Survey of Bisphenol A in Canned Liquid Infant Formula Products

Bureau of Chemical Safety
Food Directorate
Health Products and Food Branch

A WHO Collaborating Centre for Food Contamination Monitoring

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Health Canada is the federal department responsible for helping the people of Canada maintain and improve their health. We assess the safety of drugs and many consumer products, help improve the safety of food, and provide information to Canadians to help them make healthy decisions. We provide health services to First Nations people and to Inuit communities. We work with the provinces to ensure our health care system serves the needs of Canadians.

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Background

Bisphenol A (BPA) is the common name for 2,2-(4,4'-dihydroxydiphenyl)propane, 4,4'-isopropylidenediphenol, or 2,2'-bis(4-hydroxyphenyl)propane. It is used as an intermediate in the production of epoxy resins which are used in the internal coating for food and beverage cans to protect the food from direct contact with metal. BPA can migrate from cans with epoxy coating into foods, especially at elevated temperatures (for example, for hot-fill or heat-processed canned foods). BPA is one of the 23000 chemical substances on the CEPA (Canadian Environmental Protection Act) Domestic Substance List (DSL) identified for further evaluation under government of Canada’s Chemical Management Plan (CMP).

BPA was included in Batch 2 of the Challenge under CMP carried out by Health Canada and Environment Canada. On October 18, 2008, the Government of Canada released its final assessment report, including the Government’s proposed risk management approaches to reduce Canadian exposure to BPA. Health Canada has committed to a research and monitoring agenda to further investigate potential human health effects of BPA and improve its understanding of Canadian exposure to this chemical through food sources. The purpose of this survey was to gather occurrence levels of BPA in canned liquid infant formula products to contribute in updating the BPA exposure estimate for Canadians. The survey results were also published in the peer-reviewed scientific literature1.

Sampling Plan and Analytical Methodology

In this survey, samples of 21 canned liquid infant formula products of various brands were analysed for BPA using a method with a quantification limit as low as 0.5 ng/g*, and the results were used to estimate dietary intakes of BPA for infants in different age groups.

A minimum of 3 cans (with the same lot number) of each of the 21 liquid infant formula products were purchased in October 2007 in a local grocery store in Ottawa. These products covered 8 brands from 4 companies. Among the 21 products, 17 products were milk based and 4 were soya based; 18 were concentrated and 3 were ready to use. All samples were stored at room temperature before analysis.

The samples were analysed by a gas chromatography-mass spectrometry method after solid phase extraction and derivatization with acetic anhydride.


* 1 ng/g is equivalent to 1 part per billion (ppb)
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Notes:

- The canned liquid infant formula samples were tested as sold. Note that concentrated infant formulas are diluted with drinking water prior to consumption. Concentrated liquid infant formula is usually diluted by a factor of 2 prior to consumption. These results have been adjusted to account for the product-recommended dilution factor and represent as consumed levels.

- It should be noted that the absence of any particular brand from this survey means only that the brand was not included in the survey. No particular inference should be drawn from the presence or absence of any brand.

- Samples represent a “snapshot” of the market at the time of sampling and do not represent market share. Product names and availability correspond to the time of sampling and may not represent current products on the market. Differences between brands do not necessarily reflect differences in consumer exposure to BPA.

- The results shown in Table 1 are generated for research purposes and should not be considered as representative of the distribution of BPA in canned liquid infant formula products or to assist or guide product choices for consumers.

BPA Levels in Canned Liquid Infant Formula Products

Table 1 summarizes the levels of BPA determined in samples of the canned liquid infant formula products. BPA was detected in all 21 products. Concentrations of BPA ranged from 1.14 to 5.44 ng/g* with an average of 2.88 ng/g*, well below the specific migration limit of 600 ng/g* set by the EC Directive for BPA in food or food simulant.

Health Significance of the Survey Results

The levels of BPA detected in canned liquid infant formula available for sale in Canada are low. In March, 2008, Health Canada’s Food Directorate completed a Health Risk Assessment of Bisphenol A from Food Packaging Applications† which used the results of this survey to determine exposure estimates to BPA. Health Canada’s Food Directorate has concluded that:

- The current dietary exposure to BPA through food packaging is not expected to pose a health risk to the general population, including newborns and young children.
  - The nutritional benefits of infant formula far outweigh any possible risk.

