Docket ID No. EPA-HQ-OPPT-2007-1080

Submission to OMB under EO 12866

Attached is a copy of the information that was provided to OIRA for review under the Executive Order:

1. Draft Federal Register document entitled: “Endocrine Disruptor Screening Program (EDSP); Policies and Procedures for Initial Screening; Notice” (08/11/2008).

2. Draft Response to Comment document entitled: “Endocrine Disruptor Screening Program (EDSP): Policies & Procedures for Initial Screening and Testing; Response to Public Comments (Docket ID #: EPA-HQ-OPPT-2007-1080)” (08/12/2008).

EDSP-Policy_2008-08-11.doc

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPPT–2007–1080; FRL–_____]

RIN [2070–AD61]

Endocrine Disruptor Screening Program (EDSP); Policies and Procedures for Initial Screening

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This document describes the policies and procedures EPA generally intends to adopt for initial screening of chemicals under the EDSP. The EDSP is established under section 408(p) of the Federal Food, Drug, and Cosmetic Act (FFDCA), which requires endocrine screening of all pesticide chemicals and was established in response to growing scientific evidence that humans, domestic animals, and fish and wildlife species have exhibited adverse health consequences from exposure to environmental chemicals that interact with their endocrine systems. In December 2007, EPA sought comment on its draft policies and procedures for initial screening under the EDSP. Following review and revision based on the public comments, EPA is now describing the specific details of the policies and procedures that EPA generally intends to adopt for initial screening under the EDSP, including the statutory requirements associated with and format of the test orders, as well as EPA's procedures for fair and equitable sharing of test costs and handling confidential data.

FOR FURTHER INFORMATION CONTACT: William Wooge, Office of Science Coordination and Policy (OSCP), Mailcode 7201M, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (202) 564–8476; fax number: (202) 564–8482; e-mail address: *wooge.william@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you produce, manufacture, use, or import pesticide/agricultural chemicals and other chemical substances; or if you are or may otherwise be involved in the testing of chemical substances for potential endocrine effects. Potentially affected entities, identified by the North American Industrial Classification System (NAICS) codes, 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. To determine whether you or your business may be affected by this action, you should carefully examine the applicability provisions in Unit IV.E. of this document, and examine section 408(p) of the FFDCA. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Get Copies of this Document and Other Related Information?

1. Docket. EPA has established a docket for this action under docket identification (ID) number EPA-HQ-OPPT-2007-1080. All documents in the docket are listed in the docket's index available at http:// www.regulations.gov. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available electronically 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 Federal 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.

2. Electronic access. In addition to accessing the public docket for this document through *www.regulations.gov*, you can access other information about the EDSP through the Agency's website at *http://www.epa.gov/scipoly/oscpendo/index.htm*. You may also access this Federal Register document electronically through the EPA Internet under the “Federal Register” listings at http://www.epa.gov/fedrgstr.

II. Overview

A. What Action is the Agency Taking?

Following review of public comments received on the Draft Policy and Procedures in response to the Federal Register notice of December 13, 2007 (72 FR 70842) (FRL–8340–3), EPA is describing the policies and procedures it generally intends to use to issue and enforce test orders pursuant to the authority provided by section 408(p)(5) of the Federal Food, Drug, and Cosmetic Act (FFDCA). This document provides specific details on the requirements associated

with section 408(p) of FFDCA, format of FFDCA section 408(p) test orders, and the associated Agency policies and procedures. This document also describes the actions and/or procedures that EPA intends to use to:

- Minimize duplicative testing (see Unit IV.C.).
- Promote fair and equitable sharing of test costs (see Unit IV.C.).
- Address issues surrounding data compensation (see Unit IV.C.) and confidentiality (see Unit IV.D.).
- Determine to whom orders would generally be issued (see Unit IV.E.).
- Identify how order recipients should respond to FFDCA section 408(p) test orders, including procedures for challenging the orders (see Unit IV.F. and H.).
- Ensure compliance with FFDCA section 408(p) test orders (see Unit IV.G.).

This document only addresses the procedural framework applicable to EPA's implementation of FFDCA section 408(p)(5), and it does not address the tests or assays that will be used to screen chemicals for their potential to interact with the endocrine system or the approach for selecting chemicals under the EDSP. Elsewhere in today's **Federal Register**, the Agency is publishing documents that present the final list of the first group of chemicals to undergo screening, and the final list of assays to be included in the Tier 1 battery of assays used to screen chemicals for their potential to interact with the endocrine system.

B. Does this Document Contain Binding Requirements?

This document describes the administrative policies and procedures that EPA generally intends to use in implementing the EDSP for initial screening. While the requirements in the statutes and the Orders are binding on EPA and the Order recipients, this document does not impose any binding requirements. Although EPA tried to develop policies that could be used in subsequent data collection efforts, these policies may be modified in response to the Agency's experience during initial screening. The policies outlined in this document are intended to further the general goals of the program, and to the extent the policies need to be amended to further those programmatic goals, EPA may do so. The policies and procedures presented in this document are not intended to be binding on either EPA or any outside parties, and EPA may depart from the policies and procedures presented in this document where circumstances warrant and without prior notice.

C. What is the Endocrine Disruptor Screening Program (EDSP)?

The EDSP was established in 1998 to carry out the mandate in section 408(p) of the FFDCA [21 U.S.C. 346a et. seq.], which directed EPA "to develop a screening program . . . 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 the Administrator may designate." If a substance is found to have an endocrine effect on humans, FFDCA section 408(p)(6) directs the Administrator to take action under available statutory authority to ensure protection of public health. That is, the ultimate purpose of the EDSP is to provide information

to the Agency that will allow the Agency to evaluate the risks associated with the use of a chemical and take appropriate steps to mitigate any risks (Ref. 1). The necessary information includes identifying any adverse effects that might result from the interaction of a substance with the endocrine system and establishing a dose-response curve (Ref. 1). Section 1457 of the Safe Drinking Water Act (SDWA) also authorizes EPA to screen substances that may be found in sources of drinking water, and to which a substantial population may be exposed, for endocrine disruption potential. [42 U.S.C. 300j–17].

The Agency first proposed the basic components of the EDSP on August 11, 1998 (63 FR 42852) (FRL–6021–3). After public comments, external consultations and peer review, EPA provided additional details on December 28, 1998 (63 FR 71542) (FRL–6052–9). The design of the EDSP was based on the recommendations of the Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC), which was chartered under the Federal Advisory Committee Act (FACA) [5 U.S.C. App.2, 9(c)]. The EDSTAC was comprised of members representing the commercial chemical and pesticides industries, Federal and State agencies, worker protection and labor organizations, environmental and public health groups, and research scientists. EDSTAC recommended that EPA's program address both potential human and ecological effects; examine effects on estrogen, androgen, and thyroid hormone-related processes; and include non-pesticide chemicals, contaminants, and mixtures in addition to pesticides (Ref. 1). In addition, because of the large number of chemicals that might be included in the program, EDSTAC also recommended that EPA establish a priority-setting approach for choosing chemicals to undergo Tier 1 screening. The Science Advisory Board (SAB)/Scientific Advisory Panel (SAP) Subcommittee further recommended that initial screening be limited to 50 to 100 chemicals.

Based on the EDSTAC recommendations, EPA developed a two-tiered approach to implement the statutory testing requirements. The purpose of Tier 1 screening (referred to as "screening") is to identify substances that have the potential to interact with the estrogen, androgen, or thyroid hormone systems using a battery of assays. The fact that a substance may interact with a hormone system, however, does not mean that when the substance is used, it will cause adverse effects in humans or ecological systems. The purpose of Tier 2 testing (referred to as "testing"), is to identify and establish a dose-response relationship for any adverse effects that might result from the interactions identified through the Tier 1 assays (Ref. 1).

EPA is implementing its EDSP in three major parts developed in parallel. This document deals only with the third component of the EDSP (i.e., the administrative policies and procedures related to the issuance of orders). The other aspects of the EDSP are being addressed in separate documents published in today's **Federal Register**. The three parts are briefly summarized as follows:

1. *Assay validation.* Under FFDCA section 408(p), EPA is required to use "appropriate validated test systems and other scientifically relevant information" to determine whether substances may have estrogenic effects in humans. Validation is defined as the process by which the reliability and relevance of test methods are evaluated for the purpose of supporting a specific use (Ref. 2). The proposed EDSP Tier 1 Screening Battery of Assays was presented to the SAP during a public meeting on March 25-27, 2008. The FIFRA SAP report covering the meeting is available at *http://www.epa.gov/scipoly/sap/meetings/2008/march/minutes2008-03-25.pdf*. At this moment, validation is complete for all but 1 of the assays that are included in the

final Tier 1 screening battery that is being announced separately in today's **Federal Register**. Until validation for that assay is complete, EPA intends to inform Order recipients that they will not be expected to begin that assay. EPA is also in the process of developing and validating Tier 2 tests. The status of each assay can be viewed on the EDSP website in the Assay Status table: *http://www.epa.gov/scipoly/oscpendo/pubs/assayvalidation/status.htm*.

2. *Priority setting*. EPA described its priority setting approach to select pesticide chemicals for initial screening on September 27, 2005 (70 FR 567449), and announced the draft list of initial pesticide active ingredients and pesticide inerts to be considered for screening under FFDCA on June 18, 2007 (72 FR 33486). The first group of pesticide chemicals to undergo screening is also referred to as "initial screening" in this document. The Agency is publishing in today's **Federal Register** a final list of chemicals that will be subject to initial screening. EPA anticipates that it may, in the future, modify its approach to selecting chemicals for screening. Information and factors that EPA may consider in selecting chemicals could include: public input; the results of testing chemicals on the initial list; management considerations to increase the integration of screening with other regulatory activities within the Agency; implementation considerations flowing from a decision to extend screening to additional categories of chemicals (e.g., non-pesticide chemical substances); and the availability of new priority setting tools (e.g., High Throughput Pre-screening or Quantitative Structure Activity Relationships models). More information on EPA's priority setting approach and the list of chemicals is available at *http://www.epa.gov/scipoly/oscpendo/pubs/prioritysetting*.

3. *Procedures*. This document describes the administrative policies and procedures that EPA generally intends to use in implementing the EDSP for initial screening. Specifically, the general policies and procedures relating to:

- The issuance of FFDCA 408(p) testing orders.
- Responses and related activities for order recipients to use in responding to an order.
- Joint data development, cost sharing, data compensation, and data protection.
- Other related procedures or policies.

D. What Chemicals May Be Covered by the EDSP?

FFDCA section 408(p)(3) specifically requires that EPA "shall provide for the testing of all pesticide chemicals." 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." [FFDCA section 201(q)(1), 21 U.S.C. 231(q)(1) (Note that section 201(q) contains certain minor exceptions that do not affect these policies and procedures.)]. Active ingredients are the substances that prevent, repel, suppress, control or kill the target pests. [FIFRA section 2(a); 7 U.S.C. 136(a)] Pesticide inert ingredients (also referred to as "other pesticide ingredients") are any ingredients in a pesticide product that are not active. [FIFRA section 2(m); 7 U.S.C. 136(m)]. Pesticide inert ingredients may simply dilute the active ingredient or they may perform some function such as allowing the product to adhere better to leaves or other surfaces to improve contact with the pests. Pesticide inert ingredients also include fragrances, which may mask the smell of

residential pesticides, and odorizers, which may act as warning agents. Many of these chemicals, including both pesticide active and inert ingredients, also have other, non-pesticidal uses.

FFDCA also provides EPA with discretionary authority to "provide for the testing of any other substance that may have an effect that is cumulative to an effect of a pesticide chemical if the Administrator determines that a substantial population may be exposed to such a substance." [21 U.S.C. 346a(p)(3)].

In addition, EPA may provide for the testing of "any other substance that may be found in sources of drinking water if the Administrator determines that a substantial population may be exposed to such substance." [SDWA section 1457, 42 U.S.C. 300j–17].

Lastly, it is important to clarify that the procedures and policies described in this document do not in any way limit the Agency's use of other authorities or procedures to require testing of chemicals for endocrine disruptor effects. For example, section 4 of the Toxic Substances Control Act (TSCA) provides EPA with the authority to require testing of TSCA chemical substances, provided that the Agency makes certain risk and/or exposure findings. [15 U.S.C. 2603]. Similarly, section 3(c)(2)(B) of FIFRA grants EPA the authority to require pesticide registrants to submit additional data that EPA determines are necessary to maintain an existing registration. [7 U.S.C. 136a(c)(2)(B)].

As discussed in EPA's priority setting approach for the EDSP (70 FR 56449, September 27, 2005), the Agency is initially focusing its chemical selection on pesticide chemicals, both active ingredients and high production volume chemicals used as a pesticide inert ingredient in pesticides. If chemicals identified for future screening and testing under the EDSP are not used in pesticides, the Agency intends to consider whether the policies and procedures identified in this document would be appropriate for other categories of substances.

E. How Will EDSP Data be Used?

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, that 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 (*i.e.*, disruption of the estrogen, androgen, or thyroid hormone systems) will be made on a weight-of-evidence basis taking into account data from the Tier 1 assays, as well as other available 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 Tier 2 for testing. Tier 2 testing data will identify any adverse endocrine-related effects caused by the substance, and establish a quantitative relationship between the dose and that adverse effect.

III. Authority

A. What is the Statutory Authority for the Policies Discussed in this Document?

FFDCA section 408(p)(1) 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)].

FFDCA section 408(p)(3) expressly requires that EPA "shall provide for the testing of all pesticide chemicals." FFDCA section 201 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." [FFDCA section 201(q)(1), 21 U.S.C. 231(q)(1)]. The statute also provides EPA with discretionary authority to "provide for the testing of any other substance that may have an effect that is cumulative to an effect of a pesticide chemical if the Administrator determines that a substantial population may be exposed to such a substance." [21 U.S.C. 346a(p)(3)].

FFDCA section 408(p)(5)(A) 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.

FFDCA section 408(p)(5)(B) 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)].

If a registrant fails to comply with a FFDCA section 408(p)(5) test order, the Administrator is required to issue "a notice of intent to suspend the sale or distribution of the substance by the registrant. Any suspension proposed under this paragraph shall become final at the end of the 30–day period beginning on the date that the registrant receives the notice of intent to suspend, unless during that period, a person adversely affected by the notice requests a hearing or the Administrator determines that the registrant has complied fully with this paragraph." [21 U.S.C. 346a (p)(5)(C)]. Any hearing is required to be conducted in accordance with section 554 of the Administrative Procedures Act (APA). [5 U.S.C. 554]. FFDCA section 408(p) explicitly provides that "the only matter for resolution at the hearing shall be whether the registrant has failed to comply with a test order under subparagraph (A) of this paragraph." [21 U.S.C. 346a (p)(5)(C)(ii)]. A decision by the Administrator after completion of a hearing is considered to be a final Agency action. [21 U.S.C. 346a (p)(5)(C)(ii)]. The Administrator shall terminate a suspension issued with respect to a registrant if the Administrator determines that the registrant has complied fully with FFDCA section 408(p)(5). [21 U.S.C. 346a (p)(5)(C)(iii)].

FFDCA section 408(p)(5)(D) 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 TSCA section 16. [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 section 16 of TSCA, civil penalties of up to $25,000 per day may be assessed, after notice and an administrative hearing held on the record in accordance with section 554 of the APA. [15 U.S.C. 2615(a)(1)–(2)(A)].

B. Other Statutory Authorities Relevant to this Notice

A number of other statutory provisions are discussed in this document, and consequently, are described below. This document does not reopen in any way or otherwise affect the existing policies or related procedures that have been established under these other provisions. The following is a brief summary of these other relevant authorities.

1. *FIFRA.* FIFRA section 3(c)(1)(F) provides certain protections for people who submit data to EPA in connection with decisions under EPA's pesticide regulatory program. Specifically, FIFRA section 3(c)(1)(F) confers "exclusive use" or "data compensation" rights on certain persons ("original data submitters") who submit data (in which they have an ownership interest), in support of an application for registration, reregistration, or experimental use permit, or to maintain an existing registration. Applicants who cite qualifying data previously submitted to the Agency by the original data submitter must certify that the original data submitter has granted permission to the applicant to cite data or that the applicant has made an offer of compensation to the original data submitter. In the case of "exclusive use" data, the applicant must obtain the permission of the original data submitter and certify to the Agency that the applicant has obtained written authorization from the original data submitter. (Data are generally entitled to "exclusive use" for 10 years after the date of the initial registration of a pesticide product containing a new active ingredient.) If data are not subject to exclusive use but are compensable, an applicant may cite the data without the permission of the original data submitter, so long as the applicant offers to pay compensation for the right to rely on the data. (Data are "compensable" for 15 years after the date on which the data were originally submitted.) If an applicant and an original data submitter cannot agree on the appropriate amount of compensation, either may initiate binding arbitration to reach a determination. If an applicant fails to comply with either the statutory requirements or the provisions of a compensation agreement or an arbitration decision, the application or registration is subject to denial or cancellation. [See also 7 U.S.C. 136a (c)(1)(F)(ii)–(iii)].

FIFRA section 3(c)(2)(B) provides that:

> . . .[i]f the Administrator determines that additional data are required to maintain in effect an existing registration of a pesticide, the Administrator shall notify all existing registrants of the pesticide to which the determination relates and provide a list of such registrants to any interested person." [7 U.S.C. 136a(c)(2)(B)].
> Continued registration of a pesticide requires that its use not result in "unreasonable adverse effects on the environment" (defined as "any unreasonable risk to man or the environment, taking into account the economic, social, and environmental cost and benefits of the use of any pesticide, or a human dietary risk from residues that results from a use of a pesticide in or on any food inconsistent with the standard under section 408 of the [FFDCA].

FIFRA section 3(c)(2)(B) contains a mechanism by which recipients of notices of data requirements (referred to as "Data Call-In notices" or "DCI notices") may jointly develop data and provides that "[a]ny registrant who offers to share in the cost of producing the data shall be entitled to examine and rely upon such data in support of maintenance of such registration." The section establishes procedures to allow registrants who received DCI notices to use binding arbitration to resolve disputes about each person's fair share of the testing costs.

