

**Update of the Opinion
of the
SCIENTIFIC STEERING COMMITTEE
on the
Geographical Risk of
Bovine Spongiform Encephalopathy
(GBR)**

adopted on 11 January 2002

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**KEYWORDS: BSE, GBR (GEOGRAPHICAL BSE RISK), RISK ASSESSMENT
METHODOLOGY AND PROCESS, ORIGIN OF BSE, TRANSMISSION OF BSE**

1. INTRODUCTION

The Geographical BSE-Risk (GBR) is a qualitative indicator of the likelihood of the presence of one or more cattle being infected with BSE (Bovine Spongiforme Encephalopathy), pre-clinically as well as clinically, at a given point in time, in a country. Where its presence is confirmed, the GBR gives an indication of the level of infection.

GBR level	Presence of one or more cattle clinically or pre-clinically infected with the BSE agent in a geographical region/country
I	Highly unlikely
II	Unlikely but not excluded
III	Likely but not confirmed or confirmed, at a lower level
IV	Confirmed, at a higher level

Table 1 - Definition of GBR and its levels

The final opinion of July 2000 describes a transparent methodology that the Scientific Steering Committee (SSC) has developed, over about two years, to assess the GBR for any country that provides the information required for the assessment. This methodology is limited to bovines and feed based transmission of BSE. It does not take into account any other initial sources of BSE than the import of infected cattle or contaminated feed. It is assumed that the disease first appeared in the UK from a still unknown initial source. An important characteristic of the methodology is that it does not depend on the confirmed incidence of clinical BSE, which is sometimes difficult to assess due to serious intrinsic limitations of surveillance¹ systems.

The qualitative nature of this methodology and its limitations should be understood in the context of present scientific knowledge on BSE and of the availability and quality of data. As they both evolve, and with the advancement of new diagnostic methods, the need may arise for the methodology to be revised and/or its application to particular countries to be repeated.

The present update of the opinion follows from this statement.

¹ Surveillance should be understood as the process of identifying BSE-cases and animals at risk of being infected.

2. THE GEOGRAPHICAL BSE-RISK (GBR)

2.1 NEW SCIENTIFIC KNOWLEDGE AND DATA

Germany, Italy, Spain, and the Czech Republic and the Slovak Republic all were classified as GBR III before they detected their first case. The GBR-assessment for Denmark was already in an advanced stage, pointing to GBR III, when the first case was confirmed. In addition Japan and Greece have now confirmed first domestic BSE-cases. Also Austria, Finland and Slovenia, all three in GBR-II, recently detected a first domestic case of BSE. In all cases active² surveillance detected BSE-cases that would have remained undetected by the already existing, passive³ surveillance, which was targeted at animals with neurological symptoms.

2.2 METHODOLOGY FOR ASSESSING THE GBR

The methodology of the GBR-assessment, and the model and assumptions it is based on, remains unchanged. Consistency of the past and future assessments is therefore ensured, but the assessment of the external challenge is refined and the process is streamlined.

Basically the GBR – methodology tries to answer two questions:

1. Is there a risk that the BSE-agent was imported into the country under consideration?
2. If the BSE-agent was introduced into a country, would it have been recycled and amplified or was the BSE/cattle system of that country able to eliminate the agent?

2.21 Basic assumptions

Origin and transmission of BSE⁴: The assessment of the GBR continues to be based on the assumption that BSE arose in the United Kingdom (UK) and was propagated through the recycling of bovine tissues into animal feed. Later the export of infected animals and infected feed provided the means for the spread of the BSE-agent to other countries where it was again recycled and propagated via the feed chain.

For all countries other than the UK, import of contaminated feed or infected animals is the only possible initial source of BSE that is taken into account. Other sources such as a spontaneous occurrence of BSE at very low frequency, or the transformation into BSE of other (animal) TSEs (scrapie, CWD, TME, FSE⁵) being present in, or imported into a country are not considered, as they are not scientifically confirmed. In addition surveillance data on other TSEs are generally inadequate for assessing their prevalence.

The only transmission vector considered in the model continues to be feed. Blood, semen and embryos/ova⁶ are not seen as effective transmission vectors⁷ and accordingly, blood-meal or embryos/ova and semen are not taken into account. The recent results of large

² Active surveillance = testing of cattle that are not notified as BSE-suspects but belong to risk sub-populations.

³ Passive surveillance = surveillance of notified BSE-suspects, i.e. cattle that are notified because of clinical signs compatible with BSE.

