

## Status on EPA's Endocrine Disruptor Screening Program (August 28, 2008)

### Questions Specific to August 2008 Delay

#### 1. Why is EPA going to be late in issuing the test orders?

The Agency recently concluded that additional time is needed to complete the necessary steps before it can begin issuing orders. EPA needs to:

- Address matters related to the proposed Tier 1 battery from EPA's independent expert review committee, the FIFRA Scientific Advisory Panel.
- Respond to a Request for Correction (RfC) on one of the assay validations, filed in July 2008 by the Center for Regulatory Effectiveness (CRE) under the Agency's Information Quality Guidelines (IQG).
- Respond to a petition to delay the EDSP orders received in July 2008 from Crop Life America.
- Address complex regulatory, policy, and scientific issues raised during extended comment periods on the draft list of initial pesticide active and inert ingredients to be considered for screening and the draft policies and procedures for initial screening.
- Complete the interagency review packages for related documents.

#### 2. What is EPA's timeline for conducting the EDSP program?

EPA plans to expedite the remaining procedural and administrative steps, so that test orders can be issued in early 2009.

#### 3. Does the public have opportunities to comment or otherwise be involved in the program?

EPA continues to strive to make the implementation, development, and conduction of the EDSP as transparent a process as is possible. This transparent process has included multiple opportunities for the public to be involved in the program and EPA is committed to include more opportunities in the future. The general public, stakeholders and the regulated community have participated in open Federal Advisory committee meetings, workshops held by EPA, as well as public comment periods advertised in the Federal Register. Also, the Agency has always been agreeable to meet with any person or group on an individual basis when it has been requested by an outside party.

4. What is the process for getting the EDSP paperwork reviewed by the Office of Management and Budget (OMB)? Is the Information Collection Request (ICR) the first step? Does it have to be approved by OMB before test orders can be issued?

The Paperwork Reduction Act (PRA, 44 U.S.C. 3501 et seq.) defines the process that agencies must follow to submit the Information Collection Request paperwork to OMB. The PRA also requires that agencies get approval before doing any information collections with identical questions involving 10 or more entities. The EDSP packages (draft final List and draft final Policy & Procedures) are expected to go to OMB shortly for interagency review after which EPA expects the ICR to be submitted under the PRA for OMB review and approval.

5. Why is EPA sending an ICR to OMB when there is a pending Data Quality Act (DQA) petition from the Center for Regulatory Effectiveness? Will a response to the DQA petition be sent before the ICR goes to OMB?

The procedures for responding to any "DQA petition" are separate and unrelated to the ICR procedures under the PRA. EPA's response to the CRE request is currently with OMB for review under the IQG procedures, and EPA expects its response to be issued before the Agency formally submits the ICR to OMB.

6. What response does EPA have to the petition? Will the battery of assays be truncated as suggested by CropLife America?

Until interagency review is complete, it is premature to discuss any details or final agency decisions.

## Basic Questions

7. What is the Endocrine Disruptor Screening Program?

The Endocrine Disruptor Screening Program (EDSP) is a program to provide for the screening of pesticides, chemicals and environmental contaminants for their potential to affect the estrogen, androgen and thyroid hormone systems using a two-tiered system. Tier 1 will be comprised of a battery of screening assays that would identify substances that have the potential to interact with the estrogen, androgen, and/or thyroid hormone systems. Tier 2 assays will be used to identify and establish a dose response relationship for any adverse effects that might result from the interactions identified through the Tier 1 assays.

8. What is the Agency's authority for the Endocrine Disruptor Screening Program (EDSP)?

EPA is implementing the EDSP in response to a 1996 Congressional mandate in the Federal Food, Drug, and Cosmetic Act (FFDCA) to "develop a screening program, using appropriate validated test systems and other scientifically relevant information, to determine whether certain substances may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or such other endocrine effect as [EPA] may designate" (21 U.S.C. 346a (p)). When carrying out the program, the statute

generally requires EPA to “provide for the testing of all pesticide chemicals.” “Pesticide chemical” is defined as “any substance that is a pesticide within the meaning of the Federal Insecticide, Fungicide, and Rodenticide Act, including all active and inert ingredients of such pesticide.” (FFDCA section 201(q) (1) (21 U.S.C. 231(q)(1))). In addition, section 1457 of the Safe Drinking Water Act (SDWA) provides EPA with discretionary authority to provide for testing, under the FFDCA 408(p) screening program, “of any other substances that may be found in sources of drinking water if the Administrator determines that a substantial population may be exposed to such substance.”

9. [What progress has been made in implementing the EDSP so far?](#)

The EPA is implementing its EDSP in three major parts. The major milestones for each are described below:

(1) Development and validation of the test systems and selection of the Tier 1 battery

- Completed inter-laboratory validation studies and began peer review of all except one Tier 1 assay by June 2008.
- EPA’s proposed Tier 1 battery was reviewed by the Scientific Advisory Panel in March 2008.

