Chocolate Bayou Facility (Solutia) for two Class I injection wells located at Alvin, Texas. As required by 40 CFR Part 148, the company has adequately demonstrated to the satisfaction of the Environmental Protection Agency by the petitions and supporting documentation that, to a reasonable degree of certainty, there will be no migration of hazardous constituents from the injection zone for as long as the waste remains hazardous. These final decisions allow the underground injection by Solutia, of the specific restricted hazardous wastes identified in these exemptions, into Class I hazardous waste injection wells Nos. WDW–13 and WDW–318 at the Chocolate Bayou, Alvin, Texas facility, until December 31, 2020, unless EPA moves to terminate these exemptions under provisions of 40 CFR 148.24. Additional conditions included in these final decisions may be reviewed by contacting the Region 6 Ground Water/UIC Section. As required by 40 CFR 148.22(b) and 124.10, a public notice was issued October 15, 2007. The public comment period closed on November 29, 2007. No comments were received. These decisions constitute final Agency action and there is no Administrative appeal. These decisions may be reviewed/appealed in compliance with the Administrative Procedure Act.

DATES: These actions are effective as of December 4, 2007.

ADDRESSES: Copies of the petitions and all pertinent information relating thereto are on file at the following location:

Environmental Protection Agency, Region 6, Water Quality Protection Division, Source Water Protection Branch (6WQ–S), 1445 Ross Avenue, Dallas, Texas 75202–2733.

FOR FURTHER INFORMATION CONTACT: Philip Dellinger, Chief Ground Water/UIC Section, EPA—Region 6, telephone (214) 665–7150.

Dated: December 4, 2007.

William K. Honker,

Acting Division Director, Water Quality Protection Division (6WQ).

[FR Doc. E7–24173 Filed 12–12–07; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–8505–3]

Intent To Grant an Exclusive Patent License

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of Intent To Grant an Exclusive License.

SUMMARY: Pursuant to 35 U.S.C. 207 (Patents) and 37 CFR part 404 (U.S. Government patent licensing regulations), EPA hereby gives notice of its intent to grant, for a specific field of use, an exclusive, royalty-bearing, revocable license to practice the invention described and claimed in the U.S. Patent No. 6,821,425, entitled ''Biomass Concentrator Reactor,'' issued November 23, 2004, and all corresponding patents issued throughout the world, and all reexamined patents and reissued patents granted in connection with such patent, to Purestream ES, L.L.C. of Walton, Kentucky.

The invention was announced as being available for licensing in the October 11, 2007 issue of the **Federal Register** (72 FR 57937). The proposed exclusive license will contain appropriate terms, limitations, and conditions to be negotiated in accordance with 35 U.S.C. 209 and 37 CFR 404.5 and § 404.7 of the U.S. Government patent licensing regulations.

EPA will negotiate the final terms and conditions and grant the exclusive license, unless within 15 days from the date of this notice EPA receives, at the address below, written objections to the grant, together with supporting documentation. The documentation from objecting parties having an interest in practicing the above patents should include an application for an exclusive or nonexclusive license with the information set forth in 37 CFR 404.8. The EPA Patent Attorney and other EPA officials will review all written responses and then make recommendations on a final decision to the Director or Deputy Director of the National Risk Management Research Laboratory, who have been delegated the authority to issue patent licenses under EPA Delegation 1–55.

DATES: Comments on this notice must be received by EPA at the address listed below by December 28, 2007.

FOR FURTHER INFORMATION CONTACT: Laura Scalise, Patent Attorney, Office of General Counsel (Mail Code 2377A), Environmental Protection Agency, Washington, DC 20460, telephone (202) 564–8303.

Dated: December 7, 2007.

Geoffrey Cooper,

Acting Associate General Counsel, General Law Office.

[FR Doc. 07–6043 Filed 12–12–07; 8:45 am]

BILLING CODE 6560–50–M

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPPT–2007–1080; FRL–8340–3]

RIN [2070–AD61]

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

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This document announces the availability of and solicits public comment on EPA's draft policies and procedures for initial screening under the Agency's Endocrine Disruptor Screening Program (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. This document provides specific details on the policies and the related procedures that EPA is considering adopting for initial screening under the EDSP. In general, the Agency has tried to develop policies that could be used in subsequent data collection efforts. However, EPA expects that these policies may be modified as a result of the Agency's experience applying them to the first chemicals to undergo testing. This document also discusses 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 data confidentiality. EPA will also be holding a public meeting to discuss these policies and procedures. A separate **Federal Register** document announced the details of the public meeting.