⁴ See also Opinion of the SSC on the origin and transmission of BSE, 28/29 November 2001

⁵ TSE=Transmissible Spongiform Encephalopathy; CWD=Chronic Wasting Disease; TME=Transmissible Mink Encephalopathy; FSE=Feline Spongiform Encephalopathy

⁶ See declaration of the IETS (International Embryo Transfer Society) on bovine embryos and BSE that a trial involving embryos collected from BSE infected cattle strongly indicates that transmission of BSE by embryos does not occur. OIE website: www.oie.int

⁷ See SSC-opinion on vertical transmission, 19/03/1999 and on the safety of ruminant blood (14/04/2000)

scale BSE-testing in combination with reports on feed controls have further underpinned the opinion of the SSC that any cross contamination of cattle feed with mammalian MBM, even well below 0.5%, represents a risk of transmitting the disease⁸. However, the influence of potential cross-contamination on the GBR has to be seen in the light of the risk that the animal protein under consideration could carry BSE-infectivity.

Other transmission routes than feed are debated but they are not scientifically confirmed and anyway their potential impact on the GBR is regarded negligible in comparison to contaminated feed. This includes vertical transmission as well as any unknown third mode of transmission of BSE. Also transmission via the environment or the possibility that sheep and goats may have become infected with BSE⁹ and could be a source of BSE are not scientifically confirmed. They will be taken into account once scientific evidence of their existence is available allowing assessing their impact on the GBR.

Geographical limitation: So far the present GBR risk assessments are only addressing entire countries and national herds. This is because of the limited availability of detailed, regionalised data. The SSC does not discount the issue of regional differences, for example in the types of animal husbandry, e.g. dairy or beef, or with regard to feeding or to slaughtering ages. If complete data sets could be provided on a regional scale, i.e. clearly relating to a defined geographical area smaller than a country, these could be assessed in the same way as data referring to entire countries.

2.23 Refining the external challenge assessment

The term “**external challenge**” is referring to both the likelihood and the amount of the BSE agent entering into a defined geographical area in a given time period through infected cattle¹⁰ or MBM (SSC, 07/07/2000).

The following basic guidelines for assessing the external challenge that were defined in the GBR-opinion of July 2000 remain valid:

1. The external challenge is regarded independent from the size of the challenged BSE/cattle system and in particular the size and structure of the cattle population.
2. The assumed challenge resulting from imports from the UK during the peak of the BSE-epidemic in the UK is the point of reference.
3. The challenge resulting from imports during other periods and from other BSE-affected countries is established in relation to this baseline.

Therefore, the figures given in table 2 below and the explanations given in the GBR-opinion of July 2000 remain valid.

In the light of the new scientific knowledge and data described above under point 2.1, it is necessary when assessing the external challenge to take account of imports from all countries with a BSE risk. This includes all countries with one or more confirmed domestic cases or being classified in GBR III while not having identified any domestic cases.

⁸ In its opinion on cross-contamination of 25/09/1998, the SSC already expressed this position.

⁹ See SSC opinion on the risk of infection of sheep and goats with BSE, 24/25 September 1998 and 18.10.2001

¹⁰ Import via other TSE-susceptible species is not taken into account.

EXTERNAL CHALLENGE	Cattle (n° of heads) imports		MBM ¹ (tons) imports	
	1988 - 93 from UK	UK-imports before 88 and 94-97: * 10; after 97: * 100 Imports from other countries with a BSE risk: R1*1000, R2* 100	1986 - 90 from UK	UK-imports before 86 & 91-93: * 10, after 93 * 100 Imports from other countries with a BSE-risk: R1*100, R2* 10
Extremely High	≥10.000		≥10.000	
Very High	1.000 - < 10.000		1.000 - < 10.000	
High	100 - < 1.000		100 - < 1.000	
Moderate	20 - < 100		20 - < 100	
Low	10 - < 20		10 - < 20	
Very low	5 - < 10		5 - < 10	
Negligible	0 - < 5		0 - < 5	

¹ “MBM” refers to MBM, MMBM, BM, or Greaves but not to composite feed that could contain it.

Table 2: Definition of BSE-challenge levels

From the GBR assessments so far available it can be seen that the first occurrence of an internal challenge is rather variable. Therefore in all cases where this information is available, only exports after a first internal challenge could possibly have been present in the exporting country shall be regarded as an external challenge to importing countries.

