When Did BPA Stop Being Toxic?

BY STEVE HENTGES | MARCH 1ST 2018 04:55 AM

If you've ever heard of the chemical bisphenol A (BPA), and who hasn't, you probably have the distinct impression that it's highly toxic. After a steady drumbeat of more than 15 years suggesting that BPA is linked to virtually every health effect known to man, how could you think any differently?

There are literally thousands of studies on BPA in the scientific literature, many of which report biological effects of one sort or another. But separate from the sheer volume of data, what the data mean is the key question. The consensus of government bodies worldwide, based on their independent evaluations of the data, has been that BPA is safe for use. Nevertheless the conventional wisdom is the opposite: that BPA is dangerous.

In light of that conventional wisdom, you might be puzzled by recent headlines such as "BPA unlikely to be harmful, federal study shows" and "Plastic Additive BPA Not Much Of A Threat, Government Study Finds." Clearly there is some sort of a disconnect between the recent headlines and the conventional wisdom.

Unless you've been paying very close attention to the scientific literature, you probably didn't know that U.S. government scientists have been conducting an in-depth research program on BPA for more than 10 years. This multi-million dollar sustained effort was aimed at resolving any remaining uncertainties about the safety of BPA.

What led to these headlines is that the U.S. National Toxicology Program (NTP) just released the findings of the capstone study of that research program. Known as the CLARITY Core study, it's the largest study ever conducted on BPA. The study successfully resolved uncertainties as intended 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 in the conclusion of the study report, "*BPA produced minimal effects that were distinguishable from background*." In a statement released in conjunction with the report, Dr. Steven Ostroff, Deputy Commissioner for Foods and Veterinary Medicine at the U.S. Food and Drug Administration (FDA) noted: "*our initial review*

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

What's All the Controversy Been About?

It's been known for many decades that BPA is weakly estrogenic. By itself that biological property doesn't mean much and it didn't attract much interest until about 20 years ago. From that point forward scientists worldwide have been fascinated by BPA and have conducted thousands of studies of every type imaginable. Of particular interest is the potential for BPA to cause health effects at low levels of exposure, for example even in the very low dose range of typical consumer exposure.

The conclusions of scientific assessments by government bodies worldwide consistently support the safety of BPA. The most straightforward conclusion is the one from FDA, which is summarized with their Q&A: "Is BPA safe? Yes." To address residual controversy, FDA worked in conjunction with other U.S. federal government agencies to design a research program that would resolve any remaining uncertainties.

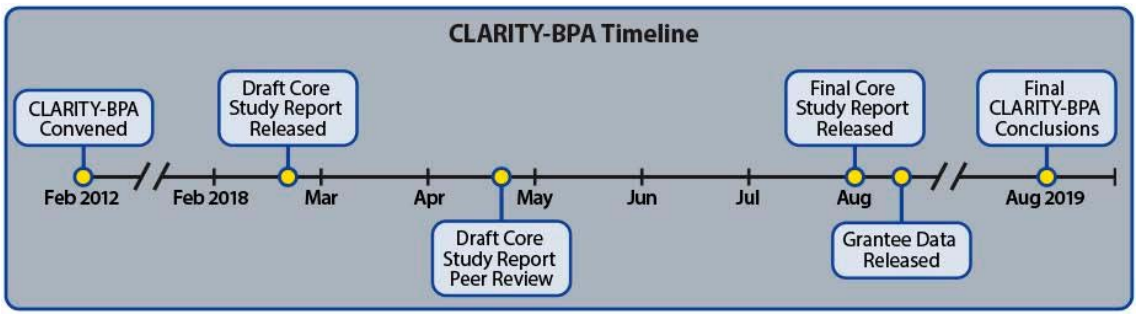
How the U.S. Government Set Out to Resolve the Controversy

To comprehensively understand the safety of BPA, several complementary types of scientific data are necessary. In particular, we need to understand levels of exposure, what happens to BPA when it enters the body, and the potential for actual exposures to cause health effects.

To fill the first need, the U.S. Centers for Disease Control and Prevention (CDC) has conducted biennial biomonitoring studies of the U.S. population since 2003 to monitor consumer exposure to BPA (and many other substances). From these studies we know that human exposure to BPA is quite low, typically below 0.1 micrograms BPA/kilogram bodyweight/day.

From a comprehensive set of pharmacokinetic studies conducted by FDA and NTP scientists on rodents, non-human primates and human volunteers, we know that BPA is quickly eliminated from the body after exposure. Even more importantly, as BPA is absorbed into the body after oral exposure it is efficiently converted into a

metabolite, which is the biologically inactive form of BPA that actually enters the body and is then quickly eliminated in urine.



Based on the pharmacokinetic and exposure data, we can predict that BPA is unlikely to cause health effects at typical consumer exposure levels. The results of the CLARITY Core study, which was conducted by FDA senior scientists in FDA's research laboratory, resoundingly confirm that prediction.

The scope and magnitude of the CLARITY Core study are unprecedented, but size alone is not what makes the results so compelling. The laboratory animals in the CLARITY Core study were exposed to BPA from pregnancy, through early-life development, and continuing through their entire lifetime. The exposure levels ranged from very low to an upper level that is more than 250,000 higher than typical consumer exposure levels.

Exposure occurred during all developmental stages of life, which are likely to be the most sensitive life stages. Potential health effects were monitored throughout the animals' lifetimes, which ensured that any delayed effects from early-life exposure would be found.

Because of this comprehensive and rigorous study design, FDA can confidently reaffirm their perspective that "*currently authorized uses of BPA continue to be safe for con*sumers." The perspective of FDA is fully supported by solid scientific evidence, just as it should be.

What's Next?

The study will next undergo peer-review by a panel of experts selected by NTP. That will actually be the second peer-review since the pathology results have already been peer-reviewed through an earlier NTP process known as a Pathology

Working Group. Comments from that process have already been addressed in the report that was recently released.

The upcoming peer-review process includes a public meeting scheduled for April 26, after which the NTP draft report will be released in final form with responses to any peer-review comments. The study will also be published in the scientific literature, which will add a third layer of peer-review as part of the normal publication process.

Without a doubt, the results of the CLARITY Core study will be of high interest to government bodies worldwide that have assessed the safety of BPA. Similar to the perspective of FDA, we can anticipate that other government bodies will also rely on the CLARITY Core study finding to conclude, again, that BPA is safe.

So going back to the top, when exactly did BPA stop being toxic? Based on the collective results from the CLARITY Core study and the in-depth U.S. government research program, that's a trick question. It never was toxic.