



Chemical Producers & Distributors Association

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VIA E-MAIL

Ms. Elizabeth Sommer
Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency
Ariel Rios Building (MC 7406M)
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460

**RE: Comments on the Design for the Environment Program Alternatives Assessment
Criteria for Hazard Evaluation**

Dear Ms. Sommer:

The Chemical Producers & Distributors Association (“CPDA”) appreciates this opportunity to comment on the proposed changes to the above-referenced Design for the Environment (“DfE”) alternatives assessment criteria for evaluating hazards (“Criteria Document”). CPDA is the primary advocate on federal legislative and regulatory issues for generic pesticide registrants, adjuvant and inert ingredient manufacturers, and product formulators and distributors.

CPDA supports the U.S. Environmental Protection Agency’s (“EPA” or “Agency”) DfE initiative and its efforts to “reduce risk to people and the environment by finding ways to prevent

pollution.” However, we believe that EPA needs to clarify the level of information the Agency requires to “evaluate a chemical of concern and its likely alternatives” in order to “reduce the likelihood of the unintended consequences that might result if poorly understood alternatives are chosen.” We are specifically concerned with EPA’s definition of the term “endocrine activity”¹ and subsequent reference to the term in Subsection 4.1.9 of the Criteria Document.²

CPDA believes that the proposed definition of “endocrine activity” is not consistent with any other defined toxicological criteria used by the DfE program or EPA in general, and as such is misleading, not useful for assessment and comparison purposes, and not scientifically supported. In fact, the Agency offers no literature reference for the definition set forth in section 3.14 of the Criteria Document or the potential data sources and criteria listed in section 4.1.9 for the evaluation of human health effects of potential endocrine disruptors.³ With respect to endocrine disruptors, we believe it is scientifically premature to posit criteria by which DfE could compare alternatives and “reduce the likelihood of the unintended consequences that might result if poorly understood alternatives are chosen.”

EPA has only recently validated screening assays to gauge a chemical’s potential to interact with the endocrine system (Tier 1 screening) and has not yet validated tests to measure dose-response relationships and adverse effects (Tier 2 testing). Therefore, the Agency cannot at this point identify the criteria for “adverse” effects (versus imparting temporary system perturbations) and consequently what alternatives might be “safer.” EPA understands this and has repeatedly stated:

“[B]ased on current information, the public should not presume that the listing of a chemical or substance [on the Tier 1 list] indicates in any way that EPA currently suspects that such chemical or substance interferes with the endocrine systems of humans or other species simply because it has been listed for screening under the EDSP.”⁴

These EPA lists for chemicals and substances to be screened under the EDSP are based only on their pesticide registration status and/or because such substances may occur in sources of drinking water to which a substantial population may be exposed. Only when the potential to interact with the endocrine system has been confirmed during the Tier 1 screening will

¹ Criteria Document at p. 6.

² Id. at p. 16. (This section addresses endocrine activity as a toxicological criterion for assessing Human Health Effects under section 4.1).

³ Id. (Section 4.1.9 (A) & (B)).

⁴ 75 Fed. Reg. 70248, 70250 (November 17, 2010); *see also* 74 Fed. Reg. 17579, 17579 (April 15, 2009).

mandatory testing be used to determine any actual endocrine effects.⁵ Under the EDSP, EPA has not yet elucidated a weight-of-evidence process by which information of the type listed as potential data sources in section 4.1.9 can be evaluated for potential endocrine system interaction, much less for adverse effects.

Therefore, CPDA recommends that human health endocrine effects criteria not be proposed in the Alternatives Assessment Criteria until such time as 1) a sound, scientifically-based set of criteria can be developed for comparison of alternatives; 2) chemicals or substances have been found to be endocrine disruptors through adequate, reliable, and reproducible scientific studies; and 3) their endocrine-related human health endocrine effects have been elucidated.

⁵EPA has not yet selected and fully validated the tests needed to determine actual endocrine effects.