ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPPT–2007–1080; FRL–8848–9]

Endocrine Disruptor Screening Program; Draft Policies and Procedures for Screening Safe Drinking Water Act Chemicals

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This document describes EPA's draft policies and procedures for requiring 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). FFDCA section 408(p) directed EPA to develop a chemical screening program using appropriate validated test systems and other scientifically relevant information to determine whether certain substances may have hormonal effects. These draft policies and procedures are intended to supplement the existing EDSP policies and procedures that were published in the **Federal Register** on April 15, 2009 (74 FR 17560); however, this document was drafted with the intent of explaining the policies and procedures relevant to EDSP Safe Drinking Water Act chemicals.

DATES: Comments must be received on or before January 18, 2011.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA–HQ–OPPT–2007–1080, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the on-line instructions for submitting comments.
- *Mail:* Document Control Office (7407M), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.
- *Hand Delivery:* OPPT Document Control Office (DCO), EPA East Bldg., Rm. 6428, 1201 Constitution Ave., NW., Washington, DC. Attention: Docket ID Number EPA–HQ–OPPT–2007–1080. The DCO is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the DCO is (202) 564–8930. Such deliveries are only accepted during the DCO's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to docket ID number EPA–HQ–OPPT–2007–1080. EPA's policy is that all comments received will be included in the docket without change and may be made available on-line at *http://www.regulations.gov,* including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through regulations.gov or e-mail. The regulations.gov Web site is an "anonymous access" system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through regulations.gov, your e-mail address will be automatically captured and included as part of the comment that is placed in the docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: All documents in the docket are listed in the docket index available at *http://www.regulations.gov.* Although listed in the index, some information is not publicly available, *e.g.,* CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either in the electronic docket at *http://www.regulations.gov,* or, if only available in hard copy, at the OPPT Docket. The OPPT Docket is located in the EPA Docket Center (EPA/DC) at Rm. 3334, EPA West Bldg., 1301 Constitution Ave., NW., Washington, DC. The EPA/DC Public Reading Room hours of operation are 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number of the EPA/DC Public Reading Room is (202) 566–1744, and the telephone number for the OPPT Docket is (202) 566–0280. Docket visitors are required to show photographic identification, pass through a metal detector, and sign the EPA visitor log. All visitor bags are processed through an X-ray machine and subject to search. Visitors will be provided an EPA/DC badge that must be visible at all times in the building and returned upon departure.

FOR FURTHER INFORMATION CONTACT: *For technical information contact:* Susan Sharkey, Chemical Control Division, Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (202) 564–8789; e-mail address: *sharkey.susan@epa.gov,* or Bill Wooge, Office of Science Coordination and Policy, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (202) 564–8476; e-mail address: *wooge.william@epa.gov*.

For general information contact: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554–1404; e-mail address: *TSCA–Hotline@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you manufacture or import chemical substances (including pesticide chemicals) that may be found in sources of drinking water; if you manufacture or import chemical substances that degrade to chemical substances found in sources of drinking water; or if you are, or may otherwise be, involved in the testing of chemical substances for potential endocrine effects. Potentially affected entities may include, but are not limited to:

- Chemical manufacturers, importers and processors (NAICS code 325), *e.g.,* persons who manufacture, import or process chemical substances.
- Pesticide, fertilizer, and other agricultural chemical manufacturing (NAICS code 3253), *e.g.,* persons who manufacture, import or process pesticide, fertilizer and agricultural chemicals.
- Scientific research and development services (NAICS code 5417), *e.g.,* persons who conduct testing of chemical substances for endocrine effects.

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining

whether this action might apply to certain entities. To determine whether you or your business may be affected by this action, you should carefully examine the applicability provisions in Unit III.C. of this document, and examine the Federal Food Drug and Cosmetic Act (FFDCA) section 408(p). If you have any questions regarding the applicability of this action to a particular entity, consult the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

B. What should I consider as I prepare my comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through regulations.gov or e-mail. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD–ROM that you mail to EPA, mark the outside of the disk or CD–ROM as CBI and then identify electronically within the disk or CD–ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When submitting comments, remember to:

i. Identify the document by docket ID number and other identifying information (subject heading, **Federal Register** date and page number).

ii. Follow directions. The Agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.

iii. Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.

iv. Describe any assumptions and provide any technical information and/or data that you used.

v. If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.

vi. Provide specific examples to illustrate your concerns and suggest alternatives.

vii. Explain your views as clearly as possible, avoiding the use of profanity or personal threats.

viii. Make sure to submit your comments by the comment period deadline identified.

II. Background

A. What action Is the agency taking?

The Agency is proposing, and seeking public comment on, a number of draft policies and procedures for issuing EDSP test orders for substances based on the Agency's authority under the Safe Drinking Water Act (SDWA) section 1457 (*i.e.,* "SDWA chemicals"). SDWA authorizes EPA to issue EDSP test orders to manufacturers and importers of substances that may be found in sources of drinking water and to which a substantial population may be exposed (42 U.S.C. 300j–17). SDWA chemicals encompass a wide variety of substances, including industrial and pesticide chemicals, ingredients in pharmaceuticals and personal care products, and degradates.

These draft policies and procedures are intended to supplement the existing EDSP policies and procedures that were published in the **Federal Register** on April 15, 2009 (74 FR 17560) (FRL–8399–9) (FIFRA/FFDCA policies and procedures) (Ref. 1). The policies discussed in the April 15, 2009, document were developed based primarily on considerations applicable to the issuance of EDSP test orders on pesticide active and inert ingredients, which were the chemicals comprising the first EDSP chemical list. It is important to note that chemicals on the first EDSP list may also fit the criteria to be considered a SDWA chemical and, therefore, these draft policies and procedures also may apply to those chemicals. Consequently, some of the existing policies and procedures reflect issues uniquely associated with the pesticide market and the specific regulatory context under which EPA regulates pesticide chemicals, *i.e.,* FIFRA. In this document, EPA describes the policies and procedures associated with Tier 1 screening of SDWA chemicals, including certain modifications to those original policies and procedures that are intended to address issues that are unique to SDWA chemicals, or to address the circumstances where other competing considerations for SDWA chemicals warrant a modification of those earlier policies.

This document discusses the policy considerations for SDWA chemicals and the procedural modifications and clarifications the Agency is considering for the following areas:

- Who would receive EDSP test orders on SDWA chemicals? [Unit V.A.]
- How will recipients of orders on SDWA chemicals be notified? [Unit V.B.]
- How will the public know who has received a test order on a SDWA chemical or who has supplied the needed data? [Unit V.C.]
- How will the Agency minimize duplicative testing? [Unit V.D.]
- What are the potential responses to test orders on SDWA chemicals? [Unit V.E.]
- How can order responses and data be submitted electronically? [Unit V.F.]
- How will EPA facilitate joint data development and cost sharing for SDWA chemicals? [Unit V.G.]
- What procedures can EPA apply for handling CBI for SDWA chemicals? [Unit V.H.]
- What is the process for contesting a test order or consequences for failure to respond or comply with a test order? [Unit V.I.]
- What is the informal administrative review procedure? [Unit V.J.]
- What are the adverse effects reporting requirements? [Unit V.K.]

