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 February 23 in the form of a draft report, which was accompanied by a statement from FDA.

What are the key results of the CLARITY study?

The overall conclusion of the study states "BPA produced minimal effects that were distinguishable from background in this study." These results are consistent with previous studies from the CLARITY program, which indicate that BPA is unlikely to cause health effects at the very low levels to which people are exposed.

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 are the origins of CLARITY?

CLARITY stands for the **C**onsortium **L**inking **A**cademic and **R**egulatory **I**nsights on BPA **T**oxicity. 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).

The CLARITY program builds upon the work of earlier U.S. federal government studies that collectively will 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.

To date, the findings from these studies tell us that consumer **exposure to BPA is extremely low, BPA is rapidly eliminated** from the body, and that there is **no risk of health effects** from BPA at typical human exposure levels. Results from the CLARITY program are expected to resolve remaining uncertainties about the safety of BPA.

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:

Steven G. Hentges, Ph.D.
Polycarbonate/BPA Global Group
American Chemistry Council

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What are CLARITY researchers studying?

The CLARITY Core Study builds on an early 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 will likewise assess the potential for BPA to cause health effects, but 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 13 academic centers to further explore potential health effects from BPA.

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?

The draft report will next be peer-reviewed by an expert panel that has been organized by the U.S. National Toxicology Program (NTP), which is the government entity that funded the study. The peer-review process will include a public meeting of the peer-review panel at which the panel will discuss its findings.

It is expected that the report will then be finalized and the study will also be published in the scientific literature. The timeline for these steps is not yet known.