



Chemical Producers & Distributors Association

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VIA WWW.REGULATIONS.GOV

Mr. William Wooge
Office of Science Coordination and Policy
U.S. Environmental Protection Agency (MC 7203M)
1200 Pennsylvania Avenue, NW
Washington, DC 20460-0001

RE: Endocrine Disruptor Screening Program; Second List of Chemicals for Tier 1 Screening; Notice; 75 Fed. Reg. 70248 (November 17, 2010); EPA-HQ-OPPT-2009-0477; FRL-8848-7.

Dear Mr. Wooge:

The Chemical Producers & Distributors Association (“CPDA”) appreciates this opportunity to comment on the above-referenced notice (“List 2 Notice”) for the second list of chemicals (“List 2”) to be screened under the Endocrine Disruption Screening Program (“EDSP”). 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.

Introduction

As we discuss below, CPDA does not believe EPA is under any statutory mandate to test SDWA chemicals at this time. While we do not object to prioritizing chemicals for future screening, we do think that initiating Tier 1 screening for these chemicals now, however, is imprudent and will result in a missed opportunity to make experience and science--based improvements to improvements to the EDSP before additional testing. We also address our concerns about the Agency's need to be consistently and fully transparent while implementing the EDSP. The EDSP is a complex program, with ambitious testing requirements being implemented under new statutory authority. It is also a very costly program for which industry expects EPA to consistently make transparent decisions that demonstrate genuine consideration given to achieving the maximum practical utility of the data collected while minimizing the burden on those subject to testing requirements.¹ Finally, we appreciate and support the Agency's continued use of qualifying language to emphasize that chemicals listed for purposes of screening under the EDSP are not endocrine disrupting chemicals, and that the purpose of Tier 1 screening is only to assess a chemical's potential to interact with the human endocrine system.

EPA Should Complete Screening of the First List of Chemicals before Requiring Ordering Additional EDSP Screening

EPA intends to expand the EDSP effort by requiring that screening begin on an additional 134 chemicals ("SDWA chemicals")² before receiving and evaluating the results of the current screening effort on pesticide chemicals.. This significant expansion of Tier 1 screening is neither required by statute nor prudent in light of EPA's failure to timely develop functional weight of evidence guidance, more detailed evaluation procedures for other scientifically relevant information ("OSRI"), and the need for sufficient information about the successes and failures of the initial screening approach to inform future decisions about the EDSP. CPDA does not object to EPA's appropriately prioritizing additional chemicals for future Tier 1 screening; however, we do object to the Agency rushing to issue new test orders for twice the numbers of chemicals in the first screening effort without first evaluating that effort and improve the EDSP.

¹ Paperwork Reduction Act of 1995, 44 U.S.C. chapter 35.

² EPA uses this term in the companion "policies and procedures" document (75 Fed. Reg. 70558; November 17, 2010) and we use it here for consistency.

In the List 2 Notice, EPA sets forth its authority for developing the list of SDWA chemicals, citing section 408(p) of the Federal Food, Drug, and Cosmetic Act (“FFDCA”),³ section 1457 of the Safe Drinking Water Act (“SDWA”),⁴ and a House Appropriations Committee report.⁵ However, neither the FFDCA nor the SDWA contains a mandated time period or a deadline for EPA to begin EDSP screening generally or for SDWA chemicals specifically. Moreover, EPA incorrectly interprets language in the Appropriations Committee report as a constitutionally valid legislative mandate to initiate EDSP screening. This rush to screen additional chemicals without a statutory deadline is premature and will undermine the valuable opportunity the initial Tier 1 screening can provide for future experience and science-based to improvements to this highly complex program.

CPDA is particularly concerned about EPA’s unsupported reliance on a non-legislative Congressional directive to undertake this very costly information collection. EPA notes in the List 2 Notice that a House Appropriations Committee report directed EPA “to publish within 1 year of enactment [of the appropriations bill] a second list of no less than 100 chemicals for screening...and issue 25 orders per year for the testing of these chemicals.”⁶ What EPA fails to disclose, however, is that reports issued by only the House or the Senate are not authoritative or binding on an agency.⁷ Moreover, the U.S. Supreme Court has expressly cautioned against treating legislative reports as binding law:

³ 21 U.S.C. § 346(a)(p)

⁴ 42 U.S.C. § 300j-17.