The FIFRA/FFDCA policies and procedures remain relevant to recipients of FIFRA chemical test orders. SDWA chemical test order recipients should refer to this document and any subsequent revised document for policies and procedure guidelines. In addition, a new draft order template for issuance of orders under SDWA section 1457 and FFDCA section 408(p)(5) is available in the docket for this **Federal Register** notice (Ref. 2).

EPA has also published two related documents elsewhere in today's **Federal Register**. One announces the second list of EDSP chemicals, which includes both SDWA chemicals and pesticide active ingredients (PAIs). Some of the listed chemicals may be both SDWA chemicals and PAIs. The other requests public comment on a draft supplemental Information Collection Request (ICR), which describes the estimated paperwork burden and costs associated with the second list of EDSP chemicals.

B. What are the statutory authorities for the policies discussed in this document?

SDWA is the primary Federal law that ensures the quality of Americans' drinking water. Under SDWA, EPA sets standards for drinking water and works closely with states, localities, and water suppliers to implement these standards. SDWA authorizes EPA to set national standards for drinking water to protect against both naturally occurring and man-made contaminants that may be found in drinking water (42 U.S.C. 300g–1).

Section 1457 of SDWA authorizes EPA to require testing, under FFDCA section 408(p) (21 U.S.C. 346(a)(p)), of

any substance that may be found in sources of drinking water, based on a determination that a substantial population may be exposed to such a substance. (42 U.S.C. 300j–17).

Section 408(p)(1) of FFDCA requires EPA "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 effects as [EPA] may designate." (21 U.S.C. 346a(p)(1)).

Section 408(p)(3) of FFDCA expressly requires that EPA "shall provide for the testing of all pesticide chemicals." (21 U.S.C. 346a(p)(3)). Section 201 of FFDCA defines "pesticide chemical" as "any substance that is a pesticide within the meaning of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), including all active and pesticide inert ingredients of such pesticide." (21 U.S.C. 231(q)(1)).

Section 408(p)(5)(A) of FFDCA provides that the Administrator "shall issue an order to a registrant of a substance for which testing is required [under FFDCA section 408(p)], or to a person who manufactures or imports a substance for which testing is required [under FFDCA section 408(p)], to conduct testing in accordance with the screening program, and submit information obtained from the testing to the Administrator within a reasonable time period" that the Agency determines is sufficient for the generation of the information. Based on the statutes discussed in this subsection, EPA has the discretion to require testing of a pesticide chemical under FFDCA solely, FIFRA/FFDCA, SDWA/FFDCA or FIFRA/SDWA/FFDCA.

Section 408(p)(5)(B) of FFDCA requires that, "to the extent practicable, the Administrator shall minimize duplicative testing of the same substance for the same endocrine effect, develop, as appropriate, procedures for fair and equitable sharing of test costs, and develop, as necessary, procedures for handling of confidential business information. * * *" (21 U.S.C. 346a(p)(5)(B)).

Section 408(p)(5)(D) of FFDCA provides that any person (other than a registrant) who fails to comply with a FFDCA section 408(p)(5) test order shall be liable for the same penalties and sanctions as are provided for under section 16 of the Toxic Substances Control Act (TSCA). (21 U.S.C. 346a(p)(5)(D)). Such penalties and sanctions shall be assessed and imposed in the same manner as provided in TSCA section 16. Under TSCA section 16, civil penalties may be assessed, after notice and an administrative hearing held on the record in accordance with section 554 of the Administrative Procedure Act (APA). (15 U.S.C. 2615(a)(1)–(2)(A)).

C. Does this document contain binding requirements?

While the requirements in the statutes and in any test orders ultimately issued under FFDCA section 408(p) are binding, the policies outlined in this notice are not. The policies outlined in this notice merely represent the general procedures and statutory interpretations on which EPA may rely to implement the existing goals of the statutory program. These policies and procedures may be modified at any time by EPA and the Agency may depart from these policies and procedures where circumstances warrant and without prior notice.

III. Background on the EDSP

A. What is the EDSP?

EPA developed the EDSP in response to a Congressional mandate in FFDCA "to determine whether certain substances may have an effect in humans that is similar to an effect produced by naturally occurring estrogen, or such effects as [EPA] may designate" (21 U.S.C. 346a(p)). As part of the EDSP, EPA issues orders to collect certain test data on selected chemical substances. In general, EPA intends to use the data collected under the EDSP, along with other information, to determine if a pesticide chemical, or other substances, may pose a risk to human health or the environment due to disruption of the endocrine system. The determination that a chemical does or is not likely to have the potential to interact with the endocrine system will be made on a weight of evidence basis taking into account data from the Tier 1 assays and/or other scientifically relevant information. Chemicals that go through Tier 1 screening and are found to have the potential to interact with the estrogen, androgen, or thyroid hormone systems will proceed to the next stage of EDSP where EPA will determine which, if any, of the Tier 2 tests are necessary based on the available data. Tier 2 testing is designed to identify any adverse endocrine-related effects caused by the substance, and establish a quantitative relationship between the dose and that endocrine effect. Further information regarding the EDSP and requirements for Tier 1 and Tier 2 can be found on the Agency's EDSP Web site, at *http://www.epa.gov/endo/* (Ref. 3). EPA is aware of no issue specific to the chemicals in the second list of screening that would warrant any modification to the existing testing scheme, and is not proposing to adopt any.

B. Why is EPA publishing a second edsp policies and procedures used to require the submission of test data?

As stated in the April 15, 2009, document (Ref. 1), EPA generally developed EDSP policies and procedures that could be used in subsequent data collection efforts, including those under SDWA, but indicated that EPA may make modifications as appropriate. The Agency believes that some significant modifications are needed because the existing policies were designed to address screening of pesticide chemicals which are regulated under FIFRA, a statute that does not apply to non-pesticides. For example, much of the data that would be generated in response to an EDSP test order (particularly for pesticide active ingredients) would be entitled to the data compensation protections available under FIFRA (7 U.S.C. 136a(c)(1)(F); FFDCA 21 U.S.C. 346a(i)). Additionally, FIFRA section 10 prohibits EPA from releasing study data on pesticide chemicals unless the person seeking access to the information certifies that he is not an agent or employee of any multinational pesticide company (7 U.S.C. 136h(g)). Because FFDCA section 408(p) did not authorize EPA to modify these FIFRA requirements, EPA needed to ensure that the procedures adopted to implement section 408(p) would operate in a manner that would be compatible with EPA's implementation of the existing FIFRA mandates. Moreover, the fact that a long-standing FIFRA mechanism was already effectively minimizing duplicative testing and promoting cost sharing among order recipients meant that EPA could rely on the existing mechanisms as a uniquely relevant model for screening of pesticides under the EDSP. By contrast, the SDWA chemicals that may be subject to EDSP screening include pesticide chemicals, industrial (non-pesticide) chemicals, as well as ingredients in pharmaceuticals and personal care products, among others.