DATES: Comments must be received on or before February 11, 2008.

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

• *Federal e-Portal*: *http://www.regulations.gov*. Follow the on-line instructions for submitting comments.

• *Mail*: Document Control Office (7407M), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.

• *Hand Delivery*: OPPT Document Control Office (DCO), EPA East Bldg., Rm. 6428, 1201 Constitution Ave., NW., Washington, DC. Attention: Docket ID number EPA–HQ–OPPT–2007–1080. The DCO is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the DCO is (202) 564–8930. Such deliveries are only accepted during the DCO's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

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

Docket: All documents in the docket are listed in the docket index available at *http://www.regulations.gov*. Follow the instructions on the regulations.gov website to view the docket index or access available documents. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, 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.

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. To determine whether you or your business may have an interest in this notice you should carefully examine section 408(p) of the Federal Food, Drug, and Cosmetic Act (FFDCA) (21 U.S.C. 346a(p)). Potentially affected entities and others may use the North American Industrial Classification System (NAICS) codes to assist in determining whether this action might apply an entity. Potentially affected entities may include, but are not limited to:

• Chemical manufacturers, importers and processors (NAICS code 325), e.g., persons who manufacture, import or process chemical substances.

• Pesticide, fertilizer, and other agricultural chemical manufacturing (NAICS code 3253), e.g., persons who manufacture, import or process pesticide, fertilizer and agricultural chemicals.

• Scientific research and development services (NAICS code 5417), e.g., persons who conduct testing of chemical substances for endocrine effects.

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. 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. What Should I Consider as I Prepare My Comments for EPA?

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

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

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

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

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

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

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

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

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

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

C. Where Can I Access Information about the EDSP?

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*.

II. Overview

A. What Action is the Agency Taking?

The Agency is announcing the availability of and seeking public comment on the draft policies and procedures that it is considering to issue test orders pursuant to the authority provided by section 408(p)(5) of 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 procedures. This document also describes the actions and/or procedures that EPA is considering 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 will 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.).

EPA has also developed a template for the test order and an information collection request (ICR) to obtain the necessary clearances under the Paperwork Reduction Act (PRA). The templates for the test orders and the draft ICR are available in the docket associated with this **Federal Register** Notice. In addition, through a separate **Federal Register** document, EPA is seeking public comment on the draft ICR and draft templates.

In addition, EPA will be holding a public meeting to discuss these draft policies and procedures. In the **Federal Register** of November 23, 2007 (72 FR 65732) (FRL–8341–3), EPA announced the details of the public meeting, which is posted on the EDSP website at*www.epa.gov/scipoly/oscpendo/meetings/mtg_121707.htm*.

This document is intended to describe the administrative policies and procedures that EPA is considering adopting as part of the Endocrine Disruptor Screening Program (EDSP). 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. The policies and procedures presented in this document may eventually be incorporated into an order issued pursuant to section 408(p) of FFDCA.

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 are under development for use under the EDSP or the approach for selecting chemicals under the EDSP. In a September 27, 2005, **Federal Register** Notice (70 FR 56449) (FRL–7716–9), the Agency announced the approach that was used to identify chemicals for initial screening under EDSP. The draft list of 73 chemicals to undergo initial screening was published in a June 18, 2007 **Federal Register** Notice (72 FR 33486) (FRL–8129–3). In a separate public process, the Agency is coordinating the scientific validation and peer review of the assays, which includes the development of protocols for the assays. Additional information about all aspects of the EDSP, including current status of these related parallel activities, is available at *http://www.epa.gov/scipoly/oscpendo/pubs/edspoverview/index.htm*.

B. 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 Federal Food, Drug, and Cosmetic Act (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 effect, 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). Based on these 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 (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.

EPA currently is implementing its EDSP in three major parts that are being

developed in parallel, with substantial work on each well underway. This document 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 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. 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 (Ref. 2). 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.

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 Agency expects to publish 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 procedures are addressed by this document, which describes 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.

C. 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 inert ingredients of such pesticide.'' [FFDCA section 201(q)(1), 21 U.S.C. 231(q)(1)]. Active ingredients are the substances that suppress, control or kill the target pests. Inert ingredients generally have no direct effect on the target pests although they may have some degree of toxicity. 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. 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 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 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 the Federal Insecticide, Fungicide, and Rodenticide Act (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. 346a(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 an inert ingredient in pesticides. If chemicals identified for future screening and testing under the EDSP are not used in pesticides, the Agency will consider whether the policies and procedures identified in this document and used for pesticide chemicals would be appropriate for other categories of substances.