Further, FIFRA section 3(c)(1)(F) makes clear that data submitted under FIFRA section 3(c)(2)(B) are also "compensable" when cited in support of an application for a registration. In other words, a pesticide company that chooses to rely on such data rather than develop its own data must offer compensation to the original data submitter – usually the data generator. Lastly, the Agency may suspend the registration of a pesticide if the registrant fails to take appropriate steps to provide data required under a DCI notice in a timely manner.

Finally, FIFRA section 3(c)(2)(D) contains a provision, referred to as the "formulator's exemption" that is intended to simplify and promote equity in the implementation of the data compensation program under FIFRA section 3(c)(1)(F). This exemption relieves an applicant of the obligation to submit a study, or to cite and obtain permission or offer to pay data compensation to cite the results of a study if the study is relevant to the safety assessment of a registered product that the applicant buys from another person and uses to make the applicant's product. Congress' rationale for this exemption is that the seller will recover any data generation costs through the purchase price of its product. Thus, if a pesticide formulator applies to register a product containing an active ingredient that the formulator purchased from the basic manufacturer of the active ingredient, the formulator does not need to submit or cite and offer to pay compensation for any data specifically relevant to the purchased product. The Agency has extended the principles of the formulator's exemption to data requirements under FIFRA section 3(c)(2)(B). Consequently, if the formulator received a DCI notice requiring data on the active ingredient, the formulator could comply by providing documentation that it bought the active ingredient from another registrant.

2. *SDWA.* SDWA section 1457 provides EPA with discretionary authority to require testing, under the FFDCA section 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." [42 U.S.C. 300j–17]. Because SDWA section 1457 specifically mandates that EPA "may provide for testing. . . in accordance with the provisions of [FFDCA section 408(p)]," EPA may rely on many of the procedures discussed in this document to require testing under SDWA section 1457.

3. *Other sections of FFDCA.* FFDCA section 408(f) establishes procedures that the Agency "shall use" to require data to support the continuation of a tolerance or exemption that is in effect. The provision identifies three options:

- Issuance of a notice to the person holding a pesticide registration under FIFRA section 3(c)(2)(B) [FFDCA section 408(f)(1)(A)].

- Issuance of a rule under section 4 of TSCA [FFDCA section 408(f)(1)(B)].

- Publication of a notice in the **Federal Register** requiring submission, by certain dates, of a commitment to generate the data "by one or more interested persons." [FFDCA section 408(f)(1)(C)].

Before using the third option, however, EPA must demonstrate why the data "could not be obtained" using either of the first two options. FFDCA section 408(f)(1) expressly provides that EPA may use these procedures to "require data or information pertaining to whether the pesticide chemical may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen or other endocrine effects." Finally, FFDCA section 408(f)(1)(B)

provides that, in the event of failure to comply with a rule under TSCA section 4 or an order under FFDCA section 408(f)(1)(C), EPA may, after notice and opportunity for public comment, modify or revoke any tolerance or exemption to which the data are relevant.

In addition, FFDCA section 408(i) provides that "[d]ata that are or have been submitted to the Administrator under this section or FFDCA section 409 in support of a tolerance or an exemption from a tolerance shall be entitled to confidential treatment for reasons of business confidentiality and to exclusive use and data compensation to the same extent provided by section 3 and section 10 of [FIFRA]."

IV. Policies and Procedures for Initial Screening Under the EDSP

This Unit describes the policies and procedures that EPA generally intends to adopt for the initial screening required under the EDSP. In general, the Agency has tried to develop policies that could be used in subsequent data collection efforts, including those under SDWA. However, these policies and procedures may be modified as a result of the Agency's experience applying them to the first chemicals to undergo screening and testing under the EDSP. In addition, EPA may modify these policies and procedures during the initial screening as circumstances warrant.

A. Background

On December 13, 2007 (72 FR 70842), EPA announced availability of and solicited public comment on EPA's draft policies and procedures for initial screening under the EDSP. EPA held two public workshops, one on December 17, 2007 and another on February 28, 2008, to discuss the proposed policies and procedures with stakeholders. Following review and revision based on the public comments, EPA is now describing the specific details of the policies and procedures that EPA generally intends to use for initial screening under the EDSP.

After reviewing all of the public comments received, EPA has decided to make some changes and/or clarifications to the draft policies and procedures. The Agency's responses to public comments are discussed in more detail in the document entitled "Response to Comments on the Endocrine Disruptor Screening Program: Draft Policies and Procedures for Initial Screening and Testing" (Ref. 3), a copy of which is in the docket. The following is a discussion of the major changes and/or clarifications to the policies and procedures.

1. *Modified the Response Options for Inerts.* The Agency originally proposed to relieve a manufacturer or importer of a pesticide inert ingredient of the requirement to generate EDSP data only if the manufacturer or importer agreed to discontinue selling and distributing the ingredient for any use, whether the use was as a pesticide inert ingredient in a pesticide product or for a non-pesticidal purpose. As explained more fully in its Response to Comments document, after considering all of the comments, EPA is persuaded that it should change the EDSP initial screening policies and procedures and allow a manufacturer or importer to comply with an order by agreeing to discontinue sale of the chemical into the pesticide market. This change leads to other modifications to the procedures to ensure effective enforcement of data use protections as well as maintaining a "level playing field."

Specifically, EPA intends to establish a Pesticide Inert Ingredients Data Submitters & Suppliers List (PIIDSSL) to identify any entity who has submitted compensable data on a

pesticide inert ingredient in response to a test order issued under section 408(p). Pursuant to FIFRA section 3(c)(1)(F), when a new pesticide registration applicant's product contains a pesticide inert ingredient on the PIIDSSL, EPA intends to require the applicant to identify the source of the pesticide inert ingredient. If the applicant's source does not appear on the PIIDSSL, EPA intends to require the applicant either to switch to a source on the PIIDSSL; offer to pay compensation to the original data submitter(s) on the PIIDSSL; or generate their own data to support their application.

The Agency also intends to continue to issue "catch-up" orders to any manufacturer or importer of a pesticide inert ingredient who enters the market place after EPA receives data in response to an initial test order for that ingredient. The Agency thinks that the combination of procedures – issuance of "catch-up" orders and establishment of the PIIDSSL – will result in a system that effectively provides data use protections to generators of endocrine data on pesticide inert ingredients. EPA agrees that industry will have a strong interest in self-policing to ensure that competitors are not reneging on their commitment not to sell to the pesticide market and EPA accepts the commenters' claims that the industry can effectively identify for EPA any companies that do not abide by a commitment to cease sales into the pesticide market. However, in the event that significant problems arise, EPA intends to reevaluate this policy, along with evaluating options for responding. For example, EPA considers that reexamination of this policy would be warranted if all manufacturers of a particular inert ingredient opted out of the pesticide market, given the likely impact this would have on end-use formulators. Another consideration would be if EPA discovers that these measures are ineffective at keeping the chemical out of the pesticide market. Under those circumstances, EPA may consider reissuing FFDCA section 408(p) orders to the original manufacturers, with the requirement that the manufacturers and importers provide data in response to the order unless they agree to cease entirely all manufacture or importation of the chemical. EPA may also consider issuing orders to end-use registrants, if circumstances warrant.

2. *Catch-up Orders.* The Agency intends to issue "catch-up" orders for 15 years after the initial test order(s) for the chemical is issued.

3. *Clarifications.* The Agency has provided additional clarifications, including the policies and statutory interpretations relating to pre-enforcement review and informal administrative review.

4. *Paperwork Activities and Estimates.* The Agency has also revised the Initial Response Form and related estimated paperwork burden and costs.

B. Testing of Pesticide Chemicals Under the EDSP

For the initial screening, EPA generally intends to issue "test orders" pursuant to section 408(p)(5) of FFDCA. This is consistent with the December 1998 Notice, where EPA indicated that it intended to rely primarily on FFDCA and SDWA to require testing, and would "use other testing authorities under FIFRA and TSCA to require the testing of those chemical substances that the FFDCA and SDWA do not cover." (Ref. 1). Because EPA is focusing on pesticide chemicals in registered pesticide products for initial screening, there is no need to rely on TSCA or SDWA. However, as discussed in Unit IV.C.–IV.D., in order to address some of the more complex issues surrounding joint data development and the availability of data compensation and

data protection, EPA intends to issue some orders jointly under the authority of FFDCA section 408(p)(5) and FIFRA section 3(c)(2)(B). A diagram that graphically depicts the overall process is available in the docket.

The Agency has developed two templates for the test orders that reflect the policies and procedures discussed in this document, and which outline the basic framework that EPA generally intends to use to issue Orders for the EDSP initial screening. The test orders differ according to whether the recipient is a: 1) Pesticide registrant, or 2) Manufacturer and/or importer of a pesticide inert ingredient (aka "other ingredient"). In addition, the templates accommodate differences in the Agency's procedures for data compensation, and for the minimization of duplicative data, which varies based on the Order recipient. Copies of the test order templates are included in the docket.

There are some pesticide active and pesticide inert ingredients that are not registered in the U.S. but for which there are tolerances on foods imported from other countries. When these chemicals are to be tested in the future, EPA may rely on FFDCA 408(f)(1) to require "interested persons" to submit data for the EDSP.

C. What is EPA Doing To Minimize Duplicative Testing and Promote Cost Sharing and Data Compensation Under EDSP?

One of the complex issues discussed in the December 1998 Notice related to joint data development, and how EPA would implement the FFDCA section 408(p)(5)(B) directive that "[t]o the extent practicable, the Administrator shall minimize duplicative testing of the same substance for the same endocrine effect. . . ." As noted in the December 1998 Notice (63 FR 71563), EPA originally contemplated that it would adopt new procedures unique to the EDSP.

As explained in its 2007 Draft Policies and Procedures (72 FR 70842) (FRL–8340–3), however, the Agency does not now think FFDCA section 408(p) provides EPA with the legal authority to establish procedures that alter or expand on companies' existing rights. After considering public comment, EPA is adopting an approach that follows closely the draft procedures to promote cost sharing and data compensation described in the December 2007 document.

EPA's approach to "minimize duplicative testing of the same substance" and to promote the "fair and equitable sharing of test costs" is intended to achieve the following goals essentially the same outcome for all inert ingredients as the outcome the procedures under FIFRA section 3(c)(2)(B) and section 3(c)(1)(F) produce for active ingredients. That is:

- The companies who are the basic producers of an active ingredient or pesticide inert ingredient would typically bear the costs of testing. Those who purchase a pesticide inert ingredient from a basic producer (who becomes/is an original data submitter) or another "approved inert supplier" would not typically have to participate in joint development of, or offer to pay compensation for the right to rely on, required EDSP data. See Unit IV.C.3.c.

- The recipients of the FFDCA section 408(p) test orders have a mechanism to resolve disputes and enforce agreements to develop data jointly and to share test costs.

• Subsequent entrants into the marketplace are, for an appropriate period of time, subject to the same data requirements, with provisions that would allow them to share the test costs rather than submit duplicative data.

• The recipients of the FFDCA section 408(p) test orders may cite or submit existing data in lieu of developing new data, and ask EPA to determine whether the data adequately responds to the requirements of the order.

EPA believes its approach will achieve essentially the same outcome for all inert ingredients as the outcome the procedures under FIFRA section 3(c)(2)(B) and section 3(c)(1)(F) produce for active ingredients.

In summary, EPA generally intends to adopt a policy that encourages data developers to join forces and agree on how to share costs, and that also encourages companies entering the marketplace after the data are developed to pay reasonable compensation to those that developed the data. To the extent permitted by FFDCA, EPA's intended policies and procedures for EDSP resembles the policies and procedures used for Data-Call-Ins under FIFRA.

1. *Minimizing duplicative testing*. As a point of clarification, a substantial amount of overlap exists between the goal of minimizing duplicative testing and the topic discussed in the next Unit, allowing parties to share the costs of conducting the tests. Consequently, some of the measures discussed in this Unit to minimize duplicative testing will have certain implications for the decisions pertaining to cost sharing, and vice versa.

In developing its policy and procedures, EPA draws on years of experience with pesticide registrants. This experience has shown that reducing the costs of complying with a test order is a powerful incentive in bringing companies together to jointly develop and submit data. However, there may also be disincentives to joint data development including the costs of organizing a consortium. EPA policy and procedures are primarily designed to minimize the disincentives.

a. Recipients of 408(p) test orders. The Agency recognizes that, as the number of recipients of test orders increases, organizational costs also increase. EPA must balance the second goal mentioned in FFDCA section 408(p)(5)(B)--promoting “fair and equitable sharing of test costs” -- with the organizational costs of a large number of order recipients. As is discussed more fully in Section IV.E, under FFDCA section 408(p), EPA may issue orders to pesticide registrants or manufacturers and importers. While EPA could issue orders to all the interested parties, including the registrants of end-use products containing the active or inert ingredient would greatly expand the number of order recipients and complicate the organization of consortia. Under FIFRA, data generation is typically undertaken by the technical registrant, who is also a producer or importer of the chemical. EPA generally intends to issue FFDCA 408(p) test orders to the basic producers of active or inert ingredients, balancing the goal of fairness with the need to keep the number of recipients low to avoid high organizational costs.

Further, by issuing orders to manufacturers and importers of inert ingredients, EPA is able to avoid the confidentiality issues associated with inert ingredients. Most manufacturers claim their inert ingredients to be confidential; accordingly, EPA cannot reveal the inert ingredients in pesticide products and therefore generally could not reveal the companies to whom an order was issued. By issuing orders to manufacturers and importers, EPA can, with

few exceptions, immediately inform a recipient of the identity of all other recipients, facilitating communication and the formation of a consortium.

b. Resolving disputes and enforcing agreements. As described in the December 2007 Draft Policy and Procedures, 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. At the same time, however, each recipient of an order under FFDCA section 408(p) has a separate obligation to fulfill the requirements of that order. 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 studies, or

- 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 anther 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, and 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).

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 "catch up" FFDCA 408(p) orders, who enter the market after the data have been submitted.

c. *Submission/Citation of existing data*. As under FIFRA, EPA provides the recipients of FFDCA 408(p) test orders with the option of submitting or citing existing data, along with a rationale that explains how the study satisfies the requirements in this Order. Any such hazard-related data would be scientifically comparable to data that would be generated by the EDSP and the submitted or cited study must have been conducted in accordance with a scientifically validated protocol.

In summary, EPA 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.

2. *Promoting cost sharing and data compensation*. As noted in Unit IV.C.1., FFDCA section 408(p)(5)(B) directs the Agency to "develop, as appropriate, procedures for fair and equitable sharing of test costs." Informed by its experience under FIFRA, EPA sees this provision as containing two related directives:

- Promotion of the sharing of costs by companies that agree to develop data jointly ("cost sharing").

- Payment of compensation to a data generator by a person whose activity subsequent to the submission of the required data would make such payment equitable ("data compensation").

The first directive relates to sharing the cost of developing data between parties on the market when a test order is issued. The second directive relates to the payment by a person (who was not part of a joint data development agreement) to those that originally generated and submitted data, in exchange for relying on the results of their previously submitted study. These mirror the data generation and data compensation processes that have been followed for years under FIFRA, and the Agency believes those processes are a good starting point for dealing with these issues in the context of 408(p)(5) orders. Consistent with section 408(p)(5)(B), EPA intends, "to the extent practicable," to "develop procedures for fair and equitable sharing of test costs" not only by persons in business when the initial 408(p) test orders were issued, but also by persons who enter the marketplace after the data are submitted.

As discussed in Unit IV.C.1., EPA has developed procedures to implement FFDCA section 408(p) screening that minimize duplicative testing; these measures also have the effect of substantially fostering cost sharing among those who receive the initial test order. By using an

approach which parallels that used under FIFRA section 3(c)(2)(B), any disincentives for the recipients of FFDCA section 408(p) test orders to develop data jointly are addressed. EPA's experience with FIFRA section 3(c)(2)(B) indicates that when multiple registrants receive DCI notices to produce the same data on the same active ingredient, they form consortia that work together to develop the required data. If manufacturers and importers receive FFDCA section 408(p) test orders containing the provisions previously discussed, EPA expects that they would behave in the same manner.

a. Compensable Data under the EDSP With respect to determining the extent to which compensation for previously submitted studies is warranted, the threshold issue is what EDSP data will be "compensable." Given EPA's conclusion that FFDCA section 408(p)(5)(B) does not give EPA the inherent authority to create new rights to compensation, the threshold for what is "compensable" requires consideration of existing statutory authority for compensation. To the extent the data are otherwise covered by any provision of FFDCA or FIFRA that requires a person to offer compensation for the right to cite or rely on data submitted by another person in connection with a pesticide regulatory matter, EPA must continue to enforce those provisions.

FFDCA section 408(i) provides that data submitted under FFDCA section 408 "in support of a tolerance or an exemption from a tolerance shall be entitled to . . . exclusive use and data compensation to the same extent provided by section 3 of [FIFRA]." The Agency considers any data generated in response to requirements under FFDCA section 408(p) on a pesticide chemical for which there is an existing tolerance, tolerance exemption, or pending petition to establish a tolerance or an exemption to be data submitted in support of a tolerance or an exemption. In fact, FFDCA section 408(b)(2)(D)(viii) explicitly requires EPA to consider "such information as the Administrator may require on whether the pesticide chemical may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen or other endocrine effects," as part of its determination that a substance meets the safety standard. [21 U.S.C. 346a(b)(2)(D)(viii)]. Thus, EDSP data on active and pesticide inert ingredients for which there is a tolerance or tolerance exemption are compensable as outlined under FIFRA section 3(c)(1)(F).

Moreover, data establishing whether a pesticide chemical (either active or inert) has the potential to interact with the endocrine system would be relevant to a FIFRA registration decision. Under FIFRA, EPA has a continuing duty to ensure that a pesticide meets the registration standard; EPA must consider all available data relevant to this determination. [See 7 U.S.C. 136a (bb) and 3(c)(5)]. In the terms of FIFRA section 3(c)(1)(F), such data "support or maintain in effect an existing registration." Thus, data generated in response to a FFDCA section 408(p) test order are compensable as outlined in FIFRA section 3(c)(1)(F) if the data are submitted by a pesticide registrant because FIFRA specifically grants those rights to registrants.