Country Name	GBR	R1	R2
Albania	III	No data	1988
Austria	III ⁶	1988	1990
Belgium	III	1983	1987
Cyprus	III	1980	1990
Czech Republic	III	No data	1988 ¹
Denmark	III	1985	1990
Estonia	III	1987 ²	1988 ²
Finland	III ⁶	1980	1990
France	III	1979	1980
Germany	III	1980 ³	1988 ³
Hungary	III	1981	1982
Ireland (Eire)	III	1980	1980
Italy	III	1983	1990
Lithuania	III	No data	1994 ²
Luxembourg	III	1983	1987
Netherlands	III	1985	1987
Poland	III	1980	1987
Portugal	IV	1979	1987
Romania	III	No data	1981
Slovak Republic	III	No data	1988 ¹
Slovenia	III ⁶	1981 ⁴	1991 ⁴
Spain	III	1985	1987
Switzerland	III	1979	1980
Greece ⁵	III	1985 ⁵	1990 ⁵
Japan ⁵	III	1985 ⁵	1990 ⁵

Table 3: Countries in GBR III and IV and the year since when it is regarded possible (R1) or likely (R2) that exports of life bovine or MBM could have represented an external challenge to the importing country. UK is not listed in this table as it is used as reference case and already addressed in table 2. ¹Part of CSSR, ²part of Soviet Union, ³only FRG – incl. GDR only after 1988, ⁴former Republic of Yugoslavia, ⁵pending a GBR assessment the dates for R1 and R2 are preliminary estimates, ⁶Austria, Finland and Slovenia were earlier classified as GBR II but due to confirmed presence of one or more cattle clinically or pre-clinically infected with the BSE agent they now fall into GBR III. A revision of their GBR-reports is ongoing.

Table 3 provides for each of the already assessed countries, and Greece and Japan, the year since when it is regarded possible (R1) or likely (R2) that exports represented an external

challenge to the importing country. To assess the level of this external challenge the following factors shall be used when working with table 1:

R1 = factor 1000 for live cattle and factor 100 for MBM

R2 = factor 100 for live cattle and factor 10 for MBM.

The dates in the table were derived from the available GBR-reports and relate to the time when an internal challenge became possible (R1) or likely (R2) in the respective country. The factors are the same as previously used, only for the periods R1 another order of magnitude was added to reflect the lower but not negligible risk.

Greece and Japan are countries with confirmed BSE. Pending the outcome of the ongoing GBR-assessment it is assumed that Greece and Japan posed a potential risk (R2) since 1990, i.e. about two incubation periods before the confirmation of the first case. It is also assumed that a lower risk existed already one incubation period before (R1 for the period from 1985-1989).

2.24 Other Updates

2.241 Editorial improvement of the GBR reports and opinions

Presenting certain data in form of overview tables has amended the clarity of the GBR-reports and opinions. The SSC will adopt this presentation also for updates of GBR-assessments, should these be eventually necessary. An overview table is provided in annex, indicating for 51 countries their GBR-classification and the date when this classification was adopted by the SSC.

2.242 Refinement of the process

Since the GBR-opinion of July 2000 the process of establishing a GBR-opinion was streamlined.

The secretariat of the SSC is now in charge to carry out the first analysis of the data provided by the countries under assessment. This analysis is then scrutinised by a small group of independent external experts, the GBR-Peer Group, who guarantees that the guidelines of the SSC are respected. The particular responsibility of the GBR-Peer Group lies on the conclusions drawn from the data provided by the country in question. This group also suggests up-dates of the SSC-guidelines, as necessary. The members of the GBR-Peer Group are selected by the SSC.

Once the GBR-Peer Group has collectively agreed to a first draft report, the country in question receives a copy with an invitation to comment. Normally it is also invited to provide additional information to replace those reasonable worst case assumptions that were necessary for the first draft report.

The response of the country is then analysed by the SSC secretariat and the resulting draft final report is reviewed and finalised by the GBR-Peer Group. Once the group is satisfied, the draft final report is sent to the country, for final comments, and to the TSE/BSE ad-hoc group for review and subsequent transmission to the SSC for adoption.

At the next possible plenary meeting of the SSC, those draft final reports and opinions are put on the agenda that were accepted by the TSE/BSE ad-hoc group. If new information from the assessed country is received prior to the SSC meeting, this information will be taken into account by the SSC when adopting its opinion on the GBR of the country in question. If necessary the report on the GBR will be amended accordingly before it appears, together with the opinion, on the Internet. If the additional/new information requires substantially changing the assessment, the SSC would send the file back to the GBR-Peer Group who would re-draft the final report.

While the Commission provides significant input into the processing of the information provided by the assessed countries, the SSC confirms that the responsibility for and control of the GBR-assessment remains with a number of independent external scientists and finally with the SSC.