* 1 ng/g is equivalent to 1 part per billion (ppb)
In view of uncertainties related to datasets on possible neurodevelopmental and behavioural effects that BPA may have in experimental animals, Health Canada’s Food Directorate has recommended that precaution be exerted on products consumed by the sensitive subset of the population, i.e. infants and newborns, by applying the ALARA (as low as reasonably achievable) principle to reduce their exposure to BPA through food packaging applications.

Other international food regulatory agencies – notably in the United States, Europe, the United Kingdom and Australia-New Zealand – have reviewed the “Health Risk Assessment of Bisphenol A from Food Packaging Applications”, prepared by Health Canada’s Food Directorate, and have confirmed that the conclusions reached are supported by the current scientific evidence as described in the document.

Based on the overall weight of evidence, as described in the “Health Risk Assessment of Bisphenol A from Food Packaging Applications”, the results of this survey further confirms Health Canada’s previous assessment conclusion that the current dietary exposure to BPA through food packaging uses is not expected to pose a health risk to the consumer.

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Table 1: Concentrations (ng/g) of BPA in canned liquid infant formula products as consumed

- It should be noted that the absence of any particular brand from this survey means only that the brand was not included in the survey. No particular inference should be drawn from the presence or absence of any brand.
- Samples represent a "snapshot" of the market and do not represent market share. Product names and availability correspond to the time of sampling and may not represent current products on the market. Differences between brands do not necessarily reflect differences in consumer exposure to BPA.
- The results shown in the table are exploratory and should not be used to indicate the distribution of BPA in canned infant formula products or to assist or guide product choices for consumers.

