International Government Agency Findings of BPA Safety in Metal Packaging

United States

Food and Drug Administration

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 the ongoing scientific research and evaluation of bisphenol A (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 has not been proven to harm children or adults in current uses. On the basis of some 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 seeking additional research to answer key 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.

California Developmental and Reproductive Toxicant Identification Committee

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.

Europe

European Food Safety Authority

In September 2010, the European Food Safety Authority (EFSA) issued its latest review of the scientific research on BPA concluding that, based on current scientific evidence, there is no

reason to revise the current recommended human exposure level for BPA. Specifically, the members of this renowned international government authority on food safety, in a majority opinion, stated clearly that they "could not identify any new evidence which would lead them to revise the current Tolerable Daily Intake for BPA of 0.05 mg/kg body weight" as previously established by EFSA in 2006.

Following a "detailed and comprehensive review" of recent scientific literature and studies, EFSA also stated "the data currently available do not provide convincing evidence of neurobehavioral toxicity of BPA." The panel specifically considered recent neurotoxicity studies, including the research conducted by Stump *et al.*, and found the Stump data to be "inconclusive with respect to learning and memory and of limited value for the risk assessment of BPA." Based on the 2010 literature review, EFSA "…does not consider the currently available data as convincing evidence that BPA has any adverse effects on aspects of behaviour, such as learning and memory."

This latest assessment is consistent with EFSA's past statements that the current Tolerable Daily Intake (TDI) provides a sufficient margin of safety for the protection of infants, children, or adults. 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.

European Commission's Institute for Health and Consumer Protection

In February 2010, the European Commission's Institute for Health and Consumer Protection issued a complete risk assessment report for BPA and included a new 2008 addendum to the substance's original 2003 report. In this latest update, EU 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.

Germany

In July 2010, the German Federal Institute for Risk Assessment (BfR) -- the German equivalent of the U.S. FDA -- released its latest assessment of two new studies that sought to determine effects of BPA on neurological and behavioral development in test animals exposed to the chemical. Following its review of the two studies (Stump *et al*. and Ryan), the BfR concluded that the results "do not substantiate the concerns for a specific toxic potential of bisphenol A adverse to neurological and behavioural development."

This latest action by the BfR is consistent with its previous assessments of BPA, released on October 2, 2009, when the agency 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 "Following 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 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 EFSA that the levels of exposure are very low and do not pose a significant health risk."

Canada

Despite advising Canadian consumers that BPA does not pose a human health risk, the Canadian government took action in October 2010 to add BPA to its list of toxic substances, under the Canadian Environmental Protection Act (CEPA). The decision was based on findings by the Canadian government of potential human health and environmental effects, stemming from concerns with effects to aquatic environment and previously cited uncertainties raised in some studies relating to the potential effects of low levels of BPA exposure on infants and young children. There are no regulations associated with the CEPA listing, aside from providing Canada the ability to consider regulatory options that may or may not involve food packaging at some point in the future.

The CEPA listing of BPA does not negate the perspective offered by Health Canada regarding use of BPA in food contact applications. A government fact sheet advises Canadian consumers that they can continue to use polycarbonate water bottles and consume canned foods and

beverages because exposure levels are very low. The Health Canada Food Directorate specifically states "the current dietary exposure to BPA through food packaging uses is not expected to pose a health risk to the general population, including newborns and infants."

The government's reiteration of the safety of BPA for use in food packaging is supported by several recent studies conducted by Health 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."

In 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 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.

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 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.