



## Bisphenol A (BPA) Safety 101

### Executive Summary

#### Is Bisphenol A (BPA) Safe When Current Applications are Used as Intended and How Do We Know?

- BPA has a **50-year history of safe use**.
- BPA's safety has been tested and studied by scientists **more than almost any other chemical**.
- BPA **does not accumulate** in the human body over time.
- The margin of safety between actual human exposure and the safe level recently established in Europe is **approximately 1,000**.
- A **100-fold safety factor** is already built into this safe exposure level for BPA.
- Consumers would have to consume **more than 1,300 pounds (600 kilograms)** of food and beverages in contact with polycarbonate plastic **every day of their lives** to exceed the safe level recently set in Europe.

#### What About the Low Dose Debate?

- The low dose debate over BPA originated from **small exploratory studies**.
- The exploratory studies **were not performed using internationally accepted Good Laboratory Practice guidelines** or validated testing guidelines.
- The studies were conducted with a **limited number of lab animals** that reported reproductive effects from exposure to low doses of BPA.
- These effects were **not found when the experiments were repeated** by other researchers.
- **Large-scale research** sponsored by industry and government agencies found no evidence of such effects.
- The large-scale research was performed with **internationally accepted Good Laboratory Practice guidelines** and **validated testing guidelines** designed specifically to look for low-dose reproductive and developmental effects.

#### What Do the Experts Have to Say?

- An extensive scientific database on BPA has supported comprehensive safety assessments by independent government and scientific bodies around the world.
- These assessments support the conclusion that exposure to trace levels of BPA from consumer products is **not a risk to human health**.
- BPA is **not been banned or restricted anywhere** in the world.
- **Polycarbonate plastic is authorized for use in food and beverage contact applications** by regulators around the world, including the U.S. Food and Drug Administration and Health Canada.
- Multiple assessments that support the safety of BPA are available from the following organizations:
  - U.S. Food and Drug Administration
  - Harvard Center for Risk Analysis
  - European Food Safety Authority (EFSA)
  - The European Union Scientific Committee on Food (now EFSA)
  - The European Commission
  - Japanese National Institute of Advanced Industrial Science and Technology
  - National Toxicology Program (NTP) Center for the Evaluation of Risks to Human Reproduction (CERHR)

Learn more about the above information in the following pages. For additional information, please visit [www.bisphenol-a.org](http://www.bisphenol-a.org).

## Bisphenol A (BPA) Safety 101

### Is Bisphenol A (BPA) Safe When Current Applications are Used as Intended and How Do We Know?

With its 50-year history, BPA has not only developed a long track record of safe use but its safety has been tested and studied by scientists more than almost any other chemical.

BPA is essentially all eliminated from the human body within the day of exposure and does not accumulate over time. During the short time it is in the body, BPA is in the form of a biologically inactive metabolite. Based on this information, it could be predicted that BPA is not likely to have high toxicity.

The margin of safety between actual human exposure and the safe level recently established in Europe is approximately 1000, which is in addition to the 100-fold safety factor that is already built into the safe exposure level.

It is estimated that consumers would have to consume more than 1,300 pounds (600 kilograms) of food and beverages in contact with polycarbonate plastic every day of their lives to exceed the safe level recently set in Europe.

### What About the Low Dose Debate?

The low dose debate over BPA originated with small exploratory studies not performed with internationally accepted Good Laboratory Practice guidelines or with validated testing guidelines. The exploratory studies were conducted with a limited number of lab animals that reported reproductive effects from exposure to low doses of BPA. However, the effects were not repeated and published by those researchers or found when the experiments were repeated by other researchers.

Large-scale research sponsored by industry and government agencies (performed with internationally accepted Good Laboratory Practice guidelines and validated testing guidelines designed specifically to look for low-dose reproductive and developmental effects) found no evidence of such effects.

### What Do the Experts Have to Say?

An extensive scientific database on BPA has supported comprehensive safety assessments by independent government and scientific bodies around the world in recent years. These assessments support the conclusion that exposure to trace levels of BPA from consumer products is not a risk to human health. As a result, BPA is not banned or restricted anywhere in the world. Polycarbonate plastic is authorized for use in food and beverage contact applications by regulators around the world, including the U.S. Food and Drug Administration and Health Canada.

