the RoHS directive.

RoHS relevant waste encompasses post-consumer WEEE, which contains TBBP-A mainly in form of an additive flame retardant in plastic components (such as ABS-parts). Reacted TBBP-A occurs in rigid FR4 PWB but does no longer exist in its original substance identity (see 2.2). Hence, TBBP-A cannot be analytically identified in PWB fractions of WEEE except for unreacted TBBP-A from the original PWB production. TBBP-A detected otherwise in WEEE cannot be attributed to the PWB.

It must be noted, that the literature does not always clearly distinguish the difference between reacted and not reacted TBBP-A in WEEE. Moreover, accounts on the TBBP-A contents, found in WEEE categories are at odds with the figures on TBBP-A used, reported in section 2.3.

Taverna et al. (2017)[73] for instance, examine typical EEE flame retardants as part of the material flows in the Swiss WEEE treatment system. In this study, 220 tons of WEEE with a typical composition with regard to the WEEE categories[74] was examined based on the statistical WEEE composition of Switzerland in the year 2009. This study found that, out of the 18 flame retardants examined, TBBP-A was the most abundant one with a mean concentration of > 600 mg/kg waste in composite samples from all output streams of WEEE processing. With focus on TBBP-A, the following three output streams (out of 13 examined in total) are important:

- PWBs (representing 2 % of the total WEEE output mass flow),
- polymer components from dismantled EEE housings (5 % of the total WEEE output mass flow),
- polymer particle fraction generated by shredding of WEEE (23 % of the total output mass flow).

In these three outputs, TBBP-A was always found to be the most abundant flame retardant. For the PWB output stream, TBBP-A was found with an average concentration of 390 mg/kg by far more than from other FR (next followed by DecaBDE with 110 mg/kg). In computer and notebook housings made form polymeric material, TBBP-A was present with 4,000 mg/kg (next followed by DBDPE with 1,400 mg/kg); and finally, an average concentration of 1,700 mg/kg was detected in the polymer particle fraction with diameters < 25 mm (next followed by DBDPE 1,100 mg/kg).

From the distribution of TBBP-A in the examined output streams it can be concluded that > 90 % of additively applied TBBP-A content in WEEE ends up in the polymer fraction (housings + polymer particles) as can be seen from Figure 5-1. The PWB output stream holds a share of only 1 % of the TBBP-A. This result proves the assumption that the release of unreacted TBBP-A from poly epoxy

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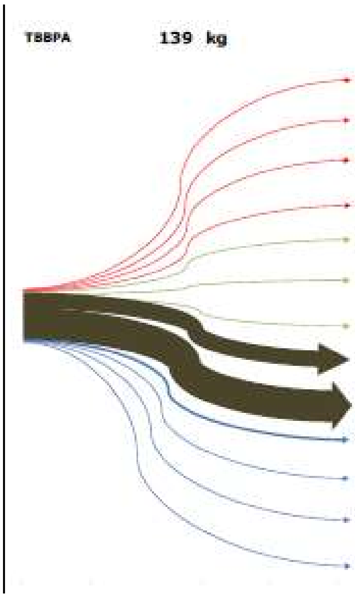
[72] BSEF, Fact sheet TBBP-A: Tetrabromobisphenol A for Printed Circuit Boardsand ABS plastics. 2007: Brussels, Belgium

[73] Taverna, R. et al. (2017): Stoffflüsse im Schweizer Elektronikschrott. Metalle, Nichtmetalle, Flammschutzmittel und polychlorierte Biphenyle in elektrischen und elektronischen Kleingeräten. Bundesamt für Umwelt, Bern. Umwelt-Zustand Nr.1717

[74] Based on Taverna (2017): Figure 5, pg. 30, the investigated composition included: 25% IT equipment without monitors; 1% laptops; 3% LCD monitors; 9% CRT monitors; 3% communications equipment; 7% mixed consumer electronics without TVs; 9% LCD TVs; 14%CRT TVs; and 27% small household appliances.

resins is only a very small source for this substance in the waste stream. Moreover, the findings suggest a focus for this chapter on the waste management of TBBP-A containing plastic fractions.

Figure 5-1: Distribution of TBBP-A in the examined output waste streams



Output	*Percentage of mass*
Pollutant carriers	-
Background lighting of flatscreen displays	-
LCD panels	-
Dust	2 %
Copper cables	-
PWBs	1 %
Components of cathode ray tubes	-
Computerdisplay and notebook housings	31 %
Polymer particles < 25 mm diameter	62 %
Undersize particles	4 %
Fine-grained metal fractions	-
Scrap metal fractions	-
Iron scrap	-

Source: Taverna et al. 2017.

5.1.1. Main materials where the substance is contained

As explained in section 2.2, there are two main application forms for TBBP-A in EEE:

1) Covalently bound TBBP-A in epoxy and polycarbonate resins that form the main constituent of rigid (FR4) PWB.

2) Additive TBBP-A (non-covalently bound) in ABS based plastic components, mainly EEE housings. Small amounts of non-covalently bound TBBP-A may occur in rigid (FR4) PWB as a residue from their production.

Kousaiti et al. (2020)[75] evaluated the TBBP-A content per polymer type[76]: The range of TBBP-A per polymer type varies among ABS and PP and PP blends, as the following Figure 5-1 shows. It was not detected in PC and PC blends. Amongst the same type of polymer, values varied significantly (see the error bares in the boxplot below). The highest average value was found in ABS-containing samples (1.2 mg/kg), followed by PP (0.4 mg/kg). Kousaiti et al. explain that the reason for not detecting TBBP-A in PC and PC/ABS blends is possibly due to different kinds of FRs in those PC-containing polymers, in addition to high uncertainties due to a limited number of PC samples tested (n=2). HIPS samples were not evaluated in this study.

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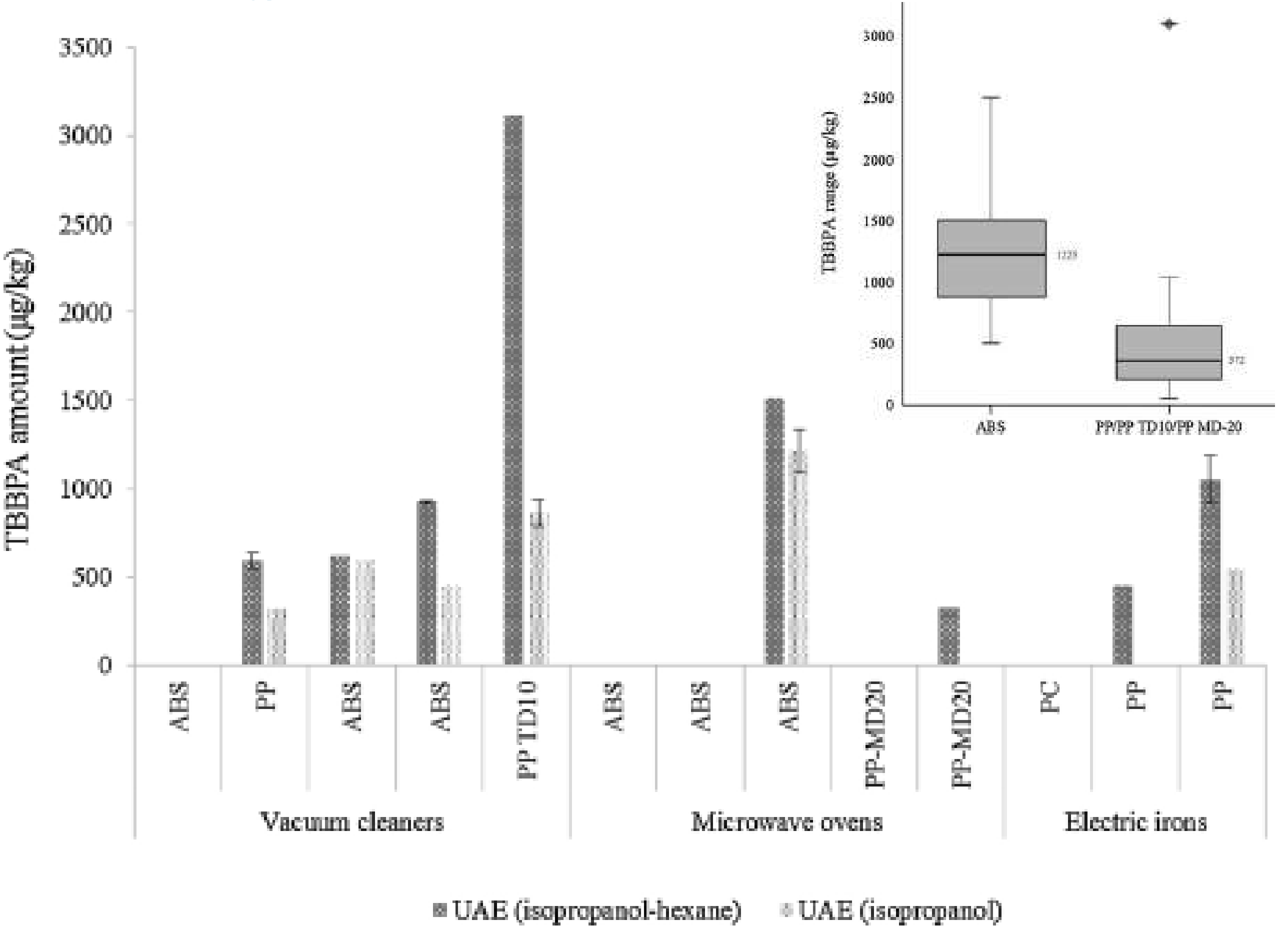
[75] Kousaiti et al. (2020): Assessment of tetrabromobisphenol-A (TBBPA) content in plastic waste recovered from WEEE. Journal of Hazardous Material, 390, 121641

[76] (1) ABS; (2) Polypropylene and blends (PP-TB10, PP-MD20); and (3) Polycarbonate and PC blends (PC/ABS)

Figure 5-1: **Mean and range values of TBBP-A content in plastic matrices per polymer type**



Source: Kousaiti et al. (2020)[77]

5.1.2. WEEE categories containing the substance

WEEE, containing reacted TBBP-A

FR4-type PWBs consist of reacted TBBP-A. PWBs are found in a multitude of EEE products that contain electronic components. This is true for almost all modern appliances that are equipped with electronics to provide “smart” functions (e.g. Internet / cloud connectivity). Also, EEE products without smart functions are likely to be equipped with PWBs if they provide any kind of functions that go beyond a simple on/off switch. Examples of PWB mounted electronic components in EEE are LED indicator lights, sensors, control units, displays, speakers, buzzers, digital data ports (e.g. USB), wireless connectivity etc.

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[77] Op. cit. Kousaiti et al. (2020)

Table 5-1: Annex I categories of WEEE containing reacted TBBP-A

No.	Categories name	Examples
1	Large household appliances	Fridges, freezers, air conditioners, white goods
2	Small household appliances	Coffee machines,
3	IT and telecommunications equipment	Personal computers, printer, notebooks, tablets, mobile phones
4	Consumer equipment	TV Sets
5	Lightning equipment	Surface mounted LED on PWBs including controllers
6	Electrical and electronic tools	PWBs in different products of the category
7	Toys, leisure and sports equipment	PWBs in different products of the category
8	Medical devices (except all implanted and infected products)	Imaging systems, monitors, infusion pumps
9	Monitoring and control instruments	Navigation, sensors, control systems
10	Automatic dispensers	PWBs in different products of the category

Source: adopted from Fraunhofer ITEM IPA[78]

Noteworthy, the reacted TBBP-A resides solely in rigid FR4 PWBs whereas flexible PWBs are not expected to contain the substance. Consequently, EEE that do not contain FR4 PWBs is unlikely to contain reacted TBBP-A with the exception of encapsulated EE components.

However, rigid FR4 PWBs are not considered to contain TBBP-A in its original substance identity, because reacted TBBP-A becomes an inherent building block of covalently bound epoxy resins. PWBs may contain residues of not-reacted TBBP-A in traces only. According to Rachmilevich (2015), to which several stakeholders refer to (e.g. MedTech 2018, JEITA 2018), the unreacted residues of TBBP-A in epoxy based PWBs can be considered as very low: TBBP-A concentrations in samples at different production stages of PWBs (CCL, unclad laminates, prepregs) from four different manufacturers were found to be lower than the methods' detection limits of either 10 or 20 ppm[79] which is estimated to be less than 0.006 % of the original used TBBP-A[80]. Sellstrom and Jansen (1995) found 0,7 mg residual TBBP-A per gram of PWB, thus 0.7 ppm, which in 2015 was the only published concentration of TBBP-A in laminate material according to US EPA (2015). From the bromine and the TBBP-A concentrations found in the separated PWB output stream investigated by Taverna et al. (2017), the amount of unreacted TBBPA was in a comparable order of magnitude, though understood to relate to the complete PWB and not necessarily to the homogenous material (see calculations in footnote[81]).

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[78] With information from inter alia obt cit. Wibbertmann, Axel and Hahn, Stefan (2018)

[79] Rachmilevich, Y., Determination of unreacted TBBP-A in different production stages of printed circuit boards. 2015, ICL Industrial Products

[80] Op. cit. Fraunhofer ITEM IPA, Wibbertmann and Hahn 2018

[81] The total Br from reactive and additive use in PWB was found to be m(Br_total) = 89,000 mg/kg which corresponds to n(Br_total) = 1.11 mol/kg; while the m(TBBP-A) = 390 mg/kg (assumed to be the unreacted TBBP-A) corresponds to n(TBBP-A) = 0.0007 mol/kg. With n(Br from TBBP-A) = 4x n(TBBP-A) = 2.87x10^-3 mol/kg, the ratio of n(Br from TBBP-A)/n(Br_total) = 0.00258 --> devision with 4 as 4xBr per TBBPA results in a concentration of 0.000645 (based on data from Taverna et al. 2017).

Hence, it has to be noted that **WEEE containing reacted TBBP-A in its polymeric backbone is not considered relevant for the further analysis**. In other words, epoxy-based PWBs that are found in WEEE are not considered to contain TBBP-A in relevant amounts.

WEEE, containing non-covalently bound TBBP-A

Additive TBBP-A is likely to be found in WEEE items that contain plastics housing parts of ABS. Such components are to be expected in a multitude of products. Müller et al. (2012)[82] studied TBBP-A concentrations in WEEE categories 1 to 4, which are known to contain cover parts made from ABS polymer. TBBP-A was detected in most samples with average concentration levels typically ranging from 1 to 10 g/kg. The highest concentrations were found in mixed plastics from CRT monitors[83] with an average concentration of 37 g/kg and a maximum level of 63 g/kg. The lowest detected value, namely 0.1 g/kg, was found in a single sample of mixed plastics from small appliances for high-temperature applications. The results suggest that TBBP-A has to be expected in concentrations between 1 and 10 g/kg or above in mixed plastics from WEEE categories 2−4, whereas there are indications that they do not occur in mixed plastics from WEEE category 1.

Kousaiti et al. (2020)[84] review ten additional studies from 2005 to 2014 that report measurements of TBBP-A concentrations in different waste streams of categories 1 to 4 as well as different types of polymers. The study confirms the trends identified by Müller et al. (2012). According to Gallen et al. (2014), maximum values exceeded 140 g TBBP-A per kg WEEE in toys, leisure and sports equipment, small appliances and ICT equipment.[85]

Table 5-2: Annex I categories of WEEE containing additive TBBP-A

No.	Categories name	Examples
1	Large household appliances	Fridges, freezers, microwave ovens, white goods
2	Small household appliances	e.g. Coffee machines
3	IT and telecommunications equipment	e.g. personal computers, printer, notebooks, tablet, mobile phones
4	Consumer equipment	e.g. TV Sets
8	Medical devices (except all implanted and infected products)	e.g. imaging systems, monitors, infusion pumps

Source: adopted from Fraunhofer ITEM IPA[86]

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[82] E. Müller, M. Schluep, P. Wäger and P. Leroy: "RoHS - regulated substances in mixed plastics from waste electrical and electronic equipment," *2012 Electronics Goes Green 2012+*, Berlin, 2012, pp. 1-6

[83] Cathode ray tube monitors and TV had been legacy WEEE back in 2012 but were still found abundantly in WEEE at the time of that study. Nowadays, the number of CRT devices in WEEE has declined substantially.

[84] Op. cit. Kousaiti et al. (2020)

[85] Gallen et al. (2014) Towards development of a rapid and effective non-destructive testing strategy to identify brominated flame retardants in the plastics of consumer products. Science of the Total Environment 491-492, 255-265 cited by Kousati et al (2020)

[86] With information from inter alia obt cit. Wibbertmann, Axel and Hahn, Stefan (2018)

Overall, WEEE categories 2 to 4 play the major role concerning housings (additive use), whereas all WEEE categories are relevant for printed wiring boards (reactive use), since these are present in almost all pieces of equipment.

5.2. Applied waste treatment processes

According to the WEEE directive, waste electric and electronic equipment is to be collected and treated separately from household waste. The WEEE collection target level in the EU, in effect since 2019, is 65 percent of EEE placed on the market during the three previous years. This applies for all WEEE regardless of the presence and the form of TBBP-A (reacted or additive) in the respective WEEE items.

5.2.1. Initial treatment processes

Following the separate collection of WEEE from households, general handling processes of WEEE waste encompass pre-treatment (e.g. removal of specific hazardous components), manual or mechanical dismantling (e.g. shredding) sorting, recovery, processing, incineration or landfilling of residues. WEEE that was not separately collected is likely to be co-processed as part of municipal solid waste. The following assessment applies under the condition of separate collection and treatment of current operational conditions in the EU. WEEE that is exported outside the EU might be recycled by means of crude process technologies (see 5.5).

Separately collected WEEE undergoes the following principal treatment processes:[87]

- Transport of mixed WEEE to processing plants,
- Manual pre-dismantling of parts containing hazardous materials (e.g. batteries),
- Manual dismantling has been applied in the past[88] and is increasingly being replaced by mechanical dismantling (shredding / crushing). Manual work is still an option for niche applications although semi-automatic options are available too,[89]
- Screening and separation: before shredding, TBBP-A containing plastic parts need to be separated using XRT/XRF technologies. [90] Else they will most likely end up in the plastics fraction (separated whole ABS parts and shredded polymer flakes). The shredded plastics fraction needs to be tested according to standard EN 50625-3-1 to confirm less than 2,000 ppm bromine content.

5.2.2. Subsequent treatment processes of secondary wastes

Under current operational conditions in the EU, further waste treatment processes for products and components with additive TBBP-A are:

- Storage and transports of intermediate recycling fractions (including shredded polymer flakes),
- Gravimetric sorting of shredded polymer flakes,

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[87] Op. cit. Fraunhofer ITEM IPA, Wibbertmann and Hahn (2018)

[88] Op. cit. Oeko-Institut (2008)

[89] Op. cit. Fraunhofer ITEM IPA Wibbertmann and Hahn (2018)

[90] Maisal, F et. Al (2020): Preparing WEEE plastics for recycling – How optimal particle sizes in preprocessing can improve the separation efficiency of high quality plastics" Resources, Conservation & Recycling: 154.

- Plastics recovery: ABS, originating from plastic parts that are free of flame retardants is recovered to a certain extent. ABS, containing flame retardants with a bromine content above 2,000 ppm[91], is usually incinerated and recycling processes for TBBP-A-containing plastic housings have not been reported (as far as the concentration is > 2,000 ppm),[92] [93]
- Incineration of residues in municipal waste incinerators,
- Co-incineration of bromine-free plastic waste as substitute fuel in cement kilns[94]

The WEEE Directive[95] requires that plastics containing brominated flame-retardants have to be removed from any separately collected WEEE. Recycling of polymers (epoxy resins or ABS) containing TBBP-A is usually not practiced in the EU. Though, there would be a market for plastics with TBBP-A, using XRT/XRF recycling technologies allows for the detection of total Br concentration but cannot distinguish different brominated flame retardants.[96] Hence, ABS recyclates from WEEE (such as inner and outer plastic housing, front or rear cover plates) that are tested (CEN 50625-3-3) and contain >2,000 ppm of total Bromine need to be sent to incineration.

In this respect, in their contribution to the consultation, EuRIC (2020)[97] states that "*total bromine content is useful for separating low brominated fraction from high brominated fractions, according to standard CEN TS 50625-3-1. Both antimony (Sb) and bromine (Br) are used by state-of-the-art recycling techniques to separate flame retardant from non-flame-retardant plastics*". XRF sensors and density separation are mentioned in this respect.

EuRIC (2020)[98] raises concern whether XRF and density separation techniques can properly deal with phosphorus-based flame retardants which may be used as substitutes for TBBP-A. It is explained that XRF sensors cannot detect phosphorus-based flame retardants and density-based separation may not allow the correct separation of plastics containing phosphorus-based flame retardants (PFR) from "clean" plastic fractions, because of the density overlap between PFR and non-PFR plastic fractions. EuRIC are concerned that a restriction could "*lead, via the substitution by PFRs, to a higher residual fraction of non-recycled plastics (if a restriction is implemented), and of lesser quality of recycled plastics, containing PFR*".

KU Leuven (2018) also refer to this point, explaining that "*With post-shredder sorting techniques plastics containing bromine/antimony-based flame retardants can be separated with a high efficiency from other non-flame-retardant plastic types, as the density is significantly higher, and the bromine*

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[91] The threshold is specified in the WEEE CEN standard series 50625 technical specification TS 50625-3-1, under Section 8.3 for CRT display appliances, but also referring to its applicability to "*plastic fractions that can contain Brominated Flame Retardants (i.e. plastics from all categories of WEEE except large appliances and cooling and freezing appliances)*"

[92] Op. cit. Fraunhofer ITEM IPA, Wibbertmann and Hahn (2018)

[93] http://www.recplas.co.uk/abs-recycling.html (last viewed 08.10.2019)

[94] Op. cit. BSEF (2020)

[95] Annex VII on the selective treatment for materials and components of waste electrical and electronic equipment referred to in Article 8(2) of the Directive 2012/19/EU of the European Parliament and of the Council of 4 July 2012 on waste electrical and electronic equipment (WEEE) (recast); https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32012L0019&from=EN, last viewed 02.07.2018

[96] EERA (2020) Contribution submitted during the TBBP-A stakeholder consultation conducted from 5 Dec 2019 to 13 Feb 2020 by Oeko-Institut in the course of the study to support the review of the list of restricted substances and to assess a new exemption request under RoHS (Pack 15); see the link to the contribution in the Annex.

[97] EuRIC (2020) The European Recycling Industries' Confederation. Contribution submitted during the TBBP-A stakeholder consultation conducted from 5 Dec 2019 to 13 Feb 2020 by Oeko-Institut in the course of the study to support the review of the list of restricted substances and to assess a new exemption request under RoHS (Pack 15); see the link to the contribution in the Annex

[98] Op. cit. EuRIC (2020)

content is sufficient for good detection by XRF. However, with these techniques it is today not economically viable to separate bromine/antimony containing plastics for mechanical recycling, as further sorting of these plastics to obtain the required purity is not possible post-shredder, as no techniques exist to sort for example ABS BrFR and HIPS BrFr post shredder. It should also be considered that the same issues are valid for phosphor-based flame-retardant plastics".[99]

In the consultant's view, though this argumentation may show that the waste management sector may be challenged by the possible content of phosphorus-based flame retardants in EEE polymer fractions, it does not support the further use of TBBP-A as a flame retardant in additive applications, should this be found to fulfil the criteria for restriction. To begin with, it is noted that there is a time lag between when EEE products are placed on the market and the time they arrive at end-of-life, i.e. at waste management facilities. It is also assumed that should TBBP-A be restricted under RoHS, a transition period would be specified and would provide additional time for the sector to develop suitable separation and recycling techniques. This conclusion is furthermore supported by the understanding that phosphorus-based flame retardants as well as other substitutes are already in use by some manufacturers and are expected to enter the waste stream to some degree regardless of the future use of TBBP-A (see section 8.3). Whether such substitutes may also result in impacts in the use phase or the waste phase and in the fulfilment of the RoHS criteria for restriction is of relevance for considering whether additional substances should be addressed by RoHS to avoid regrettable substitution.

PWBs are usually sent to copper smelters for metal recovery. The reacted TBBP-A, contained in epoxy resin based PWBs, is usually co-incinerated in process of metal smelting where waste gas cleaning devices are expected to be installed.[100] The bromine is thus removed as a salt, which is disposed of in landfills.

5.3. Waste treatment processes relevant for assessment under RoHS

While reacted TBBP-A, being part of FR4 PWBs, is unlikely to be liberated in its original chemical signature, the additive form of application as a flame retardant in thermoplastic ABS parts may be released during abrasive and thermal recycling and disposal processes. Releases of TBBP-A during WEEE treatment are to be expected above all during the **shredding of mixed WEEE,** which takes place at several stages of the overall treatment chain at a large number of installations. Shredding residues that contain polymers are likely to contain various brominated flame retardants, with TBBP-A among them. Such residues are to be incinerated. The importance of the different subsequent treatment processes for the assessment under RoHS will be commented on in the following sections.

The following WEEE treatment processes are considered of low relevance regarding TBBP-A releases:

- Manual dismantling of WEEE (e.g. housings) is unlikely to cause airborne emissions due to the high vapour pressure of TBBP-A. However, dermal contact of workers to TBBP-A bearing plastic

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[99] KU Leuven-University of Leuven (2018): Contribution submitted by Jef Peeters, Department of Mechanical Engineering, Faculty of Engineering & Engineering Technology, KU Leuven-University of Leuven on 15.06.2018 during the stakeholder consultation conducted from 20 April 2018 to 15 June 2018 by Oeko-Institut in the course of the study to support the review of the list of restricted substances and to assess a new exemption request under RoHS 2 (Pack 15); http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Pack_15/1st_Consultation_Contributions/Contribution_KU_LEUVEN_Diantimony_Trioxide_20180615.pdf, last viewed 26.06.2018

[100] Op. cit. Fraunhofer ITEM IPA, Wibbertmann and Hahn (2018)

parts could be a possible exposure pathway if personal protection equipment (gloves) is insufficiently used.

- Manual dismantling of PWBs seems to be of low relevance due to chemically bound state of TBBP-A in the polymeric resin. Yet, dermal contact of workers to un-reacted TBBP-A (concentrations below 0.006 % see 5.1.1) cannot be ruled out.
- Uncontrolled heating and burning of TBBP-A bearing plastics can lead to the formation of dibenzo-p-dioxins and furans,[101] in particular in the presence of copper. However, this risk is not specific to TBBP-A, but applies to all species of brominated flame retardants in WEEE.

5.4. Releases from (relevant) WEEE treatment processes

In its contribution, AEM[102] states on behalf of their members that in the EU, waste management and WEEE recycling processes are carried out by professional waste treatment companies that comply with EU waste treatment legislation. Thus, emissions of brominated pollutants from WEEE are thought to be under control in the EU.

In relation to emissions, EERA (2020)[103] further states that "*the BAT/BREF requirements for shredder processes, ensure that the shredder dust is captured, and that this shredder dust is incinerated, hence the shredder processes do not pose a risk for human health or the environment. For CRT appliances a manual separation of the plastics is state of the art. At the workstations of the manual dismantling, dust extraction systems ensure the reduction of any human health and environmental risks to an absolute minimum*".

Other stakeholders do not provide information on waste phase or, as JEITA,[104] focus on exposure of TBBP-A during the use phase rather than during the WEEE processing.

Though approaches concerning releases of TBBP-A and its degradation products have been published (e.g. EU RAR), quantitative exposure estimations for WEEE treatment are rarely found and mainly based on a limited number of monitoring data.[105]

In terms of suspected pathways of TBBP-A release, shredding of mixed WEEE and pre-sorted ABS fractions are the most relevant processes as they may cause TBBP-A bearing dust emissions at the working place and into the environment. In particular, polymer particles with diameters below 25 mm are seen of high relevance for TBBP-A releases (Taverna et al. 2017).

Shredding processes may differ with regard to the composition of WEEE feedstock, the shape and particle size distribution of shredded materials and residues, dustiness and emission prevention appliances, ventilation conditions, the grade of automatisation, and the work pace situation (indoor or outdoor), just to name some aspects. This leads to the conclusion that the occupational and environmental exposure risk to TBBP-A differs per shredding site.[106]

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[101] Op. cit. Oeko-Institut. 2008,

[102] Op. cit. AEM (2018)

[103] EERA (2020) Contribution submitted during the TBBP-A stakeholder consultation conducted from 5 Dec 2019 to 13 Feb 2020 by Oeko-Institut in the course of the study to support the review of the list of restricted substances and to assess a new exemption request under RoHS (Pack 15); see the link to the contribution in the Annex

[104] Op. cit. JEITA (2018)

[105] Ob cit. Fraunhofer ITEM IPA, Wibbertmann and Hahn (2018)

[106] Op. cit. Environmental Agency Austria (2008), see the chapter „Workplace description of mechanical treatment of WEEE"

Fraunhofer ITEM and IPA conclude from an extrapolation for a – in their opinion – typical WEEE shredding site (throughput of 250 t WEEE/day) a diffuse release of 130 g TBBP-A per day. Out of this amount, a release rate of 0.52 g TBBP-A per ton WEEE treated in such a site can be calculated.

This extrapolation is based on data from 2004 and may therefore be considered outdated. No more recent publicly available data could be found in this study, nor did the stakeholders in the second consultation provide information on actual TBBP-A releases from WEEE in Europe. Against this background, the assumption that emissions of brominated pollutants from WEEE in Europe are under control is not supported.

Regardless the poor information on environmental entry pathways, inter-compartment transport and transformation, TBBP-A has been detected in various environmental compartments related to the disposal phase (see chapter 6.3.3).

Releases of toxic degradation products

Thermal waste treatment processes, applied to plastic parts containing additive TBBP-A, are suspected to result in a release of bromine in form of chemical compounds of low molecular weight, specifically hydrobromic acid (HBr). That substance can act as a precursor to the formation of brominated dioxin species if the WEEE underdoes crude thermal treatment processes in presence of copper (which is almost certainly the case if PWBs are combusted in open fire). However, the aforementioned pathway to the formation of brominated pollutants is not specific to TBBP-A. It can occur with any brominated compound that has been added to EEE during their manufacturing.

5.5. Crude WEEE treatment in non-OECD countries

This includes mechanical treatment of residual waste, incineration in municipal waste incinerators but also landfilling or transboundary movements outside the EU cannot be ruled out. WEEE, exported towards non-OECD countries is likely to be subjected to all sorts of informal recycling and waste treatment processes, such as uncontrolled combustion, grilling, desoldering, uncontrolled dumping of residues, and generally uncontrolled treatment under crude circumstances. Due to their content of precious metals, PWBs are particularly prone to crude recycling treatment, including open burning, roosting, and hydro chemical acid leaching. The presence of reacted TBBP-A in FR4 PWB does impose special precautions to be applied in informal recycling businesses. The fate of plastic parts containing additive TBBP-A is uncertain. Some ABS plastic parts might be landfilled or burned while others are subjected to manual sorting and recovery of ABS. The latter pathway poses a risk of cross-contamination, which means an uncontrolled pollution of recycled ABS feedstock with a mixture of additives, among them TBBP-A. There is a risk of re-imports of products (not only EEE) containing cross-contaminated plastic recyclates into the EU.

6. EXPOSURE ESTIMATION DURING USE AND DURING WEEE TREATMENT

6.1. Basis of exposure estimation

Before becoming WEEE, products containing covalently bound TBBP-A as part of epoxy or polycarbonate resin based PWBs are not thought to release the substance to the environment.[107] The stakeholder contribution of ZVEI (2018) underpins this claim by referring e.g. to the status report of the ICL. JEITA and AEM stress the fact that no TBBP-A emissions from PWCs could be detected although evidence was not provided.[108] The presence of unreacted TBBP-A as a production residue in finished epoxy-based printed wiring boards is negligible according to information provided by stakeholders from industry. The FR4 laminates contain TBBP-A at levels of less than the detection limits of either 10 or 20 ppm. Therefore, the unreacted residue levels can be considered as very low (see also section 2.1).

The possibility of TBBP-A exposure resulting from additive use in polymers is higher than from residues of unreacted TBBP-A residues in PWBs. In its form as an additive, TBBP-A is non-covalently and therefore more loosely bound to the polymer than in its reacted form. Therefore, the substance has a higher likelihood to be released from products in the use phase and when WEEE is recycled or disposed of. However, as the volatility of TBBP-A is negligible air emissions will be extremely small (US EPA 2015). TBBP-A may be released in the form of dust particles in the process of shredding, crushing, and milling of flame retarded ABS plastics contained in WEEE.

6.2. Human exposure estimation

6.2.1. Exposure of workers of EEE waste processing plants

Modelled data

According to the waste streams examined in chapter 5.3 and 5.4 exposition of workers in WEEE processing plants to TBBP-A can occur during the processes of dismantling and shredding. The exposure can occur through inhalation of dust and dermal contact. The exposure route via inhalation is assumed to be the more relevant one.

Exposure estimation for workers was modelled in the course of the preparation of the dossier at hand by using the ECETOC's Targeted Risk Assessment (TRA)[109] tool. It helps calculating the risk of exposure from chemicals to workers, consumers and the environment. The ECETOC TRA tool is intended for manufacturing and formulation processes, therefore no appropriate processes to describe the exposure conditions of waste treatment processes are available so far.

The process category 24: "*high (mechanical) energy work-up of substances bound in materials and/or articles*" has been selected to calculate the exposure of workers of EEE waste processing plants. This approach has been first introduced by the Austrian Umweltbundesamt for the RoHS assessment of the phthalates DEHP, DBP and BBP; it has also been used by KEMI for the MCCP

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[107] Op. cit. Alaee, M., et al. 2003 and Buekens A. and Yang J. (2014)

[108] Op. cit. ZVEI, JEITA and AEM (2018)

[109] http://www.ecetoc.org/tools/targeted-risk-assessment-tra/

dossier[110] and was used by the Fraunhofer ITEM IPA in this case as well.[111] In contrast to the modelling carried out by Fraunhofer ITEM IPA, Wibbertmann and Hahn (2018), the lowest possible default value concentration for the substance in preparation of <1 % was chosen, based on measured concentration of TBBP-A in Taverna et al. (2017) as follows:

- Dust from pre-shredding and from the impact mill: 300 mg TBBP-A / kg;
- TBBP-A content in screen and notebook enclosures: 4,000 mg TBBP-A / kg;
- Fine-grained plastic fraction: 1,700 mg TBBP-A / kg.

The input parameters for the exposure estimation are shown in Table 6-1.

Table 6-1: Input parameters used in ECETOC TRA for worker exposure

Scenario name	Shredding of WEEE plastic and cables
Treatment setting	Professional
Duration of activity	>4 hours/day
Use of ventilation	Outdoors
Respiratory protection	No
Substance in preparation	<1 %

Source: Own compilation based on ECETOC TRA 3.1

Within the process category 24 (PROC 24), subcategories a (Process temperature< melting point: Low fugacity), thus, PROC24a with a low fugacity was chosen. This leads to the following exposure values, concentrations are given in mg/m^3:

Table 6-2: Exposure estimates with ECETOC TRA for TBBP-A in PROC 24a

Process Category (PROC)	Long-term Inhalative Exposure Estimate [mg/m^3]	Long-term Dermal Exposure Estimate [mg/kg/day]
	c= <1 %	c= <1 %
PROC 24a	2.10E-01	2.83E-01

Source: Own compilation based on ECETOC TRA 3

The exposure estimation with ECETOC TRA was made with rather conservative assumptions. The results give a rough indication on whether risk management measures at the workplace are necessary. As a rule, the DNEL for workers is taken to compare the estimated exposure to the identified limits to decide whether there is a risk expected for workers. The actual DNEL provided by the REACH registrants is 17.6 mg/m³ for inhalation exposure and 250 mg/kg bw/day for dermal exposure. The significance of these DNELs will be discussed in the section on impact and risk evaluation (section 7.2).

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[110] Swedish Chemicals Agency KEMI (2018): ROHS Annex II Dossier MCCP, Proposal for a restriction of a substance in electrical and electronic equipment under RoHS; https://www.kemi.se/global/rapporter/2018/report-4-18-rohs-annex-ii-dossier-mccp.pdf, last viewed 24.07.2018

[111] Op. cit. Fraunhofer ITEM IPA, Wibbertmann and Hahn (2018)

Monitoring data

In Sweden and Norway, serum samples of recycling plant employees have been analysed regarding TBBP-A concentrations. As presented in Table 6-3, mean concentrations were found between 0.64 and 4.0 ng/g lipid weight.

Table 6-3: Concentrations of TBBP-A reported in serum of workers

Species	No of samples	Location	Mean concentration (range) or range [ng/g lipid weight]	Reference
Workers in electronics dismantling	4	Sweden	< 1.1 - 4.0	Hagmar et al. (2000)
Workers in electronics dismantling[112]	5	Norway	1.3 (0.64 – 1.8)	Thomsen et al. (2001)
Associated workers				
Computer technicians	19	Sweden	0.54 – 1.85	Jakobusson et al.(2002)
Wiring board producers	5	Norway	0.54 (<0.1 – 0.8)	Thomsen et al. (2001)
Laboratory personnel	5	Norway	0.34 (<0.1 – 0.52)	Thomsen et al. (2001)

Source: Data collected in IARC 2015

Various TBBP-A concentrations in indoor dust and air at recycling facilities in European countries were collected from different studies by Fraunhofer ITEM IPA, Wibbertmann and Hahn (2018) as shown in the following table.

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[112] Work included manual dismantling of WEEE. Dust protection masks occasionally on a voluntary basis, Shredder located outdoor.

Table 6-4: TBBP-A concentrations in indoor dust and air in European WEEE treatment sites

Type of sample	Location		Results	Reference
Indoor dust	Switzerland	Recycling site	653 µg/ g dust	Morf et al. (2003)
	Sweden	Electronics dismantling facility, removal area	31 µg/g	Pettersson et al. (2001) cited in EU RAR 2008
	Sweden	Electronics dismantling facility, dismantling hall	4.1 µg/g	Pettersson et al. (2001) cited in EU RAR 2008
Air	Finland	Four different WEEE recycling sites	Nd – 1.1 µg/m³	Rosenberg et al. (2011)
	Sweden	Electronic recycling plant, dismantling hall	0.014 µg/m³	Tollbäck et al. (2006)
	UK	Mean from 16 individual measurements at 2 PWB shredding sites	4.58 µg/m³ (0.019 – 20.8)	DEPA (2015)

Source: compilation of studies carried out by Fraunhofer ITEM IPA, for concrete references see Appendix

Even if maximum values were found for dust samples from WEEE treatment facilities, TBBP-A concentrations in dust ranged in a similar order of magnitude compared to indoor dust samples, e.g. from offices. The authors conclude that not all processed WEEE items contain TBBP-A in significant amounts while additively incorporated TBBP-A might be released from office equipment.

The comparison of TBBP-A concentrations in air samples is misleading because air sampling strategies differed from case to case. The same applies for parameters such as protective measures, ventilation and exact WEEE treatment processes. Thus, comparing measured values with estimated data, concentrations of TBBP-A in measured air samples were two orders of magnitude (factor ~ 100) smaller than the estimation results derived from ECETOC TRA.

The potential formation of dibenzo-p-dioxins and furans[113] from TBBP-A during incineration of plastics is not further assessed. It is assumed, that in the EU, municipal waste incinerator plants and metal smelters are equipped with state-of-the-art waste gas treatment so that emissions of these pollutants into the environment are below the allowed thresholds.

In contrast, WEEE exported in non-OECD countries (e.g. in Nigeria, Ghana) is likely to be processed under very crude conditions, e.g. open burning of PWBs and plastic parts in presence of copper. Therefore, brominated dibenzo-p-dioxins and furans are likely to be released in considerable amounts. Since emission monitoring and exposure control equipment as well as the use of protective gear by workers are almost absent, the TBBP-A contained in exported WEEE is likely to contribute significantly to occupational and environmental exposure in the respective countries. Systematic exposure measurement data is not available for these countries.

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[113] Op. cit. Oeko-Institut (2008)

6.2.2. Exposure of neighbouring residents of EEE waste processing plants

No information could be identified in the course of this project about measured TBBP-A concentrations related to neighbouring residents of WEEE processing plants.[114]

6.2.3. Consumer exposure

Exposure of the general population predominantly may occur through oral uptake (e.g. via food) and through ingestion of indoor dust.

A scientific opinion of the European Food Safety Authority (EFSA) on TBBP-A and its derivatives in food[115] arrives at the conclusion that the exposure scenario based on average human milk consumption and the reported range for TBPP-A in human milk (0.06 to 37.3 ng/g fat) results in daily exposures of 0.28 to 171 ng TBBP-A/kg body weight. For infants with high human milk consumption the respective daily exposures ranged from 0.41 to 257 ng/kg bodyweight. The hypothetical worst-case dietary exposure for the specific group of adult high fish consumers[1] was 2.6 ng/kg bodyweight per day. Categorising the TBBP-A containing food samples (n=652), “Fish and other seafood” was the dominant category (~71 %), followed by “meat and meat products” (~8 %) and “milk and dairy products” (~6 %).

The inhalation of TBBP-A vapour is rather unlikely, given its low vapour pressure. Sjödin et al. (2011) confirmed that airborne TBBP-A exists primarily in a particulate phase rather than in the vapour phase. Generally, very young children will predominantly be affected via ingestion of dust compared to adults.[116] As an example, in the United Kingdom, average estimated daily intakes of TBBP-A from the ingestion of dust were 1.6 and 4.4 ng/day for adults and toddlers, respectively,[117] contributing 34 % and 90 % of their overall daily intake from air, dust and diet (Abdallah et al., 2008).

As for dust, a compilation of relevant peer-reviewed studies was reviewed by Fraunhofer ITEM IPA, Wibbertmann and Hahn (2018). Building upon a number of similar primary studies (see Table 6-5), the conclusion can be drawn that the exposure to TBBP-A would not pose elevated concern for the health of the general population. On the other hand: An evaluation by the International Agency for Research on Cancer (IARC 2015) mentioned several affirmative proofs for indoor dust being a relevant exposure route basing their opinion on the similar primary studies. In contrast to EFSA & Fraunhofer ITEM IPA, Wibbertmann and Hahn (2018), the majority of the IARC Working Group on TBBP-A considered that the strong mechanistic evidence that TBBP-A can operate through some key characteristics of carcinogens and that these can be operative in humans. This fact – together with the ubiquitous occurrence in almost all biotic and abiotic compartments worldwide – finally lead to considerations to propose an upgrade of TBBP-A to the Cancer Group 2A.

EFSA (2011) summarises that dust in homes, classrooms and cars can be an additional source of exposure to TBBP-A, particularly for children. A typical exposure scenario would be 1.2 ng/kg bw per day.[118] Comparing the exposure resulting from this scenario with the $BMDL_{10}$ of 16 mg/kg bw results in an MOE of about 1.3×10^7 that indicates that exposure of children to TBBP-A from dust does not raise a health concern. Based on the large MOEs derived for both dietary exposure and

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[114] Op. cit. Fraunhofer ITEM IPA, Wibbertmann and Hahn (2018)

[115] EFSA Panel on Contaminants in the Food Chain (CONTAM); Scientific Opinion on Tetrabromobisphenol A (TBBPA) and its derivatives in food. EFSA Journal 2011; 9 (12):2477.

[116] Op. cit. IARC report 2015; and Abdallah et al. (2016), Emerging Contaminants, 2, 73-79

[117] Not with regard to the body weight!

[118] Considering the 95th percentile TBBP-A concentration of 460 ng/g in dust.

airborne exposure through dust, the EFSA expert group concluded that it is unlikely that combined exposure through food and dust would result in a health concern.

Fraunhofer ITEM IPA, Wibbertmann and Hahn (2018) refer to the results from EFSA (2011) concerning the daily intake of TBBP-A via food (2.6 ng/kg bw) per day); and sum up their literature review on TBBP-A in house dust with the conclusion that – with some exemptions - mostly all values were below 600 ng/g dust. In their study, EU and non-EU countries were addressed while in this report only EU data is shown (Table 6-5) where in total concentrations were measured with a highest median concentration of 79 ng/g. Fraunhofer ITEM IPA, Wibbertmann and Hahn (2018) used as inhalation DNEL of 300 mg/m^3 and the oral DNEL of 2.5 mg/kg/day; applying these DNELs, Fraunhofer ITEM IPA, Wibbertmann and Hahn (2018) concludes that no risk could be expected for consumers. It should be noted that the actual DNEL for the general population for inhalative exposure according to the ECHA Brief profile on TBBP-A[119] is 4.3 mg/m^3.

The following table summarises studies reporting TBBP-A concentrations in dust from consumer environments such as houses, cars and offices, carried out in different European countries.

