GOVERNMENT AND INDEPENDENT SCIENTIFIC ASSESSMENTS

United States

- **U.S. Food and Drug Administration (FDA)** – In August 2008, FDA released a draft safety assessment of BPA in food-contact products (e.g., baby bottles, water bottles, food containers). The assessment was conducted by a cross-agency task force of FDA scientists and included data and information from recent government reviews of BPA, from non-governmental sources and the scientific literature. In particular, the findings of the National Toxicology program were incorporated into FDA's analysis. Overall, FDA concluded: "***an adequate margin of safety exists for BPA at current levels of exposure from food contact uses, for infants and adults***."

  FDA continues to review BPA based on peer review comments from its Science Board. In February 2009, FDA stated ***"With regard to BPA generally, based on all available evidence, the consensus of regulatory agencies in the United States, Canada, Europe and Japan is that the current levels of exposure to BPA through food packaging do not pose an immediate health risk to the general population, including infants and young children."***

- 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***."

- **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.

- **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.

Canada

- **Health Canada** – In October 2008, the Canadian government announced the conclusion of its screening risk assessment stating: "***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.***" Health Canada announced it will move forward with achieving the lowest reasonably achievable levels of BPA in infant formula and a regulation to ban polycarbonate baby bottles, noting that the proposed ban applies only to baby bottles and not to polycarbonate bottles, tableware and food containers. A ban on polycarbonate baby bottles in Canada has not yet taken effect.

Europe

- **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. The panel increased by a factor of five the safe intake level for BPA (known as the Tolerable Daily Intake or TDI) that was established in 2002. The increase was based on the panel's view that recent data provided more certainty about the safety of BPA.

  In July and October 2008, EFSA updated its 2007 assessment of BPA. EFSA reconfirmed its position that BPA-based polycarbonate and epoxy food contact products are safe for their intended uses. These updates examined recent data and concluded that newborns are able to metabolize. EFSA concluded that the TDI "***provides a sufficient margin of safety for the protection of the consumer, including fetuses and newborns.***"

- The **French Food Safety Authority** (AFSSA, November 2008), the **Danish Environmental Protection Agency** (October 2008), the **German Federal Institute for Risk Assessment** (BfR, September 2008), the **Dutch Food and Consumer Product Safety Agency** (VWA, November 2008), and the **Swiss Federal Office of Public Health** (BAG/OFSP, February 2009) 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.**

- The French Minister of Health (March 31, 2009) questioned the Canadian government's use of the precautionary principle and stated: ***"Precautionary measures should only be applied in the absence of reliable studies confirming the safety of Bisphenol A. In fact, reliable studies do exist in accordance with the present science on the safety…The Canadian authorities decided to prohibit Bisphenol- A as a result of pressure from public opinion rather than on the basis of any serious scientific evidence… The principle of precautionary measures is based on reason and never on emotion."***

- **European Union** – In June 2008, an updated comprehensive **European Commission** risk assessment report confirmed low risk of BPA to human health, including use of polycarbonate plastic and epoxy resins in consumer products. The 2008 update takes into account the latest scientific studies available (through 2007) and completes a comprehensive assessment process undertaken on BPA over 10 years. Based on this report, no bans or restrictions have been proposed.

  100% of tests required by REACH to assess risk to human health have been completed. All of that test data, plus hundreds of other studies, were reviewed by the European Chemicals Bureau in the EU Risk Assessment. The conclusion of the EU Risk Assessment is that bisphenol A does not pose a risk to the general public from all current sources of exposure.

Japan

- **Japanese National Institute of Advanced Industrial Science and Technology** (affiliated with the Japanese Ministry of Economy, Trade and Industry) **–** In November 2005, a comprehensive report confirmed no risk of BPA to human health, including infants and children, and noted that no bans or restrictions are needed.

- **Japanese Ministry of Environment** – In 2005, based on its own comprehensive testing, 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) - On March 19, 2009 FSANZ reaffirmed the safety of BPA and stated: "***FSANZ has assessed the risk to infants from exposure to BPA and concurred with the conclusions reached by the US FDA and the EFSA that the levels of exposure are very low and do not pose a significant health risk***."