

## **CPDA Petition and EPA's Endocrine Disruptor Screening Program (EDSP)**

### Background

Section 408(p)(5)(A) of the Federal Food, Drug and Cosmetic Act (FFDCA) authorizes EPA to screen "pesticide chemicals" and other chemicals for their potential to interact with the human endocrine system, and section 1457 of the Safe Drinking Water Act (SDWA) also authorizes EPA to conduct such screening for substances that "may be found in sources of drinking water" if the Agency determines that "a substantial population may be exposed" to those substances. Pursuant to FFDCA authority, EPA developed the EDSP and published a list of pesticide active and inert ingredients for testing and issued testing orders to manufacturers and importers of those chemicals in 2009. In late 2010, the Agency published a draft second list of chemicals and the associated draft policies and procedures for testing under its SDWA authority. CPDA submitted comments to EPA on these actions, as well as the related information collection requests (ICR). In 2009, the Office of Management and Budget (OMB) issued "Terms of Clearance" (TOC) approving the ICR for EPA's initial collection of information under the FFDCA. The TOC sets forth specific actions EPA must undertake before and during implementation of the EDSP, including preparation of certain guidance documents and procedures and a report on all instances where existing data or other scientifically relevant information (OSRI) was found insufficient for satisfying test orders, "to ensure that EPA has maximized the practical utility of the Tier 1 assays" as required by the Paperwork Reduction Act (PRA).

### Update

EPA has not adequately complied with the PRA and the TOC in implementing the EDSP, and CPDA and other trade associations have petitioned the Agency for compliance. In June 2011, CLA, CSPA, and RISE co-petitioned EPA requesting that the Agency develop and publish guidance explaining the criteria by which it will demonstrate the practical utility of the information collected in response to Tier 1 test orders. In November 2011, CPDA, the Halogenated Solvents Industry Alliance, Inc., and People for the Ethical Treatment of Animals jointly petitioned EPA to comply with the PRA as specified in the TOC before issuing test orders for Tier I screening of additional chemicals. The petition asserts that EPA has not demonstrated, as required by the PRA, (1) that the information collection is not duplicative of information to which the Agency may have access, and (2) that the Tier 1 assays will provide the scientific support needed to determine whether a chemical "may" or "may not" have the potential to interact with the endocrine system (i.e., they have PRA-mandated practical utility). CPDA also recommended specific actions EPA should take to fully comply with the PRA.