Table 6-5: Median concentrations (range) of TBBP-A in dust samples from consumer environments in several EU countries

Country (year of sampling)	Environment (no. of samples)	Concentration median (range) [ng/g]	Reference[120]
France (2008)	Homes (9)	44 (7-165)	Abdallah et al. 2016
	Offices (11)	79 (32-1,255)	
	Cars (7)	47 (9-66)	
UK (2007)	Homes (35)	62 (<LOD-382)	Abdallah et al. 2008
	Offices (28)	36 (<LOD-140)	
	Cars (20)	2 (<LOD-25)	
Germany (not reported)	Homes (20)	28 (3-233)	Fromme et al. 2014
Belgium (2007/08)	Homes (16)	10 (1-1,481)	Geens et al. 2009
Belgium (2008)	Offices (10)	70,4 (<LOD-212)	D'Hollander et al. 2010
	Homes (45)	11,7 (<LOD-141)	
Greece (not reported)	House dust (28)	11 (<1-630)	Wang et al. 2015
Romania (not reported)	House dust (23)	6 (<1-380)	

Sources: as indicated in the table, compilation of Wibbertmann and Hahn 2018, EFSA 2011 and IARC 2015; LOD: Limit of detection

TBBP-A was also measured in all umbilical cord samples from 16 Japanese mothers in concentrations of 16 +- 5.5 pg/ g wet weight (IARC 2015). Therefore, it has to be assumed that prenatal exposure occurs. In this period of its development the human embryo is very vulnerable towards exposure to hazardous chemicals.

The exposure of consumers is addressed in several review studies based on similar information, but different conclusions are drawn by the reviewers.

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[119] Op. cit. ECHA Brief Profile: Entry for 2,2',6,6'-tetrabromo-4,4'-isopropylidenediphenol

[120] See the details of these references in the list of references

6.3. Environmental exposure estimation

Environmental exposure estimation for TBBP-A is based on modelling of environmental concentrations (see section 6.3.1) and on monitoring data. A large amount of monitoring data has been published. Specific data is available for concentrations found near waste processing sites (see section 6.3.3). TBBP-A has also been found in remote regions and in a large number of biota (see 6.3.2).

6.3.1. Exposure modelling

Modelling of environmental concentrations has been done for TBBP-A within the EU RAR (2008). Results of modelling based on more recent data has been published by Fraunhofer ITEM IPA, Wibbertmann and Hahn (2018). They used the ECETOC TRA model, the most frequently used model under REACH for Tier 1 exposure estimates. Modelling has been performed for two different Koc values to take into account the variability and uncertainty within the assessment parameter. The following two tables show the predicted concentrations in water. For further predicted concentrations (for air, soil and secondary poisoning) see Fraunhofer ITEM IPA, Wibbertmann and Hahn (2018).

Table 6-6: Predicted Environmental Concentrations (PECs) in water for TBBP-A, Koc = 49,726 l/kg

Information	PEC
Local PEC in surface water during emission episode (dissolved)	3.62E-07 [mg.l-1]
Annual average local PEC in surface water (dissolved)	3.62E-07 [mg.l-1]
Local PEC in fresh-water sediment during emission episode	5.74E-04 [mg.kgwwt-1]
Local PEC in seawater during emission episode (dissolved)	4.69E-08 [mg.l-1]
Annual average local PEC in seawater (dissolved)	4.69E-08 [mg.l-1]
Local PEC in marine sediment during emission episode	7.45E-05 [mg.kgwwt-1]

Source: Fraunhofer ITEM IPA, Wibbertmann and Hahn 2018

Table 6-7: Predicted Environmental Concentrations (PECs) in water for TBBP-A, Koc = 147,360 l/kg

Information	PEC
Local PEC in surface water during emission episode (dissolved)	9.56E-08 [mg.l-1]
Annual average local PEC in surface water (dissolved)	9.56E-08 [mg.l-1]
Local PEC in fresh-water sediment during emission episode	3.06E-04 [mg.kgwwt-1]
Local PEC in seawater during emission episode (dissolved)	1.78E-08 [mg.l-1]
Annual average local PEC in seawater (dissolved)	1.78E-08 [mg.l-1]
Local PEC in marine sediment during emission episode	5.72E-05 [mg.kgwwt-1]

Source: Fraunhofer ITEM IPA, Wibbertmann and Hahn 2018

6.3.2. Monitoring data: remote regions, biota

TBBP-A has been first detected in the environment 1983 in sediments from the Neya River in Japan, in concentrations at a level of 20 ng/g in sediments (Watanabe et al. 1983). In a large number of studies TBBP-A has been found in various biotic and abiotic matrices from different parts of the world over the past few years (IARC 2015).

Recently, Fraunhofer ITEM IPA, Wibbertmann and Hahn (2018) summarised the findings of general monitoring data of TBBP-A in abiotic matrices in areas which have not been used for waste treatment (see the following table).

Table 6-8: Environmental Exposure/ monitoring data for TBBP-A not related to waste treatment (dw: dry weight; LOD: Limit of detection; n.d.: not detectable)

	Matrix	**Minimum**	**Maximum**	**Unit**
1	**STP sludge** (Italy, Korea, Spain, Sweden, Germany, NL, UK, Ireland, Finland, Canada)	<0.01	617	ng/ g
2	**Sediment** (Arctic environment, China, Norway, Czech Republic, Germany, Japan, UK, NL, Asia (general), USA)	n.d.	330,000	ng/ g dw
3	**Air** (Arctic environment, Northeast Atlantic, Russia, US, Japan, China, UK, Sweden, Germany, “8 EU countries”)	< LOD	1,800	ng/m^3
4	**Soil** (Israel, US, China, Switzerland, Spain)	5	45,000	ng/g
5	**Water** (France, Germany, Japan, Finland, NL, UK, Canada, China, Belgium, Sweden)	< LOD	130	ng/l

Source: Fraunhofer ITEM IPA, Wibbertmann and Hahn 2018

Fraunhofer ITEM IPA, Wibbertmann and Hahn (2018) conclude that the available monitoring data suggest that WEEE treatment facilities are not the main sources of release for TBBP-A. More relevant sources are manufacturing plants (BFR manufacturing or EEE manufacturing). They further conclude that usually the measured data are below the PNEC for the respective environmental compartment:

> *“Usually, all water samples are below the PNECs for fresh and marine water (0.0013, 0.00025 mg/l). However, one study in China results in values in lake water up to 4.87 µg/l in the summer month. All other studies from China results in significantly lower values, The highest values in Europe were found in river and lake water in Poland with values between 0.26 and 0.49 µg/l[37].*
>
> *For soil and sediment some values are found as well which are above the corresponding limit values (sediment 12.4 mg/kg dw (freshwater), 2.48 mg/kg dw (marine water), 0.055 mg/kg dw (soil)). Again the covered range is large for all compartments, going over several orders of magnitude.*
>
> *For sediment, two values are above the PNEC (see details in the Annex of Fraunhofer ITEM IPA, Wibbertmann and Hahn (2018)): One measured in 1977 in the US near a BFR manufacturing site (330 mg/kg dw) and one from the UK (9.8 mg/kg dw), all other values are below 1 mg/kg dw.*
>
> *For soil also two values are affected: One from Israel measured near a contaminated site (450 mg/kg dw) and one from China, measured near a BFR manufacturing site (up to 7.76 mg/kg dw; mean 0.672 mg/kg dw). All other values are below the PNEC.*
>
> *Again this indicates that safe use, including manufacture of TBBP-A, is in general possible. However, under uncontrolled conditions without appropriate.”*

A summary of monitoring data from biota is given in IARC (2015). Accordingly, TBBP-A has been found in humans (in serum, adipose tissue, breast milk, cord serum) as well as in animals (common whelk, sea star, hermit crab, fish (e.g. whiting, cod, hake, eel, vendace trout, bull shark), African penguins, cormorant, eggs of predatory birds, seals and dolphins). Examples for concentration ranges found in different species of animals are given in the following table.

Table 6-9: Environmental exposure: TBBP-A in animals. Unit: nanogram / g lipid weight

	Species, matrix, location	Concentration mean / range	Unit
1	Common whelk, whole body, North Sea	5.0 - 96	ng/g lip.w.
2	Sea star, whole body, Tees estuary, UK	205	ng/g lip.w.
3	Fish, muscle, Czech Republic	5 - 203	ng/g lip.w.
4	Bull shark, muscle, Florida USA	0.03 – 35.6	ng/g lip.w.
5	Predatory birds, egg, Norway	<0.003-0.013	ng/g lip.w.
6	Harbour porpoise, blubber, North Sea	83 / 0.1 – 418	ng/g lip.w.
7	Bottlenose dolphin, blubber, Florida, USA 0,05 – 8.48	0.05 – 8.48	ng/g lip.w.

Source: IARC 2015

6.3.3. Monitoring data: waste management

A recent summary of monitoring data of TBBP-A in environmental compartments near waste-treatment sites and landfill sites has been given by Fraunhofer ITEM IPA, Wibbertmann and Hahn (2018). Accordingly, most concentrations are not significantly higher than the range of values found at other points of the environment: e.g. in water, one concentration could be found (68 pg/l). In sediments, concentrations range between 0 and 21 ng/g dw (up to 44.4 ng/g ww). In soil, concentrations have been found in the range from < 0.025 – 1,800 ng/g dw.

Taken together, this data indicates that disposal and treatment of WEEE can lead to release of TBBP-A if emission control is not properly implemented. If such standards are not met, high TBBP-A emissions can take place. Leaching studies with extractions of housings and printed wiring boards show that TBBP-A can be leached out from WEEE with a leaching rate of usually less than 1 % (Fraunhofer ITEM IPA, Wibbertmann and Hahn 2018):

"*Available leaching studies show that the leaching rate of TBBP-A is depending on the pH of the extracting liquid, with higher pH values obviously giving higher leaching rates. However, all studies indicate comparably low leaching rates of usually less than 1 %. Concentrations in extraction liquid go up to 0.012 mg/l which is above the PNECs for fresh and marine water as suggested by the EU RAR (0.0013 and 0.00025 mg/l). However, concentrations in laboratory extraction studies on only one product type (printed wiring boards, housings) are not representative for actual concentrations found in leachate. Concentrations found in landfill leachate go up to 0.00062 mg/l. This is still above the PNECs, however, the measured concentrations include values before waste water treatment, which usually happens before leachate is released into a water compartment (see ECHA guidance R18). After on-site treatment and dilution happening during the release concentrations are expected to be below the applicable PNECs.*

Particulate, "leachate sediment" and sludge concentrations are in the ng/g region and thus, all below the PNECs for soil and sediment."

7. IMPACT AND RISK EVALUATION

The substance evaluation of the human health and environment hazards of TBBP-A under REACH is currently ongoing. EU wide, no conclusion is reached so far on whether TBBP-A has endocrine disruptive properties and whether it is to be considered as PBT, respectively. Any evidence regarding one of these properties may affect the impact and risk evaluation here at hand because as a result of either properties, the current DNELs and PNEC may no longer be applicable:

- As pointed out in section 3.3, there are substantial structural similarities of TBBP-A and bisphenol A. In the document on the identification of bisphenol A as an SVHC due to its endocrine disrupting properties, the structural alerts have been described that are necessary for the different modes of action for BPA, the estrogenic activity, the anti-androgenic activity and the thyroid hormone activity. Having in mind that TBBP-A is currently under review by the ED expert group of ECHA concerning its possible endocrine disrupting properties, it is suggested here that similar hazards are to be expected for TBBP-A as for BPA.
- Though the evaluation whether TBBP-A is a PBT substance is still ongoing, substances with PBT properties have the potential to persist and accumulate in the environment. ECHA (2017b) emphasises that the effects of such accumulation are unpredictable in the long–term and that such accumulation is in practice difficult to reverse as cessation of emission will not necessarily result in a reduction in chemical concentration. They circulate in the global environment for long times and if further released the environmental concentration is constantly increasing.

As explained below, workers and consumers as well as the environment are subjected to exposure, which, however, on the basis of the threshold values, is not assessed as posing a risk. However, the risk characterisation ratios provided by the study of the Fraunhofer ITEM IPA, Wibbertmann and Hahn (2018) would no longer be valid if TBBP-A were to be recognised as endocrine disrupter and as a type of PBT substance.

As for human health it should further be noted that according to the Fraunhofer ITEM IPA, Wibbertmann and Hahn (2018), the DNELs available were provided by the REACH registrants (industry). These DNELS have not been officially reviewed by ECHA or by an EU expert group. However, they have decreased significantly in recent years.

As pointed out earlier, exposure is mainly due to the additive use of TBBP-A in plastic enclosures and housings. Stakeholders, e.g. the ZVEI (2018) pointed out that the manufacture of EEE containing additive applications of TBBPA would not take place in Europe. Based on this information, it is assumed that plastic containing additive TBBP-A occurs solely in imported goods.

7.1. Impacts on WEEE management as specified by Article 6(1)a

Article 6(1)a demands for a potential Annex II candidate the assessment of whether a substance/ substance group “*could have a negative impact during EEE waste management operations, including on the possibilities for preparing for the reuse of WEEE or for recycling of materials from WEEE*”.

According to Annex VII of the WEEE Directive,[121] plastics used in EEE containing brominated flame-retardants have to be removed from any separately collected WEEE. It is understood that the presence of a restricted BFR causes disproportionate costs for plastic recyclers because expensive testing techniques, such as XRT/XRF technologies, are necessary to distinguish plastic parts

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[121] Directive 2012/19/EU of the European Parliament and of the Council of 4 July 2012 on waste electrical and electronic equipment (WEEE) (recast)

containing restricted BFR from non-legacy BFRs. However, the use of XRT/XRF spectrometers appear to be best available technology (BAT), which is not current state of the art at most of the WEEE- polymer recycling businesses. Contemporary semi-automatic separation processes may not be able to identify TBBP-A containing ABS from other, possibly restricted additives (e.g. OctaBDE). This was the reason for DEPA (2010) to conclude that the presence of additively used TBBP-A plastic parts may hinder the recycling of the corresponding plastic. Given the low profit margin in recycling of WEEE-plastic, the presence of bromine is usually a reason to send the material to incineration instead of using more advanced separation technologies.

It is therefore concluded that TBBP-A used as additive flame retardant has a double-edged impact on the recycling of WEEE: On the one hand, it supports the separation of plastics containing flame among other non-flame-retardant plastic types (due to its higher density). On the other hand, it necessitates investment in XRT/XRF technologies in order to maintain compliance of the recycled plastic to the Annex VII on the selective treatment for materials and components of WEEE.

As mentioned before, the concentration of residual TBBP-A in resins is low so that the substance does not contribute to the classification of printed wiring board as hazardous waste according to the Commission’s decision 2014/955/EU.[122]

7.2. Risks for workers and neighbouring residents

According to section 5, shredding of WEEE and the further processing of plastic waste are the most relevant TBBP-A exposure scenarios.

Fraunhofer ITEM IPA, Wibbertmann and Hahn (2018) compared the modelled data for exposure according to ECETOC TRA to the DNELs as provided by the REACH registrants that result in a risk characterization ratio (RCR) value below 1. Assuming additionally that not all shredded material contains housings and not all housings have been treated with TBBP-A as a flame retardant, Fraunhofer ITEM IPA, Wibbertmann and Hahn (2018) do not expect risks for workers.

It is stressed again that this conclusion is based on DNELs that do not take into account potential endocrine disrupting properties. Workers of EEE waste processing plants are exposed to TBBP-A which is suggested by exposure estimations, by measurements of TBBP-A in EEE waste streams (see Taverna et al. 2017) and results from human biomonitoring (concentrations of TBBP-A reported in serum of workers) (for details see section 6.2.1). Based on these considerations and in contrast to Fraunhofer ITEM IPA, Wibbertmann and Hahn (2018), an impact on worker in EEE waste processing plants is seen here.

If DNEL values of BPA are taken into account as suggested in section 3.3, in order to reflect the potential endocrine disrupting properties of TBBP-A, the estimated exposure by ECETOC TRA rather indicates a risk for workers via dermal exposure then via inhalation.

For workers in third countries where crude WEEE treatment takes place, additional health concerns arise from hazardous transformation products in uncontrolled combustion, grilling, desoldering, uncontrolled dumping of residues, and generally uncontrolled treatment under crude circumstances.

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[122] 2014/955/EU: Commission Decision of 18 December 2014 amending Decision 2000/532/EC on the list of waste pursuant to Directive 2008/98/EC of the European Parliament and of the Council Text with EEA relevance

7.3. Risks for consumers

As mentioned above, the risk assessments conducted by Fraunhofer ITEM IPA, Wibbertmann and Hahn, (2018) as well as previous assessments (EFSA, 2015), all referring to quite the same set of literature data, concluded that the exposure via indoor dust does not pose a risk to the general population. Nonetheless, IARC (2015) draws a contradictory conclusion.

Based on assumptions on the house dust ingestion and inhalation as documented by Oomen et al. (2008)[123] and the identified maximum concentration of TBBP-A in house dust (1,480 ng/g) a daily exposure via dust has been estimated as shown in the following table.

Table 7-1: Worst case exposure to TBBP-A via house dust (ingestion + inhalation)

Population	Exposure
Child	0.015 mg/day/kg
Adult	0.0013 mg/day/kg

Source: Fraunhofer ITEM IPA, Wibbertmann and Hahn 2018

If DNEL values of BPA are taken into account as mentioned in section 3.3, in order to reflect the potential endocrine disrupting properties of TBBP-A, a risk characterisation ratio of > 1 is reached for children that indicates a risk. The DNEL for bisphenol A for oral exposure is at 4 µg/kg body weight per day.

7.4. Risks for the environment

The exposure modelling for PECs of Fraunhofer ITEM IPA, Wibbertmann and Hahn (2018) does not indicate a risk for the different environmental compartments if the PNECs as presented in section 4.4 are taken into consideration. The highest risk characterisation ratios are reached for the soil compartment which reflects the adsorption behaviour of TBBP-A to particles. However, these considerations do not take into account the persistent properties of TBBP-A.

The monitoring data in biota can be summarised in a way that TBBP-A is frequently detected and can be seen as a ubiquitous contaminant. This indicates that it is continuously released into the environment. It is an indication for its persistency and thus an indication that the normal risk assessment, by means of the ratio of the expected environmental concentration (Predicted Environmental Concentration, PEC) and an estimated non-effect threshold (Predicted No-effect concentration, PNEC), is not applicable. Substances with PBT properties have the potential to persist and thereby accumulate in the environment. ECHA (2014) emphasises that the effects of such accumulation are unpredictable in the long–term and that such accumulation is in practice difficult to reverse as cessation of emission will not necessarily result in a reduction in chemical concentration. They circulate in the global environment for long times and if further released the environmental concentration is constantly increasing.

For third countries, where informal recycling of WEEE take place, Fraunhofer ITEM IPA, Wibbertmann and Hahn (2018) note that *“exposure to TBBPA and its decomposition products may*

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[123] Oomen, A.G.; Janssen, P.J.C.M.; Dusseldorp, A.; Noorlander, C.W. (2008): Exposure to chemicals via house dust; https://www.rivm.nl/bibliotheek/rapporten/609021064.html

Also cited in: European Chemicals Agency ECHA (2015): Guidance on Information Requirements and Chemical Safety AssessmentChapterR.15: Consumer exposure estimation; Draft (Public)Version 3.0 October 2015; https://echa.europa.eu/documents/10162/23047722/draft_201510_r15_peg_infreq_uses_en.pdf/4c52b39e-ca5e-4cb2-a6e3-b8020dc8d047 *be higher. Available monitoring data suggest that soil will probably be the most critical compartment for TBBPA exposure in these cases. Concerning degradation products information cited in the previous section concerning PCDD/F levels as well as further information published e.g. by Hu et al. [149] also suggests that other environmental compartments will show increased concentrations of these contaminants. However, it is not possible to quantify the influence of TBBPA on the overall exposure to these potential decomposition products."*

8. ALTERNATIVES

The discussion on alternatives addresses the two application areas - reactive applications in PWBs and additive applications in plastic housings.

In relation to epoxy resins (**reactive use of TBBP-A in PWBs**), it is understood that industry is actively investigating substitution strategies for brominated flame retardants. The stakeholder contributions to support this study mention that halogen-free PWB laminate materials were available.[124] However, no concrete alternatives are proposed as they would not have all necessary safety approvals and greater percentages of the substitutes would be required within the products. In addition, ASD state that "*the substitutes are unlikely to perform sufficiently well when subjected to heat and vibration in high-stress environments"* and TMC points out that "*they do not exist for all applications, especially in high-frequency circuitry."*

Nonetheless, the most successful and already applied alternatives to TBBP-A in PWBs are phosphorus compounds like DOPO (9,10-Dihydro-9-oxa-10-phosphaphenanthrene-10-oxide), poly phosphates or metal phosphinates, from time to time in combination with inorganics synergists like ATH or silica, bound to epoxy resins. Concerning DOPO, moderate human health concern is assumed but this compound and its derivates are expected to be highly environmental persistent.

Commonly used substitutes for **TBBP-A in housings** for EEE (additive use) also include halogen-free organic phosphorus compounds. The human health hazards of the organophosphate esters are estimated to be lower than those of TBBP-A though some substitution candidates still meet the PBT criteria regarding the environmental risks.

In this area elimination is also possible through the substitution of polymers such as ABS and HIPS with polymers such as PC and PPE.[125]

8.1. Availability of substitutes / alternative technologies

In the following information is specified summarising the potential substitutes separately presented for reactive (see also Table 8-1) and additive (see also Table 8-2) TBBP-A applications.

Alternatives to TBBP-A in reactive applications

In relation to epoxy resins, it is understood that industry is actively investigating substitution strategies for brominated flame retardants. In some cases, this may only entail a substitution of one brominated flame retardant by other types rather than by bromine free alternatives. However, it is also clear that non-halogenated flame retardants are in development for such purposes. Rakotomalala et al.[126] mention that since disputable additives can leach out of a polymer while being processed and/or while being used, there is always a potential health risk when such systems are used. In addition, the environmental and end-of-life issues have led to strong efforts in replacing halogenated systems.

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[124] Op. cit. TCM (2018)

[125] Op. cit UBA (2008): This source specifies "*this goes hand in hand with the substitution of polymers such as PC and PPE for ABS and HIPS, or the use of polymer blends*". Semantically PC and PPE are referred to as alternatives for both ABS and HIPS using TBBP-A. As current data suggests that only ABS is a housing material in which TBBP-A is used, this data has been reformulated here in this respect.

[126] Rakotomalala, M.; Wagner, S.; Döring, M.: Recent Developments in Halogen Free Flame Retardants for Epoxy Resins for Electrical and Electronic Applications. *Materials* 2010, *3*, 4300-4327; Data presented by Rakotomalala et al show that bromine-based flame retardants account for only 10% market share of flame retardants used for EEE. Non-halogenated substitutes account for a larger market share: metal hydroxide-based flame retardants (56%), non-halogenated phosphorus ones (9%) and melamine-based ones (3%).

Table 8-1: Existing alternatives for reactively used TBBP-A in epoxy resins

Category	Functional principle	Name/ specification	Advantages and limitations in application	Hazardous properties
Nitrogen components		Melamine polyphosphate based products		May show moderate concerns for human health effects, high concerns for reproductive effects and a high tendency for persistence (modelled data).
		Melamine cyanurate	Advantage of cheap and high availability but poor flame retardancy and high dosages required.	
Non-halogenated phosphorus FR	Function as a mono- or bifunctional cross-linking agent and in combination with aluminium-hydroxide. [127] Converted into a phosphorus-containing epoxy material.	Non-halogenated PFR in general	Have a higher moisture absorption than TBBP-A based.	The inorganic part of phosphor containing flame retardants “is not harmful and does not tend to form toxic gases since phosphorus is mostly locked into the char.[128]
		DOPO (9,10-Dihydro-9-oxa-10-phosphaphenanthrene-10-oxide); Derivates: • DOPO-HQ • DOPO-PEPA[129] • EDA-DOPO[130] • Ethylen-(DOP)2	• Compared to TBBP-A, this substitute has higher costs which can be lowered with ATH or silica as fillers, or in combination with metal phosphinates; • is monofunctional, meaning that there is more potential for releases from products compared to bifunctional alternatives (such as TBBP-A).	• According to REACH Registration data, causes allergic skin reactions and irritation of the eye[131]. Furthermore, the US EPA identifies: • moderate hazard concerning carcinogenicity, developmental and neurological effect; • moderate concern for aquatic toxicity; • a high tendency for persistence.
		FyrolPMP: phosphorous content of 17.5 %[132]	**Hazardous properties** • moderate hazard for reproductive, developmental, neurological and repeated dose effects (estimated); • high concerns for acute/chronic aquatic toxicity (estimate); • a very high tendency for persistency and bioaccumulation[133].	
		Dow XZ-92547: reaction product of an epoxy phenyl novolak with DOPO	**Hazardous properties** Related from the structure of the components • phosphinate esters: environmental toxicity; • epoxy groups/epoxides: dermal sensitization, cancer, reproductive effects, developmental toxicity; • organophosphorus compounds: neurotoxicity.	
		Poly 2-(6-oxido-6H-debenzo(c,e)(1,2)oxaphosphorin-6-yl)- 1,4-benzenediol (POBPP) *(no further information available)*		

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[127] Op. cit. Rakotomalala, M. et. al 2010

[128] *Under thermal stress, the major part of phosphorus is oxidised to phosphorus pentoxide (P_2O_5) which then hydrolyses to polyphosphoric acid ($H_xP_yO_z$). Polyphosphoric acid in particular plays an important role in creating carbonaceous char*.” The PO and PO2 derivates that are formed when phosphorus FR react via the gas phase can be rapidly oxidised to P_2O_5 which in turn forms polyphosphoric acid *(*Rakotomalala et al, 2010).

[129] Yan Zhang, Bin Yu, Bibo Wang, Kim Meow Liew, Lei Song, Chengming Wang, and Yuan Hu: Industrial & Engineering Chemistry Research 2017 56 (5), 1245-1255

[130] N.M. Neisius, M. Lutz, D. Rentsch, P. Hemberger, S. Gaan: *Synthesis of DOPO-based phosphonamidates and their thermal properties*. In: *Ind. Eng. Chem. Res.* Band 53, Nr. 8, 2014

[131] REACH registration on ECHA website

[132] A reaction product of Phosphonic acid, P-methyl-, diphenyl ester, polymer with 1,3-benzenediol (= Aryl alkylphosphonate)

[133] Environmental degradation of this polymer by hydrolysis or direct photolysis is not expected to be significant as the functional groups present do not tend to undergo these reactions under environmental conditions. Possible degradation products from sequential dephosphorylation are phosphinates, phenol or resorcinol. Op. cit. US EPA 2015

Fillers	Applicable in combination with other flame retardants	Aluminium diethylphosphinate and silica	(no further information available)	
Metal-based substitutes	Will not be covalently integrated in the surrounding polymer matrix.	Metal-based FR in general	Are to be considered rather as additives and may also distort the technical performance (e.g. dielectric properties) of PWB.	
		Red phosphor in combinations with ATH or MDH	Red phosphor can form phosphine (PH3) and acidic oxides under hot and humid conditions.	Highly flammable and handling is difficult until it is incorporated into the polymer. Traces of phosphine and corrosive phosphorus acids are generated under moist conditions. Moreover, red phosphorus is toxic to aquatic organisms.[134]
		Metal hydroxides	• Cheap and easy to obtain; • High loadings are a condition for effective flame-retardant effect; • Looking at ATH, the use is only possible under low temperature conditions. In contrast, MDH is usable at ~330 °C due to an endogenic reaction under water release.	are understood to be non-toxic and environmentally friendly

Source: Frauenhofer ITEM IPA, Wibbertmann and Hahn 2018, US EPA 2015 and Morose, G. 2006 ;other sources are cited in the footnotes

In addition, on the material level, alternative epoxy resin material could be applied aiming to phase out halogenated flame retardants (elimination) e.g. non-flammable resins or those materials with which halogen free flame retardants are applicable. According to Morose:

- for low-end applications of wiring boards, less expensive resins such as phenolics, melamines, vinyl esters, and polyesters may be used;
- while for high frequency applications, poly(tetrafluoroethylene) (PTFE) are applicable;
- for high temperature applications, PTFE, other fluoropolymers, cyanates and epoxy-PPE blends or even ceramics are an alternative whereas cyanates, PTFE, and inorganic substrates are usually inherently flame retardant."[135]

In general, estimations made by Bergendahl et al.[136] suggest, that costs will increase by approximately 35-50 % for the manufacture of printed wiring boards if a switch to halogen free resins is performed. In addition, the cycle time, i.e. the maximum time allowed at each workstation in the assembly line to complete its assembly tasks on the board, may increase.

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[134] Weil, Edward D., and Levchik, Sergei, A.: Review of Current Flame Retardant Systems for Epoxy Resins, Journal of Fire Sciences, Vol. 22, January 2004 (cited by Morose, 2006)

[135] Op. cit. Frauenhofer ITEM IPA, Wibbertmann and Hahn (2018)

[136] Bergendahl, C.G., et al.: Environmental and economic implications of a shift to halogen-free printed wiring boards. Electronics Goes Green 2004 (Plus): Driving Forces for Future Electronics, Proceedings, 2004: p. 783-788.

Alternatives to TBBP-A in additive applications

Whereas **additively used TBBP-A** was substituted by (organo-)phosphorus or nitrogen FR in polyurethane foams – to name one example,[137] this cannot be adapted directly to EEE applications because the functional requirements may differ from case to case.

From the available data, it can be understood that for obtaining flame retardancy in additive applications either other brominated flame retardants are applied or various non-halogenated flame retardants.

- Other brominated compounds that provide flame retardancy, e.g. Decabromodiphenylehter (decaBDE) or brominated epoxy oligomers (BEOs),[138] do not represent a legally acceptable substitute since they are themselves prohibited under various legislation including RoHS (as part of the prohibition of polybrominated diphenyl ethers), and Annex A of the Stockholm Convention. Thus, these substitution candidates are not further addressed here.
- As for non-halogenated substance substitutes, these include halogen-free organic phosphorus compounds. The human health hazards of the organophosphate esters are estimated to be lower than those of TBBP-A though some substitution candidates still meet the PBT criteria regarding the environmental risks.

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[137] According to Zevenhoven (2004), the use of brominated flame retardants (BFRs) in polyurethanes in form of an additive FR has been in decline already back in 2004. The reasons for decreasing use were environmental and health concerns. Moreover, flame retardants based on (organo-)phosphorus or nitrogen alternatives were becoming more common. PU foams are often flame-retarded using phosphate polyols, which contain ~10 %-wt phosphorus. The open cell structure of PUF foams makes flame retardation difficult and increasing the tendency of the foam to char is an important effect. For PUR foams additive flame retardants are used.

[138] Posner, S.: Survey and technical assessment of alternatives to TBBPA and HBCDD. 2006, KEMI: Sweden; and op. cit. DEPA 2010

Table 8-2: Possible alternatives for the additive use of TBBP-A in housings

Category	Functional principle	Name/ specification	Advantages and limitation in application	Hazardous properties
Metal hydroxides	Often used as synergists with phosphorus based flame retardants	• Aluminium hydroxide (ATH) • Magnesium hydroxide (MDH)	Very high loadings (~30–60 %) are required to obtain flame retardancy. Thus, it cannot be used in applications where the high loadings may affect processing and required material properties.	Are understood to be non-toxic and environmentally friendly.
Zinc borate	Halogen-free application with silica[139]	Tradename *Firebrake*, is described as *"combines the best of zinc and boron oxides with water release"*.[140]	Only applicable in low temperature environments.	Toxic to aquatic organisms, but is not expected to bio-concentrate. However, at high concentrations, it can be harmful to boron sensitive plants[141]
Non-halogenated organophosphorus FR	In combination with PPE/PS or PC/ABS blends, in parts accompanied by ATH	• Resorcinol-bis-diphenylphosphat (PBDPP); • Resorcinol-diphosphat; • Bisphenol-A-bis-diphenylphosphat (BPA-BDPP); • Bisphenol-A-diphosphat; • Triphenylphosphat (TPHP); • Diphenyl-cresylphosphat; • Aluminium-diethylphosphinate;		The inorganic part of phosphor containing flame retardants "*is not harmful and do not tend to form toxic gases since phosphorus is mostly locked into the char*."[142] Structural alerts:[143] • Phosphinate esters - environmental toxicity (aquatic toxicity); • Organophosphorus compounds – neurotoxicity; • Phenols (for the hydrolysis product) – neurotoxicity. Further specific hazardous properties can be read in Table 8-3.

Source: US EPA 2015, DEPA 2015 and Morose, G. 2006

UBA (2008) mentions that PC and PPE could be used as alternatives on the material level for ABS so as to eliminate the use of TBBP-A[144]. For now, it is not yet clear to which extent, housing materials used for other equipment could substitute ABS/TBBP-A systems.[145]

8.2. Hazardous properties of substitutes

In general, when substituting one brominated flame retardant for another, the change in hazardousness shall be determined by the substance to be applied as an alternative, resulting in

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[139] Op. cit. Morose (2006)

[140] https://www.borax.com/products/firebrake (last access 24-10-2019)

[141] HDP User Group International, Inc., Design for Environment – Phase II, January, 2004; Gardner, Donald, et al, Toxicological Risks of Selected Flame-Retardant Chemicals, National Academy Press, Washington D.C., 2000 (cited by Morose, 2006)

[142] See footnote 128

[143] Op. cit. US EPA (2015)

[144] Op. cit UBA (2008)

[145] Op. cit. Morose (2006)

either a higher, similar or lower toxicity. Detailed information on hazardous properties of substitutes categories are presented in the tables above.

In a report published by US EPA 2015, **ten flame-retardant** chemicals and resins **for FR4 laminate materials for PWBs** were evaluated in relation to their hazardous properties. It is explained that the level of available information on human health and environmental toxicity varies widely between flame-retardant chemicals. Little information exists concerning many of the alternative flame-retardant materials evaluated and thus EPA used the tools and expertise developed for the New Chemicals Program to estimate the potential impacts of flame retardants for which no experimental data were available. Unfortunately, the evaluation of the chemicals and resins relates mainly to trade names, which makes it impossible to interpret and assess the results in the dossier at hand.

On the environmental fate of DOPO and its hydrolysis product [2-(2'-hydroxyphenyl)phenyl] phosphonic acid, US EPA (2015) explains that they are expected to be found primarily in soil and to a lesser extent, in water. Both are expected to be highly mobile in soil based on an experimental Koc value. These compounds have the potential to migrate from soil into groundwater. In the atmosphere, DOPO is expected to exist in both the vapour and particulate phase, based on its vapour pressure and [2-(2'-hydroxyphenyl)phenyl] phosphonic acid is expected to exist primarily in the particulate phase. Vapor-phase DOPO is expected to have limited potential for photodegradation. Particulates will be removed from air by wet or dry deposition.

In the consultants' perspective, seeing as DOPO is monofunctional and has a higher potential for release than TBBP-A, the environmental fate could be a reason for concern where DOPO emits into the environment. Looking at the specified hazardous properties also raises concern in this regard, though certainty is not clear given that there is currently no harmonised CLP classification[146]: The REACH registration data refers to possible skin reactions and eye irritations. The US EPA identifies DOPO as a moderate hazard in relation to cancer, neurological effects and aquatic toxicity, while also referring to its high tendency for persistence. Though additional studies on the toxicity of DOPO may be needed, this suggests that DOPO may also be associated with hazardous concerns.

As it comprises one of the more promising alternatives for **TBBP-A applied in additive uses**, the category of the **organophosphates** is further addressed as follows:

According to REACH[147], from this group the following classifications are specified

- Triphenylphosphate is classified as:

very toxic to aquatic life;

toxic to aquatic life with long lasting effects; and

potential endocrine disruptor.

- Tricresylphosphate is classified as

toxic to aquatic life with long lasting effects;

suspected as mutagenic and skin sensitising.

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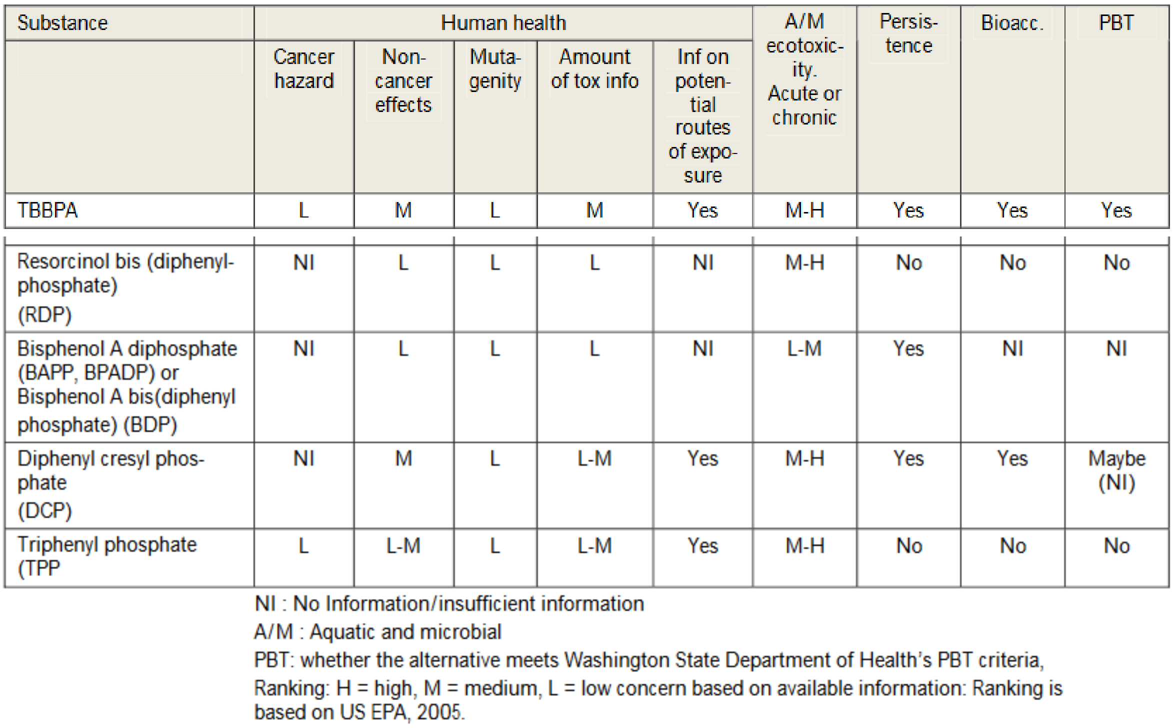
[146] The REACH Registration dossier submitted refers to H317 (may cause an allergic skin reaction) but does not specify further classification. See https://echa.europa.eu/de/information-on-chemicals/cl-inventory-database/-/discli/details/104051

[147] Op. cit. ECHA Registered Substance Database: Entry for Tricresylphosphate & Triphenylphosphate

The following table summarises the persistence, bioaccumulation potential and toxicity information for other selected alternatives of the organo-phosphorus group.[148]

Table 8-3: Human health and environmental impact indicators for different organo-phosphorus based FR as compared to TBBP-A



Substance	Human health					A/M ecotoxicity. Acute or chronic	Persistence	Bioacc.	PBT
	Cancer hazard	Non-cancer effects	Mutagenity	Amount of tox info	Inf on potential routes of exposure				
TBBPA	L	M	L	M	Yes	M-H	Yes	Yes	Yes
Resorcinol bis (diphenyl-phosphate) (RDP)	NI	L	L	L	NI	M-H	No	No	No
Bisphenol A diphosphate (BAPP, BPADP) or Bisphenol A bis(diphenyl phosphate) (BDP)	NI	L	L	L	NI	L-M	Yes	NI	NI
Diphenyl cresyl phosphate (DCP)	NI	M	L	L-M	Yes	M-H	Yes	Yes	Maybe (NI)
Triphenyl phosphate (TPP	L	L-M	L	L-M	Yes	M-H	No	No	No

NI : No Information/insufficient information

A/M : Aquatic and microbial

PBT: whether the alternative meets Washington State Department of Health's PBT criteria,

Ranking: H = high, M = medium, L = low concern based on available information: Ranking is based on US EPA, 2005.

Source: Danish EPA 2010

8.3. Data basis for alternatives and uncertainties

It is understood that alternatives exist and are also applied in some cases. Though data is not always detailed there are indications that alternatives are already in use by certain manufacturers, particularly among manufacturers of ICT products.

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[148] **Data** from Washington State (2006): Polybrominated Diphenyl Ether (PBDE). Chemical Action Plan: Final Plan. Department of Ecology Publication No. 05-07-048. Washington State Department of Health. **Layout**: Danish EPA 2010 Inclusion of HBCDD, DEHP, BBP, DBP and additive use of TBBPA in annex IV of the Commission's recast proposal of the RoHS Directive - Socioeconomic impacts

Some companies restrict the use of halogenated substances in all materials and components on a voluntary base. For example, companies like Apple[149], Dell[150], Lenovo[151], HP[152] and Samsung[153] have TBBP-A on their supply chain specifications for use of restricted substances in products with thresholds of 900 ppm (HP, Apple, Samsung) or 1000 ppm (Lenovo, Dell). These thresholds are quite high for the case of unreacted traces of TBBP-A when applied in reactive uses (epoxy laminates in PWBs). It is thus not clear whether these companies use alternatives to TBBP-A in FP4 applications in PWBs, or whether the voluntary restriction is complied with given the very low amounts of unreacted TBBP-A left in the final product. In this respect, most companies do not specify the application form of TBBP-A and the restriction is understood to apply to all forms which result in higher concentrations in the final product. In contrast, Lenovo specifies reactive TBBP-A as an exemption to their TBBP-A threshold, whereas Samsung includes reactive TBBP-A in the restrictions. The 1000 ppm threshold corresponds to 0.1 % per weight which is the threshold applied for most RoHS restricted substances of Annex II. In addition, this threshold is in line with the thresholds for "low halogen" presented in an iNEMI statement from 2009 mentioned above. Apple states that the company "*replaced brominated flame retardants […] using safer metal hydroxides and phosphorus compounds in their place.*"[154] DEPA 2010 present non-halogenated polymer-flame retardant combinations used by important European producers of TV-sets. The producers were mostly using different polymer blends (PC/ABS, PS/PPE, HIPS/PPO) in combination with non-halogenated flame retardants but the actual flame retardants were not reported.

An additional proof for the application of halogen-free housings is the fact that phosphorous based flame retardants in EEE enclosures (e.g. LCD TVs) are reported to be found in the waste stream.[155]

The stakeholder contributions to support this study mention that halogen-free PWB laminate materials were available.[156] However, no concrete alternatives are proposed as they would not have all necessary safety approvals and greater percentages of the substitutes would be required within the products. In addition, ASD state that "*the substitutes are unlikely to perform sufficiently well when subjected to heat and vibration in high-stress environments*" and TMC points out that "*they do not exist for all applications, especially in high-frequency circuitry.*"

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[149] Apple (2019): Environmental Responsibility Report 2019 Progress Report, covering fiscal year 2018;
https://www.apple.com/environment/pdf/Apple_Environmental_Responsibility_Report_2019.pdf
Apple Regulated Substances Specification 069-0135-K, September 2018;
https://www.apple.com/environment/pdf/Apple_Regulated_Substances_Specification_Sept2018.pdf (assessed 07.11.2019)

[150] Dell Specification, Materials Restricted for Use, Document Number: ENV0424 Revision:A03-00;
https://i.dell.com/sites/doccontent/shared-content/solutions/en/Documents/ENV0424-A02.pdf (assessed 07.11.2019)

[151] Lenovo Engineering Specification 41A7731, Baseline Environmental Requirements for Lenovo Products, Materials and Parts; 01 May2019, Version 7.5; https://www.lenovo.com/us/en/pdf/41A7731.pdf (last assessed 07.11.2019)

[152] HP Standard 011 General Specification for the Environment, HX-00011-00, 26-Jul-2018;
(last assessed 07.11.2019)

[153] Samsung Electronics, Standards for Control of Substances used in products (SEC Registration No. 0QA-2049), Revision 19, October 13, (2017);
https://www.samsung.com/us/smg/content/dam/samsung/sg/aboutsamsung/2017/environment/pdf/standard-substances-products-en.pdf (last assessed 07.11.2019)

[154] Environmental Responsibility Report (2019), Apple

[155] KU Leuven-University of Leuven (2018): Contribution submitted by Jef Peeters, Department of Mechanical Engineering, Faculty of Engineering & Engineering Technology, KU Leuven-University of Leuven on 15.06.2018 during the stakeholder consultation conducted from 20 April 2018 to 15 June 2018 by Oeko-Institut in the course of the study to support the review of the list of restricted substances and to assess a new exemption request under RoHS 2 (Pack 15);
http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Pack_15/1st_Consultation_Contributions/Contribution_KU_LEUVEN_Diantimony_Trioxide_20180615.pdf, last viewed 26.06.2018 and op. cit. ZVEI (2018)

[156] Op. cit. TCM (2018)

8.4. Conclusion on alternatives

The environmental fate in the case of alternatives may differ from case to case due to physico-chemical characteristics of the substitutes. It is inherently difficult to conclude as to actual impacts resulting from the application of alternatives. Nonetheless, conclusions on the most promising possibilities are drawn as follows:

For reactive use

The most successful and already applied alternatives to TBBP-A in PWBs are phosphorus compounds like DOPO. Concerning this substitution candidate, moderate human health concern is assumed and this compound and its derivates are expected to be highly environmentally persistent. As DOPO is mono-functional compared to the bi-functional TBBP-A, a one-to-one substitution cannot take place. Furthermore, its use implies higher costs which can be reduced by using ATH or silica as fillers, or by combining it with metal phosphinates.