EPA has also drafted these new policies and procedures to address issues specific to SDWA chemicals beyond those associated with the applicability of FIFRA. The rationale and statutory authority for listing SDWA chemicals, the sources of SDWA chemicals and EPA's ability to identify manufacturers and importers, and other considerations unique to SDWA

chemicals create a need for policies and procedures specific to EDSP screening under SDWA/FFDCA authority. For example, some registered pesticide ingredients have additional uses that account for a much larger percentage of total manufacture and import. In such cases, the Agency seeks to be able to identify, and issue orders to, all relevant manufacturers and importers in a manner that creates a fair and level playing field for complying with the order. In addition, many of the companies likely to receive SDWA/FFDCA test orders may be unfamiliar with the initial policies and procedures because those companies are not associated with the pesticide market, were unaffected by that earlier proposal, and consequently had no interest in commenting. EPA also believes it would be inappropriate to publish this document in a manner identifying only the changes to the existing policies and procedures because the procedures are inherently complex and would require numerous cross referencing by parties unfamiliar with the referenced regulation.

C. When do these policies and procedures apply?

These policies and procedures apply to all SDWA chemicals listed for screening under the EDSP. EPA has the discretion to issue EDSP test orders under the authorities of SDWA section 1457 and FFDCA section 408(p) for all SDWA chemicals, including PAIs. As described in this document, EPA generally intends to use SDWA authority (1) to require testing of SDWA chemicals that are not PAIs, and (2) to require testing of SDWA chemicals that are also PAIs if the initial FIFRA/FFDCA orders to technical registrants did not generate the required data. Note that, in the event that FIFRA/FFDCA order recipients exercise the option to exit the pesticide market and the Agency subsequently sends such recipients a SDWA/FFDCA order, the recipient would be required to submit data or otherwise respond to the SDWA/FFDCA test order, even if they previously responded to an earlier FIFRA/FFDCA order.

For a variety of reasons, EPA generally intends to issue FIFRA/FFDCA orders to manufacturers and registrants of PAIs. For such order recipients, the policies discussed in the April 15, 2009, document would be applicable, rather than the policies discussed in this document. EPA believes that this will minimize administrative burdens and ultimately be less confusing to order recipients. Burdens and confusion should be reduced because many of the policies for these chemicals were driven by existing statutory requirements applicable to the test order recipients for these chemicals, such as the requirements for data compensation and confidentiality established by FIFRA sections 3(c)(1)(F) and 12, as well as FFDCA section 408(i). These requirements would remain applicable, whether or not the test orders are issued for SDWA chemicals, and EPA lacks the authority to modify them. Thus, EPA believes that continuing to issue FIFRA/FFDCA orders to the manufacturers and registrants of these chemicals would generally be appropriate, to avoid any confusion, and to simplify Agency policies, even though EPA has determined that these chemicals meet the standards laid out in SDWA section 1457.

IV. EDSP Policy Considerations for SDWA Chemicals

The Agency used the following policy considerations to guide development of procedures for issuing EDSP Tier 1 screening test orders on SDWA chemicals:

- A core part of EPA's mission is to promote public understanding of the potential risks posed by chemicals in commerce.
- The basis for an order with respect to SDWA chemicals is that a substance may be found in sources of drinking water and a determination that a substantial population may be exposed to such substance. Thus, SDWA procedures should not be unnecessarily tied to the use of the chemical in any given market and should instead focus on obtaining data from companies that might be expected to contribute to a chemical's presence in drinking water.
- For simplicity, procedures for SDWA chemicals should be consistent with existing EDSP procedures unless there is a reason for modifying them (*e.g.,* different statutory requirements), though for the sake of clarity EPA has written these draft policies and procedures as a complete, stand alone document.
- Procedures for EDSP testing of SDWA chemicals should strive to minimize duplicative testing and promote fair and equitable sharing of test costs, as described in section 408(p)(5)(B) of FFDCA.
- The Agency expects to issue SDWA/FFDCA orders for pesticide inert ingredients that are listed for EDSP screening with a SDWA section 1457 finding; it has also been the Agency's experience that pesticide inerts generally have a much larger market than solely as ingredients in pesticide formulations. For these reasons EPA believes it is reasonable and equitable to initially issue SDWA/FFDCA orders on all SDWA chemicals that are not PAIs.
- EPA intends, where appropriate, to rely on FIFRA and FFDCA when issuing orders to technical registrants of a pesticide chemical. If, however, recipients of such test orders fail to provide the required information, EPA may choose to reissue test orders under SDWA/FFDCA authority based on the SDWA criteria. EPA would then rely on the policies and procedures established in this document.

V. Proposed Procedures for Requiring Testing Under the EDSP Pursuant to SDWA

For purposes of discussing the EDSP procedures in this document, SDWA chemicals can be described as either currently registered PAIs (SDWA PAIs) or Other SDWA Chemicals (including currently registered pesticide inert ingredients). As previously noted, EPA generally intends to issue FIFRA/FFDCA orders to manufacturers and registrants of PAIs. EPA would retain, however, the discretion to issue an SDWA/FFDCA order to any substance that meets the statutory criteria in SDWA section 1457. Consequently, in the event that no FIFRA/FFDCA test order recipient generates the required data, either because all registrations containing the PAI or inert ingredient has been cancelled, or because all manufacturers decide to "opt out" of the pesticide market, EPA may determine to issue testing orders based on the SDWA authority in order to obtain the data. In such instances, the policies outlined in this document would be applicable.

By contrast, for SDWA chemicals that are not PAIs (*i.e.,* "Other SDWA Chemicals"), EPA may determine to issue test orders relying on both SDWA section 1457 and FFDCA section 408(p)(5). For readers associated with the pesticide community, EPA notes that in several respects, the Other SDWA Chemicals are similar to the non-food use inert ingredients discussed in EPA's April 15, 2009 policies; the similarities are reflected in the policies that EPA is proposing in this document. Subsections A–K of this unit describes the policies and procedures that relate to EDSP test orders issued under SDWA/FFDCA authority.

A. Who would receive EDSP test orders on SDWA chemicals?

Under FFDCA section 408(p)(5)(A), EPA "shall issue" EDSP test orders "to a registrant of a substance for which testing is required * * * or to a person who manufactures or imports a

substance for which testing is required * * *" (21 U.S.C. 346(a)(p)(5)(A)). The process for issuing test orders for SDWA chemicals depends on whether the chemical is a SDWA PAI or an Other SDWA Chemical. A chart depicting the process for issuing test orders on SDWA chemicals is included in the docket (Ref. 4).

As noted for SDWA PAIs, the Agency is not proposing to modify the FIFRA policies and procedures. Readers potentially affected by FIFRA/FFDCA test orders should review the April 15, 2009, document. As described in that document, EPA intends to use internal databases—principally the Office of Pesticide Program's Information Network (OPPIN)—to identify technical registrants with a current pesticide registration containing a SDWA chemical as the active ingredient, and anticipates issuing a FIFRA/FFDCA test order to all identified technical registrants.

