Was FDA's Recent Statement on BPA Premature?



<u>Steven Hentges, Ph.D</u> Monday, March 26, 2018 <u>SAFETY</u>

A few weeks ago the U.S. National Toxicology Program (NTP) released the results of the largest study ever conducted on bisphenol A (<u>BPA</u>). The CLARITY Core study was conducted by senior scientists with the U.S. Food and Drug Administration (FDA) in their own laboratory in Arkansas known as the National Center for Toxicological Research (NCTR).

More important than size is the unprecedented scope of the study for this substance. The laboratory animals were exposed to BPA from the beginning of pregnancy through the full lifetime of the offspring. A wide range of BPA doses was tested, ranging from a low dose near actual human exposure levels to a high dose approximately 250,000 times above typical human exposure. The world has never seen a study on BPA of this scope and magnitude.

The results indicate that BPA has very little potential to cause health effects even when we are exposed to it throughout our lives. As stated in the conclusion of the <u>study report</u>, *"BPA produced minimal effects that were distinguishable above background."*

Considering that BPA has been a controversial topic for many years, including public concerns about the safety of food that contains traces of BPA, it would be inexcusable if FDA did not communicate with the public on what the study means. As part of its <u>mission</u>, FDA is "*responsible for protecting the public health by … ensuring the safety of our nation's food supply*."

"...our initial review supports our determination that currently authorized uses of BPA continue to be safe for consumers."



And, very appropriately, FDA did communicate to the public. In conjunction with release of the NTP report, FDA released a <u>statement</u> that provided its current perspective on the safety of BPA. With the new information from the CLARITY Core study in hand, FDA stated: "*our initial review supports our determination that currently authorized uses of BPA continue to be safe for consumers.*"

Importantly, the statement also included additional context on the CLARITY study and a short summary of FDA's extensive activity related to BPA over many years, including both scientific review and research. Nevertheless, <u>some have criticized</u> FDA as having spoken prematurely, saying that FDA should have waited for the results of additional studies.

Taken out of context, FDA's statement could seem premature. But there is context, quite a bit of it in fact, that gives FDA a clear basis to make a timely statement now. Not only does FDA have a strong scientific basis to support its statement, its mission gives it a mandate to inform its stakeholders – the U.S. public – on matters related to food safety.

The recent FDA statement also included the context that this was the agency's initial review of the CLARITY Core study and that FDA would fully participate in the upcoming peer review of the study. And, as noted on its <u>website</u>, "*FDA continues to review the available information and studies on BPA, including the newly released draft NTP report (CLARITY-BPA), and will update its assessment of BPA and take additional action if warranted.*" As it should be, FDA's actions now and in the future are based on science, not speculation.