

EPA's Endocrine Disruptor Screening Program (List 2 Policies and Procedures)

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 screen substances that “may be found in sources of drinking water” if EPA determines that “a substantial population may be exposed” to those substances. EPA published its final policies and procedures for 67 pesticide chemicals in April 2009 (List 1 Policies and Procedures), began issuing test orders pursuant to them in late 2009, and then in November 2010 proceeded to publish draft policies and procedures for 134 SDWA chemicals (Draft List 2 Policies and Procedures).

Update

On January 18, 2011, CPDA submitted comments on the Draft List 2 Policies and Procedures, admonishing EPA for initiating screening under the SDWA when the Agency is years from completing the screening of List 1 chemicals. EPA's actions are contrary to recommendations of the Agency's Scientific Advisory Board, and its own statements. In addition, neither the FFDCA nor the SDWA contains a mandated time period or deadline for EPA to begin EDSP screening generally or for SDWA chemicals specifically. CPDA's comments also highlight the Agency's failure to interpret key aspects of section 1457, which is necessary for the public to assess whether the Agency is acting in accordance with the Administrative Procedure Act. In addition, CPDA noted the Agency's failure to have developed meaningful weight of evidence (WoE) guidance before expanding the screening effort. This guidance is essential to the Agency, its contractors, and the public to ensure a transparent, scientific, and consistent process for evaluating the potential for a chemical to interact with the endocrine system. EPA has also failed to develop meaningful guidance for industry and contractors on evaluating other scientifically relevant information (OSRI). The agency must have detailed, functional WoE and OSRI guidance to avoid making arbitrary and capricious decisions, and industry must have the guidance to assess what information should be submitted to the Agency and otherwise properly prepare for responding to test orders. CPDA also commented on several other issues, including requests that EPA (1) make binding by rule certain non-binding Agency commitments in the Draft List 2 Policies and Procedures, (2) issue test orders only to current manufacturers and importers, (3) not consider a chemical's persistence when issuing orders, and (4) provide meaningful and enforceable data compensation provisions.