D. How Will EDSP Data be Used?

In general, EPA will use data collected under the EDSP, along with other information, to determine if a pesticide chemical, or other substance that may be found in sources of drinking water, may pose a risk to human health or the environment due to disruption of the endocrine system. Under the tiered approach, Tier 1 screening data will be used to identify substances that have the potential to interact with the endocrine system. Chemicals that go through Tier 1 screening and are found to exhibit 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. As the EDSP screening and testing requirements mature into routine evaluations, the Agency intends to utilize the pesticide registration review process as the framework for managing its responsibilities regarding the endocrine screening of pesticides, and intends to eventually incorporate these requirements into the pesticide registration review process. At that point, EPA will regard the endocrine disruptor screening and testing required under FFDCA as part of the risk characterization of the pesticide that is intrinsic to the FIFRA decision. While EPA has discretionary authority to issue, at any time, testing orders requiring manufacturers to conduct Tier 1 assays, the Agency plans to assess the performance of the Tier 1 battery based on the test data received for the initial list of chemicals before beginning to routinely issue orders to test additional chemicals. If EDSP data exist at the time of a pesticide's registration review, the

Agency will consider the data when it makes its FIFRA (3)(c)(5) finding under registration review.

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 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 under section 16 of the Toxic Substances Control Act (TSCA) [15 U.S.C. 2615] in the case of a violation referred to in that section. [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 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 submitter has been granted permission to cite data or that an offer of compensation has been made 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 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) explicitly directs EPA to send notices of data requirements (referred to as ''Data Call-In notices'' or ''DCI notices'') to all registrants affected by the data requirement. It also contains a

mechanism by which recipients of 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 data generator if the data are relevant to the company's product and the company applies to register its product after the required data have been submitted to EPA. Lastly, the Agency may suspend the registration of a pesticide if the registrant fails 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). The generic data exemption, in effect, relieves an applicant of the obligation to cite and obtain permission or offer to pay data compensation to cite the results of any 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 associated with its product by charging buyers a higher purchase price. 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 generic data 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 provide for 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 the EDSP (Initial Screening)

This Unit describes the policies and procedures that EPA is considering to adopt for the initial screening required under the program referred to above in Unit II.B. In general, the Agency has tried to develop policies that could be used in subsequent data collection efforts, including those under SDWA. However, the Agency expects that these policies may be modified as a result of the Agency's experience applying them to the first chemicals to undergo testing. A diagram that graphically presents the overall process is available in the docket.

A. Background

On December 28, 1998 (63 FR 71542) (Ref. 1), EPA first discussed a number of the more complicated policy issues relating to the implementation of the screening program. These issues included:

- Under what authority EPA would require testing.
- How EPA would approach issues relating to minimizing duplicative testing; sharing of test costs; and appropriate compensation for the use or reliance on data submitted by a company (i.e., data compensation).
- EPA's approach to protecting CBI and trade secrets, and the public release of such information.
- Who would be required to conduct testing, including whether exemptions would be available. (Ref. 1).

In this document, EPA is describing the policies and procedures that it intends to use for the initial EDSP screening of pesticide chemicals. For some of these issues, EPA now has a preferred policy approach; for other issues, EPA has laid out the various considerations for public comment.

EPA is soliciting comment on all of the draft policies announced in this document. Prior to requiring screening and testing under the EDSP, EPA will publish in the **Federal Register** the announcement of the final policies and procedures it will adopt for initial screening. However, EPA anticipates that it may modify the policies and procedures for future EDSP screening efforts based on EPA's experience in applying these policies and procedures during initial screening.

B. How Will EPA Require Testing of Pesticide Chemicals Under the EDSP?

For the initial screening, EPA 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 is proposing to issue some orders jointly under the authority of FFDCA section 408(p)(5) and FIFRA section 3(c)(2)(B).

The Agency has drafted basic templates that would be used for such test orders. These templates, which reflect EPA's preferred approaches, differ according to whether the recipients are:

- Pesticide registrants, or
- Manufacturers and importers of inert ingredients.

Finally, the test order templates may differ to accommodate differences in the Agency's procedures for data compensation, and for the minimization of duplicative data. Copies of the current draft test order templates are included in the Docket and the Agency welcomes your comments on the structure and clarity of these documents.

There are some pesticide active and 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 Can EPA Do 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 also considered it appropriate to promote cost sharing and data compensation. EPA also originally contemplated that it would adopt new procedures unique to the EDSP. After considering all of the issues, EPA is currently considering adopting an approach that is similar to that announced in the December 1998 Notice, but with some significant distinctions which are discussed in more detail in this section.

