

The Updated Exposure Assessment for Acrylamide

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Uncertainties, and Research Strategies, April 13, 2004



History and Background

- Sweden – April 2002
 - Estimated Mean Exposure to Acrylamide
 - 40 $\mu\text{g}/\text{person}/\text{day}$ (0.67 $\mu\text{g}/\text{kgbw}/\text{day}$, 60 kg bw/person)
 - Very limited data, included “expected” value for food groups not covered in their sampling
- FAO/WHO – June 2002
 - “Long-Term” Exposure Estimates
 - 0.3 - 0.8 $\mu\text{g}/\text{kgbw}/\text{day}$



US/FDA Estimates

- Proposed model presented at Food Advisory Subcommittee meeting, Dec. 2002
- First estimates presented to full Food Advisory Committee, Feb. 2003
 - Updates to be prepared as additional residue data collected according to draft Action Plan



Simplified Exposure Equation

$$EDI_x = \sum_{f=1}^F \frac{Freq_f \cdot Port_f \cdot Conc_{xf}}{N}$$

EDI_x = The Estimated Daily Intake of Substance x

F = Total no. of foods in which x can be found

$Freq_f$ = No. of eating occasions for food f over N survey days

$Port_f$ = Average portion size for food f

$Conc_{xf}$ = Concentration of the substance x in the food f

N = No. of survey days

Exposures for Individuals Combined



Probabilistic Modeling

- Distributions Used in Place of Point Estimates
- Food Consumption
 - Typically Lognormal
- Concentration Data
 - Determined Experimentally
- Number of Consumers
 - Food Surveys



Probabilistic Modeling

- Iterative Process
- Computer Generated
- Each Iteration Contains Values for Food Consumption, AA level, and Percentage of Eaters Chosen from their Underlying Distributions



Acrylamide Intake Modeling

$$\text{AA Intake} = (\text{Eaters}_{(\text{yes or no})}) \times (\text{Food Amt.}) \times (\text{AA Level})$$

Eaters_(yes or no) – Either 0 or 1 in Proportion to Percent Eaters

Food Amount – Food Consumption Value from Survey Data

Acrylamide Level – Value from Laboratory Data –
Each Value Equally Likely on Each Iteration

Results are Summed over Foods and Individuals



Acrylamide Intake Modeling

- Each Iteration is a Virtual Consumer
- 25,000 Iterations
- No Accounting for Correlations Between Food Choices
- Truncation of Distributions Removes Irrationally High Values
 - 13 L of Coffee Per Day – 100th Percentile



Food Consumption Surveys

- CSFII Surveys
 - 1989-92 (3-day) and 1994-6, 8 (2-day)
- MRCA Survey
 - 1982-1988 (14-day frequency survey)



Laboratory Data

- Primary Limitation in Model
- Some Food Types Represented by Fewer than Five Samples
 - TDS foods have either 2 or 4 samples
- Variability in AA Levels
 - Consistency Within Brand or Restaurant
 - Brand-to-Brand
 - Foods Prepared at Home



Factors Applied to Food AA Concentration

- Coffee as Consumed x 24 = Ground Coffee (Experimentally Derived)
- Instant Coffee as Consumed x 60 = Instant Coffee Crystals (3g Coffee/6oz Cup)
- Soup as Consumed x 12 = Dry Soup Mix (15g Soup Mix/6 oz Cup)
- Cocoa as Consumed x 10 = Dry Cocoa Powder (17g Cocoa Powder/6oz Cup)



Results – Feb. 2003

Survey used	Age Group	Exposure (mean)	90 th %ile
MRCA	2+ years	0.48 µg/kgbw-day	0.91
CSFII (3-day)	2+ years	0.32	0.66
CSFII (2-day)	2+ years	0.37	0.81
MRCA	2-5 year olds	1.26	2.33
CSFII (3-day)	2-5 year olds	0.78	1.63
CSFII (2-day)	2-5 year olds	1.00	2.15



