American Chemistry Council

BISPHENOL A OVERVIEW

Regulatory bodies around the world have assessed the science on bisphenol A (BPA). As detailed below, not one has concluded that BPA has been proven to be unsafe in its current uses. Products made with BPA contribute to the health and safety of Americans and contribute to the US economy with more than 100,000 jobs totaling $6.1 billion in wages.

1. **US Food and Drug Administration and Department of Health and Human Services reaffirmed that "BPA is not proven to harm children or adults" (January 2010).**

As stated by FDA: "Studies employing standardized toxicity tests have thus far supported the safety of current low levels of human exposure to BPA." As further noted by Dr. Joshua Sharfstein of FDA: "If we thought it was unsafe, we would be taking strong regulatory action."

In recognition of some concerns related to effects reported in certain recent studies, FDA is carrying out in-depth studies in conjunction with the National Toxicology Program to answer key questions and clarify uncertainties. 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."

2. **Regulatory bodies around the world have assessed the science on BPA and have determined that BPA is safe for use in food contact products.**

- European Food Safety Authority (January 2007, July 2008, October 2008)
- European Commission Risk Assessment (June 2008)
- Swiss Federal Office of Public Health (February 2009)
- French Food Safety Authority (February 2010)
- Dutch Food and Consumer Product Safety Authority (November 2008)
- Danish Environmental Protection Agency (October 2008)
- German Federal Institute for Risk Assessment (January 2010)
- Food Standards Australia and New Zealand (January 2010)
- Japanese National Institute of Advanced Industrial Science and Technology (November 2005)
- Health Canada (October 2008, July 2009)

- A 2010 prohibition of polycarbonate baby bottles in Canada was based on precaution; the Canadian scientific assessment concluded that exposure, including from baby bottles, is below levels that pose a risk. Similarly, a 2010 temporary ban on food contact products for infants in Denmark was based on precaution; a Danish expert review found no clear evidence of harmful effects.
- 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.
- In March 2010, the US Environmental Protection Agency (EPA) released an "action plan" on BPA that outlines EPA's review of BPA and their plan for follow-up actions. Notably, EPA did not propose any actions, regulatory or otherwise, regarding human health but will continue to coordinate with FDA and other agencies.

May 2010

- Existing food safety programs are already precautionary - they employ safety factors, typically between 100 and 1000, to create a margin of safety between public exposure and levels found to cause effects in laboratory animals.

  For example, the European Food Safety Authority (EFSA) set a Tolerable Daily Intake (TDI), which is the amount of BPA a consumer (including babies and infants) can safely ingest without harm over a whole lifetime. The TDI was set by applying a safety factor of 100 to the No-Observed-Adverse-Effect-Level determined from studies on laboratory animals.

  - A consumer would have to ingest more than 500 pounds of food and beverages in contact with BPA every day for a lifetime to exceed the TDI set by EFSA
  - A 22 pound infant would have to drink more than 423 4 oz bottles per day to exceed the TDI

3. Products Made with BPA Contribute to the Health and Safety of Americans

- Epoxy resins are used as a protective coating in most metal food and beverage containers to help prevent corrosion and contamination, avoid food spoilage and provide a shelf life of two years or more.
  - Canned infant formula is provided to more than 8 million low-income women, infants and children at nutritional risk under the federal Special Nutrition Program for Women, Infants and Children (WIC)
- Shatter-resistant polycarbonate plastic made with BPA can be found in many products that contribute to health and safety:
  - Plastic bottles and cups without the risk of cuts from broken and chipped glass
  - Sports safety glasses (polycarbonate lenses are recommended by the American Academy of Ophthalmology)
  - Helmets
  - Sports safety equipment, such as face shields and face guards
  - Life-saving medical devices such as incubators and kidney dialysis machines
  - Blast and bullet resistant shielding to protect government officials, police, prison officials, military personnel, as well as bank tellers and convenience store clerks
- Polycarbonate is used to make lightweight products such as automotive parts that save energy and reduce green house gas emissions.

4. BPA Makes an Important Contribution to U.S. Economy (2007 data)

- Along with 9 plants that manufacture BPA, polycarbonate plastic or epoxy resins, approximately 1,400 downstream facilities in the U.S. process polycarbonate or epoxy into finished products – nearly all states are represented – with an investment value of $6 billion.
- More than 39,000 workers are employed *directly* in chemical processing and plastic/resin facilities and downstream fabrication facilities.
- An additional 64,700 workers are employed *indirectly*. These individuals are employed in the wide network of supplier industries that provide goods and services (raw materials, utilities, capital goods, services) to businesses that rely on polycarbonate plastic and epoxy resins.
- $6.1 billion in total wages (direct and indirect employment).
- Over $1.3 billion in federal/state/local taxes, plus $894 million in Social Security and Medicare taxes are paid in relation to the 39,000 workers directly employed in chemical processing and plastic/resin facilities and downstream fabrication facilities.

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GOVERNMENT AND INDEPENDENT SCIENTIFIC ASSESSMENTS

United States

- **U.S. Food and Drug Administration (FDA) and Department of Health and Human Services (HHS)** – In January 2010, FDA and HHS reaffirmed that "*BPA is not proven to harm children or adults.*"

  As stated by FDA: "*Studies employing standardized toxicity tests have thus far supported the safety of current low levels of human exposure to BPA.*" As further noted by Dr. Joshua Sharfstein of FDA: "*If we thought it was unsafe, we would be taking strong regulatory action.*"

  In recognition of some concern related to effects reported in certain recent studies, FDA is carrying out in-depth studies in conjunction with the National Toxicology Program to answer key questions and clarify uncertainties. 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.*"

- **U.S. Environmental Protection Agency (EPA)** – In March 2010, EPA released an "action plan" on BPA 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.*"

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."* 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.

  In July 2009, Health Canada released several reports with new data on BPA in bottled water, baby food and infant formula. According to Health Canada, these new data confirm Health Canada's previous conclusion that *"the current dietary exposure to BPA through food packaging is not expected to pose a health risk to the general population, including infants and children."*

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, 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, February 2010), the **Danish Environmental Protection Agency** (October 2008), the **German Federal Institute for Risk Assessment** (BfR, January 2010), 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. 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 have been proposed. The update takes into account the latest scientific studies available (through 2007) and completes a comprehensive assessment undertaken on BPA over 10 years. The conclusion of the EU Risk Assessment is that.

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) – In January 2010, FSANZ reaffirmed the safety of BPA and stated: *"FSANZ has assessed the studies that led to the USFDA decision to undertake a review and further research, and our view remains that BPA in baby bottles and food packaging in Australia and New Zealand is still safe."*

May 2010