



Understanding the Basis for Scientific Research

Understanding the reason behind a scientific research study is the first step in evaluating the relevance of any given study. Some studies are designed to test a theory. Others are designed to provide specific answers to targeted questions intended to assess risk. These are two very different functions that can lead to very different perspectives on the science.

The studies most often making news are those that are often referred to as “hypothesis-driven” research. These are studies that include a proposed explanation, based on limited evidence, as a starting point for further investigation. Simply put, such studies are intended to test theories about possible effects. Academic institutions most commonly conduct these kinds of studies. Such studies also represent the vast majority of the research frequently cited by the media regarding bisphenol A (BPA) and a host of other substances. While the results of hypothesis-driven studies provide useful insight and information into a given substance, they are, by design, not intended to give specific answers regarding the substance’s potential impact on human health. They offer, however, information that can help inform priority setting and the regulatory process needed to assess risks to humans, and are often used to help design a study that can answer specific questions raised by the hypothesis-driven research.

The scientific research studies used in the regulatory rulemaking process represent another type of research. Within the regulatory review process, these scientific studies are specifically designed to provide data about a chemical or substance to assess the potential risk a substance may present to humans. This research falls into the category known as “guideline” studies, or research designed to provide a more biologically-based interpretation of the data and a much more rigorous scientific basis for extrapolation beyond the conditions under which the original, hypothesis-driven data were obtained.

These are the studies used by U.S. regulatory agencies in conducting risk assessments on various substances. Guideline studies are routinely conducted by industry scientists, often with significant input and guidance from federal regulators, to ensure that specific criteria are met, as required for regulatory rulemaking. The data from such studies are submitted to regulators for their thorough review and evaluation. They are required to meet specific criteria and follow specific laboratory practices to be considered and relied upon in rulemaking processes. Given that guideline studies are typically more complex and of much longer duration than hypothesis-based studies, there are usually fewer of them for any given substance. It should be noted that to date, for BPA, the hypothesis-driven theories regarding potential health effects from exposure to low doses have not been proven in multigenerational, guideline studies being considered by federal regulators.

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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.