2004 Update

- Additional Residue data published on FDA Website, Mar. 2004
 - 48 additional samples collected during 2003
 - Noteworthy additions: canned black olives, prune juice, Postum
- Total Diet Study data published Mar. 2004
 - 286 foods in 4 market baskets
 - 750 data points added to model



Top 20 Foods by Mean Acrylamide Intake

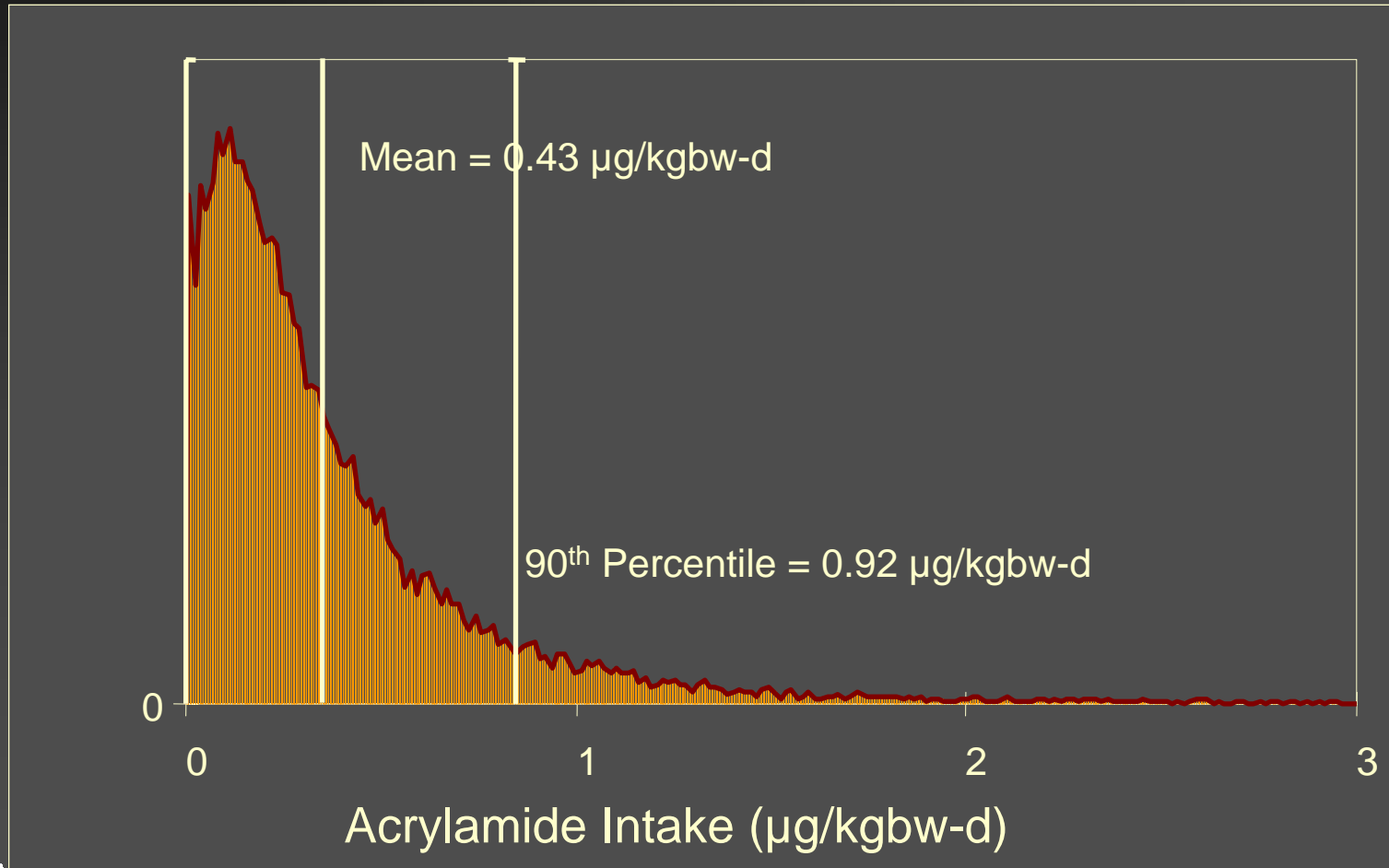
Food	Mean AA intake ($\mu\text{g}/\text{kgbw}\text{-day}$)	Cumulative Percentile
French Fries (RF)	0.058	0.13
French Fries (OB)	0.051	0.25
Breakfast Cereal	0.043	0.35
Potato Chips	0.041	0.45
Cookies	0.036	0.53
Brewed Coffee	0.029	0.60
Toast	0.023	0.66
Pies and Cakes	0.020	0.70
Soft Bread	0.019	0.75
Chile con Carne	0.015	0.78

