

## **EDSP Weight of Evidence Guidance**

### Background

Congress has required EPA to screen certain chemicals for their potential to interact with the human endocrine system, and EPA has established the Endocrine Disruptor Screening Program (EDSP) to implement that mandate. The initial EDSP screening effort addressed pesticide chemicals under section 408(p) of the Federal Food Drug and Cosmetic Act, and EPA recently published for comment a new list of chemicals for screening under section 1457 of the Safe Drinking Water Act. The Agency has stated that it published the draft weight of evidence (WoE) guidance for comment in response to a directive in a House Appropriations Committee report and to a requirement of the Office of Management and Budget's Terms of Clearance for EPA's Information Collection Request governing the list of pesticide chemicals. This guidance is essential for making consistent scientific decisions about whether screening assay results indicate a chemical may have the potential to interact with the endocrine system. However, CPDA does not believe the draft WoE guidance document provides any meaningful guidance.

### CPDA's Comments

By February 3, 2011, CPDA will have submitted comments to EPA on its draft WoE guidance document in which it calls upon the Agency to revise its approach so as to provide the necessary detail that would allow users to ascertain why each specific Tier 1 assay result can be relied upon and how that assay should be integrated with the other assays to assess a chemical's potential to interact with the endocrine system. CPDA emphasizes that as written, the document does not provide useful guidance for evaluating Tier 1 screening results or for assessing "Other Scientifically Relevant Information" (OSRI) for use in the EDSP. Specifically, CPDA notes that the Guidance Document fails to include an explanation of which assays and which endpoints carry the greatest weights for evaluating potential hormonal activity within the Tier 1 battery, nor does it provide an explanation of how a response pattern for a chemical can be extrapolated across all Tier 1 assays to determine a chemical's overall potential to interact with each hormonal pathway covered by the Tier 1 assays. In its other comments, CPDA points out that the data evaluation criteria referenced in the Guidance Document, such as "nature of the effect(s) seen," "potency of the responses," and "dose-and time-dependent changes" are typically used for weighing adverse effects in toxicological data evaluation. In contrast, the singular purpose of Tier 1 screening is to assess the potential of a chemical to interact with the endocrine system, not assess adverse effects. As such, CPDA urges the Agency to develop an approach to a weight-of-evidence evaluation that is specific to potential endocrine disruptors. CPDA emphasizes that such an approach must be premised on scientifically supported and peer reviewed criteria thus ensuring that the data generated through the Tier 1 assays and offered through existing OSRI can be reliably, repeatedly and consistently evaluated.