(2) Priority setting and chemical selection

- Published the approach for selection of the first 50 - 100 chemicals for testing in September 2005.
- Draft list of 73 chemicals for initial Tier 1 screening published in June 2007.

(3) Implementation policies and procedures

- Draft implementation policies and procedures (including draft Information Collection Request and draft 408(p) orders) were published for comment in a Federal Register notice in December 2007.
- Anticipate publication of final implementation policies and procedures and issuance of endocrine disruptor testing orders in early 2009.

10. [What is the Agency currently working on under the EDSP?](#)

The Agency is:

- Finalizing the battery of assays that will be used for Tier 1 screening.
- Finalizing the selection of the initial list of chemicals to undergo screening in the battery of Tier1 assays.
- Finalizing the policies and procedures the Agency will use to require testing. This includes review by the Office of Management and Budget.

11. [What is the general approach the Agency used for selecting the initial list of chemicals for screening?](#)

The Agency's approach for selecting the initial list of chemicals for screening was published in a Federal Register Notice on September 27, 2005 (70 FR 56449). EPA selected pesticide active and pesticidal inert ingredients based on potential human exposure (i.e., High Production Volume (HPV) chemicals used as pesticide inerts).

For pesticide active ingredients, EPA used data that indicated the potential for human exposure via the following pathways: (1) consumption of food containing pesticide residues; (2) consumption of drinking water containing pesticide residues; (3) residential exposure to pesticide products; and/or (4) certain occupational exposures following application of agricultural pesticides. Substances having potential exposure through all four pathways were considered the highest priority for inclusion on the draft list of chemicals for screening. Chemicals having potential exposure via three pathways where the food and occupational exposure pathways were represented were considered next highest in priority.

For HPV/pesticide inert chemicals, EPA used data that indicated potential human exposure, based on the following types of monitoring data: (1) human biological samples; (2) ecological tissues that have human food uses (i.e., fish tissues); (3) drinking water; and/or (4) indoor air. EPA considered HPV/pesticide inert chemicals present in multiple pathways as having higher priority for screening. Substances having potential exposure through all four pathways were considered the highest priority for inclusion on the draft list of chemicals for screening. Chemicals having potential exposure via three pathways where the human biological monitoring exposure pathway was represented were considered next highest in priority.

12. [Does the draft initial list of chemicals represent chemicals that EPA suspects are endocrine disruptors?](#)

Because this list of chemicals was selected on the basis of exposure potential alone (i.e., rather than on the basis of both exposure and effects), the initial list of chemicals should not be understood or described as a list of known or likely endocrine disruptors. Nothing in the approach for selecting the initial list would provide a basis to infer that any of the chemicals selected for the list interferes with or is suspected to interfere with the endocrine systems of humans or other species.

13. [How will other chemicals be chosen in the future?](#)

It is anticipated that subsequent testing priorities will be based on existing Agency programs for determining data needs (e.g., part of the Office of Pesticide Programs' pesticide Registration Review process, or Office of Water's development of the Contaminant Candidate List).

EPA anticipates making endocrine disruptor screening a routine part of the registration review process. For chemicals other than pesticide active ingredients testing priorities

will be based on both exposure and hazard as new technologies for selecting and prioritizing large numbers of chemicals emerge (e.g., [ToxCast™ Program](#)).

14. [Will all pesticides be tested eventually?](#)

Yes, FFDCA 408(p) requires all pesticides to be screened in the EDSP.

15. [When will all of the pesticide chemicals be screened as the statute requires?](#)

Assuming that 70 pesticide active ingredient cases were opened each year under the registration review program, it would take approximately 15 years to complete the process of requiring data and completing the screening of all of the 680 pesticide cases comprising about 1,080 active ingredients.

It would take considerably longer to screen the approximately 2,775 inert pesticide chemicals with the existing technologies; however, EPA has been investing substantial resources in the development and validation of high throughput assays and predictive computer models for endpoints involving the endocrine system. If this research is fruitful, it should be possible both to set priorities for further testing and to screen large numbers of chemicals in a shorter period of time in the future.

16. [When will all the other chemicals of potential concern be screened under the SDWA authority?](#)

Using existing technology, it would take decades to screen all possible chemicals under the SDWA authority. However, many of the contaminants found in sources of drinking water are also pesticide active ingredients and inerts and would be tested under FFDCA §408(p) authority. Also, testing of other chemicals under SDWA authority can occur concurrently with the testing of pesticide chemicals. As with pesticide chemicals the Agency expects that, when available, fully validated high throughput approaches will greatly accelerate this process.

17. [Registered pesticides have already been extensively tested. Why is more testing needed?](#)

The database on pesticides varies in terms of the data quality and the degree to which the data cover endocrine effects. Existing information will be used to the extent that it is scientifically relevant to determine the potential of a chemical to interact with the endocrine system but will be supplemented by Tier 1 screening where appropriate.