Food	Mean AA intake ($\mu\text{g}/\text{kgbw}\text{-day}$)	Cumulative Percentile
Corn Snacks	0.011	0.81
Crackers	0.011	0.83
Pizza	0.007	0.85
Pretzels	0.007	0.87
Popcorn	0.007	0.88
Canned Black Olives	0.005	0.89
Peanut Butter	0.004	0.90
Bagels	0.004	0.91
Soup Mix	0.003	0.92
Breaded Chicken	0.003	0.93



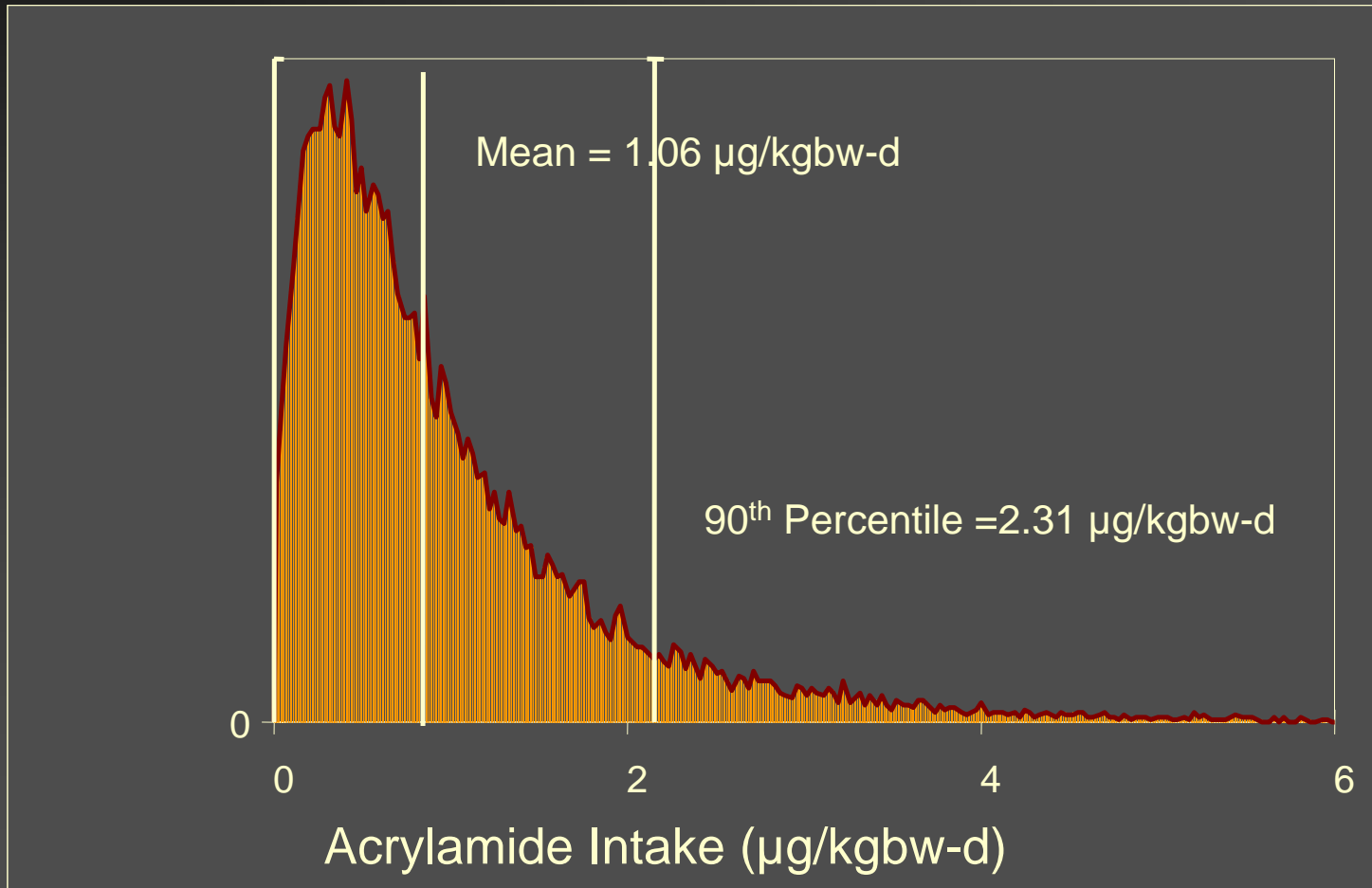
Acrylamide Intake Distribution

CFSII 1994-96, 1998; 2+ Population



Acrylamide Intake Distribution

CFSII 1994-96, 1998; 2-5 Population



Top Eight Foods by Acrylamide Per Portion

Food	AA Conc ($\mu\text{g}/\text{kg}$)	Portion Size (g)*	AA (μg) Portion
Breakfast Cereal	131.0	55	7.3
Brewed Coffee	8.5	240	3.2
Postum	93	240	22.3
French Fries (RF)	333.7	70	23.3
French Fries (OB)	697.8	70	48.8
Potato Chips	545.9	30	16.4
Canned Black Olives	550	15	8.2
Prune Juice	174	140	24.4

* Portion Sizes From 21 CFR 101.12, Table 2



What-If Scenarios