⁵ U.S. House of Representatives. 2009. Committee on Appropriations Report 111-180 on Department of the Interior, Environment, and Related Agencies Appropriation Bill, 2010.

⁶ List 2 Notice, p. 70250.

⁷ Northwest Environmental Defense Center et al. v. Bonneville Power Administration, 447 F. 3d 668, ___ (9th Cir. 2007). (“The principle that committee report language has no binding legal effect is grounded in the text of the Constitution and in the structure of separated powers the Constitution created. Article I, section 7, clause 2 of the Constitution is explicit about the manner in which Congress can take legally binding action. Members of Congress cannot use committee report language to make an end run around the requirements of Article I. If Congress wishes to alter the legal duties of persons outside the legislative branch, including administrative agencies, it must use the process outlined in Article I” (internal footnotes omitted). . . .”

“Treating legislative reports as binding law also undermines our constitutional structure of separated powers, because legislative reports do not come with the traditional and constitutionally-mandated political safeguards of legislation. As noted above, legislative reports are not acts of law satisfying the precise requirements of Article I, which were devised by the Framers to ensure separation of powers and a careful legislative process. By contrast, legislative reports may in some cases be written by an individual legislator, congressional staffers, or even

“[L]egislative materials like committee reports, which are not themselves subject to the requirements of Article I, may give unrepresentative committee members-or, worse yet, unelected staffers and lobbyists-both the power and the incentive to attempt strategic manipulations of legislative history to secure results they were unable to achieve through the statutory text.”⁸

Therefore, EPA cannot rely on committee report language to infer a statutory duty or mandate, and its authority to impose testing requirements under the Safe Drinking Water Act is limited.⁹ Until the screenings on the first list has concluded, and EPA is in a position to make decisions informed by that experience, the Agency should not undertake this major expansion of the program. The EDSP is a new and ambitious testing program. It orders the use of a battery of new and controversial test methods with which the Agency, laboratories and industry have little experience. Tier 1 screening costs alone will run \$500,000 to \$1,000,000 per chemical and Tier 2 costs could reach several million dollars per chemical. Given the expense of, and lack of experience with, EDSP screening and testing, it is imperative that the Agency collect and analyze data from the pesticide chemicals currently being screened before expanding screening to additional chemicals. This approach would allow EPA to examine and revise the Tier 1 assays, the complete Tier 1 battery and EDSP policies and procedures to address issues such as “functional equivalence” and “other scientifically relevant information,” before undertaking additional testing. We believe this approach is supported with EPA’s Science Advisory Board/Science Advisory Panel recommendation to “pilot” the EDSP a limited number of chemicals:

“There was broad support among the Subcommittee for the concept that the Agency should convene a panel of independent scientists to review all the screening data for 50-100 compounds, with an eye towards revising the process and eliminating those methods that don’t work.”¹⁰

lobbyists.13 Giving binding effect to passages in legislative reports may thus give binding legal effect to the unchecked will of a lone person, and that is not what our Constitution envisions.”) Id.

⁸ Exxon Mobil Corp. v. Allapattah Services, Inc., 125 S. Ct. 2166, 2626 (2005).

⁹ SDWA §1457; 42 USC §300j-17. Generally, EPA must first show that a substance “may be found in sources of drinking water” and “that a substantial population may be exposed to such substance.” No such showings are presented in the Agency’s proposed listing decision (List 2 Notice).

¹⁰ EPA, Review of the EPA’s Proposed Environmental Endocrine Disruptor Screening Program. Joint Subcommittee of the Science Advisory Board and Scientific Advisory Panel, EPPA-SAB-EC-99-013, July 1999.

Therefore, CPDA requests that EPA suspend further actions to issue test orders for the List 2 chemicals until the Tier 1 screening effort currently underway has been completed.. EPA is under no statutory mandate to begin screening chemicals under the SDWA at this time. .

