



Measuring Relevance of BPA Studies -- NIEHS Research Criteria

The North American Metal Packaging Alliance, Inc. (NAMPA) takes very seriously safety issues related to metal packaging. Over the past several years, we have continued to follow emerging science around the issue of bisphenol A (BPA)-based epoxy resin linings of food and beverage cans. We remain confident in the safe use of epoxy resins in metal packaging, based on thorough reviews of the science on BPA by the U.S. Food and Drug Administration (FDA), and other leading international regulatory bodies, regarding its use in food contact applications, and we fully support the established scientific review process that has served the public for decades.

A key question with any new research centers on its relevance to human health. In light of the myriad BPA research studies being released daily, NAMPA strongly encourages all stakeholders to consider carefully what these studies mean or contribute in terms of human health. To do this, NAMPA recommends that stakeholders rely on parameters posted by the National Institute for Environmental Health Sciences (NIEHS) in 2009. According to NIEHS, these parameters provide the greatest impact for assessing human health effects of BPA.

Specifically, to ensure that data contribute to the ability to assess BPA's human health impact, NIEHS recommended the following criteria:

- The diet of test animals must not interfere with the sensitivity of the model to BPA.
- The species and strain of animals used in research must be sensitive to estrogenic chemicals at low doses.
- There must be sufficient sample size to ensure power to detect a statistical difference between experimental groups.
- The internal dose of BPA (both total and free BPA) should be measured in blood and if possible also in urine throughout the study.
- Single dose experiments are not acceptable.
- Research must focus on a specific endpoint, not just toxicity. In other words, the endpoint must be an actual observable characteristic, disease, or dysfunction.
- A litter must be used as the statistical unit for developmental exposures.
- The route of exposure should be oral or justified to provide similar blood levels as the oral route.



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- Animals should include both males and females when feasible.
- The molecular targets and mechanism should be assessed when possible, including gene expression, receptor binding, and epigenetic studies. These effects should be linked to the exposure and the disease/dysfunction.

NAMPA and its members support the use of these criteria in evaluating the potential health impacts on people from BPA and other studied substances. We encourage the open and transparent sharing of all new and relevant information via the established scientific review processes for a fair judgment of its scientific validity. It is only by following this open review process that the public will be able to have confidence in the safety of the nation's food supply.

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About NAMPA

The North American Metal Packaging Alliance, Inc. and its members support sound science and trust the scientific review process that has protected our food supply for decades. For further information, visit www.metal-pack.org.

September 2013