<table>
<thead>
<tr>
<th>Company / Manufacturer</th>
<th>Brand Name</th>
<th>Product Description</th>
<th>Type</th>
<th>Infant Age (months)</th>
<th>BPA Concentration (ng/g)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abbott Laboratories</td>
<td>Isomil</td>
<td>Isomil Advance Concentrate Soya Infant Formula with Omega-3 and Omega-6</td>
<td>Soya</td>
<td>0 - 12</td>
<td>4.47</td>
</tr>
<tr>
<td></td>
<td>Isomil</td>
<td>Isomil Infant Formula with Soya for Allergy and Sensitivity to Milk Protein</td>
<td>Soya</td>
<td>0 - 12</td>
<td>3.18</td>
</tr>
<tr>
<td>Similac</td>
<td>Similac</td>
<td>Similac Advance with Omega-3 Omega-6 Infant Formula with Iron with Eye Q Nutrition System</td>
<td>Milk</td>
<td>0 - 12</td>
<td>4.25</td>
</tr>
<tr>
<td>Similac</td>
<td>Similac</td>
<td>Similac Advance Lactose Free Concentrate Infant Formula</td>
<td>Milk</td>
<td>0 - 12</td>
<td>4.89</td>
</tr>
<tr>
<td>Similac</td>
<td>Similac</td>
<td>Similac Advance with Omega-3 and Omega-6, Calcium enriched, Iron fortified Infant Formula</td>
<td>Milk</td>
<td>6 - 18</td>
<td>5.12</td>
</tr>
<tr>
<td>Similac</td>
<td>Similac</td>
<td>Similac Advance Regular Concentrate Infant Formula</td>
<td>Milk</td>
<td>0 - 12</td>
<td>4.33</td>
</tr>
<tr>
<td>Similac</td>
<td>Similac</td>
<td>Similac Advance Concentrate Infant Formula with Iron</td>
<td>Milk</td>
<td>6 - 18</td>
<td>4.08</td>
</tr>
<tr>
<td>PediaSure</td>
<td>PediaSure</td>
<td>PediaSure Complete Nutrition for Kids</td>
<td>Milk</td>
<td>12 and up</td>
<td>3.91</td>
</tr>
<tr>
<td>Loblaws Inc.</td>
<td>President's Choice</td>
<td>President's Choice Infant Formula Concentrate with Iron + Omega-3 and Omega-6</td>
<td>Milk</td>
<td>0 - 12</td>
<td>1.87</td>
</tr>
<tr>
<td>Loblaws Inc.</td>
<td>President's Choice</td>
<td>President's Choice Soya Infant Formula Concentrate Plus Omega-3 and Omega-6 with Iron</td>
<td>Soya</td>
<td>0 - 12</td>
<td>2.5</td>
</tr>
<tr>
<td>Loblaws Inc.</td>
<td>President's Choice</td>
<td>President's Choice Infant Formula Concentrate</td>
<td>Milk</td>
<td>0 - 12</td>
<td>1.6</td>
</tr>
<tr>
<td>Mead Johnson Nutritionals</td>
<td>Enfamil</td>
<td>Enfamil Enfamil Calcium Enriched Concentrate Infant Formula</td>
<td>Milk</td>
<td>6 and up</td>
<td>1.71</td>
</tr>
<tr>
<td>Mead Johnson Nutritionals</td>
<td>Enfamil</td>
<td>Enfamil with Iron Fortified Infant Formula</td>
<td>Milk</td>
<td>0 - 12</td>
<td>2.72</td>
</tr>
<tr>
<td>Mead Johnson Nutritionals</td>
<td>Enfamil</td>
<td>Enfamil A+ with LIPIL our blend of Omega-3 &amp; Omega-6. Our closest formula to breast milk Infant Formula Iron Fortified</td>
<td>Milk</td>
<td>0 - 12</td>
<td>2.19</td>
</tr>
<tr>
<td>Mead Johnson Nutritionals</td>
<td>Enfamil</td>
<td>Enfamil Lower Iron than other Enfamil brands Concentrate Infant Formula</td>
<td>Milk</td>
<td>0 - 12</td>
<td>2.43</td>
</tr>
<tr>
<td>Enfagrow</td>
<td>Enfagrow</td>
<td>Enfagrow Toddler Nutrition High in Iron and Calcium Nutritional Supplement</td>
<td>Milk</td>
<td>12 and up</td>
<td>5.44</td>
</tr>
<tr>
<td>Nestlé Nutrition</td>
<td>Nestlé</td>
<td>Nestle Alsoy Iron Fortified Soy Infant Formula Lactose Free and Vegetarian Omega-3 Omega-6</td>
<td>Soya</td>
<td>0 - 12</td>
<td>1.35</td>
</tr>
<tr>
<td>Nestlé Nutrition</td>
<td>Nestlé</td>
<td>Nestle Follow-Up Transition Iron Fortified Infant Formula Calcium Enriched</td>
<td>Milk</td>
<td>6 - 18</td>
<td>1.14</td>
</tr>
<tr>
<td>Nestlé Nutrition</td>
<td>Nestlé</td>
<td>Nestle Good Start 2 Iron Fortified with Added Calcium with Omega-3 Omega-6 Easier to Digest Infant Formula with Whole whey protein partially hydrolyzed by an exclusive process</td>
<td>Milk</td>
<td>6 - 18</td>
<td>1.14</td>
</tr>
<tr>
<td>Nestlé Nutrition</td>
<td>Nestlé</td>
<td>Nestle Good Start Iron Fortified with Omega-3 Omega-6 Easier to Digest Infant Formula Whole whey protein partially hydrolyzed by an exclusive process</td>
<td>Milk</td>
<td>0 - 12</td>
<td>1.15</td>
</tr>
<tr>
<td>Nestlé Nutrition</td>
<td>Nestlé</td>
<td>Nestle Good Start Iron Fortified Infant Formula with Whole whey protein partially hydrolyzed by an exclusive process</td>
<td>Milk</td>
<td>0 - 12</td>
<td>1.16</td>
</tr>
</tbody>
</table>

* A nutritional supplement. Although typically consumed less frequently than infant formula, nutritional supplements do contribute to the overall BPA exposure for this sensitive subset of the population (i.e. infants).