

bisphenol-A

and the CANADIAN MEDICAL DEVICES INDUSTRY


MEDEC

CANADA'S MEDICAL DEVICE TECHNOLOGY COMPANIES
LES SOCIÉTÉS CANADIENNES DE TECHNOLOGIE DES
DISPOSITIFS MÉDICAUX



MEDEC POSITION

Medical devices are not currently the focus of Health Canada and Environment Canada's concern in regards to bisphenol-A (BPA), however, MEDEC is proactively monitoring this issue in order to prepare for any questions or concerns. The medical device industry is working with experts to get a comprehensive understanding of the use, exposure levels and risks of BPA in medical devices.

With and on behalf of our members, MEDEC will offer advice, support, and recommendations to Health Canada and to all stakeholders to ensure a science-based and patient-safety focused approach to the future use of BPA in medical devices.

The medical device industry only provides products to the Canadian marketplace that meet the safety, effectiveness and quality requirements of applicable regulations such as the Canadian Medical Devices Regulations. If new scientific information and risk assessment will require the review of current products, MEDEC and its members will address this in the appropriate manner in order to ensure that patient safety is protected.



BACKGROUND

Bisphenol-A (BPA) is an organic compound used to make plastic materials such as polycarbonate, polyester, polyether ketone, polysulfone, and PVC. Risks associated with manufactured goods containing BPA are unique to each individual product, as the use of different products leads to varying levels of exposure. Health and environmental concerns around BPA have increased steadily over the past months amongst Canadian government regulators. BPA is one of 200 chemicals listed on the Federal Chemical Management Plan, which was launched in December 2006. As a part of this list, BPA was earmarked as requiring an update in knowledge and understanding and subsequently investigated in 2007.

ABOUT MEDEC

- MEDEC is the national association representing medical device and diagnostic companies. Our members are dedicated to serving the healthcare community through research and development and the provision of high quality medical products and services that benefit Canadians - safely and efficaciously.
- MEDEC members are committed to advancing healthcare in Canada by ensuring patients have access to safe medical device technologies.
- Member companies represent a range of medical devices such as operating room devices and hospital equipment as well as medical specialties such as cardiovascular, orthopaedic, ophthalmic, diabetes, and in-vitro diagnostics.
- The medical device industry in Canada employs over 35,000 Canadians in close to 1,500 corporate facilities, and contributes nearly \$6 billion in national sales per annum.
- MEDEC's mission is to strengthen and grow the industry in Canada by working closely with governments, medical associations and the public to establish an environment that supports the adoption of new technology from both regulatory and reimbursement perspectives.
- MEDEC members are committed to the highest standards of professional conduct. MEDEC has designed and adopted a Code of conduct to promote ethical business practices and socially responsible industry conduct to govern interactions with healthcare professionals.

→ BACKGROUND (continued)

A draft risk assessment report published by the Minister of Health and the Minister for the Environment on April 18, 2008 re-affirmed the safety of BPA in the general population, but has taken a precautionary approach with BPA that is contained in baby bottles and baby food containers. Thus these products will be the first products affected by the changed classification of BPA under the Canadian Environment Protection Act (CEPA). A tool of the CEPA is the 'precautionary principle' that allows the government to take action prior to the completion of a full scientific inquiry and public consultation.

The risk assessment finds that infants less than 18 months of age are the most vulnerable group due to a relatively high amount of BPA that leaches into baby formula from feeding bottles. Health Canada contends that studies suggest that the migration of BPA into the contents of baby bottles is most elevated when bottles are filled with hot liquids (i.e. boiled water used to prepare baby formula).

Health Canada states that both globally and in Canada, the assessment of the general public's exposure to BPA is considered an insignificant risk. On April 14, 2008 the U.S. Center for the Evaluation of Risks to Human Reproduction concluded that the weight of evidence that BPA causes adverse developmental or reproductive effects in humans is insufficient to draw any conclusions.

In the case of pregnant women, the Canadian government is considering additional recommendations regarding exposure to products containing BPA as part of an overall 'Healthy Living' program that is targeted towards the special dietary considerations of this group. It may take up to a year to conduct these studies but recommendations may happen within this timeframe.

The Canadian government also plans to work with the food and packaging industry to find alternate solutions for canned goods where the inner lining contains BPA.

→ THE IMPACT FOR MEDICAL DEVICES

Medical devices are currently not among the products of immediate concern to the Ministries of Health and Environment. However, once the results of the re-evaluation of BPA and the risk assessment of other products are finalized, action may be taken. Given that BPA will likely be designated as "toxic" substance under CEPA, the precautionary principle could be invoked allowing the Minister greater discretion to broadly apply restrictions to other products.

Future action may include:

- Setting allowable threshold concentrations of BPA
- Substitution of a current product by one made from different materials
- Replacement of the compound BPA by one that is proven safer
- Restriction of use of a current product for certain uses or user groups
- Increasing public awareness through changes in labeling to products containing BPA

SOURCES

Substance profile of bisphenol-A from the Federal Chemicals Management Plan

www.ec.gc.ca/substances/ese/eng/challenge/batch2/batch2_80-05-7.cfm

Fact sheet on bisphenol-A

www.chemicalsubstanceschimiques.gc.ca/challenge-defi/bisphenol-a_fs-fr_e.html

Government of Canada Chemicals Management Plan

www.chemicalsubstanceschimiques.gc.ca/plan/index_e.html

Information on the Canadian Government's approach to bisphenol-A

www.chemicalsubstanceschimiques.gc.ca/challenge-defi/bisphenol-a_e.html

Center for the Evaluation of Risks to Human Reproduction (U.S) draft review of bisphenol-A

http://cerhr.niehs.nih.gov/chemicals/bisphenol/BPADraftBriefVF_04_14_08.pdf