CSFII, 1994-96, 98, 2+ Population

- Mean=0.43 $\mu\text{g}/\text{kgbw-d}$, 90th=0.92 $\mu\text{g}/\text{kgbw-d}$
- Remove AA from French Fries
 - Mean – 0.37 $\mu\text{g}/\text{kgbw-d}$; 90th Percentile – 0.78 $\mu\text{g}/\text{kgbw-d}$
- Remove AA from Snack Foods
 - Mean – 0.38 $\mu\text{g}/\text{kgbw-d}$; 90th Percentile – 0.85 $\mu\text{g}/\text{kgbw-d}$
- Remove AA from Breakfast Cereal
 - Mean – 0.38 $\mu\text{g}/\text{kgbw-d}$; 90th Percentile – 0.84 $\mu\text{g}/\text{kgbw-d}$
- Remove AA from Coffee
 - Mean – 0.40 $\mu\text{g}/\text{kgbw-d}$; 90th Percentile – 0.88 $\mu\text{g}/\text{kgbw-d}$



Summary

- Original “crude” estimates, 2002
 - 0.7 $\mu\text{g}/\text{kg}\text{-bw}\text{-d}$
 - 0.3-0.8 $\mu\text{g}/\text{kg}\text{-bw}\text{-d}$
- First FDA model, 2003
 - 0.4 $\mu\text{g}/\text{kg}\text{-bw}\text{-d}$
- Updated FDA model, 2004
 - 0.4 $\mu\text{g}/\text{kg}\text{-bw}\text{-d}$