As PWBs are ubiquitous in EEE of all categories with TBBP-A being one of the most important flame retardants in this application, the question remains whether DOPO could substitute the large amount of TBBP-A used there and as to how this alternative would compare in terms of hazardous properties.

For additive use

Common substitutes for TBBP-A in housings are halogen-free organo-phosphorus compounds, while elimination of TBBP-A may also take place where ABS/TBBP-A systems are replaced with polymers such as PC and PPE, or other polymer blends.[157] This exchange in host material entails higher costs for manufacturers (typically 10-50 % higher). The costs may decrease over the years as a result of a larger market for the alternatives.[158] The human health hazards of the organophosphate esters differ depending on the side group of the phosphate. To sum it up, non-chlorinated alkylated organophosphates are registered without restriction under REACH; in contrast, some arylated and chlorinated organophosphates meet the PBT criteria or are suspected of being potential endocrine disruptors (triphenyl phosphate).

As outlined earlier, companies exist that have voluntarily phased out TBBP-A especially in additive use, thus substitution is concluded as possible here both from the technical perspective (substitutes comparable and reliable) as well as in terms of the economic perspective (additional costs, in conclusion, considered to be acceptable). The environmental and human health risks of several of the organophosphorus compounds suggest that additional data is needed concerning the available alternatives to allow conclusions to be drawn as to their level of hazardousness and as to the possible need for further restrictions to avoid regrettable substitution.

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[157] Op. cit UBA 2008, DEPA (2010)

[158] Op. cit. DEPA (2010)

9. DESCRIPTION OF SOCIO-ECONOMIC IMPACTS

9.1. Approach and assumptions

In this section, possible socio-economic impacts of a scenario in which TBBP-A is to be restricted are compared with the current situation (business as usual) in which TBBP-A is not restricted. In this respect, the section shall address the differences between two scenarios:

- a restriction scenario; and
- the current non-restriction scenario.

The essence of this analysis is based on the understanding as to which applications shall be affected by a restriction scenario. In principal, as presented in the above sections as well as in section 10, TBBP-A is applied in two application areas which could be affected from a restriction; reactively in epoxy resins of PWBs and additively in plastic housings and enclosures of EEE.

In reactive applications, TBBP-A undergoes a chemical reaction and is generally not present in the final component in its original form. On the condition of good practice, existing evidence suggests that the concentration of TBBP-A remaining in cases of its application in epoxy resins in PWBs is well below the proposed restriction threshold (see section 10). In such cases impacts are not expected and shall not be addressed in the sub-sections below. Cases of bad practice, where TBBP-A may remain at higher levels in the final component, may be affected if they exist. Since in such cases substitution of this substance may be avoided through the application of good practice, this sub-case shall also not be looked into separately: As in most cases, standard manufacture practices do not result in residual TBBP-A in concentrations above the proposed threshold, it must be assumed that the costs of improvements in production practices are acceptable and would be justified with the benefit of reducing the amount of residual TBBP-A and preventing possible emissions.

In the case of additive uses, it has been shown that these remain in the final product and may emit through use or at end-of-life, resulting in possible impacts on consumers and or on workers of waste management facilities. Emissions have shown up in the environment, suggesting that TBBP-A is a persistent substance and its increasing presence could result in an impact on the environment (aquatic toxicity). Thus, other impacts related to a restriction are to be weighed against the benefits of removing TBBP-A from the plastic material cycle and thus to preventing (or decreasing) possible impacts on the environment and on health with which its presence and emissions are related.

9.2. Impact on chemicals industry

Manufacturers of flame retardants

In terms of the manufacture of TBBP-A, BSEF specify that it is produced mainly in Israel, Jordan, the United States, Japan and the PR of China.[159] These countries are understood to be the main countries where bromine is sourced and bromine-based chemicals are manufactured.

To understand how these industries shall be affected, it is necessary to know how the restriction shall affect the use of TBBP-A in articles placed on the EU market as well as in the global production of EEE. Generally, in a restriction scenario, it can be expected that the production of TBBP-A is to decrease, as it shall no longer be permitted in EEE to be placed on the EU market. It is, however, also possible that the EU restriction will affect EEE to be placed on other markets:

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[159] BSEF, Fact sheet TBBP-A: Tetrabromobisphenol A for Printed Circuit Boardsand ABS plastics (2007): Brussels, Belgium

- In part, this can be attributed to the fact that many countries have established legislation similar to the RoHS Directive, and that these may adapt their legislation to include the proposed restriction. In the current context, this is observed to derive knowledge on the range of impacts on the manufacture and marketing of TBBP-A. However, proceeding from the assumption that the TBBP-A restriction shall result in environmental and health benefits; this should also be viewed as an added benefit of an EU restriction. In other words, the benefit of a restriction can be expected to extend beyond the European market (i.e. consumers and waste management can be expected to have environmental and health benefits also beyond the EU).
- Additionally, though in some sectors EEE is manufactured to some degree for specific markets, in others, equipment design targets the global markets, and substance restrictions that need to be complied with in one country shall often lead to compliance of all equipment. This is for example the case in the medical device sector and the monitoring and control sector, where equipment is manufactured in small annual volumes and thus models are developed for the most part for all markets.

In this sense, a restriction can be expected to lead to a decrease in the manufacture of TBBP-A somewhere in the range of the TBBP-A currently in use for EEE in the EU and for EEE globally. Subsequently, this may affect the total amounts of bromine sourced. The data presented in 2.3 suggests that a decrease in used quantities is already underway. The most recent data on global use originate from UBA[160] who estimated in 2008 that 145,000t/a TBBP-A were used globally (with 7,000 t/a being used in the EU). This number does not reflect the total amount that is placed on the EU market through EEE, nor the amounts relevant for additive applications. Additional data on this aspect is still being sought, but the existing data provides a first indication as to the potential decrease in the amount of TBBP-A produced globally.

In parallel, in terms of alternatives, it is observed that different types of substitutes exist, namely halogenated FR and non-halogenated ones. Of the first group, some of these can be expected to be brominated FRs, which shall also be manufactured by the bromine industry in the countries mentioned above. In this sense, though TBBP-A manufacture is expected to decrease, industries affected can also be expected to see a certain increase in the manufacture of other bromine-based FR which shall set off lost revenue to some degree.

In parallel, manufacturers of non-halogenated alternatives can be expected to see an increase in business. According to DEPA[161], three of the bromine manufacturers also manufacture different halogen-free flame retardants like organo-phosphorous compounds and magnesium hydroxide. In this sense, here too, TBBP-A losses could be expected to be set off by gains related to the marketing of non-halogenated alternatives. DEPA further quote a study by Lassen et al.[162] and specify that "*halogen-free alternative flame retardants that may serve as alternatives to TBBPA in EEE are manufactured primarily by 6 European companies, of which 5 have headquarters within the EU*".

Though it is difficult to estimate how the losses of TBBP-A manufacturers shall be set-off by the gains of manufacturers of alternatives, it is noted that at least some alternatives are currently more expensive and require higher concentrations to provide the same flam retardancy effect. It is thus

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[160] Op. Cit. UBA (2008)

[161] Op cit. Depa (2010)

[162] Cited by Depa (2010) as Lassen C., A. Leisewitz and P. Maxson. 2006. Deca-BDE and alternatives in electrical and electronic equipment. Environmental Project no. 1141, 2006. COWI, Öko-Recherche and Concorde East/West for the Danish Environmental Protection Agency. www.mst.dk.

assumed that within the chemical industry, losses of TBBP-A manufacturers shall be set-off by gains of manufacturers of other alternatives.

Resin manufacturers

According to a DEPA[163] study “*plastic resins are produced and formulated by relatively few large companies in Europe. The resins are mixed with additives (in so-called “masterbatches”) to form compounds, which are the raw materials for further processing. Compounding may take place by the resin manufacturer, by specialised compounders or by the company manufacturing the plastic parts*”.

Resin manufacturers can be expected to be affected in so far that they shall need to reformulate resins where TBBP-A is phased out. Nonetheless, stakeholder information suggests that EU manufacturers no longer use TBBP-A in their equipment (see ZVEI contribution[164]) and in this sense, it is only resin manufacturers outside the EU (or EU manufacturers exporting to non-EU countries) that may be affected. Though some resin formulators who have been using TBBP-A may experience loss of business, some of these may revert themselves to alternatives to prevent such losses and others that are already applying alternatives may see an increase of business. Though resin reformulation may be associated with expenses, these costs are understood to be passed on to the manufacturer who, if needed, shall adapt the price of the product. In this sense, estimations were not made separately for this part of the value chain. Furthermore, as some EEE manufacturers have phased-out TBBP-A voluntarily, it needs to be assumed that this process did not have a severe effect on resin manufacturers and thus no adverse impacts are anticipated as a result of a TBBP-A restriction at present either.

9.3. Impact on EEE producers

A few of the stakeholder contributions refer to aspects of relevance for analysing socio-economic impacts of a restriction. For example, the Test and Measurement Coalition (TMC) stated that “restricting TBBP-A will lead to:

- Forced redesign and requalification testing of entire portfolio;
- Lost opportunity for introduction of new, cutting edge products;
- Withdrawal of products from EU market;
- Impacts on innovation of users unable to access withdrawn products.” [165]

“*And we anticipate that our entire portfolio of products will be impacted […] (portfolio scale of 2,000 to 3,000 products (average of members) with tens of thousands of product plus option combinations)*”[166]. However, TMC neither provide estimations as to the range of such costs e. g. for third-party certification, nor does the contribution distinguish between additive and reactive use of TBBP-A. However, TMC mentions the need for a transition period for EEE Cat. 9 of 12 years. In the

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[163] Op cit. Depa (2010)

[164] ZVEI (2019): 1st Stakeholder Consultation–QuestionnairefortetrabromobisphenolA–TBBP-A(CAS79-94-7), submitted by Zentralverband Elektrotechnik- und Elektronikindustrie e. V. on 14.06.2018 available under : https://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Pack_15/1st_Consultation_Contributions/Contribution_TBBPA_ZVEI_Answers_RoHS_Pack_15_Fragebogen_TBBP-A.pdf, last viewed 19.11.2019

[165] Op. cit. TMC (2018)

[166] TMC (2020): Contribution submitted during the TBBP-A stakeholder consultation conducted from 5 Dec 2019 to 13 Feb 2020 by Oeko-Institut in the course of the study to support the review of the list of restricted substances and to assess a new exemption request under RoHS (Pack 15); see the link to the contribution in the Annex

case of additive use, some manufacturers have already reverted to alternatives voluntarily, thus the relevance of these comments to additive applications is to be viewed with caution. Though manufacturers who still apply plastic with TBBP-A shall incur redesign costs, these must be assumed to be at an acceptable level, seeing as other manufacturers have already made a phase-out. From the availability of substitutes, it is also clear that higher costs are not to be expected in such applications for identifying suitable alternatives. Alternatives are understood to be suitable for consumer products. Should there by some cases with more challenging performance conditions, exemptions could be applied as to ensure that sufficient time is available to test existing alternatives and develop suitable formulations. In this sense, impacts referred to by TMC such as product withdrawal and lost opportunity for introducing new cutting-edge products cannot be followed in this area of application.

In terms of the actual expected costs, a DEPA[167] study looked into the costs of replacing ABS/TBBP-A systems in the case of a RoHS restriction. In this study, cost estimations initially prepared in relation to the phase-out of ABS/octa-BDE for other alternatives (ABS/TBBP-A as well as other alternatives) were used to estimate costs of a phase-out of TBBP-A in ABS housings. "*The total price increase of changing ABS with TBBPA by copolymers with halogen-free flame retardants can [...] roughly be estimated at 0.3-0.7 €/kg ABS including R&D costs distributed over 5 years. The price increase is based on European prices - as much of the TBBPA is imported with EEE from Asia the actual price difference may be lower, but European prices are used here for indication of the incremental costs*". In this respect, DEPA also estimates that "*the prices of alternatives are typically 10-50 % higher than ABS/TBBPA/ATO systems and it is estimated that the total incremental costs at the production level of replacing additively used TBBPA in all EEE may likely be some 5-30 million €/year depending on the actual alternatives being introduced (European prices). The costs may decrease over the years as result of a larger market for the alternatives*".

A cost estimation performed in the Fraunhofer ITEM IPA study[168] used this data as a basis for calculating the total costs of replacing ABS/TBBP-A with copolymers with non-halogenated flame retardants. For the estimated amount of ~8000 t/a TBBPA in ABS assumed in the DEPA study (i.e., 36,364 t/a ABS with ~22 % TBBPA content) this resulted in 11-25 million € additional costs per year. The range of 5-30 million €/year is explained to consider the uncertainties of the DEPA study assumptions.

As Fraunhofer ITEM IPA had assumed a lower tonnage in other estimations performed in their study, costs were also calculated for the lower amount of ~4,800 t/a (applied in their exposure assessment), resulting in 6.5-15.3 million € per annum. After consideration of uncertainties, Fraunhofer ITEM IPA specify the range at roughly 3-20 million € per year. To take these costs into account, the study estimated the turnover of the EU electrical equipment industry to amount to 279 billion € in 2010 (Eurostat 2013), explaining that the costs for the TBBP-A phase-out from additive applications may be a small fraction of the industries' total turnover; however, there is concern that these costs could burden SMEs heavier than other companies.

Fraunhofer ITEM IPA[169] also assumes that the increased turnover in the flame retardant and plastic industry will probably lead to some additional jobs, however, this impact could not be finally quantified. In general, it can be assumed that this shall mainly affect the supply chain of EEE manufacturers: companies that produce TBBP-A-based components shall have increased costs where they need to substitute or will lose some of their business in some cases where they are too

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[167] Op cit. Depa (2010)

[168] Op. cit. Fraunhofer ITEM IPA, Wibbertmann and Hahn (2018)

[169] Op. cit. Fraunhofer ITEM IPA, Wibbertmann and Hahn (2018)

slow. Other companies already applying alternatives may benefit from an increase in business which can be expected to set off the latter.

9.4. Impacts on SME

DEPA[170] explain that "the market for plastic parts is characterised by many small and medium-sized enterprises (SMEs)". A study is cited that looked into the market structure of plastic part manufacture in the UK[171]. Here it was found that 5,260 companies from a total of 14,540 plastics manufacturers were to be considered as small companies (< 50 employees) and that the majority of these (3,365) were micro-enterprises (< 9 employees). The study also provided insight for the EU, estimating a total 55,000 companies manufacturing rubber and plastics in the EU with an average enterprise size of 25 employees. It is not clear how many of these companies supply EEE parts, or how many supply parts that are flame retarded with TBBP-A. Though such SMEs can be expected to be familiar with the RoHS Directive now, it is possible that they shall have a heavier burden in terms of identification of suitable alternatives and R&D connected with the introduction of alternatives. Nonetheless, it is also possible that some of these smaller companies have already moved to alternatives and that they will benefit from the restriction.

9.5. Impact on EEE users

Aside from the costs of a phase-in, impacts on consumers also need to take into consideration the benefits of phasing-out TBBP-A. According to the exposure estimations in Section 7.3, and assuming DNEL values of BPA according to the precautionary principle, results in a risk characterisation ratio of > 1 which is considered a risk for children. Though TBBP-A dust may be generated also from other than EEE products, the elimination of part of this equipment from consumer homes is expected to result in a health benefit against which additional costs are to be weighed.

In terms of the restriction for consumers, the DEPA[172] study refers to the impact that the phase-out of TBBP-A shall have on consumer prices, basing estimations on what is understood to be conservative assumptions. The basis for the calculation is understood to be the additional costs of manufacture that shall be shifted to consumers.

"*The total incremental costs to the consumers can be roughly estimated using the following assumptions:*

- *Total volume of additively used TBBPA in EEE: 8,000 tonnes year.*
- *Total volume of ABS polymer assuming a maximum TBBPA load of 22 %: 36,000 tonnes/year.*
- *Total incremental costs assuming that all TBBPA is used in ABS and re-placed by copolymers with non-halogenated flame retardants: 11-25 million €/year.*

Considering the uncertainties related to the assumptions the total incremental costs are roughly estimated to be in the range of 5-30 million €/year. The costs may decrease over the years as result of a larger market for the alternatives".

As mentioned by the DEPA study, all TBBP-A is not assumed to be used in ABS and therefore the consultants understand these estimations to be conservative.

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[170] Op cit. Depa (2010)

[171] Cited in DEPA (2010) as Corden, C. and M. Postle. 2002. Risk Reduction Strategy and analysis of ad-vantages and drawbacks for octabromodiphenyl ether. RFA for U.K. Department for Environment, Food and Rural Affairs (DEFRA).

[172] Op cit. Depa (2010)

Fraunhofer ITEM IPA[173] refers to a further estimation made as to the percentage increase in the average price of products for consumers. This estimation derived an increase of between 0.19 % and 0.30 % of the product costs, if the increased costs for a replacement of TBBPA in ABS were passed on to the consumer.

The latter estimation allows a more comprehensive assessment of how the total costs would affect the individual. Beyond the observation that an increase of between 0.19 % and 0.30 % in product costs is not expected to deter consumers from purchases, the fact that some companies have voluntarily phased-out TBBP-A further strengthens this conclusion, i.e., seeing as this voluntary phase-out was possible and seeing as losses in product quality have not been reported in this respect.

The above estimations, though applying in general to all EEE, are understood to be more relevant for consumer products, whereas for industrial and commercial equipment, often manufactured in lower volumes, delays in the time to market of some equipment may affect consumers to some degree.

In this respect the Association of Equipment Manufacturers (AEM)[174] point out the recertification needs of some equipment and how this may affect the time to compliance and subsequently the availability of equipment on the market. For example, they state that "*If TBBP-A were to be restricted before fully RoHS compliant equipment can be tested and gain EU NRMM Emissions Regulation approval from a Notified Body, many types of equipment could not be sold in the EU*." The possibility that some equipment may require redesign and recertification that would extend beyond the initial transition period of a restriction could lead to impacts upon equipment users. Though for private consumers, it can be expected that relevant equipment (particularly ICT equipment, electric appliances) will either already be compliant for some manufacturers or will achieve compliance before the end of a transition period, this may differ for commercial and industrial users. For example, the medical facilities depend on medical equipment which can also be expected to require recertification in cases where changes to design shall be needed to substitute TBBP-A. The same is true for example for equipment using combustion engines which must be approved according to the Non-Road Mobil Machinery Regulation (Regulation (EU) 2016/1628), addressed by AEM.

Though in these cases additional time may be needed for a phase-out, this could be bridged through a longer transition period or, through the provision of an exemption in cases where relevant sectors can communicate the scope of equipment where phase-out of TBBP-A requires additional time. This approach would enable equipment still using TBBP-A to be placed on the market until the phase-in is accomplished, at least by some manufacturers.

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[173] Op. cit. Fraunhofer ITEM IPA, Wibbertmann and Hahn (2018): referred in the text as DEPA 2010, but cited epr footnote as Corden, C. and M. Postle. 2002. Risk Reduction Strategy and analysis of advantages and drawbacks for octabromodiphenylether. RFA for U.K. Department for Environment, Food and Rural Affairs (DEFRA). (cited by DEPA, 2010)

[174] Op. cit. AEM (2018)

9.6. Impact on waste management

According to chapter 5, shredding of WEEE and the further processing of plastic waste are the most relevant TBBP-A exposure scenarios. Such exposures provide part of the justification for this restriction. Thus, an important positive impact of the restriction scenario is attributed to the reduction of TBBP-A in EEE and thus also to the prevention of impacts linked to exposure of workers to its presence through inhalation or dermal contact (see Section 6.2.1). Additional positive impacts on the health of workers may be relevant in the recycling of WEEE in third world countries (for example where EEE is exported through secondary market operations or where WEEE is exported illegally), where crude treatment practices may result in additional transformation products that emit from treatments such as uncontrolled combustion and uncontrolled dumping of residues.

As has been pointed out in Section 7.1, the presence of TBBP-A in plastic parts (ABS housings) at concentrations > 2,000 ppm results in such parts being separated from other plastic streams and incinerated. This is in part related to the small volume of this stream, which would render its separate recycling as economically not feasible, but is also explained to be the practice so as to avoid contamination of other streams (ABS that is free of TBBP-A or other BFR). In this sense, a restriction of TBBP-A would result in a change in the plastic stream available for recycling as explained below. Given the lifetimes of typical products in which ABS/TBBP-A systems are still in use, it may take time until a restriction can be observed in the WEEE arriving at waste management. Once this change is noticeable, a few cases may exist:

- In cases where ABS shall be used with alternative halogen-based additives, though impacts of TBBP-A on workers are to be prevented, other additives may have similar impacts depending on their identity. In general, in this case, it is still to be expected that the ABS fraction in which BFRs are present is to be separated and sent to incineration, so aside from possible positive impacts where alternatives have lower impacts on health and/or environment, additional benefits described below would not be expected in terms of the volumes of recovered of ABS.
- In cases where ABS shall be used with alternative halogen-free additives, it is expected that once TBBP-A-free ABS parts arrive at End-of-life, an increase in the amounts of ABS available for recycling is to be expected. The Fraunhofer ITEM IPA study states that ABS / housings are usually not recycled but rather energy recovered in light of the small volumes, however suppliers are available with equipment for recycling ABS[175] and it is thus assumed that ABS recycling is already in place and that additional amounts are not expected to lead to a need for additional investments in equipment, but rather to an increase in ABS recovery and a subsequent increase in the use of recycled ABS. It should be noted that this positive impact may be limited in some cases, depending on the identity of alternative additives. This view has been supported by the waste management sector[176], who raise concerns as to whether current waste management techniques can properly deal with phosphorus-based flame retardant).
- In cases where ABS is to be substituted with other polymers, contributions to the amount of plastics recovered would depend on the new polymers to be used and possible systems for flame retardancy.

To summarise, though in some cases (halogenated alternatives) a restriction may not lead to significant benefits, in other (non-halogenated alternatives benefits are expected in the form of additional secondary material, beyond the health benefits expected to arise from the phase-out of TBBP-A. Such impacts are however expected to incur in the mid- or long-term, seeing as it shall

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[175] See for example: https://www.schmaus-kunststoffaufbereitung.de/technische-kunststoffe/abs-kunststoffe.htm

[176] Op. cit. EERA (2020) and op. cit. EuRIC (2020)

take time until EEE that has been affected from the restriction shall turn into waste and arrive at treatment facilities.

9.7. Impact on administration

DEPA[177] estimates that costs of companies already in compliance with RoHS are to be minimal. This is based on the understanding that such companies shall already have prepared similar compliance documentation in the past for parts where deca-BDE or octa-BDE were traditionally used as additive FR and where TBBP-A is used at present.

According to DEPA,[178] most administration costs are expected to be associated with checking the presence of TBBP-A in EEE (compliance monitoring). This applies to manufacturers, importers and regulators alike, who can be expected to perform testing in order to ensure that TBBP-A is not present in EEE to be placed on the market. In this regard DEPA explains that simple XRF screening only detects the presence of Br and Sb, whereas for TBBP-A detection, sampling, extraction and laboratory analysis shall be required, as however is already the case for other RoHS substances (e.g. octa-BDE or deca-BDE). In this sense, the additional costs would only be in relation to the need for additional laboratory analysis. "*The extra costs of an analysis for TBBPA in ABS in Denmark, if the sample is already analysed for PBDE, is reported to be about 40€ (excl. VAT). The extra costs of analysis of TBBPA and HBCDD in HIPS, if the sample is already analysed for deca-BDE is about 60€ (excl. VAT). All prices are per sample when more than 20 samples are analysed*."

Fraunhofer ITEM IPA[179] refer to another source suggesting that the overall costs are between 150 and 500 €, depending on the availability/ level of standardisation of the technique and requirements such as good laboratory practice.[180] On this basis the Fraunhofer ITEM IPA study estimates total costs, assuming that for the EU as a whole 7,000 tests per annum (250 tests per EU Member State/annum) are sufficient to control a ban of additively used TBBPA ban. In this case, the total costs for the EU would be 0.28 Mio € annually using the estimated 40 € per test as specified by DEPA. Assuming a higher cost of ~300 € per test would result in a total of approximately 2.1 Mio € for additive use. It is further stated in this respect that the administrative costs cannot be seen as lost costs, as they would increase the turnover of the chemical analysis sector.

Though this view can be followed, the consultants assume that the market surveillance and independent sampling efforts that are performed for a newly restricted RoHS substance are of a larger range than for substances that have been phased-out. In this sense, it would be expected that the costs related to surveillance and sampling of TBBP-A would be expected to be largest following the restriction and to decrease gradually. From the phase-out of the phthalates, the consultants are aware that these activities started well before the end of the transition period, with the aim of seeing where such substances are still used. Further surveillance and sampling shall still take place following the end of the transition period of a restriction, but can be expected to decrease to a lower "routine" level as it becomes apparent that the substance has been phased-out for the most part. In any case, such surveillance costs are understood to be an acceptable effect of substance restrictions, as can also be understood form past restrictions.

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[177] Op cit. Depa (2010)

[178] Op cit. Depa (2010)

[179] Op. cit. Fraunhofer ITEM IPA, Wibbertmann and Hahn 2018: cited as S. Schuchardt, personal communication, 03. (2015)

[180] The difference between this estimation and the DEPA one may have to do in part with price changes throughout time or may reflect prices of single costs in comparison to the DEPA value which refers to the price of a single sample when multiple samples are analysed.

9.8. Total socio-economic impact

To summarise the above, though a restriction of TBBP-A under RoHS is likely to involve various costs, these, in conclusion, need to be accepted as costs necessary to bring about environmental and health benefits.

The restriction is expected to reduce the risks of exposure for consumer's (particularly for children) and for workers of waste management who may currently be exposed through inhalation or dermal contact. Further benefits may be relevant where TBBP-A is replaced with non-brominated alternatives, driving an increase in the amount of ABS to be available for recycling.

In terms of costs, both in the chemicals industry and in the EEE industry, though some manufacturers may incur loss of business or costs of substitution, others are understood to have already switched to alternatives voluntarily and may even experience a business growth. This last point also explains why the costs of a phase-out of TBBP-A are to be considered as acceptable. Though it can be understood that TBBP-A is still used additively in plastic parts, some EEE manufacturers have already phased-out this flame retardant voluntarily and it is also understood that additive use of TBBP-A as a flame retardant in EEE housings is no longer practiced in the EEE. It thus needs to be concluded that the available alternatives are suitable and will not lead to changes in product qualities and that costs of a restriction are acceptable. This applies to:

- the total costs estimated for the phase-in (5-30 million €/annum according to DEPA or 6.5-15.3 million €/annum according to newer estimations of Fraunhofer ITEM IPA);
- their implications for consumers (increase in product costs in a range of 0.19 % and 0.30 %); and
- the compliance monitoring and surveillance costs associated with a restriction (between 0.28 Mio €/annum based on DEPA data to 2.1 Mio € based on Fraunhofer ITEM IPA data).

10. RATIONALE FOR INCLUSION OF THE SUBSTANCE IN ANNEX II OF ROHS

TBBP-A is used in relevant quantities in EEE. Despite some data gaps it can be stated that the largest part of the TBBP-A (about 90 %) is used as a reactive component in epoxy resins. Epoxy resins for their part are the essential component of PWB type FR4 and can be found in practically every type of EEE. In addition, epoxy resins can also be used as a sealing compound for electronic components. The remaining 10 % of the TBBP-A applied in EEE is used as an additive flame retardant, especially for plastic housings. On the basis of the data available and presented in this dossier, it is open whether the quantities used for these applications have actually decreased or whether this only applies to European manufacture, and whether the quantities of TBBP-A in imported EEE components and equipment have remained stable or even increased in view of the continuing consumption of EEE.

TBBP-A as a precursor for epoxy resins is the main application, however, releases of TBBP-A during waste phase can mainly be attributed to its second application, the additive use as a flame retardant in housings and encapsulations. This can be attributed to the fact that TBBP-A undergoes a chemical transformation when used as a reactive component and – apart from low residual monomer contents – is no longer present as such substance.

With regard to emissions of TBBP-A from WEEE treatment processes, it should be noted that the relevant exposure of TBBP-A by dust in shredding processes of plastic housings and enclosures is assumed to be the most relevant exposure scenario. Monitoring data from recent years was not made available, so it is not possible to determine whether effects occur in EU facilities at a sufficient magnitude at this stage or if the opposite is the case.

With regard to risks for human health, there are some reasons in favour of a restriction of TBBP-A under RoHS:

- The current DNELs for TBBP-A do not take into account potential endocrine disrupting properties. Instead, given the structural similarity of TBBP-A and BPA, it is proposed to take the DNELs of bisphenol-A into account as a precautionary approach in order to reflect the potential endocrine disrupting properties of TBBP-A. It is worth noting that this preliminary recommendation requires further in-depth evaluation to validate the proposed results.
- The observation that workers of EEE waste processing plants are exposed to TBBP-A is confirmed by exposure estimations, by measurements of TBBP-A in EEE waste streams and results from human biomonitoring suggesting that TBBP-A has been detected in the serum of workers. Based on these considerations, an impact on workers in EEE waste processing plants has been observed and the estimated exposure by ECETOC TRA rather indicates a risk for workers via dermal exposure than via inhalation.
- The general population is exposed to a TBBP-A pre-load through ingestion and inhalation of house dust. Taking into account pre-load exposure to TBBP-A via house dust and taking the DNEL for bisphenol A for oral exposure at 4 µg/kg bw/day as a precautionary approach, a risk characterisation ratio of > 1 for children indicates a risk.
- As for the environment, according to monitoring data, TBBP-A is frequently detected and can thus be seen as a ubiquitous contaminant. This indicates that it is continuously released into the environment. For persistent substances, the normal risk assessment, by means of the ratio of the expected environmental concentration (Predicted Environmental Concentration, PEC) and an estimated non-effect threshold (Predicted No-effect concentration, PNEC) is not applicable. Substances with PBT properties have the potential to persist and thereby accumulate in the

environment. ECHA (2014) emphasises that the effects of such accumulation are unpredictable in the long–term and that such accumulation is in practice difficult to reverse as cessation of emissions will not necessarily result in a reduction in chemical concentration. They circulate in the global environment for long periods of time and, if further released, the environmental concentration will increase constantly. Should TBBPA be identified as a PBT substance, it would follow that it has an impact on the environment.

With regard to Article 6(1) of RoHS 2, it should therefore be noted that TBBP-A meets the criteria for inclusion in the list of prohibited substances in several respects:

- *given its uses, could give rise to uncontrolled or diffuse release into the environment of the substance, or could give rise to hazardous residues, or transformation or degradation products through the preparation for reuse, recycling or other treatment of materials from waste EEE under current operational conditions, and*
- *could lead to unacceptable exposure of workers involved in the waste EEE collection or treatment processes.*

With regard to the disposability of alternatives, it should be noted that they are available when TBBP-A is used as an additive flame retardant:

- Alternatives seem readily available and are applied, however in some cases, this may result in significant trade-offs in terms of functional performance and/or hazard issues. Nevertheless, some companies demonstrate that voluntary substance restriction policies can help reducing the use of brominated FR such as TBBP-A. Resorcinol-bis-diphenylphosphat (PBDPP) and Resorcinol-diphosphat as well as some non-halogenated organophosphate esters present themselves as alternatives with a more favourable hazard profile. However, on the basis of risks already known and suspected several phosphorus compounds like DOPO and aryl-substituted organophosphate esters such as triphenyl phosphate and tricresylphosphate should be further evaluated concerning their risk potential before being applied as substitutes in the short term. If a restriction is considered, it may be relevant to assess these substances to ensure whether they are suitable substitutes or whether a regrettable substitution should be avoided through their simultaneous substitution. In such cases, it is noted that assessments under REACH are in some cases underway and necessary to ensure a first basis of information is available for an assessment in the context of RoHS. In addition, it should be noted that most of the non-halogenated phosphorus FR entail a shift from ABS polymers to PPE/PS or PC/ABS blends.
- Regarding the use of TBBP-A as a reactive component for the production of epoxy resins, including the pertinent use as a component of FR4 PWB, few alternatives are currently available. Since the residual levels of TBBP-A in these applications are very low due to the chemical reaction in the production of epoxy resin, they are not affected by the recommended restriction for additive TBBP-A uses.

To summarise, it is **proposed to amend Annex II** through the addition of the following restriction:

Recommended substance restriction formulation

additive application of 2,2',6,6'-tetrabromo-4,4'-isopropylidenediphenol or tetrabromobis-phenol A (TBBP-A) (0,1 % per weight)

Reactive TBBP-A applications and in particular its use as a component of FR4 PWB is not subject to the recommended restriction.

It is stressed that the preliminary conclusions on possible PBT and/or endocrine disruptive properties of TBBP-A need to be reappraised as soon as new evidence becomes available. A REACH classification as endocrine disrupting and/or PBT would corroborate a restriction under RoHS too. Under REACH, assessments of TBBP-A as endocrine disruptive and/or as PBT are underway and additional information, requested by ECHA, shall become available by January 2021. From this background, the final decision on a RoHS restriction of TBBP-A should take into account the outcome of the REACH process, i.e. whether TBBP-A is identified as endocrine disrupting and/or PBT properties. If so, the current guidance values (e.g. no effect levels) would become obsolete. A postponement of the final restriction decision until after January 2021 shall also provide additional time for a further assessment of a few of the substitutes for TBBP-A, and for decisions on whether certain substitutes should be considered for restriction jointly with the restriction of TBBP-A.

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Appendix I: Contributions to 1st stakeholder consultation hold from 20 April 2018 to 15 June 2018

The following non-confidential contributions were submitted during the 1st stakeholder consultation (see also: https://rohs.exemptions.oeko.info/index.php?id=291):

Contribution of the **BSEF, aisbl – The International Bromine Council**, submitted on 23.04.2018: PDF1, PDF2, PDF3, PDF4, PDF5

Contribution of the **Swedish Chemicals Agency (KEMI)**, submitted on 11.06.2018: Report with information on TBBP-A in Swedish (summary in English): PDF

Contribution of the **Norwegian Environment Agency**, submitted on 14.06.2018 https://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Pack_15/1st_Consultation_Contributions/Contribution_Norwegian_Environment_Agency_TBBPA_MCCPS_20180614.pdf

Contribution of the **Zentralverband Elektrotechnik- und Elektronikindustrie e. V. (ZVEI)**, submitted on 14.06.2018: PDF

Contribution of **the Danish Environmental Protection Agency (DEPA)**, submitted on 14.06.2018: Part 1: PDF; Part 2: PDF

Contribution of **MedTech Europe**, submitted on 15.06.2018: PDF

Contribution of the **JBCE – Japan Business Council in Europe aisbl**, submitted on 15.06.2018: PDF

Contribution of the **Test and Measurement Coalition (TMC)**, submitted on 15.06.2018: PDF

Contribution of the **Association of Equipment Manufacturers (AEM),** submitted on 15.06.2018: PDF

Contribution of the **Japanese electric and electronic (E&E) industrial associations**, submitted on 14.06.2018: PDF

Contribution of the **AeroSpace and Defence Industries Association of Europe (ASD)**, submitted on 14.06.2018: PDF

Appendix II: Contributions to 2nd stakeholder consultation hold from 05 December 2019 to 13th February 2020

The following non-confidential contributions were submitted during the 2nd stakeholder consultation (see also: https://rohs.exemptions.oeko.info/index.php?id=333):

Contribution of the **Norwegian Environment Agency**, submitted on 27.01.2020: PDF

Contribution of **COCIR (European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry),** submitted on 28.01.2020: Contribution: PDF and Annex 1: PDF

Contribution of the **Test and Measurement Coalition (TMC),** submitted on 12.02.2020: PDF

Contribution of **MedTech Europe,** submitted on 12.02.2020: PDF

Contribution of **EuRIC – The European Recycling Industries' Confederation,** submitted on 12.02.2020: PDF

Contribution of **EERA – European Electronics Recyclers Association**,submitted on 12.02.2020: PDF

Joint Contribution of **Digital Europe** and the **JBCE – Japan Business Council in Europe** , submitted on 13.02.2020: PDF

Contribution of **ZEBRA Technologies,** submitted on 13.02.2020: PDF

Contribution of the **BSEF – The International Bromine Council**, submitted on 13.02.2020: Part 1: PDF; Part 2: PDF

A.9.0 Report on the Identification and Prioritisation of Substances for Inclusion in the List of Restricted Substances (Annex II) under the RoHS 2 Directive

Report on the Identification and Prioritisation of Substances for Inclusion in the List of Restricted Substances (Annex II) under the RoHS 2 Directive

Study to support the review of the list of restricted substances and to assess a new exemption request under RoHS (RoHS Pack 15 - Task 3)

Under the Framework Contract: Assistance to the Commission on technical, socio-economic and cost-benefit assessments related to the implementation and further development of EU waste legislation

(Final)

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Disclaimer

Oeko-Institut and Fraunhofer IZM have taken due care in the preparation of this report to ensure that all facts and analysis presented are as accurate as possible within the scope of the project. However, no guarantee is provided in respect of the information presented, and Oeko-Institut and Fraunhofer IZM are not responsible for decisions or actions taken on the basis of the content of this report.

The information and views set out in this study are those of the author(s) and do not necessarily reflect the opinion of the Commission. The recommendations provided in this study do not preclude future decisions to be taken by the Commission.

EUROPEAN COMMISSION

Directorate-General for Environment

Directorate B - Circular Economy & Green Growth

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Abbreviations and Definitions

AUBA	Austrian Umweltbundesamt GmbH
CAS	Chemical Abstracts Service
CLP	Classification and Labelling Regulation
CMR	Carcinogenic, mutagenic, toxic for reproduction - A substance that is classified as carcinogenic category 1 or 2, and/or mutagenic category 1 or 2, and/or toxic for reproduction category 1 or 2
ECHA	European Chemicals Agency
EEE	Electrical and electronic equipment, which according to RoHS Article 3(1) means equipment which is dependent on electric currents or electromagnetic fields in order to work properly and equipment for the generation, transfer and measurement of such cur-rents and fields and designed for use with a voltage rating not exceeding 1 000 volts for alternating current and 1 500 volts for direct current;
IEC	International Electrotechnical Commission
PBT	Persistent, bioaccumulative and toxic - A substance that fulfils the persistence, bioaccumulation and toxicity criteria set out in Annex XVIII of REACH
POP	Persistent organic pollutants
REACH	Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals, establishing a European Chemicals Agency
RoHS	Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment
SCIP	A database for information on Substances of Concern In articles and in Products
SPIN	Substances in Preparations in Nordic Countries
SU	Description of use
vPvB	Very persistent, very bioaccumulative - A substance that fulfils the very persistent and very bioaccumulative criteria set out in Annex XVIII of REACH
ZVEI	Zentralverband Elektrotechnik- und Elektronikindustrie e. V. (German Electrical and Electronic Manufacturers' Association)

1. Summary

This report describes activities carried out in the scope of the project Identification and Prioritisation of Substances for Inclusion in the List of Restricted Substances (Annex II) under the RoHS Directive. All activities are based on the Manual Methodology for Identification and Assessment of Substances for Inclusion in the List of Restricted Substances (Annex II) under the RoHS 2 Directive (dated 26.09.2019), here after "the manual".

The report describes the work carried out in accordance with the following parts of the manual:

- PART I: Identification of substances used and/or present in EEE, which may have negative impacts on human health, the environment or resource efficiency during use and/or during WEEE management according to RoHS Article 6(1). The existing inventory of a previous study was used as a basis to be updated. Existing databases and computer-based tools were then used to establish a comprehensive database with information on the substances concerned, with a focus on hazard properties (human health and environmental hazards) and use aspects (typical applications, volumes of use). This work resulted in an inventory of 897 substances that were indicated to be present in EEE or used during the manufacturing of EEE. Those substances were then pre-assessed according to a range of criteria to provide a first indication regarding the substances priority for further assessment, resulting in 10 groups, from group I (priority for further assessment, 57 substances) to group X (no priority for further assessment).
- PART II: Prioritisation of substances used in EEE, which may most likely have negative impacts on human health, the environment or resource efficiency during use and/or during WEEE management according to RoHS Article 6(1). This part was applied to a sub-selection of the sub-stances identified in P I, understood to have the highest priority for further assessment according to the guidance in P III of the manual. Information was collected and reviewed on volumes of use and on typical applications in EEE. Based on this information and the hazard properties of the substance, a sorting and clustering of the prioritised substances was carried out, resulting in five clusters of substances (clusters I a) to I e)). The seven substances in cluster I a) are of the highest hazard group and were indicated to be used in high volumes or as nano-material or were indicated to be potential substitutes for substances listed under Annex II of the RoHS Directive or substances that are currently under assessment for a possible inclusion in Annex II. The further clusters of substances incrementally fulfil fewer criteria.

The following documents were produced that constitute the results of this work:

- Pre-prioritised substance inventory: A spreadsheet format list containing more than 900 substances that are indicated to be present in EEE or used in the manufacture of EEE, including information on their identity (CAS number, EC number, substance name), their legal status under various directives and regulations (CLP, REACH, RoHS, POPs Regulation, among others), their hazardous properties (CMR, PBT/vPvB, endocrine disrupting properties, etc.), and their volumes of use in EEE. The substances in this list have been pre-prioritised in accordance with criteria de-scribed in the manual, into ten priority groups, with group I associated with the highest and group X with the lowest priority (refer to manual P I Step 2: Priority pre-assessment of inventory sub-stances).

- List of prioritised substances: A spreadsheet format list containing 43[1] substances from the priority group I of the Pre-prioritised substance inventory mentioned above, complemented with information on their use (applications) in general and in EEE as well as their volumes of use in general and in EEE, where such information was available. Substances on this list were further sorted into five clusters to improve the clarity of results.

Three stakeholder consultations were conducted to request additional information from participating organisations, with a focus on applications of substances in EEE and volumes of use (quantities) of substances in EEE in the EU. While many organisations contributed information on applications of substances, and some information on the amount of specific substances used in articles manufactured by those organisations, no data could be retrieved regarding the amount or order of magnitude of substances in EEE in total in the EU. This lack of data was a limitation of the study regarding the prioritization of substances. Limited information could be retrieved from the Urban Mine Platform. Additional data on presence in articles may be in the future available through the SCIP data base and other future initiatives.

2. About this document

This document describes the steps that were carried out according to the methodology manual. The manual describes the approach and provides instructions on how to carry out the compilation of an inventory and prioritisation of substances. This document describes the results of applying this methodology in the course of this study and deviations from it, where applicable. To increase the readability of this document, parts of the methodology manual have been copied in for the convenience of having the description of the approach and the results in one place. Paragraphs copied from the manual are formatted in italics.

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[1] Two substances are considered to be interchangeable and were therefore combined into a single entry.

3. Part I IDENTIFICATION OF SUBSTANCES

The aim of Part I is to identify all substances in EEE, which may cause risks for the environment during use[2] *or risks for the environment and workers during WEEE management or have any other negative impacts during waste management, as specified by RoHS 2, Article 6.*

Approach: The standardized methodology allows for a stepwise procedure for assessing substances for possible future restriction under RoHS in order to fulfil the overall goal of protecting human health and the environment from negative impacts related to use or to WEEE management.

The identification of potentially RoHS-relevant substances used in EEE involves three major tasks:

- *Creation of an inventory of substances (P I Step 1):*
  - *Updating information on substances classified or suspected as hazardous (P I Step 1a);*
  - *Updating information on substances used and/or present*[3] *in EEE (P I Step 1b);*
- *Pre-assessment of priority of substances listed in the inventory (P I Step 2):*
  - *First run of the pre-assessment to establish classification of substances to priority groups (P I Step 2a);*
  - *Stakeholder consultation for collecting information on substances in the inventory with focus on the substances in the highest priorities (P I Step 2b);*
- *Update information in the inventory and re-run pre-assessment to conclude on substances in highest priorities*[4] *to be subject refined prioritisation in P II (P I Step 3).*

An inventory of substances used in EEE was established during the first review of Annex II of RoHS in 2013-2014. The inventory established in 2013 AUBA[5] *(Karigl et al. 2014) provides a first basis to be updated in the following periodic reviews. Each further revision should use the initial inventory of the last revision as a first basis to be*

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[2] Article 6(1)(b) provides inter alia the basis for restricting a substance, should its uses give rise to uncontrolled or diffuse release into the environment of the substance. This is understood to refer to possible releases related to the intended use of a substance but also to non-intended use, for example in the case of breakage.

[3] Substances used in manufacture of EEE may or may not be present in the final product. Similarly, substances present in EEE may or may not have been applied in this form in the manufacture. The inventory shall update information on substances used in manufacture and on substances present in EEE, specifying presence where this data is found to allow a differentiation at later stages.

[4] The number of substance (priority classes) to be subjected to the prioritisation of P II shall be discussed and approved with the EC, also depending on the study scope.

[5] Abbreviation for Austrian Umweltbundesamt GmbH (AUBA)

updated, adding and updating existing data before applying the various selection and prioritisation stages.