For Other SDWA Chemicals, EPA intends to issue SDWA/FFDCA test orders following the polices and procedures proposed in this document. Generally, EPA intends to rely primarily on information reported to the Agency under the TSCA Inventory Update Reporting (IUR) Rule (Ref. 5) to identify the initial SDWA/FFDCA test order recipients. The IUR Rule requires manufacturers and importers of certain chemical substances included on the TSCA Inventory to report site and manufacturing information for chemicals manufactured (including imported) in amounts of 25,000 lb. or more at a single site. The Agency believes that the IUR information is an appropriate source for identifying test order recipients for four primary reasons:

(1) It has been EPA's experience that relying on companies that have reported to the IUR is the most reliable mechanism for identifying manufacturers and importers of (non-pesticide) industrial chemicals. Such manufacturers and importers are required, by regulation, to report under the IUR rule.

(2) Companies that report under the IUR Rule generally account for most of a chemical in commerce; therefore these companies can be expected to account for most of a chemical when it is found in drinking water, which is the basis for listing a chemical under SDWA authority (see Unit II.B.). As relatively large manufacturers and importers, EPA also believes that companies reporting under IUR comprise the majority of the volume associated with the chemical; these companies are more likely to be able to afford the cost of EDSP testing than companies manufacturing volumes below the IUR reporting threshold. EPA believes that, in general, these manufacturers are analogous to the technical registrants, who received orders in the first round of EDSP screening.

(3) Using the IUR information to identify order recipients will facilitate joint data development as reporters for these chemicals are generally publicly known and not numerous.

(4) EPA anticipates that initially sending orders on Other SDWA Chemicals to all potential manufacturers and importers may lead to unnecessary administrative costs to the regulated industry and EPA. EPA's experience in the first round of EDSP screening identified that, to date, for the nine inert pesticide chemicals, only 10 of the 524 orders issued have resulted in an initial response of entering a consortia or otherwise providing the data. The remaining 514 responses have been either no response, returned to the Agency as undeliverable, or a response indicating not subject to the order, discontinued manufacture or import, or will not sell for a pesticide use. Should EPA send a SDWA/FFDCA order to these recipients as a follow-up, the Agency anticipates that the 115 responses of "will not sell for a pesticide use" are manufacturers or importers which would need to provide data under the SDWA/FFDCA order. (Ref. 6) A *de minimis* exemption for very low volume producers is discussed later in this subsection.

If there are no companies reporting in response to the IUR rule for a given chemical, EPA intends to use other publicly-available databases, such as the Toxic Release Inventory (TRI), to identify possible test order recipients. For Other SDWA Chemicals that are also regulated or tracked by another agency (*e.g.,* pharmaceuticals by the Food and Drug Administration), EPA may also consult with that agency as appropriate to identify main manufacturers and importers. EPA is interested in finding other sources of information for reliably identifying test order recipients and requests comment on other means of identifying potential test order recipients.

In addition to using IUR, TRI, and other Federal Agency data, EPA intends to issue orders to manufacturers and importers who are subsequently identified as such. In the interest of equity and shared test cost burden, EPA believes it is important to identify and issue orders to all significant manufacturers and importers of a listed chemical; the Agency will follow up on any new information it receives to this effect and issue orders accordingly. Of particular interest to the Agency are companies whose production or import of a listed chemical fluctuates year-by-year or who can otherwise be considered current manufacturers or importers even though they did not report under the most recent IUR. Information submitted that identifies potential test order recipients not listed on the most recent IUR should pertain to those companies who manufacturer or import the chemical in relevant quantities. That is, EPA does not intend to issue orders to companies who manufacture or import a chemical for research and development purposes only, or who otherwise manufacture or import quantities of a chemical that are more appropriately measured in grams (as opposed to thousands of pounds). The rationale for this *de minimis* exemption is also based on the authority for listing an Other SDWA Chemical for EDSP screening (*see* Unit II.B.).

The Agency is also considering issuing catch-up orders for manufacturers or importers who are identified as beginning manufacture or import within five years of the issuance of the SDWA/FFDCA test order. The catch-up order process would be similar to the catch-up order process described in the April 15, 2009, document, except EPA intends to rely on the public to identify such manufacturers. A recipient of such catch-up orders would be expected to participate in the cost sharing if it relies on data developed or submitted by another recipient or consortia to satisfy its test order obligation.

If, after going through this process, all test order recipients have ceased to manufacture a SDWA chemical and the Agency has not received the required data, the SDWA chemical would be considered an "orphan." The Agency 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. How will recipients of orders on SDWA chemicals be notified?

Order recipients would receive a test order in one of two ways: By registered mail or electronically, once a process has been established. In addition to the test order, EPA will send each recipient a packet that contains the instructions, background materials, and forms needed to comply with the order or will provide directions as to the location of such materials.

EPA is moving toward electronic exchange of information in many of its programs. For instance, reporting for the IUR Rule is anticipated to be fully

electronic sometime in 2011. The Agency seeks comment as to whether companies who already have a Central Data Exchange (CDX) (Ref. 7) account would prefer to receive the notification electronically, either as a standard procedure or upon request. EPA requests that commenters include some discussion of the mechanisms by which EPA can ensure that accurate records documenting that the individual has received the order, as well as the date of receipt of the test order, can be obtained through the use of electronic reporting mechanisms.

C. How will the public know who has received a test order on a SDWA chemical or who has supplied data?

EPA intends to publish the list of all test order recipients on the Agency's public Web site, *https://www.epa.gov/endo*. EPA invites the submission of information (with proper substantiation) identifying additional entities—including entities who manufacture for export only—who should have received a test order. Commenters could either identify themselves or another person as additional candidates for the receipt of an order.

D. How will the agency minimize duplicative testing?

The Agency also intends to post the status of the test orders, including recipients' responses, on the EPA Web site so that both order recipients and the public can determine the status of responses. EPA is making such information available to enable test order recipients to identify and join other order recipients to develop the data in response to the order, thereby helping to achieve EPA's goals of minimizing duplicative testing and promoting fair and equitable sharing of test costs.

E. What are the potential responses to test orders on SDWA chemicals?

The options for responding to a SDWA/FFDCA test order are similar to those established in the existing policies and procedures except that the option of exiting the pesticide market will not be available. The basis for a SDWA/FFDCA order is that a chemical may be found in sources of drinking water to which substantial populations may be exposed. Exiting any given market (*e.g.,* the pesticide market) is not sufficient if the SDWA chemical is manufactured or imported for other uses because the chemical may still be found in sources of drinking water. Accordingly, if sufficient data on a SDWA chemical is not generated in response to a FIFRA/FFDCA order (*e.g.,* all FIFRA/FFDCA order recipients exit the market or otherwise indicate that they are not providing data), a subsequent SDWA/FFDCA order may be issued.