EPA Should Respond to Comments Submitted on the Draft EDSP List 2

EPA has stated in the List 2 Notice that “[t]he Agency does not plan to respond formally to information or comments that may be submitted on this document....”¹¹ This position is contrary to the general public process envisioned by the Administrative Procedures Act (“APA”)¹² for federal agency actions and is inconsistent with open and transparent regulatory practices. When final, List 2 will create new duties and obligations for specific members of the regulated community, particularly when the Agency issues test orders. Consequently, EPA has a legal obligation under the APA to avoid arbitrary and capricious actions in interpreting applicable law and in identifying chemicals and manufacturers and importers that will be subject to enforceable EDSP testing requirements.

EPA’s actions related to issuing List 2 are, in essence, a rule making and the Agency should fully comply with the APA’s notice and comment provisions for three important reasons. First, EPA’s decision to include a chemical on List 2 is the initial step in the process of issuing binding EDSP test orders and, as such, is a regulatory action subject to the APA. Second, EPA considers issuance of test orders “final agency action subject to review,”¹³ and the SDWA provides for general judicial review of EPA final actions.¹⁴ Third, final review of agency actions is based on the relevant administrative record, of which EPA’s written responses to formally submitted comments are an important component. Therefore, EPA should engage in robust notice and comment on List 2, including a response to comments, to avoid the appearance of acting arbitrarily, to provide a proper administrative record, and to ensure an open and transparent process.

¹¹ List 2 Notice at p. 70251.

¹² 5 U.S.C. §§ 500-706.

¹³ 75 Fed. Reg. 70558, 70566 (November 17, 2010).

¹⁴ SDWA § 1448.

EPA Should Be Fully Transparent in the Procedures Used to Develop List 2

Although EPA has provided the initial list of “over 200” candidate chemicals it compiled, the Agency has not been fully transparent about the “streamlining” process used to reduce those 200 plus chemicals to the 134 chemicals on the draft List 2. In the List 2 Notice, EPA describes the categories of chemicals excluded from screening at this time,¹⁵ but the Agency has not disclosed the actual physiochemical criteria and data it relied on to make the exclusion decisions. Since the Agency has not provided the scientific basis for its decision to retain or remove chemicals, independent verification of EPA’s consistent application of the six specified categories is simply not possible at this time. Therefore, CPDA requests that EPA publish the specific criteria the Agency employed to determine whether or not a chemical falls into exclusion category (i) as a biological agent or naturally occurring chemical; exclusion category (ii) as a chemical for which the manufacturer, importer or registrant cannot be clearly identified; or exclusion category (v) as a chemical not likely to be biologically active or which is incompatible with testing assays for various reasons due to one or more of their physiochemical properties (e.g., gases, strongly acidic or basic, solubility, vapor pressure molecular weight).

EDSP Test Order Authority Applies to Currently Manufacturers and Importers

Section 1457 of the SDWA authorizes EPA to include in the EDSP “any other substance that may be found in sources of drinking water” provided EPA determines a “substantial population may be exposed to such substance.” However, section §408(p)(5) of the FFDCFA dealing with test orders states that:

“The Administrator shall issue an order to a registrant of a substance for which testing is required under this subsection, or to a person who manufactures or imports a substance for which testing is required under this subsection, to conduct testing in accordance with the screening program”

CPDA believes this statutory use of the present tense in section 408(p)(5) precludes EPA from issuing EDSP test orders for SDWA chemicals that are no longer manufactured or imported, but which may be found in sources of drinking water. The Agency has provided no evidence of the practical utility of collecting the information on these chemicals. Thus, EPA should neither list

¹⁵ List 2 Notice, p. 70251.

nor issue test orders for chemicals that are not currently manufactured or imported.

Conclusion

CPDA believes that EPA has unnecessarily rushed forward with Tier 1 screening of SDWA chemicals and requests that EPA suspend all action to issue test orders for the List 2 chemicals until the current Tier 1 screening effort has been completed. This would provide the Agency with timely information to improve the EDSP.