3.1. P I Step 1: Compile inventory of substances

The final inventory from the previous study (Karigl et al. 2014) was used as a first basis and was updated where relevant in relation to additional substances present in EEE or used in the manufacturing of EEE (e.g. new substances). Additional substances or substance groups (hereafter: substances) were added to the inventory from the following sources:

- IEC 62474 Database „Declarable substance groups and declarable substances“ (IEC 62474 - Material Declaration for Products of and for the Electrotechnical Industry)[6]:
  - 77 additional entries were added to the inventory.
- ZVEI umbrella specifications could not be consulted as they are no longer updated and were no longer available online. Therefore, no new information has become available after the initial study by AUBA (Karigl et al. 2014) from this source. Instead, material data sheets from TDK/Epcos on a range of passive electronic components, including capacitors, inductors, and sensors were evaluated (see next bullet).
- 791 Material Data Sheets showing typical compositions of specific electronic product groups published by TDK Electronics[7]:
  - 72 substances were identified; of those, 44 were already contained in the EEE inventory;
  - 28 additional substances were added to the inventory.
- Requests for new RoHS exemptions / renewal of exemptions / withdrawal of exemptions, in which potential substitutes were specified. No additional substances were identified for addition to the inventory.
- The following reports/studies were evaluated:
  - Bundesamt für Umwelt: “Substance flows in Swiss e-waste” (BAFU 2017)
  - DANISH EPA: “Hazardous substances in plastic” (Hansen et al. 2014)
  - DANISH EPA: “Survey of brominated flame retardants” (Lassen et al. 2014)
  - DANISH EPA: “Shredder residues: Problematic substances in relation to resource recovery” (Hyks et al. 2014)
  - DANISH EPA: “Environmental and health screening profiles of phosphorous flame retardants” (Lassen et al. 2016)

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[6] Refer to Website of the IEC 62474 - Material Declaration for Products of and for the Electrotechnical Industry: http://std.iec.ch/iec62474 [accessed on 25th February.2020]

[7] Material Data Sheets published by TDK Electronics: https://www.tdk-electronics.tdk.com/en/176050/company/environmental-protection/material-data-sheets [accessed on 20th July 2018]

- DANISH EPA: “Category approach for selected brominated flame retardants” (Wedebye et al. 2016)
- DANISH EPA: “Pre-screening of REACH registration dossiers for 9 brominated flame retardants” (Nielsen et al 2016)
- Nordic Council of Ministers: “Hazardous substances in plastics” (Stenmarck et al. 2017)
- Oeko-Institut: “Study for the Review of the List of Restricted Substances under RoHS2” (Gensch et al. 2014)
- Oeko-Institut: “Evaluation of small brominated alkyl alcohols for a possible RoHS restriction” (Baron et al. 2017)
- RISE: “Mapping and Evaluation of some Restricted Chemical Substances in Recycled Plastics Originating from ELV and WEEE Collected in Europe” (Andersson et al. 2019)
- Swico, SENS, SLRS Report: “Fachbericht 2017” (Böni et al. 2017)

The reports/studies listed above, found to be relevant to EEE, were scanned for lists of hazardous substances or other references to hazardous substances present in EEE or used in the manufacturing of EEE.

- 90 different substances are described in the reports/studies, 50 of which were already contained in the inventory; 40 additional substance were identified
- 5 of those 40 substances were contained in the AUBA list “substances removed”[8]. These substances were nevertheless added to the inventory, as it could not be excluded that new information had become available since the previous study was carried out.
- The 40 substances/groups were added to the inventory as separate entries, which resulted in the addition of 73 substances with unique CAS numbers in total, as members of substance groups were listed individually.

Discussion of the feasibility of an alternative approach for updating the EEE inventory

An alternative approach to updating the initial EEE inventory was investigated but not found to be feasible. The approach was to compile a new inventory from relevant sources rather than to incrementally update the AUBA inventory. The sources would have been substance lists specific for EEE (IEC 62474, SPIN), REACH registered substances with specific use descriptors (to be specified in search under Uses and

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[8] The finale EEE inventory produced by AUBA (Karigl et al. 2014) contained a separate list of substances that had been removed from the inventory before its finalization, as information had become available indicating a substance would not be relevant for an inventory listing hazardous substances understood to be present in EEE.

exposures>Sector of use), as well as relevant studies/reports. However, there were two main issues with this approach:

- The number of substances in the sources was enormous, and considered too large to be workable, particularly in stakeholder processes;
- The sources often do not differentiate between substances present in EEE and substances used in the manufacture of EEE or intermediates.

To illustrate the first issue, Table 3-1 lists the number of substances listed in each source. It was decided that a substance inventory with several thousand entries was not a workable approach. Additionally, none of the listed sources indicate whether a substance is merely used in production of EEE but is not contained in the final article (e.g. solvents). Consequently, it was decided to incrementally update the AUBA EEE inventory instead, as described above.

Table 3-1: Sources considered in the alternative approach to updating the EEE sub-stance inventory and number of entries

Source	Number of unique entries
REACH substances with use descriptor SU 2a “Mining, (without offshore industries)”	573
REACH substances with use descriptor SU 9 “Manufacture of fine chemicals”	8888
REACH substances with use descriptor SU 11 “Manufacture of rubber products”	1463
REACH substances with use descriptor SU 12 “Manufacture of plastics products, including compounding and conversion”	2643
REACH substances with use descriptor SU 15 “Manufacture of fabricated metal products, except machinery and equipment”	1109
REACH substances with use descriptor SU 16 “Manufacture of computer, electronic and optical products, electrical equipment”	1197
SPIN database substances with Nace Code 26 “Manufacture of computer, electronic and optical products”	665
SPIN database substances with Nace Code 27 “Manufacture of electrical equipment”	478

3.1.2. P I Step 1a): Update information on substances which are hazardous

Data on hazardous properties of all substances in the inventory was updated by consulting the sources prescribed in the methodology manual, listed in Table 3-2.

Table 3-2: Criteria for the identification of candidates in the inventory master list as hazardous

The substance is/shows…
Listed in Annex VI CLP (or fulfils the criteria that would justify a listing in Annex VI CLP)
Carcinogenic OR mutagenic OR reprotoxic [Categories 1A and 1B and 2]
PBT (persistent, bio-accumulative, toxic)

The substance is/shows…
vPvB (very persistent, very bio-accumulative)
PB (persistent, bio-accumulative)
Listed as substance of very high concern (SVHC) under REACH
Subject to authorisation (Annex XIV) under REACH
Subject to restriction (Annex XVII) under REACH
Considered to have endocrine disrupting and/or other properties identified in accordance with Article 57(f) of
Suspected as any of the above (based on CoRAP; SIN List)
Listed under the ECHA public activities coordination tool (PACT)
Substances used as nanomaterial in EEE

3.1.1. P I Step 1b): Update information on use and presence of substances in EEE

The list updated through Step 1a was further updated in relation to available information as to the use and/or presence of the substance in EEE. For the purpose of this step, the following lists and sources were consulted:

- Substances listed in the IEC 62474 Database „Declarable substance groups and declarable substances“. It is understood that substances or substance groups are added to the list of declarable substances on the basis for example of regulatory requirements or requirements of industry standards that set reporting thresholds[9]. The following information was extracted:
  - Information on typical applications of substances in EEE was added to the EEE inventory;
  - Presence in EEE was considered plausible, if a substance was listed in the IEC 62474 Database.
- TDK/Epcos Material Data Sheets:
  - Presence in EEE for listed substances is considered plausible.
- Substances with the use descriptor SU 16 “Manufacture of computer, electronic and optical products, electrical equipment”:
  - Substances listed with this use descriptor are considered to possibly be present in EEE, as the source does not differentiate between substances used during manufacturing and substances contained in final articles.
- Information from requests for new RoHS exemptions / renewal of exemptions / withdrawal of exemptions, in which potential substitutes are addressed.

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[9] For further details see: http://std.iec.ch/iec62474/iec62474.nsf/MainFrameset [accessed 20th Juy 2018]

Volumes of use

Little information is publicly available on the volumes of use of specific substances in EEE within the EU. Various sources of information were checked in terms of their relevance for the purpose of this study:

- Volumes of use from the REACH registration process (tonnage bands) is not useful for the current task due to the following reasons:
  - The tonnage bands refer to a substance being manufactured in the EU or imported into the EU. The data does not account for volumes of a substances imported as constituent of articles that are manufactured overseas and imported into the EU. As the majority of EEE are produced outside the EU (Asia), the REACH registered volume data do not account for substances contained in the vast majority of EEE in the EU.
  - In correspondence with ECHA[10] it was confirmed that although registrants do provide indications regarding downstream uses of manufactured or imported substances (sectors, processes, products), there is no data to indicate amounts of a specific substance in specific product categories (such as EEE). Registrants do not provide indications on the share of the substances in different sectors. Additionally, registrants typically do not have data on the total amount of a substance as a constituent of products (see bullet point above).
- Literature, reports:
  - Previously used literature and reports (including literature listed in chapter 3.1) have been checked for data on the amount of specific substances in EEE in the EU. No references could be identified that provide such specific data.
- The Urban Mine Platform[11] that was generated as a part of a European research project (ProSUM[12]) and provides projected data of volumes of materials and elements within EEE placed on the European market by year was checked for relevant information. Data was extracted on listed materials and elements. However, only relevant materials and elements are referred to in the platform, while specific flame retardants or phthalates are not accounted for.
- Data on volumes of use in EEE were requested in all stakeholder consultations within the project. A few contributions included indications on the volume of specific substances used in EEE, the frame of reference for provided data was generally specific to the contributing organisation. This did not allow projections from one manufacturer to the entirety of EEE included in the scope of RoHS.
- Direct correspondence with selected stakeholders (incl. ZVEI) did not result in further data on the volumes of specific substances used in EEE in the EU.

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[10] Personal communication on 30. July 2019

[11] http://www.urbanmineplatform.eu/composition/eee/elements [last accessed on 19th February 2020]

[12] H2020 project “Prospecting Secondary raw materials in the Urban mine and Mining wastes” (ProSUM) project website: http://www.prosumproject.eu/ [last accessed on 19th February 2020]

3.1.2. Stakeholder Consultation 2018-2

A first stakeholder consultation with relation to the substance inventory was carried out between 26th October 2018 and 21st December 2018[13]. The substance inventory at the time comprised 815 entries and included the following information, where available:

- Substance identity (CAS No., EC No., Name, Group);
- Source of information (e.g. IEC 62474);
- Uses in EEE (category, main function, additive or reactive use);
- Nanomaterial;
- Estimated volume of use in EEE in the EU (in tonnage bands).

A guidance document included questions to stakeholders pertaining to verifying and complementing the information provided in the inventory.

Contributions were received from 9 organisations or groups of organisations[14]. Contributions directly related to the questions asked in relation to the EEE inventory have been summarised in Table 3-3, including the actions that were taken accordingly. Further contributions were focused on the Substance Methodology and were not considered in the further development of the inventory.

Table 3-3: Stakeholder comments received and actions taken

Stakeholder	Comments directly related to the questions asked in relation to the substance inventory	Action taken
Alliance Elektronique – ACSIEL	Provision of list containing 5 substances, 2 of which were new additions to the inventory	Added 2 new entries to the inventory
EUROMOT and AEM	Provision of Excel file with 23 substances incl. use examples for engines (engine BOM). All 23 substances were already contained in the EEE inventory	Added additional information on use of substances in EEE

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[13] https://rohs.exemptions.oeko.info/index.php?id=302 [last accessed 19th April 2020]

[14] https://rohs.exemptions.oeko.info/index.php?id=304 [last accessed 19th February 2020]

Stakeholder	Comments directly related to the questions asked in relation to the substance inventory	Action taken
PI Ceramic GmbH	Provision of data on 11 substances; all 11 substances already in inventory; provision of data on volume of use in piezo electronic components	Data on volumes of use added to the EEE inventory
ZVEI	Marking of duplicate entries in EEE inventory; marked substances as intermediates (not present in EEE due to reactivity)	Duplicates were removed; substances pointed out as intermediates were marked as such in the EEE inventory

In summary, after the stakeholder consultation, 2 additional entries were added to the inventory. 16 entries were removed from the inventory as they were duplicates. 12 substances were marked as “intermediates” following stakeholder feedback.

3.2. P I Step 2: Priority Pre-assessment of priority of inventory substances

Pre-assessment of the identified relevant substances aims at determining which substances / substance groups have the highest potential for fulfilling the Article 6(1) criteria and should be subjected to the prioritisation in P II. The process described in this section aims at establishing a sub-selection of the substances initially identified for the inventory regarding their priority for further assessment.

3.2.1. P I Pre-Step 2 Evaluation of the legal restriction status

The aim of the Pre-step is to exclude substances, where a restriction under RoHS is not required, as the substance is already restricted under RoHS or at a level overruling RoHS in other legislation or where a legally binding restriction is underway, i.e., expected in the foreseeable future.

Criteria: The substance is excluded if it is:

- *Restricted or to be restricted (within duration of the transition period) under the RoHS Directive.*
- *Restricted in accordance with the REACH Regulation (Annex XVII), provided that the scope of the restriction would make a RoHS restriction redundant;*

- *Prohibited and/or restricted in accordance with the POPs Regulation (EC) No 850/2004 and its amendments, provided that the scope of the decision (exemptions/acceptable uses) would make a RoHS restriction redundant;*
- *A decision to list the substance (or substance group) in Annex A (elimination) and/or Annex B (restriction) of the Stockholm Convention has been taken by the Conference of the Parties (COP) and its implementation is pending, provided that the scope of the decision (exemptions/acceptable uses) would make a RoHS restriction redundant*[15]
- *Covered by the Montreal Protocol, the Regulation (EC) No 1005/2009 on substances that deplete the ozone layer, and the F-gas Regulation (EC) No 842/2006*[16]*.*

Out of the 897 substances contained in the substance inventory, 44 entries were removed after above steps were completed.

3.2.2. P I Step 2a) Pre-prioritisation of substances

The aim of step 2 is to identify those substances or groups of substances which are of highest concern regarding their potential negative impact on human health and/or the environment during use and/or WEEE management. In order to prioritise substances, a grouping system based on the assessment of the following three attributes was applied in accordance to the manual:

- Hazardous properties / Human Health & Environment (including special consideration where substances appear in Annex XIV or Annex XVII of REACH);
- High volumes of use and/or presence in EEE (including special consideration for substances used among others in nano-material form); and
- Possible use of a substance as a substitute for a substance restricted or to be restricted (in transition period) under RoHS.

1) Hazardous properties

The results of the categorisation of substances into hazard groups in accordance with the manual are shown in Table 3-4. Please note that substances may both fulfil human

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[15] See further information under:

- Convention text and amendments: http://chm.pops.int/TheConvention/Overview/TextoftheConvention/tabid/2232/Default.aspx [last accessed on 19th February 2020]
- Reports and decisions of the COP: http://chm.pops.int/TheConvention/ConferenceoftheParties/ReportsandDecisions/tabid/208/Default.aspx [last accessed on 19th February 2020]

[16] See: http://ozone.unep.org/montreal-protocol-substances-deplete-ozone-layer/32506 [last accessed on 19th February 2020]

hazard and environmental hazard criteria and may therefore be accounted for in both parts of the table.

Table 3-4: Number of substances in each hazard group

Hazard group	# of substances
Human Health Hazard	
- Group I	122
- Group II	39
- Group III	78
Environmental Hazard	
- Group I	92
- Group II	3
- Group III	19
No relevant hazard criteria	640

Refinement of the Criteria A: Prioritisation due to authorisation/restriction under REACH

In certain cases a substance may be addressed under the REACH Regulation (Authorisation, Restriction) or regulation may be under consideration. On the basis of the Common Understanding (COM 2014), and to ensure coherence with REACH, in such cases, it shall be of a higher priority to assess whether such substances when used and/or present in EEE fulfil the RoHS Article 6(1) criteria and whether a RoHS restriction would achieve a higher level of protection than the REACH route. Therefore, where a substance is listed in Annex XIV and/or in Annex XVII of the REACH Regulation or if such a listing is under consideration, a RoHS assessment should be prioritised for this purpose and would result in the substance being moved to Group I in relation to its hazard group prioritisation (i.e. red colour).

- Criterion A was found to be true for 52 substances in the EEE inventory. These were all grouped into the overall priority group I.

2) Use relevance

Methodology

Where information indicates use and/or presence of the substance /substance group in EEE in high volumes it is assumed to indicate a higher potential for the criteria *specified in Article 6(1) of RoHS to be fulfilled. Thus for the following grouping system, the information required under P I, Step 1b, shall be analysed systematically and shall constitute the following criterion:*

- *Criterion B: There is evidence that the substance/ substance group is used and/or present in EEE in high volumes;*
- *For the purpose of determining this criterion, the REACH registration volume principles are to be used. High volume of a substance is to be assumed when*
- *the annual use is ≥ 1 tonne for substances exhibiting CMR properties; or*
- *the annual use is ≥ 100 tonnes for substances classified as very toxic to aquatic organisms; or*
- *the annual use is ≥ 1000 tonnes for all other substances.*

Additionally, criterion B is to be considered fulfilled when a substance may be used in nanomaterial form in certain EEE applications, despite its EEE use volume being below the above specified thresholds.

<u>Results</u>

Criterion B was found to be true for 43 substances in the EEE inventory.

3) Determination of the overall priority of substances / substance groups

<u>Methodology</u>

The pre-prioritisation was carried out in accordance with the manual as shown in Table 3-5.

Table 3-5: Overview of possible colour combinations for the highest overall priority categories

Criteria	**Colour coded priority**									
Human Health & Environment (REACH Annexes)	🟥	🟧	🟥	🟧	🟨	▒	🟨	▒		
High volume of use (nano)	🟥	🟥			🟥	🟥			🟥	
Resulting overall priority of substances / substance groups	**I**	**II**	**III**	**IV**	**V**	**VI**	**VII**	**VIII**	**IX**	**X**

Additionally, the status of substances under REACH was taken into account as described in the methodology manual: Substances currently listed in REACH Annex XIV or XVII or that are recommended for inclusion in either annex were also given high priority.

<u>Results</u>

Prioritisation resulted in the following distribution of substances into the ten priority groups (number of substances in brackets):

Table 3-6: Number of substances in each priority group

Priority group	# of substances
Group I	57
Group II	1
Group III	111
Group IV	27
Group V	1
Group VI	3
Group VII	61
Group VIII	22
Group IX	32
Group X	538

3.2.3. P I Step 2b): Stakeholder Consultation 2019-3

A second stakeholder consultation with relation to the substance inventory was carried out between 26th September 2019 and 7th November 2019. The pre-prioritized substance inventory at the time comprised 853 entries and included the following information:

- Substance identity (CAS No., EC No., Name, Group)
- Uses in EEE (category, main function, additive or reactive use, indication whether presence in EEE considered plausible, indication whether substance is a substitute for another listed substance)
- RoHS status (currently under assessment or previously assessed under RoHS)
- Hazard group (combined results for human health and environmental hazard properties)
- Use relevance (high volumes of use and/or used as nanomaterial in EEE)
- REACH relevance (listed or proposed for listing under REACH Annex XIV or XVII)
- Resulting overall priority (Groups I – X)
- Previously received stakeholder comments
- Estimated volume of use in EEE in the EU (in tonnage bands)
- Waste / use phase / comments (requesting information on possible use phase / waste management impacts acc. RoHS Art. 6(1); other comments)

A guidance document included questions to stakeholders pertaining to verifying and complementing the information provided in the inventory. Stakeholders were requested to provide additional information, with the aim of either:

- Providing evidence that a substance in the highest priorities should have a lower priority based on new evidence related to, e.g. a lower volume of use or no use in EEE;
- Providing evidence that a substance in a lower priority group should have a higher priority, based on new evidence related to, e.g. a high volume of use in EEE

Comments were received from 12 organisations or groups of organisations[17]. The following comments were directly related to the substance inventory:

- five substances were identified as already restricted under RoHS and were consequently removed from the inventory
- one substance was identified as currently restricted under the POPs Regulation and was consequently removed from the inventory
- Several substances were highlighted as not present in EEE, and were consequently marked as such
- Five phthalates were incorrectly grouped in hazard group I due to an error in the algorithm for automated grouping, which was corrected. Those five phthalates are no longer in group I but sorted into their various correct groups.

Additionally, stakeholders provided volumes of use for a few substances and indicated more substances that are used during manufacturing but are not present in the final EEE. This was noted in the inventory.

3.3. P I Step 3: Update inventory based on stakeholder contributions and re-run pre-assessment

Methodology

At this stage, it should also be considered that substitutes for substances that are already restricted, soon to be restricted (transition) or that shall possibly be restricted (recommended for restriction) should be attributed a higher priority if it has been determined during a substance assessment that they have a similar potential for fulfilling the Article 6(1) criteria and thus could be considered a regrettable substitution. In cases of a substance being recommended for restriction, the Commission could conclude on regrettable substitution based on the information available and could initiate a substance assessment bypassing the identification and prioritisation process.

Substances in the highest priority groups shall be put on a short list, creating a so called "RoHS-Working-List"[18]. This list shall be subjected to the prioritisation in P II.

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[17] https://rohs.exemptions.oeko.info/index.php?id=339 [last accessed on 19th February 2020]

[18] The groups for which the refinement is to be performed shall be discussed and approved with the Commission. The selection can be performed automatically using the features of the established substance database (RoHS-working-list.xls)

Results

At the time this step was finalised, the assessment of the seven substances (or substance groups) to be performed as part of this study had not concluded yet. Therefore, this step was carried out according to the information on possible substitutes contained in the draft substance dossiers.

4. Part II: PRIORITISATION OF SUBSTANCES: Targeted approach for refined prioritisation of high priority substances

Methodology

For substances / substance groups of the highest priority, additional information shall be compiled to allow a refined prioritisation of substances in the "RoHS-Working-List" according to the following approach.

For all substances from the highest priority groups, information shall be collected from publicly available sources and compiled into a tabulation. The tabulation should include the information for each substance regarding the following parameters and topics:

- *Substance identity (Name, CAS and EC identifiers);*
- *Information on the substance classifications as collected in the inventory.*
- *Information on uses (i.e. typical general uses and applications, and typical EEE uses and applications);*
- *Quantities of use (i.e. typical use volumes and EEE use volumes for the EU and/or globally, depending on availability of information);*
- *First indication if the use and presence of the substance in EEE could potentially lead to impacts related to Article 6(1). This should be estimated based on a short review of the most recent available REACH documents (Annex XV Dossier, SEAC and RAC opinions, etc. and in relation to the information available on hazards and use ad presence of the substance in EEE);*

Results

The following 43 substances comprised the group of the highest priority substances:

- Boric acid
- 1-bromopropane
- Bis(2-methoxyethyl) ether (Diglyme)
- Tris(2-chloroethyl)phosphate (TECP)
- Bis(2-methoxyethyl) phthalate
- C,C'-azodi(formamide) (ADCA)
- N,N-dimethylacetamide (DMAC)
- Diarsenic pentaoxide; Arsenic pentoxide; Arsenic oxide

- Diboron trioxide
- Disodium tetraborate, anhydrous
- Dipentyl phthalate (DPP)
- Nickel monoxide
- Zinc oxide
- Diarsenic trioxide; Arsenic trioxide
- Tris(2-chloro-1-methylethyl)phosphate (TCCP)
- Tris[2-chloro-1-(chloromethyl)ethyl] phosphate (TDCP)
- Hexahydro-4-methylphthalic anhydride
- Henicosafluoroundecanoic acid
- Trixylyl phosphate (TXP)
- Hexahydromethylphthalic anhydride
- 2-(2H-benzotriazol-2-yl)-4,6-ditertpentylphenol (UV-328)
- Tricosafluorododecanoic acid
- Perfluorodecanoic acid (PFDA)
- 2-(2H-benzotriazol-2-yl)-4-(tert-butyl)-6-(sec-butyl)phenol (UV-350)
- Perfluorononan-1-oic-acid (PFNA)
- Heptacosafluorotetradecanoic acid
- 2-benzotriazol-2-yl-4,6-di-tert-butylphenol
- 2,4-di-tert-butyl-6-(5-chlorobenzotriazol-2-yl)phenol (UV-327)
- Hexahydro-1-methylphthalic anhydride
- Formaldehyde
- [4-[4,4'-bis(dimethylamino)benzhydrylidene]cyclohexa-2,5-dien-1-ylidene]dimethylammonium chloride
- Hexahydro-3-methylphthalic anhydride
- N,N-dimethylformamide (DMF)
- 1,2-Benzenedicarboxylic acid, di-C7-11-branched and linear alkyl esters (DHNUP)
- 1,2-Benzenedicarboxylic acid, di-C9-11-branched alkyl esters, C10-rich (DIDP)
- 1,2-Benzenedicarboxylic acid, dihexyl ester, branched and linear
- 1,2-benzenedicarboxylic acid, di-C6-10-alkyl esters or mixed decyl and hexyl and octyl diesters
- 1,2-Benzenedicarboxylic acid, di-C6-8-branched alkyl esters, C7-rich (DIHP)
- Perfluorotridecanoic acid
- Nickel (Ni)
- Cyclohexane-1,2-dicarboxylic anhydride
- 1-methyl-2-pyrrolidinone (NMP)
- reaction mass of 2-ethylhexyl 10-ethyl-4,4-dioctyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate and 2-ethylhexyl 10-ethyl-4-[[2-[(2-ethylhexyl)oxy]-2-oxoethyl]thio]-4-octyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate (reaction mass of DOTE and MOTE)

4.1. Stakeholder Consultation 2019-4

A third stakeholder consultation with relation to the substance inventory was held from 5th December 2019 until 13th February 2020[19]. The purpose of this consultation was to collect input concerning quantitative usage data for the 43 priority substances in EEE identified in the highest priority group of the substance inventory (i.e., the prioritised shortlist).

The prioritized shortlist included the following information:

- Substance identity (CAS No., EC No., Name, Group)
- Description of the known uses (applications) and volumes of use (quantities) in general
- Description of the known uses (applications) and volumes of use (quantities) in EEE
- Indication whether substance is used as nanomaterial in EEE

A guidance document included questions to stakeholders pertaining to verifying and complementing the information provided in the prioritised shortlist. The main purpose of this consultation was to collect input concerning quantitative usage data for the 43 priority substances in EEE identified in the highest priority group of the substance inventory. Where this was not possible, estimations on the range of use was requested, with a view to a refined prioritisation for future review cycles. Stakeholders were also asked to specify whether they supported the information compiled and to contribute information as to possible impacts that the presence of the substance may cause during use and/or waste management (relating to RoHS Article 6(1) criteria).

Comments were received from 4 organisations[19]:

- Nickel Institute
- Wirtschaftsverband Stahl- und Metallverarbeitung e.V. (WSM)
- MedTech Europe
- Japan Electronics and Information Technology Industries Association (JEITA)

Contributions directly related to the questions asked in relation to the prioritised shortlist have been summarized in Table 4-1, also listing the actions that were taken accordingly. Other received contributions were more focused on the Substance Methodology and are thus not listed here.

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[19] https://rohs.exemptions.oeko.info/index.php?id=347 [last accessed on 19th February 2020]

Table 4-1: Stakeholder comments received, and actions taken

Stakeholder	Comments directly related to the questions asked in relation to the substance inventory	Action taken
Nickel Institute	Additional information on general uses of nickel	Added to the information on nickel
MedTech Europe	Additional information on main uses, presence in EEE, REACH SVHC status, and further comments for all substances in the priority list	Relevant information was added
JEITA	Additional information on main uses, presence in EEE, REACH SVHC status, and further comments for all substances in the priority list	Relevant information was added

Further comments pointed out:

- A lack of transparency in the hazard grouping of substances;
- A previous study by the Danish EPA was quoted to state “Nickel in stainless steel is generally not a concern”;
- Germany regulates nickel via a national German OEL for nickel at 0.030 mg Ni/m^3 (respirable fraction) and 0.006 Ni/m^3 (alveolar fraction) under the German Technical Regulation for Hazardous Substances (TRGS) 900 “Occupational Exposure Limits”;
- ECHA RAC recommended a rounded value of 0.005 mg Ni/m^3 as an OEL for the respirable fraction of nickel metal in March 2018.

4.2. Finalization and clustering of substances

Taking into account stakeholder contributions, the final results of the prioritisation were generated. In this step, a last modification to the list of substances was necessary as detailed below.

Three substances were added, that were falsely eliminated from the list in a previous step[20]:

- Di-"isodecyl" phthalate (DIDP) (CAS Nr.: 26761-40-0)
- Di-"isononyl" phthalate (DINP) (CAS Nr.: 28553-12-0)
- Di-n-octyl phthalate (DnOP) (CAS Nr.: 117-84-0)

As the substance 1,2-Benzenedicarboxylic acid, di-C9-11-branched alkyl esters, C10-rich (CAS Nr.: 68515-49-1) was already contained in the inventory and is considered fully interchangeable with DIDP[21], both substances were merged into a single entry in the list.

One substance was removed, that was previously falsely listed as used as nanomaterial in EEE (this changed resulted in its reclassification into group III):

- reaction mass of 2-ethylhexyl 10-ethyl-4,4-dioctyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate and 2-ethylhexyl 10-ethyl-4-[[2-[(2-ethylhexyl)oxy]-2-oxoethyl]thio]-4-octyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate (reaction mass of DOTE and MOTE)

The final RoHS Working List therefore contains 44 entries (substances / substance groups). The substances were clustered into five groups to provide more structure to the list. A further prioritisation of substances on the list according to the methodology was only possible to a limited degree, as usage data (volumes of use; use as nanomaterial) for the substances was absent in the majority of cases.

For the sorting and clustering, the following criteria were accounted for:

- Hazard group
- High volume of use and/or use as nanomaterial
- Indication that substance is a potential substitute for substances that are listed on RoHS Annex II or are under assessment for possible inclusion on RoHS Annex II
- Indication that substance is a potential substitute for another substance on the list (to facilitate parallel assessments);
- Indication that substance may possibly not be present in EEE[22];

Usage data was available only for three substances/groups (with one of the individual substances being in scope of one group of substances included therein). The relevance

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[20] Elimination from the RoHS Working List due to low hazard grouping; however, relevance under REACh (Criterion A) required reinstating substances when this became clear

[21] https://echa.europa.eu/documents/10162/b66cca3a-5303-455b-8355-63bf741e263b [last accessed on 17th April 2020)

[22] In cases where substances were indicated to not be present in EEE, for instance according to IEC 62474 or statements by contributing stakeholders. Those indications were, however, not considered sufficient to remove substances from the list as it could not be ensured that such statements were representative for EEE of various sectors and manufacturers.

of this differentiator should be checked in relation to the availability of data in the future (for example, additional data on presence in articles may be available through the SCIP data base and other future initiatives).

The result of the sorting and clustering is listed in the following. Differentiators of relevance to the cluster are specified only when at least one substance in the cluster fulfils the differentiator or a combination of differentiators. More details on each substance are included in the RoHS Working List (see Annex I).

It should be noted that the inclusion of a substance in the below list does not presume a recommendation for the inclusion in Annex II of the RoHS Directive. The inclusion in the below list indicates that a substance is of the highest priority for a detailed assessment according to the methodology manual. Only the detailed assessment (Part III of the methodology manual) may result in a recommendation to restrict a substance for the use in EEE under RoHS Annex II.

Cluster I a)

Cluster I a) comprises substances for which data indicated

- the highest hazard group and high volume of use, or
- the highest hazard group and the use as nanomaterial in EEE, or
- substitution potential for other RoHS-relevant substances in this cluster (to facilitate parallel assessments) and listed or recommended for inclusion on REACh Annex XIV or XVII.

CAS No	EC No	Name
1313-99-1	215-215-7	Nickel monoxide
1314-13-2	215-222-5	Zinc oxide
25155-23-1	246-677-8	Trixylyl phosphate (TXP)
68515-42-4	271-084-6	1,2-Benzenedicarboxylic acid, di-C7-11-branched and linear alkyl esters (DHNUP)
28553-12-0	249-079-5	Di-"isononyl" phthalate (DINP)
26761-40-0; 68515-49-1	247-977-1; 271-091-4	Di-"isodecyl" phthalate (DIDP)

Cluster I b)

Cluster I b) comprises substances for which data indicated

- the highest hazard group, or

- substitution potential for other RoHS-relevant substances in this cluster (to facilitate parallel assessments) and listed or recommended for inclusion on REACh Annex XIV or XVII.

CAS No	EC No	Name
3864-99-1	223-383-8	2,4-di-tert-butyl-6-(5-chlorobenzotriazol-2-yl)phenol (UV-327)
36437-37-3	253-037-1	2-(2H-benzotriazol-2-yl)-4-(tert-butyl)-6-(sec-butyl)phenol (UV-350)
3846-71-7	223-346-6	2-benzotriazol-2-yl-4,6-di-tert-butylphenol (UV-320)
25973-55-1	247-384-8	2-(2H-benzotriazol-2-yl)-4,6-ditertpentylphenol (UV-328)
131-18-0	205-017-9	Dipentyl phthalate (DPP)
71888-89-6	276-158-1	1,2-Benzenedicarboxylic acid, di-C6-8-branched alkyl esters, C7-rich = Diisoheptyl phthalate (DIHP)
68515-50-4	271-093-5	1,2-Benzenedicarboxylic acid, dihexyl ester, branched and linear (DIHP)
115-96-8	204-118-5	Tris(2-chloroethyl)phosphate (TCEP)
13674-87-8	237-159-2	Tris[2-chloro-1-(chloromethyl)ethyl] phosphate (TDCP)
13674-84-5	237-158-7	Tris(2-chloro-1-methylethyl) phosphate (TCCP)
10043-35-3	233-139-2	Boric acid
375-95-1	206-801-3	Perfluorononan-1-oic-acid (PFNA)
50-00-0	200-001-8	Formaldehyde

Cluster I c)

Cluster I c) comprises substances for which data indicated

- the highest hazard group, but for which
- the presence in EEE has been doubted (incl. information from IEC 62474, stakeholder contributions from industry associations, or from individual stakeholders, as noted in the RoHS Working List), or
- substitution potential for other RoHS-relevant substances in this cluster (to facilitate parallel assessments) and listed or recommended for inclusion on REACh Annex XIV or XVII.

CAS No	EC No	Name
1303-96-4	603-411-9	Disodium tetraborate, anhydrous

1303-86-2	215-125-8	Diboron trioxide
335-76-2	206-400-3	Perfluorodecanoic acid (PFDA)
117-82-8	204-212-6	Bis(2-methoxyethyl) phthalate (DMEP)
85-42-7	201-604-9	Cyclohexane-1,2-dicarboxylic anhydride
548-62-9	208-953-6	[4-[4,4'-bis(dimethylamino)benzhydrylidene]cyclohexa-2,5-dien-1-ylidene]dimethylammonium chloride (Crystal Violet)
123-77-3	204-650-8	C,C'-azodi(formamide) = Diazene-1,2-dicarboxamide (C,C'-azodi(formamide)) (ADCA)
106-94-5	203-445-0	1-bromopropane (n-propyl bromide)
111-96-6	203-924-4	Bis(2-methoxyethyl) ether (Diglyme)
68-12-2	200-679-5	N,N-dimethylformamide (DMF)
872-50-4	212-828-1	1-methyl-2-pyrrolidinone (NMP)
25550-51-0	247-094-1	Hexahydromethylphthalic anhydride (MHHPA)
19438-60-9	243-072-0	Hexahydro-4-methylphthalic anhydride
48122-14-1	256-356-4	Hexahydro-1-methylphthalic anhydride
57110-29-9	260-566-1	Hexahydro-3-methylphthalic anhydride
127-19-5	204-826-4	N,N-dimethylacetamide (DMAC)
1303-28-2	215-116-9	Diarsenic pentaoxide; Arsenic pentoxide; Arsenic oxide
1327-53-3	215-481-4	Diarsenic trioxide; Arsenic trioxide

Cluster I d)

Cluster I d) comprises substances for which data indicated

- lower hazard groups, or
- substitution potential for other RoHS-relevant substances in this cluster (to facilitate parallel assessments) and listed or recommended for inclusion on REACh Annex XIV or XVII.

CAS No	EC No	Name
7440-02-0	231-111-4	Nickel
68515-51-5	271-094-0	1,2-benzenedicarboxylic acid, di-C6-10-alkyl esters or mixed decyl and hexyl and octyl diesters

Cluster I e)

Cluster I e) comprises substances for which data indicated

- lower hazard groups, for which
- the presence in EEE is uncertain (incl. information from IEC 62474, stakeholder contributions from industry associations, or from individual stakeholders, as noted in the RoHS Working List), or
- substitution potential for other RoHS-relevant substances in this cluster (to facilitate parallel assessments) and listed or recommended for inclusion on REACh Annex XIV or XVII.

CAS No	EC No	Name
2058-94-8	218-165-4	Henicosafluoroundecanoic acid (PFUnDA)
376-06-7	206-803-4	Heptacosafluorotetradecanoic acid (PFTDA)
307-55-1	206-203-2	Tricosafluorododecanoic acid (PFDoDA)
72629-94-8	276-745-2	Perfluorotridecanoic acid

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A.1.1 Annex I: RoHS Working List

For an excel version of the RoHS working list (prioritised substances) and a list of non-prioritised substances, please see: http://rohs.exemptions.oeko.info/typo3/index.php

Sorting of prioritised substances		Substance identity			Known uses						Volumes of use in the EU			Hazardous properties						REACh status				Waste / use phase / comments
Sorting clusters	Rationale	CAS No	EC No	Name	Category	Main function / use	Uses (General)	Uses in EEE	Substitute for other substance with relevance to RoHS (this list, Annex II substances, substances under assessment)	Stakeholder comments on presence in EEE	General use	Use in EEE	Criterion B: High volumes of use and/or used as nanomaterial in EEE	Harmonized classification (CLP)	endocrine disruptive	PBT/vPvB/PB	Human Health Hazard	Environmental Hazard	Criterion A: Hazard group	SVHC	REACh Annex XIV	REACh Annex XVII	Criterion A Refinement: Listed on REACh Annex XIV or XVII, or proposed for listing	Stakholder comments on possible use phase / waste management impacts acc. to RoHS Art. 6(1); other comments received
Cluster I a)	- highest hazard group - use as nanomaterial in EEE	1313-99-1	215-215-7	Nickel monoxide	Metal compound	NA	This substance is used in t	Nickel monoxide ist used i			This substance is manufactured	n.d.i.	Nano	Carc. 1A STOT RE 1			Group I	Group III	Group I			X		Already restricted under REACh in artic
	- highest hazard group - use as nanomaterial in EEE	1314-13-2	215-222-5	Zinc oxide	Metal compound	NA	This substance is used in t	Zinc oxide is used in EEE as		Some stakeholders reporte	This substance is manufactured	n.d.i.	Nano	Aquatic Acute 1 Aquatic Chronic 1			Group I	-	Group I					
	- highest hazard group - potential substitute for MCCPs	25155-23-1	246-677-8	Trixylyl phosphate (TXP)	Additive - Flame Retardant	Flame Retardant	This substance is used in t	This substance can be foun	substitute for MCCPs (und		This substance is manufactured	n.d.i.		Repr. 1B			Group I	-	Group I	X			X	
	- highest hazard group - potential substitute for DIDP	68515-42-4	271-084-6	1,2-Benzenedicarboxylic acid, di-C7-11-branched and linear alk	Additive - Plasticizer	Plasticizer	DHNUP is used in polyviny	After 2006, the use of DHN	potential substitute for DI		Based on information from Eur	One EU-based producer of elect		Repr. 1B			Group I	-	Group I	X	X		X	
	- potential substitute for DEHP, MCCPs, DIHP	28553-12-0	249-079-5	Di-"isononyl" phthalate (DINP)	Additive - Plasticizer	Plasticizer	DINP is a high molecular w	Plasticizer for PVC, used as	substitute for DEHP, MCCP		This substance is manufactured	n.d.i.			II		-	-	Group IV			X	X	
	- potential substitute for DEHP, MCCPs	26761-40-0; 68515-49-1	247-977-1; 2	Di-"isodecyl" phthalate (DIDP)	Additive - Plasticizer	Plasticizer	DIDP is a common phthala	Used mainly as plasticizer	substitute for DEHP, MCCP		This substance is manufactured	n.d.i.			II		-	-	Group V			X	X	
Cluster I b)	- highest hazard group	3864-99-1	223-383-8	2,4-di-tert-butyl-6-(5-chlorobenzotriazol-2-yl)phenol (UV-327)	Additive	UV stabilizer	Used as UV stabilizer for p	UV stabilizer in plastics, pa	potential substitute to UV		This substance is manufactured	n.d.i.				vPvB	-	Group I	Group I	X			X	
	- highest hazard group	36437-37-3	253-037-1	2-(2H-benzotriazol-2-yl)-4-(tert-butyl)-6-(sec-butyl)phenol (UV	Additive	UV stabilizer	Used as UV stabilizer in pr	UV stabilizer in plastics, pa	potential substitute to UV		This substance is manufactured	n.d.i.				vPvB	-	Group I	Group I	X			X	
	- potential substitute for UV-327/350	3846-71-7	223-346-6	2-benzotriazol-2-yl-4,6-di-tert-butylphenol (UV-320)	Additive	UV stabilizer	Used in products to protec	UV-stabilizer in adhesives,	potential substitute to UV		This substance is expected to be	n.d.i.					-	-	Group IV	X			X	
	- potential substitute for UV-327/350	25973-55-1	247-384-8	2-(2H-benzotriazol-2-yl)-4,6-ditertpentylphenol (UV-328)	Additive - Stabilizer	UV stabilizer	This substance is used in t	This substance has been re	potential substitute to UV		This substance is manufactured	n.d.i.					-	-	Group IV	X			X	
	- highest hazard group	131-18-0	205-017-9	Dipentyl phthalate (DPP)	Additive - Plasticizer	Plasticizer	Plasticizer in PVC and nitro	Plasticizer in PVC and nitro			n.d.i.	n.d.i.		Repr. 1B Aquatic Acute 1	III		Group I	Group I	Group I	X	X		X	
	- highest hazard group	71888-89-6	276-158-1	1,2-Benzenedicarboxylic acid, di-C6-8-branched alkyl esters, C7	Additive - Plasticizer	Plasticizer	Diisoheptyl phthalate is a p	Phthalates are widely used			Manufacturers of phthalates in	n.d.i.		Repr. 1B			Group I	-	Group I	X	X		X	
	- highest hazard group	68515-50-4	271-093-5	1,2-Benzenedicarboxylic acid, dihexyl ester, branched and linea	Additive - Plasticizer	Plasticizer	This substance has been re	Used as a plasticizer for ce			n.d.i.	n.d.i.		Repr. 1B			Group I	-	Group I	X			X	
	- highest hazard group	115-96-8	204-118-5	Tris(2-chloroethyl)phosphate (TCEP)	Additive - Flame Retardant	Flame retardant	Mainly used as an additive	Flame retardant. Electroni			The current registration data in	n.d.i.		Carc. 2 Repr. 1B			Group I	Group I	Group I	X	X		X	
	- potential substitute for TCEP	13674-87-8	237-159-2	Tris[2-chloro-1-(chloromethyl)ethyl] phosphate (TDCP)	Additive - Flame Retardant	Flame Retardant	This substance is used in p	This substance is used in p	substitute for TCEP		This substance is manufactured	n.d.i.		Carc. 2			Group III	-	Group III				X	
	- potential substitute for TCEP	13674-84-5	237-158-7	Tris(2-chloro-1-methylethyl) phosphate (TCCP)	Additive - Flame Retardant	Flame Retardant	This substance is used in t	This substance has been re	substitute for TCEP		This substance is manufactured	n.d.i.					-	-	Group V				X	
	- highest hazard group	10043-35-3	233-139-2	Boric acid	Additive - Flame Retardant	Flame Retardant	This substance is used in t	Widely used in electroplati			This substance is manufactured	n.d.i.		Repr. 1B			Group I	-	Group I	X			X	
	- highest hazard group	375-95-1	206-801-3	Perfluorononan-1-oic-acid (PFNA)	Additive - Surfactant	Surfactant	It is used as a lubricating o	Surfactant in the productio			n.d.i.	n.d.i.		Carc. 2 Repr. 1B		PBT#vPvB high PB score	Group I	Group I	Group I	X			X	
	- highest hazard group	50-00-0	200-001-8	Formaldehyde	Intermediate chemical	Resins	This substance is used in t	This substance can be foun			This substance is manufactured	n.d.i.		Carc. 1B Muta. 2			Group I	-	Group I			X	X	ECHA published a draft dossier for rest
Cluster I c)	- highest hazard group - presence in EEE doubted	1303-96-4	603-411-9	Disodium tetraborate, anhydrous	Additive - Flame Retardant	Flame Retardant	This substance is used in t	This substance is used in t		One stakeholder stated th	This substance is manufactured	n.d.i.		Repr. 1B			Group I	-	Group I				X	
	- highest hazard group - presence in EEE doubted	1303-86-2	215-125-8	Diboron trioxide	Additive - Flame Retardant	Flame Retardant	This substance is used in t	This substance can be foun		Stakeholders have reporte	This substance is manufactured	n.d.i.		Repr. 1B			Group I	-	Group I	X			X	
	- highest hazard group - presence in EEE doubted	335-76-2	206-400-3	Perfluorodecanoic acid (PFDA)	Additive - Flame Retardant	Insulation in certain electr	Used in automotive and av	Flame retardants, weather		One stakeholder stated th	n.d.i.	n.d.i.		Carc. 2 Repr. 1B		PBT high PB score	Group I	Group I	Group I	X			X	
	- highest hazard group - presence in EEE doubted	117-82-8	204-212-6	Bis(2-methoxyethyl) phthalate (DMEP)	Additive - Plasticizer	Plasticizer	Plasticiser in the productio	This substance has been re		One stakeholder stated th	n.d.i.	n.d.i.		Repr. 1B			Group I	-	Group I	X	X		X	
	- highest hazard group - presence in EEE doubted	85-42-7	201-604-9	Cyclohexane-1,2-dicarboxylic anhydride	Additive - Curing agent	Hardner	This substance is used in t	Hardener for epoxy resins,		Substance not contained i	This substance is manufactured	n.d.i.		Eye Dam. 1 Resp. Sens. 1			Group I	-	Group I	X			X	
	- highest hazard group - presence in EEE doubted	548-62-9	208-953-6	[4-[4,4'-bis(dimethylamino)benzhydrylidene]cyclohexa-2,5-die	Dyes, Pigments	Pigment	Also known as Crystal Viol	It is used in toners, as well		No EEE application identifi	This substance is manufactured	n.d.i.		Carc. 1B Acute Tox. 4 *			Group III	Group I	Group I	X			X	
	- highest hazard group - presence in EEE doubted	123-77-3	204-650-8	C,C'-azodi(formamide) = Diazene-1,2-dicarboxamide (C,C'-azodi	Surfactant	Foaming agent	This substance is used in p	One specific example of us		Substance not contained i	This substance is manufactured	n.d.i.		Resp. Sens. 1			Group I	-	Group I	X			X	
	- highest hazard group - presence in EEE doubted	106-94-5	203-445-0	1-bromopropane (n-propyl bromide)	Solvent	Solvent	This substance is used in w	The largest use of 1-BP is a		No EEE application identifi	This substance is manufactured	n.d.i.		Flam. Liq. 2 Repr. 1B			Group I	-	Group I	X	X		X	As solvent is not only used in EE indust
	- highest hazard group - presence in EEE doubted	111-96-6	203-924-4	Bis(2-methoxyethyl) ether (Diglyme)	Solvent	Electrolyte	This substance is used in la	Diglyme is used in the mar		Stakeholders have reporte	This substance is manufactured	n.d.i.		Flam. Liq. 3 Repr. 1B			Group I	-	Group I	X	X		X	As solvent is not only used in EE indust
	- highest hazard group - presence in EEE doubted	68-12-2	200-679-5	N,N-dimethylformamide (DMF)	Solvent	Electrolyte	DMF is used in the produc	Used in production of high	potential substitute for NM	Stakeholders have reporte	This substance is manufactured	n.d.i.		Repr. 1B Acute Tox. 4 *			Group I	-	Group I	X			X	As solvent is not only used in EE indust
	- highest hazard group - presence in EEE doubted	872-50-4	212-828-1	1-methyl-2-pyrrolidinone (NMP)	Solvent	NA	This substance is used in t	NMP is used as a solvent f	potential substitute for DM	Substance not contained i	This substance is manufactured	n.d.i.		Repr. 1B STOT SE 3			Group I	-	Group I	X	X		X	
	- highest hazard group - presence in EEE doubted	25550-51-0	247-094-1	Hexahydromethylphthalic anhydride (MHHPA)	Additive	Hardener for epoxy resins	Used for the manufacture	Hardener for epoxy resins		This substance does not re	This substance is manufactured	n.d.i.		Eye Dam. 1 Resp. Sens. 1			Group I	-	Group I	X			X	
	- highest hazard group - presence in EEE doubted	19438-60-9	243-072-0	Hexahydro-4-methylphthalic anhydride	Additive	Hardener for epoxy resins	Used as a hardener in poly	Hardener for epoxy resins	isomer of MHHPA	This substance does not re	This substance is manufactured	n.d.i.		Eye Dam. 1 Resp. Sens. 1			Group I	-	Group I	X			X	
	- highest hazard group - presence in EEE doubted	48122-14-1	256-356-4	Hexahydro-1-methylphthalic anhydride	Additive	Hardener for epoxy resins	Hardener for epoxy resins	Hardener for epoxy resins	isomer of MHHPA	This substance is not prese	n.d.i.	n.d.i.		Eye Dam. 1 Resp. Sens. 1			Group I	-	Group I	X			X	
	- highest hazard group - presence in EEE doubted	57110-29-9	260-566-1	Hexahydro-3-methylphthalic anhydride	Additive	Hardener for epoxy resins	Hardener for epoxy resins	Hardener for epoxy resins	isomer of MHHPA	This substance is not prese	n.d.i.	n.d.i.		Eye Dam. 1 Resp. Sens. 1			Group I	-	Group I	X			X	
	- highest hazard group - presence in EEE doubted	127-19-5	204-826-4	N,N-dimethylacetamide (DMAC)	Intermediate chemical	NA	It is used in the production	In electronics, DMAC is use		Substance not contained i	This substance is manufactured	n.d.i.		Repr. 1B Acute Tox. 4 *			Group I	-	Group I	X			X	
	- highest hazard group - presence in EEE doubted	1303-28-2	215-116-9	Diarsenic pentaoxide; Arsenic pentoxide; Arsenic oxide	Intermediate chemical	Byproduct	It is used in wood preserva	A small amount of arsenic		Stakeholders have reporte	An ECHA document from 2009	n.d.i.		Carc. 1A Acute Tox. 3 *			Group I	Group I	Group I	X	X		X	
	- highest hazard group - presence in EEE doubted	1327-53-3	215-481-4	Diarsenic trioxide; Arsenic trioxide	Intermediate chemical	Byproduct	This substance is used in t	This substance is used in t		Stakeholders have reporte	This substance is manufactured	n.d.i.		Carc. 1A Acute Tox. 2 *			Group I	Group I	Group I	X	X		X	
Cluster I d)	- lower hazard group - high volume of use	7440-02-0	231-111-4	Nickel	Metal compound	NA	This substance is used in t	Nickel is used in alloys and			This substance is manufactured	Projected data: 80.000 t/a in EE	High volume	Carc. 2 STOT RE 1			Group II	-	Group II				X	Already restricted under REACh in artic
	- lower hazard group	68515-51-5	271-094-0	1,2-benzenedicarboxylic acid, di-C6-10-alkyl esters or mixed de	Specialty, Other	Plasticisers, lubricants, adh	This substance is used in t	This substance has been re			This substance is manufactured	n.d.i.					-	-	Group V	X			X	
Cluster I e)	- lower hazard group - presence in EEE doubted	2058-94-8	218-165-4	Henicosafluoroundecanoic acid (PFUnDA)	Specialty, Other	Insulation in certain electr	It is used in automotive an	This substance has been re		Substance not contained i	n.d.i.	n.d.i.					-	-	Group V	X			X	
	- lower hazard group - presence in EEE doubted	376-06-7	206-803-4	Heptacosafluorotetradecanoic acid (PFTDA)	Specialty, Other	Insulation in certain electr	It is used in automotive an	This substance has been re		Substance not contained i	n.d.i.	n.d.i.					-	-	Group V	X			X	
	- lower hazard group - presence in EEE doubted	307-55-1	206-203-2	Tricosafluorododecanoic acid (PFDoDA)	Specialty, Other	Insulation in certain electr	It is used in automotive an	This substance has been re		Substance not contained i	n.d.i.	n.d.i.					-	-	Group V	X			X	
	- lower hazard group - presence in EEE doubted	72629-94-8	276-745-2	Perfluorotridecanoic acid	Specialty, Other	Insulation in certain electr	It is used in automotive an	It is used in flame retardan		Substance not contained i	n.d.i.	n.d.i.					-	-	Group V	X			X	

