

BPA Case Study

The NIEHS and the NCTR of the FDA collaborated in order to assess the potential toxicity of chronic exposure to BPA as an indirect food additive. There are two cores of this study, one is a guideline-compliant chronic study utilizing FDA's Good Laboratory Practice (GLP) regulations, the other involves studies on the various health endpoints of the rats born to the same exposed rats of the GLP study. This report is only relegated to the aforementioned core, which in itself could lead to bias when making assumptions from this portion of the study alone. In a sense, at this point, only half of the study is available.

The study showed no statistical difference for the BPA stop dose arm in pairwise comparisons of treatments to control for PND at vaginal opening. In the continuous dose arm, no significant differences were seen for body weight and PND at vaginal opening. The EE2 treatment group also saw no significant differences for either body weight or PND at vaginal opening. Data collected included body weights, litter parameters, age at vaginal opening, vaginal cytology, clinical chemistry, sperm parameters, organ weights, and histopathology. To have a better sense of the toxicity of chronic BPA exposure, they should have looked at LH, FSH, and testosterone levels and ovarian functions. According to Gail Prins from the University of Illinois at Chicago, other studies have shown that BPA at lower doses have been linked to many health effects including: changes in brain region sizes and gene expression, spatial navigation, memory deficits, and sex steroid levels, just to name a few. Instead, the scientists of this core focused on weight and histological endpoints, as well as tumor development. Although, this portion of the study shows little to no significance differences in data, the data collected is insufficient to draw conclusions on the toxicity of chronic BPA exposure. Both body weight and organ weight are neither sensitive nor specific to endocrine disruption; something as simple as eating behavior can affect both of these outcomes. The other core will give a more comprehensive view of the health outcomes related to chronic BPA exposure and only then would it be safe to extrapolate the effects of BPA.

It seems that the lack of assessing the more proven markers of effect may have been a deliberate act by the study program, Clarity-BPA. Gail Prins, a principal investigator of Clarity-BPA, stated that the point of Clarity was to compare standard toxicological assays to more sensitive assays like endocrine-disrupting chemical (EDC) as an attempt to determine the best approach when dealing with EDCs in the future. If this was the case, however, then it should have been explicitly stated in the report. Instead, nothing to this effect is mentioned at all. The FDA did not do their due diligence when they released a report that suggests that there were no effects of BPA exposure in the range of everyday human exposure.

A guideline study is supposed to quantify the exposure limit to a substance. Many critics to this type of study, using GLP, say that the rules and standards for of a GLP study has become a barrier to using the most advanced scientific tools, which as a result, would potentially miss some markers that would reflect effects on the endocrine system.

Simply put, the study design was insufficient to be able to discern whether chronic BPA exposure is safe because the endpoints that were evaluated were not comprehensive enough to draw conclusions from. It seems unusual that the FDA would draw conclusions or even suggest conclusions when only half of the study has been conducted. Only organ weights and histology were measured which potentially has a number of confounders like maternal age and stress levels. The gavage system may even be a potential source of stress, as food is literally forced down the rat's throat into its stomach. As of now, it seems the only interpretations that can be drawn from this study is that chronic BPA exposure may not have have an effect on organ and body weights. It is not safe to say that chronic BPA exposure is safe for humans. In conclusion, I do not think that the FDA did their due diligence in accurately conveying the meaning of their study and the results derived from the study. If this portion of the study was meant to compare standard toxicological assays to more sensitive assays like endocrine-disrupting chemical (EDC) as an attempt to determine the best approach when dealing with EDCs in the future, it should have been explicitly stated.