Was FDA's Recent Statement On BPA Premature?

BY STEVE HENTGES | MARCH 26TH 2018 11:02 AM

A few weeks ago the U.S. National Toxicology Program (NTP) released the results of the largest study ever conducted on bisphenol A (BPA). 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 study report, "*BPA produced minimal effects that were distinguishable above background*."

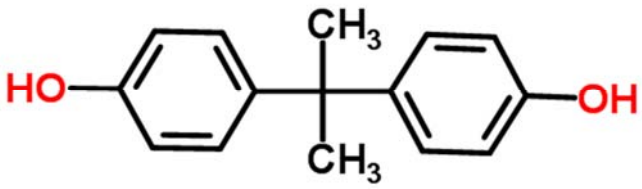
Considering that BPA has been a controversial topic for many years, including public concerns about the safety of food that contains traces of BPA, it would be inexcusable if FDA did not communicate with the public on what the study means. As part of its mission, FDA is "*responsible for protecting the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

And, very appropriately, FDA did communicate to the public. In conjunction with release of the NTP report, FDA released a statement 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, some have

criticized 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 website, "*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.

What Data Was FDA's Statement Based On?

As noted at the very beginning of FDA's recent statement, "*FDA looks at all available scientific evidence when reviewing the safety of foods and food*

packaging" and "*[w]e base our regulatory decisions on robust science*." That's not just empty talk since there is ample documentation of FDA's intensive review over many years of the safety of BPA.

Its previous updated safety assessment from June 2014 is readily available on the FDA website along with a series of lengthy reports that document FDA's detailed review of numerous studies that are potentially relevant for its assessment. Rather than being premature, FDA's recent statement builds on its previous reviews to incorporate significant new information from the CLARITY Core study.

And FDA has done far more than just review scientific evidence. As further noted in FDA's statement, "*we not only continue to evaluate available data – but also conduct FDA research on the safety of the use of BPA for food packaging*."

Over the last 5+ years, FDA scientists have generated some of the most important scientific data on BPA, with the CLARITY Core study being only the most recent of a series of in-depth studies. For example, from studies in rodents and non-human primates, we know that BPA is deactivated and quickly eliminated from the body after exposure. From this data it can be predicted that BPA is not likely to be harmful, which was resoundingly confirmed in the CLARITY Core study.

Along with these important contributions from FDA, scientists from NTP and the U.S. Centers for Disease Control and Prevention (CDC) have also conducted studies that provide critical support for FDA's safety assessment. In particular, NTP's study on human volunteers confirmed the rapid elimination of BPA from the human body. A series of six biennial studies (so far) from CDC confirm that human exposure to BPA in the U.S. population is extremely low.

What Data Is Yet To Come?

The CLARITY program (**C**onsortium **L**inking **A**cademic and **R**egulatory **I**nsights on BPA **T**oxicit**y**) was designed by a consortium that consists of FDA, NTP, the National Institute of Environmental Health Sciences (NIEHS) and thirteen academic scientists. The CLARITY Core study, which is the principal part of the program, was funded by NTP and conducted by FDA scientists at NCTR. The academic scientists not only participated in the study design, but each received funding from NIEHS to conduct additional measurements on animals or biological samples that were taken

from the Core study. The funding for the academic studies has all been provided and the animals or biological samples were all provided 4-5 years ago.

As noted by Dr. John Bucher of NTP: "*It would have been nice if we would have been able to have all of the grantee information available at the same time as the core study information, to be evaluated together. The process wasn't optimal*." That begs the question why the grantee information is not available.

Up to the present time, only four of the thirteen academic scientists have published their results in the scientific literature, with the first paper published in 2015. Similar to the results of the CLARITY Core study itself, the published results collectively show minimal effects above background.

The other nine academic scientists have not yet published their results, even though they have received their funding and all animals or biological samples for their research were provided 4-5 years ago. This does not seem to be matter of a suboptimal process.

Ironically, some of the scientists who have not published their results are ones who have criticized FDA for a premature statement. Regardless of whether the academic scientists publish their results or not, all raw data from their research is now scheduled to become publicly available in August 2018, at which time it can be evaluated by others.

The bottom line is that FDA's recent statement on BPA is neither premature nor unfounded. It was simply transparent and responsible. The research and analysis conducted by FDA scientists, along with supporting data generated by other federal government scientists, is truly monumental and fully supports FDA's perspective on the safety of BPA. Furthermore, the recent statement is timely and fully within FDA's public health mission regarding the safety of our food supply.