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Report Name: European Food Safety Authority Issues Updated Opinion on BPA

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Report Highlights:

Bisphenol A (BPA) is a chemical used in the manufacture of polycarbonate plastics and epoxy resins. On April 19, 2023, the European Food Safety Authority (EFSA) issued an updated scientific opinion that deemed BPA a consumer health risk. The European Commission is now evaluating EFSA's conclusions. A potential EU-wide BPA ban would cause significant trade disruptions for the U.S. food industry.

Executive Summary:

Bisphenol A (BPA) is a ubiquitous chemical in the United States due to its usage in the manufacture of widely used polycarbonate plastics and epoxy resins in food industry applications. On April 19, 2023, the European Food Safety Authority (EFSA) issued an updated scientific opinion that the tolerable daily intake (TDI) of BPA is 0.2 nanograms per kilogram of body weight per day (ng/kg/day). While EFSA deems the current average consumer exposure to BPA a health risk, the U.S. Food and Drug Administration (FDA) maintains its rating of safety for BPA at the current levels occurring in foods. More specifically and based on FDA's safety review of scientific evidence, the available information continues to support the safety of BPA for the currently approved uses in food containers and packaging. Several European Union (EU) member states have already restricted BPA, and a potential EU-wide ban on the chemical would present a major challenge for U.S. food exporters.

Background:

BPA is a chemical used in the manufacture of polycarbonate plastics and epoxy resins. Polycarbonate plastics are utilized in food packaging applications due to their strength and visual clarity, and epoxy resins are used as coatings for metal food cans to prevent chemical reactions and prolong product shelf life. BPA is ubiquitous in the U.S. food supply because of its long-term and widespread usage, and consumer concerns about its safety persist. However, people are exposed to low levels of BPA because very small amounts may migrate from the food packaging into foods or beverages.

EFSA conducted its first risk assessment of BPA in November 2006 and set a TDI of 50 micrograms per kilogram of body weight per day (µg/kg/day). After the publication of new research, EFSA reevaluated BPA and set a temporary TDI of 4 µg/kg/day in January 2015, but maintained that it was not a health risk at levels that consumers were typically exposed to. EFSA adopted a new protocol for assessing scientific literature on BPA toxicity in December 2017, and on April 19, 2023, EFSA set a TDI for BPA at 0.2 ng/kg/day, which is 20,000 times lower than the temporary TDI set in 2015. EFSA believes that the average level of BPA exposure is a present health risk to consumers, specifically in regards to immune system function.

BPA Bans:

Several EU member states banned or restricted BPA before the European Commission (EC). In 2013, Belgium outlawed packaging for food and food utensils containing BPA for children under three, and France passed a similar regulation that prohibited the usage of BPA on food contact surfaces in baby food. France would later expand that regulation to prohibit using BPA in all food contact applications in 2015.

In 2011, the European Commission prohibited the use of BPA in the manufacture of polycarbonate infant feeding bottles. In 2018, the European Commission banned BPA varnishes and coatings in plastic bottles and packaging containing food for children and infants under three years through the passage of Commission Regulation (EU) 2018/213. The EC also established a Specific Migration Limit of 0.05 mg

of BPA per kg of food (mg/kg) for plastic food contact materials and articles based on EFSA's t-TDI from 2015. In 2022, Germany proposed a restriction on BPA and other bisphenols to the European Chemicals Agency (ECHA) of the EU due to environmental health concerns regarding its pollution of surface waters. As far as consumer safety, the German Federal Institute for Risk Assessment (BfR) disagrees with EFSA's newest TDI, but it calculated a TDI of 200 ng/kg/day which is still 20 times lower than the 2015 TDI. This indicates that BfR also reevaluated BPA as less safe than previously thought, but just not to the extent of EFSA's reevaluation.

FDA raised concerns with EFSA's opinion on the safety of BPA and its TDI; FDA's stance on BPA is that it is safe at levels commonly found in food. FDA's National Center for Toxicological Research found no evidence to suggest that levels of BPA found in food are a threat to human health, and FDA food additive regulations were amended in July 2012 and July 2013 to no longer provide for the use of polycarbonate resins in products such as baby bottles and infant formula packaging. This amendment was not based on safety, but because polycarbonate resins were no longer used in the manufacturing of these products.

In February 2022, FDA issued a public comment on EFSA's draft opinion released two months prior. FDA's comments notably included concerns that EFSA deviated from the internationally accepted study, "Principles and methods for the risk assessment of chemicals in food (Environmental Health Criteria (EHC) 240)," which was published by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) and the Joint FAO/WHO Meeting on Pesticide Residues (JMPR). More specifically, in its public comment, FDA raised concerns on the biological plausibility of the EFSA approach (for example by not addressing contradictory data regarding human health impacts in their literature review), the lack of consideration for the control of laboratory contamination by endogenous BPA in evaluating the merits of the studies used in this assessment, and offered too brief of an opportunity for interested parties to fully consider and provide meaningful input on such a complex topic.

Outlook:

A BPA ban for the European Union would present a major challenge for the U.S. food industry. BPA is a high production volume chemical, and it is prevalent in almost all U.S. industries. Most human exposure is from food packaging, but this medium only accounts for 5% of all BPA used in the United States. An EU-wide ban would cause significant trade disruptions for U.S. food exporters and shake consumer confidence in the safety of BPA usage in U.S. food products domestically. Currently, ECHA is developing an opinion on Germany's proposal to restrict BPA after reviewing public comments on two Calls for Evidence to EU and third-country stakeholders. The European Commission is reviewing ECHA's scientific opinion and drafting legislation to ban the use of BPA in food contact materials by the first quarter of 2024.

Attachments:

No Attachments.