Given EPA's position that FFDCA section 408(p)(5)(B) does not give EPA the authority to modify FIFRA data compensation rights, the fact that EDSP data are potentially compensable under FIFRA raises questions about the interplay between the two statutes. For example, unlike FIFRA section 3(c)(2)(B), FFDCA section 408(p) does not give EPA the authority to enforce an offer to pay compensation by suspending the registration of a noncompliant company. Thus, unless and until such data are used in support of a pesticide regulatory action under FIFRA, if a recipient of a test order made an offer but then refused to pay compensation or to participate in binding arbitration following the data submitters acceptance of that offer, the data generator's

only recourse would be to seek any judicial remedies that may be available. Consequently, rather than leave recipients with any ambiguity, EPA intends to issue orders to registrants to conduct EDSP testing pursuant to both FIFRA section 3(c)(2)(B) and FFDCA section 408(p).

In summary, most EDSP data are compensable under FIFRA or FFDCA section 408(i). Data for active and pesticide inert ingredients that have a tolerance or tolerance exemption or are the subject of a pending petition are compensable regardless of what companies submit the data. EDSP data generated from testing other active and inert ingredients are also compensable as long as, in the case of a joint submission, at least one of the submitters is a pesticide registrant or applicant.

While much EDSP data are compensable under FIFRA or FFDCA section 408(i), some EDSP data will be generated by chemical manufacturers and importers of pesticide inert ingredients that have neither a tolerance nor tolerance exemption and are not the subject of a pending tolerance petition. (EPA refers to these substances as "non-food use inerts.") Because such EDSP data could not be considered "data submitted in support of a tolerance or exemption," the data submitted on such substances in response to a FFDCA section 408(p) test order are not entitled to compensation under FFDCA section 408(i). Moreover, since FIFRA section 3(c)(1)(F) establishes compensation rights only for data submitted by an applicant or a registrant and inert ingredients do not have separate or technical registrations, data submitted to EPA in response to a FFDCA section 408(p) order by a person who is neither a registrant nor an applicant are not compensable under FIFRA. However, although data on a non-food use pesticide inert are not compensable when submitted by a non-registrant pursuant to FFDCA section 408(p), such data would become compensable when submitted jointly by an applicant or registrant to support initial or continued registration of a pesticide product containing that inert ingredient. That is, if the submitters of data for a non-food use inert ingredient include a product registrant, EPA intends to consider the data compensable.

In addition, EPA believes that the internal procedures it has adopted effectively provide manufacturers and importers with the same opportunity for cost sharing/compensation available to all other order recipients.

Because EPA believes there are ways to make all EDSP data generated on pesticide inert ingredients compensable, EPA must consider what procedures to use to ensure persons who did not share in the cost of testing, but who benefit from the existence of such data, actually pay compensation. Under FIFRA section 3(c)(1)(F), companies that apply for registrations of pesticide products after the data were submitted either would have to offer to pay compensation for the right to cite the data or would have to generate comparable data. Consequently, in the case of active ingredients, everyone who benefits from the existence of EDSP data on an active ingredient either shares the cost of the testing as part of the joint data development under FIFRA section 3(c)(2)(B) or offers to pay compensation to the original data submitter under FIFRA section 3(c)(1)(F).

The same is not true for pesticide inert ingredients. There is no mechanism under either FIFRA or FFDCA for directly requiring payment of compensation by companies that start to manufacture or import a pesticide inert ingredient after an original data submitter has provided EDSP data on the pesticide inert ingredient. Such companies are not subject to FIFRA data compensation obligations because they are not registrants or applicants for registration.

Nonetheless, EPA believes that, by using its discretion under FFDCA section 408(p) to issue test orders to new manufacturers or importers of a substance for which EDSP data had previously been submitted, EPA can achieve substantially the same ends.

FFDCA section 408(p)(5) provides that "[t]he Administrator shall issue an order to ". . .a person who manufactures or imports a substance for which testing is required under this subsection, to conduct testing in accordance with the screening program . . . ." Thus, under FFDCA section 408(p)(5), following the submission of required EDSP data on the ingredient by manufacturers or importers who were in the marketplace when the initial test orders were issued, EPA generally intends to issue a test order to a manufacturer or importer who begins to sell a pesticide inert ingredient after the test orders requiring the data were issued. The Agency refers to these as "catch-up" test orders. As with the initial FFDCA section 408(p) test order, recipients could fulfill the testing requirement either by submitting the results of a new study or by citing the data submitted by another person or by agreeing not to sell into the pesticide market. In furtherance of the goal of "fair and equitable sharing of test costs," the Agency would accept citation of existing data under the same circumstances that it would accept the citation for recipients of the original order—*e.g.*, where the recipient of a catch-up test order either had the original data submitter's permission or the recipient had made an appropriate offer to pay compensation to the original data submitter that also determined how disputes would be resolved.

Unless new manufacturers or importers requested pesticide registrations, EPA cannot readily identify new entrants in the market. EPA is largely relying on the manufacturers and importers who are part of the data submitters' task force to inform the Agency about new entrants to the market, at which time EPA intends to issue the FFDCA section 408(p) "catch-up" orders. Currently, EPA only intends to send "catch-up" FFDCA section 408(p) test orders to subsequent entrants into the marketplace within 15 years after the initial EDSP test order(s) for the chemical is issued--a time frame matching the period of compensability under FIFRA section 3(c)(1)(F).

b. Who provides compensation under this approach? Although the procedures described would result in having all companies that manufacture or import a pesticide inert ingredient share equitably in the cost of generating required EDSP data, FIFRA imposes additional compensation requirements on the customers of such companies who purchase the pesticide inert ingredients for use in formulating their registered pesticides. Specifically, FIFRA section 3(c)(1)(F) requires an applicant for a new or amended registration to offer to pay compensation to the original submitter of EDSP data if the applicant's product contains an ingredient (active or inert) for which EDSP data have been submitted.

For all compensable data, the Agency interprets the formulator's exemption to be applicable. The formulator's exemption under FIFRA section 3(c)(2)(D) would only be applicable to EDSP data generated on non-food use pesticide inerts if the data are submitted jointly by a registrant or applicant for registration. However, EPA believes that it can effectively achieve the same ends through the internal procedures it adopts, and through its discretion to selectively issue FFDCA section 408(p) test orders only to importers and manufacturers of such pesticide inert ingredients. The policy rationale underlying FIFRA's formulator's exemption is equally applicable in the case of non-food use pesticide inerts. Specifically, Congress believed that, so long as the requirements apply equally to manufacturers of a particular ingredient, the price of their product should also reflect any data development costs. Accordingly, requiring

compensation of product purchasers would have the effect of requiring purchasers to pay data development costs twice--once as a condition of satisfying a FFDCA section 408(p) test order, and thereafter as part of the price of the pesticide inert ingredients they purchase to make their products. [See 49 FR 30892, August 1, 1984]. As a result, EPA has adopted the following procedures to determine whether the end-use formulators have met their obligations to submit EDSP screening data.

c. *Determining whether compensation obligations have been met.* Currently, EPA maintains a list of all data on active ingredients that would support a technical registration along with contact information for the owners of the data. This is the Data Submitters List. Product applicants must identify the chemicals in their product and, in the case of the active ingredient(s), they must identify the source of the ingredient(s). If the source of the active ingredient is a registered product that is labeled for the same (or more) uses as the applicant's product, the applicant is entitled to claim the formulators' exemption from all data requirements relating to the purchased product and need not submit or cite such data. If the applicant is not eligible for the formulators' exemption, an applicant must submit or cite required data (for a technical product registration, the required data are typically data submitted on the active ingredients to support a technical registration). The citation is accompanied by a certification that an offer to pay was made to the owners of the data. FIFRA requires that an applicant/registrant agree to binding arbitration to resolve disputes regarding compensation. If the applicant or registrant fails to fulfill either the terms of a compensation agreement or an arbitrator's award, the owner of the data may petition the Agency to cancel the registration. These procedures are also applicable to EDSP data that are subject to FFDCA section 408(i).

The approach outlined here to address compensation for EDSP data on pesticide inert ingredients is consistent with those adopted generically for all food use pesticide inert data, as there is no reason for creating separate procedures for EDSP pesticide inert data and all other food use pesticide inert data.

First, for each pesticide inert ingredient on which EPA receives EDSP data, EPA intends to identify the data submitter on a "Pesticide Inert Ingredients Data Submitters & Suppliers List" (PIIDSSL) This list identifies every company that submits the required EDSP data (original data submitters). The PIIDSSL also contains the names of every company that fulfilled its obligation under a FFDCA section 408(p) test order by offering to share the cost of testing with other data developers, as well as any other company that the original data submitter identifies as entitled to serve as a source of the pesticide inert ingredient from whom an applicant or registrant may obtain the pesticide inert without making an offer to compensate the original data submitter ("approved inert suppliers" or "approved sources.").

Second, under FIFRA section 3(c)(1)(F), the action of submitting an application of a pesticide containing the pesticide inert ingredient will trigger the obligation for the applicant to provide compensable EDSP data. The applicant may satisfy this requirement by submitting new data or citing existing data. In most cases, however, EPA expects an applicant to comply by claiming that the pesticide inert ingredient comes from an "approved source" and therefore that the principles of the formulator's exemption apply. To fulfill the obligation in this manner, EPA intends to require a pesticide applicant to identify the source of pesticide inert ingredients for which there are compensable EDSP data. Then, EPA would agree that the applicant had adequately complied with FIFRA section 3(c)(1)(F) and FFDCA section 408(p)(3)'s

requirements if the person identified as the source for the pesticide inert ingredient appears on the PIIDSSL as either an original data submitter or an approved source for that pesticide inert ingredient.

Third, on a case-by-case basis, EPA may require current registrants to identify the source of a pesticide inert ingredient on which EDSP data have been submitted. If the registrant of a pesticide product identifies a source for the pesticide inert ingredient that is not on the PIIDSSL, the registrant would have the choice of changing its supplier of the pesticide inert ingredient to an approved source on the PIIDSSL list. (Note: EPA also intends to revise the guidance presented in PR Notice 98-10 regarding notifications to provide that a registrant may not change the source of a pesticide inert ingredient on the PIIDSL in its formulation by notification. Such a change must be made through an application for amended registration.) Should the registrant not choose to obtain the pesticide inert ingredient from an approved source, EPA generally intends to issue an order to the registrant, requiring the registrant either to generate the EDSP test data or offer to pay compensation to the original data submitter on the PIIDSSL.

D. What Procedures Apply for Handling CBI?

FFDCA section 408(p)(5)(B) also requires that EPA, to the extent practicable, develop, as necessary, procedures for the handling of CBI. Many of the same considerations laid out in Unit IV.C. are relevant to EPA's implementation of this directive. EPA has therefore adopted a consistent approach with respect to the handling of CBI.

As with the directives to develop procedures for sharing test costs and minimizing duplicative testing, EPA does not think that FFDCA section 408(p)(5)(B) provides the authority for the Agency to either create new rights or to modify existing rights to confidentiality. Rather, EPA believes that this provision directs the Agency to create procedures that operate within the existing confines of FFDCA section 408(i), FIFRA section 10, the Freedom of Information Act (FOIA), and the Trade Secrets Act.

As explained in Unit IV.C., because EPA considers much of the data submitted in response to FFDCA section 408(p) orders to be submitted in support of a tolerance or tolerance exemption, such submissions are entitled to confidential treatment to the same extent as under FIFRA section 10, pursuant to FFDCA section 408(i). In addition, CBI submitted by pesticide registrants in response to a FFDCA section 408(p) test order is considered as part of the registration process, and is therefore considered to be submitted in support of a registration. As such, that information is directly subject to FIFRA section 10. However covered, information subject to FIFRA section 10 is provided certain protections that go beyond those authorized by FOIA. For example, FIFRA section 10(g) generally prohibits EPA from releasing information submitted by a registrant under FIFRA to a foreign or multinational pesticide producer, and requires the Agency to obtain an affirmation from all persons seeking access to such information that they will not disclose the information to a foreign or multinational producer. FFDCA section 408(i) extends the protection available under FIFRA section 10 for data submitted in support of a tolerance or tolerance exemption.

All other CBI submitted in response to a FFDCA section 408(p) test order (i.e., data not in support of a registration or tolerance/tolerance exemption) is only protected by the provisions of the Trade Secrets Act which incorporates the confidentiality standard in FOIA Exemption 4. FOIA requires agencies to make information available to the public upon request, except for

information that is "specifically made confidential by other statutes" or data that are "trade secrets and commercial or financial information obtained from a person and is privileged or confidential." [5 U.S.C. 552(b)(4)]. Note that substantive criteria must be met to claim confidentiality of business information, as specified in 40 CFR 2.208.

As with EPA's approach for data compensation, EPA considers that data submitted jointly with a registrant, or as part of a consortium in which pesticide registrants participate, to be data submitted in support of a tolerance/tolerance exemption or registration, and therefore entitled to protection under FIFRA section 10. However, if a non-registrant chooses not to partner with a registrant, such data is only subject to the protections available under FOIA and the Trade Secrets Act.

E. Who Would Receive FFDCA Section 408(p) Test Orders Under the EDSP and How Would They Be Notified?

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." EPA has identified the following categories of potential test order recipients:

• *Technical registrants (basic manufacturers of pesticide active ingredients)* – Entities who manufacture or import an active ingredient *and* hold an active EPA registration (technical registrants in most cases). Usually a product with technical registration is used in the formulation of other pesticide products. However, EPA also uses this term in this policy statement to include registrants who use an integrated system, that is, those who produce their own active ingredient, as well as those who use an unregistered technical active ingredient. In the interest of simplifying this document, the phrase "technical registrant" will be used to refer to:

(1) Registrants of a technical grade of active ingredient; and

(2) Registrants whose products are produced using an integrated system, as defined in 40 CFR 158.153(g), (which includes registrants who use an unregistered technical active ingredient to manufacture their pesticide product).

• *End-use registrants (formulators/customers)* – Registrants whose products are formulated and sold for end use; such product generally contain both an active ingredient as well as pesticide inert ingredients. The registrant does not necessarily manufacture or import the active pesticide ingredient or inert.

• *Manufacturers/importer* – Entities who manufacture or import a pesticide inert ingredient that do not necessarily have to hold an EPA registration for the sale of pesticide products. This also includes those manufacturers of pesticide products that are intended solely for export, so long as another company has a U.S. pesticide registration for the chemical, or an import tolerance exists for that chemical.

1. *Pesticide active ingredients*. EPA generally intends to send test orders issued pursuant to FFDCA section 408(p) and FIFRA section 3(c)(2)(B) to technical registrants of the pesticide active ingredient. The Agency can easily identify the technical registrants of pesticide active

ingredients. As previously noted, a technical registrant holds a registration for a specific active ingredient that it then formulates into end-use (or retail) products or that its customers purchase for formulation into end-use products. Typically much of the safety data EPA requires is conducted on the technical grade active ingredient, rather than on the end-use product. [See generally, 40 CFR part 158]. Consequently, the "technical registrants," who are typically not considered to be a small business, have historically been responsible for generating most of the data that support pesticide registrations. Registrants of end-use products generally rely on the data generated by the technical registrants in accordance with the "formulator's exemption" in FIFRA section 3(c)(2)(D).

Some active ingredients are "commodity chemicals," that is, they may be used both in non-pesticidal products, such as drugs or cleaning products, and as active ingredients in pesticide products. When a company produces such a commodity chemical and that company does not sell or distribute the chemical as a pesticide within the meaning of FIFRA section 2(u) and 40 CFR 152.15, FIFRA does not require registration of the chemical until it is sold or distributed in a product that is intended for a pesticidal purpose. However, FFDCA section 408(p)(5) specifies that EPA is to send test orders to manufacturers and importers of "a substance for which testing is required under this subsection," and does not limit testing requirements only to manufacturers/importers of a pesticide chemical. Once EPA issues a test order for a pesticide chemical, a person who manufactures that chemical, even if not for use as a pesticide, is clearly manufacturing a substance for which testing is required, and consequently, is potentially subject to EPA's authority under the plain language of FFDCA section 408(p)(5).

Since EPA's goal is to follow as closely as feasible its existing practices for data generation under FIFRA, EPA generally intends to issue FFDCA section 408(p) test orders initially only to current pesticide registrants (and if there are any, only to technical registrants). Such orders would be issued under the authority of both FFDCA section 408(p) and FIFRA section 3(c)(2)(B). The Agency expects to issue "catch-up" test orders to any entity selling a commodity chemical into the pesticide market. This will occur when a commodity chemical company is discovered to be selling into the pesticide market for 15 years subsequent to the initial issuance of the testing orders.

2. *Pesticide inert ingredients*. EPA generally intends to send test orders issued pursuant to FFDCA section 408(p) to current manufacturers and importers; and "catch-up" FFDCA section 408(p) test orders to manufacturers and importers who subsequently enter the marketplace for 15 years after the initial test order(s) for the chemical is issued. For pesticide inert ingredients, manufacturers/importers include any company that manufactures or imports the chemical regardless of whether it is a registrant and regardless of whether it directly sells the chemical for use as a pesticide inert.

For the purposes of discussion, EPA identified two subclasses of pesticide inerts:

- Food use pesticide inerts, i.e., pesticide inert ingredients with an existing or pending tolerance or tolerance exemption.

- Non-food use pesticide inerts.

a. *Food-use pesticide inerts*. If a pesticide inert ingredient has an existing or pending tolerance or tolerance exemption, data compensation and data confidentiality protection are

available pursuant to FFDCA section 408(i). For this class of pesticide inert ingredients, EPA generally intends to issue FFDCA section 408(p) test orders to manufacturers and importers.

b. *Non-food use pesticide inerts.* EPA generally intends to send the FFDCA section 408(p) test orders only to manufacturers/importers of the substance used as a non-food use pesticide inert ingredient. Note that EDSP data submitted on non-food use pesticide inerts are not covered by the data compensation and data confidentiality provisions of FFDCA section 408(i) or by FIFRA, unless the data are submitted by a registrant or a consortium that includes at least one registrant. Therefore, although EPA does not currently intend to send initial test orders to registrants, EPA encourages non-registrant recipients who submit data to partner with a registrant, so they will receive added protections under FIFRA for proprietary information or compensation from applicants who use the inert ingredient to formulate their pesticide products. Bear in mind, however, that even where FIFRA's compensation provisions do not apply, EPA expects that the Agency's procedures (*e.g.*, whereby companies entering the market after submission of the EDSP data would receive "catch-up" FFDCA section 408(p) test orders) would lead to the manufacturers and importers subject to the initial FFDCA section 408(p) test orders receiving offers to share test costs equitably.

