



International Government Agency Findings of BPA Safety in Metal Packaging

United States

On January 15, 2010, the U.S. Food and Drug Administration (FDA) issued an interim update of its review of bisphenol A (BPA), and announced its intention to continue its ongoing scientific research and evaluation of BPA. In a statement consistent with other international regulatory bodies, FDA reiterated its fundamental position that FDA approved uses are safe and that BPA exposure resulting from current approved uses have not been proven to harm children or adults. On the basis of recent studies, however, the agency slightly modified its previous stance to reflect “some” concern with BPA, a position similar to that expressed by the National Toxicology Program (NTP). As a result, the agency is undertaking additional research to answer questions and clarify uncertainties about the risks of BPA.

Prior to the January announcement, FDA had been reviewing emerging literature on BPA on a continuous basis for years. In 2008, FDA issued a report stating that there is a large body of evidence indicating that FDA-regulated products containing BPA 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. In October of 2008, the FDA Science Board recommended that FDA re-examine its conclusion, given a host of new studies, paucity of sample data, and several other issues. The latest review and assessment occurred in response to that recommendation.

In July 2009, an independent regulatory panel in the State of California completed a thorough review of all the scientific evidence on BPA as part of a chemical review process required under Proposition 65, the state’s listing of dangerous chemicals. Following its review, the California Developmental and Reproductive Toxicant Identification Committee (DARTIC) concluded that BPA is not toxic and does not pose a risk to consumers. Committee members determined that BPA is not a developmental or reproductive toxicant, and as a result, the Committee voted unanimously not to include BPA on Proposition 65.

Germany

On October 2, 2009, the German Federal Institute for Risk Assessment (BfR) -- the German equivalent of the U.S. FDA -- reiterated its conclusions that BPA does not pose a health risk to people. In an updated Frequently Asked Questions (FAQ) document posted to its website, BfR responded to several questions about the safety of BPA in plastic baby bottles, stating that “[f]ollowing careful examination of all studies, in particular the studies in the low dose range of bisphenol A, BfR comes to the conclusion in its scientific assessment that the normal use of

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International Government Agency Findings of BPA
Safety in Metal Packaging
March 2010
Page 2

polycarbonate bottles does not lead to a health risk from bisphenol A for infants and small children.”

In evaluating the effects of BPA, the German body concluded that BPA has low acute toxicity, has no carcinogenic effects, and though it is considered an “endocrine disruptor,” the effects are significantly different in humans versus laboratory animals. BfR stated: “In the human body bisphenol A is rapidly converted into a metabolite that no longer has any oestrogenic activity and is eliminated via the kidneys. More recent findings indicate that this constitutes a major difference to rodents which present slower elimination of bisphenol A in experimental studies.”

Australia/New Zealand

In March 2009, Food Standards Australia New Zealand (FSANZ), an independent statutory agency responsible for setting food standards in the two countries, issued an unequivocal statement that BPA does not cause cancer nor do low levels of exposure to BPA pose a significant health risk. FSANZ stated that it has assessed the risk to infants from exposure to BPA and “concurred with the conclusions reached by the US FDA and the [European Food Safety Authority (EFSA)] that the levels of exposure are very low and do not pose a significant health risk.”

Canada

In March 2009, Health Canada released research findings that showed levels of BPA in soft drinks were far below established regulatory levels. The report concludes: “The results of this survey clearly indicate that exposure to BPA through the consumption of canned drink products would be extremely low. The low levels of BPA found in canned drink products available for sale in Canada confirm Health Canada’s previous assessment conclusion that the current dietary exposure to BPA through food packaging uses is not expected to pose a health risk to the general population.”

As recently as July 2009, Health Canada released the results of a series of new studies investigating BPA exposure levels in baby food in glass jars with metal lids, powdered infant formula, and bottled water. The results from these three government studies provided definitive confirmation that baby food products packaged in glass jars with metal lids, powdered infant formula, and bottled water do not pose a health risk. Researchers found that all levels of BPA found in tested products were exceedingly low and all are well below the level established as safe for consumers by the Canadian government. In issuing the final reports, Canadian officials concluded that the assessments of baby food, powdered infant formula, and bottled water all confirmed that current dietary exposure is “not expected to pose a health risk to the general



International Government Agency Findings of BPA
Safety in Metal Packaging
March 2010
Page 3

population, including infants and newborns.” Moreover, exposure to BPA through consumption of bottled water or jarred food would be “extremely low” and far below the migration limit set by Health Canada.

This is a reaffirmation of the statements made in an October 2008 letter sent to the North American Metal Packaging Alliance, Inc. (NAMPA), in which Health Canada stated: “This assessment confirmed earlier results, which indicated that the general public need not be concerned by the potential exposure to BPA regulating from its use in food packaging applications including can lining. Based on all information available to date, it has been concluded that the potential exposure to BPA from food packaging applications is extremely low and does not represent a health risk to consumers.”

Europe

In February 2010, the European Commission’s Institute for Health and Consumer Protection issued a complete risk assessment report on BPA and included a new 2008 addendum to the substance’s original 2003 report. In this latest update, European Union officials concluded that for consumers exposed to BPA, “there is at present no need for further information and/or testing or for risk reduction measures beyond those which are being applied already.” The Commission stated that there are no risks from physico-chemical properties arising from the use of BPA, and as a result there is no need for further information and/or testing and for risk reduction measures beyond those that are being applied already.

In 2006, EFSA reviewed all of the work on BPA, including the additional 200+ studies published after 2002, and concluded that the strength of the scientific database supports a five-fold increase in the TDI (Tolerable Daily Intake). This full TDI recommendation translates to a BPA-specific migration limit of 3 mg/kg/food (3,000 ppb).

In July 2008, the EFSA Panel reaffirmed its 2006 risk assessment findings on BPA. The Panel also concluded that the differences in age-dependent toxicokinetics of BPA in animals and humans would have no implication for its original findings.

Japan

In 2007, Japan’s National Institute of Health and Science, in conjunction with Can Manufacturers Institute of Japan, completed a BPA migration study of the Metal Packaging Specification Standard, with various types of metal packaging in commercial use in the Japanese market. The study, sponsored by the Japanese Ministry of Health, Labor, and Welfare, concluded that BPA levels in current metal packaging in the Japanese market are well below the



International Government Agency Findings of BPA
Safety in Metal Packaging
March 2010
Page 4

lowest regulatory limit in the world of 600 ppb set in the European Union based on the TDI of 0.05 mg/kg bw/day.

United Kingdom

In 2001, the Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment (COT), an independent scientific committee that provides advice to the Food Standards Agency (FSA), the Department of Health, and other government departments and agencies in the United Kingdom, was asked to comment on the health implications of a survey on whether migration from BPA occurs from can coatings. COT carefully reviewed all the data on potential endocrine effects of BPA and acknowledged the uncertainties that exist in the current scientific understanding. Nevertheless, COT concluded that “the levels of BPA identified in canned foods analysed in the FSA survey are unlikely to be of concern to health, and that there is no reason for consumers to change their source of foodstuffs as a result of these findings.”