



FDA Research Answers Key Questions About BPA Safety

About BPA

Bisphenol A (BPA) is used to make polycarbonate plastic and epoxy resins that are essential for many consumer and industrial products. Included are many applications important to public health and food safety. BPA is one of the most thoroughly tested chemicals used today and has a safety track record of more than 50 years.

Government and scientific bodies worldwide have weighed the scientific evidence and concluded that BPA is safe as used. Nevertheless, BPA has been the subject of controversy for many years because of claims that it has the potential to cause adverse health effects. Such claims led the U.S. Food and Drug Administration (FDA) and the U.S. National Toxicology Program (NTP) to fund and conduct an in-depth research program on BPA. So far, the results of the research provide strong support for the safety of BPA.

Q: Why is BPA Controversial?

A: It's well known that BPA is weakly estrogenic, but the health significance of that biological characteristic is not clear. Controversy about the potential for BPA to cause adverse health effects goes back to the late 1990s, when several small-scale studies on laboratory animals reported effects from low doses of BPA.

Additional small-scale studies further contributed to the controversy around BPA, claiming a wide array of health effects. In contrast, several large-scale studies using globally accepted testing methods consistently could not replicate the low dose findings, yet the controversy continued.

Q: Why did FDA and NTP Design a BPA Research Program?

A: Both polycarbonate plastic and epoxy resins are regulated by FDA for food contact applications and polycarbonate is widely used in FDA-regulated medical devices. Since regulation of these materials and products is based on safety, FDA chose to resolve the scientific controversy. Seeking to provide the soundest basis for its regulatory decisions, FDA, in conjunction with the NTP, designed a robust research program to answer key scientific questions and resolve uncertainties about the safety of BPA.

Q: Where is the Research Being Conducted?

A: Research on laboratory animals is being conducted at FDA's National Center for Toxicological Research (NCTR) in Arkansas. Studies on human volunteers are being conducted at NTP's clinical facility in North Carolina.

Q: What Do the Results Say About BPA?

A: Overall, the results *"both support and extend the conclusion from the U.S. Food and Drug Administration that BPA is safe as currently used,"* said Daniel Doerge, one of the key FDA scientists conducting the studies at NCTR, in a recent interview. The series of studies build on one another to provide a comprehensive understanding of BPA.

The potential for a chemical to cause toxicity is substantially impacted by its pharmacokinetic properties, which describe how a substance is absorbed into the body, how it's distributed and in what form (e.g., parent compound or metabolites), how long it lasts in the body, and how it's eliminated. Building on earlier

pharmacokinetic studies, FDA has conducted a set of in-depth studies in laboratory animals and NTP has conducted a study on human volunteers to confirm and refine existing knowledge, as well as to examine several important and contentious issues.

In general, these studies show that BPA is rapidly metabolized and eliminated from the body, and does not accumulate or persist in the body. This efficient metabolic process occurs not only in adults, but also in pregnant animals, neonates and the fetus. Taken together, these results predict that typical human exposure to BPA is unlikely to cause health effects at any age.

In 2015, FDA published the results of what may be the largest-scale toxicity study ever conducted on BPA. In this study, rats were exposed to BPA during gestation and continuing through 90 days after birth, which covers all developmental stages. The study examined seven low doses of BPA, which were the primary focus of the study. Also included were two high doses of BPA and two doses of a known estrogen.

Notably, no effects were found at any of the seven low doses, which are of most importance for evaluating the safety of BPA. These results confirm the prediction of low toxicity based on pharmacokinetic data. The effects observed with the high doses of BPA and the known estrogen were expected and served to validate the study by confirming that the test animals were sensitive to estrogenic effects and responsive to BPA.

Q: Has FDA Completed Its Research Program?

A: To date, FDA has published 20 papers in the peer-reviewed scientific literature, but there is more to come. In particular, FDA is now conducting a chronic toxicity study in rats. As in the subchronic study, dosing started during gestation but will continue in the offspring for two years. NTP is conducting additional pharmacokinetic studies on human volunteers to determine how BPA is processed in the human body after dermal exposure. These studies will provide important information to bring closure to the ongoing controversy about the safety of BPA.

Q: What is FDA's Current Perspective on BPA?

A: In February 2016 FDA updated its perspective on the safety of BPA. As part of the update, FDA unambiguously answered the question "Is BPA safe?" with a clear answer: *"Yes. Based on FDA's ongoing 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."*

Q: What Have Other Government Bodies Said About BPA?

A: Many government bodies have evaluated the safety of BPA, in particular in products that contact food. In January 2015, the European Food Safety Authority (EFSA) released a final report on its full re-evaluation of BPA. Based on conservative assessments of hazard and exposure, EFSA concluded "BPA poses no health risk to consumers of any age group (including unborn children, infants and adolescents) at current exposure levels."

Along with FDA and EFSA, other government bodies around the world, including the German Federal Institute for Risk Assessment, South Korean Ministry of Food and Drug Safety, Health Canada, Food Standards Australia New Zealand and the Japanese National Institute of Advanced Industrial Science and Technology, have reached similar conclusions.

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