3. *How would EPA identify order recipients*? For FFDCA section 408(p) test orders involving pesticide active ingredients, the Agency intends to rely on the Office of Pesticide Programs' (OPP's) Office of Pesticide Programs Information Network (OPPIN). OPPIN is an internal OPP database for query, input and tracking of pesticide products, ingredients, studies, regulatory decisions and other information. The OPPIN system is typically used to produce study bibliographies or lists of registered products. EPA intends to use OPPIN to identify registrants of the pesticide active ingredients identified for initial screening under the EDSP.

For FFDCA section 408(p) test orders involving pesticide inerts, the Agency intends to use OPPIN (where applicable), information from the TSCA Inventory Update Rule (IUR), and rely on other databases to identify appropriate manufacturers/importers and end-use registrants. These other databases may include publicly available sources like Dun and Bradstreet, online marketing material, etc.

EPA intends to make public the list of recipients of FFDCA section 408(p) test orders and DCI notices and invite the public to identify additional persons who should have received the FFDCA section 408(p) test order. Commenters could either identify themselves or another person as additional candidates (with proper substantiation) for receipt of a FFDCA section 408(p) test order. If the identity of a company subject to the 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, we intend to make the name of the agent (instead of the company) public by including it on the list of recipients of FFDCA section 408(p) test orders and DCI notices. 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 testing orders, including the recipient's response, on the Agency website 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.

4. *How would EPA notify order recipients?* Order recipients would be notified through their direct receipt of a FFDCA section 408(p) test order via first-class mail, with return receipt. Each Order recipient would receive an "EDSP Order Packet" that EPA expects will contain the signed Order, a list of other Order recipients for that chemical, and the Initial Response Form, pre-populated with the recipient specific information and due dates for complying with the order.

F. Potential Responses to a Test Order

In general, EPA expects that the Orders would direct recipients to utilize the following procedures to respond either to an initial FFDCA section 408(p) test order or to a "catch-up" test order issued to a person who began to manufacture or import a pesticide inert ingredient for 15 years after the initial test order(s) for the chemical is issued. These options are also appropriate for responding to test orders issued jointly under the authority of FFDCA section 408(p) and FIFRA section 3(c)(2)(B). A recipient must respond separately to each data requirement and may choose a different response for different data requirements.

1. Initial response. Each recipient would be directed to provide an initial response to EPA within 90 days of the issuance of the order. This initial response is intended to be used to report the recipient's commitment to act in response to the test order in one of several ways. To facilitate completion of this initial response within the 90 days, EPA has created a simple Initial Response Form that it intends to pre-populated with the basic information about the chemical and recipient to connect it to the specific order. EPA intends to include the Initial Response Form in the EDSP Order Packet that is sent to the recipients. Please note that in calculating the due date for the Initial Response Form, the Agency intends to include an additional 10 calendar days to account for the Agency processing of the final order package for delivery to the Post Office.

Any recipient who did not fulfill the commitments made in its initial response would be subject to enforcement action for its failure to comply with the FFDCA section 408(p) order, in accordance with section 408(p)(5)(D). Having failed to perform the actions necessary for this response option, the recipient would be obliged to immediately comply with the order—*i.e.*, to provide the data, within the time frame that had originally been required by the order. In addition, the recipient would potentially be subject to penalties, pursuant to 18 U.S.C. §1001, for willfully making any false or misleading statements to the Federal government.

The recipient of a test order has several potential initial responses from which it can choose. The 90–day initial response options include the following.

a. *Recipient indicates that it intends to generate new data.* Recipients would choose this option to indicate that it agrees to individually generate new data for the test(s) specified to meet the requirements of the order. In the case of data pertaining to a pesticide inert ingredient for which there is no tolerance or exemption (a "non-food use" inert ingredient), the recipient may negotiate an agreement to have a registrant of a product containing the pesticide inert ingredient submit the data after it is generated so that the data qualify for compensation under FIFRA--the

data generator and the registrant could work out among themselves the details of such an agreement.

b. *Recipient indicates that it is citing existing data.* The recipient would choose this option to indicate that it is submitting or citing existing data (including data previously submitted to the Agency) that they believe satisfy the request in the test order. The recipient's initial response would include either the data or a reference to the data for each test specified. Data compensation procedures may apply to data previously submitted to the Agency. If the study is not exactly as specified in the protocols attached to the test order, the recipient would also identify the deviations from the attached protocol(s), along with an explanation for the deviations, including an explanation as to why, notwithstanding the deviations, the protocol could still be considered "validated," and any other information to support a decision to accept the data in satisfaction of the test order. In order to be acceptable, the Agency expects that any such hazard-related data would be scientifically comparable to data that would be generated by the EDSP.

EPA would review any existing study submitted or cited in response to the Order to determine whether the study is acceptable and satisfies the requirements of the Order. The Agency would notify the recipient in writing of its determination. If the Agency determines that the study is acceptable, the Initial Response Form is the only response required to satisfy the Order. If, however, EPA determines that the study is not acceptable, the recipient must still satisfy the requirements of the Order.

c. Recipient indicates that it intends to enter (or offer to enter) into an agreement to form a consortium to provide the data. The recipient would choose this option to indicate that it intends to enter (or has offered to enter) an agreement with other order recipients to form a consortium or task force to comply with the test order. Each consortium participant or potential participant is expected to submit an Initial Response Form within 90 days. The lead for the consortium is expected to submit documentation confirming the formation of the consortium or task force within 150 calendar days of issuance of the Order/DCI, or as part of their initial response. Such documentation would include the contact information for the primary consortia contact, a list of participants, and the intended consortia action/response for each assay. EPA's typical practice has been that, if the consortia fails to satisfy the order, all parties would be held to have violated the test order.

Alternatively, recipients may provide EPA with documentation that they have made an offer to join the consortium or commence negotiations regarding the amount and terms of paying a reasonable share of the cost of testing, and have included an offer to submit to a neutral third party with authority to bind the parties to resolve any dispute over the recipient's share of the test costs, (e.g., through binding arbitration). Note: EPA's typical practice has been that, if the required data are not generated by the person(s) to whom the offer is made, all parties, including those that have made offers to pay or otherwise joined the consortium, would be held to have violated the test order.

d. *Recipient claims that they are not subject to the test order.* The recipient would choose this option to indicate that they are not subject to the order because:

(i) In the case of a test order that requires data on an active ingredient, the recipient is not a pesticide registrant, or

(ii) In the case of an initial test order that requires data on a pesticide inert ingredient, the recipient does not currently manufacture or import the chemical.

(iii) In the case of a "catch-up" order, the recipient obtains the chemical solely from persons who are either (1) the original data submitter; (2) a person who has complied with a test order by offering compensation; or (3) a person who is otherwise an approved source (*i.e.*, is listed on the PIIDSSL) for that inert. An explanation of the basis for the claim, along with appropriate information to substantiate that claim, is required to allow EPA to evaluate the claim.

The recipient's initial response would include an explanation and documentation supporting their claim. If EPA verifies your claim of not being subject to the order, the Initial Response Form is the only response you are required to complete to satisfy the Order. If, however, EPA can not verify your claim, you must still comply with the Order and the deadline(s) for responding remain.

e. *Recipient indicates that it intends to voluntarily cancel their registration(s).* Registrants may request voluntary cancellation of their product's pesticide registration(s) pursuant to FIFRA section 6(f). Such a request must be submitted within 90 days of the issuance of the order. Doing so would initiate the existing procedures for a voluntary cancellation (see 40 CFR 152.99). Under those procedures, the registrant may either adopt the standard provisions for sale or use of existing stocks of their pesticide, or may propose an alternative procedure. If the recipient chooses this option, the Initial Response Form is the only response required to satisfy the Order as long as the Registrant completes the voluntary cancellation procedures. When their product's pesticide registration(s) is cancelled, the recipient would be considered to have satisfied the Order.

f. *Recipient indicates that it intends to reformulate their product(s) to exclude the chemical from the formulation.* In place of submitting the data required in this Order, a registrant may submit an application to amend the formulation of its product by removing as an ingredient of their product the chemical that is the subject of the Order. For example, this may occur in the case of a pesticide inert ingredient if EPA issues orders to end-use registrants. Submitting such an application would initiate the existing procedures for reformulation, and such a request must be submitted within 90 days of the issuance of the order. If the recipient chooses this option, the Initial Response Form is the only response required to satisfy the Order as long as the Registrant completes the reformulation procedures. When their product's formulation has been changed, the recipient would be considered to have satisfied the Order.

g. *Recipient claims a formulator's exemption.* A product registrant who receives an order to test a chemical and who purchases the chemical from another recipient that has agreed to generate the data may be eligible for a formulator's exemption. The recipient's initial response would include an explanation and documentation supporting their claim. EPA will confirm such claims of eligibility. A response asserting the formulator's exemption would no longer be considered an appropriate response to a test order if the supplier of the chemical fails to comply with the test order (i.e., it fails to submit the data either individually or jointly with other recipients or it fails to comply with the terms of a compensation agreement or the binding decision of a neutral third party regarding the terms of compensation). If EPA confirms the eligibility claim, the Initial Response Form is the only response required to satisfy this Order. If,

however, EPA determines that the Order recipient is not eligible, the recipient must comply with the Order.

h. *Recipient indicates that is has or is in the process of discontinuing the manufacture or import of the chemical.* The recipient of an order for a pesticide inert ingredient (i.e., manufacturer/importer) would choose this option to indicate that they are in the process of discontinuing the manufacture or import of the chemical. The recipient's initial response would include an explanation and documentation supporting their claim. EPA intends to verify such a claim. If EPA confirms the claim, the Initial Response Form is the only response required to satisfy this Order. If, however, EPA determines that the claim is false, the recipient must comply with the Order.

i. *Recipient indicates that it does not and will not sell the chemical for use in pesticide products.* The recipient of an order for a pesticide inert ingredient (i.e., manufacturer/importer) would choose this option to indicate that they do not currently or agree to no longer sell their chemical for use in the pesticide market. To elect this option, the order recipient would indicate, as part of its initial response, that they commit to discontinue, on or before a date six months after the issuance of the test order, all sale and distribution of the pesticide inert ingredient that is the subject of the test order to any person who the recipient knows or reasonably should know, intends to use the substance in the formulation of a pesticide product. The order recipient would also indicate that it will include in all contracts for sale or distribution of the material a provision that contractually prohibits the purchaser from using the substance in the formulation of a pesticide product. As part of its initial response, the order recipient would be asked to provide a copy of the contract provision and a certification to include this contractual provision in any contracts entered into on or after a date six months after the issuance of the test order.

j. *Request an exemption under FFDCA section 408(p)(4).* EPA recognizes that FFDCA section 408(p)(4) provides that "the Administrator may, by order, exempt from the requirements of this section a biologic substance or other substance if the Administrator determines that the substance is anticipated not to produce any effect in humans similar to an effect produced by a naturally occurring estrogen." In 1998, the Agency assessed the need to develop a specific list of substances to be exempted from EDSP testing or an exemption process for those substances that might not be anticipated to produce endocrine effects in humans (See section L of the December 1998 notice at 63 FR 71542). In the 1998 FR notice, EPA also provided several examples of substances that might possibly be exempted. As the EDSP has evolved and more endocrine research has been conducted, it has become evident that, at this time, development of criteria to exempt certain substances or to otherwise identify any pre-determined or blanket exemptions from endocrine disruptor testing is premature.

For the initial screening, EPA is not aware of sufficient data that would allow the Agency to confidently determine that a chemical meets the statutory standard for an exemption--i.e., that it is not anticipated to interact with the endocrine system. Although a relatively broad range of toxicity data are available for pesticide active ingredients regulated under FIFRA, in most cases EPA has not yet established how the available data might be confidently used to predict the endocrine disruption potentials of these chemicals. This may be due to the non-specific nature of an effect or effects observed, questions related to whether the mode of action in producing a given effect or effects is or are endocrine system-mediated in whole or in part, or the lack of relevant data to make a judgment altogether.

However, if an order recipient believes that this showing can be made for its chemical, the Agency would consider requests to issue such an exemption order on a case-by-case or chemical-by-chemical basis in response to individual submissions. In order for the Agency to make the necessary statutory finding to issue the exemption, the request would need to provide any hazard-related information that you believe would allow EPA to determine that your chemical is anticipated to not be an endocrine disruptor, i.e., is not anticipated "to produce any effect in humans similar to an effect produced by a naturally occurring estrogen."

k. *Other initial responses – pre-enforcement challenges to a test order*. A recipient may wish to challenge the test order. Unit IV.H., describes the informal process by which a recipient may raise, and EPA may review, objections to the issuance of a test order or to specific provisions in the order. In order for EPA to be able to respond to the objections in a timely manner, the recipient would need to state with particularity the scope and basis of the objection, providing sufficient detail to allow the Agency to evaluate the objection. For further information refer to Units IV.H. and IV.I.

2. *Generate the data specified in the test order*. As indicated in the Initial Response Form, the recipient's next step will vary depending upon their initial response. The process diagram in the docket outlines the overall process with the various response options. In general, assuming that the order recipient indicated that they will generate the data individually or as part of a consortium, the next step in responding to the order would be the generation of the data as specified.

The tests would generally be conducted using the test protocols cited in the order because FFDCA requires that the test method be validated. If, however, an order recipient believes a deviation from the required protocol is needed, they would first consult with the Agency before deviating from the test protocol. All requests would be submitted with a clear rationale to allow the Agency to evaluate the request in a timely manner. EPA intends to review all protocol variations and send a written response to the specific order recipient in a timely fashion.

In addition, order recipients generating data must adhere to the good laboratory practice (GLP) standards described in 40 CFR part 160 when conducting studies in response to a FFDCA section 408(p) test order.

3. *Submit a progress report.* Unless EPA has notified the recipient that they have satisfied the order, EPA generally intends to ask each order recipient to submit a progress report to EPA 12 months after issuance of the order. Each progress report would provide a brief description of the status of the recipients planned activities for each assay, and, if applicable, a description of any problems encountered or expected difficulties in meeting the schedule for complying with the order.

4. *Submit the data specified in the test order*. Assuming that the order recipient indicated that they would generate the data individually or as part of a consortium, the next step in responding to the order would be the submission of the data as specified. The Agency generally intends for the order to include a final submission due date of 24 months after the issuance of the order. In establishing this timeframe, the Agency considered: a) The timeframes set for the initial response and consortia documentation; b) The duration of each assay in terms of estimated timeframes for planning, performing the tests and documenting results; and c) The estimated timeframes for preparing and completing the final data submission to EPA. EPA believes that

having a single due date allows the order recipients to efficiently plan the activities necessary for generating and submitting the data, including entering into joint agreements and sequencing the laboratory activities as appropriate. Although EPA intends to establish a single due date, if the order recipient or consortia choose to submit the results from each assay individually, the order would be satisfied when the Agency determines the results submitted satisfy the Order.

The Agency intends to use the same submission procedures as those that are currently used for submitting other data in support of a pesticide registration, with only a few modifications. Once the data are generated, the recipient would prepare a submission package for transmittal to EPA. EPA intends for the orders to include requirements on how the data would be formatted or presented for submission to EPA. In general, EPA expects the orders to include the following instructions.

a. *Format for data submission.* As part of a cooperative NAFTA project, EPA and the Canadian Pest Management Regulatory Agency (PMRA) developed standard data evaluation formats, or templates. The templates have been in use by these agencies since 2002 for writing their data evaluation records (DERs) of studies submitted under FIFRA and FFDCA to EPA and the Canadian data codes (DACOs). Although such templates do not currently reflect the assays being considered for the EDSP Tier 1 battery, the Agency intends to review and, as necessary, develop new or revised templates before the deadlines for submission of the data under the EDSP.

The DER that the agencies prepare contains a study profile documenting basic study information such as materials, methods, results, applicant's conclusions and the evaluator's conclusions. The templates provide pesticide registrants and the public an opportunity to gain a better understanding of the regulatory science review and decision-making process. The agencies encourage registrants to include study profiles based on these templates in their study documents for all pesticide types. These templates describe the layout and scope of information that would be contained within a study profile and can serve as guides for preparation of study documents. Use of the templates improves the likelihood of a successful submission, since the information necessary for an efficient agency review is outlined. Additional details about these templates are available at: *http://www.epa.gov/pesticides/regulating/studyprofile_templates/*.

In addition, Pesticide Registration (PR) Notice 86–5, entitled *Standard Format for Data Submitted Under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and Certain Provisions of the Federal Food, Drug, and Cosmetic Act (FFDCA)*, describes how to organize and format submittals of data supporting a pesticide registration (*http://www.epa.gov/PR_Notices/pr86-5.html*). The Agency has begun the process of updating the guidance in PR Notice 86–5 to further clarify the data submission process for pesticide related submissions and intends to provide the public with an opportunity to comment on the proposed revisions to PR 86–5 consistent with the procedures described in PR Notice 2003–3, entitled *Procedural Guidance for EPA's Office of Pesticide Programs Procedures Concerning the Development, Modification, and Implementation of Policy Guidance Documents*; (*http://www.epa.gov/PR_Notices/pr2003-3.pdf*).

