FDA Activities on Acrylamide, Furan, and Perchlorate

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Acrylamide
Background on Acrylamide

- First report, Sweden, April 2002
- Neurotoxicant and potential human carcinogen
- Found in a wide range of foods, including dietary staples
- Formed through traditional cooking methods
- During food processing and at home
- From nutrients in food (asparagine and reducing sugars)
FDA Action Plan for Acrylamide in Food

- Specific action areas
  - Methodologies
  - Research on Formation
  - Measuring Exposure
  - Toxicology and Health Effects
  - Epidemiology
  - Risk Assessment
  - Meetings
  - Inform and Educate the Public

Acrylamide information page

http://www.cfsan.fda.gov/~lrd/pestadd.html#acrylamide
FDA Acrylamide Highlights

- Developed very sensitive LC/MS/MS method for measuring acrylamide in food and shared the method on the FDA website.
- Analyzed acrylamide levels in more than 2100 food samples, and shared results on FDA website.
- Conducted exposure assessments that indicate how much acrylamide U.S. consumers are exposed to through the diet and what foods are the primary sources of exposure.
FDA Acrylamide Highlights

- Conducted research at NCFST on factors affecting formation of acrylamide in food and the effect of home cooking on acrylamide levels.
- Conducting a wide range of studies on acrylamide toxicology at NCTR, including a chronic carcinogenicity assay expected to be completed in 2007.
- Encouraged research, data sharing, and collaborative efforts at home and abroad.
- Reached out to consumers with public meetings on acrylamide, by posting information on the FDA web site, and by releasing a dietary message on acrylamide.
# Top 20 Foods by Mean Acrylamide Intake

<table>
<thead>
<tr>
<th>Food</th>
<th>Mean AA intake (µg/kg bw-day)</th>
<th>Cumulative Percentile</th>
</tr>
</thead>
<tbody>
<tr>
<td>French Fries (R)</td>
<td>0.070</td>
<td>0.16</td>
</tr>
<tr>
<td>French Fries (O)</td>
<td>0.051</td>
<td>0.27</td>
</tr>
<tr>
<td>Potato Chips</td>
<td>0.046</td>
<td>0.38</td>
</tr>
<tr>
<td>B. Cereal</td>
<td>0.041</td>
<td>0.47</td>
</tr>
<tr>
<td>Brewed Coffee</td>
<td>0.028</td>
<td>0.53</td>
</tr>
<tr>
<td>Cookies</td>
<td>0.026</td>
<td>0.59</td>
</tr>
<tr>
<td>Toast</td>
<td>0.023</td>
<td>0.65</td>
</tr>
<tr>
<td>Pies and Cakes</td>
<td>0.018</td>
<td>0.69</td>
</tr>
<tr>
<td>Crackers</td>
<td>0.017</td>
<td>0.73</td>
</tr>
<tr>
<td>Chili con Carne</td>
<td>0.016</td>
<td>0.76</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Food</th>
<th>Mean AA intake (µg/kg bw-day)</th>
<th>Cumulative Percentile</th>
</tr>
</thead>
<tbody>
<tr>
<td>Soft Bread</td>
<td>0.015</td>
<td>0.80</td>
</tr>
<tr>
<td>Corn Snacks</td>
<td>0.011</td>
<td>0.82</td>
</tr>
<tr>
<td>Popcorn</td>
<td>0.008</td>
<td>0.84</td>
</tr>
<tr>
<td>Pretzels</td>
<td>0.006</td>
<td>0.85</td>
</tr>
<tr>
<td>Pizza</td>
<td>0.008</td>
<td>0.87</td>
</tr>
<tr>
<td>Burritos</td>
<td>0.005</td>
<td>0.88</td>
</tr>
<tr>
<td>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>0.003</td>
<td>0.91</td>
</tr>
<tr>
<td>Soup Mix</td>
<td>0.003</td>
<td>0.92</td>
</tr>
</tbody>
</table>
# 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>Brewed Coffee</td>
<td>8.0</td>
<td>240</td>
<td>1.9</td>
</tr>
<tr>
<td>Breakfast Cereal</td>
<td>124.6</td>
<td>55</td>
<td>6.9</td>
</tr>
<tr>
<td>Canned Black Olives</td>
<td>498.5</td>
<td>15</td>
<td>7.5</td>
</tr>
<tr>
<td>Potato Chips</td>
<td>608.1</td>
<td>30</td>
<td>20.4</td>
</tr>
<tr>
<td>Postum</td>
<td>93</td>
<td>240</td>
<td>22.3</td>
</tr>
<tr>
<td>French Fries (RF)</td>
<td>401</td>
<td>70</td>
<td>28.1</td>
</tr>
<tr>
<td>Prune Juice</td>
<td>206.3</td>
<td>140</td>
<td>28.8</td>
</tr>
<tr>
<td>French Fries (OB)</td>
<td>697.8</td>
<td>70</td>
<td>48.8</td>
</tr>
</tbody>
</table>

