

ABOUT BISPHENOL A REGULATION

WEIGHT OF SCIENTIFIC EVIDENCE SUPPORTS THE SAFETY OF BPA

Government and scientific bodies around the globe have extensively evaluated the weight of scientific evidence on Bisphenol A (BPA) and have declared that BPA is safe for its intended uses, including in materials which come into contact with food, such as reusable food-storage containers and linings in metal cans.

Regulatory agencies that have recently ruled on the safety of BPA include:

- European Food Safety Authority (December 2011, September 2010)
- Japanese National Institute of Advanced Industrial Science and Technology (July 2011)
- Swiss Federal Office of Public Health (June 2011, February 2009)
- Food Standards Australia New Zealand (July 2011, November 2010)
- German Society of Toxicology, Advisory Committee (April 2011)
- German Federal Institute for Risk Assessment (July 2010)
- U.S. Food and Drug Administration (January 2010)
- WHO and FAO (November 2010)
- Health Canada (March 2010, October 2008)
- European Union (June 2008)

SAFETY OF BPA CONFIRMED BY REGULATORY AUTHORITIES AND SCIENTIFIC EXPERTS

European Food Safety Authority (EFSA) – December 2011, September 2010

In December 2011, after consideration of a French report on health effects of BPA, EFSA concluded that this does not change the views expressed by the panel in its 2010 opinion on the safety of BPA. No new evidence was found that would lead to revise the current Tolerable Daily Intake (the safe intake level) for BPA of 0.05 mg/kg body weight. For its 2010 opinion EFSA had reviewed more than 800 new studies including exploratory, non-GLP-studies, and confirmed its earlier position that BPA-based polycarbonate and epoxy food-contact materials are safe for its intended uses. This followed similar EFSA statements in July and October 2008, and was based on its January 2007





release of a comprehensive scientific assessment of BPA conducted by a panel of independent scientific experts. In the 2007 review, based on the then available scientific database, EFSA increased five-fold the safe intake level for BPA (TDI). Extensive data from bio monitoring studies show that typical human exposure to BPA from all sources is approximately 1,000 times below the safe intake level set by

EFSA. Nevertheless, based on a highly precautionary approach the EU Commission decided to restrict the use of BPA in baby bottles as of June 2011 in Europe.

Advisory Committee of the German Society for Toxicology - April 2011

In its review published in Critical Reviews in Toxicology, the Advisory Committee concluded, "BPA exposure represents no noteworthy risk to the health of the human population, including newborns and babies." Furthermore, the Committee found, "To date, more than 5,000 studies on BPA have been published. It is obvious that this should be enough information to resolve the controversy, but nevertheless this has not yet been achieved and those not directly involved in BPA research are usually puzzled by the never-ending and sometimes emotional debate." After reviewing all available evidence and controversial arguments, the Committee concluded that the "current Tolerable Daily Intake (TDI) level for BPA is adequately justified." In its specific evaluation of studies reporting that low doses of BPA cause adverse health effects in laboratory animals, the Committee found that these studies "failed to meet minimal quality criteria for experimental design and statistical analysis" and that

their results were inconsistent with more robust studies on similar endpoints.

World Health Organization (WHO) and Food and Agriculture Organization of the United Nations (FAO) – November 2010

WHO and FAO jointly held an expert meeting to assess the safety of BPA. The meeting included representatives from the European Food Safety Authority (EFSA), Health Canada, the National Institute of Environmental Health Sciences and the U.S. Food and Drug Administration (FDA). The experts concluded that levels of BPA in the human body "are very low, indicating that BPA is not accumulated in the body and is rapidly eliminated." The gathering of global experts concluded that at this time no public health measures are needed.

U.S. Food and Drug Administration (FDA) - January 2010

In an update on BPA, the FDA Deputy Commissioner stated that "if [FDA] thought it was unsafe, we would be taking strong regulatory action." FDA made it clear that BPA "is not proven to harm children or adults...". This is consistent with FDA's earlier draft safety assessment from August 2008, which concluded that overall, "an adequate margin of safety exists for BPA at current levels of exposure from food contact uses, for infants and adults."

More information on BPA is available at the following Web sites:

EFSA:

www.efsa.europa.eu/en/topics/topic/bisphenol.htm

PlasticsEurope: www.bisphenol-A-Europe.org

Or by contacting:

Jasmin Bird
Polycarbonate/Bisphenol-A
Group PlasticsEurope
Email:
jasmin.bird@plasticseurope.org



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