

## **Bisphenol A Safety Overview Executive Summary**

### **1. What Is Bisphenol A and How It Is Used**

Bisphenol A (BPA) is a chemical building block used to make polycarbonate plastic and epoxy resins. The unique attributes of these materials make them ideal for use in a wide variety of products, many of which improve the health and safety of consumers, including children. Both materials have a long history of safe use, more than 50 years, and an equally long history of testing to support the safety of these products.

Polycarbonate is a lightweight, heat-resistant and nearly shatter-proof plastic that is as clear as glass. Some examples of the many uses of polycarbonate plastic include: shatter-resistant food storage containers and bottles, components of life-saving medical devices, incubator domes, lightweight and virtually unbreakable corrective eyeglass lenses, sports safety equipment, CDs and DVDs, and bullet-resistant windows.

Epoxy resins are particularly useful as protective coatings, including the coating on the interior surface of most metal food and beverage cans. The coating provides an essential public health benefit by preventing corrosion of the can and contamination of food with dissolved metals or bacteria, while also extending shelf life.

### **2. Government Bodies Worldwide Support the Safety of BPA**

The scientific evidence supporting the safety of BPA has been repeatedly and comprehensively examined by government bodies worldwide in recent years. **No government body worldwide has banned or restricted BPA, polycarbonate plastic or epoxy resins, in particular for use of these materials in food contact or children's products.** Key examples of the most recent government assessments include:

- **US Food and Drug Administration (FDA)** – In a November 2005 letter to the California Legislature, FDA stated: *“based on all the evidence available at this time, FDA sees no reason to change its long-held position that current uses with food are safe”* and *“Considering all the evidence, including measurements by FDA chemists of levels found in canned foods or migrating from baby bottles, FDA sees no reason at this time to ban or otherwise restrict the uses now in practice.”*
- A comprehensive report published by the **Japanese Ministry of Economy, Trade and Industry** in November 2005 confirmed no risk of BPA to human health, including infants and children, and noted that no bans or restrictions are needed.
- In 2005, the **Japanese Ministry of Environment** concluded, based on their own comprehensive testing, that there were no clear endocrine disrupting effects found at low doses and that no regulatory action is required to manage risks.

- A comprehensive 2003 **European Union** risk assessment report confirmed low risk of BPA to human health, including use of polycarbonate plastic and epoxy resins in consumer products. Based on this report, no bans or restrictions have been proposed.
- In 2002, the **European Union Committee on Toxicity, Ecotoxicity, and the Environment** – an independent scientific committee – affirmed the key conclusions of the EU risk assessment report.
- In 2002, the **European Union Scientific Committee on Food** – another independent scientific committee – published a detailed assessment of BPA focused on food contact applications. Conclusions reached support the continued safe use of polycarbonate plastic and epoxy resins with food and beverages.
- In 2001, the **United States National Toxicology Program (NTP)** reviewed the evidence for reproductive and developmental effects from exposure to low doses of chemicals, including BPA. The review confirmed that “low-dose” effects for BPA have not been conclusively established as a general or reproducible finding.

In light of the frequency, consistency, and timeliness of government assessments of BPA, it is apparent that there is no need for additional legislation or regulation for BPA.

**Existing regulatory processes are adequate to protect human health**, including children’s health, and have proven to be functional and timely.

### **3. Safety of BPA Confirmed by the Weight of Scientific Evidence**

The weight of scientific evidence demonstrates that BPA is not a risk to human health, including children’s health, at the extremely low levels to which people might be exposed. A complete understanding of the safety of BPA requires detailed knowledge of several areas of research: metabolism and pharmacokinetics, toxicity, and human exposure.

#### Metabolism and Pharmacokinetics

- Humans efficiently metabolize and eliminate BPA from the body. BPA metabolites are not estrogenic and have no known biological activity.
- BPA is rapidly eliminated with a half-life of about 4 hours and does not accumulate in the body.
- Pregnant women and children also efficiently metabolize and eliminate BPA.
- Human metabolism and elimination of BPA is more efficient than rodents. Health effect studies on rodents must be evaluated cautiously for relevance to humans.
- Non-oral routes of exposure, which are commonly used in health effect studies on laboratory animals, are of little relevance to humans.

## Human Exposure

- Human exposure to BPA has been confirmed to be extremely low in numerous biomonitoring studies. Exposure levels are well below even the “low doses” claimed to cause effects in laboratory animals.
- Consumer products contain very little BPA – polycarbonate and epoxy resins contain only trace levels of BPA; the vast majority of BPA is consumed when these materials are manufactured.
- Migration studies show low potential for human exposure to BPA, consistent with the extremely low levels found in biomonitoring studies.
- Exposure to BPA poses no known risk to human health. Typical exposure levels are about 1,000,000 times lower than levels shown to cause no adverse effects in the most comprehensive, multi-generation animal studies, indicating a large margin of safety.

## Toxicity and Endocrine Disrupting Effects

- BPA has low oral toxicity and is not carcinogenic, mutagenic, teratogenic or a selective reproductive toxicant
- Estrogenic effects at low doses have not been confirmed. Reported low-dose effects have not been replicated in repeat studies conducted in independent laboratories and low-dose effects have not been found in large-scale multi-generation studies that follow internationally accepted guidelines.
- The weight of scientific evidence does not support low-dose effects. An expert scientific panel at Harvard concluded “*the weight of evidence for low-dose effects is very weak,*” and “*the panel found no consistent affirmative evidence of low-dose BPA effects for any endpoint.*”
- In an updated weight-of-evidence evaluation, an expert scientific panel stated in November 2005 “*Taken together, we conclude that the weight of evidence does not support the hypothesis that low oral doses of BPA adversely affect human reproductive and developmental health.*”
- No confirmed endocrine disrupting effects from BPA have been found in humans.

## **4. Conclusions**

Overall, the weight of scientific evidence from the many studies summarized above demonstrates that BPA is not a risk to human health at the extremely low levels to which people might be exposed. This conclusion is supported by multiple weight-of-evidence-assessments conducted recently by scientific and government bodies worldwide. Notably, each of these assessments has included or specifically focused on claims that BPA can cause adverse health effects at low doses by disruption of natural hormonal processes. In every case, these assessments have found that the scientific evidence does not support the validity of low-dose health effects from BPA.

No government body worldwide has banned or restricted BPA, including no bans or restrictions on the use of polycarbonate plastic or epoxy resins for children’s products.