The Updated Exposure Assessment for Acrylamide

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FDA/CFSAN

Acrylamide in Food: Update – Scientific Issues, Uncertainties, and Research Strategies, April 13, 2004
History and Background

- **Sweden – April 2002**
  - Estimated Mean Exposure to Acrylamide
    - 40 µg/person/day (0.67 µg/kgbw-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 µg/kgbw-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

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

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

AA Intake = (Eaters_{yes or no}) \times (Food Amt.) \times (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

<table>
<thead>
<tr>
<th>Survey used</th>
<th>Age Group</th>
<th>Exposure (mean)</th>
<th>90&lt;sup&gt;th&lt;/sup&gt; %ile</th>
</tr>
</thead>
<tbody>
<tr>
<td>MRCA</td>
<td>2+ years</td>
<td>0.48 µg/kgbw-day</td>
<td>0.91</td>
</tr>
<tr>
<td>CSFII (3-day)</td>
<td>2+ years</td>
<td>0.32</td>
<td>0.66</td>
</tr>
<tr>
<td>CSFII (2-day)</td>
<td>2+ years</td>
<td>0.37</td>
<td>0.81</td>
</tr>
<tr>
<td>MRCA</td>
<td>2-5 year olds</td>
<td>1.26</td>
<td>2.33</td>
</tr>
<tr>
<td>CSFII (3-day)</td>
<td>2-5 year olds</td>
<td>0.78</td>
<td>1.63</td>
</tr>
<tr>
<td>CSFII (2-day)</td>
<td>2-5 year olds</td>
<td>1.00</td>
<td>2.15</td>
</tr>
</tbody>
</table>
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

<table>
<thead>
<tr>
<th>Food</th>
<th>Mean AA intake (µg/kgbw-day)</th>
<th>Cumulative Percentile</th>
</tr>
</thead>
<tbody>
<tr>
<td>French Fries (RF)</td>
<td>0.058</td>
<td>0.13</td>
</tr>
<tr>
<td>French Fries (OB)</td>
<td>0.051</td>
<td>0.25</td>
</tr>
<tr>
<td>Breakfast Cereal</td>
<td>0.043</td>
<td>0.35</td>
</tr>
<tr>
<td>Potato Chips</td>
<td>0.041</td>
<td>0.45</td>
</tr>
<tr>
<td>Cookies</td>
<td>0.036</td>
<td>0.53</td>
</tr>
<tr>
<td>Brewed Coffee</td>
<td>0.029</td>
<td>0.60</td>
</tr>
<tr>
<td>Toast</td>
<td>0.023</td>
<td>0.66</td>
</tr>
<tr>
<td>Pies and Cakes</td>
<td>0.020</td>
<td>0.70</td>
</tr>
<tr>
<td>Soft Bread</td>
<td>0.019</td>
<td>0.75</td>
</tr>
<tr>
<td>Chile con Carne</td>
<td>0.015</td>
<td>0.78</td>
</tr>
<tr>
<td>Corn Snacks</td>
<td>0.011</td>
<td>0.81</td>
</tr>
<tr>
<td>Crackers</td>
<td>0.011</td>
<td>0.83</td>
</tr>
<tr>
<td>Pizza</td>
<td>0.007</td>
<td>0.85</td>
</tr>
<tr>
<td>Pretzels</td>
<td>0.007</td>
<td>0.87</td>
</tr>
<tr>
<td>Popcorn</td>
<td>0.007</td>
<td>0.88</td>
</tr>
<tr>
<td>Canned Black Olives</td>
<td>0.005</td>
<td>0.89</td>
</tr>
<tr>
<td>Peanut Butter</td>
<td>0.004</td>
<td>0.90</td>
</tr>
<tr>
<td>Bagels</td>
<td>0.004</td>
<td>0.91</td>
</tr>
<tr>
<td>Soup Mix</td>
<td>0.003</td>
<td>0.92</td>
</tr>
<tr>
<td>Breaded Chicken</td>
<td>0.003</td>
<td>0.93</td>
</tr>
</tbody>
</table>
Acrylamide Intake Distribution
CFSII 1994-96, 1998; 2+ Population

Mean = 0.43 µg/kgbw-d

90th Percentile = 0.92 µg/kgbw-d
Acrylamide Intake Distribution
CFSII 1994-96, 1998; 2-5 Population

Mean = 1.06 µg/kgbw-d

90th Percentile = 2.31 µg/kgbw-d
# Top Eight Foods by Acrylamide Per Portion

<table>
<thead>
<tr>
<th>Food</th>
<th>AA Conc (µg/kg)</th>
<th>Portion Size (g)*</th>
<th>AA (µg) Portion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Breakfast Cereal</td>
<td>131.0</td>
<td>55</td>
<td>7.3</td>
</tr>
<tr>
<td>Brewed Coffee</td>
<td>8.5</td>
<td>240</td>
<td>3.2</td>
</tr>
<tr>
<td>Postum</td>
<td>93</td>
<td>240</td>
<td>22.3</td>
</tr>
<tr>
<td>French Fries (RF)</td>
<td>333.7</td>
<td>70</td>
<td>23.3</td>
</tr>
<tr>
<td>French Fries (OB)</td>
<td>697.8</td>
<td>70</td>
<td>48.8</td>
</tr>
<tr>
<td>Potato Chips</td>
<td>545.9</td>
<td>30</td>
<td>16.4</td>
</tr>
<tr>
<td>Canned Black Olives</td>
<td>550</td>
<td>15</td>
<td>8.2</td>
</tr>
<tr>
<td>Prune Juice</td>
<td>174</td>
<td>140</td>
<td>24.4</td>
</tr>
</tbody>
</table>

* Portion Sizes From 21 CFR 101.12, Table 2
What-If Scenarios
CSFII, 1994-96, 98, 2+ Population

- Mean=0.43 µg/kgbw-d, 90th=0.92 µg/kgbw-d
- Remove AA from French Fries
  - Mean – 0.37 µg/kgbw-d; 90th Percentile – 0.78 µg/kgbw-d
- Remove AA from Snack Foods
  - Mean – 0.38 µg/kgbw-d; 90th Percentile – 0.85 µg/kgbw-d
- Remove AA from Breakfast Cereal
  - Mean – 0.38 µg/kgbw-d; 90th Percentile – 0.84 µg/kgbw-d
- Remove AA from Coffee
  - Mean – 0.40 µg/kgbw-d; 90th Percentile – 0.88 µg/kgbw-d
Summary

- Original “crude” estimates, 2002
  - 0.7 µg/kg-bw-d
  - 0.3-0.8 µg/kg-bw-d

- First FDA model, 2003
  - 0.4 µg/kg-bw-d

- Updated FDA model, 2004
  - 0.4 µg/kg-bw-d