

CLARITY – Just Another Study?



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You may have already heard that the U.S. National Toxicology Program recently released the results of an important new study on BPA known as the CLARITY Core study. One reason it's important is because the goal of the study was to resolve any remaining uncertainties about the safety of BPA, which has been a controversial topic for quite some time.

With that goal in mind, a key conclusion in the [study report](#) is that “BPA produced minimal effects that were distinguishable from background.” In a [statement](#) released in conjunction with the report, Dr. Stephen Ostroff, Deputy Commissioner for Foods and Veterinary Medicine at the U.S. Food and Drug Administration (FDA) stated: “our initial review supports our determination that currently authorized uses of BPA continue to be safe for consumers.”

You're forgiven if you glossed over this news because it may have sounded like déjà vu all over again. Another day, another study you might have thought. After all, countless studies have been conducted on BPA leading to claims that it's safe, it's not safe, and just about everything in between.

But not all studies are created equal, and this one is anything but equal to any of the preceding studies on BPA. By design, the scope of this study is truly unprecedented.

The study was designed to evaluate several important concerns about how BPA may act in the body. One concern is that exposure to BPA early in life, in particular during sensitive developmental stages, may lead to health effects that only occur much later in life. To address this concern, the laboratory animals were dosed with BPA starting in pregnancy

and continuing throughout their lives. Health effects at any stage of life could be detected, regardless of when the dosing occurred.

A second concern is that low doses of BPA, in particular in the range of actual human exposure, might cause health effects even though higher doses do not cause health effects. This counterintuitive relationship between dose and health effect is known scientifically as a [“non-monotonic dose-response”](#) relationship (NMDR). To address this concern, five groups of animals were given a very wide range of BPA doses, from low doses close to [actual human exposure](#) to levels about 250,000 times higher. Any NMDR relationships that occurred would have been observed.

A third concern is that BPA may act in the body as an estrogen to disrupt normal hormonal functions and result in health effects. To address this concern, two groups of the animals were given doses of a known estrogenic compound to ensure that the animals were sensitive to estrogenic effects.

Finally, size does matter in this type of study. If the study is too small, the study results may not be robust and the study goals will not be met. In the CLARITY Core study, all of the groups with lifetime BPA exposure included 46-50 animals. The result is that the study is statistically powerful, meaning that we can have confidence in the validity of the results.

Although the nature of science is that more research is always possible, the goal of the CLARITY Core study was to resolve remaining uncertainties about the safety of BPA. That goal was certainly met, which is why FDA could confidently reaffirm the safety of BPA. As concisely stated on FDA’s website: [“Is BPA safe? – Yes.”](#) In light of the results of the CLARITY Core study, and the strengths of that study, FDA’s conclusion seems sound.