A.10.0 Exemption methodology

Exemption evaluation methodology manual

Study to support the review of the list of restricted substances and to assess a new exemption request under RoHS (RoHS Pack 15 - Task 4)

Under the Framework Contract: Assistance to the Commission on technical, socio-economic and cost-benefit assessments related to the implementation and further development of EU waste legislation

(Final)

November 2020

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Disclaimer

Oeko-Institut and Fraunhofer IZM have taken due care in the preparation of this report to ensure that all facts and analysis presented are as accurate as possible within the scope of the project. However, no guarantee is provided in respect of the information presented, and Oeko-Institut and Fraunhofer IZM are not responsible for decisions or actions taken on the basis of the content of this report.

The information and views set out in this study are those of the author(s) and do not necessarily reflect the opinion of the Commission. The recommendations provided in this study do not preclude future decisions to be taken by the Commission.

EUROPEAN COMMISSION

Directorate-General for Environment

Directorate B - Circular Economy & Green Growth

Unit B3 - Waste Management & Secondary Materials

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Abbreviations

LCA	life cycle assessment
HMPS	high melting point solder
EEE	Electrical and Electronic Equipment
REACH	Regulation No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)
RoHS	Directive 2011/65/EU on the Restriction of the use of certain Hazardous Substances in Electrical and Electronic Equipment
SVHC	Substances of Very High Concern

1. Executive summary – English

Under Framework Contract no. ENV.A.2/FRA/2015/0008, DG Environment of the European Commission requested a consortium led by Oeko-Institut has developed a methodology to support the evaluation of exemption applications according to the criteria in Article 5(1) of Directive 2011/65/EU (RoHS hereinafter).

The methodology developed takes into account the practice used in previous exemption assessments under the RoHS Directive.

The methodology also provides elements for the comparison of quantified impacts, on the basis of life cycle analyses, in cases where the justification of an exemption is argued by the applicant relying on the third Article 5(1)(a) criterion.[1] This may be the case where the use of a RoHS substance may result in lower environmental impacts stemming for example from energy efficiency gains or of the use of recycled materials, in comparison to alternatives. The work has been undertaken by the Oeko-Institut and Fraunhofer Institute IZM.

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[1] The criterion referred to: "*the total negative environmental, health and consumer safety impacts caused by substitution are likely to outweigh the total environmental, health and consumer safety benefits thereof*."

2. Task 4: Update of the exemption evaluation methodology based on RoHS Art. 5(1)(a)

2.1. Background and Basic Principles

The core objective of the exemption evaluation process is to assess whether an exemption from the substance restriction under Article 4(1) of RoHS is justified in the light of the criteria set out in RoHS Art. 5(1)(a). RoHS Art. 5 provides the base for the evaluation of exemptions, i.e. renewals of exemptions prior to their expiry following a request for renewal or for revoking of valid exemptions currently listed in Annex III or Annex IV of RoHS or requests for new exemptions. RoHS Annex III lists the exemptions that are applicable to electrical and electronic equipment under categories 1 to 11, listed in Annex I of the RoHS Directive. Annex IV lists exemptions that are applicable only to equipment under categories 8 (medical devices) and 9 (monitoring and control instruments).

RoHS Art. 5(1)(a) stipulates[2]:

1. *“For the purposes of adapting Annexes III and IV to scientific and technical progress […] the Commission shall adopt […] the following measures:*

   (a) *inclusion of materials and components of EEE for specific applications in the lists in Annexes III and IV, provided that such inclusion does not weaken the environmental and health protection afforded by Regulation (EC) No 1907/2006* [referred to as the threshold criteria hereinafter] *and where any of the following conditions is fulfilled*:

   — *their elimination or substitution via design changes or materials and components which do not require any of the materials or substances listed in Annex II is scientifically or technically impracticable* [referred to as (I) hereinafter],

   — *the reliability of substitutes is not ensured [referred to as* (II) hereinafter],

   — *the total negative environmental, health and consumer safety impacts caused by substitution are likely to outweigh the total environmental, health and consumer safety benefits thereof* [referred to as (III) hereinafter].

   Decisions on the inclusion of materials and components of EEE in the lists in Annexes III and IV and on the duration of any exemptions shall take into account the availability of substitutes and the socioeconomic impact of substitution [referred to as (IV) hereinafter].

   Decisions on the duration of any exemptions shall take into account any potential adverse impacts on innovation. Life-cycle thinking on the overall

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[2] Different from the original wording in Directive 2011/65/EU, numbering has been added in brackets to the conditions specified under the reproduced Article 5(1)(a) text for clarity and easier referencing in following sections.

> *impacts of the exemption shall apply, where relevant* [referred to as (V) hereinafter];”

As stated in the Directive, the three conditions mentioned above (I, II and III) are to be regarded as alternatives, i.e. fulfilment of one of the conditions is sufficient to justify an exemption from the requirements of the Directive.

This document describes the current practice of how the above criteria are applied and operationalised in the technical assessments supporting the evaluation of exemption requests carried out by a contractor for the European Commission.

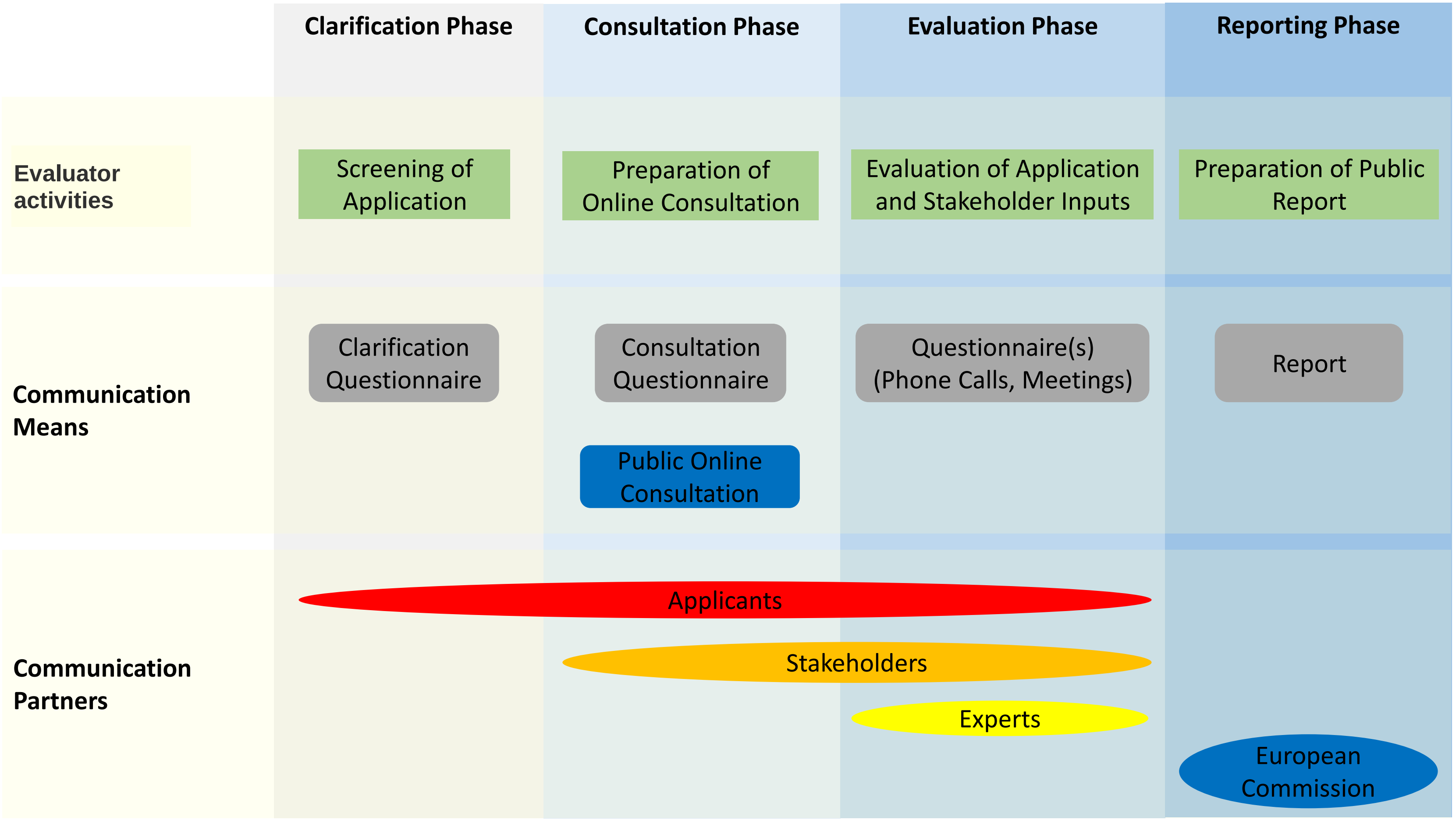
2.2. Overview of the exemption assessment

Applicants can request new exemptions, the renewal or revoking of exemptions listed in RoHS Annexes III and IV, providing information according to RoHS Annex V (Applications for granting, renewing and revoking exemptions). On the basis of the provisions specified under Article 5 of the Directive, the Commission receives requests for (granting, renewing, or revoking) exemptions that need to be evaluated in order to assess whether it is justified to grant the request in view of requirements of Article 5(1) being fulfilled the requirements order to grant.

Following the submission of exemption requests to the Commission, a technical and scientific assessment is launched by the Commission (containing single or multiple exemption requests). The outcome of the assessment is a technical report providing an analysis on all relevant aspects related to the criteria listed in Article 5(1)(a) and including the consultants’ recommendation.

Figure 2-1 illustrates the four different stages of the technical assessment including the actors and groups of stakeholders involved and the ways of communication and information exchange that have been applied over the past years.

Figure 2-1: Overview of the exemption assessment



Source: own illustration

The next chapters describe in more detail the objectives and activities of the above phases.

2.3. The clarification phase

In the clarification phase, the consultants first examine the exemption requests to determine whether the application has been prepared in accordance with the minimum information requirements listed in RoHS Annex V. This implies that the information submitted and the way it is presented is sufficiently complete, stringent and comprehensible so to understand:

- what the applicants request, i.e. which substance(s) and which components and/or materials are concerned,
- the technical background of the request, i.e. in which devices and components the substance is used and what the substance's functionality is,
- the applicants' justification why the substance cannot or should not be substituted or eliminated based on the criteria of Art. 5(1)(a),
- the proposed exemption wording including the requested validity period.

Where the information submitted in the request does not fulfil the Annex V minimum information requirements, the applicant shall be requested to complete missing information to ensure the above. Where information provided in response to such requests still does not sufficiently comply with the Annex V requirements to an extent which would prevent a successful conclusion of the assessment, this could lead to a recommendation to the Commission to not proceed with the assessment of such request.

The applicant is sent a clarification questionnaire and asked to answer the questions within a reasonable period, depending on the number and complexity of the questions. The response must be a written document that can be made publicly available for the purpose of the consultation to be performed in the next stage.

To summarise, the aim of this phase is to ensure that the available information base is sufficient to allow stakeholders to fully understand the request during the consultation phase.

2.4. The consultation phase

A targeted online consultation of stakeholders, organised and conducted by the consultants via a dedicated website, is the core element of the consultation phase. This also fulfils the requirement of Article 5(7) that requires the Commission to "*consult economic operators, recyclers, treatment operators, environmental organisations and employee and consumer associations and make the comments received publicly available*". Stakeholders are invited to submit their comments concerning the requested exemptions. Relevant stakeholders, in accordance with Article 5(7), are notified per email about the start and the duration of the consultation and instructed on how to participate. This may include for example business associations representing manufacturers of the EEE or its components (OEMs and supply chain), manufacturers of the relevant material, waste management operators, but also individual companies and operators. It is good practice to ask the applicant which other manufacturers of the equipment or materials in scope of the request are active on the market and to invite these to participate in this process. The consultation is held on a publicly available platform and is usually held for a period of eight weeks, though longer and shorter periods may apply if necessary.

The consultants prepare a Consultation Questionnaire with the following main objectives:

- to collect stakeholders' comments and evidence as to whether they support, the respective request for exemption, its scope and formulation and its requested duration;
- to obtain information from stakeholders in order to assess whether the requested exemption is required, i.e. whether the substance for which the exemption is requested can be substituted or eliminated in the application(s) in focus of the exemption request.

After the consultation phase, the consultants start assessing the exemption requests in relation to the Article 5(1) criteria.

2.5. The evaluation phase

The evaluation of exemption requests strictly follows the criteria of Art. 5(1)(a) of the RoHS Directive, c.f. section 2.1 on page 8.

For the assessment of exemption requests, information requirements stated in RoHS Annex V are of particular interest:

"[…]*(b) information on the material or component and the specific uses of the substance in the material and component for which an exemption, or its revocation, is requested and its particular characteristics;*

(c) verifiable and referenced justification for an exemption, or its revocation, in line with the conditions established in Article 5;

(d) an analysis of possible alternative substances, materials or designs on a life-cycle basis, including, when available, information about independent research, peer-review studies and development activities by the applicant and an analysis of the availability of such alternatives;

(e) information on the possible preparation for reuse or recycling of materials from waste EEE, and on the provisions relating to the appropriate treatment of waste according to Annex II to Directive 2002/96/EC;

(f) other relevant information;

(g) the proposed actions to develop, request the development and/or to apply possible alternatives including a timetable for such actions by the applicant;

(h) where appropriate, an indication of the information which should be regarded as proprietary accompanied by verifiable justification;

(i) when applying for an exemption, proposal for a precise and clear wording for the exemption;

(j) a summary of the application".

As part of this assessment, the consultants ascertain whether the applicant's justification for the exemption is comprehensible as well as scientifically and technically substantiated to allow conclusions on the practicability of substitution or elimination of the restricted substance. During the assessment process, the consultants communicate with the applicant mainly via questionnaires, until the practicability or impracticability of substitution or elimination is clarified. A stakeholder meeting (virtual or physical) may also be held where considered more efficient. The applicant or the interested parties should summarise oral arguments in writing in order to document their contribution and ensure transparency. The applicant has a general obligation to substantiate its allegations (for example the impracticability of substitution and elimination) as far as possible with evidence. A time period for providing the supporting information can be set by the consultants to enable performing the assessment. Based on all gathered evidence, the consultants conclude whether the exemption can be justified based on Article 5(1)(a) and recommend the Commission if it should be granted or not.

Consideration of stakeholders' information

In cases where the applicant is not the only manufacturer of the electrical/electronic component or EEE in the scope of the requested exemption, other relevant manufacturers are an important source of information.

These might provide relevant information in support or against the requested exemption as part of the stakeholder consultation or might be specifically contacted by the consultants as to their support or objection. In these cases, the consultant would seek to clarify if a component or product in the scope of the exemption request comparable in its functionality and other properties thereof can be manufactured without using the restricted substance, or not. If other manufacturers claim that substitution or elimination of the restricted substance is practicable, clear evidence confirming their claim will be sought.

Where such information is made available, it shall be communicated to the applicant who shall be invited to provide a detailed written justification of his claim in the light of this new information. The situation will be clarified in the course of information exchanges and discussions between the applicant, the consultants and the other manufacturers concerned. In some cases, stakeholders may be asked to participate in teleconferences or meetings to support this process.

If needed, the consultants may also consult their network of experts for more information, or for identifying issues to be further clarified.

The following sections address each of these criteria separately, explaining consideration in evaluation their fulfilment. The focus is in relation to requests for exemption renewal or for new exemptions, while requests for revoking exemptions are addressed more specifically directly below.

Revocation of Exemptions

Requests to revoke exemptions in principle also follow the procedures and conditions described below. Applicants have to plausibly explain and provide respective evidence that the conditions of Art. 5(1)(a)(I/II/III) are no longer fulfilled for a given exemption, i.e. that substitution or elimination of the restricted substance in the scope of the exemption, the revocation of which is requested, is scientifically and technically practicable and reliable and that it does not result in total negative environmental, health and consumer safety impacts that are higher than the application of the restricted substance.

In cases where other stakeholders raise objections against such a revocation in the online stakeholder consultation, the situation will be assessed following the approach described in the following sections of this chapter, resulting in a recommendation whether to revoke the exemption in line with Art. 5(1)(a)(I/II/III) or not.

If, during the stakeholder consultation, no other stakeholders express objections relating to the request for revoking the exemption, the consultants may, based on evidence provided by the applicant, recommend the Commission to repeal the exemption on the ground that substitution by non RoHS controlled substances or elimination are practicable, and that the original reason for the exemption has ceased to exist and the continuation of the exemption can no longer be justified under Art. 5(1)(a)(I/II/III).

2.5.2. Compliance of the requested exemption with Regulation (EC) No 1907/2006 (threshold criterion)

Art. 5(1)(a)(I) (see section 2.1 on page 8) requires that the exemption, if granted, does not weaken the environmental and health protection afforded by Regulation (EC) No 1907/2006 concerning the **R**egistration, **E**valuation, **A**uthorisation and **R**estriction of **Ch**emicals (REACH), which regulates the use of chemical substances on the Union market. REACH, for its part, addresses substances of concern through processes of authorisation (substances of very high concern) and restriction (substances of any concern):

- Substances that may have serious and often irreversible effects on human health and the environment can be added to the candidate list to be identified as Substances of Very High Concern (SVHCs). Following the identification as SVHC, a substance may be included in the Authorisation list, available under Annex XIV of the REACH Regulation, the “List of Substances Subject to Authorisation”, short “**Authorisation list**”. If a SVHC is placed on the Authorisation list, companies (manufacturers and importers) that wish to continue using it, or continue placing it on the market, must apply for an authorisation for a specified use.
- If a Member State(s) or the European Chemicals Agency (ECHA), upon request of the Commission, considers the use of a substance (or compound) in specific articles, or its placement on the market in a certain form to pose an unacceptable risk to human health and/or to the environment that is not adequately controlled, it shall prepare a restriction dossier. ECHA can also on its own initiative prepare a restriction dossier for any substance in the authorisation list if the use of that

substance in articles poses a risk to human health and the environment that is not adequately controlled. These restrictions are laid down in Annex XVII of the REACH Regulation: “Restrictions on the Manufacture, Placing on the Market and Use of Certain Dangerous Substances, Mixtures and Articles”. The provisions of the restriction may be made subject to total or partial bans, or conditions for restrictions, based on an assessment of the risks and the assessment of the socio-economic elements.

REACH Annex XIV and Annex XVII are essential for the evaluation of RoHS exemptions. If the substance in the scope of the exemption request is included in REACH Annex XIV, and/or its intended use is restricted in REACH Annex XVII at the time of the evaluation, it must be evaluated whether the environmental and health protection afforded by REACH would be weakened if the exemption would be granted under the provisions of RoHS.

Furthermore, substances which are subject to authorisation or restriction processes are also reviewed so that future developments may be considered where relevant.

2.5.3. Scientific and technical practicability of substitution or elimination and reliability of alternatives (criteria I and II)

Art. 5(1)(a)(II) allows an exemption to be granted if the elimination or substitution via design changes or materials and components which do not require any of the materials or substances listed in Annex II is scientifically or technically impracticable. For the purpose of the exemption assessment, ‘elimination’ is defined as avoidance of a restricted substance by changing the design or technology so that the material or component containing the restricted substance is no longer required. ‘Substitution’ is defined as replacing a restricted substance in a material by another substance.

The reliability of substitutes in Art. 5(1)(a)(III) is an inherent condition of the ‘scientific or technical practicability of substitution or elimination’ since a substitute whose reliability is not ensured is technically impracticable. If the substitute was not reliable, it would not be proposed as a viable alternative to the use of the RoHS restricted substance in question. It is therefore evaluated in this context and not separately. Nonetheless, in some cases, there may be substitutes that are suitable for a certain range of applications, but not for all (for example for general use but not for industrial use where conditions of use may demand more robust devices). Such aspects are to be considered in the assessment.

Assessment of fulfilment of this criterion

For the assessment of criteria I and II, it is of importance:

- To clarify the scope of applications to be covered by the requested exemption;
- To clarify the function of the RoHS substance within the application in terms of how the substance properties and qualities enable its function in the application;
- To clarify the availability (at present or in the future) and reliability of possible alternatives for the use of the RoHS substance in relation to options for substitution and elimination;

2.5.4. Impacts of substitution or elimination on environment, health and safety (criterion III)

Art. 5(1)(a)(III) justifies granting exemptions if the total negative environmental, health and consumer safety impacts caused by the substitution of the substance(s) addressed by RoHS are likely to outweigh the total environmental, health and consumer safety benefits thereof. Like for the impracticability of substitution and elimination and lack in the reliability of substitutes, applicants raising environmental, health and safety arguments to justify their exemption request need to provide the respective evidence, which in practice can be more challenging compared to technical evidence related to substitution and elimination. The holistic consideration of environmental and / or health and/or safety-related impacts requires a far more complex methodological approach and is a very data-intensive endeavour. Thus, it can be observed that where possible, applicants usually argue the justification of a request based on technical arguments for or against the scientific and technical practicability of substitution or elimination and the reliability of substitutes. In such cases, environmental, health and safety aspects may be raised to strengthen the argumentation. However, such impacts are less frequently presented as justification for exemptions than technical arguments as it is difficult to conclude as to fulfilment of this criterion without specifying the full range of related impacts.

Life Cycle Assessment (LCA) is one method which could be used to derive results supporting this kind of justification for exemptions. However, it has to be borne in mind that LCA only addresses potential environmental impacts throughout a product’s life cycle (see EN ISO 14040:2006). Health and safety aspects are not covered by this method. Against this background, applicants and other stakeholders have to take into consideration whether other methods or a combination of methods (e.g. risk assessment, exposure assessment, safety analysis, etc.) could be more appropriate to cover health and consumer safety impacts caused by substitution, in order to support or object a request for exemption or its revocation.

LCA is an internationally harmonised and standardised method. EN ISO 14040 sets out the principles and provides a framework for such analysis and EN ISO 14044 provides specific requirements and guidelines for application of the analysis method. Several requirements depend on the intended use of the results. The most extensive requirements, especially with regard to reporting as well as in relation to the need for a formal critical review, have to be met in those cases where LCA studies include comparative assertions intended to be disclosed to the public. In the case of supporting or refusing a request for exemption, both criteria apply: the results have to be publicly available and the LCA necessarily implies the comparison between a situation with / without use of the requested exemption at hand.

The ISO standards allow several methodological choices and leave some room for implementation, e.g. the selection of impact assessment models etc. Against this background, additional requirements based on the EU methodology on Product

Environmental Footprint (PEF)[3] are introduced below in order to provide conclusions from LCA studies that are reproducible, comparable and verifiable. It is noted that at the time of writing of this manual, the Commission methodology on PEF is specified as a suggestion for methodology improvements. Once this initiative is transferred to a Commission Communication, the weighting approach of PEF could be applied (based on available specific PEF-CR category rules or on the general PEF approach).

Further product specific specifications such as typical bill of materials (BOM) and standardised conditions of usage are available for different product groups in the context of the Ecodesign Directive, which provides consistent EU-wide rules for improving the environmental performance of products.

Based on these preliminary considerations, LCA studies intended to be considered in relation to Art. 5(1)(a)(IV) shall meet the following requirements. In accordance with the PEF methodology, the terminology is defined as follows:

- The term “shall” is used to indicate what is required from a LCA study intended to be used to support or to object a request for exemption.
- The term “should” is used to indicate a recommendation rather than a requirement. Any deviation from a “should” requirement has to be justified by the applicant or stakeholder who uses LCA studies in the exemption context.
- The term “may” is used to indicate an option that is permissible without further justification.

Requirements:

- The data to be used for the LCA study shall be in accordance with the exemption considered/ requested in relation to (i) time-related coverage, (ii) geographical coverage, and (iii) technological coverage of the exemption and relevant substitutes. In particular, the comparison must be representative in terms of the technologies used and their state of development over time.
- As generally results of LCA studies strongly depend on data and assumptions in relation to energy supply and recycling, the LCA shall comply with the modelling requirements on electricity use and end of life modelling of the EU PEF methodology.
- The LCA shall take into account a comprehensive set of impact categories and should use the 16 PEF impact categories and models, including the characterisation factors provided.
- If the exemption considered relates to products which are covered by implementing measures according to the Ecodesign Directive (e.g. lighting, displays), LCA studies shall take basic definitions in relation to BOM and condition of usage into consideration.

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[3] The requirements are based on both, the Recommendation 2013/179/EU on the use of common methods to measure and communicate the life cycle environmental performance of products and organisations and the recently published suggestions for updating the PEF method (Zampori and Pant, 2019).

- The LCA reports submitted shall comply with the reporting requirements of EN ISO 14044, section 5.1 to 5.3. The report shall include the identification of hotspots to be understood as (i) most relevant impact categories, (ii) most relevant life cycle stages, (iii) most relevant processes, and (iv) most relevant elementary flows.
- The LCA study shall include a critical review according to EN ISO 14044, section 6.3. This means that the critical review has to be carried out by interested parties. The chairperson of the review shall select at least one representative of the EU Commission as a member of the group of interested parties.
- The scope of the critical review shall be documented according to the requirements of ISO TS 14071.

2.5.5. Availability of substitutes and socioeconomic impact of substitution (criterion IV)

Article 5(1)(a)(V) stipulates that "*Decisions on the inclusion of materials and components of EEE in the lists in Annexes III and IV […] shall take into account the availability of substitutes and the socioeconomic impact of substitution*." According to Art. 3(25), the "'*availability of a substitute means the ability of a substitute to be manufactured and delivered within a reasonable period of time as compared with the time required for manufacturing and delivering the substances listed in Annex II*."

In respect of the 'availability of substitutes' and 'socio-economic impact of substitution', the European Commission's Frequently Asked Questions Document for RoHS[4] specifies that "*an exemption cannot be based on these parameters only. These are not considered to be as significant as the three criteria mentioned above. If a criterion is fulfilled, the parameters may subsequently influence the decision-making*."

Where lacking information does not allow ascertaining the fulfilment of criteria (I-III), but where data suggest that the socioeconomic impacts of substitution or the limited availability of the substitutes might reach a level where impacts are comparable to the scientific and technical impracticability of substitution or elimination, i.e. resulting in a market supply gap, or in outweighing the total environmental, health and consumer safety benefits of the substitution. In such cases, an exemption might be justifiable in line with Art. 5(1)(a) based on socioeconomic impacts or the non-availability of the substitute.

2.5.6. Assessing the duration of exemptions

Article 5(1)(a)(VI) requires decisions on the duration of an exemption to consider adverse impacts on innovation and life-cycle thinking. Recommendations as to the duration of an exemption shorter than the maximum period are justified if substitution or elimination of the restricted substance in the applications in scope of the exemption is expected to be possible within a shorter time period. Applicants sometimes already

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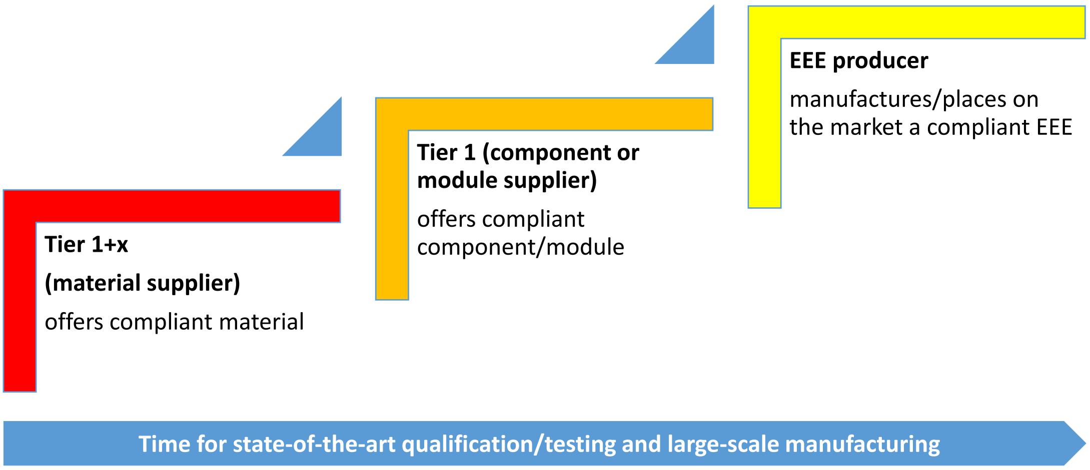
[4] See: https://ec.europa.eu/environment/waste/rohs_eee/pdf/faq.pdf, pg. 25

mention upcoming RoHS-compliant solutions in their exemption application. Stakeholders may also address such solutions during the stakeholder consultation, or the consultants may come across such alternatives in the course of the evaluation. Provided these solutions for substitution or elimination are scientifically and technically practicable, it may still be justified to grant the exemption for a certain time, mainly for testing and qualification, the duration depending on the stage of development and where in the supply chain the solution is available. Figure 2-2 and the following explanations illustrate the situation.

Figure 2-2: Compliant solutions in the supply chain and duration of exemptions



Source: Own illustration

1. Substitution or elimination have been practiced successfully on material supplier level
    - A supplier offers a compliant material, which, however, needs to be tested or qualified in the supply chain, i.e. in the component or module in which it shall be used, and in the EEE.
    - Example: A new type of lead-free solder which can replace lead high melting point solder (lead HMPS, c.f. exemption 7 (a) listed in Annex III).

2. Substitution or elimination have been practiced successfully on component or module level
    - A manufacturer of a component or module has successfully substituted or eliminated the restricted substance, but the component/module still needs to be tested and qualified for use in EEE.
    - Example: The new type lead HMPS has been tested and qualified for die attach.

3. Substitution or elimination have been practiced successfully on EEE producer level

- A producer of EEE can apply the compliant component or module in EEE, but is not yet ready for industrial scale production.

Since producers are responsible for the reliability and safety of their products, the time for state-of-the-art testing and qualification needs to be taken into account when deciding about the duration of exemptions. The earlier in the supply chain substitution or elimination has been practiced, the more time may be required to allow for testing and qualification of the compliant solution up to the use in EEE. Additional time may also be required for the industrialisation and production ramp up of the compliant product and also for recertification of equipment which may be a condition for marketing in some sectors (e.g., medical devices).

According to Art. 5(1)(a), "Decisions […] on the duration of any exemptions shall take into account the **availability of substitutes** and the **socioeconomic impact of substitution**" and "[…] any potential adverse **impacts on innovation**. Life-cycle thinking on the overall impacts of the exemption shall apply, where relevant".

RoHS Art. 3(25) defines the *"availability of a substitute' as […] the ability of a substitute to be manufactured and delivered within a reasonable period of time as compared with the time required for manufacturing and delivering the substances listed in Annex II*". Lacking availability of substitutes could, for example, occur in cases where substitution is in principle possible, but the industrial scale production is still in the ramp up phase resulting in undue delivery times in the supply chain. In such a case, an exemption could be granted for a period after which it is foreseeable that the substitute will be available.

Socioeconomic impacts of relevance for the duration of an exemption could arise, for example, if the use of a substitute requires the requalification of staff to warrant its safe and reliable use. Another possibility could be that the cost of substitutes is prohibitively high in the initial phase until foreseeably more than one manufacturer produces the substitute, thus spurring competition and decreasing prices. In such cases, an exemption could be renewed or granted for a certain time despite of scientifically and technically practicable substitution or elimination.

Negative impacts on innovation could emerge if a substitute is in development and expected to be market ripe within a few years. Specifying a shorter duration in this case would ensure that the assessment is revised when the substitute becomes available to clarify if the exemption is still needed or if it can be revoked.

2.6. The preparation of the Report

After the evaluation has been closed, the consultants prepare a report for the Commission providing the following core information:

- the technical background of the requested exemption;
- the applicants' and other stakeholders' justification why the exemption is required and should be granted;
- other stakeholders' justifications and arguments why the exemption from their point of view is not required and should therefore not be granted;

- the consultants' assessment of the presented evidence and arguments and of their relation to Article 5(1)(a) – here additional information retrieved from publicly available sources or through contact with relevant experts and professionals is also to be assessed;
- the consultants' recommendation for the requested exemption(s) including the wording and an expiry date.

The Commission might ask the consultants for feedback and clarifications on technical and other aspects, or adjustments of certain aspects e.g. regarding how the requirements of Art. 5(1)(a) were applied. The report as approved is published.

A.11.0 Exemption evaluation

Assessing three exemption requests for the use of cadmium in quantum dot applications in displays and lighting

Study to support the review of the list of restricted substances and to assess a new exemption request under RoHS (RoHS Pack 15 - Task 5, final)

Under the Framework Contract: Assistance to the Commission on technical, socio-economic and cost-benefit assessments related to the implementation and further development of EU waste legislation

November 2020

Prepared by Oeko-Institut e.V., Institute for Applied Ecology, and Fraunhofer-Institut for Reliability and Microintegration (IZM)

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Disclaimer

Oeko-Institut and Fraunhofer IZM have taken due care in the preparation of this report to ensure that all facts and analysis presented are as accurate as possible within the scope of the project. However, no guarantee is provided in respect of the information presented, and Oeko-Institut and Fraunhofer IZM are not responsible for decisions or actions taken on the basis of the content of this report.

The information and views set out in this study are those of the author(s) and do not necessarily reflect the opinion of the Commission. The recommendations provided in this study do not preclude future decisions to be taken by the Commission.

EUROPEAN COMMISSION

Directorate-General for Environment

Directorate B - Circular Economy & Green Growth

Unit B3 - Waste Management & Secondary Materials

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1. Executive summary – English

Under Framework Contract no. ENV.A.2/FRA/2015/0008, DG Environment of the European Commission contracted a consortium led by Oeko-Institut for "*Assessing an exemption request for the use of cadmium in luminescent material for on-chip application on LED semiconductor chips*". This request was submitted by LightingEurope (hereinafter referred to as LE) and applied for a new exemption. In an amendment to this contract, this task was expanded to include the evaluation of two further requests "for renewal of exemption 39(a) in Annex III to Directive 2011/65/EU". The requests were submitted by Najing technology Co.Ltd (hereinafter referred to as Najing) and by OSRAM Opto Semiconductor GmbH (hereinafter referred to as OSRAM).

1.1. Background and objectives

The RoHS 2 Directive 2011/65/EU entered into force on 21 July 2011 and led to the repeal of Directive 2002/95/EC on 3 January 2013. The Directive can be considered to have provided for two regimes under which exemptions could be considered, RoHS 1 (the former Directive 2002/95/EC) and RoHS 2 (the current Directive 2011/65/EU).

- The scope covered by the Directive is now broader as it covers all electrical and electronic equipment (EEE; as referred to in Articles 2(1) and 3(1));
- The former list of exemptions has been transformed in to Annex III and may be valid for all product categories according to the limitations listed in Article 5(2) of the Directive. Annex IV has been added and lists exemptions specific to categories 8 and 9;
- The RoHS 2 Directive includes the provision that applications for exemptions have to be made in accordance with Annex V. However, even if a number of points are already listed therein, Article 5(8) provides that a harmonised format, as well as comprehensive guidance – taking the situation of SMEs into account – shall be adopted by the Commission; and
- The procedure and criteria for the adaptation to scientific and technical progress have changed and now include some additional conditions and points to be considered. These are detailed below.
- The new Directive details the various criteria for the adaptation of its Annexes to scientific and technical progress. Article 5(1)(a) details the various criteria and issues that must be considered for justifying the addition of an exemption to Annexes III and IV:
- The first criterion may be seen as a threshold criterion and cross-refers to the REACH Regulation (1907/2006/EC). An exemption may only be granted if it does not weaken the environmental and health protection afforded by REACH;
- Furthermore, a request for exemption must be found justifiable according to one of the following three conditions:
- Substitution is scientifically or technically impracticable, meaning that a substitute material, or a substitute for the application in which the restricted substance is used,

is yet to be discovered, developed and, in some cases, approved for use in the specific application;

- The reliability of a substitute is not ensured, meaning that the probability that EEE using the substitute will perform the required function without failure for a period of time comparable to that of the application in which the original substance is included, is lower than for the application itself;
- The negative environmental, health and consumer safety impacts of substitution outweigh the benefits thereof.
- Once one of these conditions is fulfilled, the evaluation of exemptions, including an assessment of the duration needed, shall consider the availability of substitutes and the socio-economic impact of substitution, as well as adverse impacts on innovation, and life cycle analysis concerning the overall impacts of the exemption; and
- A new aspect is that all exemptions now need to have an expiry date and that they can only be renewed upon submission of a new application.

Against this background, and taking into account that exemptions falling under the enlarged scope of RoHS 2 can be applied for since the entry into force of the Directive (21.7.2011), the consultants carried out evaluation of three exemptions in this study: two request for a renewal of an existing exemption and one request for a new exemption).

1.2. Key findings – Overview of the evaluation results

The exemption requests covered in this project and the applicants concerned, as well as the final recommendations and proposed expiry dates are summarised in Table 1-1. One request has been made for a new exemption and two requests exemption renewal were included in the scope of this project.

All three requests concern cadmium quantum dot applications and thus these exemptions have been evaluated jointly to allow an alignment of possible future exemptions (new, renewed or amended) for such applications. The requested exemptions are specified in Table 1-1 below along with the details of submission.

