



Review of the Environmental Protection Agency's State-of-the-Science Evaluation of Nonmonotonic Dose-Response Relationships as they Apply to Endocrine Disruptors

Committee to Review EPA's State of the Science Paper on Nonmonotonic Dose Response, Board on Environmental Studies and Toxicology, Division on Earth and Life Studies, National Research Council

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Potential health effects from chemicals that disrupt endocrine function pose an environmental health concern because of their ability to interfere with normal hormone function in human and wildlife populations. The endocrine system regulates biological processes throughout the body and is sensitive to small changes in hormone concentrations. Endocrine-disruptor research has focused primarily on chemicals that affect three hormone pathways that play important roles in reproduction and development - the estrogen, androgen, and thyroid hormone pathways. Some of this research has identified dose-response relationships that have nonmonotonic curves. Nonmonotonic dose-response curves (NMDRs) are of concern because they do not follow the usual assumption made in toxicology that as dose decreases the response also decreases.

The existence of NMDRs has been a controversial topic for decades, and there has been considerable debate about their implications for how chemicals are tested and for how risks from such chemicals are assessed. Toxicity tests are designed to identify hazards and to characterize dose-response relationships, so tests are aimed at finding a (high) dose that elicits a response, and dose-response is explored by testing lower doses spaced to identify statistically a no- or lowest-observed-adverse-effect level. The concern for NMDRs is that such studies, as currently designed, might not detect the inflection of the dose-response curve if only a few doses are tested or if the change in inflection occurs below the range of doses tested. Another concern is that some NMDRs are found for biological effects that are not usually evaluated in toxicity tests. If current testing strategies are inadequate to account for NMDRs, changes to risk assessment practices might be necessary. To help address these issues, the U.S. Environmental Protection Agency (EPA) developed a draft State-of-the-Science Evaluation: Nonmonotonic Dose Responses as they Apply to Estrogen, Androgen, and Thyroid Pathways and EPA Testing and Assessment Procedures. EPA asked the National Research Council to conduct an independent review of this evaluation to ensure that it is scientifically sound and of high quality.

Review of Environmental Protection Agency's State-of-the-Science Evaluation of Nonmonotonic Dose-Response as they Apply to Endocrine Disrupters evaluates whether EPA's evaluation presents a scientifically sound and high-quality analysis of the literature on NMDRs. This report reviews how well the EPA evaluation described how the assessment was performed, whether consistent methods and criteria were applied in the analysis of different evidence streams, and whether appropriate methods were applied to evaluating the evidence. The report makes recommendations to improve EPA's process and strengthen the evaluation.

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