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Ms. Susan Sharkey  
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Environmental Protection Agency  
1200 Pennsylvania Ave., NW.  
Washington, DC  20460–0001

Dr. William Wooge  
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Dear Ms. Sharkey and Dr. Wooge:

These comments are submitted on behalf of People for the Ethical Treatment of Animals and the Physicians Committee for Responsible Medicine. The parties to this submission are national animal protection, health, and scientific advocacy organizations with a combined constituency of more than two million Americans who share the common goal of promoting reliable and relevant regulatory testing methods and strategies that protect human health and the environment while reducing, and ultimately eliminating, the use of animals.

In the Federal Register on November 17, 2010, the Environmental Protection Agency (EPA), announced the availability of draft policies and procedures for Tier 1 screening under the Endocrine Disruptor Screening Program (EDSP) of substances for which EPA may issue testing orders pursuant to section 1457 of the Safe Drinking Water Act (SDWA) and section 408(p) of the Federal Food, Drug, and Cosmetic Act (FFDCA), and requested general and specific comments on these policies and procedures.

General Comments

Since the Policies and Procedures regarding Pesticide Active Ingredients and minimizing duplicative testing are largely unchanged, our comments regarding the original Policies and Procedures still hold.¹

“SDWA chemicals” are defined as substances which “may be found in sources of drinking water if the Administrator determines that a substantial population may be exposed” (SDWA Section 1457). EPA divided SDWA chemicals into two groups: those that are pesticide active ingredients (PAI) and those that are “Other SDWA chemicals.” The latter category includes Toxic Substances Control Act (TSCA) chemicals, pharmaceuticals, and personal care product chemicals, and others. Obviously, the universe of chemicals that can be tested based on the above definition is quite large, creating the potential for a huge cost in lives of animals used for testing. **In order to focus the program on those chemicals with the greatest chance of causing harm, EPA should explicitly define the terms “may be found”, “sources of drinking water”, “substantial population” and “may be exposed.”** Does “may be found” mean substances currently found as well as those that were found in the past? And found at what levels and frequency? Do “sources of drinking water” include private wells, and if so, how many in aggregate would have to be contaminated by a chemical to be considered under this program? How many persons make up a “substantial population?” Finally, does “may be exposed” mean exposure to any chemical that could find its way into the environment, regardless of amount, frequency, or whether there is a reasonable means for mitigation?

EPA should focus on chemicals for which there is a clear regulatory need, for example, those chemicals for which appropriate mitigation: (1) is not currently being carried out (i.e. removal of POPs from drinking water by filtration); and (2) is feasible. For substances that are no longer manufactured or imported into the US, mitigation is not possible by restricting use. **Therefore, for substances that are not persistent, the regulatory “need” for testing is unjustifiable.**

**Minimizing duplicative testing:** EPA states that while FFDCA Section 408(p) does not allow it to impose binding arbitration requirements identical to those authorized by FIFRA Section 3, EPA believes it has the authority under FFDCA Section 408(p) to develop procedures that would facilitate joint data generation. “Specifically, the Agency has discretion to determine what actions constitute compliance with a FFDCA Section 408(p) test order, and EPA intends to apply this discretion in a manner that creates strong incentives for companies to develop data jointly voluntarily.” EPA states that “each recipient” of an order has a “separate obligation” to satisfy the order and EPA will consider a recipient’s obligation to provide data fulfilled if the recipient jointly or individually submits results from the required assays, or “EPA judges that it would be equitable to allow the recipient to rely on, or cite, results of studies submitted by another person.” EPA believes that it would generally be equitable to allow a recipient of a test order to rely on the results of studies submitted by another person where: (1) the data generator has given permission to the recipient to cite the results; or (2) the recipient has made an offer to commence negotiations and made provisions for resolving disputes. **We do not consider such an approach a strong incentive for companies to jointly develop data.**

While EPA’s experience to date with Phase I of the EDSP may lead it to assume that test order recipients will generally form consortia, this experience has been with mostly
pesticide manufacturers - companies in the same sector, familiar with each other and perhaps belonging to a single or a few trade groups. However, the test order recipients for chemicals on the second list may not belong to the same sectors and/or trade groups, and are more analogous to the sponsors of the High Production Volume Chemical Challenge Program. Our experience with this program is that companies did not always form consortia to share testing duties, even when it would have been economically feasible for them to do so, either due to ignorance as to the existence of other potential producers or unwillingness to cooperate. Therefore, EPA should require that data and cost-sharing be thoroughly explored before a recipient is allowed to undertake testing individually. In other words, the formation of consortia should be mandatory unless compelling reasons are given as to why this cannot be done.