Table 1-1: Exemption overview

Ex. Req. No.	**Requested exemption**	**Applicant**	**Recommendation**	**Expiry date and scope**
Request 2018-1	"Cadmium (<1000 ppm) in luminescent material for on-chip application on LED semiconductor chips for use in lighting applications of at least CRI 80" requested to be valid for 5 years	*LE*	*"Cadmium in downshifting semiconductor nanocrystal quantum dots* *I. directly deposited on LED semiconductor chips for use in*	5 years

Annex III, Ex. 39a	“Cadmium in downshifting semiconductor nanocrystal quantum dots directly deposited on LED chips for use in display and projection applications (< 5 µg Cd per mm² of light emitting LED chip surface)” requested to be valid for 5 years	*Osram*	*display and projection applications (< 5 µg Cd per mm² of light emitting LED chip surface)* *II. directly deposited on LED semiconductor chips for use in lighting applications of at least CRI 90 (< 1.000 ppm in the luminescent material)* *provided that applications comply with entry 72 of Annex XVII of Regulation 1907/2006.”*	
Annex III, Ex. 39a	“Cadmium selenide in downshifting cadmium-based semiconductor nanocrystal quantum dots for use in display lighting applications (<0.1 µg per mm2 of display screen area)” requested to be valid until October 31, 2021	Najing	Denied	

Note: As in the RoHS legal text, commas are used as a decimal separator for exemption formulations appearing in this table, in contrast to the decimal point used throughout the rest of the report as a separator.

The work has been undertaken by the Oeko-Institut.

2. Introduction

2.1. Project scope and methodology

The scope of the project covers the evaluation of three exemptions: two for exemption renewal and one request for new exemptions. An overview of the exemption requests is given in Table 1-1 in the Executive Summary.

In the course of the project, a stakeholder consultation was conducted. The stakeholder consultation was launched on 18 March 2019 and was planned for duration of eight weeks and was then extended by another five days thus concluding 13 May 2019.

The specific project website was used in order to keep stakeholders informed on the progress of work: http://rohs.exemptions.oeko.info. The consultation held during the project was carried out according to the principles and requirements of the European Commission. Stakeholders who had registered at the website were informed through email notifications about new steps within the project.

Information concerning the consultation was provided on the project website, including a general guidance document, the applicants' documents for each of the exemption requests, results of earlier evaluations where relevant, a specific questionnaire and a link to the EU CIRCA website. Contributions were not made to either of the exemptions.

Following the stakeholder consultations, an in-depth evaluation of the exemptions began. The requests were evaluated according to the relevant criteria laid down in Article 5(1) of the RoHS 2 Directive, as shown in the section on background and objectives.

The assessment of the exemptions evaluated in the course of the project were carried out as a joint evaluation as they all concern cadmium in quantum dot applications. The assessment appears in chapter 4. The information provided by the applicants and by stakeholders is summarised in the first sections of the respective chapters. This includes a general description of the application and requested exemption, a summary of the arguments made for justifying the exemption, information provided concerning possible alternatives and additional aspects raised by the applicants and other stakeholders. In the Critical Review part, the submitted information is discussed, to clarify how the consultants evaluate the various information and what conclusions and recommendations have been made. The general requirements for the evaluation of exemption requests as set by the European Commission may be found in the technical specifications of the project.[1]

2.2. Project set-up

Assignment of project tasks to Oeko-Institut, started in 12 December 2018. The overall project has been led by Carl-Otto Gensch. At Fraunhofer IZM the contact person is Otmar Deubzer.

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[1] Cf. https://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Pack_17/Technical_Request_RoHS_Pack_17.pdf

3. Links between the RoHS Directive and the REACH Regulation

Article 5 of the RoHS 2 Directive 2011/65/EU on "Adaptation of the Annexes to scientific and technical progress" provides for that:

> "*inclusion of materials and components of EEE for specific applications in the lists in Annexes III and IV, provided that such inclusion does not weaken the environmental and health protection afforded by Regulation (EC) No 1907/2006*".

Regulation (EC) No 1907/2006 on the **R**egistration, **E**valuation, **A**uthorisation and Restriction of **Ch**emicals (REACH) regulates the manufacturing, use or placing on the market of chemical substances on the Union market. REACH, for its part, addresses hazardous substances through processes of authorisation (substances of very high concern) and restriction (substances of any concern):

- Substances that may have serious and often irreversible effects on human health and the environment can be added to the candidate list to be identified as Substances of Very High Concern (SVHCs). Following the identification as SVHC, a substance may be included in Annex XIV of the REACH Regulation (Authorisation list): "List of Substances Subject to Authorisation". If a SVHC is placed on the Authorisation list, companies (manufacturers and importers) that wish to continue using it, or continue placing it on the market, must apply for an authorisation for a specified use. Article 22 of the REACH Regulation states that: *"Authorisations for the placing on the market and use should be granted by the Commission only if the risks arising from their use are adequately controlled, where this is possible, or the use can be justified for socio-economic reasons and no suitable alternatives are available, which are economically and technically viable."*
- If a Member States or the European Chemicals Agency (ECHA) upon request of the Commission considers that the manufacture, placing on the market or use of a substance on its own, in a mixture or in an article poses a risk to human health or the environment that it is not adequately controlled, it shall prepare a restriction dossier. ECHA has also the initiative to prepare a restriction dossier for any substance in the authorisation list if the use of that substance in articles poses a risk to human health and the environment that is not adequately controlled. The provisions of the restriction may be made subject to total or partial bans, or conditions for restrictions, based on an assessment of the risks and the assessment of the socio-economic elements.

The approach adopted in this report is that once a substance has been included into the Annexes related to authorisation or restriction of substances and articles under the REACH Regulation, the environmental and health protection afforded by REACH may be weakened in cases where an exemption would be granted for these uses under the provisions of RoHS. This is essentially the same approach as it has first been adopted for the re-evaluation of some existing RoHS exemptions 7(c)-IV, 30, 31 and 40,[2] and in the following for the evaluation of a range of requests assessed through previous projects in respect of RoHS 2.[3] Substances for which an authorisation or restriction process is underway may be discussed in some cases in relation to a specific exemption, in order to check possible overlaps in the scope of such processes and of requested RoHS exemptions and to identify the need for possible alignments of these two legislations.[4]

When evaluating the exemption requests, with regard to REACH compliance, we have checked whether the substance / or its substitutes are:

- on the list of substances of very high concern (SVHCs- the Candidate List);
- in the recommendations of substances for Annex XIV (recommended to be added to the Authorisation List);
- listed in REACH Annex XIV itself (the Authorisation List); or
- listed in REACH Annex XVII (the List of Restrictions).

As ECHA is *"the driving force among regulatory authorities in implementing the EU's chemicals legislation"*, the ECHA website has been used as the reference point for the aforementioned lists, as well as for the register of the amendments to the REACH legal text.

The figure below shows the relationship between the two processes under REACH as well as the process on harmonized classification and labelling under the CLP regulation (Regulation (EC) No 1272/2008 on Classification, Labelling and Packaging). Substances included in the red areas may only be used when certain specifications and or conditions are fulfilled.

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[2] See Zangl, S.; Blepp, M.; Deubzer, O. (2012) Adaptation to Scientific and Technical Progress under Directive 2011/65/EU - Transferability of previously reviewed exemptions to Annex III of Directive 2011/65/EU, Final Report, Oeko-Institut e.V. and Fraunhofer IZM, February 17, 2012, http://rohs.exemptions.oeko.info/fileadmin/user_upload/Rohs_V/Re-evaluations_transfer_RoHS_I_RoHS_II_final.pdf

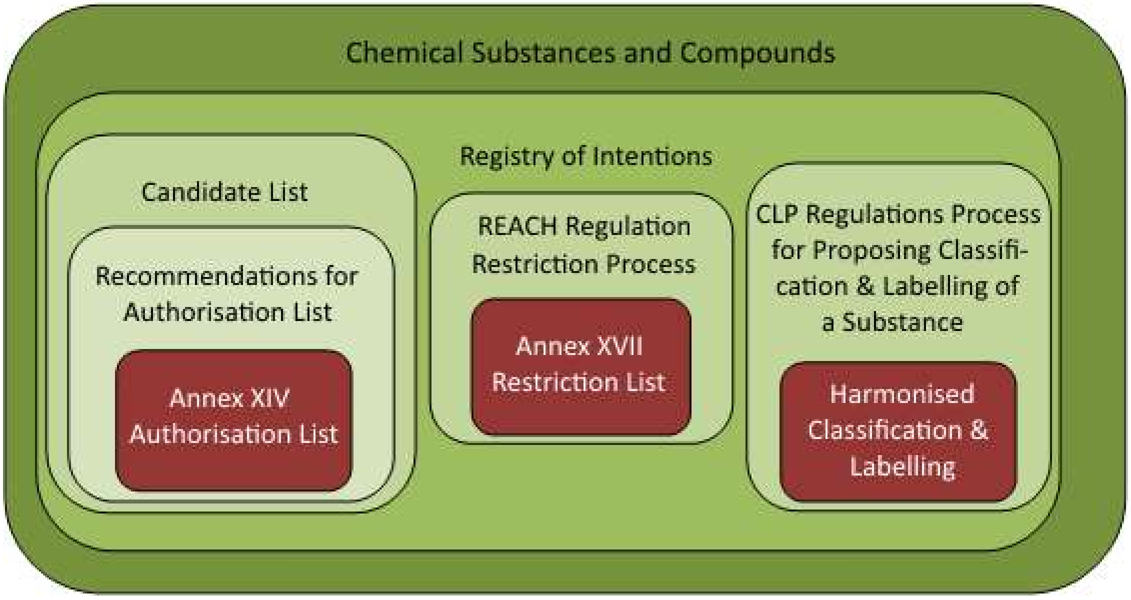
[3] Gensch, C., Baron, Y., Blepp, M., Deubzer, O., Manhart, A. & Moch, K. (2012) Assistance to the Commission on technological, socio-economic and cost-benefit assessment related to exemptions from the substance restrictions in electrical and electronic equipment (RoHS Directive), Final Report, Oeko-Institut e.V. and Fraunhofer IZM, 21.12.2012 http://rohs.exemptions.oeko.info/fileadmin/user_upload/Rohs_V/RoHS_V_Final_report_12_Dec_2012_final.pdf

For further reports, see archive of reports of Oeko-Institut e.V. and Fraunhofer IZM at http://rohs.exemptions.oeko.info/index.php?id=164

[4] In 2014, the European Commission has prepared a Common Understanding Paper regarding the REACH and RoHS relationship in 2014 with a view to achieving coherence in relation to risk management measures, adopted under REACH and under RoHS:

REACH AND DIRECTIVE 2011/65/EU (RoHS) A Common Understanding; Ref. Ares(2014)2334574 - 14/07/2014 at http://ec.europa.eu/DocsRoom/documents/5804/attachments/1/translations

Figure 3-1: Relation of REACH Categories and Lists to Other Chemical Substances



Source: Own illustration

Before reaching the "Registry of Intentions" as shown in the figure above, there are additional activities and processes in order to identify substances of potential concern conducted by the ECHA together with the Member States and different ECHA Expert Groups.[5] If a Member State evaluates certain substance to clarify whether its use poses a risk to human health or the environment, the substance is subject to a Substance Evaluation. The objective is to request further information from the registrants of the substance to verify the suspected concern. Those selected substances are listed by ECHA in the community rolling action plan (CoRAP).[6] If the Substance Evaluation concludes that the risks are not sufficiently under control with the measures already in place and if a Risk Management Option (RMO) analyses does not conclude that there are appropriate instruments by other legislation / actions, the substance will be notified in the Registry of Intentions.

The following bullet points explain in detail the above-mentioned lists and where they can be accessed:

- Member States Competent Authorities (MSCAs) / ECHA, on request by the Commission, may prepare Annex XV dossiers for identification of SVHCs, Annex XV dossiers for proposing a harmonised Classification and Labelling, or Annex XV

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[5] For an overview in these activities and processes see the ECHA webpage at: https://echa.europa.eu/substances-of-potential-concern

[6] Updates and general information can be found under: https://echa.europa.eu/information-on-chemicals/evaluation/community-rolling-action-plan/corap-list-of-substances. The list can be found on the following page: https://echa.europa.eu/information-on-chemicals/evaluation/community-rolling-action-plan/corap-table

dossiers proposing restrictions. The aim of the public Registry of Intentions is to inform interested parties of the substances for which the authorities intend to submit Annex XV dossiers and, therefore, to facilitate timely preparation of the interested parties for commenting later in the process. It is also important to avoid duplication of work and encourage co-operation between Member States when preparing dossiers. Note that the Registry of Intentions is divided into three separate sections: listing new intentions; intentions still subject to the decision-making process; and withdrawn intentions. The registry of intentions is available at the ECHA website at: https://echa.europa.eu/registry-of-intentions;

- The identification of a substance as a Substance of Very High Concern and its inclusion in the Candidate List is the first step in the authorisation procedure. The Candidate List is available at the ECHA website at https://echa.europa.eu/candidate-list-table;
- The last step of the procedure, prior to inclusion of a substance into Annex XIV (the Authorisation list), involves ECHA issuing a Recommendation of substances for Annex XIV. The previous ECHA recommendations for inclusion in the Authorisation List are available at the ECHA website at https://echa.europa.eu/previous-recommendations;
- Once a decision is made, substances may be added to the Authorisation List available under Annex XIV of the REACH Regulation. The use of substances appearing on this list is prohibited unless an Authorisation for use in a specific application has been approved. The Annex can be found in the consolidated version of the REACH legal text;
- In parallel, if a decision is made concerning the Restriction on the use of a substance in a specific article, or concerning the restriction of its provision on the European market, then a restriction is formulated to address the specific terms, and this shall be added to Annex XVII of the REACH Regulation. The Annex can be found in the consolidated version of the REACH legal text; and

As of April 2020, the consolidated version of the REACH legal text, dated 27.02.2020, was used to reference Annexes XIV and XVII: The consolidated version is available at the EUR-Lex website: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02006R1907-20200227. Relevant annexes and processes related to the REACH Regulation have been cross-checked to clarify:

- In what cases granting an exemption could "weaken the environmental and health protection afforded by Regulation (EC) No 1907/2006" (Article 5(1)(a) of the RoHS Directive).
- Where processes related to the REACH Regulation should be followed to understand where such cases may become relevant in the future.

In this respect, restrictions and authorisations as well as processes that may lead to their initiation, have been reviewed, in respect of where RoHS Annex II substances are mentioned (i.e. lead, mercury, cadmium, hexavalent chromium, polybrominated biphenyls (PBB) and polybrominated diphenyl ethers (PBDE) as well as bis(2-ethylhexyl) phthalate (DEHP), butyl benzyl phthalate (BBP), dibutyl phthalate (DBP), diisobutyl phthalate (DiBP).[7]

Compiled information in this respect has been included, with short clarifications where relevant, in Tables 1 and 2, which appear in Appendix 1.

The information has further been cross-checked in relation to the exemption evaluated in the course of this project. This has been done to clarify that the Article 5(1)(a) threshold-criteria quoted above is complied with in cases where an exemption is to be granted / its duration renewed / its formulation amended / or where it is to be revoked and subsequently to expire as an exemption. The considerations in this regard are addressed in the separate chapter in which the exemption evaluation is documented (Chapter 4) under the relevant section titled "REACH compliance – Relation to the REACH Regulation" (Section 4.4.1).

4. Joint evaluation of three exemptions for cadmium quantum dots applications in display and lighting

Declaration

In the sections that precede the "Critical review" the phrasings and wordings of applicant's and stakeholders' explanations and arguments have been adopted from the documents provided by the stakeholders as far as required and reasonable in the context of the evaluation at hand. Formulations were only altered or completed in cases where it was necessary to maintain the readability and comprehensibility of the text. These sections are based exclusively on information provided by applicants and stakeholders, unless otherwise stated.

Acronyms and definitions

BLU	Back light unit
CCT	Correlated Color Temperature
Cd	Cadmium
CdS	Cadmium sulfide
CdSe	Cadmium Selenide
CRI	Color Rendering Index
FWHM	Full width half maximum
InP	Indium phosphide
LCA	Life cycle assessment

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[7] The four phthalates, DEHP, BBP, DBP and DIBP have been added to the Annex according to Commission Delegated Directive (EU) 2015/863 of 31 March 2015.

LE	LightingEurope
Najing	Najing technology Co. Ltd
OSRAM	OSRAM Opto Semiconductor GmbH
PFS	Potassium fluorosilicate
QD	Quantum dots
SSL	Solid state lighting

4.1. Background

LightingEurope (2017) explains that quantum dots (QDs) are a relatively new material class that, like phosphors, down convert light from higher energy wavelengths of typically blue light to lower energy wavelengths in the visible and near-infra-red range. Key characteristics of quantum dots are explained to be their potentially very high efficiency, their narrow emission spectrum, and that their emission wavelength can be accurately tuned across the entire visible spectrum. The narrow emission spectrum prevents the needless generation of invisible infrared radiation. No other downconverter exists which exhibits narrow emission (<40 nm full width at half maximum, or FWHM), is wavelength-tunable to within 1 nm, and has very high photoluminescence quantum efficiencies, both at room temperature and LED operating temperatures. Considering these features, QDs can be used to improve the performance and energy efficiency of today’s white phosphor-converted LEDs by replacing one or more of the phosphors used as light down converting elements.

Quantum dots (QDs) are to have sizes ranging from 1~100 nm, that have a quantum confinement effect. By tuning the sizes of the crystals through their synthesis process, QDs can be produced to emit different wavelengths. Such wavelengths can cover the whole visible light spectrum from blue wavelength range to red wavelength range. The possibility to tune the light emitting properties of QDs is explained to differentiate them from other photo-luminescent materials, such as phosphor, or organic dye. (Najing 2018)

According to the information provided by the applicants (LightingEurope 2017; Najing 2018; OSRAM 2018), QDs are used among others in display applications and in lighting applications (solid state lighting or SSL). LightingEurope (2017) explains that cadmium is a component in II-IV semiconductor quantum dots (typically based on CdSe or CdS) and is used in the quantum dot core or quantum dot shell.

Besides their colour emission properties, Cd QDs show higher energy efficiency as compared with other traditional components used in displays, such as phosphor LED or cold cathode fluorescent lamps. Through their development, cadmium-based QDs now achieve around 20~30 nm of FWHM and are stable in display applications, with expected lifetime for 10 years. (Najing 2018)

As for use in solid state lighting, LightingEurope (2017) further explains that the use of Cd-containing quantum dots in on-chip LED applications will enhance the luminous efficacy[8] of LEDs by 10-20 % (based on Correlated Color Temperature (CCT) and Color Rendering Index (CRI)) above best-available conventional phosphors. This provides significant energy savings said to outweigh the potentially negative effects of the amount of cadmium entering the market through this application.

Najing technology Co. Ltd (hereinafter Najing) requests (Najing 2018) a renewal of exemption 39a of Annex III of RoHS for a period of two years. The exemption is requested with the following formulation:

> "*Cadmium selenide in downshifting cadmium-based semiconductor nanocrystal quantum dots for use in display lighting applications (<0.1 µg per mm^2 of display screen area)*"

Najing (2018) requests the exemption for quantum dot light converting film used in display devices and specifically addresses category 1 (Large household appliances); category 2 (small household appliances); category 4 (consumer equipment) and category 5 (lighting equipment) in its request. Though its application provides detail only for on-surface applications, Najing contends that the scope of the exemption should not be limited to on-surface applications, but should remain available to all application configurations. Najing (2019) later specified that it requests the exemption be renewed until 31 October 2021.

Najing (2018) explains that the use of Cd QD in various application areas allows producing devices (e.g., lighting applications, display applications) that provide improved colour performance (e.g., warmer light output in lighting, higher colour gamut in displays). Additionally, this improved performance can be achieved alongside higher energy efficiency of the product in comparison to alternative technologies (examples are given to show the benefit in terms of energy consumption). In this respect the applicants' main justification for the exemption request refers to the potential for savings in energy consumption in relation to similar EEE.

OSRAM GmbH and OSRAM Opto Semiconductor GmbH (hereafter OSRAM) also request to renew the exemption for 5 years, but propose the following wording for this purpose (OSRAM 2018):

> "*Cadmium in downshifting semiconductor nanocrystal quantum dots directly deposited on LED chips for use in display and projection applications (< 5µg Cd per mm² of light emitting LED chip surface)*"

OSRAM (2018) explains that the change of wording is mainly related to the shift from surface and edge illumination to on-chip technology. The on-chip technology is explained to be innovative and to require additional research for the development of the LED itself as well as existing and new applications.

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[8] According to LightingEurope (2018), "*luminous efficacy is a measure of how efficiently a light source produces visible light. It is the ratio of luminous flux to input electrical power, measured in lumens per watt of energy used.*"

Aside from the justification raised by Najing, OSRAM (2018) further contends that in the on-chip application, there is no alternative to Cd QDs that can convert blue LED light efficiently into narrow red or green colour and that can withstand the reliability requirements on LEDs. This is particularly relevant for very small converters in nano-meter size.

LightingEurope (2017) requests a new exemption, explaining it to be "*more narrowly limited to the specific use of this new technology in LED semiconductor chips*". The following exemptions is requested for a five-year duration:

> "*Cadmium (<1000 ppm) in luminescent material for on-chip application on LED semiconductor chips for use in lighting applications of a* Color Rendering Index (CRI) of *at least 80*."

LightingEurope (2017) also refers to the use of Cd QD being the only type of QD that can currently be used in an on-chip configuration with the aforementioned advantageous properties. The quantum efficiency and reliability under on-chip operating conditions has not been resolved for alternative non-cadmium materials.

LightingEurope (2018) provides the following information as to the application areas of Cd QD for lighting applications: The Lighting Industry expects that Cd QD LEDs will first enter markets where accurate colour rendering is of high importance, i.e. when the surroundings should look natural and realistic. The general lighting market can be divided in multiple ways. In their 2012 report McKinsey divides the general lighting market into seven categories: residential, office, shop, hospitality, industrial, outdoor and architectural lighting. High quality of light is not limited to a specific application. In cases where it is only relevant to see an object, but not see colour accurately, light can be of a lower colour quality (e.g. in parking lots) and these markets are currently not the main target groups. Examples of specific applications are provided below:

- bathrooms (to be able to accurately apply makeup, to accurately see the colour of your skin, teeth etc. in the mirror);
- living rooms, dining rooms (to accurately see the colour of food, artwork, people);
- museums (to accurately see the colour of paintings);
- retail/shops (to accurately and appealingly reproduce the colour of objects for sale);
- hospitality/hotels (to appealingly represent the colours of artwork, furniture, and people);
- stadium lighting (to accurately represent the colours of the athletes both to the audience and the TV cameras);
- surgical lighting (to ensure the colours of tissue are accurately represented indicating to the surgeon the oxygenation level of tissue. In this instance high efficiency lighting has added importance beyond simply energy savings; it means the surgeon does not sweat under the heat of the lamps generating the intense light required for surgery).

4.1.1. The history of exemptions for Cd QD applications

The exemption was first requested in 2008 by 3M as an alternative to mercury-based lamps. 3M justified at the time that this application would lead to a reduction in the quantity of heavy metals released to the environment, a reduction in energy consumption of related products and a reduced quantity of E-waste in light of longer product lifetimes. The argumentation could be followed and the following wording was recommended and added as an exemption to the RoHS Directive (Gensch et al. 2009):

> *"Cadmium in colour converting II-VI LEDs (< 10 µg Cd per mm2 of light-emitting area) for use in solid state illumination or display systems".*

Following the recast of the RoHS Directive, the exemption was carried over to RoHS 2 and listed in Annex III as Ex. 39.

In 2013, the European Commission received two requests related to this application, from 3M and from QD Vision. The requests were evaluated and recommended to be granted in April 2014. Based on the evaluation report, the European Commission (EC) decided to amend Ex. 39 of Annex III and prepared a delegated act for this purpose. On the 20 May 2015, the European Parliament objected to the Commission Delegated act adopted based on the mentioned report[9], claiming that the report need be updated. This update led to a new recommendation to amend the exemption wording and grant it for a limited period for display applications only. Ex. 39 was deleted, and the following wording was added to annex III as Ex. 39(a):

> "*Cadmium selenide in downshifting cadmium-based semiconductor nanocrystal quantum dots for use in display lighting applications (< 0,2 µg Cd per mm2 of display screen area)*" Expires for all categories on 31 October 2019

4.1.1. Amount of cadmium used under the exemptions

In relation to the content of Cd in the homogeneous material Najing (2018) generally explains that in Cd QD film applications in displays, as the area of the film increases, its thickness decreases and the weight percentage of cadmium thus also increases. This is demonstrated in Table 4-1. Najing estimates that "*typically 101 kg of cadmium will be placed on the EU market annually by this application*" and provides Table 4-2 demonstrating the calculations supporting this estimation and explaining the assumptions behind this estimation (see application for further details).

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[9] EP (2015), European Parliament, European Parliament resolution of 20 May 2015 on the Commission delegated directive of 30 January 2015 amending, for the purposes of adapting to technical progress, Annex III to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for cadmium in illumination and display lighting applications (C(2015)00383 – 2015/2542(DEA)), available under: http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+TA+P8-TA-2015-0205+0+DOC+XML+V0//EN&language=EN

Table 4-1: Amounts of Cd in CdQD film applications used in displays

Display device categorized by screen area	ppm
TV	240~500
Monitor	300~400
Pad	600~800
Cellphones	800~1000

Source: (Najing 2018)

Table 4-2: Calculations of Cd in CdQD film applications used in displays and placed on the market annualy

Application	EU Annual shipment	LCD %[3]	EU Annual LCD Area (m^2)	% Using QD Film in EU (m^2)	LCD Area Using QD Film in EU (m^2)	Typical Cd content per LCD Screen Area ($\mu g/mm^2$)	Total EU Cadmium (kg)
4K/8K TV	24,000,000	85%	17,013,600	5%	850,680	0.05	42.534
Monitor	24,000,000	85%	2,019,600	10%	201,960	0.05	10.098
Notebook	25,000,000	80%	920,000	35%	322,000	0.08	25.76
Pad	32,000,000	80%	345,600	25%	86,400	0.08	6.912
Small displays (phones, etc)	180,000,000	50%	630,000	25%	157,500	0.1	15.75
Total							101.054

Source: (Najing 2018)

Generally, Najing (2018) explains this to be an optimistic estimation, seeing as last year in China the share of [displays – consultants addition] using QD was around 2%. It is further explained that it has been assumed in this calculation that the "quantum dot tube" will disappear as its sales are currently in decrease. The consultants assume that the on-edge configuration is meant here, in which a tube with QD material is applied at the sides of the display instead of the sheet applied in "on-surface" applications.

As for on-chip applications, OSRAM (2018) specifies that the closer the converter material is placed towards the blue emitter the less material is needed. It refers to the

Yole report[10] that estimates that ~ 40mg cadmium is applied per 55" TV screen when a QD film is in use (on-surface). The Yole report further estimates that less than 1 mg Cd would be needed for one 55" TV when directly converted LEDs are used (on-chip). The concentrations of the near-chip solutions are higher in the applicable homogenous material than in the QD film but the absolute amount is much lower. Depending how the converter is applied within the LED and the desired degree of conversion the amount of converter differs significantly. For conversion to cold-white much less converter is needed than for warm-white or full colour conversion. However, if a very concentrated layer is placed directly on the chip less converter is needed than compared to the usual amount in volume cast which is a common conversion type. Using a very rough estimation OSRAM (2018) estimates that 100 Mio TV screens (55" diameter) would need less than 100 kg cadmium (compounds). The realistically estimated amount of cadmium to be put on the market would be a few kg per year.

LightingEurope (2017) provides an estimation for the amount of Cd that would be placed on the market through on-chip applications if all light sources[11] in the entire EU were converted to Cd containing QD LEDs overnight as well as more realistic scenarios of a 1%, 2% and 5% transition of all light sources. These scenarios would result in the placing of 163 kg, 1.63, 3.26 and 8.15 kg of Cd on the market, respectively, in LED on-chip applications. The range of between 1.63 and 8.15 kg per annum is specified as the more realistic scenario. Details of the calculation can be viewed in the application.

4.2. Technical description of the requested exemption

Conventional solid-state lighting technology is based on blue LEDs exciting a green, yellow and/or a red phosphor (phosphorescent light downconverter) to generate green, yellow and some red light. For white LEDs this is mixed together to form white light for illumination purposes. White LEDs are used as well for backlighting purposes. Here, the light is then filtered and combined with LCD technology to end up in pure colours. In projectors single-coloured LEDs are used in red, green, and blue. Direct emitters are in use for this purpose but as it is more energy efficient, full-conversion is used to make green LEDs from blue-emitting LEDs. However, as the green spectrum has a large bandwidth, still a high amount of light (=energy) is wasted as it needs to be filtered for a proper colour. (OSRAM 2018)

The materials used as down-converters typically are garnets and nitrides for illumination purposes. For displays more narrow phosphors are advantageous. There, also oxynitrides are in use. Partly, sulfides are in discussion as well, however they suffer from reliability issues. In recent years, two new types of down-converters came to market. One is PSF (potassium fluorosilicate) as a new material class between the established inorganic phosphors. This is a manganese doped material that emits from

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[10] Quoted in OSRAM (2018) as: Yole report 2017, YOLE Development: Phosphors and Quantum Dots: LED Downconverters for Lighting and Display Applications: http://www.yole.fr/Phosphors_QD_BusinessOverview.aspx#.WucPipVPq71

[11] A light source is assumed to mean a single LED package. In a later communication LightingEurope (2018) state that "One LED package contains typically less than 5µg of Cd.2018 replacement lamp contains typically 7-8 LEDs, resulting in <40 µg Cd per lamp.

an f-f transition leading to several very narrow peaks between orange and infrared that has replaced other nitride phosphors in backlighting diodes to enhance the colour gamut. The others are Quantum Dots. (OSRAM 2018)

OSRAM (2018) explains that similarly to phosphors, QDs down-convert light from higher energy wave-lengths (like blue) to lower energy wavelengths (like red or green). Several material classes are known here, however "*the ones with the by far best performance contain cadmium as main element. Their beneficial properties are a high efficiency coming with a narrow full width half maximum making it attractive for any display or projection applications, i.e. where very pure colours are required, but for illumination as well as one can avoid typical losses in infrared making high quality light. Further they offer a tunability in wavelengths that is not given in any other phosphor material system – especially not in PSF*".

From prior evaluations, the consultants are aware that there are three strategies or configurations in which QDs can be applied:

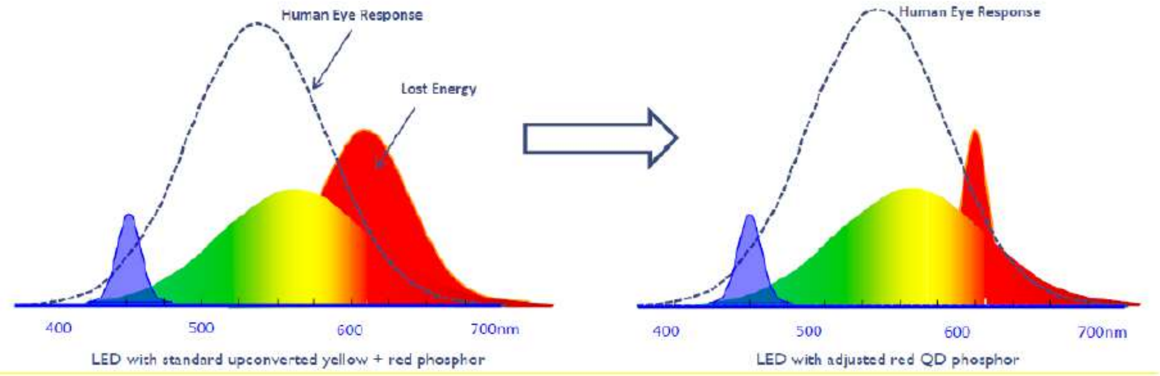
- '<u>On-edge technology</u>' has QDs incorporated into a remote component situated in close proximity to the LED chips. This can be done for instance in an adjacent capillary. On-edge technologies allow a compromise between the risk of thermal degradation and the respective QD material requirements. This configuration was addressed in past evaluations but was not initially mentioned by the applicants in the current review. It is understood to have become obsolete (Nanosys 2019).
- In '<u>on-surface technology</u>' the QDs are encapsulated in a film that covers the complete display area. This technology is the most intensive in terms of QD material usage, but can operate at near room temperatures, so that the thermal degradation risk is not an obstacle for practical application. On-surface technologies are also known as QD-films. Najing address such configurations in their request, referring only to display applications.
- In '<u>on-chip technology</u>', the QDs are placed on the LED surface, encapsulated within its package. This technology requires the lowest amount of QD material, however, due to the proximity to the light source, practical application was difficult to accomplish in the past as the QD material undergoes thermal degradation in light of the proximity to the light emitting source. This configuration is addressed in the requests of LightingEurope and OSRAM and can be applied in both solid-state lighting and display applications. OSRAM (2019) further explains that there are two sub-cases for on-chip applications:
  - the dots are used close to the chip, around it, confined by the dimensions of an LED package, or
  - the quantum dots are highly concentrated in a thin layer on top of the chip whereas this layer has got similar outer dimensions as the chip, i.e. smaller as the package.

LightingEurope (2017) explains that through 2016 Cd QDs could only be employed in remote locations, i.e. in on-edge and on-surface applications. However, recently, technology has been developed which allows QDs to be deployed inside the LED package. This allows LED manufacturers to use the least amount of QD material per lumen of light and is also the lowest cost and most flexible way to utilize QDs in either lighting or displays.

"QDs developed for use inside LED packages [consultants note: on-chip] *contain significantly less total cadmium than the remote QD implementations* [consultants note: on-edge and on-surface] *that are currently available and still preserve the performance benefits of increasing energy efficiency, higher quality of light and better colour gamut that have been documented in previous RoHS exemption applications for cadmium in lighting and display applications."* (LightingEurope 2017)

Cd QD are explained to have two advantages over conventional phosphor solutions, the one relating to the spectral output and the other to their energy consumption. These properties are intertwined, seeing as the Cd QDs allow the spectral output to be closely tuned towards the areas to which the human eye is sensitive. LightingEurope (2017) explains that the narrow emission spectrum prevents the generation of invisible infrared radiation (see Figure 4-1). This decrease in waste heat contributes to the energy consumption being lower than conventional phosphors.

Figure 4-1: Comparison of QD and conventional phosphor spectrum



Source: LightingEurope (2017) specifies the source as: Yole Développement, "Phosphors and Quantum Dots 2015: LED Downconverters for Lighting and Display Applications", 2015

4.3. Applicant's justification for the requested exemption

Najing (2018) justifies the exemption based on the inferiority of available substitutes for cadmium selenide quantum dots (Cd QDs), stating that Cd QDs have excellent luminescent properties and energy effectiveness, "*while cadmium free QDs still cannot satisfy customers with its normal performance even in October 2019*". The information put forward by Najing is related to Cd QD applications in on-surface configurations and is thus further detailed under Section 4.3.1.

Aside from the colour gamut superiority, OSRAM (2018) explains that the shift towards the on-chip configuration requires the QDs to withstand more severe performance conditions than the earlier on-surface and on-edge configuration. The main argumentation in this case is that alternatives in this application configuration are explained not to be available, meaning that substitution is still not possible. LEDs with an on-chip configuration are understood to be applicable both for lighting applications and for display applications, though current development is understood to be focused at lighting applications. Further information regarding available substitutes for Cd in on-chip applications is presented under section 4.3.2.

LightingEurope (2017) justifies the exemption based on the third criterion of Article 5(1)(a), explaining that "*the safe use of minimal amounts of cadmium leads to a significant increase in the luminous efficacy of LED lighting, especially for warm-white light sources of CRI of at least 80. The same energy savings cannot currently be reached with similar technologies while maintaining product reliability and lifetime. As a result, utilization of cadmium-containing quantum dots has an overall positive environmental impact due to their lower energy consumption compared with currently available technologies*". Aside from the reduction in energy and CO_2 emissions, on-chip QD technology enables the use of significantly less cadmium than used in remote applications and other emissions derived from power plants, including cadmium emissions, will also decrease.

To substantiate its justification, LightingEurope (2017) provides an estimation as to the amount of Cd to be used in this application and the savings that this would generate in comparison with the use of conventional LEDs. The amount of Cd that would be placed on the market through on-chip applications if all light sources in the entire EU were converted to cadmium containing quantum dot LEDs overnight accounts for 163 kg of cadmium. However, this subsequently saves 14.134 GWh of energy and reduces emissions of cadmium by 54 kg per year. This scenario is expected to be fictional, however transition scenarios more likely to reflect real margins are also calculated representing a transition of 1%, 2% and 5% transition of the total lighting capacity installed in the EU. In these cases, 1.63, 3.26 and 8.15 kg of Cd would be placed on the market resulting in savings of 141.34, 282.68 and 706.71 GWh of energy and in the avoidance of 0.54, 1.07 and 2.69 kg of Cd respectively. Details of the calculation can be viewed in the application.

4.3.1. Substitution or Elimination of cadmium in on-surface applications

Najing (2018) explains that there is no question as to the reliability of InP QDs in display applications, but rather the comparability of their performance is the concern and thus their main justification for the exemption. "*Two major challenges need to be addressed to release the full potential of InP QDs in display applications. First, the colour purity of InP QDs needs to be improved. The commercialized cadmium-free QDs film of Samsung have 40nm full width at half maximum (FWHM), which are wider than Cd QDs (<30nm FWHM). Second, the quantum efficiency need to be increased. The high quantum efficiency of the Cd QDs is typically higher than 88%, which is necessary for QD film-based backlights to deliver higher power efficiency (12%-45% more energy efficient than traditional LED LCDs for colour gamut sizes from 70% NTSC to 100% NTSC). However, the quantum efficiency of the Cd-free QDs is lower than 70%* [...] *The performance of Cd-free quantum dots (based in InP) is expected to reach the current colour quality and energy consumption performance of cadmium quantum dots by 2020.*

Full commercialization will be achieved by 2022." To summarise, Najing states that the two aspects of InP QD need to improve:

- The colour quality (high colour gamut), which is an extremely important factor in determining a display's perceptual quality. The FWHM of the InP dots needs to be minimized for this purpose.
- The energy consumption, of InP QDs needs to be lowered to improve the quantum yields of the InP dots.

To support their view, Najing (2018) provides the following comparison of a Cd QD based display and a InP QD based display (see Table 4-3), showing a 16% difference in terms of energy consumption.

Table 4-3: Performance comparison of CdQD based display and a InP QD based display

TV	QD Film	Luminance(nit)	Power (W)	Luminance Efficiency (nits/W)	Energy saving	NTSC Area (1931)
TCL X3	CdSe-based	484.5	170	2.85	116%	110.32%
Samsung Q7C	InP-based	686	280	2.45	100%	99%

Source: (Najing 2018)

To show further differences, also in relation to colour quality performance, a further comparison was provided by Najing (2019). The comparison was based on results of an experiment in which QD films from three TVs (Najing's QD film of TCL TV (XESS 55" X2), 3M's QD film of Hisense XT910 and Samsung's QD film of Samsung 55KS7300) were removed and inserted into the same fixture to allow a comparison where equipment differences could be excluded. For this purpose, the TCL 55X2 was used as the "test fixture". Regarding the results, Najing points out that "*The highest quantum efficiency of the CdSeQD is 92.81%, and the quantum efficiency of the Cd-Free QD is 67.69% in the same test fixture. We can conclude that the quantum efficiency of the Cd-free QD are 27.07% lower than the Cd QD in the same test fixture. It is also apparent that the free-Cd QD's brightness is 25% lower than the CdSe's. The NTSC-1931 colour gamut of the fixture of CdSe QD is 16.47% higher than the Cd-free QD-LCF. The DCI-P3 colour gamut of the fixture of CdSe QD is 4.16% higher than Cd-free QD-LCF. Based on the above results, CdSe is superior to the Cd-free in brightness and colour gamut*."

Table 4-4: The comparative test spectrum with the three QD films using the same test fixture (TCL 55X2)

TV product NO.	Hisense XT910	TCL55 X2			Samsung 55KS7300		
QD film's information	3M (CdSe)	Najing (CdSe)			Samsung(Cd-free)		
Test fixture	TCL 55 X2	TCL 55 X2			TCL 55 X2		
Quantum efficiency (QE)	92.81%	89.56%			67.69%		
Relative QE ratio	100%	96.50%			72.93%		
NTSC(1931)		105.48%			89.01%		
DCI-P3		95.59%			91.43%		
		Luminance(nit)	x	y	L(nit)	x	y
White		432	0.2839	0.2966	324	0.2840	0.2964
R		92	0.6871	0.3004	64.97	0.6825	0.3093
G		293.33	0.2156	0.7146	227.55	0.2779	0.6547
B		45.16	0.1535	0.0613	32.7	0.1492	0.0685

Source: Najing (2019)

The information provided by Najing is only related to the use of on-surface applications of Cd QD in displays. They do not provide information as to possible use in lighting applications. In this respect, OSRAM (2019) state that in general it is technically possible to use on-edge or on-surface technologies for general lighting in order to realize flat area light sources. "*However, we see substantial disadvantages today for this kind of usage e.g. coloured areas in off-state which might be unacceptable to customers as well as unpredictable high costs due to the application of the colour converting QDs over large areas. Therefore, we do not believe these configurations will be used for lighting in foreseeable future*".

4.3.2. Substitution or Elimination of cadmium in on-chip applications

Both OSRAM and LightingEurope refer to on-chip technologies in their requests for exemptions, however it can be understood that OSRAMs request to renew Ex. 39a is aimed at enabling the use of such technologies in displays, back lighting units of various size and projection applications, whereas the LightingEurope request is directed at lighting applications.

LightingEurope (2017) claims that other than quantum dots, no other downconverter exists which has a narrow emission band (<35 nm FWHM at room temperature), is emission tunable to within 1 nm, and has very high luminescence quantum efficiencies, both at room temperature and LED operating temperatures. These attributes allow QDs to increase the efficiency of a white lighting LED by up to 20% while giving the LED manufacturer precise control over the light output spectrum (and therefore colour quality). The efficiency benefit will significantly reduce the cost per lumen for the consumer and drive the adoption of solid-state lighting, thus having a very meaningful net benefit to the environment due to lower energy consumption.

OSRAM (2018) explains that there are currently no alternatives to Cd QD in the on-chip configurations as the operation conditions on the LED are too severe and existing alternatives currently do not provide sufficient reliability. Here too, the Cd QD system is also explained to be more energy efficient and the gamut colour quality to be higher. In general, an advantage of the on-chip configuration is that the trend towards miniaturisation means that less material is needed. Future innovations require µ-displays (see further details below) where small converter grains are needed in the size of nanoparticles that in addition allow dense packing to realize very thin converter layers (~1µm). At present, it is stated that this can only be done with Cd QDs. As the size of these components is very small, the amount of converter material needed for is very low and subsequently also the amount of Cd and the energy needed to produce the converter material.

From OSRAMs (2018) point of view, "*currently and in the foreseeable near future there is no technical alternative to Cd containing Quantum Dot materials with comparable high energy saving potential. In addition, the material has technical advantages making innovative new applications possible. The potential to save energy is so high that from a life cycle perspective, considering the EU energy mix, LightingEurope believes the amount of Cadmium emissions from power plants that can be avoided is higher than the Cd amount needed for the products. In addition, the Cd in products can be collected by the EU WEEE take back and recycling schemes, while Cd from power plants currently is emitted to air*".

In relation to Cd-free quantum dot materials, OSRAM (2019) explains that:

- the Cd-free QD spectral width is in the 40nm range and above, while CD QDs have FWHM <30nm;
- Cd-free quantum efficiency as measured under high temperature and high flux conditions is <50%, while for Cd QDs under the same conditions it is >80%.
- It is further emphasized that there is currently not a Cd-free material /technology that can withstand the high flux and temperatures involved in the on-chip configuration. Benchmark testing of Cd-free QD on-chip has shown immediate loss of optical performance in minutes/few hours, whereas it is stated that OSRAM Cd QDs under the same standard backlighting LED test conditions can withstand >1000 hours as far as tested at the time of writing (March 2019).

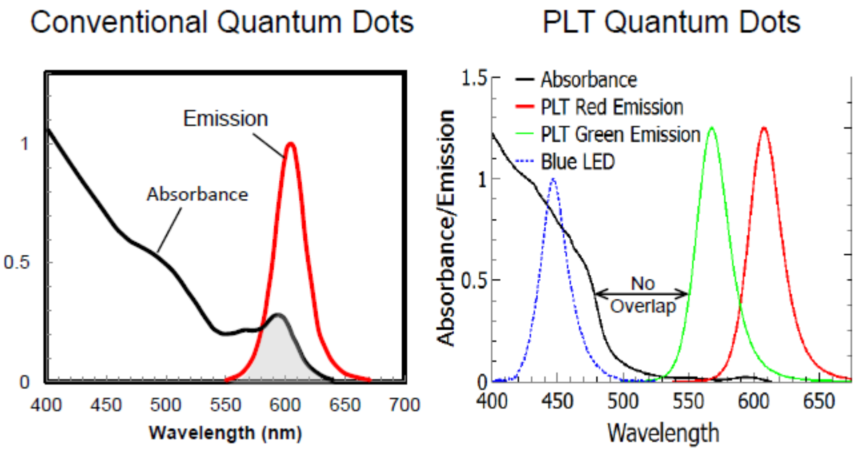
According to OSRAM (2018), for **future technologies µ-LEDs** are needed for the use in displays and projectors. µ-LEDs are either LEDs that are much smaller in size than classical LEDs, e.g. 10µm x 10µm compared to 1mm², or a regular sized LED is segmented in a higher amount of small or tiny pixels that are individually addressable. For a µ-display or a µ-projector the pixels need to be much smaller and need to be converted individually to red or green. µ-displays and µ-projectors will enable the field of augmented and virtual reality as well as make for instance head-up displays more efficient. Augmented reality displays and Smart Glasses require micro-displays for image generation. Current technologies are based on reflective micro-displays like DLP (Digital Light Processing) and LCoS (Liquid Crystal on Silicon) or Micro-OLED displays. Looking at such alternative technologies:

- The reflective micro-displays are passive i.e. require an illumination optics which adds complexity and size to the system. The illumination is independent of image content i.e. all pixels are illuminated even if they are in off status. This means that power consumption is high.
- Micro-OLED are emissive i.e. active micro-displays. There is no need for illumination optics. There is no power consumption for pixel in off mode. The disadvantage of Micro-OLED is the relative low luminance and lifetime issues especially for blue.

