

New report on important chemical released by US-authorities

Safety of BPA confirmed in largest-ever study

The largest-ever study on Bisphenol A (BPA) confirmed according to US authorities that BPA is safe for consumers. A draft report of the comprehensive survey was officially published on 23 February 2018. European plastics manufacturers using BPA welcomed the publication. BPA is a key component for high performance plastics and coatings materials used also in food contact applications.

The so-called CLARITY-BPA core study is the capstone of a multi-year in-depth research program conducted by the U.S. Food and Drug Administration (FDA). In a statement released in conjunction with the report, Dr. Steven Ostroff, FDA Deputy Commissioner for Foods and Veterinary Medicine, noted, "our initial review supports our determination that currently authorized uses of BPA continue to be safe for consumers."

"The results of the CLARITY-BPA core study once again demonstrate that BPA is safe at the very low levels to which people are typically exposed", added Jasmin Bird, spokesperson of the Polycarbonate/BPA-group of PlasticsEurope. "This largest ever study conducted on the topic indicates that BPA has very little potential to cause health effects even when people are exposed to it throughout their lives," she said.

Years of research work

The report issued by the U.S. National Toxicological Program (NTP) presents the results of a multi-million dollar study conducted for more than five years by scientists at FDA's National Center for Toxicological Research with funding from NTP¹. It looked at the effects of different doses of BPA evaluating chronic and early life exposure in two different groups of rodents. In the chronic part, laboratory animals were exposed to BPA from pregnancy, through early-life development, and continuing through their entire lifetime. The doses ranged from low doses that would be comparable to typical human exposures, to doses that vastly exceed human exposures. A variety of endpoints were evaluated. The CLARITY-BPA core study confirms the absence of health effects at typical human exposure levels.

After peer-review process the report will be finalized, and the results are expected to be published in the scientific literature.

The European Commission has mandated the European Food Safety Authority (EFSA) to reassess BPA also in the light of the CLARITY-BPA core study. EFSA expects the outcome of their assessment to become available at the end of 2019 at the earliest.

¹The National Toxicology Program (NTP), National Institute of Environmental Health Sciences (NIEHS), National Center for Toxicological Research (NCTR)

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Polycarbonate/Bisphenol A group (PC/BPA)
Epoxy Resin Committee (ERC)

NTP CLARITY-BPA core study report

https://ntp.niehs.nih.gov/ntp/about_ntp/rrprp/2018/april/rr09peerdraft.pdf

FDA statement

<https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm598100.htm>

EFSA protocol information

<http://www.efsa.europa.eu/en/press/news/171214>

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Background info on the CLARITY-BPA study

(see also: <http://www.factsaboutbpa.org/scientific-assessments/clarity-study>)

What is CLARITY-BPA?

CLARITY stands for **C**onsortium **L**inking **A**cademic and **R**egulatory **I**nsights on **B**PA **T**oxicity. It is a multi-generation, large-scale US study program on BPA, initiated by the US Food and Drug Administration (FDA) and conducted by a consortium of US government scientists (from National Toxicology Program (NTP), National Institute of Environmental Health Sciences (NIEHS), National Center for Toxicological Research (NCTR) and several specialized academic research groups. Goal of CLARITY-BPA is to investigate remaining uncertainties related to BPA by determining if endpoints reported to be affected by BPA in hypothesis-driven studies are reproducible when assessed under controlled conditions of a guideline-compliant study.

What does it consist of?

The CLARITY-BPA study was funded by NTP (National Toxicology Program) and conducted in the FDA laboratory (NCTR, National Center for Toxicological Research). The 2-year core chronic study contains the essential elements of a guideline-compliant study, such as standard protocols and endpoints typically considered by regulatory agencies in hazard identification and risk assessment. The inlife phase of the core chronic study was completed early 2015.

Along with the chronic study conducted in the FDA laboratory, 13 academic scientists received funding to conduct additional tests on animals or biological samples from the chronic study. So far, four of those scientists have published their findings, the timing for publication of results from the other 9 academic studies is unknown.

What is the timing?

Publication of the draft technical report of the core chronic study is anticipated for end of February. The draft technical report will be peer-reviewed by an expert panel selected by NTP. Included in the peer-review process is a public meeting of the peer-review panel, currently expected end of April. The peer-review panel will also consider any public comments submitted on the draft report. After public and peer-review panel comments are addressed, the NTP report will be finalized. Eventually the results will be published in the scientific literature.

What is the relevance of CLARITY-BPA for EFSA?

The European Commission mandated EFSA to reassess BPA upon availability of the US studies. In a multi-step process the *scientific protocol* was developed and published end of 2017. The protocol transparently details upfront the scope, methodology and information before the assessment starts. It was developed by an EFSA international working group under the guidance of the CEF Panel. Experts from Denmark, France, Germany, the Netherlands, Norway, Sweden and Switzerland were appointed by their governments to take part in the protocol working group as well as four independent scientists appointed by EFSA. EFSA will now set up a new working group and start collecting scientific papers and data. This will include the report of the CLARITY-BPA two-year core study on rodents and publications of academic studies developed from the CLARITY-BPA study, when they become available. EFSA expects the outcome of their assessment to become available at the end of 2019 at the earliest. <http://www.efsa.europa.eu/en/press/news/171214>