Order recipients provide their initial responses on an "Initial Response Form for Individual Order Recipients" (Ref. 8). Response options that EPA anticipates including in SDWA/FFDCA test orders are as follows:

Option 1: *Recipient indicates that it intends to generate data.* The test order recipient may decide to generate new data for each test specified in the order, and would then comply with the procedures prescribed in the test order. In general, this option would be identical to the option discussed in the original policies and procedures. EPA is not proposing to make any changes for SDWA chemicals. Data generated and submitted would need to comply with Good Laboratory Practices (GLP). Good Practices have been set out both in FIFRA for pesticides in 40 CFR part 160 and for TSCA chemicals in 40 CFR part 792. Test order recipients would need to follow appropriate GLPs, protocol requirements identified in the order, and procedures described in test order for submitting the data.

Option 2: *Recipient indicates that it is submitting or citing existing data or other scientifically relevant information (OSRI).* The recipient would choose this option to indicate that it is submitting or citing existing data (including citing data previously submitted to the Agency) that it believes is relevant to one or more of the requests in the test order. The recipient's initial response would include either the data or a reference to the data for each assay specified in the order. In submitting or citing existing data, the order recipient or other party should follow, as appropriate, relevant format guidelines described in the test order and provide an explanation of the relevance of the data to the order, including, where appropriate, a cogent and complete rationale for why it believes the information is or is not sufficient to satisfy part or all of the Tier 1 order.

Data compensation procedures may apply to data previously submitted to the Agency. If the data cited or submitted are from a study that was not conducted exactly as specified in the protocols referenced in the test order or in accordance with accepted scientific methodology or protocol, including but not limited to those presented in EPA's harmonized test guideline compendium (*see http://www.epa.gov/ocspp/pubs/frs/home/guidelin.htm*) (Ref. 9), the recipient would also identify the deviations from the applicable protocol(s), along with an explanation for the deviations, including an explanation as to why, notwithstanding the deviations, the protocol used for developing the cited or submitted data should still be considered as providing an accepted scientific methodology or protocol, and any other information relevant to a decision to accept the data as satisfaction of the order.

EPA would review any existing relevant information submitted or cited (including other scientifically relevant information) to determine whether the information is acceptable *i.e.,* the study was not rejected by the Agency for any reason related to completeness or quality) and satisfies the order. Decisions about whether the information satisfies part or all of the Tier 1 order will be based on the weight-of-evidence from all relevant information available. The Agency would notify the recipient in writing of its determination.

If the Agency determines that the information cited or submitted as part of the initial response received from an order recipient can be used to satisfy the Tier 1 order, which will be based on the weight-of-evidence from all relevant information available to the Agency, the Initial Response Form is the only response required.

If, however, EPA determines that the information cited or submitted as part of the initial response is insufficient to satisfy the Tier 1 order, although it may satisfy part of the order, the recipient would still need to satisfy the remainder of the order.

As indicated previously, EPA intends to use a weight-of-evidence basis, taking into account data from the Tier 1 assays and any other scientifically relevant information available, to determine whether the chemical has the potential to interact with the endocrine system. Chemicals that go through Tier 1 screening and are found to have the potential to interact with the estrogen, androgen, or thyroid hormone systems will proceed to the next stage of the EDSP where EPA will determine which, if any, of the Tier 2 tests are necessary based on the available data. Tier 2 testing is designed to identify any adverse endocrine-related effects caused by the substance, and establish a quantitative relationship between the dose and that endocrine effect.

EPA is not currently able to provide definitive examples of the specific circumstances in which a chemical would be able to go directly to Tier 2 testing; however, if an order recipient chooses to make such a request, EPA will consider it, along with any justification provided. In general, it may in some cases be possible to determine

that a particular chemical has the potential to interact with the endocrine system and therefore could proceed to Tier 2 even if Tier 1 data are limited. However, if only some of the Tier 1 data are available, there may not be sufficient information to determine that some of the Tier 2 data are not necessary. These determinations will be made in a weight-of-evidence judgment on a case-by-case basis and made publicly available for consideration by others with the same or similar circumstances.

Option 3: *Recipient indicates that it intends to enter (or offer to enter) into an agreement to form a consortium to provide the data.* The recipient may choose to form a consortium to share in the cost of producing the required data. All participants of the consortium must submit their own "Initial Response Form for Individual Order Recipients," providing the name of the party who will be submitting the data on the recipient's behalf.

The designated lead for the consortium would need to complete the "Initial Response Form for Consortium" to provide the primary contact for the consortium, the list of participants, and an indication of the consortium's planned response for each assay, along with documentation of its formation (such as a copy of the joint agreement or a written statement by all the parties that an agreement exists). The joint agreement to produce the data would not need to specify all of the terms of the final arrangement between the parties or the mechanism to resolve the terms. The designated lead for the consortium would need to follow the mailing instructions on the order to submit the consortium's initial response and accompanying information to EPA by the due date for the consortium's response, which would be indicated in the test order.

Once the consortium submits the data and EPA has completed its initial review, EPA would provide written notification to the contact of the consortium indicating whether the order has been satisfied. If satisfied, such an action would satisfy test order obligations for each of the consortium participants.

If the consortium fails to submit the data or meet the requirements of the order in a timely and adequate manner, each recipient would be subject to penalties, unless it were to commit to submit, and then did submit, the required data by the dates specified in the order. The Agency would generally not grant time extensions for the submission of data.

The Agency intends to provide to every test order recipient a list of the other manufacturers and/or importers (to the extent permitted by confidentiality requirements) that have also received an EDSP order for the specified SDWA chemical. This list would be intended to help order recipients identify other companies with whom they could form agreements to develop data jointly, or otherwise collaborate on a response to satisfy the requirements in the order. If the identity of a company subject to the SDWA/FFDCA test order is claimed as CBI, EPA intends to offer the company an opportunity to identify an agent who would act on their behalf in all matters relating to the EDSP program. For any company that chooses to designate an agent, the Agency intends to make the name of the agent (instead of the company) public by including it on the list of recipients of SDWA/FFDCA test orders. This name use would be similar to the process used for FIFRA/FFDCA test orders and presented in the April 15, 2009, document. If the identity of a company subject to the test order is claimed as CBI, and yet the company does not name an agent, that company's ability to obtain data compensation from other parties (or rely on compensable data submitted by other parties) would likely be affected. EPA generally intends to publish the list of order recipients in the **Federal Register** and post it on the Agency's Web site. EPA intends to update the list with subsequent publication(s) and posting(s) as appropriate. For example, the Agency intends to post the status of the test orders, including the recipient's response, on the Agency Web site so that both order recipients and the public can check on the status of responses to the orders. This public listing is intended to also facilitate the formation of consortia to develop data jointly since recipients would know all other entities required to generate the same data.

Option 4: *Recipient claims that it is not subject to the test order.* Under this option, a recipient would claim that it is not subject to the order because it does not manufacture or import the chemical identified for testing, or because it believes the order was otherwise erroneously sent. An explanation of the basis for the claim, along with appropriate information to substantiate the claim, would accompany the Initial Response. The Agency intends to evaluate the claim and respond to any request in writing within 90 days of receipt. If EPA was unable to verify the claim, the original requirements and deadlines in the order would be expected to remain. If EPA could verify the claim, such a response would satisfy the order and no further response would be necessary. This option would be similar to the option discussed in the original policies and procedures for manufacturers of inert ingredients. EPA is not proposing to make any changes for SDWA chemicals.