OSRAM (2018) thus concludes that a Micro-LED micro-display would be a good solution. Luminance would be about 10x higher compared to Micro-OLED. RGB Pixel pitch needs to be in a range of 5µm and pixel count from 500k up to 2kk. Conventional inorganic phosphors come in grains of ~20µm in diameter. Obviously, it is not possible to convert pixels of 5µm or 10µm edge length with such grains. Therefore, converter material is needed that is much smaller in dimensions. QDs are only few nm in size. Organic molecules are even smaller but are, unfortunately, very instable against blue light. With having an extremely tiny emission area, e.g. 100µm², conventional volume cast techniques or similar is not an option. What is needed is a very thin concentrated conversion layer. Further, no high conversion thicknesses – if it is too high, there will be cross-talk between the pixels ending in unwanted colour mixing. Therefore, a highly concentrated thin conversion film is necessary.

OSRAM (2018) further explains that most phosphor show re-absorption and concentration quenching effects that lower the efficiency of the device. It helps therefore to separate absorption and emission of the emitter. In QDs this is possible due to the core shell system in case the shell is grown adequately. Figure 4-2 shows the absorption and emission characteristics of conventional quantum dots (left side) and quantum dots where absorption and emission are more separated by a different core-shell concept (right side). With this separation the self-absorption effect is smaller allowing more dense packing.

Figure 4-2: Example of absorption and emission spectra of conventional QD and QD with a different core-shell concept that separates absorption and emission



Source: OSRAM (2018) refers to: Yole report 2017, YOLE Development: Phosphors and Quantum Dots: LED Downconverters for Lighting and Display Applications; http://www.yole.fr/Phosphors_QD_BusinessOverview.aspx#.WucPipVPq71

In a later communication, OSRAM (2019) provides a comparison of two types of on-chip applications in LED with a phosphor alternative. It is explained that one type uses less than 100 ppm cadmium and can be placed on the market already without an exemption due to the small amount of Cd. In contrast, the other type requires a higher content of Cd (<1000 ppm) but would also be more efficient in terms of energy consumption. Its placing on the market relies on the granting of an exemption.

Table 4-5: Comparison of CdQD on-chip based LED with a phosphor only alternative

3000K CRI 90 0,2W LED	Phosphor-only LED (best in class)	CdQD LED 2019	based on this exemption - CdQD LED
Cd content	0 ppm	< 100 ppm	<1000 ppm
Luminous efficacy	reference	+7%	+20%
Energy consumption	reference	-7%	-20%

Source: OSRAM (2019)

In a last communication in 2020, OSRAM (2020) provides further details as to the comparison of Cd QD on-chip LEDs and other LEDs. OSRAM compares three of its own products as well as a competitor product considered best of class[12]. The following products were compared through measurements:

- Commercial phosphor-based OSRAM product with CRI 90, best OSRAM CRI >90 product without Quantum Dot technology;

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[12] Confidential market data was provided to support this claim as to the competitors LED.

- RoHS-conform Quantum Dot Gen1 < 100 ppm Cd, introduced in the market in May 2019 (“OSCONIQ® S3030”)
- Commercial-ready non-RoHS-conform Quantum Dot product with <1000 ppm Cd; this variant is widely identical to above product but includes a higher Cd amount in the luminescent material compared to OSCONIQ S3030. In preliminary tests this product revealed already much higher luminous flux and luminous efficacy
- Competitor product - Samsung LM301B, not a Quantum Dot technology; This product is available on the market and is according market information a highly competitive product for CRI >90.

Table 4-6: Efficacy white (3000k) LEDs with non-RoHS conform Cd amount

Colour Temperature: 3000K	Efficacy [lm/W]	rel. Efficacy [%]	CRI
Commercial <100ppm Cd LED (OSCONIQ S3030 Osram)	159,85	100,0%	93
Commercial-ready <1000ppm Cd LED, Osram	**193,7**	**121,2%**	**90**
Commercial no Cd LED, Osram (Duris-5 based)	154,2	96,5%	93
Commercial no Cd LED, competitor (Samsung	157,6	98,6%	94

Source: (OSRAM 2020)

In summary, OSRAM (2020) explains that Cd-based QDs have already been integrated into LEDs and commercially released (OSCONIQ S3030), and exhibit industry-leading efficiency. Allowing usage of Cd-based QDs in these same packages in amounts < 1000ppm (ca 1.6 microgram per LED) immediately enables a 22% increase of power efficiency in product-ready LEDs. This is not possible with Cd free quantum dots due to poor stability and efficiency.

As for the use of the on-chip technologies in displays, OSRAM (2019) states that applications for display backlighting and µ-displays are being developed in parallel to solid state lighting applications and require the exemption for cadmium per mm² light emitting LED chip surface. But the future development efforts on such innovative materials and applications are also dependent on the renewal of this exemption (with the proposed new wording). First products for such applications can be expected in 1-2 years.

OSRAM (2018) summarises that their request for a RoHS exemption is justified on the basis that the safe use of minimal amounts of cadmium leads to a significant increase in the luminous efficacy of LEDs. The same energy savings cannot currently be reached with similar technologies while maintaining product reliability and lifetime. As a result, utilization of cadmium-containing quantum dots has an overall positive environmental impact due to their lower energy consumption compared with currently available technologies. With reference to Article 5(1)(a) third criterion, a specific exemption for the use of cadmium for lighting applications is therefore justified. In addition to the reduction in energy and CO_2 emissions, other emissions derived from power plants will be reduced, including cadmium emissions. Additionally, on-chip QD technology enables the use of significantly less cadmium than use in remote applications.

LightingEurope (2017) further explains the key on-chip performance factors for QDs to be resistance to thermal and intensity quenching[13]:

- "Thermal quenching is either the loss of quantum efficiency and/or phosphor photoluminescence output as the temperature is increased.
- The intensity quenching is the loss of quantum efficiency or phosphor photoluminescence output as the incident blue light intensity is increased.

Most phosphor materials show some characteristic of thermal and intensity quenching at different temperatures and different flux intensities. In the case of QDs, the quenching occurs in the form of quantum efficiency loss which negatively affects both colour stability and overall LED efficiency. Temperatures at the downconverter level are typically (100-125) °C and can reach as high as 150 °C in very high-power LED chips. The flux intensity felt by the downconverter is usually in the range of (50-100) W/cm^2. Cd-based QD materials have been engineered to be reliable under conditions of high temperature and high flux. The result is that Cd-based QDs approach similar thermal and intensity quenching to red phosphor whereas Cd-free QDs suffer significantly higher quenching. (LightingEurope 2017)

From the above the consultants understand that in relation to conventional red phosphors used in LED, Cd QDs provide comparable performance in relation to these two properties, while also resulting in benefits in terms of colour gamut and energy consumptions. In relation to Cd-free QDs, it can be understood that as such substitutes do not to provide the necessary thermal and intensity quenching performance, they are currently not considered as reliable substitutes.

When asked whether Cd QD LEDs perform better than conventional LEDs under high temperature conditions, LightingEurope (2018) contended that LEDs using QDs are also sensitive to thermal stresses, and the lifetime can be shortened if excessive heat is present at the LED level. Cd-based QDs do not confer an advantage to the LED in this respect, reliability of the Cd-based QDs under heat stress is very similar to red phosphors. However, LEDs incorporating QDs have a higher efficacy which would allow for driving the parts at lower current while maintaining lumen output, and therefore would extend the lifetime of the LEDs.

LightingEurope (2017) mentions also that red phosphors have the drawback of the existence of a broad wavelength spectrum and low spectral efficiency relative to green phosphors. LEDs with Color Rendering Index (CRI) >90 are always less energy efficient than LEDs that have CRI <80 because of the red phosphor spectral inefficiency. The broad wavelength spectrum of red phosphors reaches deep red and infra-red wavelengths where the eye sensitivity is low to none. In fact, a significant proportion of

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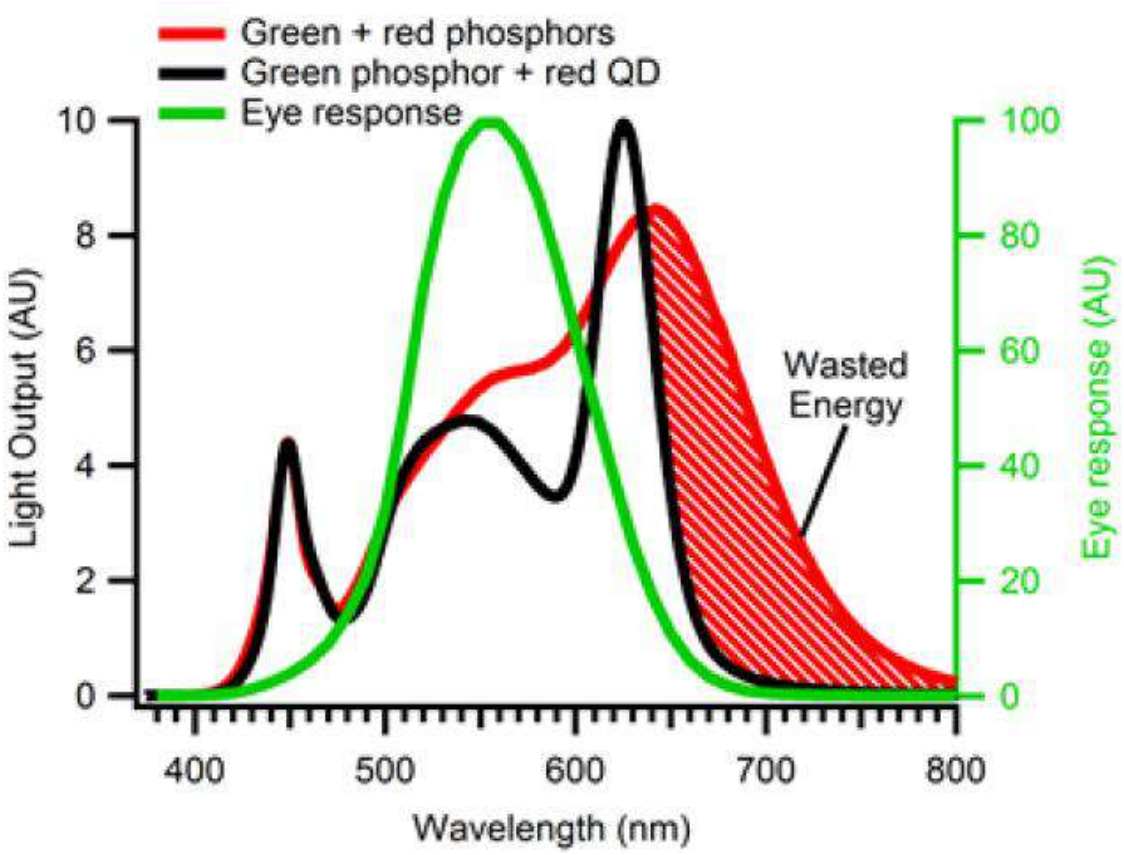
[13] LE explains that quenching is a process in the quantum dot whereby the excited state produced, by the blue light, relaxes to the ground state without producing visible radiation. The lost energy is dissipated as heat.

the efficiently produced LED light is wasted by emission in the near-infrared range where the human eye is not sensitive at all as shown in Figure 4-3.

Figure 4-3: LED light output from downconverting phosphor systems



Note: The red curve is a two phosphor system, the black curve consists of the same LED chip, the same green phosphor, but replaces the red phosphor with a red QD. The green line indicates the human photopic (eye sensitivity) response (right axis).

Source: LightingEurope (2017)

The benefits that quantum dots bring to lighting are their high light conversion efficiencies, narrow line widths, and precise emission peak placement. QDs can improve the efficiency of warm-white LEDs by up to 25%, depending on the colour rendering index and colour temperature. The higher the CRI and/or the lower the CCT, the greater the red content and therefore the greater the visual impact and benefit of the quantum dots. Downconverters in solid state lighting must maintain their optical properties over very long time (>25,000 h), under high temperature and extremely high blue light intensity. They must pass a variety of humidity tests with no special packaging to prevent degradation due to moisture-driven reactions. Without stability under these conditions, quantum dots can only be used in very specialized "remote" designs outside of the LED package. In order to make a real impact on both the market and on energy efficiency, QDs must be made to perform as well as their conventional phosphor counterparts under the same conditions – inside the LED package – on chip. To summarize, replacing the red phosphor in today's high-CRI LED packages with quantum dots results in cost-effective solutions for the illumination/lighting market that provides high quality of light with up to 20% increase in energy efficiency. (LightingEurope 2017)

Regarding Cd-free QDs, LightingEurope (2017) further mentions that there is a significant research effort on Cd-free quantum dot luminescent materials such as indium phosphide (InP) and copper indium selenide sulfide (CuInSexS2-x). These and similar compositions are generally considered to be 3 to 5 years behind Cd-based QDs in term of stability, quantum efficiency, and spectral efficiency (peak width). The most advanced cadmium-free quantum dot compositions are based on InP cores. However, their spectral width, quantum efficiency and stability remain inferior to CdSe compositions. Their use in commercial products is limited to displays with costly remote downconverter elements such as sheets, which avoid the on-chip implementation. Some additional details are provided in the application, however relating to the use of InP in display applications in on-surface configurations.

LightingEurope (2017) states that given the immaturity of Cd-free QDs and their rate of development, it is estimated that Cd-free QDs will be precluded from practical use in on-chip LED configurations for the next >5 years. LE states that there are no commercially available Cd-free QDs available for on-chip comparison to Cd-containing QDs. Measurements of LEDs incorporating Cd-free materials in development have been hindered by rapid degradation of optical characteristics once exposed to representative temperature and blue light flux conditions in the package. The applicants have evaluated Cd-free QDs which completely degrade in on-chip conditions within days or even hours. The technical incompatibility of incorporating InP-QDs onto chip arrays still remains challenging without solutions to overcome this application-limiting pitfall in the near future.

LightingEurope (2018) contends that *quantum dots can be made with alternative non-cadmium materials, but the quantum efficiency and reliability have not been resolved in other material systems such as silicon, indium phosphide, lead perovskite, copper indium sulphide, and manganese-doped zinc selenide QDs. In other words, the same energy savings cannot currently be achieved with similar technologies while maintaining product reliability and lifetime. There are also other challenges with alternative non-cadmium materials such as limitations in achieving narrow emission peak width, full tunability of the emission, or insufficient excitation at 450 nm. Finally, new materials such as lead perovskite QDs may have similar toxicity concerns as cadmium-based QDs.*

4.3.3. Environmental arguments

Najing (2018) provides some information as to possible **Cd emissions** during the display lifecycle. During manufacture it is explained that workers contamination is very low and can be kept to zero seeing as most manufacturing processes are machine operated and not manual. Najing works were tested in the past years for Cd levels in blood and all results were normal. In the use of display, there is no mechanism in which the Cd can be released from the QD film.

In relation to the **waste management** of Cd QD material, Najing (2018) explains that the plastic film in which the Cd QD are contained is made by curing a mixture of resins and QDs embedded in those resins. As quantum dots have a lifetime and the efficiency of the material starts to degrade, reuse or refurbishment is not practical. Thus, in the post-consumer phase, the QD converting film is handled by the LCD recycling system. The cadmium originating from QDs can be collected after combustion of the plastics. As with plastics in general, a mixture of plastics cannot be separated back to single plastic types or clear plastic. It is understood that assuming that the plastic is sent to energy return, the Cd will amount to the initial amount placed on the market, i.e. estimated at 101 kg per annum. The main risk at this stage is uncontrolled emissions to air. An LCA is provided in which various scenarios were checked, including the unlikely option of uncontrolled open-air incineration which is not expected in the EU.

On waste management, OSRAM (2018) specifies that LED are part of nearly every electronic product (EEE). In the requested exemption the LED are used for display illumination. LED contain different materials for recycling (e.g. gold, plastics) as well as non-recyclable materials. Most of these EEE are in the scope of EU Directive 2012/19/EU – WEEE. Take back systems are installed in all EU Member States: end users and most commercial customers can bring back display containing products (e.g. TV screens) free of charge. These end-of-life products are collected separately from general household waste and recycled in suitable facilities.

On this issue, LightingEurope (2017) explains that without exposure to the quantum dot, there is no health risk. Similar to display products, quantum dot solid-state lighting products are not likely to be handled, mechanically treated, or otherwise modified by a consumer in such a way that cadmium could be released. The cadmium element is bound by covalent bonds within the semiconductor material, the semiconductor quantum dots themselves are in turn bound inside the carrier silicone matrix cured on top of the LED chip, thus forming an LED package, which is in turn integrated into the lamp or luminaire, so the risk of consumer exposure to cadmium during the use phase is extremely low. Similarly, exposure of consumers to cadmium released to the environment from these products as a consequence of end-of-life or recycling operations is very unlikely. We have performed leaching tests on LED packages that contain cadmium quantum dots. Cadmium could not be detected in the leachate, showing that the cadmium is securely bound inside the LED package. In production, cadmium can be handled safely so as to pose no risk to workers. Cadmium is used in various production processes, e.g. for nickel-cadmium (NiCd) batteries, electrical contacts, and filter glass. Adequate measures are in place to safeguard workers in factories. The industry has extensive experience with handling dangerous substances and can do so safely.

In relation to **substitutes**, Najing (2018) expects the life cycle of cadmium free QDs to be similar to cadmium based QDs, except that cadmium free metal is less toxic to the environment. The most promising cadmium free QDs are indium phosphide.

Najing furthermore provides LCA information in the form of a few LCA reports:

- A supplemental statement on LCA and comparison of cadmium, cadmium selenide and indium phosphide, prepared by The Acta Group, L.L.C. on behalf of QD Vision, Inc.[14].
- A report of a life cycle assessment of 3M QDEF-film, prepared by the University of Antwerp[15].

These reports were prepared in the past for QD Vision and 3M respectively and were submitted by the latter in 2015 to the previous evaluation of the Cd QD exemptions. In so far, their contents is not summarised here again.

4.3.4. Socioeconomic impacts

Najing (2018) explains indium to be identified by the EC as a critical raw material (CRM), to have limited resources and an increasing demand, while its recycling is currently limited to recovery of industrial production waste. This could lead to a supply risk. Najing estimates "*the indium demand from In-based QDs suggests an increase of "just 15%" compared to standard LCD displays*" which is explained to be significant and to possibly affect the costs of InP based QDs and other indium-based products in the future.

In general, regarding the supply of InP quantum dot material Najing (2018) states that there are only a few companies, such as Samsung, Dow and Nanoco, which can produce Cd-free InP-based quantum dots. InP QDs of the various companies are explained to have different performance levels, however this is not further detailed and does not allow concluding the range of application of InP QDs of a certain company. The price of InP dots is also explained to be higher than Cd dots, because their synthetic materials are expensive, and their synthetic process is more complex.

Najing provides a socio-economic assessment for Cd QD displays prepared by Edif ERA in the past for 3M and submitted to the previous evaluation of the Cd QD exemptions[16]. The contents of this review are not summarised here again.

LightingEurope (2018) does not expect impacts on employment should the exemption for Cd in on-chip lighting applications not be granted. "The technology is an innovation which can provide significantly higher efficiency for LED. In case the technology

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[14] Available among others under: https://rohs.exemptions.oeko.info/index.php?id=265

[15] Available among others under: https://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Pack_10/Cd_Quantum_Dot_Evaluation/3M_Buyle_M_-_Braet_J_-_University_of_Antwerp_-_Report_3M_QDEF-film_-_v2.pdf

[16] Available among others under: https://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Pack_15/3rd_Consultation/annex_Najingtech_Ex_39a_appl_2_RoHS15_3M_Socio_Economic_Report_20180523.pdf

increases the change from conventional technology to solid state lighting positive indirect effects are possible."

LightingEurope (2018) provides the following quantifications of impacts "that are related to the use of cadmium in semi-conductors for lighting applications":

- **CO_2 savings**: In a case in which the exemption is granted and assuming a market penetration of 1% in 2018 rising to 5% in 2022, the EU reductions in electricity consumption during a five-year exemption period until 2022 would account for ca. 3390 giga watt hours (GWH). Assuming the German energy mix of 2016 as a reference value, 1 avoided kWh results in a reduction of 0.527 kg of CO_2 emission. Taking into consideration the savings in energy consumption, this would translate into a decrease of 1,787,694,670 kg of CO_2 emissions. Using various values for the price of carbon savings, LightingEurope estimates the monetary benefits from such savings as between 74 million euro (average price) and 12 million euro (conservative). More details are provided in the document.
- **Cd use and Cd emission savings**: the amount of cadmium needed for one LED is expected to be 1.61 microgram (1.61 10-06 gram). Even if the entirety of lighting in Europe would be provided by Cd QD LEDs, less than 163 kg of cadmium per year would be necessary to cover the demand. The use of cadmium in LEDs is explained to reduce the emissions of cadmium to the air as less electricity is consumed than with conventional LEDs. The case of market penetration of 1% in 2018 rising to 5% in 2022 would result in a use of 17.93 kg of Cd over the 5-year exemption period. The lower energy consumption would however, also result in a decrease of emissions of cadmium from energy production in an order of 12.95 kg over this period, meaning a net use of almost 5 kg Cd. More details are provided in the document.
- **Health Impacts on consumers –** Any potential health impact on consumers of LED technologies that use cadmium as semiconductor material are unlikely to occur as cadmium is safely encapsulated within a solid matrix only destructible at very high temperatures (more than 1000 °C). On the other side, LightingEurope mentions that with the growing use of LEDs and the development of new lighting technologies, many EU citizens are worried that people who have conditions that react to light might be negatively affected by this shift. LED street lighting is claimed to have been associated with reduced sleep and great incidences of obesity. Not all wavelengths of light disrupt bodies at the same level. Short wavelength blue light, which is known to help with alertness in the daytime, seems to be more disruptive at night, and induces the strongest melatonin inhibition. Therefore, new LED technologies, which allow for a more energy-efficient natural light, should be highly welcomed.

4.3.5. Roadmap to substitution

Though OSRAM does not provide detail as to when they expect substitutes to become available for Cd QD in on-chip applications, information is provided as to research efforts that OSRAM is involved in for the development of Cd-free QD materials. Among others, it is specified that the DOE (US Department of Energy) has provided funding of 1.25 million dollars over a period of two years for research into Cd-free QD alternatives. *„GaP/InP/GaP/ZnS spherical quantum well (SQW) quantum dots (QDs) with strong absorption at 450 nm and bight PLQY (> 90%)"* are being looked into and QD "on chip" architectures shall be tested to identify optimal structures. „*With the proposed QDs and high-efficacy LED devices, we aim to demonstrate devices with luminous efficacy > 200 Lumens/Watt and a warm white (3000K), high CRI (>90) spectrum*".

4.3.6. Stakeholder contributions

Five stakeholders participated actively in the consultation. Four of the stakeholders object to the exemption requests and one stakeholder is in support of the request of Najing and does not provide an opinion as to on-chip configurations and lighting applications. Though some of the stakeholders provide quantified data to support their statements, these only refer in detail to the use of Cd QD in display on-surface applications, where-as for on-chip applications only qualitative statements are made.

Nanosys (2019) supports the Najing proposal to renew the exemption based on a 50% reduction in the maximum allowable Cadmium content per display to<0.1µg cadmium per mm^2 of display screen area. This is based on the ability of displays based on Cd QD to fulfil standards for colour gamut performance, such as the BT.2020 Ultra HD standard, with high energy efficiency. Displays based on cadmium selenide consume 7% to 25% less energy compared to substitute technologies and materials. Nanosys states that it is not involved in the lighting market nor familiar with the potential benefits of any exemption for that market. It thus has no opinion on the necessity of on-chip applications with respect to lighting applications. In relation to display applications, Nanosys does not "*believe there is any scientific or technical basis to create a scope of specific configurations in a future exemption. The same 0.1µg/mm2 of display area should apply across all configurations. The display application requires narrow band red, green and blue emitters. To date, the only way in which this has been demonstrated with sufficient reliability and brightness performance has been in a QD film, or in the nomenclature of this exemption, on-surface. On-chip implementations of quantum dots to date have only been able to demonstrate performance with red emitters. Other implementations such as edge-based are no longer in the market due to issues with manufacturability as well as the move of the display industry toward direct backlight architectures*".

The **Swedish Chemicals Agency (KEMI 2019)** objects to the requests for exemption. KEMI explains that the aim of the RoHS directive is phasing out old equipment containing substances in Annex II and not expanding the market for new uses of such substances. In this respect, KEMI refers to Recital 5 of the Directive. "*The Council Resolution of 25 January 1988 on a Community action programme to combat environmental pollution by cadmium invites the Commission to pursue without delay the development of specific measures for such a programme. Human health also has to be protected and an overall strategy that in particular restricts the use of cadmium and stimulates research into substitutes should therefore be implemented*". The Resolution stresses that the use of cadmium should be limited to cases where suitable and safer alternatives do not exist. KEMI contends that an adoption of an extended or a new exemption against the aim of RoHS will encourage the development of cadmium technology and means that resources will be spent on unsustainable solutions instead of investing in cadmium free technologies under development. The refuse of an exemption could therefore act as a driving force and accelerate the development of cadmium free technology.

Looking at the exemptions in detail, KEMI (2019) further explains that the exemption requests are to allow the use of cadmium in new applications to improve colour performance. Whereas there are available techniques (both for displays and for lighting) that are free from cadmium both for quantum dot technology and for other technologies that provide the same basic function to the relevant equipment. KEMI does not find that any of the conditions in Article 5(1)(a) are fulfilled, and thus there is no basis for adoption of any exemptions from Annex II of RoHS. In terms of technical comparability of the applications for which the exemptions are requested and Cd-free applications, KEMI explains that from the implementation of other EU legislation, e.g. REACH, alternatives never give exactly the same performance but can still deliver a quality that is sufficient and generally accepted for the intended purpose. It is also explained that in the exemption requests, the introduction of new products with cadmium content on the EU market is justified by a reduction of cadmium emissions from generation of electricity due to a predicted decrease in energy consumption from equipment containing cadmium quantum dots. KEMI does not agree with this kind of argumentation. The representative energy mix for generation of electricity can always be challenged and the energy market is steadily improving in environmental performance.

Similar to KEMI, **DuPont Electronics and Imaging Division** (DuPont 2019) states that the fundamental principle should be applied that cadmium is toxic and should not be contemplated for development into EEE products. The fact that such exemptions exist only appears to encourage continued development and penalises those companies seeking to develop "non-RoHS" substance products. The latest series of applications suggests that cadmium products are not only being further developed but that new cadmium products are being researched for the market. The three current applications continue to weaken RoHS and extend the use of cadmium in the environment through EEE. On the technical level, DuPont states that there should be no need for cadmium quantum dots in either display screen technology or lighting. Major television manufacturers are already using cadmium free quantum dots as commercial alternatives. Alternative LED options for energy efficient lighting are already commercially available. In this application area, cadmium QDs would provide a wide dispersive use of cadmium domestically and in the environment.

Nanoco Technologies LTD (Nanoco 2019a) also objects to the requests for exemption, explaining that they do not meet the requirements laid out in RoHS under Article 5(1)(a) and in Annex V.

Nanoco (2019b) states that the data submitted by the applicant Najing Technology Co. Ltd. to support the Exemption Requests are outdated, incorrect and technically flawed. It is explained that Najing use outdated products and analysis that have already been considered in the previous evaluation of Ex. 39, so the data cannot be considered as updated and used again in the new consultation. Information submitted by OSRAM and LightingEurope is criticized as it mainly compares between Cd QD on-chip applications and phosphor LEDs, providing little data as to the comparison with Cd-free QDs. Nanoco (2019a) also contends that by extending the scope of the exemption to include lighting, the EU would be creating a market for cadmium in on-chip display and lighting applications where no market previously existed. In Nanoco's view, this is contrary to the purpose of RoHS exemptions, which are to allow companies time to develop restricted substance-free alternatives to existing products and not to continue to develop new and improved products reliant on highly toxic cadmium, without presenting evidence that they are developing cadmium-free alternatives instead.

In relation to the energy consumption of displays, Nanoco (2019b) mentions the test method that has been used by the applicants during the previous and also the current procedures, i.e. the 'swap test' which consists in swapping Cd/Cd-free films between different types of TVs. Nanoco refers to the recent Dyson Case T-544/13 of November 8, 2018, where the General Court held that the method of calculation of energy efficiency of vacuum cleaners must make it possible to measure the energy performance in conditions as close as possible to actual conditions of use. Nanoco claims that there is a strong interaction between the QD film design and the design of the other components in the display (LEDs, colour filters etc.) so that swapping QD films into displays that they have not been designed for is not close to the actual conditions of use. On this basis, Nanoco provides a table with comparative data of displays on the market using on-surface configurations. Nanoco summarises this data, stating that the table compares both 55"and 65" TVs, which are the most popular sizes. *"For the 55", one Cd QD TV uses 5.8% less energy than the Cd-free QD TV, but the other uses 6.5% more. For the 65" the best Cd QD TV uses 37.2% more energy than the Cd-free QD TV, but the other uses 56.1% more. From these results it is clear that Cd-free QD technology is able to deliver equivalent or even more energy efficient displays compared to Cd QD technology".*

As for the colour performance of QD material, Nanoco (2019b) quotes a table (see Table 4-2) of Nanosys comparing their Cd QD, low Cd QD(Hyperion) and Cd-free QD products in relation to various standards. Nanoco states that considering the performance using DCI P3 colour gamut (the most appropriate colour standard for EU consumer displays), the brightness of the Cd QD can be matched by both their low Cd (Hyperion) and Cd-free QD technology when used in an appropriately designed display. This provides further updated evidence that even leading Cd QD producers accept that these alternative technologies can already achieve equivalent performance for both energy efficiency and colour gamut.

Table 4-1: Nanosys comparison of Cd QD, low Cd QD(Hyperion) and Cd-free QD products

Type of QD	Traditional		Hyperion		Heavy metal free	
Colour standard	Colour gamut	Relative brightness	Colour gamut	Relative brightness	Colour gamut	Relative brightness
DCI-P3	>99%	100%	>99%	100%	>99%	100%
Adobe RGB	>99%	100%	>99%	100%	>99%	90%
NRSC	>100%	100%	>100%	100%	>100%	95%
BT2020	>90%	100%	>90%	100%	>85%	95%

Source: Reproduced from https://www.nanosysinc.com/products last viewed 15.6.2020

As regards on-chip applications, Nanoco (2019a) refers to OSRAMs's response to Clarification Question 5a, where it was stated that *"OSRAM Opto Semiconductors is currently planning to release 90 CRI OSCONIQ products in May 2019, which utilize Cd-based QD material at a level below 100 ppm Cd and are definitely compliant with the current ROHS regulations."* Nanoco states that *"the data suggests that RoHS compliant* *products (< 100 ppm Cd) can be achieved with a 7 % improvement in luminous efficacy and 7 % reduction in energy consumption compared to phosphor-only LEDs*. The Nanosy 'Hyperion' product is also mentioned in this respect, having been developed with reduced cadmium content to allow QD films which comply with RoHS without the need for Exemption 39 to be produced.

Merck KGaA (2019) supports Nanoco's objection to the exemption requests. Merck KGaA is collaborating with UK-based Nanoco Technologies Ltd. in the development of cadmium-free quantum dot solutions for the display industry. Merck KGaA explains its support with the fact that Samsung Display and LG Display have announced that all their products will be 100% Cadmium-free. Samsung's QD-based display products are explained to exceed the 100% DCI-P3 colour gamut and to show one of the highest colour gamut's in the consumer device market. Samsung is further explained to be the market leader for quantum dot film TVs, followed by Hisense, with both companies commanding more than 90% of the market. Merck KGaA expects that in the period between March 2018 and February 2019, between 182 and 450 thousand TV units (TUnits) containing a quantum dot film had been sold monthly. With a strong increase in sales during this period. The share of cadmium-containing quantum dot TV sets sold by Hisense has dropped on a global base from 38% to 22% compared to the Cadmium-free TV sets of Samsung. Merck assumes that the Hisense market share in the EU is lower than that of Samsung. This shows clearly that TV sets with cadmium-free quantum dot films are widely accepted by the market and their share is constantly increasing.

4.4. Critical review

4.4.1. REACH compliance – Relation to the REACH Regulation

Art. 5(1)(a) of the RoHS Directive specifies that exemptions from the substance restrictions, for specific materials and components in specific applications, may only be included in Annex III or Annex IV "*provided that such inclusion does not weaken the environmental and health protection afforded by*" the REACH Regulation. The article details further criteria which need to be fulfilled to justify an exemption, however the reference to the REACH Regulation is interpreted by the consultants as a threshold-criteria: an exemption could not be granted should it weaken the protection afforded by REACH. The first stage of the evaluation thus includes a review of possible incoherence of the requested exemption with the REACH Regulation.

According to OSRAM (2018), the Cd QD applied in on-chip applications may use either cadmium selenide or cadmium sulphide. LightingEurope (2017), details also the following compounds aside from those detailed by OSRAM: cadmium zinc selenide; cadmium zinc sulphide; cadmium selenide sulphide and cadmium zinc selenide sulphide.

"The raw materials for colloidal chemical synthesis of quantum dots include cadmium precursor, such as cadmium oxide, cadmium carboxylate, and organic solvent, such as octadecylene, and ligands for protecting quantum dots, such as fatty acids. Only cadmium oxide among all cadmium precursors has been entered into the SVHC list." (Najing 2018)

With regards to **Annex XIV of the REACH Regulation**, cadmium is not mentioned in the list of substances that require an **authorisation** for use.

With regards to **Annex XVII of the REACH Regulation**, cadmium is mentioned in a few of the listed restrictions.

Paragraph 1 of entry 23 of Annex XVII refers to a list of various polymers that Cd may not be used in. However, this item is understood not to apply: "*Regarding the plastic material that quantum dots embedded in, there are other options for quantum dots besides the plastic types described in REACH, such as polyacrylate, silicone, meaning Annex XVII 23 can be satisfied in practice*" (Najing 2018). Article 23 also refers to the use of Cd in paints, cadmium plating, brazing filers and jewellery. However, none of these application areas are of relevance to the exemption requests at hand.

Entry 28 of Annex XVII does not allow the placing on the market, or use of various substances as such, as constituents of other substances, or in mixtures. Various compounds are mentioned in this respect, including among others cadmium sulphide. Nonetheless, the use of cadmium compounds within an application (a film placed n proximity or on the LED) is not understood as supply of such compounds to the general public and thus this article would not apply.

Entry 72 refers among others to cadmium and its compounds as listed under entry 28 and restricts their use in clothing and textiles. The requests for exemption refer to display and lighting applications. Though not specifically mentioned, lighting may be applied as part of textiles. If light sources containing Cd QD would be used as part of clothing or textiles, this would be understood to fall under this item and would be restricted above a threshold of "*1 mg/kg after extraction (expressed as Cd meta that can be extracted from the material)*".

To conclude, most of the entries currently listed under REACH would not apply to the case at hand. Use of Cd in lighting and in displays would not be considered to weaken the protection afforded by REACH if not applied in applications in the scope of entry 72 of Annex XVII of the Regulation (clothing, textiles) above the specified threshold. For the case that such applications could become relevant in the future, they should be excluded from an exemption, should one be granted.

4.4.2. Scientific and technical practicability of substitution

The exemption requests refer to the use of Cd compounds in QD applications. The amount of Cd used depends on how the material is applied, i.e. on the configuration as well as on the application.

On edge-applications are understood to have become obsolete and shall not be further discussed. Such configurations should be excluded from exemptions to derive from this evaluation, seeing as there is currently no data that would allow their comparison with other available configurations.

Both on-surface configurations and on-chip configurations are addressed in the requests at hand. In displays, on-chip configurations are understood to require significantly lower amounts of Cd than on-surface configurations. OSRAM (2018) quotes the Yole report in this regard, which estimates that for a 55" display, 40 mg Cd would be needed for on-surface configurations in comparison to only 1 mg that would be needed should on-chip configurations be applied. Other stakeholders also mention that on-chip configurations use significantly less Cd than remote ones. In this sense, where viable, on-chip applications would be understood to be preferable to on-surface applications as they allow development of the same applications (display, lighting) with significantly lower amounts of Cd.

Looking at possible alternatives, it is clear that there are display and lighting applications that do not apply Cd QD material and these are considered to be reliable where they are made available on the market. The question thus arises as to whether the use of Cd QD supports technical performance which is not provided by various alternatives.

In the case of on-surface applications, Najing states that "*The performance of Cd-free quantum dots (based in InP) is expected to reach the current colour quality and energy consumption performance of cadmium quantum dots by 2020. Full commercialization will be achieved by 2022" (Najing 2018).* Cd-free QD alternatives are understood to be more developed in on-surface configurations. Such Cd-free alternatives (based on indium) have been on the market for quite a few years. For example, they were already on the market during the last evaluation of this request which took place in 2015-2016. Information from Merck KGaA (2019) also suggests that Samsung is a market leader for quantum dot film TVs, but applies only Cd-free quantum dot materials. In this case it is thus apparent that regardless of possible differences in the colour performance of the various QD materials, consumers accept Cd-free alternatives.

As for on-chip configurations, these are understood to have only become market ready in the last years. OSRAM already started marketing LED with Cd QDs in 2019 (e.g., OSCONIQ S3030 Osram), with amounts that are below the RoHS substance threshold and such materials are also made available by material suppliers (e.g., Nanosys 'Hyperion' product). Such components do not require an exemption in light of the low amount of Cd in %/weight applied. The use of higher amounts of Cd is however explained to provide performance advantages of relevance both to display and projector applications and to lighting applications.

Regarding general performance of Cd-free quantum dot materials, OSRAM (2019) explains that:

- the Cd-free QD spectral width is in the 40nm range and above, while CD QDs have FWHM <30nm;
- Cd-free quantum efficiency as measured under high temperature and high flux conditions is <50%, while for Cd QDs under the same conditions it is >80%.

Both aspects support that Cd-based QD have certain advantages over Cd-free QDs, while it is also explained that currently, the development of Cd-free QDs does not allow their use in on-chip configurations. Benchmark testing of Cd-free QD on-chip has shown immediate loss of optical performance in minutes/few hours (OSRAM 2019).

According to OSRAM (2018), for future technologies µ-LEDs are needed for the use in displays and projectors where small converter grains are needed in the size of nanoparticles that in addition allow dense packing to realize very thin converter layers

(~1µm). At present, OSRAM states that this can only be done with on-chip Cd QDs. These applications have benefits over reflective micro-displays in terms of power consumption and size and over micro-OLED technologies that suffer from relative low luminance and lifetime issues. In such display applications, Cd QD LEDs are thus understood to provide technical advantages, also showing environmental benefits (energy consumption, device lifetime).

Though it can be understood that Cd-based QD support a better quality of light, particularly in the green and red spectral output ranges, an important advantage is understood to relate to the improvement of luminous efficacy of the LED, which translates into lower energy consumption when comparing LEDs with similar technical properties. Additional details of such benefits are thus provided in Section 4.4.3.

LightingEurope also refers to the advantage of Cd-based QD in relation to thermal and intensity quenching. Cd-based QDs are explained to have better performance in comparison to Cd-free QDs and remain "*reliable under conditions of high temperature and high flux. The result is that Cd-based QDs approach similar thermal and intensity quenching to red phosphor whereas Cd-free QDs suffer significantly higher quenching*" (LightingEurope 2017). However, this quality is understood to be of relevance only in the comparison of QD alternatives, whereas at least some phosphor alternatives are understood to provide comparable performance. Here too, the main advantage is understood to be related to the lower energy consumption that Cd QD on-chip configurations can provide in both displays and lighting applications.

4.4.3. Environmental arguments

To show the preference of Cd QD applications, OSRAM and LightingEurope provide various data and comparisons. The most recent data provided by OSRAM compares between both conventional LED components and CD QD based ones. Table 4-6 which appears in section 4.3.2 is reproduced with modifications below (Table 4-7) and provides comparative data of such components in relation to both Color Rendering Index (CRI), nominal efficacy and the efficacy in reference to the OSRAM OSCONIQ S3030 LED which uses Cd QD in an amount below the RoHS restriction threshold.

Table 4-7: Efficacy white (3000k) LEDs with non-RoHS conform Cd amount

Color temperature: 3000 K	Efficacy [lm/W]	Rel. Efficacy [%]	CRI
Commercial no Cd LED, Osram (Duris-5 based)	154.2	96.5%	93
Commercial no Cd LED, competitor (Samsung)	157.6	98.6%	94
Commercial <100 ppm Cd LED (OSCONIQ S3030 Osram) – *can be POM without an exemption*	159.85	100%	93
Commercial-ready >1000 ppm CD LED, Osram – *requires an exemption*	193.7	121.2%	90

Source: reproduced with modifications from (OSRAM 2020)

All components compared have a CRI of 90 and above and thus it is understood as explained above, that Cd-free LED can also achieve similar performance in terms of light colour and quality. In fact, OSRAMs CD-QD based LED that requires the exemption has the lowest CRI (90 in comparison to 93 and 94), though the OSCONIQ component achieves the higher range in this regard. In terms of energy performance, the OSCONIQ component is used as the reference for efficacy performance. The two Cd-free LED (one from OSRAM and one from a competitor) have a slightly lower efficacy performance than this component (between 1.4 and 3.5% lower efficacy), whereas the Cd-QD based component that would need the exemption shows an efficacy which is 21,2% above that of the OSCONIQ component and 22.5% above the next best performing Cd-free LED.

The applicants also mention further environmental benefits of the use of Cd QD in lighting and display applications. The most relevant of these relates to the comparison between the amount of Cd needed in the application and the amount of Cd emissions that can be saved as a result of the lower consumption of energy. LightingEurope (2017) provides estimations as to the amount of Cd to be used in this application and the savings that this would generate in comparison with the use of conventional LEDs. The estimation is based on a lighting capacity of 10.77 tera lumen in the EU. Details are provided in earlier sections and summarised in Table 4-8 below.

Table 4-8: Summary of decrease in emissions as a result of the use of Cd in on-chip configurations

Market penetration	Amount of Cd placed on the market in light sources	Energy savings per annum	Reduced Cd emissions per annum
100%	163 kg	14.134 GWh	54 kg
5%	3.26 kg	706.71 GWh	2.69 kg
3%	3.26 kg	282.68 GWh	1.07 kg
1%	1.63 kg	141.34 GWh	0.54 kg

Source: Own compilation based on LightingEurope (2017)

LightingEurope (2018) also quantifies various impacts for a scenario in which the exemption is granted, resulting in a gradual market penetration, starting at 1% in 2018 and rising to 5% in 2022. Details of the annual increase and how it translates to energy savings are given in the original document. The main impacts estimated are summarised in the following: _

- Over this five-year period, QD based LEDs that have been placed on the market are estimated to have generated energy savings in an order of 3392.21 GWh.
- Using the German energy mix of 2016 as a reference value, 1 avoided kWh results in a reduction of 0.527 kg of CO2 emission.
- On this basis, LighhtingEurope estimates that the above stated electricity reduction translates into reduced CO_2 emissions in the order of 1,787,695 tonnes.
- Looking at the average price of carbon, LightingEurope quantifies this into monetary terms, estimating that the analyzed market penetration of Cd QD LEDs would save European society 75 million EUR due to reduced CO_2 emissions.

Though at present this line of argumentation shows that aside from saving energy, Cd QD can also allow decreasing the emissions of Cd from energy production, the consultants agree with KEMI that the energy mix is expected to change in the following years and differs between countries. Thus, though such benefits also support the justification of an exemption it is not clear to what degree, as their nature will differ from country to country and also depend on the use pattern of the consumers.

4.4.4. Socioeconomic impacts

Although stakeholders have provided data as to possible socio-economic impacts of not recommending an exemption, this argumentation is not central to the justification of this request and is thus not evaluated in this respect.

4.4.5. Scope of the exemption

Both OSRAM and LightingEurope refer to on-chip technologies in their requests for exemptions, the one referring to display applications and the other to lighting applications. OSRAM (2019) explains "*The basic technology of QDs as wavelength converter to generate green or red light from the blue LED light is the same*.

- In lighting, the mixture of conventional phosphors and QD wavelength converters shall generate high-quality white light. Here only red QDs are required to enhance the emission spectrum of conventional phosphors (especially if high Color Rendering Index is required);
- In contrast, for display applications, spectrally narrow green and red light is needed for a high colour gamut. In addition to fulfil the demanding optical requirements for a display system, the phosphor layer is typically much thinner and thus requires a very high weight percentage of Cd in that layer than used in the relatively thick layers in lighting applications.