* Portion Sizes From 21 CFR 101.12, Table 2
Acrylamide Exposure 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
• Updated FDA model, 2005
  – 0.4 µg/kg-bw-d
Furan
Background on Furan

- Furan is an industrial compound that has occasionally been reported to be found in foods.
- On May 7, 2004, scientists at FDA announced that furan forms in a variety of foods more commonly than previously thought.
- Furan is an animal carcinogen, and thus a potential human carcinogen.
Furan in Foods

- Furan formation results from traditional heat treatment techniques, such as retorting foods in cans and jars.
- Mechanisms of formation: multiple possibilities, including oxidation of polyunsaturated fatty acids, decomposition of ascorbic acid derivatives, and degradation of amino acids or carbohydrates.
FDA Action Plan for Furan in Food

- Specific action areas
  - Methodologies
  - Measuring Exposure
  - Toxicology, Risk Assessment, and Risk Management
  - Meetings and Education

- Furan information page
  http://www.cfsan.fda.gov/~lrd/pestadd.html#furan
FDA Furan Highlights

- Developed a GC/MS method for measuring furan in food and posted the method on the FDA website.
- Analyzed and posted furan levels in more than 300 food samples.
- Conducted preliminary exposure assessments that indicate how much furan U.S. consumers are exposed to through the diet and what foods are the primary sources of exposure.
FDA Furan Highlights

- Published request for information on furan and outline of research gaps in the Federal Register in May 2004.
- Held Food Advisory Committee meeting in June 2004 to seek input on data needed to fully assess the risk, if any, posed by furan to consumers.
FDA Exploratory Survey of Furan in Foods

  - Infant foods and formulas
  - Coffee
  - Soups
  - Sauces and syrups
  - Chili and canned pasta
  - Canned tuna
  - Canned fruit, fruit juices and vegetables
  - Nutritional drinks
Preliminary Furan Exposure Assessments

- June 2004
  - Adults (2+ years olds), 0.3 µg/kg/day
  - Infants (0-1 year olds), 0.4 µg/kg/day
  - Infant formula, 0.9 µg/kg/day

- June 2005
  - Adults (2+ years olds), 0.2 µg/kg/day
  - Mean intake (users only) has fallen as more foods/consumers are brought into the survey.
Background on Perchlorate

- Perchlorate is a naturally occurring and manmade compound
- Detected in numerous surface and ground waters in the U.S.
- Can inhibit iodide uptake into the thyroid
- Relatively high (pharmacologic) doses can lead to hypothyroidism
Background on Perchlorate

- Hypothyroidism may affect the fetus and newborn, resulting in delayed development and decreased learning capacity
- National Academy of Sciences recommended and EPA adopted an RfD = 0.7 µg/kg/day in 2005.
Perchlorate Strategy Goals

- Determine the occurrence of perchlorate in a variety of foods
- Evaluate exposure to perchlorate from food
- Support any action that might be needed to protect the public health

- Perchlorate information page
  http://www.cfsan.fda.gov/~lrd/pestadd.html#perchlorate
FDA Perchlorate Highlights

- Developed Ion Chromatography-Tandem Mass Spectrometry (IC-MS/MS) method for measuring perchlorate in foods.
- Conducted FY04 Exploratory Survey of almost 450 samples (produce, bottled water, milk), and posted first set of data on FDA website.
- Conducted preliminary exposure assessment
Perchlorate Exposure Summary

- Very limited range of foods included in the survey
- Mean population exposure was much less than the NAS/EPA RfD (0.7 µg/kg bw/day) for the limited number of foods in the survey
FDA Perchlorate Highlights

- Ongoing FY05 surveys (approximately 850 samples)
  - Wider range of produce and juices, aquaculture fish and shellfish, grain products; infant formulas; infant foods from the Total Diet Study; and farm milk, water, and cattle feed.
- FY06 survey planned for approximately 800 Total Diet Study samples and 100 additional samples
Conclusions

Acrylamide

Furan

Perchlorate