Option 5: *Recipient intends to discontinue the manufacture or import of the chemical.* Under this option, the recipient would indicate it has or is in the process of discontinuing all manufacture and import of the chemical. As noted previously, manufacture would also include manufacture for the purposes of export only. The recipient's "Initial Response Form" would need to include an explanation and documentation supporting its claim, which EPA could verify. If EPA verifies the claim, the initial response is all that would be required to satisfy the order. If EPA could not verify the claim, the recipient's obligation to comply with the test order would remain.

Unlike the existing policies and procedures, which enable a manufacturer or importer of a pesticide chemical to comply with the FIFRA/FFDCA test order by discontinuing the sale of the chemical into the pesticide market, SDWA/FFDCA test orders cannot be satisfied in this manner. A chemical manufacturer or importer that receives a SDWA/FFDCA test order would need to cease all manufacture and import of that chemical. Simply exiting the pesticide market would not necessarily address the chemical's potential presence in "sources of drinking water to which a substantial population may be exposed" and it would therefore be inappropriate to allow companies to satisfy a test order with such a response.

Option 6: *Recipient responds according to one of three other response options.* As part of the Initial Response, a recipient may also ask EPA to reconsider some or all of the testing specified in the order if:

6a. The recipient can demonstrate (supported by appropriate data) that the chemical is an endocrine disruptor and that additional EDSP Tier 1 screening is unnecessary.

6b. The recipient can demonstrate (supported by appropriate data) that the chemical meets the standard for an exemption under FFDCA section 408(p)(4) (*i.e.,* "that the substance is not anticipated to produce any effect in humans similar to an effect produced by a naturally occurring estrogen").

6c. The chemical was used by EPA as a "positive control" to validate one or more of the screening assays. EPA generally expects that if the chemical

was used by EPA as a "positive control" to validate one or more of the screening assays, only the data submitted related to those assays for which the chemical was used to complete the testing as part of the validation effort would be sufficient to satisfy the Tier 1 Order.

The Agency intends to make a determination on any claim and respond to the recipient in writing within 90 days of receipt. If EPA cannot verify the claim, the original requirements and deadlines in the order would remain. If EPA could verify the claim, EPA would consider the response to fully satisfy the order and no further response would be required.

F. How can order responses and data be submitted electronically?

EPA is developing a new electronic submission system for data submitted in response to SDWA/FFDCA test orders following the general process established for TSCA Section 5 Premanufacture Notices and under development for other TSCA reporting, including TSCA Section 8 IUR. The order electronic reporting system will take advantage of the Agency's CDX to allow order recipients to respond to an order and to submit test data via the Internet. See *http://www.epa.gov/cdx* for additional information about CDX. (Ref. 7) Recipients, if not already registered with CDX, will need to complete a simple registration process, thereby establishing a secure log-on to CDX. Specific requirements associated with these orders will be provided directly to the order recipients, and are expected to include:

- Registration with CDX, resulting in the establishment of an electronic signature usable for electronically submitting test order responses;
- Access to a web-based response form, including the ability to attach PDF files;
- Encrypted submission to EPA via CDX.

Each test order would contain specific, updated information regarding the most current process to use to respond to the order. If the CDX registration process and/or web-based response form are not fully established at the time of your response, EPA intends to provide an alternate methodology in each order which may be one or more of the following:

- Fillable-PDF response form available from the Agency's Web site, which can be completed, printed, signed, and mailed or delivered to EPA with attachments included as PDF files on a CD;
- Form provided along with the order which can be completed, signed, and mailed or delivered to EPA with attachments included as PDF files on a CD.

Specific instructions for mailing or delivering the response package to the Agency would be provided on the Order Response Form.

G. How will EPA facilitate joint data development and cost sharing for SDWA chemicals?

As described in the existing policies and procedures (74 FR 17560), the Agency has concluded that FFDCA section 408(p)(5) does not provide the authority to create requirements for joint data development, including a requirement to use binding arbitration to resolve disputes, as does FIFRA section 3. In EPA's view, FFDCA section 408(p)(5)(B) merely establishes a qualified direction that the Agency "[t]o the extent practicable * * * minimize duplicative testing * * *." This, standing alone, does not create new authority to compel companies to use arbitration to resolve disputes arising from an effort to develop data jointly, nor does it even authorize EPA to impose a requirement for joint data development. Rather, EPA believes that this provision directs the Agency to create procedures that operate within the confines of existing statutory authorities. While FFDCA section 408(p) does not allow EPA to impose requirements identical to those authorized by FIFRA section 3, EPA has the authority under FFDCA section 408(p) to develop Agency 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 voluntarily develop data jointly. Section 408(p) of FFDCA confers adequate discretion for EPA to consider whether a recipient has fulfilled its obligation to provide data when the recipient individually or jointly submits results from the required studies, or when EPA judges that it would be equitable to allow the recipient to rely on, or cite, results of studies submitted by another person.

At the same time, however, each recipient of an order under FFDCA section 408(p) has a separate obligation to satisfy the Tier I order that it received. EPA thinks that FFDCA section 408(p) confers adequate discretion to consider that a recipient has fulfilled its obligation to provide data when:

- The recipient individually or jointly submits results from the required assays.
- EPA judges that it would be equitable to allow the recipient to rely on, or cite, results of studies submitted by another person.

The determination of whether it would be equitable to allow citation to another recipient's data will be necessarily based on a case-by-case review of the specifics of the individual circumstances. However, the Agency believes that it would generally be equitable to allow a recipient of a FFDCA section 408(p) test order to rely on the results of studies submitted by another person where:

- The data generator has given permission to the recipient to cite the results, or
- Within a reasonable period after receiving the FFDCA section 408(p) test order, the recipient has made an offer to commence negotiations regarding the amount and terms of paying a reasonable share of the cost of testing; has included an offer to resolve any dispute over the recipients' shares of the test costs by submitting the dispute to a neutral third party with authority to bind the parties (*e.g.* through binding arbitration); and, if arbitration is requested, participates in the arbitration proceeding and complies with the terms of any arbitration award.

The Agency believes this approach to minimizing duplicative testing, which parallels that used under FIFRA section 3(c)(2)(B), provides all recipients of FFDCA section 408(p) test orders adequate incentives to develop data jointly. In the first instance, where the data generator had granted permission for another party to cite its data, the equities are clear, and EPA has no reason for refusing to allow it. In the second instance, where the data generator received an offer to commence negotiations regarding the amount and terms of compensation and to go to a neutral decisionmaker with authority to bind the parties failing successful negotiations, EPA believes that the company has demonstrated a good faith effort to develop data jointly, and consequently would typically consider that the order recipient had complied with the order. Based on EPA's experience under FIFRA, there would be little or no reason for a data generator to decline such an offer. Moreover, if EPA did not adopt such an approach, the end result would effectively confer the sort of "exclusive use" property rights established under FIFRA section 3(c)(1)(F), on a broad category of data, and EPA does not believe that FFDCA section 408(p)(5) creates such rights, or

provides EPA with the authority to create such rights. These conditions would also apply to recipients of any "catch up" FFDCA 408(p) orders, who enter the market after the data have been submitted.