For this reason, for the display applications OSRAM (2019) proposes to limit the amount of Cd per mm² chip surface instead of using an extended ppm level like in the lighting application. This is the technical background for the different wordings proposed for the exemptions for lighting and displays. In an effort to combine the exemptions OSRAM (2019) proposed the following wording. The proposal assumes that the display and projection application that OSRAM is working on and that is now understood to be market ready but still not available on the market (lacking exemption) could be included in the current exemption for Cd in QD LED:

"*Cadmium in downshifting semiconductor nanocrystal quantum dots*

I. directly deposited on LED semiconductor chips for use in display and projection applications (< 5 µg Cd per mm² of light emitting LED chip surface)
II. directly deposited on LED semiconductor chips for use in lighting applications of at least CRI 80 (< 1.000 ppm in the luminescent material)
*III. not directly deposited on LED semiconductor chips for use in display and projection applications (< 0,2 µg Cd per mm² of display screen area) * […]*

**OSRAM currently does not work on such on-edge and on-surface configurations."*

The amount of Cd permitted per surface area of display application by the above wording is much lower for item III (applicable among others to on-surface configurations in displays) than for item I (applicable to on-chip applications in displays). It has however been shown that this results in a much higher total amount of Cd that is used per display. In the consultant's opinion, granting this part of the exemption would mean that configurations are allowed on the market that make use of more Cd than is absolute necessary for providing the same performance. This would not be in line with the Directive that supports the reduction of the amounts of RoHS restricted substances where this is possible. Najing has also requested this part of the exemption only until 31 October 2021, at which time Cd-free on-surface applications are "*expected to reach the current colour quality and energy consumption performance of cadmium quantum dots*". In the presence of configurations that allow a decrease in the amounts of Cd needed, the consultants would recommend removing this part of the exemption from the formulation.

As for item II of the exemption, when asked about the Color Rendering Index threshold in their proposed exemption formulation, LightingEurope (2018) explained that the general lighting market is mainly split between CRI 80 and 90, with ~70% CRI 80 and 10-15% CRI 90 LEDs. Although the advantages provided by the inclusion of QDs is greater for CRI 90, the technology can also be applied to raise the efficiency of CRI 80 by a significant amount. Efficacy gains for CRI 80 of >10% and CRI 90 >20% are achievable if the limitation on Cd ppm is raised to 1000, making the cumulative positive effect of Quantum Dot converters in CRI 80 LEDs even higher than that of CRI 90 LEDs. As for additional parameters of relevance to the quality of light, LightingEurope states that the use of Cd-based Quantum Dot converters does not create any benefit below a certain CRI and at cool white colour points. Also, negative R9 values do not make sense for these high-colour-quality LEDs. Therefore, a limit to CRI>80 with R9>0 and CCT <6500K can be considered. LightingEurope explains that modern metrics always define several quality parameters for different (competing) targets like accuracy of rendering versus colour preference or colour gamut. Currently the most popular of these is the TM-30 metric. However, as of yet there is no commonly accepted scientific standard beyond CRI and R9.

The addition of the parameters R9>0 and CCT <6500K could be considered, but in the consultants' view, this would add to the complexity of the exemption, whereas it does not have much of a benefit in terms of limiting the scope of the exemption. A CCT of 6500 K and above is relatively "cold" light, meaning that only a marginal part of the range would be excluded from the scope of the exemption, where CD QD are understood to be of higher relevance for the "warm" range of spectral output and would not be expected to be of high significance in this area anyway. For example, according to its data sheet, the Osram OSCONIQ S3030 LED is available with various CCT between 2700 and 6500 K[17]. The addition of the R9 parameter is also not considered to add to the limitation of scope. Though R9 values can be negative, the range theoretically goes up

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[17] See OSCONIQ S3030 Osram data sheet under:https://eu.mouser.com/pdfDocs/OSCONIQ_S_3030_PB.pdf, last viewed 7.10.2020

to 100, while most lamps on the market will provide values around 50[18]. Limiting the R9 to a positive value is not expected to exclude actual applications from the scope of the exemption and is thus also not recommended.

4.4.6. Conclusions

Article 5(1)(a) provides that an exemption can be justified if at least one of the following criteria is fulfilled:

- their elimination or substitution via design changes or materials and components which do not require any of the materials or substances listed in Annex II **is scientifically or technically impracticable**;
- the **reliability** of substitutes is not ensured;
- the total negative **environmental, health and consumer safety impacts** caused by substitution are likely to outweigh the total environmental, health and consumer safety benefits thereof.

The applicants raise various arguments to justify their requests.

In relation to on-surface configurations in display applications, which are addressed by the Najing request, on-chip configurations allow a significant decrease in the amount of Cd that is to be used. This part of the exemption is thus not considered to still be justified as lower amounts of Cd can be applied to achieve similar performance. Najing furthermore have only requested the exemption until 31 October 2021, stating that "*The performance of Cd-free quantum dots (based in InP) is expected to reach the current colour quality and energy consumption performance of cadmium quantum dots by 2020. Full commercialization will be achieved by 2022*" (Najing 2018). Seeing as Najing requests a renewal of Ex. 39a, a transition period would need to be provided should the exemption request be denied in any case, and this would sufficiently cover the remaining time until 31 October 2021.

On-edge configurations are understood to have become obsolete in display applications and thus an exemption would not be justified here either.

As for on-surface and on-edge configurations in lighting applications, LightingEurope (2018) agrees that on-edge and on-surface configurations could be excluded from an exemption for SSL applications: "*Both because it is not economically viable to use surface/edge configurations in lighting and in the spirit of narrowly targeting specific applications where the greatest benefit is achieved for the least amount of Cd*."

Regarding on-chip configurations, OSRAM (2019) explains "*The basic technology of QDs as wavelength converter to generate green or red light from the blue LED light is the same*", with red QDs being relevant for lighting applications and green and red QDs for display applications. In both cases, alternatives are understood to be available on the

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[18] See https://www.waveformlighting.com/tech/what-is-cri-r9-and-why-is-it-important for additional detail.

market that can provide similar performance in terms of spectral output or colour gamut. Seeing as such products are on the market, the first and second criteria are not considered to be fulfilled, i.e. as substitutes are available and reliable.

However, as regards the third criterion, LightingEurope and OSRAM[19] provide data to show that the use of Cd-QD in on-chip configurations brings benefits in terms of energy savings of 10 % and more for a CRI over 80, and 20 % or more for a CRI over 90. Here the question is whether the benefits are significant enough to justify an exemption. In past Cd QD exemption evaluations, the observed differences, i.e., benefits, in energy consumption were also in the order of 20% and above and the exemptions were granted (renewed). Thus, the consultants conclude that here too, the evidence would support an exemption based on fulfilment of the third criteria for the use of Cd in LEDs with a CRI of 90 and above. In further support of the exemption are also technical advantages in specific application areas (μ-displays and μ-projectors) and indirect benefits to derive through the decrease in energy consumption such as decreased CO_2 emissions and decreased Cd emission from coal combustion. The range of such benefits is unclear and would depend among others on the service life of LED modules, the energy mix in various Member States and respective Cd and CO_2 emissions from energy production.

For the case of a CRI of 80 and above, only 10% benefit was stated by LightingEurope. Here too, this benefit would also have indirect effects in the form of reduced CO_2 and Cd emissions, however at a lower rate. It is not clear if this benefit would be significant enough to justify an exemption or not. The RoHS directive does not specify when a benefit is to be considered significant enough in this regard. The consultants also note the objection of KEMI and of additional stakeholders, regarding the use of the exemption mechanism for the introduction of new EEE applications using RoHS substances to the European market. The concerns raised regarding the introduction of Cd in a consumer article to be placed on the market in large volumes can be followed, particularly due to the dynamic character of the lighting and display sectors. The consultants are also concerned as to the message that such exemptions may send to industry and the impact that this could have on future innovations related to the use of hazardous substances. Nonetheless, the RoHS Directive allows applications of new exemptions and does not specify whether this is to be limited only to specific cases, EEE categories or areas of application. Past applications for exemptions in newly developed EEE have been granted in the past, for example for mercury in electric rotating connectors (Ex. 42 of Annex IV) in medical devices, and the Directive does not specify that this would not be possible for consumer products. In this sense, from a technical and scientific perspective, the exemption is concluded to be justified for on-chip applications.

A further aspect to consider relates to the impacts of an exemption, or a lack thereof, on innovation and how this is to be considered in relation to the duration of a future

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[19] Though the OSRAM data is provided in relation to an exemption for displays and projectors, it is understood that in general LED modules with the on-chip configuration could be used in both application areas. The comparative data provided by OSRAM addresses only modules with a CRI of 90 and above but also supports that such modules provide benefits in relation to energy savings in an order of 20% and above.

exemption. Various stakeholders raise concerns that renewal of the exemption for Cd QD applications could send a false message to industry in relation to the promotion of Cd-free alternatives in general as well as QD based ones. This has been highlighted in past evaluations of the Cd QD exemption, particularly for display applications where indium phosphide QDs were already on the market and acceptable for consumers in terms of colour performance and reliability. Due to the availability and expected developments of such alternatives, the consultants recommended shorter validity for Cd QD exemptions in the past. Such materials, however, have not yet reached maturity for applications in on-chip configurations and the few lighting applications brought on the market in the past with a remote QD configuration showed significantly lower luminous efficacy and are no longer available on the market:

- According to Nanoco (2019a) lamps were placed on the market in the past "*with a CCT of 6,500 K, CRI of 95.3 and R9 of 91.6. The luminous efficacy at source was 102.3 lm/W*." Nanoco further explains that these lamps applied QDs with FWHM > 60 nm and QY of 72 % and that InP quantum dots available today, have improved optical properties and could probably achieve higher luminous efficacy. However, such lamps or respective LED modules using InP are understood not to be available on the market at present. The Osram information clarifies that there is currently not a Cd-free material /technology that can withstand the high flux and temperatures involved in the on-chip configuration, i.e. a comparison between Cd QD and Cd-free QD technologies is thus not feasible at present. There is no data to suggest that this shall change in the short term and thus recommending a short-termed exemption would not be justified in this case.

Though it can be followed that an exemption may affect innovation in terms of development of alternatives to Cd QD, it is also noted that this can be viewed from the other direction as well. OSRAM is active in research into substance alternatives for Cd in QD applications, i.e. regardless of its interest in a Cd QD exemption. Furthermore, in terms of lighting, the lack of an exemption also affects innovation: OSRAM has developed LEDs to a market ready stage that could provide energy savings of 20% and above. However, such modules cannot be expected to be applied in displays or projectors by OEMs prior to an exemption being granted due to the uncertainty of marketing such devices.

4.5. Recommendation

The application of Cd in on-chip applications is considered to provide benefits in the form of decreasing the amount of energy consumed by lighting and display applications. This is considered to provide an environmental benefit to such applications in comparison with alternatives currently available on the market. Subsequently and depending on the energy mix in Member State countries, this will also support a reduction in CO_2 emissions and in Cd emissions in comparison to alternative technologies with the same technical parameters (CRT, CCT, etc.). In specific application areas (µ-displays and µ-projectors) technical advantages exist as well (miniaturisation, lifetime).

In consideration of earlier evaluations, it is assumed that a benefit of 20% lower energy consumption is significant enough to justify the use of small amounts of Cd in display and lighting applications based on Article 5(1)(a), paragraph 3. Where this is achievable (LED modules for use in displays and projectors and in lighting sources with a CRT ≥90), the exemption could be granted.

Use of Cd in lighting and in displays would not be considered to weaken the protection afforded by REACH if not applied in applications in the scope of entry 72 of Annex XVII of the Regulation (clothing, textiles) above the specified threshold.

The following formulation is recommended to be granted and added to Annex III of the RoHS Directive.

"*Cadmium in downshifting semiconductor nanocrystal quantum dots*

I. directly deposited on LED semiconductor chips for use in display and projection applications (< 5 µg Cd per mm² of light emitting LED chip surface)
II. directly deposited on LED semiconductor chips for use in lighting applications of at least CRI 90 (< 1.000 ppm in the luminescent material)

provided that applications comply with entry 72 of Annex XVII of Regulation 1907/2006."

The exemption is recommended for a period of 5 years.

As for on-surface applications currently benefiting from Ex. 39a, this application is no longer considered to justify the exemption criteria. Here a transition period should be given as required in the Directive. Seeing as it shall take time to process the exemption evaluation into a delegated act, the transition period could be limited to 12 months which is the minimum period – this period would be assumed to allow a transition to alternatives until 31 October 2021, the date specified by Najing.

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Appendix

Aspects relevant to the REACH Regulation

Relevant annexes and processes related to the REACH Regulation have been cross-checked to clarify:

- In what cases granting an exemption could "weaken the environmental and health protection afforded by Regulation (EC) No 1907/2006" (Article 5(1)(a), pg. 1)
- Where processes related to the REACH regulation should be followed to understand where such cases may become relevant in the future;

Compiled information in this respect has been included, with short clarifications where relevant, in the following tables:

Table A-1 lists those substances appearing in Annex XIV, subject to Authorisation, which are relevant to the RoHS substances dealt with in the requests evaluated in this project. As can be seen, at present, exemptions have not been granted for the use of these substances.

Table A-1: Relevant entries from Annex XIV: List of substances subject to authorization

Designation of the substance, of the group of substances, or of the mixture	Transitional arrangements		Exempted (categories of) uses
	Latest application date (1)	Sunset date (2)	
4. Bis(2-ethylhexyl) phthalate (DEHP) EC No: 204-211-0 CAS No: 117-81-7	21 August 2013 (*)	21 February 2015 (**)	Uses in the immediate packaging of medicinal products covered under Regulation (EC) No 726/ 2004, Directive 2001/82/EC, and/or Directive 2001/83/EC
5. Benzyl butyl phthalate (BBP) EC No: 201-622-7 CAS No: 85-68-7	21 August 2013 (*)	21 February 2015 (**)	
6. Dibutyl phthalate (DBP) EC No: 201-557-4 CAS No: 84-74-2	21 August 2013 (*)	21 February 2015 (**)	
7. Diisobutyl phthalate (DIBP) EC No: 201-553-2 CAS No: 84-69-5	21 August 2013 (*)	21 February 2015 (**)	
10. Lead chromate EC No: 231-846-0 CAS No: 7758-97-6	21 Nov 2013 (*)	21 May 2015 (**)	-
11. Lead sulfochromate yellow (C.I. Pigment Yellow 34) EC No: 215-693-7 CAS No: 1344-37-2	21 Nov 2013 (*)	21 May 2015 (**)	-

Designation of the substance, of the group of substances, or of the mixture	Transitional arrangements		Exempted (categories of) uses
	Latest application date (1)	Sunset date (2)	
12. Lead chromate molybdate sulphate red (C.I. Pigment Red 104) EC No: 235-759-9 CAS No: 12656-85-8	21 Nov 2013 (*)	21 May 2015 (**)	-
16. Chromium trioxide EC No: 215-607-8 CAS No: 1333-82-0	21 Mar 2016 (*)	21 Sep 2017 (**)	-
17. Acids generated from chromium trioxide and their oligomers Group containing: Chromic acid EC No: 231-801-5 CAS No: 7738-94-5 Dichromic acid EC No: 236-881-5 CAS No: 13530-68-2 Oligomers of chromic acid and dichromic acid EC No: not yet assigned CAS No: not yet assigned	21 Mar 2016 (*)	21 Sep 2017 (**)	-
18. Sodium dichromate EC No: 234-190-3 CAS No: 7789-12-0 10588-01-9	21 Mar 2016 (*)	21 Sep 2017 (**)	-
19. Potassium dichromate EC No: 231-906-6 CAS No: 7778-50-9	21 Mar 2016 (*)	21 Sep 2017 (**)	-
20. Ammonium dichromate EC No: 232-143-1 CAS No: 7789-09-5	21 Mar 2016 (*)	21 Sep 2017 (**)	-
21. Potassium chromate EC No: 232-140-5 CAS No: 7789-00-6	21 Mar 2016 (*)	21 Sep 2017 (**)	
22. Sodium chromate EC No: 231-889-5 CAS No: 7775-11-3	21 Mar 2016 (*)	21 Sep 2017 (**)	
28. Dichromium tris(-chromate) EC No: 246-356-2 CAS No: 24613-89-6	22. Jul 2017 (*)	22 Jan 2019 (**)	
29. Strontium chromate EC No: 232-142-6 CAS CAS No: 7789-06-2	22 Jul 2017 (*)	22 Jan 2019 (**)	

Designation of the substance, of the group of substances, or of the mixture	Transitional arrangements		Exempted (categories of) uses
	Latest application date (1)	Sunset date (2)	
30. Potassium hydroxyoctaoxodizincatedichromate EC No: 234-329-8 CAS No: 11103-86-9	22 Jul 2017 (*)	22 Jan 2019 (**)	
31. Pentazinc chromate octahydroxide EC No: 256-418-0 CAS No: 49663-84-5	22 Jul 2017 (*)	22 Jan 2019 (**)	

(*) 1 September 2019 for the use of the substance in the production of spare parts for the repair of articles the production of which ceased or will cease before the sunset date indicated in the entry for that substance, where that substance was used in the production of those articles and the latter cannot function as intended without that spare part, and for the use of the substance (on its own or in a mixture) for the repair of such articles where that substance on its own or in a mixture was used in the production of those articles and the latter cannot be repaired otherwise than by using that substance.

(**) 1 March 2021 for the use of the substance in the production of spare parts for the repair of articles the production of which ceased or will cease before the sunset date indicated in the entry for that substance, where that substance was used in the production of those articles and the latter cannot function as intended without those spare parts, and for the use of the substance (on its own or in a mixture) for the repair of such articles, where that substance was used in the production of those articles and the latter cannot be repaired otherwise than by using that substance.

For the substances currently restricted according to RoHS Annex II: cadmium, hexavalent chromium, lead, mercury, polybrominated biphenyls and polybrominated diphenyl ethers and their compounds, as well as bis(2-ethylhexyl) phthalate (DEHP), butyl benzyl phthalate (BBP), dibutyl phthalate (DBP), diisobutyl phthalate (DIBP), we have found that some relevant entries are listed in Annex XVII of the REACH Regulation. The conditions of restriction are presented in Table A-2 below.

Table A-2: Conditions of Restriction in REACH Annex XVII for RoHS Substances and Compounds

Designation of the substance, group of substances, or mixture	Conditions of restriction
8. Polybromobiphenyls; Polybrominatedbiphenyls (PBB) CAS No 59536-65-1	1. Shall not be used in textile articles, such as garments, undergarments and linen, intended to come into contact with the skin. 2. Articles not complying with paragraph 1 shall not be placed on the market.
16. Lead carbonates: (a) Neutral anhydrous carbonate ($PbCO_3$) CAS No 598-63-0 EC No 209-943-4 (b) Trilead-bis(carbonate)-dihydroxide $2PbCO_3\text{-}Pb(OH)_2$ CAS No 1319-46-6 EC No 215-290-6	Shall not be placed on the market, or used, as substances or in mixtures, where the substance or mixture is intended for use as paint. However, Member States may, in accordance with the provisions of International Labour Organization (ILO) Convention 13, permit the use on their territory of the substance or mixture for the restoration and maintenance of works of art and historic buildings and their interiors, as well as the placing on the market for such use. Where a Member State makes use of this derogation, it shall inform the Commission thereof.
17. Lead sulphates: (a) $PbSO_4$ CAS No 7446-14-2 EC No 231-198-9 (b) Pb_xSO_4 CAS No 15739-80-7 EC No 239-831-0	Shall not be placed on the market, or used, as substances or in mixtures, where the substance or mixture is intended for use as paint. However, Member States may, in accordance with the provisions of International Labour Organization (ILO) Convention 13, permit the use on their territory of the substance or mixture for the restoration and maintenance of works of art and historic buildings and their interiors, as well as the placing on the market for such use. Where a Member State makes use of this derogation, it shall inform the Commission thereof.
18. Mercury compounds	Shall not be placed on the market, or used, as substances or in mixtures where the substance or mixture is intended for use: (a) to prevent the fouling by micro-organisms, plants or animals of: the hulls of boats, cages, floats, nets and any other appliances or equipment used for fish or shellfish farming, any totally or partly submerged appliances or equipment; (b) in the preservation of wood; (c) in the impregnation of heavy-duty industrial textiles and yarn intended for their manufacture; (d) in the treatment of industrial waters, irrespective of their use.

18a. Mercury CAS No 7439-97-6 EC No 231-106-7	1. Shall not be placed on the market: (a) in fever thermometers; (b) in other measuring devices intended for sale to the general public (such as manometers, barometers, sphygmomanometers, thermometers other than fever thermometers). 2. The restriction in paragraph 1 shall not apply to measuring devices that were in use in the Community before 3 April 2009. However Member States may restrict or prohibit the placing on the market of such measuring devices. 3. The restriction in paragraph 1(b) shall not apply to: (a) measuring devices more than 50 years old on 3 October 2007; (b) barometers (except barometers within point (a)) until 3 October 2009. 5. The following mercury-containing measuring devices intended for industrial and professional uses shall not be placed on the market after 10 April 2014: (a) barometers; (b) hygrometers; (c) manometers; (d) sphygmomanometers; (e) strain gauges to be used with plethysmographs; (f) tensiometers; (g) thermometers and other non-electrical thermometric applications. The restriction shall also apply to measuring devices under points (a) to (g) which are placed on the market empty if intended to be filled with mercury. 6. The restriction in paragraph 5 shall not apply to: (a) sphygmomanometers to be used: (i) in epidemiological studies which are ongoing on 10 October 2012; (ii) as reference standards in clinical validation studies of mercury-free sphygmomanometers; (b) thermometers exclusively intended to perform tests according to standards that require the use of mercury thermometers until 10 October 2017; (c) mercury triple point cells which are used for the calibration of platinum resistance thermometers. 7. The following mercury-using measuring devices intended for professional and industrial uses shall not be placed on the market after 10 April 2014: (a) mercury pycnometers; (b) mercury metering devices for determination of the softening point. 8. The restrictions in paragraphs 5 and 7 shall not apply to: (a) measuring devices more than 50 years old on 3 October 2007; (b) measuring devices which are to be displayed in public exhibitions for cultural and historical purposes.

Designation of the substance, group of substances, or mixture	Conditions of restriction
23. Cadmium CAS No 7440-43-9 EC No 231-152-8 and its compounds	For the purpose of this entry, the codes and chapters indicated in square brackets are the codes and chapters of the tariff and statistical nomenclature of Common Customs Tariff as established by Council Regulation (EEC) No 2658/87 (1). 1. Shall not be used in mixtures and articles produced from the following synthetic organic polymers (hereafter referred to as plastic material): • polymers or copolymers of vinyl chloride (PVC) [3904 10] [3904 21] • polyurethane (PUR) [3909 50] • low-density polyethylene (LDPE), with the exception of low-density polyethylene used for the production of coloured masterbatch [3901 10] • cellulose acetate (CA) [3912 11] • cellulose acetate butyrate (CAB) [3912 11] • epoxy resins [3907 30] • melamine-formaldehyde (MF) resins [3909 20] • urea-formaldehyde (UF) resins [3909 10] • unsaturated polyesters (UP) [3907 91] • polyethylene terephthalate (PET) [3907 60] • polybutylene terephthalate (PBT) • transparent/general-purpose polystyrene [3903 11] • acrylonitrile methylmethacrylate (AMMA) • cross-linked polyethylene (VPE) • high-impact polystyrene • polypropylene (PP) [3902 10] Mixtures and articles produced from plastic material as listed above shall not be placed on the market if the concentration of cadmium (expressed as Cd metal) is equal to or greater than 0,01 % by weight of the plastic material. By way of derogation, the second subparagraph shall not apply to articles placed on the market before 10 December 2011. The first and second subparagraphs apply without prejudice to Council Directive 94/62/EC (13) and acts adopted on its basis.

Designation of the substance, group of substances, or mixture	Conditions of restriction
	By 19 November 2012, in accordance with Article 69, the Commission shall ask the European Chemicals Agency to prepare a dossier conforming to the requirements of Annex XV in order to assess whether the use of cadmium and its compounds in plastic material, other than that listed in subparagraph 1, should be restricted. 2. Shall not be used or placed on the market in paints with codes [3208] [3209] in a concentration (expressed as Cd metal) equal to or greater than 0,01 % by weight. For paints with codes [3208] [3209] with a zinc content exceeding 10 % by weight of the paint, the concentration of cadmium (expressed as Cd metal) shall not be equal to or greater than 0,1 % by weight. Painted articles shall not be placed on the market if the concentration of cadmium (expressed as Cd metal) is equal to or greater than 0,1 % by weight of the paint on the painted article.' 3. By way of derogation, paragraphs 1 and 2 shall not apply to articles coloured with mixtures containing cadmium for safety reasons. 4. By way of derogation, paragraph 1, second subparagraph shall not apply to: — mixtures produced from PVC waste, hereinafter referred to as 'recovered PVC', — mixtures and articles containing recovered PVC if their concentration of cadmium (expressed as Cd metal) does not exceed 0,1 % by weight of the plastic material in the following rigid PVC applications: — (a) profiles and rigid sheets for building applications; (b) doors, windows, shutters, walls, blinds, fences, and roof gutters; (c) decks and terraces; (d) cable ducts; (e) pipes for non-drinking water if the recovered PVC is used in the middle layer of a multilayer pipe and is entirely covered with a layer of newly produced PVC in compliance with paragraph 1 above. Suppliers shall ensure, before the placing on the market of mixtures and articles containing recovered PVC for the first time, that these are visibly, legibly and indelibly marked as follows: '*Contains recovered PVC*' or with the following pictogram:  In accordance with Article 69 of this Regulation, the derogation granted in paragraph 4 will be reviewed, in particular with a view to reducing the limit value for cadmium and to reassess the derogation for the applications listed in points (a) to (e), by 31 December 2017.

Designation of the substance, group of substances, or mixture	Conditions of restriction
	5. For the purpose of this entry, 'cadmium plating' means any deposit or coating of metallic cadmium on a metallic surface. Shall not be used for cadmium plating metallic articles or components of the articles used in the following sectors/applications: (a) equipment and machinery for: — food production [8210] [8417 20] [8419 81] [8421 11] [8421 22] [8422] [8435] [8437] [8438] [8476 11] — agriculture [8419 31] [8424 81] [8432] [8433] [8434] [8436] — cooling and freezing [8418] — printing and book-binding [8440] [8442] [8443] (b) equipment and machinery for the production of: — household goods [7321] [8421 12] [8450] [8509] [8516] — furniture [8465] [8466] [9401] [9402] [9403] [9404] — sanitary ware [7324] — central heating and air conditioning plant [7322] [8403] [8404] [8415] In any case, whatever their use or intended final purpose, the placing on the market of cadmium-plated articles or components of such articles used in the sectors/applications listed in points (a) and (b) above and of articles manufactured in the sectors listed in point (b) above is prohibited. 6. The provisions referred to in paragraph 5 shall also be applicable to cadmium-plated articles or components of such articles when used in the sectors/applications listed in points (a) and (b) below and to articles manufactured in the sectors listed in (b) below: (a) equipment and machinery for the production of: — paper and board [8419 32] [8439] [8441] textiles and clothing [8444] [8445] [8447] [8448] [8449] [8451] [8452] (b) equipment and machinery for the production of: — industrial handling equipment and machinery [8425] [8426] [8427] [8428] [8429] [8430] [8431] — road and agricultural vehicles [chapter 87] — rolling stock [chapter 86] — vessels [chapter 89] 7. However, the restrictions in paragraphs 5 and 6 shall not apply to:

Designation of the substance, group of substances, or mixture	Conditions of restriction
	— articles and components of the articles used in the aeronautical, aerospace, mining, offshore and nuclear sectors whose applications require high safety standards and in safety devices in road and agricultural vehicles, rolling stock and vessels, — electrical contacts in any sector of use, where that is necessary to ensure the reliability required of the apparatus on which they are installed. 8. Shall not be used in brazing fillers in concentration equal to or greater than 0,01 % by weight. Brazing fillers shall not be placed on the market if the concentration of cadmium (expressed as Cd metal) is equal to or greater than 0,01 % by weight. For the purpose of this paragraph brazing shall mean a joining technique using alloys and undertaken at temperatures above 450 °C. 9. By way of derogation, paragraph 8 shall not apply to brazing fillers used in defence and aerospace applications and to brazing fillers used for safety reasons. 10. Shall not be used or placed on the market if the concentration is equal to or greater than 0,01 % by weight of the metal in: (i) metal beads and other metal components for jewellery making; (ii) metal parts of jewellery and imitation jewellery articles and hair accessories, including: — bracelets, necklaces and rings, — piercing jewellery, — wrist-watches and wrist-wear, — brooches and cufflinks. 11. By way of derogation, paragraph 10 shall not apply to articles placed on the market before 10 December 2011 and jewellery more than 50 years old on 10 December 2011.
28. Substances which are classified as carcinogen category 1A or 1B in Part 3 of Annex VI to Regulation (EC) No 1272/2008 and are listed in Appendix 1 or Appendix 2, respectively: Cadmium carbonate Cadmium chloride Cadmium dihydroxide Cadmium dinitrate Cadmium fluoride	Without prejudice to the other parts of this Annex the following shall apply to entries 28 to 30: 1. Shall not be placed on the market, or used, — as substances, — as constituents of other substances, or, — in mixtures, for supply to the general public when the individual concentration in the substance or mixture is equal to or greater than: — either the relevant specific concentration limit specified in Part 3 of Annex VI to Regulation (EC) No 1272/2008, or,

Designation of the substance, group of substances, or mixture	Conditions of restriction
Cadmium hydroxide Cadmium (pyrophoric) Cadmium nitrate Cadmium oxide Cadmium Sulphate Cadmium sulphide Chromium (VI) trioxide Zinc chromates including zinc potassium chromate Nickel Chromate Nickel dichromate Potassium dichromate Ammonium dichromate Sodium dichromate Chromyl dichloride; chromic oxychloride Potassium chromate Calcium chromate Strontium chromate Chromium III chromate; chromic chromate Sodium chromate Lead Chromate Lead hydrogen arsenate Lead Nickel Salt Lead sulfochromate yellow; C.I. Pigment Yellow 34; Lead chromate molybdate sulfate red; C.I. Pigment Red 104;	— the relevant concentration specified in Directive 1999/45/EC where no specific concentration limit is set out in Part 3 of Annex VI to Regulation (EC) No 1272/2008. Without prejudice to the implementation of other Community provisions relating to the classification, packaging and labelling of substances and mixtures, suppliers shall ensure before the placing on the market that the packaging of such substances and mixtures is marked visibly, legibly and indelibly as follows: 'Restricted to professional users'. 2. By way of derogation, paragraph 1 shall not apply to: (a) medicinal or veterinary products as defined by Directive 2001/82/EC and Directive 2001/83/EC; (b) cosmetic products as defined by Directive 76/768/EEC; (c) the following fuels and oil products: — motor fuels which are covered by Directive 98/70/EC, — mineral oil products intended for use as fuel in mobile or fixed combustion plants, — fuels sold in closed systems (e.g. liquid gas bottles); (d) artists' paints covered by Directive 1999/45/EC; (e) the substances listed in Appendix 11, column 1, for the applications or uses listed in Appendix 11, column 2. Where a date is specified in column 2 of Appendix 11, the derogation shall apply until the said date.

Designation of the substance, group of substances, or mixture	Conditions of restriction
29. Substances which are classified as germ cell mutagen category 1A or 1B in Part 3 of Annex VI to Regulation (EC) No 1272/2008 and are listed in Appendix 3 or Appendix 4, respectively: Cadmium carbonate Cadmium chloride Cadmium dihydroxide Cadmium dinitrate Cadmium fluoride Cadmium hydroxide Cadmium nitrate Cadmium Sulphate Chromium (VI) trioxide Potassium dichromate Ammonium dichromate Sodium dichromate Chromyl dichloride; chromic oxychloride Potassium chromate Sodium chromate	
30. Substances which are classified as reproductive toxicant category 1A or 1B in Part 3 of Annex VI to Regulation (EC) No 1272/2008 and are listed in Appendix 5 or Appendix 6, respectively.’Toxic to reproduction: category 1A or 1B or toxic to reproduction category 1 or 2 According to Appendices 5 and 6: Cadmium chloride Cadmium fluoride	

Designation of the substance, group of substances, or mixture	Conditions of restriction
Cadmium Sulphate Potassium dichromate Ammonium dichromate Sodium dichromate Sodium chromate Nickel dichromate Lead compounds with the exception of those specified elsewhere in this Annex Lead Arsenate Lead acetate Lead alkyls Lead azide Lead Chromate Lead di(acetate) Lead hydrogen arsenate Lead 2,4,6-trinitroresorcinoxide, lead styphnate Lead(II) methane- sulphonate Trilead bis- (orthophosphate) Lead hexa-fluorosilicate Mercury Silicic acid, lead nickel salt	
47. Chromium VI compounds	1. Cement and cement-containing mixtures shall not be placed on the market, or used, if they contain, when hydrated, more than 2 mg/kg (0,0002 %) soluble chromium VI of the total dry weight of the cement. 2. If reducing agents are used, then without prejudice to the application of other Community provisions on the classification, packaging and labelling of substances and mixtures, suppliers shall ensure before the placing on the market that the packaging of cement or cement-containing mixtures is visibly, legibly and indelibly marked with information on the packing date, as well as on the storage conditions and the storage period appropriate to maintaining the activity of the reducing agent and to keeping the content of soluble chromium VI below the limit indicated in paragraph 1.

Designation of the substance, group of substances, or mixture	Conditions of restriction
	3. By way of derogation, paragraphs 1 and 2 shall not apply to the placing on the market for, and use in, controlled closed and totally automated processes in which cement and cement-containing mixtures are handled solely by machines and in which there is no possibility of contact with the skin. 4. The standard adopted by the European Committee for Standardization (CEN) for testing the water-soluble chromium (VI) content of cement and cement-containing mixtures shall be used as the test method for demonstrating conformity with paragraph 1. 5. Leather articles coming into contact with the skin shall not be placed on the market where they contain chromium VI in concentrations equal to or greater than 3 mg/kg (0,0003 % by weight) of the total dry weight of the leather. 6. Articles containing leather parts coming into contact with the skin shall not be placed on the market where any of those leather parts contains chromium VI in concentrations equal to or greater than 3 mg/kg (0,0003 % by weight) of the total dry weight of that leather part. 7. Paragraphs 5 and 6 shall not apply to the placing on the market of second-hand articles which were in end-use in the Union before 1 May 2015.
51. The following phthalates (or other CAS and EC numbers covering the substance): (a) Bis (2-ethylhexyl) phthalate (DEHP) CAS No 117-81-7 EC No 204-211-0 (b) Dibutyl phthalate (DBP) CAS No 84-74-2 EC No 201-557-4 (c) Benzyl butyl phthalate (BBP) CAS No 85-68-7 EC No 201-622-7	1. Shall not be used as substances or in mixtures, in concentrations greater than 0,1 % by weight of the plasticised material, in toys and childcare articles. 2. Toys and childcare articles containing these phthalates in a concentration greater than 0,1 % by weight of the plasticised material shall not be placed on the market. 4. For the purpose of this entry ‘childcare article’ shall mean any product intended to facilitate sleep, relaxation, hygiene, the feeding of children or sucking on the part of children.
62. (a) Phenylmercury acetate EC No: 200-532-5 CAS No: 62-38-4 (b) Phenylmercury propionate EC No: 203-094-3	1. Shall not be manufactured, placed on the market or used as substances or in mixtures after 10 October 2017 if the concentration of mercury in the mixtures is equal to or greater than 0,01 % by weight. 2. Articles or any parts thereof containing one or more of these substances shall not be placed on the market after 10 October 2017 if the concentration of mercury in the articles or any part thereof is equal to or greater than 0,01 % by weight.

Designation of the substance, group of substances, or mixture	**Conditions of restriction**
CAS No: 103-27-5 (c) Phenylmercury 2-ethylhexanoate EC No: 236-326-7 CAS No: 13302-00-6 (d) Phenylmercury octanoate EC No: - CAS No: 13864-38-5 (e) Phenylmercury neodecanoate EC No: 247-783-7 CAS No: 26545-49-3	
63. Lead CAS No 7439-92-1 EC No 231-100-4 and its compounds	1. Shall not be placed on the market or used in any individual part of jewellery articles if the concentration of lead (expressed as metal) in such a part is equal to or greater than 0,05 % by weight. 2. For the purposes of paragraph 1: (i) 'jewellery articles' shall include jewellery and imitation jewellery articles and hair accessories, including: (a) bracelets, necklaces and rings; (b) piercing jewellery; (c) wrist watches and wrist-wear; (d) brooches and cufflinks; (ii) 'any individual part' shall include the materials from which the jewellery is made, as well as the individual components of the jewellery articles. 3. Paragraph 1 shall also apply to individual parts when placed on the market or used for jewellery-making. 4. By way of derogation, paragraph 1 shall not apply to: (a) crystal glass as defined in Annex I (categories 1, 2, 3 and 4) to Council Directive 69/493/EEC (*); (b) internal components of watch timepieces inaccessible to consumers; (c) non-synthetic or reconstructed precious and semiprecious stones (CN code 7103, as established by Regulation (EEC) No 2658/87), unless they have been treated with lead or its compounds or mixtures containing these substances; (d) enamels, defined as vitrifiable mixtures resulting from the fusion, vitrification or sintering of minerals melted at a temperature of at least 500 °C.

Designation of the substance, group of substances, or mixture	Conditions of restriction
	5. By way of derogation, paragraph 1 shall not apply to jewellery articles placed on the market for the first time before 9 October 2013 and jewellery articles articles produced before 10 December 1961. 6. By 9 October 2017, the Commission shall re-evaluate paragraphs 1 to 5 of this entry in the light of new scientific information, including the availability of alternatives and the migration of lead from the articles referred to in paragraph 1 and, if appropriate, modify this entry accordingly. 7. Shall not be placed on the market or used in articles supplied to the general public, if the concentration of lead (expressed as metal) in those articles or accessible parts thereof is equal to or greater than 0,05 % by weight, and those articles or accessible parts thereof may, during normal or reasonably foreseeable conditions of use, be placed in the mouth by children. That limit shall not apply where it can be demonstrated that the rate of lead release from such an article or any such accessible part of an article, whether coated or uncoated, does not exceed 0,05 µg/cm 2 per hour (equivalent to 0,05 µg/g/h), and, for coated articles, that the coating is sufficient to ensure that this release rate is not exceeded for a period of at least two years of normal or reasonably foreseeable conditions of use of the article. For the purposes of this paragraph, it is considered that an article or accessible part of an article may be placed in the mouth by children if it is smaller than 5 cm in one dimension or has a detachable or protruding part of that size. 8. By way of derogation, paragraph 7 shall not apply to: (a) jewellery articles covered by paragraph 1; (b) crystal glass as defined in Annex I (categories 1, 2, 3 and 4) to Directive 69/493/ EEC; (c) non-synthetic or reconstructed precious and semi-precious stones (CN code 7103 as established by Regulation (EEC) No 2658/ 87) unless they have been treated with lead or its compounds or mixtures containing these substances; (d) enamels, defined as vitrifiable mixtures resulting from the fusion, vitrification or sintering of mineral melted at a temperature of at least 500 ° C; (e) keys and locks, including padlocks; (f) musical instruments; (g) articles and parts of articles comprising brass alloys, if the concentration of lead (expressed as metal) in the brass alloy does not exceed 0,5 % by weight; (h) the tips of writing instruments; (i) religious articles; (j) portable zinc-carbon batteries and button cell batteries; (k) articles within the scope of: (i) Directive 94/62/EC; (ii) Regulation (EC) No 1935/2004; (iii) Directive 2009/48/EC of the European Parliament and of the Council (**); (iv) Directive 2011/65/EU of the European Parliament and of the Council (***)

Designation of the substance, group of substances, or mixture	Conditions of restriction
	9. By 1 July 2019, the Commission shall re-evaluate paragraphs 7 and 8(e), (f), (i) and (j) of this entry in the light of new scientific information, including the availability of alternatives and the migration of lead from the articles referred to in paragraph 7, including the requirement on coating integrity, and, if appropriate, modify this entry accordingly. 10. By way of derogation paragraph 7 shall not apply to articles placed on the market for the first time before 1 June 2016. --- (*) OJ L 326, 29.12.1969, p. 36. (**) Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys (OJ L 170, 30.6.2009, p. 1). (***) Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (OJ L 174, 1.7.2011, p. 88).
67. Bis(pentabromophenyl)ether (decabromodiphenyl ether; decaBDE) CAS No 1163-19-5 EC No 214-604-9	1. Shall not be manufactured or placed on the market as a substance on its own after 2 March 2019. 2. Shall not be used in the production of, or placed on the market in: (a) another substance, as a constituent; (b) a mixture; (c) an article, or any part thereof, in a concentration equal to or greater than 0,1 % by weight, after 2 March 2019. 3. Paragraphs 1 and 2 shall not apply to a substance, constituent of another substance or mixture that is to be used, or is used: (a) in the production of an aircraft before 2 March 2027. (b) in the production of spare parts for either of the following: (i) an aircraft produced before 2 March 2027; (ii) motor vehicles within the scope of Directive 2007/46/EC, agricultural and forestry vehicles within the scope of Regulation (EU) No 167/2013 of the European Parliament and of the Council (*) or machinery within the scope of Directive 2006/42/EC of the European Parliament and of the Council (**), produced before 2 March 2019 4. Subparagraph 2(c) shall not apply to any of the following: (a) articles placed on the market before 2 March 2019; (b) aircraft produced in accordance with subparagraph 3(a); (c) spare parts of aircraft, vehicles or machines produced in accordance with subparagraph 3(b); (d) electrical and electronic equipment within the scope of Directive 2011/65/EU.

Designation of the substance, group of substances, or mixture	Conditions of restriction
	5. For the purposes of this entry 'aircraft' means one of the following: (a) a civil aircraft produced in accordance with a type certificate issued under Regulation (EU) No 216/2008 of the European Parliament and of the Council (***) or with a design approval issued under the national regulations of a contracting State of the International Civil Aviation Organisation (ICAO), or for which a certificate of airworthiness has been issued by an ICAO contracting State under Annex 8 to the Convention on International Civil Aviation; (b) a military aircraft. (*) Regulation (EU) No 167/2013 of the European Parliament and of the Council of 5 February 2013 on the approval and market surveillance of agricultural and forestry vehicles (OL L 60, 2.3.2013, p. 1). (**) Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery, and amending Directive 95/16/EC (OJ L 157, 9.6.2006, p. 24). (***) Regulation (EC) No 216/2008 of the European Parliament and of the Council of 20 February 2008 on common rules in the field of civil aviation and establishing a European Aviation Safety Agency, and repealing Council Directive 91/670/EEC, Regulation (EC) No 1592/2002 and Directive 2004/36/EC (OJ L 79 19.3.2008, p. 1).
72. The substances listed in column 1of the Table in Appendix 12. Appendix 12lists among others: Cadmium and its compounds; Chromium VI compounds; Lead and its compounds; Bis(2-methoxyethyl) phthalate; Diisopentylphthalate;	1. Shall not be placed on the market after 1 November 2020 in any of the following: (a) clothing or related accessories; (b) textiles other than clothing which, under normal or reasonably foreseeable conditions of use, come into contact with human skin to an extent similar to clothing; (c) footwear; if the clothing, related accessory, textile other than clothing or footwear is for use by consumers and the substance is present in a concentration, measured in homogeneous material, equal to or greater than that specified for that substance in Appendix 12. 2. By way of derogation, in relation to the placing on the market of formaldehyde [CAS No 50-00-0] in jackets, coats or upholstery, the relevant concentration for the purposes of paragraph 1 shall be 300 mg/kg during the period between 1 November 2020 and 1 November 2023. The concentration specified in Appendix 12 shall apply thereafter. 3. Paragraph 1 shall not apply to: (a) clothing, related accessories or footwear, or parts of clothing, related accessories or footwear, made exclusively of natural leather, fur or hide; (b) non-textile fasteners and non-textile decorative attachments; (c) second-hand clothing, related accessories, textiles other than clothing or footwear (d) wall-to-wall carpets and textile floor coverings for indoor use, rugs and runners.

Designation of the substance, group of substances, or mixture	Conditions of restriction
	4. Paragraph 1 shall not apply to clothing, related accessories, textiles other than clothing, or footwear within the scope of Regulation (EU) 2016/425 of the European Parliament and of the Council[1] or Regulation (EU) 2017/745 of the European Parliament and of the Council. 5. Paragraph 1(b) shall not apply to disposable textiles. 'Disposable textiles' means textiles that are designed to be used only once or for a limited time and are not intended for subsequent use for the same or a similar purpose. 6. Paragraphs 1 and 2 shall apply without prejudice to the application of any stricter restrictions set out in this Annex or in other applicable Union legislation. 7. The Commission shall review the exemption in paragraph 3(d) and, if appropriate, modify that point accordingly.

As of May 2020, the REACH Regulation Candidate list includes various substances of relevance for RoHS. Proceedings concerning the addition of these substances to the Authorisation list (Annex XIV) have begun and shall be followed by the evaluation team to determine possible discrepancies with future requests of exemption from RoHS (new exemptions, renewals and revocations).

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