The Agency also intends to encourage FFDCA section 408(p) test order recipients to submit completed study profiles and supporting data in an electronic format whether submitting one or several studies. OPP has established Adobe Portable Document Format (PDF) as the

standard file format for the electronic submission of required studies, using compact disks as the transport medium. In addition, OPP recently announced an e-Submission initiative to help EPA move toward a more paperless environment. The information exchange from industry to EPA is based on a harmonized eXtensible Markup Language (XML) schema used by Canada's PMRA, which has been adapted by EPA. This harmonization assures industry that a documentation package submitted to one participating regulatory agency can likewise be submitted to the other participating agency, thus increasing standardization and decreasing the burden on industry. EPA also believes that information submitted to EPA in the XML schema format is intended to improve data quality and allow for a more efficient pesticide registration process. To assist pesticide registrants with the creation of the e-Submission XML packages, EPA has established an e-Submission XML help desk. For more information about electronic submissions, go to *http://www.epa.gov/pesticides/regulating/registering/submissions/index.htm*.

b. *Transmittal document.* In order for EPA to effectively track the compliance of each order recipient, each submission in satisfaction of a FFDCA section 408(p) test order would need to be accompanied by a transmittal document that includes the following information:

- Identity of the submitter.
- The date on which the submission package was prepared for transmittal to EPA.
- The FFDCA section 408(p) test order number.
- Summary of the response commitment for each assay.
- A list of the individual documents included in the submission, with relationship to assay specified.

c. *Individual study or test result documents.* Unless otherwise specified by the Agency, and varying based on the order recipient's initial response, EPA would generally expect each submission package to be in the form of individual documents or studies to address each assay specified in the order. As indicated previously, EPA does not anticipate the resubmission of previously submitted documents absent a specific Agency request. Instead it would be sufficient for previously submitted documents to be cited with adequate information to identify the previously submitted document. EPA would typically expect each study or document to include the following:

i. A title page including the following information:

- The FFDCA section 408(p) test order number.
- The title of the study, including identification of the substance(s) tested and the test name or data requirement addressed.
- The author(s) of the study.
- The date the study was completed.

- If the study was performed in a laboratory, the name and address of the laboratory, project numbers or other identifying codes.

- If the study is a commentary on or supplement to another previously submitted study, full identification of the other study with which it would be associated in review.

- If the study is a reprint of a published document, all relevant facts of publication, such as the journal title, volume, issue, inclusive page numbers, and date of publication.

ii. Upon submission to EPA, any data confidentiality claims must be accompanied by a signed and dated document containing the appropriate statement(s) as described in the FFDCA section 408(p) test order, which EPA expects would reference PR Notice 86–5 or other available Agency guidance, as appropriate.

iii. A statement of compliance or non-compliance with respect to GLP standards as described in 40 CFR part 160, as applicable.

iv. A complete and accurate English translation for any information that is not in English.

5. *Submit a written request for an extension*. The FFDCA section 408(p) test order would identify a due date for submitting the data specified to EPA. If an order recipient determines that they will not be able to submit the data specified in the order to EPA by the due date, the recipient can submit a written request for a time extension that provides a clear rationale for the need for an extension, along with any supporting documentation, in order to allow the Agency to properly and timely assess the request. EPA intends to review all such requests and send a written response to the requester in a timely fashion. In most cases the original deadline would remain while EPA considers the request. The Agency intends to only grant extensions that were requested in writing. Ordinarily, extensions would only be available in cases of extraordinary testing problems beyond the expectation or control of the order recipient. Extensions would not be considered if the request for extension is not made in a timely fashion; or if it is submitted at or after the deadline. EPA intends to only grant extension requests in writing.

6. *Maintain records*. EPA generally intends for the FFDCA section 408(p) test order to identify the following records that the recipient would maintain as part of compliance with the order. Typically, the Agency expects recipients to retain copies of the data and other information submitted to the Agency in response to an order.

Under FIFRA section 8, all producers of pesticides, devices, or active ingredients used in producing pesticides subject to FIFRA, including pesticides produced pursuant to an experimental use permit and pesticides, devices, and pesticide active ingredients produced for export, are required to maintain certain records. As such, any recipients who are pesticide registrants or who otherwise submit their data in support of a pesticide registration will be held to the recordkeeping standards in 40 CFR part 169. Consistent with 40 CFR 169.2(k), this includes all test reports submitted to the Agency in support of a registration or in support of a tolerance petition, *all* underlying raw data, and interpretations and evaluations thereof. Under part 169, the

registrant must retain these records as long as the ingredient is contained in pesticide product with a valid registration and the producer is in business, and such records must be made available to EPA or its agent for inspection upon request.

Recipients who are not a registrant would also be asked to retain records related to the generation of the data and copies of other information submitted to the Agency in response to the order. In general, EPA would typically expect recipients who are not a registrant to also retain such records for the same length of time as a registrant, and to also make the records available to EPA or its agent for inspection upon request.

G. What are the Consequences for a Recipient Who Fails to Respond or Comply with the Test Order?

For pesticide active ingredients, FFDCA section 408(p)(5)(C)(i) requires EPA to issue to any registrant that fails to comply with a FFDCA section 408(p) test order "a notice of intent to suspend the sale or distribution of the substance by the registrant." The proposed suspension "shall become final at the end of the 30–day period beginning on the date that the registrant receives the notice of intent to suspend, unless during that period a person adversely affected by the notice requests a hearing or the Administrator determines that the registrant has complied" with the FFDCA section 408(p) test order. As specified by FFDCA section 408(p)(5)(C)(iii), the Administrator shall terminate a suspension if the Administrator determines that the registrant has complied fully.

For all pesticide inert ingredient manufacturers/importers, FFDCA section 408(p)(5)(D) provides for EPA to apply the penalties and sanctions provided under section 16 of TSCA (15 U.S.C. 2615) "to any person (other than a registrant) who fails to comply with an [FFDCA section 408(p)] order."

H. Process for Contesting a Test Order/Pre-enforcement Review

FFDCA section 408(p) does not explicitly address the process for challenging a test order (e.g., if the test order recipient disagrees that a particular study is appropriate or valid). The statute only specifies the rights and procedures available to test order recipients who have failed to comply with a test order. Further, the issue is somewhat complicated by the fact that the statute establishes different procedures for enforcing the test orders against pesticide registrants and against chemical manufacturers or importers. [Compare 21 U.S.C. 346a(p)(3)(C) and (D)]. Nor is this issue resolved by FFDCA section 408's general judicial review provision; that provision is applicably solely to the enumerated actions, which do not include FFDCA section 408(p) test orders. [21 U.S.C. 346a(h)]. Consequently, FFDCA section 408(p) is ambiguous on a number of issues, such as the availability of pre-enforcement review, and the issues that may be raised in an enforcement hearing.

For pesticide registrants, FFDCA section 408(p)(5)(C) directs EPA to initiate proceedings to suspend the registration when a registrant fails to comply with a test order. [21 U.S.C. 346a(p)(3)(C)(i)]. Prior to the suspension, a registrant may request a hearing, but the statute restricts the issues in the hearing solely to whether the registrant has complied with the test order. [21 U.S.C. 346a(p)(3)(C)(ii)]. The substance of the test order may not be challenged during this hearing. Thus, for example, to challenge whether EPA should have required a particular study, the registrant would need to challenge the test order itself in the appropriate

district court. *[See*, e.g., *Atochem v. EPA,* 759 F.Supp. 861, 869-872 (D.D.C 1991)]. The basis for the statutory restriction is that the FFDCA section 408(p) test order constitutes final agency action, and as such, is subject to review *upon issuance*. [*See, Atochem, supra]*. In addition, as discussed above, EPA currently intends to issue the test orders for testing of active ingredients jointly under FFDCA section 408(p) and FIFRA section 3(c)(2)(B). The procedures discussed above for challenging an FFDCA section 408(p) test order are wholly consistent with the procedures applicable to FIFRA section 3(c)(2)(B), which similarly limits the issues for resolution in any suspension hearing held for failure to comply with the order. [See 7 U.S.C. 136a(c)(2)(B)(iv)]. Accordingly, EPA believes that for pesticide registrants, pre-enforcement review of the test order would be available directly in federal district courts under any approach, and based on the plain meaning of the statute, would be the only means to obtain judicial review of the validity of the test order itself.

By contrast, FFDCA section 408(p)(5)(D) provides that non-registrants (manufacturers or importers of pesticide inert ingredients) are subject to monetary penalties through an enforcement proceeding, using the process established by TSCA section 16. Under TSCA section 16, civil penalties of up to $25,000 per day may be assessed, after an administrative hearing is held on the record in accordance with section 554 of the Administrative Procedures Act (APA). [15 U.S.C. 2615(a)(1)–(2)(A)]. Before issuing a final penalty order, EPA must provide notice of its intention to assess the penalty, including a draft of the final penalty order, and provide the recipient with the opportunity to request a hearing within 15 days of the date the notice has been received. [15 U.S.C. 2615(a)(2)(A)]. [*See also*, 40 CFR 22.13–22.14]. TSCA section 16 also specifies that the following issues shall be taken into account in determining the amount of a civil penalty: The nature, circumstances, extent and gravity of the violation(s); the violator's ability to pay; the effect on the violator's ability to continue to do business; any history of prior violations; the degree of culpability; and such other matters as justice may require. [15 U.S.C. 2615(a)(2)(B)].

Although neither FFDCA section 408(p) nor TSCA section 16 expressly imposes the same restriction on the issues that a non-registrant may raise in the penalty hearing, EPA's interpretation of the statutes and existing regulations is to impose a similar restriction. In large measure this interpretation turns on the fact that, at least for pesticide registrants, FFDCA section 408(p) test orders constitute final agency action, and consequently, would be subject to review in the appropriate district court. Logically, it makes sense to interpret the test order to be final for all parties, as the provisions of FFDCA section 408(p)(5)(A) that describe the test order do not distinguish between registrants and other test order recipients. Accordingly, pre-enforcement judicial review of the test order will be available, and would be the means by which any test order recipient would challenge the validity of the test order. As a consequence of that interpretation, EPA interprets TSCA section 16 to restrict the issues that may be raised in any enforcement hearing to whether the test order recipient had violated the test order, as well as the appropriate amount of any penalty. This interpretation is consistent with the issues listed in TSCA section 16(a)(2)(B), which do not expressly relate to the validity of the underlying requirement.

I. Informal Administrative Review Procedure

EPA generally intends to include a provision in the FFDCA section 408(p) test order by which order recipients would raise any questions or challenges concerning the issuance of the

test order to the Agency in response to the order. In addition, because the mere filing of the objection (or indeed, the filing of a judicial challenge) would not necessarily extend the deadline for submission of the studies, in order for this process to be completed in a timely fashion, EPA expects order recipients to present their objections with sufficient specificity and detail to allow the Agency to adequately and fairly evaluate the issue(s) presented. EPA intends to review the issues presented and provide a written response within a reasonable amount of time. The Agency understands that it will need to respond within sufficient time for the order recipient to either comply with the order or determine whether to pursue its concerns through judicial review.

J. How Would EPA Handle Responses from Recipients of Test Orders?

Just as there are many different, acceptable responses that recipients may provide to a test order, so too are there many actions that EPA may take. In some cases, a recipient's response would affect only the recipient. This would be the case for a response from a test order recipient:

- who claims that it is not subject to the order (see Unit IV.F.1.d.); or
- who voluntarily cancels its registration (see Unit IV.F.1.e.); or
- who reformulates its registered products (see Unit IV.F.1.f.); or
- who claims that it qualifies for the formulator's exemption (see Unit IV.F.1.g.); or
- who claims that it does not or no longer manufacture(s) or import(s) the chemical (see Unit IV.F.1.h.).

Each of these responses would only affect the specific recipient's obligation under the order. If EPA agreed with the response, the recipient would not be required to generate the EDSP data (not subject to the order or qualified for the formulator's exemption) or EPA would cancel the recipient's registration as requested. EPA actions on these kinds of responses would not affect other order recipients; they would still be required to respond to the order by generating the data or making one of the other acceptable responses.

In some cases, however, another recipient's response may have consequences for other recipients. This would be the case for a response from a test order recipient:

- who intends to generate the data (see Unit IV.F.1.a.); or
- who cites or submits existing data (see Unit IV.F.1.b.); or
- who enter (or offer to enter) a joint agreement to generate the data (see Unit IV.F.1.c.); or
- who commits to not sell their chemical for use in the pesticide market (see Unit IV.F.1.i.).

The following discussion summarizes how EPA expects to handle responses to test orders that may have consequences for other recipients.

1. *Publication order recipients, responses, and order status.* As noted earlier, EPA intends to publish the list of all order recipients in the **Federal Register** and post the list on the

Agency's website. The Agency intends to also post the status of the testing orders, including recipients' responses, on the Agency Web site so that both order recipients and the public can check on the status of responses to the orders. This information is intended to enable recipients of test orders to identify and join other order recipients to develop the data in response to the order, which in turn would help achieve EPA's goals of minimizing duplicative testing and promoting fair and equitable sharing of test costs. For example, if more than one recipient has agreed to perform the required studies (see Unit IV.F.1.a.), it will be reflected on the list and having this information will help them explore the possibility of generating the data jointly. In addition, a recipient who has agreed to generate required EDSP data can see all other recipients who have informed the Agency that they would be willing to share the cost of performing the required studies (see Unit IV.F1.b.). This information will aid in their sorting of offers to share the cost of generating the required data from any recipient whom EPA indicates has promised to make an offer to share test costs, but hasn't yet contacted the recipient.

2. *Publication of EPA decisions regarding reliance on existing data or requests for an exemption under section 408(p)(4), and decisions challenging the issuance of the test orders.* The EPA Web site would also contain information on decisions about whether a test recipient may rely on existing data (see unit IV.F.1.c.). If so, the Agency intends to regard the existing data as meeting the requirement for all test order recipients. Similarly, if EPA determines that a recipient has demonstrated that the Agency should exempt the chemical from testing under section 408(p)(4) (see Unit IV.F.1.h.), that decision would apply equally to all test order recipients. Finally, a recipient's challenge to the legal basis for a test order (see Unit IV.F.1.i.) might be resolved in a way that affects the validity of the order for other recipients. Publishing these decisions may also be considered by others with similar questions.

3. *Generation of Data, Tracking Compensability of Submitted Data, and Enforcing Compensation Obligations*. When EDSP data on an active ingredient are submitted, EPA intends to handle the submission in the same manner used under FIFRA. The name of the data submitter would be added to the Data Submitters List and all future applicants for registration of a pesticide containing the active ingredient would be required to cite and offer to pay compensation in order to rely on the data for the 15-year period following submission of such data.

In the case of EDSP data on pesticide inert ingredients, as explained in Unit IV.C.2.c, EPA intends to establish a Pesticide Inert Ingredients Data Submitters & Suppliers List (PIIDSSL) to identify any person who has submitted compensable data on a pesticide inert ingredient in response to a test order issued under FFDCA section 408(p). Assuming at least one recipient of a test order submits the required EDSP data, EPA would add the name of the submitter to the PIIDSSL under the name of the ingredient as an "original data submitter." The PIIDSSL would also include any other test order recipient who has made an offer to share the cost of testing as an "approved source," i.e., a source from whom an applicant or registrant may obtain the pesticide inert and not have to offer to pay compensation to the original data submitter. Since it is important to have as complete a list of approved sources as possible, EPA encourages original data submitters to identify additional companies as approved sources, for example, because they have a contract to buy from the data submitter. Then, pursuant to FIFRA section 3(c)(1)(F), when an applicant's product contains a pesticide inert ingredient on the PIIDSSL, the applicant would identify the source of the pesticide inert ingredient. If the applicant's source does not appear on the PIIDSSL, the applicant would either switch to a source

on the PIIDSSL, offer to pay compensation to the original data submitter(s) on the PIIDSSL, or generate their own data.

EPA intends to also take a number of measures to ensure that pesticide registrants are not obtaining the pesticide inert ingredient from an "unapproved" source. Shortly after the receipt of test order responses, EPA intends to make public the commitments made by recipients of test orders – the names of the companies that have agreed to generate (or share in the cost of generating) test data ["data generators"] and the names of the companies that have committed to discontinue selling into the pesticide market. If at least one order recipient has agreed to generate the required data, EPA intends to inform registrants that in the future they will need to obtain the pesticide inert ingredient only from a data submitter or approved source, offer to pay compensation to the data submitter for the right to rely on existing data, or generate new data.

The Agency thinks these procedures will result in a system that effectively provides data use protections to generators of EDSP data on pesticide active and inert ingredients. Through this system all manufacturers and importers of pesticide inert ingredients will understand whether or not they are allowed to sell into the pesticide market. If a manufacturer or importer takes the necessary steps that allow it to sell into the pesticide market, such a company would be listed on the PIIDSSL. Those manufacturers and importers whose products reached the pesticide market through other suppliers could add the names of the suppliers to the PIIDSSL. Similarly, through this system applicants for new products and registrants of existing products will understand from which sources they may purchase a pesticide inert ingredient without having to offer to pay compensation, or without running the risk of needing to generate their own data.

The Agency recognizes that these safeguards do not automatically ensure compliance with the data use protections. But the Agency expects that manufacturers and importers who commit not to sell their chemical into the pesticide market will adhere to this promise and will work with their customers to ensure they also observe this market constraint.

EPA also intends to take steps to try to prevent companies from inadvertently subverting the commitment made by order recipients. For example, the Agency's **Federal Register** document that announces the issuance of the FFDCA section 408(p) order(s), would also inform those companies who sell a chemical that is used as a pesticide inert ingredient (other than test order recipients) that they may receive and become subject to an FFDCA section 408(p) order if they obtain the pesticide inert ingredient (either directly or indirectly) from a source who has not committed to generate the EDSP data but then sell the pesticide inert ingredient into the pesticide market. EPA intends to inform manufacturers who agree to generate the data that EPA intends to rely on them to bring to EPA's attention information indicating that a pesticide registrant appears to be obtaining the pesticide inert ingredient from an "unapproved" source. As indicated previously, EPA intends to issue "catch-up" orders to any manufacturer or importer of a pesticide inert ingredient who enters the market place after EPA has issued a test order for that ingredient.

4. *All Test Order Recipients for a Pesticide Inert Ingredient "Opt Out" of the Pesticide Market.* If no test order recipient has agreed to generate the required data, the Agency intends to issue a **Federal Register** notice informing registrants that the pesticide inert ingredient will no longer be available for use in formulating pesticide products unless someone commits to generate the required data. EPA intends to ask for a commitment to generate the required data

within six months of publication. After that date, EPA would take steps to remove the pesticide inert ingredient from its list of cleared pesticide inerts and to revoke any tolerances or tolerance exemptions for the pesticide inert ingredient. EPA would also remind registrants that under existing regulations, they must apply to amend their registrations before they may sell a pesticide product that has a composition that differs from the approved Confidential Statement of Formula for the product. On a case-by-case basis, EPA may issue a DCI notice and/or a section 408(p) test order for the required data to registrants whose products contain the pesticide inert ingredient.