H. What procedures can EPA apply for handling CBI for SDWA chemicals?

As stated in the April 15, 2009, document, FFDCA does not authorize EPA to either create new rights or to modify existing rights to confidentiality, but directs the Agency to create procedures that operate within the existing confines of FIFRA, the Freedom of Information Act (FOIA), and the Trade Secret Act (TSA). SDWA has no provisions that authorize EPA to extend protections for handling CBI beyond those established by TSA. Thus data submitted in response to SDWA/FFDCA orders would only be subject to the protections under FOIA and TSA, with the notable possible exception of data for pesticide food-use inert chemicals. Registrants of a food-use inert ingredient that is also identified as a SDWA chemical should expect to receive SDWA/FFDCA test orders; however, all CBI and data compensation provisions established in FIFRA would still apply. Test order recipients with a current registration for the food-use inert, or a pesticide with a food tolerance or exemption, should consult the April 15, 2009, document for a more detailed explanation of the FIFRA provisions that apply.

For chemicals on the non-confidential TSCA Inventory (*i.e.,* the chemical identity of the chemical substance is publicly known), health and safety data may not be claimed as CBI when it is submitted to EPA. Because the chemical identity is public for all SDWA chemicals on the second EDSP chemical list, EPA expects that there would be no need to claim submitted information as confidential. EPA also believes that it would be particularly difficult to substantiate such a claim, given that the information would already be publicly available.

As described in Unit V.E. under Option 3, when the identity of a company subject to the SDWA/FFDCA test order is claimed as CBI, EPA intends to offer the company an opportunity to identify an agent who would act on their behalf in all matters relating to the EDSP program. For any company that chooses to designate an agent, the Agency intends to make the name of the agent (instead of the company) public by including it on the list of recipients of SDWA/FFDCA test orders.

I. What is the process for contesting a test order or consequences for failure to respond or comply with a test order?

Section 408(p) of FFDCA [21 U.S.C. 34a] does not explicitly address the process for contesting a test order. EPA's interpretation is that a test order is final agency action subject to review by all order recipients, including non-registrants. (EPA believes this is an appropriate conclusion because the provisions in FFDCA section 408(p)(5)(A) describing "Collection of Information" for a test order does not distinguish between FIFRA registrants and other test order recipients.)

If anyone potentially subject to an order wishes to challenge the validity of the factual predicate for issuance of the Order, specifically the EPA determination that the chemical or substance for which testing is required by the order is a "substance that may occur in sources of drinking water" and/or that "a substantial population may be exposed to such substance," that person would only be able to do so under SDWA section 1448 [42 U.S.C. 300j–7(a)] by filing a petition for review in the United States Court of Appeals for the circuit in which the recipient resides or transacts business within 45 days of the date of the SDWA determination, plus 14 days provided under 40 CFR 23.7. EPA interprets the date of the determination to be the date that EPA publishes the finalized EDSP list along with the Schedule for Issuance of Orders.

If the order recipient wishes to challenge the validity of any other the provisions of the order, including the requirement to conduct any test or use the specific test protocols required by the order, it must submit to the Agency a detailed explanation of the basis for its challenge that provides sufficient information for the Agency to evaluate the issue. While EPA is considering the submission, the original deadline would remain. The Agency intends to respond to a request in writing within 90 days of receipt. If EPA does not grant the recipient's request, the original deadline remains.

FFDCA does specify procedures available to non-registrants who fail to comply with a test order (see FFDCA section 408(p)(5)(D)). Non-registrants who fail to comply with a test order shall be liable for the same penalties and sanctions as are provided for under TSCA section 16. [15 U.S.C. 2615(a) (1), (2)(A)]. Section 16 provides that after notice and an administrative hearing held on the record in accordance with APA section 554, civil penalties may be assessed. Additionally, for EDSP test orders issued under the authorities of FIFRA/FFDCA or SDWA/FFDCA, the enforcement response described in the FIFRA policies and procedures apply (Ref. 1).

J. What is the informal administrative review procedure?

As described in the April 15, 2009, document, EPA generally intends to include a provision in test orders issued under FFDCA section 408(p) by which recipients could raise any questions or challenges concerning the issuance of the order. EPA expects order recipients who file a challenge to present their objections with sufficient specificity and detail to allow the Agency to effectively evaluate the issue(s) presented. The filing of a challenge or objection does not extend the test order timeline, and EPA recommends that order recipients who respond with a challenge do so in a timely manner, and with adequate detail. EPA would review the objections and respond in writing. The Agency understands the appropriateness of responding to such objections with sufficient time for an aggrieved order recipient to comply with the orders, or to pursue judicial review.

K. What are the adverse effects reporting requirements?

Adverse effects reporting requirements for pesticide chemicals in registered products are established in FIFRA section 6(a)(2) and can be found in the existing policies and procedures (74 FR 17560). In addition to requirements under FIFRA, TSCA section 8(c) allows EPA to request that companies record, retain and/or report "allegation of significant adverse reactions" to a chemical substance or mixture that the company produces, imports, processes or distributes (15 U.S.C. 2607(c)). Additional information can be found in 40 CFR part 717. Chemical substance is defined in TSCA (15 U.S.C. 2602(2)).

Under TSCA section 8(e), U.S. chemical manufacturers, importers, processors, and distributors are required to notify EPA within 30 days of new unpublished information regarding their chemical substance if the information may lead to a conclusion that the chemical substance poses substantial risk to human health or the environment (15 U.S.C. 2607(e)). "Substantial risk" information is information that offers reasonable support for a conclusion that the subject chemical substance or mixture poses a substantial risk of injury to health or the environment. The information need not, and typically

does not, establish conclusively that a substantial risk exists.

Any information that has been previously submitted under FIFRA section 6(a)(2), TSCA section 8(c), or TSCA section 8(e), to the extent the test order recipient believes that it is responsive to the test order, need not be resubmitted to satisfy the FFDCA section 408(p) test orders. The test order recipient need only cite the previously submitted information in lieu of re-submission.

VI. Request for Comment

A. Response Option To Cease Manufacture

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 issues 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." The chemical's current presence in sources of drinking water and the corresponding potential for public exposure is not altered by the fact that a particular company may subsequently choose to no longer manufacture or import the chemical in response to the order. The potential for continued exposure to the chemical exists despite any potential decrease that might be caused by the exit of one or more test order recipients. Moreover, given that past actions contributed to the source of the current exposure, the company should remain responsible for generating the data to allow the Agency to characterize the significance of that exposure. On the other hand, if test order recipient stops manufacturing and importing a chemical, it will lead to less exposure to the chemical in sources of drinking water. (The decline will happen at different rates, depending on the chemical and whether the chemical is found in surface water or ground water.) Moreover, an order recipient who ceases to manufacture or import a chemical that 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, 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. Consequently, EPA seeks comment on whether it is generally inappropriate to allow companies to comply with an order by agreeing to cease manufacture or import of a SDWA chemical.