2.3 THE NEED TO REGULARLY UPDATE GBR-ASSESSMENTS

Already in its opinion in July 2000 the SSC has stated that from new scientific knowledge and data a need might arise to update the GBR-methodology and to re-apply this to countries that are already assessed. The BSE-cases, recently confirmed in Austria, Finland and Slovenia that were classified as GBR II, underlines the appropriateness of this statement. One of the possible explanations for these cases could be that imports into these countries from GBR-III countries were not regarded as external challenge when the GBR of these countries was assessed.

It is therefore appropriate to verify for all countries, classified so far as GBR I or II, if external challenges can now be identified that were not previously been taken into account in the GBR assessment. If necessary the GBR-report/opinion should be updated.

2.31 Updates of GBR-level

From the definition of the GBR-levels (see table 1), it follows that Greece and Japan (not yet assessed); Austria, Finland and Slovenia (previously assessed as GBR-II) now fall under GBR-III because they have confirmed at least one domestic case. However, a revision of the GBR-reports for Austria, Finland and Slovenia will be carried out and for Greece and Japan GBR-assessments are ongoing. Pending the outcome of their revision, a reference to this update should be added to the reports and opinions for Austria, Finland and Slovenia on the Internet.

3. CONCLUSION

In its opinion of July 2000 the SSC stated that “it is expected that the presented framework of analysis would need to be revised if novel findings emerge, i.e. the opinion is dynamic in process as more scientific evidence will be available. These may relate to the source of BSE, to the diagnosis and transmissibility of BSE or to the infective dose for man. It can also be expected that novel developments in surveillance and management techniques or new tests to assess the prevalence of sub-clinical BSE conducted in a country may also precipitate the need for a selective re-assessment of a particular GBR”. This update of the opinion takes account of this statement and it informs, in the spirit of transparency, on the evolution of the process and the adaptation of the external challenge assessment to new data that became available. All aspects addressed in the GBR-opinion of July 2000 that are not mentioned in this update remain unchanged.

ANNEX: OVERVIEW TABLE OF ALL COUNTRIES WITH A GBR CLASSIFICATION

N°	Country	Dossier in	GBR	Year of adoption
1	Albania	19/10/00	III	2001
2	Argentina	1/03/99	I	2000
3	Australia	1/03/99	I	2000
4	Austria	1/10/98	II > III (case, revision pending)	2000
5	Belgium	1/10/98	III	2000
6	Botswana	31/10/00	I	2001
7	Brazil	17/09/00	I	2001
8	Canada	1/03/99	II	2000
9	Chile	1/03/99	I	2000
10	Colombia	13/11/00	II	2001
11	Costa Rica	21/03/01	I	2001
12	Cyprus	3/11/00	III	2001
13	Czech Republic	1/03/00	III	2001
14	Denmark	1/12/98	III	2000
15	El Salvador	8/11/00	I	2001
16	Estonia	7/11/00	III	2001
17	Finland	1/12/98	II > III (case, revision pending)	2000
18	France	1/12/1998	III	2000
19	Germany	1/11/98	III	2000
20	Greece	1/8/01	III (case, assessment pending)	2002
21	Hungary	3/11/00	III	2001
22	India	1/06/99	II	2001
23	Ireland (Rep.)	1/1/99	III	2000
24	Italy	1/3/99	III	2000
25	Japan	1/11/99	III (cases, assessment pending)	2002
26	Kenya	29/11/00	II	2001
27	Lithuania	31/10/00	III	2001
28	Luxembourg	1/1/99	III	2000
29	Mauritius	20/11/00	II	2001
30	Namibia	3/11/00	I	2001
31	Netherlands	1/2/99	III	2000
32	New Zealand	1/12/98	I	2000
33	Nicaragua	30/10/00	I	2001
34	Nigeria	31/10/00	II	2001
35	Norway	1/12/98	I	2000
36	Pakistan	1/07/00	II	2001
37	Panama	17/04/01	I	2001
38	Paraguay	1/03/99	I	2000
39	Poland	3/11/00	III	2001
40	Portugal (mainland)	3/3/99	IV	2000
41	Romania	1/03/01	III	2001
42	Singapore	17/11/00	I	2001
43	Slovak Republic	3/11/00	III	2001
44	Slovenia	21/02/01	II > III (case, revision pending)	2001
45	Spain	1/4/99	III	2000
46	Swaziland	24/11/00	I	2001
47	Sweden	1/12/98	II	2000
48	Switzerland	1/03/99	III	2000
49	United Kingdom	1/10/98	IV	2000
50	Uruguay	1/07/00	I	2000

51	USA	1/12/98	II	2000
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