K. Adverse Effects Reporting Requirements

Under FIFRA section 6(a)(2), pesticide product registrants are required to submit adverse effects information about their products to the EPA. Among other things, the implementing regulations in 40 CFR part 159, subpart D provide registrants with detailed instructions on whether, when, and how to report information in the possession of the registrant or its agents.

In addition, under TSCA section 8(c), companies can be required to record, retain and in some cases report "allegations of significant adverse reactions" to any substance/mixture that they produce, import, process, or distribute. EPA's TSCA section 8(c) rule requires producers, importers, and certain processors of chemical substances and mixtures to keep records concerning significant adverse reaction allegations and report those records to EPA upon notice in the **Federal Register** or upon notice by letter. The TSCA section 8(c) rule also provides a mechanism to identify previously unknown chemical hazards in that it may reveal patterns of adverse effects which otherwise may not be otherwise noticed or detected. Further information is available under 40 CFR part 717.

Under TSCA section 8(e), U.S. chemical manufacturers, importers, processors and distributors are required to notify EPA within 30 calendar days of new, unpublished information on their chemicals that may lead to a conclusion of substantial risk to human health or to the environment. The term "substantial risk" information refers to that information which offers reasonable support for a conclusion that the subject chemical or mixture poses a substantial risk of injury to health or the environment and need not, and typically does not, establish conclusively that a substantial risk exists. For additional information about TSCA section 8(e), please go to *http://www.epa.gov/oppt/chemtest/pubs/sect8e.htm*.

EPA does not require duplicate submission of EDSP results under FIFRA section 6(a)(2) or TSCA section 8(c) or (e). Any information submitted under FIFRA section 6(a)(2) or TSCA section 8(c) or 8(e) procedures does not need to be submitted again to satisfy the FFDCA section 408(p) test order. The test order recipient would instead submit the necessary information to cite to the previously submitted information as described earlier in this document.

V. Statutory and Executive Order Reviews

A. Regulatory Planning and Review

Under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993, as amended by Executive Order 13422 on January 18, 2007 (72 FR 2763), this document is considered to be a "significant guidance document" under the terms of the amended Executive Order because it might raise novel legal or policy issues arising out of legal mandates,

the President's priorities, or the principles set forth in the Executive Order. Accordingly, EPA submitted this document to the Office of Management and Budget (OMB) for review under Executive Order 12866. Any changes made in response to OMB recommendations have been documented in the docket for this action as required by section 6(a)(3)(E) of the Executive Order.

B. Paperwork Reduction Act (PRA)

The information collection requirements associated with issuing orders for Tier 1 screening under the EDSP have been submitted for review by OMB under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.* The information collection requirements in this document are not enforceable until OMB approves them under the PRA. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. As a new ICR, the Agency does not yet have an OMB control number for this information collection activity. Once assigned, EPA will announce the OMB control number for this information collection in the **Federal Register**, and will add it to any related collection instruments or forms used, and include it in the orders issued.

A copy of the Information Collection Request (ICR) document prepared by EPA, identified under EPA ICR No. 2249.01), has been placed in the docket for this policy. In addition, the Agency has established a docket for the ICR, which was issued for public comment under the PRA on December 13, 2007 (72 FR 70839) (FRL-8155-8). The ICR has been revised to address comments received, and the following is a brief summary of the ICR document, which describes the information collection activities and EPA's estimated burden in more detail.

Under the PRA, "burden" is defined at 5 CFR 1320.3(b). For the purposes of this ICR, the information collection activities include reviewing the order, providing the initial response, participating in a consortia, generating the data, preparing and submitting a progress report, submitting the data, requesting an extension, and maintaining records. As described in more detail in the ICR, the total estimated per chemical/per respondent paperwork burden is _____ hours, with an estimated cost of $_____. The total annualized estimated paperwork burden for this ICR is _____hours, with an estimated total annual cost of $___ million. This estimate assumes that the respondent actively participates in all potential activities, including developing consortia, generating all of the potential data, submitting a progress report, requesting an extension, and submitting the data.

Pursuant to 5 CFR 1320.__, EPA has announced [is announcing] the submission of the ICR to OMB in a separate document published elsewhere in today's **Federal Register**. Please follow the instructions in that document to view the ICR and submit comments within the next 30 days.

VI. References

The following is a list of the documents that are specifically referenced in this document and placed in the docket that was established under Docket ID number EPA–HQ–OPPT–2007–1080. For information on accessing the docket, refer to the **ADDRESSES** unit at the beginning of this document.

1. EPA. Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC) Final Report. August 1998. *http://www.epa.gov/scipoly/oscpendo/pubs/edspoverview/finalrpt.htm.*

2. Organization for Economic Cooperation and Development (OECD). Final Report of the OECD Workshop on Harmonization of Validation and Acceptance Criteria for Alternative Toxicological Test Methods. August 1996.

3. EPA. Response to Comments on the Endocrine Disruptor Screening Program: Draft Policies and Procedures for Initial Screening and Testing. [August 2008].

List of Subjects

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

Dated: _____

_____

Assistant Administrator for Prevention, Pesticides and Toxic Substances.

[FR Doc. 08–????? Filed ??–??–08; 8:45 am]

BILLING CODE 6560–50–S

Endocrine Disruptor Screening Program (EDSP): Policies & Procedures for Initial Screening and Testing

Response to Public Comments

Docket ID #: EPA-HQ-OPPT-2007-1080

U.S. Environmental Protection Agency
Office of Prevention, Pesticides, and Toxic Substances
Office of Science Coordination and Policy

DRAFT August 12, 2008

Table of Contents

1.0 Overview of Response to Comments Paper

1.1 Introduction

This paper provides EPA's responses to public comments received on a draft document intended to describe the administrative policies and procedures that EPA is considering adopting as part of the Endocrine Disruptor Screening Program (EDSP). The draft document was published in the **Federal Register** on December 13, 2007 (72 FR 70842) (FRL–8340–3). The initial period for public comment was to end on February 11, 2008. However, multiple parties requested an extension of the public comment period. A 30-day extension of the public comment period (from February 11, 2008, to March 12, 2008) was granted and a notice of the extension was published in the **Federal Register** on February 6, 2008 (73 FR 6963) (FRL–8351–2). EPA established a public docket for this proposal under Docket ID # EPA-HQ-OPPT-2007-1080. This docket contains the proposed initial EDSP policies and procedures, other documents as cited in EPA's proposal, and all public comments received.

The policies and procedures that were presented in the December 2007 **Federal Register** Notice were not intended to be binding on either EPA or any outside parties, and EPA may depart from the policies and procedures presented in that document where circumstances warrant and without prior notice. The policies and procedures presented in that notice may eventually be incorporated into an order issued pursuant to §408(p) of the Federal Food, Drug, and Cosmetic Act (FFDCA). The December 2007 **Federal Register** notice only addressed the procedural framework applicable to EPA's implementation of FFDCA §408(p)(5), and it did not address the tests or assays that are under development for use under the EDSP or the approach for selecting chemicals under the EDSP.

1.2 Background

The EDSP was established in 1998 to carry out the mandate in §408(p) of the Federal Food, Drug, and Cosmetic Act (FFDCA) [21 U.S.C. 346aet. seq.], which directed EPA ''to develop a screening program . . . 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 the Administrator may designate.'' If a substance is found to have an effect, FFDCA §408(p)(6) directs the Administrator to take action under available statutory authority to ensure protection of public health. That is, the ultimate purpose of the EDSP is to provide information to the Agency that will allow the Agency to evaluate the risks associated with the use of a chemical and take appropriate steps to mitigate any risks. The necessary information includes identifying any adverse effects that might result from the interaction of a substance with the endocrine system and establishing a dose-response curve. Section 1457 of the Safe Drinking Water Act (SDWA) also authorizes EPA to screen substances that may be found in sources of drinking water, and to which a substantial population may be exposed, for endocrine disruption potential. [42 U.S.C. 300j–17].

The Agency first proposed the basic components of the EDSP on August 11, 1998 (63 FR 42852) (FRL–6021–3). After public comments, external consultations and

peer review, EPA provided additional details on December 28, 1998 (63 FR 71542) (FRL–6052–9). The design of the EDSP was based on the recommendations of the Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC), which was chartered under the Federal Advisory Committee Act (FACA) [5 U.S.C. App.2, 9(c)]. The EDSTAC was comprised of members representing the commercial chemical and pesticides industries, Federal and State agencies, worker protection and labor organizations, environmental and public health groups, and research scientists. EDSTAC recommended that EPA's program address both potential human and ecological effects; examine effects on estrogen, androgen, and thyroid hormone-related processes; and include non-pesticide chemicals, contaminants, and mixtures in addition to pesticides. Based on EDSTAC recommendations, EPA developed a two-tiered approach, referred to as the EDSP. The purpose of Tier 1 screening (referred to as ''screening'') is to identify substances that have the potential to interact with the estrogen, androgen, or thyroid hormone systems using a battery of assays. The fact that a substance may interact with a hormone system, however, does not mean that when the substance is used, it will cause adverse effects in humans or ecological systems.

The purpose of Tier 2 testing (referred to as ''testing''), therefore, is to identify and establish a dose-response relationship for any adverse effects that might result from the interactions identified through the Tier 1 assays. In addition, because of the large number of chemicals that might be included in the program, EDSTAC also recommended that EPA establish a priority-setting approach for choosing chemicals to undergo Tier 1 screening. The Science Advisory Board (SAB)/Scientific Advisory Panel (SAP) Subcommittee further recommended that initial screening be limited to 50 to 100 chemicals. EPA currently is implementing its EDSP in three major parts that are being developed in parallel, with substantial work on each well underway. This paper deals only with the third component of the EDSP (i.e., policies and procedures related to the issuance of orders). The other aspects of the EDSP have been or will be addressed in separate documents published in the Federal Register.

The three parts are briefly summarized as follows:

1. **Assay validation.** Under FFDCA §408(p), EPA is required to use ''appropriate validated test systems and other scientifically relevant information'' to determine whether substances may have estrogenic effects in humans. EPA is validating assays that are candidates for inclusion in the Tier 1 screening battery and Tier 2 tests, and will select the appropriate screening assays for the Tier 1 battery based on the validation data. Validation is defined as the process by which the reliability and relevance of test methods are evaluated for the purpose of supporting a specific use. The status of each assay can be viewed on the EDSP website in the Assay Status table: http://www.epa.gov/scipoly/oscpendo/pubs/assayvalidation/status.htm. In addition, on July 13, 2007, EPA published a Federal Register document that outlined the approach EPA intends to take for conducting the peer reviews of the Tier 1 screening assays and Tier 2 testing assays and EPA's approach for conducting the peer review of the Tier 1 battery (72 FR 38577) (FRL–8138–4). EPA also announced the availability of a ''list server'' (Listserv) that will allow

interested parties to sign up to receive e-mail notifications of EDSP peer review updates, including information on the availability of peer review materials to be posted on the EDSP website. The Agency js publishing a final list of assays that will comprise the initial EDSP Tier 1 Screening Battery before EPA begins issuing orders to require testing in 2008.

2. **Priority setting.** EPA described its priority setting approach to select pesticide chemicals for initial screening on September 27, 2005 (70 FR 567449), and announced the draft list of initial pesticide active ingredients and pesticide inerts to be considered for screening under FFDCA on June 18, 2007 (72 FR 33486). Inclusion on the initial list is solely based on potential pathways of exposure to that chemical and not on any potential for that chemical to interact with the endocrine system. The Agency js publishing a final list of chemicals that will be subject to initial screening before EPA begins issuing orders to require testing in 2008. More information on EPA's priority setting approach and the draft list of chemicals is available at http://www.epa.gov/scipoly/oscpendo/pubs/prioritysetting. The first group of pesticide chemicals to undergo screening is also referred to as ''initial screening'' in this document.

3. **Procedures.** The public comments submitted under Docket ID # EPA-HQ-OPPT-2007-1080 concerning policies and procedures are addressed in this document. The December 2007 FR Notice (72 FR 70842) (FRL–8340–3) described EPA's policies relating to:

- Procedures that EPA would use to issue orders.
- How joint data development, cost sharing, data compensation, and data protection would be addressed.
- Procedures that order recipients would use to respond to an order.
- Other related procedures or policies.

1.3 Overview of Public Comments

As noted earlier in this document, the public comment period for submission of comments related to the policies and procedures for the initial EDSP screening ended on March 12, 2008. Table 1 (below) lists the twelve separate comments that the Agency received and who submitted them. Table 1 only lists distinct and separate comments that the Agency received and excludes items such as cover letters and any submissions/notices related to the public comment extension request. Each docket submission has a unique Docket Control Number (DCN) associated with it.

Table 1: Docket Submission Information

DCN	Commenter	Affiliate
EPA-HQ-OPPT-2007-1080-0008	C. Pierce	
EPA-HQ-OPPT-2007-1080-0013	Holly Carpenter	American Nurses Association (ANA)

DCN	Commenter	Affiliate
EPA-HQ-OPPT-2007-1080-0018	Klaus L.E. Kaiser	TerraBase Inc.
EPA-HQ-OPPT-2007-1080-0019.1	Thomas W. Curtis, Deputy Executive Director	American Water Works Association (AWWA)
EPA-HQ-OPPT-2007-1080-0020	John D. Gordon, Director of Research	Xenobiotic Detection Systems, Inc.
EPA-HQ-OPPT-2007-1080-0021.1	Steven J. Goldberg, Vice President and Associate General Counsel, Regulatory Law and Government Affairs	BASF Corporation
EPA-HQ-OPPT-2007-1080-0022.2	Michael P. Walls, Managing Director	Regulatory and Technical Affairs, American Chemistry Council (ACC)
EPA-HQ-OPPT-2007-1080-0024.1	Dee Ann Staats, Environmental Science Policy Leader	CropLife America
EPA-HQ-OPPT-2007-1080-0025.1	Susan Ferenc, President	Chemical Producers and Distributors Association (CPDA)
EPA-HQ-OPPT-2007-1080-0026.1	Catherine Willett, Science Policy Advisor, Regulatory Testing Division	People for the Ethical Treatment of Animals (PETA)
EPA-HQ-OPPT-2007-1080-0027.1	Beth L. Law, Assistant General Counsel	Consumer Specialty Products Association (CSPA)
EPA-HQ-OPPT-2007-1080-0028.1	Alan J. Olson, Director of Technology and Product Stewardship	Ferro Corporation

After carefully analyzing the twelve submissions, EPA determined that 257 distinct comments had been submitted that could be grouped in thirteen subject/topic areas. Table 2 (below) outlines this analysis.

Table 2: Number of Comments per Topic:

Subject/Topic	Number of Comments
Minimizing Duplicative Testing	21
Cost Sharing	3
Data Compensation	17
Confidential Business Information	5
Test Order Recipients	17
Identification of Test Order Recipients	10
Responding to Test Orders	25
Procedural Issues	20
Due Process Options	3
Estimated Test Costs and Paperwork Burden	5
Statutory Authorities	9
Order Templates	0
Other Topics	122
Total	**257**

Of the 257 distinct comments, 122 were considered “Other Topics.” In other words, these comments were not germane to the initial policies and procedures and the questions that the Agency posed in the December 2007 FR Notice. Many of these comments were related to the Assay Validation and Priority Setting components of the EDSP (see section 1.2 of this document). For convenience and transparency, EPA has included some short responses to some of the major “Other Topics” comments.

After removing the 122 “Other Topics” comments from the 257 overall distinct comments left 135 comments to be addressed. It should be noted, however, that the remaining 135 comments are not 135 “unique” comments. Many of the twelve submitters offered similar comments. This paper has grouped the similar comments together for clarity.

On a similar note, many subjects/topics groupings overlapped in general concept as well (*i.e.,* minimizing duplicative testing, promoting cost sharing & data compensation, and protecting confidential information). It made sense, for the purposes of document clarity, as well as the decrease in repetition within the document, to group some of the subjects/topics in this document together to respond to the public comments.

It should be noted that numerous comments supported the Agency’s proposed policies and procedures for the initial EDSP screening. This document concentrates on responding to the comments that raised concerns or questions regarding the proposed policies and procedures.

2.0 Response to Comments

2.1 Minimizing Duplicative Testing, Promoting Cost Sharing & Data Compensation, and Protecting Confidential Information

2.1.1 General Goal

Submitted Comment(s):

Several submitters commented that EPA should be consistent with the directive in FFDCA §408(p)(5), in that EPA should develop a comprehensive approach to the imposition of endocrine disruptor screening requirements that ensures all respondents for all different types of pesticide inert ingredients have the same procedures and the same confidentiality protection and data use protections.

EPA Response:

EPA agrees with the goal expressed by the commenters. The Agency, however, is only able to use existing statutory authorities, and these do not provide EPA the ability to establish identical procedures to provide confidentiality protections and data use protections for all affected respondents. Nonetheless, EPA thinks that the procedures it is adopting for pesticide inert ingredients will result in largely the same functional outcomes in terms of confidentiality protection and data use protections as will apply to chemicals that are active ingredients in pesticides.

2.1.2 General Problems with EPA's Proposed Approach

Submitted Comment(s):

It was commented that EPA's approach to minimizing duplicative testing relies on procedures and policies that will likely be ineffective. As a result there are likely to be instances of unnecessary, duplicative testing.

Please note: The term duplicative testing, as used here, refers to more than one order recipient submitting the same data (assay) on the same chemical.

EPA Response:

Based on nearly thirty years' experience with issuing data call-in (DCI) notices for pesticide active ingredients, EPA thinks companies have adequate incentives to join together to develop data jointly. Joint data development minimizes their overall costs.

EPA considered the possibility that a company might refuse to develop data jointly in the hopes that a competitor would be forced from the market if the rival lacked the resources to generate the data alone. However, EPA only requires an *offer* to develop data jointly to fulfill the order, thereby rendering such action

futile. At the same time, such an offer must agree to some binding authority to insure that all sides will abide by current and future agreements for cost sharing. Thus, the requirements of the order mimic the statutory requirements of FIFRA.

Orders will be sent to technical registrants of active ingredients and manufacturers and importers of inert ingredients, not to pesticide product registrants. This balances equity considerations with concerns that an overly large group is difficult and costly to organize. Moreover, this avoids confidentiality issues; all order recipients will be informed of all other order recipients so that the organization of a task force will be simplified.

