



GOVERNMENT AND INDEPENDENT SCIENTIFIC ASSESSMENTS OF BISPHENOL A

United States

- **U.S. Food and Drug Administration (FDA)** – In a March 2012 update, FDA stated that it has found “*no convincing evidence*” to support the belief that bisphenol A (BPA) is a hazard to people.

As noted by an FDA official: “*We make public health decisions based on a careful review of well performed studies, not based on claims or beliefs.*” Based on its objective review, FDA’s assessment is that “*the scientific evidence at this time does not suggest that the very low levels of human exposure to BPA through the diet are unsafe.*”

To address remaining uncertainties about the safety of BPA, FDA is carrying out in-depth studies in conjunction with the National Toxicology Program. The studies published to date provide additional strong support for the safety of BPA in food-contact materials. In the interim, FDA is taking reasonable steps to reduce human exposure to BPA in the food supply and stated:

“Given that these are preliminary steps being taken as a precaution, it is important that no harmful changes be made in food packaging or consumption, whether by industry or consumers, that could jeopardize either food safety or reduce access to and intake of food needed to provide good nutrition, particularly for infants.”

In a July 17, 2012 Federal Register notice, FDA took final action on a petition from ACC to amend FDA’s regulation on the food-contact use of polycarbonate plastic. As noted by FDA, the action to remove baby bottles and sippy cups from the regulation “*is not based on safety, but is based on the fact that regulatory authorization is no longer necessary*” for products that have been permanently and completely abandoned.

- **U.S. Environmental Protection Agency (EPA)** – In March 2010, EPA released a BPA “Action Plan” that outlines EPA’s review of BPA and their plans for follow-up actions. Notably, EPA did not propose any actions, regulatory or otherwise, regarding human health but will continue to coordinate closely with FDA, CDC and NIEHS.
- **U.S. National Toxicology Program (NTP)** – The September 2008 NTP final report on the potential for BPA to affect human reproduction or development found no direct evidence for health effects in people. It also confirmed that human exposure to BPA is very low.

On a standard five-level scale ranging from ‘serious concern’ to ‘negligible concern,’ NTP reported no concerns for any age group at the top two levels and only negligible concern for adults. Based on what NTP characterized as limited and inconclusive evidence from laboratory animal studies, NTP expressed ‘some concern’ regarding effects on the brain, behavior, and the prostate gland but noted that additional research is needed to better understand whether these findings are of any human health significance. The NTP report is designed to serve as a resource to regulatory agencies and has specifically been considered in FDA’s ongoing safety assessment.

- **California Proposition 65** – In July 2009 a panel of independent scientific experts convened by the California EPA’s Office of Environmental Health Hazard Assessment unanimously concluded that BPA should not be listed as a reproductive or developmental toxicant under California’s Proposition 65 law. That law can require warnings when listed substances are present in consumer products. The panel’s decision was based on their own review of the scientific evidence on BPA, including their assessment of the NTP report.
- **NSF International** (a not-for-profit public health and safety organization) – In February 2008, NSF published its comprehensive safety assessment of BPA and set a safe intake level for BPA in drinking water. That level is comparable to the level established by the European Food Safety Authority for BPA in food. The assessment was led by Dr. Calvin Willhite, a respected scientist with the California Department of Toxic Substances Control.
- In October 2008, an **expert scientific panel**, convened by **Gradient Corporation**, published the results of its weight-of-the-evidence evaluation of low-dose reproductive and developmental effects of BPA. This evaluation is the third in a series that began with an evaluation, published in 2004, by an independent panel of scientific experts organized by the **Harvard Center for Risk Analysis**. Based on its review of scientific literature available through July 2008, the panel concluded: “*The weight of evidence does not support the hypothesis that low oral doses of BPA adversely affect human reproductive and developmental health.*”

WHO and FAO

- In September 2011, an international panel of experts organized by WHO (World Health Organization) and FAO (Food and Agriculture Organization of the United Nations) released a report on their review of all the latest scientific evidence on BPA and concluded that “*initiation of public health measures would be premature.*” The experts also concluded that BPA does not accumulate in the body, is rapidly eliminated in urine, and that it is difficult to interpret the relevance of studies claiming adverse health effects from BPA.

Canada

Health Canada – In September 2012, Health Canada updated its exposure assessment and reaffirmed its previous conclusion on the safety of BPA.

“[B]ased on the overall weight of evidence, the findings of the previous assessment remain unchanged and Health Canada’s Food Directorate continues to conclude that current dietary exposure to BPA through food packaging uses is not expected to pose a health risk to the general population, including newborns and young children.”

The updated assessment was based on a series of recent Health Canada reports with new data on BPA in baby food, infant formula, canned food and beverages, and bottled water. The assessment indicates that exposure to BPA from the diet is approximately 3-fold lower than previously estimated.

