



Phthalate Reproductive and Developmental Toxicity: Implications for Cumulative Risk Assessment

Introduction

Phthalates are used extensively, for example in cosmetics and personal care products, medications, and some medical products, paints, adhesives, detergents, toys, and food packaging. The Centers for Disease Control and Prevention (CDC) studies have demonstrated prevalent exposure to multiple phthalates in the general U.S. population. Although epidemiology data are limited, they point to a relationship between phthalate exposure and adverse effects on male reproductive tract development and function. Similar findings are observed in toxicology studies conducted in animal models. It is clear that human health risk assessment methodologies need to address not only exposures to single phthalates, but also need to consider the broader issue of exposures to mixtures of phthalates and to other chemicals.

At the request of the U.S. Environmental Protection Agency (EPA), the National Research Council (NRC) considered the issue of cumulative risk assessment of phthalates and issued a report in 2008 that endorsed a cumulative risk assessment approach. It recommended a shift in strategy that could be broadly applicable across multiple chemical exposures and that uses common adverse outcomes (rather than similar chemical structure or mechanism of action) as a basis for cumulative risk assessment. The NRC report characterized a number of data gaps and research needs. Accurate information on potential lifestage-specific human exposure and toxicity to phthalates, their metabolites, and other toxicants is often limited.

Research

In the field of epidemiology, consideration is being given to improving research methodologies to better characterize effects of phthalate exposures on humans. Studies conducted in animal models are examining the effects of developmental exposures to mixtures of phthalates, combined with other phthalates and/or with other environmental toxicants.

The U.S. EPA is currently conducting an Integrated Risk Information System (IRIS) Human Health Risk Assessment for a group of phthalate chemicals. The assessment will address the recommendations presented in the NRC report.