B. Persistence

EPA seeks comment on whether and how to factor a chemical's persistence in the environment into EDSP policies and procedures. As discussed previously, the Agency generally intends FFDCA section 408(p) as giving the Agency 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 the ways in which this could be taken into account. For example, one option would be for EPA to issue orders to such manufacturers, to ensure that they share in the costs of generating the data. Another option would be for EPA to issue orders to such parties only where the chemical is no longer manufactured or imported in the United States.

C. Catch-Up Orders and Data Compensation

EPA seeks comment on whether 5 years is the appropriate length of time that the Agency should continue to issue SDWA/FFDCA catch-up orders as a means to ensure equitable sharing of test costs. Under FIFRA, new pesticide registrants who did not generate data on an EDSP pesticide chemical are required to pay data compensation to the registrant who sponsored the testing. Test data are compensable for a 15 year period (7 U.S.C. 136a(c)(1)(F)(ii)–(iii)). For this reason, EPA stated in the existing policies and procedures that it intends to issue catch-up orders for 15 years after the initial data were submitted. Requirements in FIFRA ensure that any new manufacturer of a pesticide chemical registers with the EPA, thus enabling EPA to identify test order recipients and issue orders accordingly. Neither SDWA nor FFDCA enable EPA to identify manufacturers or importers of SDWA chemicals so readily, and EPA would bear a substantial burden if it were to issue SDWA catch-up orders on every chemical for 15 years following issuance of the first order(s) (or receipt of the data), simply based on the effort required to identify new manufacturers and importers. Data compensation requirements are also established in TSCA for data generated in response to section 4 test rules. The reimbursement period for TSCA test data ends "after an amount of time equal to that which had been required to develop data or after five years, whichever is later." (40 CFR part 790). The Agency seeks comment in regards to the appropriate amount of time to require data compensation for EDSP data generated in response to SDWA/FFDCA orders. This data will be made public after the EPA has received it, and data compensation measures exist solely to maintain fair and equitable sharing of test costs. EPA also notes that a five-year window for issuing catch-up orders would include the next IUR collection.

D. Orphan Chemicals

As stated in Unit V.A. the Agency seeks comment on the value of testing orphan chemicals (those for which test orders do not generate the necessary data). EPA is interested in strategies for obtaining the data or sources of funding to conduct EDSP screening.

E. Electronic Notification

As stated in Unit V.B. The Agency seeks comment as to whether companies who already have a Central Data Exchange (CDX) account would prefer to receive the notification electronically, either as a standard procedure or upon request. EPA requests that commenters include some discussion of the mechanisms by which EPA can ensure that accurate records documenting that the individual has received the order, as well as the date of receipt of the test order, can be obtained through the use of electronic reporting mechanisms.

VII. References

1. EPA. Endocrine Disruptor Screening Program; Polices and Procedures for Initial Screening: Notice. **Federal Register** (74 FR 17560, April 15, 2009) (FRL–8399–9).

2. EPA. FFDCA section 408(p) Order Template for Manufacturers/Importers of SDWA Chemicals. Draft. September 22, 2010.

3. EPA. OCSPP. Endocrine Disruptor Screening Program. Available online at *http://www.epa.gov/endo/*.

4. EPA. OCSPP. Process for Issuing EDSP Second List Test Orders. September 20, 2010.

5. EPA. OCSPP. Inventory Update Reporting (IUR). Available online at *http://www.epa.gov/iur.*

6. EPA. Status of EDSP Orders/DCIs as of Thursday, September 16, 2010 (Next update September 23, 2010). Updated tables available online at *http://www.epa.gov/endo/.*

7. EPA. Central Data Exchange. Available online at *http://www.epa.gov/cdx.*

8. EPA. [DRAFT] FFDCA section 408(p) Order for SDWA Chemicals—Initial Response Form for Individual Order Recipients (EPA Form No. tba). September 20, 2010.

9. EPA. Harmonized Test Guidelines. Available online at *http://www.epa.gov/ocspp/pubs/frs/home/guidelin.htm.*

List of Subjects

Environmental protection, Chemicals, Endocrine disruptors, Pesticides and pests, Safe drinking water, Reporting and recordkeeping.

Dated: September 28, 2010.

Stephen A. Owens,

Assistant Administrator, Office of Chemical Safety and Pollution Prevention.

[FR Doc. 2010–28812 Filed 11–16–10; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPPT–2007–1081; FRL–8849–3]

Agency Information Collection Activities; Proposed Collection; Comment Request; Addendum for the Second List of Chemicals; Tier 1 Screening of Certain Chemicals Under the Endocrine Disruptor Screening Program (EDSP); EPA ICR No. 2249.02, OMB Control No. 2070–0176

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), this document announces that EPA is planning to submit a request an addendum to an existing approved Information Collection Request (ICR) to the Office of Management and Budget (OMB). This addendum simply covers the burden for a new list of chemicals to receive and respond to EDSP Orders. The activities articulated in the original ICR are not changing. This ICR addendum, entitled "Addendum for the Second List of Chemicals; Tier 1 Screening of Certain Chemicals Under the Endocrine Disruptor Screening Program (EDSP)" and identified by EPA ICR No. 2249.02 and OMB Control No. 2070–0106. Before submitting the ICR to OMB for review and approval, EPA is soliciting comments on specific aspects of the proposed information collection.

DATES: Comments must be received on or before January 18, 2011.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA–HQ–OPPT–2007–1081, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the on-line instructions for submitting comments.
- *Mail:* Document Control Office (7407M), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.
- *Hand Delivery:* OPPT Document Control Office (DCO), EPA East, Rm. 6428, 1201 Constitution Ave., NW., Washington, DC. Attention: Docket ID Number EPA–HQ–OPPT–2007–1081. The DCO is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the DCO is (202) 564–8930. Such deliveries are only accepted during the DCO's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to docket ID number EPA–HQ–OPPT–2007–1081. EPA's policy is that all comments received will be included in the docket without change and may be made available on-line at *http://www.regulations.gov,* including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through regulations.gov or e-mail. The regulations.gov Web site is an "anonymous access" system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through regulations.gov, your e-mail address will be automatically captured and included as part of the comment that is placed in the docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

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SUPPLEMENTARY INFORMATION:

I. What should I consider when I prepare my comments for EPA?

A. Considerations Under the Paperwork Reduction Act (PRA)

Pursuant to section 3506(c)(2)(A) of PRA, EPA specifically solicits comments and information to enable it to:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility.

2. Evaluate the accuracy of the Agency's estimates of the burden of the proposed collection of information, including the validity of the methodology and assumptions used.

3. Enhance the quality, utility, and clarity of the information to be collected.

4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses. In particular, EPA is requesting comments from very small businesses (those that employ less than 25) on examples of specific additional efforts that EPA could make to reduce the paperwork