Based on the conclusions of its October 2008 screening risk assessment, Health Canada had previously stated: “*The current research tells us the general public need not be concerned. In general, most Canadians are exposed to very low levels of bisphenol A, therefore, it does not pose a health risk.*”

With respect to infants under 18 months, it said “*[s]cience tells us that exposure levels are below those that could cause health effects; however, due to the uncertainty raised in some studies relating to the potential effects of low levels of bisphenol A, the Government of Canada is taking action to enhance the protection of infants and young children.*” Based on precaution, Health Canada is working with industry to achieve the lowest reasonably achievable levels of BPA in infant formula, and has recently finalized a regulation to ban polycarbonate baby bottles. The ban applies only to baby bottles and not to other polycarbonate bottles, tableware and food containers.

Europe

- **European Food Safety Authority (EFSA)** – In December 2011, EFSA updated their comprehensive scientific assessment of BPA that had been conducted by a panel of independent scientific experts from throughout the European Union. The update reaffirmed the panel’s previous conclusion (September 2010) that they “*could not identify any new evidence which would lead them to revise the current Tolerable Daily Intake,*” which is a safe intake level.

In 2007, the panel increased by a factor of five the safe intake level established in 2002, based on the panel’s view that recent data provided more certainty about the safety of BPA. With interim updates in 2008, EFSA reconfirmed its position that polycarbonate and epoxy food contact products are safe for their intended uses, stating that the TDI “*provides a sufficient margin of safety for the protection of the consumer, including fetuses and newborns.*”

Similar to Canada, the European Commission has recently decided on a precautionary ban on polycarbonate baby bottles. However, the Commission has also confirmed that there is no scientific evidence to support extending the ban to any other products.

- **German Society of Toxicology (SOT)** – In April 2011 the Advisory Committee of the SOT, comprised of leading German regulatory scientists, released their detailed review of the science on BPA. Published in the peer-reviewed scientific journal *Critical Reviews in Toxicology*, the committee concluded “*BPA exposure represents no noteworthy risk to the health of the human population, including newborns and babies.*” In regard to the safe intake level established by EFSA, the committee further concluded that the “*current Tolerable Daily Intake level for BPA is adequately justified.*”
- The **French Food Safety Authority (AFSSA)**, February 2010), the **Danish Environmental Protection Agency** (October 2008), the **German Federal Institute for Risk Assessment** (May 2011), the **Dutch Food and Consumer Product Safety Agency** (November 2008), and the **Swiss Federal Office of Public Health** (December 2011) have

all re-evaluated BPA in light of recent studies and government decisions; all conclude that BPA is safe for use in food contact applications. Based on precaution, Denmark has implemented a temporary ban on food contact products for infants in Denmark; a recent Danish expert review found no clear evidence for harmful effects.

- **European Union** – In June 2008, an updated comprehensive **European Commission Risk Assessment Report** confirmed that BPA does not pose a risk to the general public from all current sources of exposure, including use of polycarbonate plastic and epoxy resins in consumer products. No bans or restrictions were proposed based on this assessment. The update takes into account the latest scientific studies available (through 2007) and completes a comprehensive assessment undertaken on BPA over 10 years.

Japan

- **Japanese National Institute of Advanced Industrial Science and Technology** (affiliated with the Japanese Ministry of Economy, Trade and Industry) – In July 2011, AIST issued a comprehensive update to their previous assessment and confirmed no risk of BPA to human health, including infants and children. New results from FDA's in-depth studies on BPA, along with other recent studies, supported the updated conclusion. Notably, the new FDA results also provided a substantial part of the basis for a reduction in the uncertainty factor from 100 to 25, which indicates that the science supporting the safety of BPA is now stronger and with less uncertainty.
- **Japanese Ministry of Environment** – In 2005, based on its own comprehensive testing, the Ministry concluded that there were no clear endocrine disrupting effects found at low doses and that no regulatory action is required to manage risks.

Australia and New Zealand

- **Food Standards Australia New Zealand** (FSANZ – an independent statutory agency responsible for setting food standards in the two countries) – In April 2012, FSANZ reaffirmed the safety of BPA and stated: *“The weight of scientific evidence indicates that exposure to BPA in food does not present a significant human health and safety issue at current exposure levels.”*
- **Australian Competition & Consumer Commission** (ACCC – the Australian regulatory agency responsible for consumer product safety) – ACCC recently stated: *“The weight of scientific evidence currently available indicates that BPA in plastics does not present a risk to human health.”*

China and Hong Kong

- **China** – In May 2011, the Chinese Ministry of Health, along with five other government agencies stated that adverse effects of BPA on human health have not yet been found. Based on precaution, China has implemented a ban on BPA in baby bottles but has also noted that the use of BPA continues to be allowed for all other food packaging materials, coatings and containers.
- **Hong Kong Centre for Food Safety (CFS)** – Based on advice from their independent Expert Committee on Food Safety in January and December 2011, CFS stated that they concur with the conclusion of the WHO/FAO experts that *“initiation of public health measures would be premature based on current knowledge of BPA.”* The CFS is the government food authority for the Hong Kong Special Administrative Region of China.