New U.S. Government Research on BPA

The CLARITY Study

CLARITY is a multipronged U.S. federal government research program designed to assess the potential health effects of long-term exposure to bisphenol A (BPA.) The key element of the program -- the Core Study -- is the largest study every conducted on BPA and has been undertaken by expert scientists at a U.S. Food and Drug Administration (FDA) laboratory. The results of the Core Study were released on Sept. 28, 2018 in a final report from the U.S. National Toxicology Program (NTP).

What are the key results of the CLARITY study?

The study's Principal Investigator stated in a recent webinar at which the study results were discussed in detail that, *"BPA did not elicit clear, biologically plausible, adverse effects ..."* at levels even remotely close to typical consumer exposure levels.

The significance of this result for consumers cannot be overstated. In a statement released in conjunction with the study's draft report, Dr. Stephen Ostroff, Deputy Commissioner for Foods and Veterinary Medicine at the U.S. Food and Drug Administration (FDA) said: *"our initial review supports our determination that currently authorized uses of BPA continue to be safe for consumers."*

Importantly, the draft report was peer-reviewed by a panel of independent scientists convened by NTP. After a thorough review of the draft report, the panel discussed their findings in a public meeting and issued a report with their recommendations. In general, the panel endorsed the design and execution of the study as well as FDA's interpretation of the results. Their recommendations to improve the report have now been incorporated into the final report.

What are the origins of CLARITY?

CLARITY stands for the **C**onsortium **L**inking **A**cademic and **R**egulatory **I**nsights on BPA **T**oxicit**y**. Planning for CLARITY began in 2010 as a collaborative effort involving three U.S. government agencies including FDA, the National Toxicology Program (NTP) and the National Institute of Environmental Health Sciences (NIEHS).

More information on BPA is available at the following Web sites:

FDA:
fda.gov/NewsEvents/PublicHealthFocus

Health Canada:
chemicalsubstanceschimiques.gc.ca/fact-fait/bisphenol-a-eng.php

EFSA:
efsa.europa.eu/en/topics/topic/bisphenol.htm

ACC:
FactsAboutBPA.org

Or by contacting:

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The CLARITY program builds upon the work of earlier U.S. federal government studies that collectively provide a clear understanding of the potential for BPA to cause health effects. In recent years, more than 20 significant studies by U.S. government researchers have been published in the peer-reviewed scientific literature.

The findings from these preceding studies tell us that consumer **exposure to BPA is extremely low** and that **BPA is rapidly eliminated** from the body. Based on these results, it can be predicted that BPA is unlikely to cause health effects. The results of the CLARITY Core Study now confirm that there is **no risk of health effects** from BPA at typical human exposure levels, even if people are exposed to BPA throughout their lives. Results from the CLARITY program have substantially resolved uncertainties about the safety of BPA.

What did CLARITY researchers study?

The CLARITY Core Study expanded on an earlier FDA-conducted study that found no health effects from BPA at typical consumer exposure levels. This prior study assessed the potential for BPA exposure to cause health effects in the offspring of rats exposed to BPA in the womb and through the early developmental stages of life after birth.

The CLARITY Core Study, with unprecedented scope and magnitude for BPA, further assessed the potential for BPA to cause health effects over a longer time-period of exposure. Rats began exposure to BPA while in the womb, and exposure to BPA continued over their entire lifetime after birth.

In addition, the CLARITY program has funded research at 14 academic centers to further explore the potential for BPA to affect biological processes in the body.

Who conducted the CLARITY Core Study?

The CLARITY Core Study was conducted by FDA researchers at FDA's National Center for Toxicological Research. The methodology for conducting the CLARITY Core Study is consistent with established testing guidelines and the study was conducted according to Good Laboratory Practice requirements to ensure study quality.

What happens next?

It is expected that the CLARITY Core Study will also be published in the peer-reviewed scientific literature, most likely in early 2019. In addition, NTP will work to integrate all findings from the CLARITY Core Study and the academic studies. A report on this activity is expected in 2019.