### The U.S. Food and Drug Administration

*“the dietary exposure to BPA from all food contact materials is thousands of times lower than the levels that showed no adverse effects in animals. This margin is sufficiently large such that FDA has confidence that no safety concern exists for BPA in regulated food contact materials...Therefore, FDA sees no reason at this time to ban or otherwise restrict the currently authorized food contact applications of polycarbonate polymers and BPA-based coatings.”*

Source: [Statement from the FDA's Office of Food Additive Safety](#) by biologist Julie N. Mayer, M.F.S. on July 31, 2007 - sent in response to a request from Fit Pregnancy Magazine on FDA's most current position on BPA use.

## Harvard Center for Risk Analysis

*“In the case of BPA, the evidence considered by the panel suggests that the weight of the evidence for low-dose effects is very weak.”*

Source : Cohen, Joshua & Gray, George. “Weight of the Evidence Evaluation of Low-Dose Reproductive and Developmental Effects of Bisphenol A.” Harvard Center for Risk Analysis: Risk in Perspective. Aug. 2004. pg. 4.

## European Food Safety Authority (EFSA)

*“...Low-dose effects of BPA in rodents have not been demonstrated in a robust and reproducible way, such that they could be used as pivotal studies for risk assessment. Moreover, the species differences ... raise considerable doubts about the relevance of any low-dose observations in rodents for humans.”*

Source: “Opinion of the Scientific Panel AFC related to 2,2-BIS (4-HYDROXYPHENYL) PROPANE.” European Food Safety Authority. January 29, 2007.

## The European Union Scientific Committee on Food (now EFSA)

*“Many migration studies have been conducted world-wide. There is no significant effect from repeated-use, abrasion, heating, or chemical sterilization of these plastic articles. The general findings are that migration is low or not detectable.”*

*“There was no evidence of substance-related [BPA] carcinogenicity.”*

Source: “Opinion of the Scientific Committee on Food on Bisphenol A.” Scientific Committee on Food, 17 April 2002. pg. 3 & 6.

## The European Commission

In a review of the comprehensive risk assessment by the EU Commission the Scientific Committee on Toxicity, Ecotoxicity and the Environment (CSTEE) stated: *“The CSTEE agrees with the conclusion of the RAR [Risk Assessment Report] that there is no convincing evidence that low doses of bisphenol A have effects on developmental parameters in offspring.”*

Source: “Scientific Committee on Toxicity, Ecotoxicity and the Environment (CSTEE), Opinion on the results of the Risk Assessment of Bisphenol A”. 22 May, 2002, pg. 6.

## Japanese National Institute of Advanced Industrial Science and Technology

“current exposure levels of BPA will not pose any unacceptable risk to human health”

Source: A comprehensive risk assessment from the Japanese National Institute of Advanced Industrial Science and Technology, November 2005.

## National Toxicology Program (NTP) Center for the Evaluation of Risks to Human Reproduction (CERHR)

National Toxicology Program’s (NTP) Center for the Evaluation of Risks to Human Reproduction (CERHR) expressed “negligible” to “minimal” concern for all but one endpoint, which was expressed as “some” concern for two categories. The expert panel found that human exposure to BPA is extremely low and suggested additional research that might be helpful to provide further support for their conclusions. This review is generally consistent with other scientific evaluations by government agencies in the United States, Europe and Japan which support the conclusion that BPA is not a risk to human health at the extremely low levels to which consumers might be exposed.

*“The lack of reproducibility of the low dose effects, the absence of toxicity in those low-dose-affected tissues at high doses, and the uncertain adversity of the reported effects led the panel to express “minimal” concern for reproductive effects.”*

Source: "NTP-CERHR Expert Panel Report on the Reproductive and Developmental Toxicity of Bisphenol A". 26 November 2007, pg. 252.

### **Canadian Assessment Underway**

Under Canada's new Chemicals Management Plan (CMP), a new assessment of BPA has been initiated. For BPA, the information collection phase is now underway and a draft screening assessment, to be conducted by Health Canada, is expected by approximately May 2008.

### **More Information**

For more information on BPA, please visit the following websites:

BPA safety information from the Polycarbonate / BPA Global Group:

<http://www.bisphenol-a.org>

Canadian Chemicals Management Plan:

<http://www.chemicalsubstanceschimiques.gc.ca/en/index.html>

For U.S. state legislative information:

<http://www.coalitionforconsumerchoice.org/>