EPA has almost never seen instances of duplicative testing for pesticides. Since the EDSP procedures closely follow the procedures used in the DCI process, EPA believes there will not be a significant problem of duplicative testing.

Submitted Comment(s):

EPA appears to consider the goal of minimizing duplicative testing only in the context of reducing the number of screening tests of the same chemical, rather than whether such a screening test is needed at all. "Duplicative testing" means the repetition of assays that would not bring additional quality information to the EDSP assessments.

EPA Response:

EPA does recognize this aspect of the goal of minimizing duplicative testing and has, under FIFRA, long followed the policy of allowing order recipients to submit or cite alternative data that responds to the informational needs. EPA has adopted a similar policy for the EDSP, as shown in the list of response options available to order recipients.

Implicit in the comment is the idea that EPA should bear the responsibility for making a determination of whether existing data are adequate for the EDSP prior to issuing an order. However, both FIFRA and FFDCA clearly indicate that it is the responsibility of the manufacturer and/or registrant to demonstrate that their chemical and/or product can be used safely. Moreover, EPA believes that manufacturers/registrants are better placed to identify data specific to their chemical/product that addresses the chemical's potential to interact with the endocrine system. Finally, EPA believes that it is in the interest of both the Agency and industry that orders be issued and responses documented so that all parties can clearly demonstrate that the obligations imposed by FFDCA § 408 have been met.

Submitted Comment(s):

Comments were received that EPA's approach to ensuring equitable sharing of test costs for data on non-food use pesticide inert ingredients is inadequate for several following reasons:

- EPA should have the same data use protections for manufacturers and importers of all types of pesticide inert ingredients – food use and non-food use alike – as it has for producers of active ingredients.
- Manufacturers and importers of non-food use pesticide inerts may have legitimate business reasons not to submit data jointly with a pesticide registrant – the only avenue by which such entities could obtain confidentiality and data use protections.
- Although EPA proposed to issue "catch-up" orders to all manufacturers and importers of an ingredient who enter the marketplace after others have generated endocrine data on that ingredient, EPA acknowledges that it has no reliable way to identify the potential recipients of such catch-up orders.
- EPA has not established a policy for how long it would issue such catch-up orders.

EPA Response:

As explained in the proposal, the Agency has concluded that under its existing legal authorities EPA cannot establish the same data protections for all chemicals. Nonetheless, working within its existing authorities, EPA has established procedures that provide, to the extent possible, the same substantive protections for all respondents. All respondents are able to enter into joint data sharing agreements; all order recipients have incentives to do so; cost sharing agreements will be enforceable; data use will be protected for the same 15 year period; and confidential information will be protected. Manufacturers and importers of non-food use pesticide inert ingredients can obtain FIFRA data protection by submitting the data in partnership with a pesticide registrant. If a manufacturer/importer chooses not to submit data with a pesticide registrant, they may do so. However, EPA sees no basis for thinking its procedures create any further inequity. These procedures create protections comparable to those established by FIFRA §3(c)(1)(F) and FIFRA §3(c)(2)(B).

EPA generally intends to use several techniques to identify potential recipients of "catch up" orders, including allowing order recipients to identify entities who should potentially receive these "catch up" orders. In addition, many comments discussed below indicate that a company who has met its duty to generate data will help EPA to identify other, competing companies against whom the Agency should take enforcement action because the competitors were not keeping their commitment to cease selling their product into the pesticide market. The Agency thinks that, if manufacturers and importers of pesticide inert ingredients can identify competitors who are selling into the pesticide market in disregard for a previous commitment, the manufacturers and importers can also identify new market entrants who should receive "catch up" orders. Therefore EPA believes there is at most a relatively small chance that both manufacturers and importers and EPA will fail to identify potential recipients of catch up orders.

Consistent with all of the comments on this issue, EPA generally believes that it would be appropriate to provide data use protections for those who submit data relevant to pesticide inert ingredients for 15 years following the date on which the data were submitted. This time frame corresponds to the duration of protection afforded "compensable" data submitted under FIFRA. EPA received only positive feedback on the 15 year timeframe as proposed.

In sum, absent more persuasive rationales, EPA maintains its view that its procedures for implementing §408(p)(5)(B) fulfill the stated Congressional goal of promoting fair and equitable sharing of test costs.

2.2 Test Order Recipients/Identification of Test Order Recipients/Responding to Test Orders

2.2.1 To Whom Should EPA Issue Test Orders

Submitted Comment(s):

Two commenters thought EPA should issue test orders only to manufacturers and importers of pesticide inert ingredients, as was proposed. However, two other comments indicated that, if all manufacturers and importers commit not to sell a pesticide inert ingredient into the pesticide market after receiving a test order, EPA should notify registrants of pesticides that contain such a pesticide inert ingredient and give them the opportunity to generate the required data. EPA should bear this responsibility because registrants may not know the exact composition of pesticide inert mixtures that they use in formulating their products since the pesticide inert suppliers treat that as confidential business information.

EPA Response:

For the reasons expressed in the FR Notice announcing the proposed procedures (72 FR 70842) (FRL–8340–3), the Agency agrees that it should not routinely send orders requiring testing of a pesticide inert ingredient to registrants of pesticide products containing that ingredient. EPA also agrees with the comment that if all manufacturers and importers of the pesticide inert ingredient indicate that they intend no longer to sell the ingredient into the pesticide market, EPA should contact registrants to inform them of that decision and should provide those registrants an opportunity to generate the required test data.

Submitted Comment(s):

EPA should issue test orders to all manufacturers and importers of pesticide inert ingredients with commodity uses, even if some of the manufacturers and importers do not sell into the pesticide market in order to give them the option of generating the data so that they could sell into the market in the future.

EPA Response:

The Agency agrees that it should issue test orders to all manufacturers and importers of a pesticide inert ingredient. The Agency thinks that it would not be practical to limit the issuance of test orders only to manufacturers and importers who sell into the pesticide market since EPA currently has no way to tell which manufacturers and importers do so. Moreover, even if it were practical, it would not be appropriate since manufacturers and importers who did not receive test orders would be able to sell into the pesticide market. If that happened, those manufacturers and importers who did not have to pay data generation costs would have an unfair competitive advantage because they would have lower business costs than the companies that had complied with the test order.

2.2.2 When should EPA Relieve a Manufacturer or Importer of the Duty to Generate Data?

Submitted Comment(s):

One commenter recommended that EPA exempt a manufacturer or importer from the duty to generate data in response to a test order if the manufacturer or importer sells to a registrant who has agreed to generate the data.

Many commenters argued that EPA should not require a manufacturer or importer of a pesticide inert ingredient subject to a test order to generate data if the manufacturer/importer commits not to sell the pesticide inert ingredient for use in formulation of pesticide products for the following reasons:

- It is unfair to require a manufacturer or importer to cease all production of a pesticide inert ingredient when only a small part of its sales of that ingredient goes into the pesticide market.
- EPA should exempt a manufacturer or importer from a testing requirement when it would be impossible for the ingredient to be used in a pesticide, for example because the ingredient is present only in an imported mixture which is not used as a constituent of pesticide products.
- It is unreasonable to require a manufacturer or importer to cease all production of the ingredient. Basing this approach on EPA's difficulty in enforcing the commitment not to sell into the pesticide market is not compelling. EPA has the legal authority and should develop procedures allowing it to enforce a prohibition against using a pesticide inert ingredient sourced by a particular manufacturer or importer:
    - If all of the manufacturers and importers of a pesticide inert ingredient agreed not to sell into the pesticide market, EPA could easily enforce such commitments by ensuring that the ingredient was not present in any registered pesticide.
    - EPA could further effectuate this decision by publishing a FR Notice indicating that the pesticide inert ingredient was no longer approved for use in pesticide products; such a notice would serve to discourage both unknown and unidentified, as well as future, manufacturers and importers.

- Even if some but not all manufacturers and importers elected to stop selling into the pesticide market, EPA could tell whether a specific manufacturer or importer was keeping its commitment by checking the Confidential Statement of Formula (CSF) filed by a registrant.

- Moreover, the manufacturers and importers that did generate the required data would have strong incentives to police the marketplace and would surely notify EPA is another manufacturer or importer was not living up to its commitment not to sell into the pesticide market.
- If, subsequent to making a commitment not to sell into the pesticide market, EPA receives evidence that a manufacturer or importer is doing so, EPA should issue a "catch-up" order to the manufacturer or importer.

EPA Response:

The Agency originally proposed to relieve a manufacturer or importer of a pesticide inert ingredient of the requirement to generate EDSP data if the manufacturer or importer agreed to discontinue selling and distributing the ingredient for any use, whether the use was as a pesticide inert ingredient in a pesticide product or for a non-pesticidal purpose. The Agency had three reasons for its original proposal:

1] EPA expected to have considerably more difficulty enforcing a respondent's commitment not to sell an ingredient into the pesticide market than it would have enforcing a commitment to stop all sale of the ingredient.

2] EPA believed that limiting manufacturers' and importers' choices to either providing the required data or stopping all sale and distribution of the ingredient gave them stronger incentives to perform required testing.

3] Since the endocrine screening data were relevant to the chemical, regardless of its eventual use, it seemed more equitable that all manufacturers and importers share the cost of generating the data.

After consideration of all of the comments, EPA is persuaded that it should revise its original proposal, and allow companies to comply with an order by committing that they will discontinue sale of the chemical into the pesticide market. The Agency was particularly influenced by the fact that it received numerous comments on the issue from almost all affected sectors of the industry. EPA believes that the measures urged by the commenters should be effective in helping to resolve the Agency's concerns regarding the enforceability of such commitments. EPA agrees that industry will have a strong interest in self-policing to ensure that competitors are not reneging on their commitments, and EPA accepts the commenters' claims that the industry can effectively identify for EPA any companies that do not abide by a commitment to cease sales into the pesticide market. In addition, in large measure, a significant portion of the risk associated with companies' failure to abide by their commitment is to purely

private interests in desiring level playing fields and competitiveness; if, as the comments suggest, the industry feels confident that the market can adequately function to ensure the effective enforcement of the opt-out, EPA is not a position to second-guess this.

Moreover, the Agency's concern about whether there would be an adequate incentive for manufacturers and importers to generate the data was addressed by the fact that trade associations representing pesticide formulators supported the change. The comments make clear that the formulators understood that, if all manufacturers and importers decline to generate the required data, the test generation burden would effectively shift to the registrants. Nonetheless, they supported the change. Consistent with these comments, the Agency also agrees that if all manufacturers and importers decided to discontinue the sale of a pesticide inert ingredient into the pesticide market, it would be appropriate for EPA to provide registrants whose products contained the pesticide inert ingredient an opportunity to volunteer to generate the required data. Further, EPA took into account that no chemical was included on the first list of substances to be screened unless it was a "pesticide chemical," i.e., it was used as an active or pesticide inert ingredient in a pesticide product. In other words, if a chemical was not used as an ingredient in any pesticide formulation, EPA would never have considered it for screening. Thus, it seemed equitable not to require companies to test a substance if they did not sell the ingredient for use in pesticide formulations.

EPA also intends to take a number of measures to ensure that pesticide registrants are not obtaining the pesticide inert ingredient from an "unapproved" source. Shortly after the receipt of test order responses, EPA intends to issue a FR Notice announcing the commitments made by recipients of test orders – the names of the companies that have agreed to generate (or share in the cost of generating) test data ["data generators"] and the names of the companies that have committed to discontinue selling into the pesticide market. If at least one order recipient has agreed to generate the required data, the Notice will inform registrants that they need to either obtain the pesticide inert ingredient only from a data generator, or generate their own data. If no test order recipient has agreed to generate the required data, the FR notice would inform registrants that the pesticide inert ingredient will no longer be available for use in formulating pesticide products unless someone commits to generate the required data. EPA would ask for a commitment to generate the required data within 6 months of the publication of the notice. After that date, EPA would take steps to remove the pesticide inert ingredient from the list of cleared pesticide inerts and to revoke any tolerances or tolerance exemptions. EPA would also remind registrants that they must apply to amend their registrations before they may sell a pesticide product that has a composition that differs from the approved Confidential Statement of Formula.

EPA would also take steps to try to prevent companies from inadvertently subverting the commitment made by order recipients. For example, the FR notice would inform companies who sell the pesticide inert ingredient (other than

test order recipients) that they may become subject to receipt of an FFDCA § 408(p) order if they obtain the pesticide inert ingredient (either directly or indirectly) from a source who has not committed to generate the EDSP data and then sell the pesticide inert ingredient into the pesticide market. EPA would also inform manufacturers who agree to generate the data that EPA will rely on them to bring to EPA's attention information indicating that a pesticide registrant appears to be obtaining the pesticide inert ingredient from an "unapproved" source.

In addition, EPA will establish a Pesticide inert Ingredients Data Submitters List (PIIDSL) that will identify any person who has submitted compensable data on pesticide inert ingredient in response to a test order issued under FFDCA § 408(p). When EDSP data on a pesticide inert ingredient are submitted, EPA will add the name of the submitter to the Pesticide inert Ingredient Data Submitters List (PIIDSL) under the name of the ingredient. The PIIDSL will include the data submitter and any other manufacturers who have made an offer to share the cost of testing. Since the PIIDSL contains the names of companies that are "approved sources," i.e., sources from whom a registrant may purchase the pesticide inert, it is important to have as complete a list as possible. Thus, anyone on the PIIDSL may identify additional companies as approved sources, for example, because they have a contract to buy from the data submitter. Then, pursuant to FIFRA § 3(c)(1)(F), when an applicant's product contains a pesticide inert ingredient on the PIIDSL, EPA will require that the applicant identifies the source of the pesticide inert ingredient. If the applicant's source does not appear on the PIIDSL, EPA will require the applicant either to switch to a source on the PIIDLS or to offer to pay compensation to a company on the IIDSL.

EPA also intends to revise Pesticide Registration Notice 98-10 regarding notifications, to communicate to registrants that when they change the source of a pesticide inert ingredient on the PIIDSL in their formulation, the appropriate procedure is generally to apply for amended registration, rather than proceeding by notification. In unusual circumstances, when EPA deems it necessary to ensure that registrants are not obtaining a pesticide inert ingredient from an unapproved source, EPA may issue DCIs to registrants.

The Agency thinks that the combination of these procedures – issuance of catch-up orders and establishment of the PIIDSL – will result in a system that effectively provides data use protections to generators of endocrine data on pesticide inert ingredients. All manufacturers and importers of pesticide inert ingredients will understand whether or not they are allowed to sell into the pesticide market. If a manufacturer or importer takes the steps that allow it to sell into the pesticide market, such a company would be listed on the PIIDSL. Those manufacturers and importers whose products reached the pesticide market through other suppliers could add the names of the suppliers to the PIIDSL. Similarly, applicants for new products will understand from which sources they may purchase a pesticide inert ingredient without having to offer to pay compensation, or without running the risk of needing to generate their own data.

The Agency recognizes that these safeguards do not automatically ensure compliance with the data use protections. The Agency expects that every manufacturer and importer who has committed not to sell its chemical into the pesticide market will adhere to this promise and will work with its customers to ensure they also observe this market constraint.

(As noted in the proposed procedures, if the pesticide inert ingredient is a non-food use pesticide inert, a manufacturer or importer must submit the data jointly with a registrant in order for the data to be considered compensable.)

2.3 Procedural Issues

2.3.1 Additional Procedures Needed

Submitted Comment(s):

One commenter noted that EPA should finalize the policy development initiative, begun several years ago under FIFRA, to delineate an approach for dealing with data use protections (compensation) for data concerning pesticide inert ingredients in products undergoing regulatory review under FIFRA. EPA should apply this approach to data generated under FFDCA §408(p).

EPA Response:

EPA agrees that it would be helpful and plans to issue a description of its approach under FIFRA to ensuring data compensation for compensable information concerning pesticide inert ingredients. The Agency notes, however, that these procedures would apply only to regulatory actions taken under FIFRA and would not replace the procedures being used under FFDCA §408(p).

2.4 Due Process Options

2.4.1 Pre-Enforcement Review & Informal Administrative Review

Submitted Comment(s):

Several commenters supported EPA's proposed legal position that treats the issuance of a FFDCA §408(p) order to a manufacturer or importer of a pesticide inert ingredient as final agency action subject to immediate judicial review prior to the institution of potential enforcement action under TSCA. Commenters also remarked that because a manufacturer or importer who does not comply with a FFDCA §408(p) order is subject to potentially significant penalties and because EPA's legal position is subject to considerable uncertainty, the commenters encouraged EPA to revisit the basis for this position and think that EPA should provide further legal analysis to support it. A comment was also received that EPA should consider issuing a rule that codifies this position.

EPA Response:

It is unclear why the commenters believe that EPA's legal position is subject to considerable uncertainty. EPA laid out the basis for its interpretation that the orders issued to manufacturers and importers of pesticide inert ingredients are final agency action in its proposal. The commenters have not provided any analysis to support their contention, or identified any particular legal problems with the Agency's analysis. It is unclear, therefore, what further analysis the commenters are seeking to have the Agency provide.

As part of any future evaluation of whether to modify the policies adopted for implementation of FFDCA §408(p) orders, EPA will consider whether to issue a rule codifying its interpretation.

Submitted Comment(s):

EPA should provide procedures by which a recipient of a FFDCA §408(p) order may raise informally its objections to the issuance of the order. Such a procedure should have the following elements:

- The procedure should be described in the information sent with the test order.
- Participation should be voluntary.
- If the procedure is mandatory, a recipient should have 90 days within which to raise objections.
- If the process is mandatory, EPA must respond to the objections quickly (i.e., within 30 days) or toll the date for compliance with the requirement to submit data.
- All decisions must be "final agency action" subject to immediate judicial review based on the administrative record of the decision.

EPA Response:

The Agency agrees that its procedures should spell out how an order recipient could informally raise objections to the order. To ensure consistent treatment of order recipients and a complete basis for decision-making, EPA generally intends to require order recipients to raise to EPA any objections to the issuance of an order and to wait for an EPA response before the order recipient seeks any pre-enforcement judicial review of the order. Under this procedure, order recipients could file such informal objections at any time within the 90 day period for responding to the order. The Agency agrees that it should try to provide its final response to the order recipient within 30 days after receipt of informal objections and that it should consider a request to extend the order recipient's deadline for submitting data if an EPA response denying the objections substantially exceeds that goal. The Agency will ensure that these procedures are clearly spelled-out in the order sent to recipients.

