March 12, 2008

Dr. William Wooge
Office of Science Coordination and Policy (7201M)
Environmental Protection Agency
1200 Pennsylvania Ave. N.W.., NW
Washington, DC 20460-0001

Re: **72 FR 70842, December 13, 2007, Docket ID number EPA-HQ-OPPT-2007-1080; Endocrine Disruptor Screening Program (EDSP); Draft Policies and Procedures for Initial Screening; Request for Comment**

Dear Dr. Wooge:

These comments are submitted on behalf of the Alternatives Research and Development Foundation, the American Anti-Vivisection Society, Humane Society Legislative Fund, The Humane Society of the United States, 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 10 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 December 13, 2007, the Environmental Protection Agency (EPA; hereafter referred to as the Agency), announced the availability of draft policies and procedures for initial screening under the Agency's Endocrine Disruptor Screening Program (EDSP), including specific details on policies and related procedures, and requested general and specific comments on these policies and procedures.

General comments

Minimizing duplicative testing: The EPA claims that "the Agency no longer believes that FFDCA section 408(p)(5) provides the authority to create express requirements for joint data development" and that "FFCDA section 408(p) does not allow the EPA to impose requirement s identical to those authorized by FIFRA section 3…."…" However, FFDCA section 408(p)(50)(B) does, in fact, give the Agency the directive to "minimize duplicative testing" and the authority to "develop, as appropriate, procedures for the fair and equitable sharing of test costs." This stipulation expressly authorizes the EPA to create and promote rules for joint data development. The EPA clearly originally interpreted the statute in this manner; the FR notice states "the Agency originally anticipated relying on the authority of the FFDCA section 408(p) to establish new procedures to promote joint development of data by recipients of FFDCA section 408(p) test orders." Yet the EPA inexplicably reverses this decision two paragraphs later with the confusing and inconsistent sentence: "While FFDCA section 408(p) does not allow the EPA to impose requirements identical to those authorized by FIFRA section 3 that would minimize duplicative testing, EPA has the authority under FFDCA section 408(p) to develop agency procedures that achieve many of the same ends."

In lieu of developing new rules or using existing rules for data sharing (e.g. following TSCA or FQPA), the EPA claims to offer "strong incentives" to avoid duplicative testing; however, the only

real “incentive” identified in the FR notice is an Agency commitment to “typically treat a suitably expressed offer to join in the development of a required study as sufficient to comply with a test order…” This provision can hardly be considered a “strong incentive” and will do very little to prevent duplicative testing.

The EPA believes that its cost sharing provisions will promote joint data submission and that nearly all of the data requested for the EDSP will be compensable under FIFRA or FFDCA section 408(i), except in the case of “non-food use inerts,” unless they are submitted by a pesticide registrant in support of a pesticide product. In other words, the major “incentive” for minimizing data duplication is the provision of cost-sharing, which applies only to pesticide registrants and to inert ingredients for which a tolerance or a tolerance exemption has been issued. We believe the EPA has misinterpreted FFDCA section 408(p) and has neglected its statutory obligation to develop effective data sharing rules or incentives. At a minimum, cost sharing provisions should be applicable to all chemicals. Further, the Agency should mandate joint data development using its authority under authorized by FIFRA.

Exemptions: The parties to this submission challenge the Agency’s stated intent to require recipients of test orders to undertake a full Tier 1 battery for each substance in the initial screening. Many of these substances (i.e., food-use pesticide active ingredients) are extraordinarily data-rich, and may possess adequate data in relation to some endocrine parameters (e.g., anti/estrogenicity or anti/androgenicity) but not others (e.g., anti/thyroid). Thus, test orders should be tailored to reflect the dataset — and gaps — for the substances in question; they should not be carbon-copy checklists of tests that pay no regard to existing data in the interest of expediency. Moreover, per the statutory directives laid out in section 408(p), the Agency should make it clear that recipients of test orders are encouraged to utilize existing data, submit joint data, and seek data waivers as provided under FIFRA and section 408(p)(4).

Responses to specific questions:

A. Minimizing Duplicative Testing

1. If there are multiple entities who manufacture or import a substance for which EDSP data are needed, under what circumstances, if any, should EPA send test orders only to a single entity?

Under no circumstances should test orders be sent to a single entity if multiple entities manufacture or import the same substance. In fact, the formation of consortia based on the same or similar substances should be mandatory.

2. When issuing test orders for EDSP data on an active ingredient, should EPA issue the test order under the authority of FFDCA section 408(p), under FIFRA section 3(c)(2)(B), or under both authorities?

Both.

3. When issuing test orders for EDSP data on an inert ingredient, should EPA issue the test order under the authority of FFDCA section 408(p), under FIFRA section 3(c)(2)(B), or under both authorities?

Thank you for considering our comments.

Sincerely,

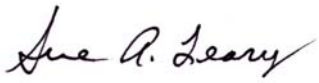
Catherine Willett, PhD
Science Policy Advisor
Regulatory Testing Division
People for the Ethical
Treatment of Animals

Troy Seidle
Science Policy Advisor
Humane Society of the United
States

Kristie Stoick, MPH
Research Analyst
Physicians Committee for Responsible
Medicine

Sara Amundson
Executive Director
Humane Society Legislative Fund

Dr. Martin Stephens
Vice President for Animal Research Issues
Humane Society of the United States



Sue A. Leary
President
Alternatives Research & Development Foundation

Tracie Letterman, Esq.
Executive Director
American Anti-Vivisection Society