



Bisphenol-A: Recent Regulatory Actions June 2008

Plastics and resins made from bisphenol A (BPA) are found in many products that make people's lives healthier and safer. Shatter-resistant and clear polycarbonate plastic is used in a wide array of products ranging from plastic bottles and eyeglasses to sports safety equipment, as well as components of life saving medical devices such as incubators and kidney dialysis machines. Durable epoxy resins are used as the coating in most food and beverage cans, helping to protect the safety and integrity of our food supply. Below are synopses of recent actions by regulatory agencies regarding BPA.

European Union: On June 11, 2008, the European Commission published a comprehensive update of its risk assessment on BPA, concluding that products made from BPA, such as polycarbonate and epoxy resins, are safe for consumers and the environment in current applications. The conclusion reaffirms the findings of the 2003 European risk assessment of BPA and is consistent with conclusions of the scientific assessments of other regulatory bodies including the U.S. Food and Drug Administration (FDA), the Japanese authorities and the European Food Safety Authority (EFSA). The update assessment takes into account the latest scientific studies available (through 2007) and completes a comprehensive assessment process undertaken on BPA over the last 10 years.

U.S. Food and Drug Administration: The FDA has repeatedly confirmed that FDA-regulated products made with BPA are safe, including in recent statements. In testimony before two separate Congressional hearings (on May 14, and again on June 10, 2008), FDA stated that: "FDA is not recommending that consumers discontinue using food contact materials that contain BPA.... [A] large body of available evidence indicates that food contact materials containing BPA currently on the market are safe, and that exposure levels to BPA from these materials, including exposure to infants and children, are below those that may cause health effects".

In April, 2008 FDA posted on its website: "[b]ased on our ongoing review, we believe there is a large body of evidence that indicates that FDA-regulated products containing BPA currently on the market are safe and that exposure levels to BPA from food contact materials, including for infants and children, are below those that may cause health effects."

U.S. National Toxicology Program: The National Toxicology Program (NTP) is engaged in multi-step review of BPA. Along the way, various draft reports are issued and public comment is solicited, but the process is not complete until the final NTP monograph on a chemical is released.

On April 14, a draft NTP brief confirmed that human exposure to BPA is extremely low and noted no direct evidence in humans that exposure to BPA adversely affects reproduction or development.



NTP's draft report found "negligible concern for adults – the lowest rating in the NTP scale and "some concern" - the third rating on the five level NTP scale - for fetuses, infants and children of neurodevelopmental, prostate gland, mammary gland effects, and of earlier onset of female puberty. NTP's draft brief concluded that there was insufficient evidence to reach a conclusion, and that more research is needed to understand the implications for humans. In the most recent step of NTP's review process, its Board of Scientific Counselors on June 11 reviewed the draft brief and recommended **lowering the level of concern in the draft brief from "some" to "minimal" for effects in the mammary gland and an earlier onset of female puberty.**

Health Canada: On April 17, 2008, after completing a screening assessment (normally the first step in a risk assessment process) the Canadian government announced "[t]he preliminary research tells us the general public need not be concerned." With respect to infants 18 months and under, it said that "[s]cience tells us that exposure levels are below those that could cause health effects, but since they are close to the levels where potential effects could occur, the Government wants to be prudent and reduce exposures further." The government announced a comment period during which it is considering whether to move forward with a ban of polycarbonate baby bottles and with setting a target level of BPA in infant formula.

On May 30, 2008, Health Canada responded to testing results published by some media outlets related to the presence of BPA in canned foods. Health Canada stated that, "[n]one of the levels found in the testing exceed current Health Canada guidelines. A preliminary examination of the results show that levels of BPA reported as migrating from canned food sources are very low, in the range of parts per billion (one billionth gram in a gram of food) and are consistent with levels of BPA reported in canned foods sold worldwide."

Health Canada went on to say, "[b]ased on the scientific evidence available to date, Health Canada does not recommend that consumers make any changes to their dietary habits as a result of the occurrence of trace levels of BPA in canned foods. **Consumers should feel confident that canned foods are safe and can continue to be part of a balanced diet.** Canadians are encouraged to eat a variety of foods as recommended by Eating Well with Canada's Food Guide."

Shortly after that Health Canada clarified in a statement on the "Safety of Plastic Containers Commonly Found in the Home" that exposure to BPA from polycarbonate is below levels that could cause human effects, but that as a precautionary measure they propose to ban "*only baby bottles made of polycarbonate. All other plastic containers can continue to be used safely.*"

European Food Safety Authority (EFSA): In January 2007, EFSA released a comprehensive scientific assessment of BPA that was conducted by a panel of independent scientific experts from throughout the European Union. Based on its review of the most recent scientific information, the panel increased by a factor of five the safe intake level for BPA that was established in 2002. The increase was based on the panel's view that there is now more certainty about the safety of BPA.

Japanese National Institute of Advanced Industrial Science and Technology: A comprehensive report published in November 2005 by the Japanese National Institute of Advanced Industrial Science and Technology (affiliated with the Japanese Ministry of Economy, Trade and Industry) confirmed that BPA does not present a risk to human health, including infants and children, and noted that no bans or restrictions are needed.

TIMELINE

June 11, 2008	The European Commission's Risk Assessment Report on BPA found that products made from BPA-based polycarbonate and epoxy resins are safe when used as intended.
June 11	NTP Board of Scientific Advisors recommends reducing from "some concern" to "minimal concern" the potential risk of effects on mammary glands and earlier onset of puberty in females
June 10	FDA reaffirms in testimony to Congress that food contact products made with BPA are safe for use and that exposure, including to infants and children are below levels that may cause effects.
June 5	Health Canada clarifies that exposure to BPA from polycarbonate is below levels that could cause human effects, but that as a precautionary measure they propose to ban <i>"only baby bottles made of polycarbonate. All other plastic containers can continue to be used safely."</i>
May 30	Health Canada releases a statement stating that BPA in food can linings is safe for use.
May 14	FDA testifies before Congress that food contact products made with BPA are safe for use and that exposure, including to infants and children are below levels that may cause effects.
April 18	FDA confirms that the data shows that plastics and can linings made with BPA are safe for use in food contact applications.
April 17	Health Canada draft screening assessment finds no current concern for the public, but does initiate a process that may result in a ban on polycarbonate baby bottles and target limits for BPA in infant formula.
April 14	NTP draft Brief concludes exposure to BPA is within safe levels "some concern" – the third lowest rating on the NTP scale - for some health effects in fetuses, infants and young children. NTP recommended more research.