2.5 Estimated Test Costs and Paperwork Burden

The notice of the availability for public comment of the proposed EDSP Draft Proposed Policies & Procedures for Initial Screening and Testing was published in the **Federal Register** on December 13, 2007 (72 FR 70842) (FRL–8340–3). On the same day, December 13, 2007, a notice of the availability for public comment of the Draft Information Collection Request (ICR) covering the information collection activities associated with the Tier 1 screening of the first group of chemicals under the Endocrine Disruptor Screening Program (EDSP) was also published in the **Federal Register** (72 FR 70839) (FRL–8155–8). Comments related to the ICR were submitted under Docket ID # EPA-HQ-OPPT-2007-1081. Comments related to the estimated test costs and paperwork burden received on the policies and procedures were duplicative of those submitted for the ICR. For clarity, these comments have been comprehensively addressed in the Agency's response to public comments document for the ICR. Please refer to the response to public comments document that will be placed in the docket under Docket ID # EPA-HQ-OPPT-2007-1081. (This document should be available in the near future.)

2.6 Statutory Authorities

2.6.1 Legal Authority

Submitted Comment(s):

Submitters commented that EPA should use the authority in FFDCA §408(f) to impose requirements for the manufacturers and importers of food use pesticide inert ingredients to perform screening studies instead of imposing testing requirements under FFDCA §408(p). Using this authority would ensure that the data generated by respondents would receive confidentiality protection and data use protections pursuant to FFDCA §408(i).

EPA Response:

The Agency does not need to rely on FFDCA §408(f) to ensure that the data on food use pesticide inerts generated by manufacturers and importers will receive confidentiality and data use protections. Pursuant to FFDCA §408(i), those rights have already been extended to data on food use pesticide inerts collected pursuant to §408(p). As explained in the December 2007 FR Notice (72 FR 70842) (FRL–8340–3):

> [t]he Agency considers any data generated in response to requirements under FFDCA §408(p) on a pesticide chemical for which there is an existing tolerance, tolerance exemption, or pending petition to establish a tolerance or an exemption to be data submitted in support of a tolerance or an exemption. In fact, FFDCA §408(b)(2)(D)(viii) explicitly requires EPA to consider ''such information as the Administrator may require on whether the pesticide chemical may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen or other endocrine effects,'' as part of its determination that a substance

> meets the safety standard. [21 U.S.C. §136a(b)(2)(D)(viii)]. Thus, EDSP data on active and pesticide inert ingredients for which there is a tolerance or tolerance exemption will be compensable as outlined under FIFRA §3(c)(1)(F). (72 FR at 70850)

In addition, the reliance on FFDCA §408(f) authority would merely complicate the issue, as EPA would need to be able to make the findings required by this subsection. One of those findings is that "the data and information could not be obtained under §3(c)(2)(B) of [FIFRA] or §4 of the Toxic Substances Control Act (TSCA)." EPA could not make this finding for EDSP data, as the information could have been collected through either of those mechanisms.

Submitted Comment(s):

One commenter disagreed with EPA's decision to rely on FFDCA §408(p) orders to require EDSP testing from manufacturers and importers, stating that "the Agency has not provided an adequate justification for its proposed approach to rely on FFDCA §408(p) to issue enforceable test orders." The commenter believes instead that EPA should rely on the Toxic Substances Control Act (TSCA) to require manufacturers and importers to provide EDSP data.

The commenter was concerned that EPA's proposed approach fundamentally departs from the longstanding, well-accepted testing schemes under FIFRA and TSCA. Historically, EPA has used its authority under FIFRA to require data from pesticide registrants and under TSCA to require data from non-registrants. In particular, EPA's approach would subject a manufacturer or importer of a pesticide inert ingredient (who typically is not a pesticide registrant) to testing requirements simply by sending an administrative order, which resembles the process EPA may employ under FIFRA to require data. This process provides relatively limited procedural protection for the order recipient compared to that necessary if EPA were to seek data using its TSCA authorities. Yet, if the order recipient did not comply with the data requirement, such a manufacturer or importer would be subject to the far more severe penalties of TSCA than could be imposed under FIFRA. The commenter alleged that EPA's proposal "upsets the balance created within and between FIFRA and TSCA" because manufacturers and importers who receive such orders "will be denied the data compensation and CBI protections offered by FIFRA if they are not pesticide registrants (with the possible exception of food use pesticide inert ingredients). They will also be denied the data compensation and CBI protections afforded by TSCA. They will however, still be subject to the severe penalties of TSCA."

The commenter questioned whether this outcome is consistent with Congressional intent. The history of FFDCA §408(p), which was initially part of the bill that became the Safe Drinking Water Act amendments of 1996, indicates that Congress expected EPA to use "enforceable consent agreements" (ECAs). Since ECAs are a part of the process by which EPA has imposed data requirements under TSCA (but not under FIFRA), the commenter argued

therefore that Congress meant EPA to use TSCA when dealing with non-registrants. The commenter also argued that Congress laid out a process in FFDCA §408(f) that EPA is to use in requiring endocrine data to support the continuation of a tolerance or tolerance exemption. This indicates that EPA should use TSCA if it cannot use FIFRA.

EPA Response:

EPA disagrees that its decision to rely on FFDCA §408(p) order authority to collect EDSP data is in any way inconsistent with Congressional intent, or otherwise insufficiently justified. FFDCA §408(p), the section that obliges EPA to establish and collect EDSP data, explicitly mandates that EPA "*shall* issue an order to a registrant…or *to a person who manufactures or imports a substance* for which testing is required under this subsection." [21 USC 346a(p)(5) (emphasis added)]. This represents clear Congressional direction to proceed as EPA has chosen to do, and use the order authority established by §408(p).

In fact, the statutory "imbalance," which the commenter attributes to EPA's choice of regulatory mechanism, actually stems from the provisions of FFDCA §408(p)(5). It is the FFDCA itself that establishes the separate procedural requirements for registrants and manufacturers, to which the commenter specifically objects (civil monetary penalties vs. registration suspension). Compare 21 U.S.C. §346a(p)(5)(C) and (D). The fact that Congress expressly chose to refer directly to particular TSCA and FIFRA provisions indicates that, if the use of FFDCA §408(p) orders upsets the existing statutory "balance," it reflects a conscious legislative choice.

Indeed, the commenter's reference to FFDCA §408(f) further supports EPA's belief that use of FFDCA §408(p) to collect EDSP data from manufacturers and importers is appropriate and consistent with Congressional intent. In contrast to FFDCA §408(f), §408(p) does not require EPA to find that the data cannot be collected under FIFRA or TSCA as a prerequisite to exercising its order authority. Nor is this conclusion altered by the commenter's reference to the House Commerce Committee Report, which accompanied an early draft of the EDSP provisions. Whatever may have been intended in early versions of the legislation—and the language cited by the commenter falls far short of a direction to the Agency to rely exclusively only on TSCA to obtain data from non-registrants–those provisions are not reflected in the version that was ultimately enacted.

In large measure, the commenter's concern stems from a perception that manufacturers and importers of non-food use pesticide inerts will necessarily receive a lesser degree of data use protection than other order recipients. As noted elsewhere in this response to comments document, this is inaccurate. Through the adoption of internal procedures, and through the exercise of agency discretion to determine compliance with the 408(p) order, EPA has developed a system that will effectively provide the same *substantive* data compensation as is statutorily provided to registrants and manufacturers and importers of pesticide

inerts. The commenter has not identified any particular areas in which the data compensation or CBI protections are substantively deficient. Rather, the commenter seems primarily concerned that the procedures EPA has developed will not function effectively.

The confusion may have stemmed from the Agency's explanation of its rationale for failing to adopt a set of procedures that are unique to the EDSP. Because existing statutory authorities distinguish between manufacturers of non-food use pesticide inerts and between manufacturers of food use pesticide inerts and registrants, both the Agency's procedures and the rationale for those procedures will necessarily vary. But that is distinct from whether the substantive degree of protection that is achieved through those procedures essentially differs, or necessarily provides lower data protections. Whether it be through the processes available under FIFRA §3(c)(1)(F) or FFDCA § 408(i), which are applicable to active ingredients and food use pesticide inerts, or through the internal procedures EPA adopts, order recipients will be able to fulfill their obligations by joining a consortium to share data development costs or by offering to pay compensation to those who have previously generated data.

Submitted Comment(s):

A submitted comment stated EPA has provided an inadequate justification for changing its position on the authority granted by FFDCA §408(p)(5). EPA's current view of FFDCA §408(p)(5) is incorrect. This provision both requires and authorizes EPA to establish procedures that mandate joint data development, as well as cost sharing and confidentiality protection.

EPA Response:

EPA disagrees. EPA laid out its rationale for its interpretation at length in the December 2007 proposal (72 FR at 70848 & 70849). By contrast, in its original December 2002 notice that indicated the Agency's intention to establish unique procedures under FFDCA §408(p), the Agency provided no explanation of why it believed that provisions authorizing the Agency to merely establish "procedures, to the extent practicable" were sufficient to allow the Agency to alter existing substantive rights, or to create new rights. It is well established that administrative agencies are only provided with the authority Congress delegates (*e.g.*, *Chrysler Corp v Brown*, 441 US 281 (1979); *Batterton v Francis*, 432 U.S. 416, 425-26 (1977)). In FFDCA §408(p)(5), Congress provided only a qualified direction to EPA to establish procedures. This simply cannot be equated with the authority to extend rights to parties that do not currently exist, or to modify rights established under other statutory provisions.

Nevertheless, working within the confines of the authority conferred upon the Agency by existing statutes, EPA has developed *procedures* that will effectively promote joint data development and cost sharing and provide confidentiality. As discussed elsewhere in this response to comments document, and in EPA's final FR notice, EPA believes that the internal procedures it has adopted would

effectively provide manufacturers and importers of all pesticide inerts with the same opportunity for joint data development, as well as cost sharing, and compensation available to all other order recipients

Submitted Comment(s):

The Agency received comments that EPA should use the authority of TSCA to require testing of non-pesticide chemicals (*i.e.,* chemicals that are not active ingredients or pesticide inert ingredients in a pesticide) so that the respondents will receive the data use and confidentiality protections afforded by TSCA. EPA should use FFDCA §408(p) orders for non-pesticide chemicals only when it cannot rely on TSCA. See the discussion of the legislative history of the SDWA amendments which the commenter believes supports this interpretation.

EPA Response:

The list of chemicals proposed for testing in the initial phase of screening does not include any non-pesticide chemicals. Therefore EPA does not need to take a position on this issue at this time. The Agency, however, will reexamine its policies and procedures before issuing any test orders for non-pesticide chemicals.

2.6.2 Need for Rulemaking to Establish Implementation Policies and Procedures

Submitted Comment(s):

One commenter agreed with EPA that rulemaking is not appropriate because the Agency should learn from its experience. The commenter also agreed that the proposed policies and procedures may not be appropriate for subsequent rounds of screening or for higher tier testing. Nonetheless, the commenter expressed concern that, because the policies and procedures were not binding on the Agency, EPA could depart from them without prior notice. The commenter recommends that EPA provide an opportunity for public comment prior to making any future changes in policies or procedures.

EPA Response:

EPA agrees to seek public comment before fundamentally changing any of the procedures used to implement test orders issued under FFDCA §408(p). However, EPA reserves the right to adapt its policy and procedures as needed to protect human health and the environment.

2.7 Order Templates

No comments on the order templates were received.

2.8 Other Topics

2.8.1 EPA Should Delay Issuance of Orders Requiring Testing of Inert Ingredients

Submitted Comment(s):

It was commented that EPA should delay issuing test orders to manufacturers and importers of inert ingredients. EPA is not under any statutory mandate to require screening of inert ingredients. By stating that EPA may issue FFDCA §408(p) orders either to registrants or to manufacturers and importers of pesticide chemicals, Congress was giving EPA discretion about what chemicals to cover.

EPA should delay issuing test orders to manufacturers and importers of inert ingredients. There are no requirements in FFDCA §408(p) that state that:

- The screening of active and inert ingredients must proceed concurrently;
- The initial test orders must be issued by a particular date; or
- The Agency must complete screening of pesticide chemicals by a particular date.

Thus, if EPA decides either it must or wishes to test inert ingredients, EPA has considerable authority about when to include inert in its screening program.

EPA Response:

FFDCA §408(p) requires that EPA screen all "pesticide chemicals." As that term is defined in FFDCA §201(q), the provision requires EPA to screen both active ingredients and inert ingredients in pesticide products. While the Agency agrees that the statute gives EPA discretion about the sequence and timing of issuance of test orders for pesticide chemicals, EPA thinks that its future implementation of the screening program will benefit from early experience with issuing test orders for a limited number of inert ingredients.

Submitted Comment(s):

EPA should delay issuing test orders to manufacturers and importers of inert ingredients and focus only on active ingredients. There are many complex issues that uniquely arise with respect to inert ingredients. EPA should restrict the program to active ingredients until it has fully resolved the issues relating to:

- Under what authority to require testing of inert ingredients;
- Which entities should receive test orders for inert ingredients;
- How to provide for cost sharing and how to ensure compensation for data generated on such ingredients;
- How to address mixtures of inert ingredients – both scientifically and in terms of data use & confidentiality procedures;

- Whether to allow a manufacturer or importer to commit not to sell into the pesticide market as an alternative to generated required data on an inert ingredient, and if so, how to enforce that commitment;
- Has not developed a process for identifying recipients of "catch-up" orders; and
- Whether FFDCA §408(p) orders to manufacturers and importers of inert ingredients are subject to pre-enforcement review.

Moreover, the universe of potentially affected entities has little experience dealing with EPA data requirements and therefore will have more difficulty with this new program than will pesticide registrants.

Finally, delay would be appropriate given that EPA cannot fulfill the mandate in FFDCA §408(p)(5) until these issues are adequately resolved.

EPA Response:

The Agency has decided to proceed with the issuance of test orders for inert ingredients. Although EPA asked for public comment on the list of topics raised by commenters, EPA did, in most cases, propose specific procedures and policies for addressing each topic. After considering public comment, EPA has reached a position on each issue and will implement its decisions with respect to the inert ingredients included in the initial round of screening. Briefly, EPA's decisions are:

- EPA will issue test orders for inert ingredients under the authority of FFDCA sec. 408(p);
- EPA will issue test orders to all manufacturers and importers of an inert ingredient;
- EPA will institute procedures and apply its enforcement discretion in such a manner that all recipients of test orders who wish to continue to sell into the pesticide market must offer to share in the cost of generating, or generate, the required data;
- EPA will not require testing of any mixture of different inert ingredients, and thus does not need to address the scientific issues of assessing the potential of mixtures (as distinguished from the constituents of a mixture) to disrupt the endocrine system; EPA has specified procedures to protect the confidentiality of information relating to inert mixtures and to provide for data use protection;
- EPA will use information from public sources, as well as information from any proprietary databases to which the Agency has access (*e.g.,* Dun & Bradstreet®), to identify potential recipients of catch-up orders. In addition, EPA will depend on the initial recipients of test orders to identify other companies that should receive catch-up orders; and
- EPA has decided that FFDCA §408(p) orders are subject to informal pre-enforcement review.

Submitted Comment(s):

Validation of the screening battery should be the first phase of EDSP. Testing other substances such as non-food use inerts, should be deferred until the screening battery is fully established. This will minimize unnecessary screening and unwarranted higher tier testing.

EPA Response:

The individual assays included in the screening battery have undergone validation with a range of compounds. Moreover, the particular choice of assays included in the screening battery has also undergone independent external scientific peer review by the FIFRA Scientific Advisory Panel (Please go to http://www.epa.gov/scipoly/sap/meetings/2008/032508_mtg.htm for more details). Neither this public comment nor any of the expert scientific peer reviews of the assays or battery have concluded that the assays and battery have not met the validation criterion with respect to inert ingredients. The Agency therefore concludes that the assays are as appropriate for use in screening inert ingredients as active ingredients.

Submitted Comment(s):

EPA should delay issuing test orders to manufacturers and importers of inert ingredients until EPA has reviewed the available databases on the inert ingredients. For example, the NTP Center for Evaluating Risk to Human Reproduction has an extensive database on phthalate esters, which appear on the proposed list of chemicals that are candidates for testing.

EPA Response:

The Agency disagrees with the comment and will not delay issuing test orders to manufacturers and importers of inert ingredients in order to review any additional databases. As described under priority setting in section 1.2 of this document, EPA's priority setting approach to select pesticide chemicals for initial screening was published in the **Federal Register** on September 27, 2005 (70 FR 567449). The approach for inclusion on the initial list for screening (for both pesticide active ingredients and inert ingredients) is based solely on potential exposure to a chemical and not on any potential of that chemical to interact with the endocrine system (*i.e.,*hazard/risk). In other words, a review of these "risk" databases would not influence the chemicals inclusion on the list of chemicals to undergo initial screening.

2.8.2 EPA Gave Inadequate Time for Public Comment

Submitted Comment(s):

Several comments were received stating that EPA has not allowed adequate time for public comment on the complex issues arising out of the proposed

procedures for inert ingredients. Furthermore, because of the many complex issues involving the application of this new program to inert ingredients, EPA should set up a stakeholder meeting where these issues are discussed and recommendations made. While such a meeting might delay implementation, the meeting could produce a more streamlined process, better understanding in the regulated community and greater compliance.

EPA Response:

The Agency has provided ample opportunity for the public to understand and to comment on its draft procedures. EPA issued a notice in the **Federal Register** explaining its proposal and giving the public 60 days to submit comments (72 FR 70842) (FRL–8340–3). At the request of several stakeholders, EPA extended the comment period for an additional 30 days ((73 FR 6963) (FRL–8351–2)). During the public comment period, EPA held two public meetings (December 17, 2007 and February 28, 2008) at which staff described the proposed procedures and answered questions from the public. In addition, in response to specific requests, EPA has held other meetings with individual stakeholders. This record demonstrates that there has been adequate time for public comment. Finally, while the Agency does not think that there is any need for an additional public meeting before it begins to send test orders under FFDCA §408(p), EPA is willing to meet with stakeholders to explain its plans.