In addition, EPA intends to publish on the EDSP website the list of all test order recipients and the status of test orders, including recipients’ responses. According to EPA, making this information available will enable test order recipients to identify and join other recipients to develop the data, thereby minimizing duplicative testing and promoting fair and equitable sharing of test costs. EPA can do more to facilitate joint development of data by including a list of other manufacturers and importers of a particular chemical, along with contact information, in the separate test orders that are issued to each recipient and by providing incentives for joining consortia, either by providing disincentives for multiple submissions or by expediting review of consortia submissions.

Responses to Specific Questions

1. Response Option to Cease Manufacture
   a. Issue: EPA seeks comment on the option for test order recipients of a SDWA/FFDCA order to comply with the order by ceasing to manufacture or import the chemical. Under SDWA, EPA will issue a test order based upon a finding that a chemical “may be found in sources of drinking water” and “that a substantial population may be exposed.” EPA presents two lines of thinking as to how to handle this as follows: (1) The chemical is still present in sources of drinking water and the corresponding potential for public exposure is not altered by a company’s subsequent choice to cease manufacture or import of the chemical, so the potential for continued exposure exists. Additionally, given that past actions contributed to the source of the current exposure, the company should remain responsible for generating the data to allow EPA to characterize the significance of that exposure. (2) If the test order recipient stops manufacturing and importing a chemical, it will lead to less exposure to the chemical in sources of drinking water. Also an order recipient that ceases to manufacture or import a chemical which is subject to EDSP screening will no longer receive any economic benefit from the sale of the chemical with which to defray the cost of testing. Finally, according to EPA, requiring a company to provide EDSP data on a chemical, even if it
ceases manufacture and import of the chemical, “removes a major incentive for companies to stop producing chemicals for which test orders are issued.”

b. **Comment:** If a company ceases manufacture, then FFDCA Section 408(p)(5)(A), which states that orders shall be issued to “a person who manufactures or imports a substance for which testing is required,” would no longer seem to apply. Therefore, what statutory authority would EPA have at that point to require testing? If no “person” or company exists who manufactures the substance, it appears that EPA would have to undertake testing itself, thus spending public dollars to obtain data of highly questionable value. EPA resources would be better spent on appropriate means of mitigation such as removal from sources of drinking water.

2. **Persistence**
   a. **Issue:** EPA seeks comment on whether and how to factor a chemical’s persistence in the environment into EDSP policies and procedures. EPA generally intends FFDCA Section 408(p) as giving it authority to issue orders to current registrants, manufacturers, and importers of a chemical. For persistent chemicals, past registrants, manufacturers, and importers (as well as processors and users) are likely to have contributed to current and ongoing contamination. EPA requests comment on how this could be taken into account. According to EPA, one option would be to issue orders to such past manufacturers, to ensure that they share in the costs of generating the data. Another option being considered would be for EPA to issue orders to such parties only where the chemical is no longer manufactured or imported in the U.S. (but presumably is elsewhere).
   b. **Comment:** The term “persistence” does not appear in the enabling legislation, and in the absence of relevant statutory provisions, we question what authority EPA may believe it has to issue unique test orders for “persistent” chemicals. EPA should be focusing its efforts on those chemicals in drinking water that are most prevalent and have a reasonable means for control.

3. **Orphan Chemicals**
   a. **Issue:** If all test order recipients have ceased to manufacture a SDWA chemical and EPA has not received the required data, the SDWA chemical would be considered an “orphan.” EPA seeks comment on the value of EDSP testing on orphan chemicals and the strategy EPA should use to obtain EDSP data on orphan chemicals.
   b. **Comment:** The issue of reasonable means for mitigation would apply here as well: if a chemical is no longer manufactured and amounts detectable in the environment are decreasing, there is little to be gained from additional testing since there are no further means available for controlling that chemical.
In summary, there are a number of measures EPA can apply to the EDSP to avoid duplicative testing, reduce the waste of animal lives and more effectively apply limited resources including strong incentives to form consortia and disincentives for submitting data individually. In addition, for chemicals that cannot be mitigated by regulating production or import, EPA should focus on non-testing mitigation measures.

Thank you for considering our comments.

Sincerely,

[Signature]

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