Listening to the Science Like FDA Does

Steven Hentges, Ph.D
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As its name implies, one of the responsibilities of the U.S. Food and Drug Administration (FDA) is "ensuring the safety of our nation's food supply." Within FDA's purview for this important responsibility are ingredients that are intentionally added to foods (e.g., the ingredients shown on packaged food labels) as well as materials such as packaging that contact food.

All food ingredients must meet FDA's high standards for safety and quite a bit of science goes into evaluating the safety of food ingredients. In a recent state-of-the-science paper published in the journal *Toxicology and Applied Pharmacology*, a group of FDA scientists discuss some of the cutting-edge tools that they use in their safety evaluations.

In particular, the paper discusses the use of pharmacokinetic methods, which refers to a field of science that describes how a substance is absorbed into the body, how it is distributed and in what form, how long it lasts in the body, and how it is eliminated. This type of information is important because it helps us to understand whether a substance could be harmful and under what circumstances.

One of the case studies discussed in the paper is BPA, which is of interest to FDA because it is used to make certain plastics and resins that may be used in products that contact food. Starting about 10 years ago, FDA scientists designed a comprehensive set of studies aimed at resolving uncertainties about the safety of BPA. Included are a series of pharmacokinetic studies that now play a key role in FDA's evaluation of the safety of BPA.

In general, these studies show that BPA is efficiently converted to a biologically inactive metabolite as it is absorbed into the body from the intestine. The metabolite is then rapidly eliminated from the body in urine with a half-life of only a few hours, and BPA does not accumulate or persist in the body.

The efficient process to metabolize and eliminate BPA occurs not only in adults, but also during developmental life stages including pregnancy, infancy and childhood. In addition, the findings from studies on laboratory animals have been confirmed in several clinical studies on adult human volunteers. Based on the way that BPA is processed in the body, these results predict that exposure to BPA at real-life levels is unlikely to cause health effects.

That prediction has now been thoroughly tested in the capstone study of FDA's research program on BPA. Known by the acronym CLARITY, the study involved lifetime exposure of laboratory animals to BPA.

The scope and magnitude of the study are unprecedented for BPA and the results indicate that BPA has very little potential to cause health effects even when people are exposed to it throughout their lives. As stated by the study's Principal Investigator, "*BPA did not elicit clear, biologically plausible, adverse effects*" at any dose even remotely close to typical human exposure levels.

The results of the CLARITY study, which was recently published in the scientific literature, confirm the prediction from pharmacokinetic studies that BPA is unlikely to cause health effects at real-life exposure levels. Taken together, the comprehensive set of data from FDA's research program provides strong support for the conclusion of FDA's safety evaluation of BPA. As succinctly stated on FDA's website: "Is BPA safe? Yes."