In summary, EPA's preferred approach to ''minimize duplicative testing of the same substance'' and to promote the ''fair and equitable sharing of test costs'' would be as follows:

- The companies, who are the basic producers of an active ingredient or inert ingredient at the time EPA issues a data requirements notice (FFDCA section 408(p) test order), would bear the costs of testing and would be informed of all other order recipients.
- The recipients of the FFDCA section 408(p) test orders would have strong incentives to work together to develop data jointly and to share test costs.
- Subsequent entrants into the marketplace would receive ''catch-up'' FFDCA section 408(p) test orders making them subject to the same data requirements with the same provisions to comply with the requirement by making an appropriate offer to share the test costs that includes a reasonable process for resolving disputes.
- Customers who purchase an inert ingredient from a basic producer (who becomes/is an original data submitter) would not have to participate in joint development of, or offer to pay compensation for the right to rely on, required EDSP data.

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

In summary, EPA is considering adopting a policy that encourages joint data developers to agree on how to share costs and also encourages companies that enter the marketplace after the data are developed to pay reasonable compensation to the data generators. EPA's policy will resemble the provisions and procedures of FIFRA to the extent allowed by FFDCA.

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 section, allowing parties to share the costs of conducting the testing. Consequently, some of the measures discussed in this section that EPA is considering adopting to try to minimize duplicative testing will have certain implications for the decisions pertaining to cost sharing, and vice versa.

The Agency recognizes that, if EPA sends test orders under the EDSP screening program to multiple companies that produce the same substance and then each recipient of the test order conducts the required studies, there could be a great deal of duplicative testing. Although not discussed in the 1998 Notice, one way to avoid such duplicative testing is to send the test orders only to a single person who would be responsible for producing the required data. Unlike FIFRA section 3(c)(2)(B), FFDCA section 408(p) does not specifically require that test orders be sent to all registrants of a particular pesticide. But, when there are multiple people that produce the substance to be tested, such an approach could potentially undercut the second goal mentioned in FFDCA section 408(p)(5)(B)—promoting ''fair and equitable sharing of test costs.'' Each company that manufactures a substance subject to EDSP screening would benefit from the production of the data, and under the most equitable approach, each should potentially pay a fair share of the cost of testing. As a practical matter, however, people would have little or no incentive to contribute to the cost of generating EDSP data unless they each received a test order. Therefore, when there are multiple producers of the substance, EPA believes that EDSP test orders should generally be issued to each producer, and not just to a single producer.

The Agency originally anticipated relying on the authority of FFDCA section 408(p) to establish new procedures to promote joint development of data by recipients of FFDCA section 408(p) test orders (63 FR 71563). Now, however, the Agency no longer believes that FFDCA section 408(p)(5) provides the authority to create express requirements for joint data development. 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 that would minimize duplicative testing, EPA has the authority under FFDCA section 408(p) to develop Agency procedures that achieve many of the same ends. Specifically, the Agency has discretion to determine what actions constitute compliance with a FFDCA section 408(p) test order, and EPA can apply this discretion in a manner that creates strong incentives for companies to voluntarily develop data jointly. While

there are good policy reasons not to require the same data from multiple entities, under FFDCA section 408(p), each recipient of a data requirements notice has a separate obligation to provide the required data. 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 actually 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 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 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 or through a state or federal court action).

The Agency believes this approach to minimizing duplicative testing, which parallels that used under FIFRA section 3(c)(2)(B), would adequately address any disincentives for the recipients of FFDCA section 408(p) test orders 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 would have 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 should 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.

In addition to the specific procedures discussed in Unit IV.C.1., many of the procedures EPA is considering adopting to address cost sharing and data compensation will effectively function to minimize duplicative testing. Similarly, EPA has taken the directive to minimize duplicative testing to the extent practicable into account in determining who would receive FFDCA section 408(p) test orders. See Units IV.C.2. and IV.D. for further discussion of these topics.

In summary, EPA currently intends that it will typically treat a suitably expressed offer to join in the development of a required study as sufficient to comply with a test order under FFDCA section 408(p).

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 would, ''to the extent practicable,'' like 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.

FFDCA section 408(p)(5)(B) merely establishes a qualified direction that the Agency develop ''as appropriate, procedures for fair and equitable sharing of test costs.'' This, standing alone, does not create new data compensation rights, nor does it authorize EPA to create such rights. EPA has no inherent authority to create new rights to compensation; such rights are created only by Congress, and must be explicitly created by statute. FFDCA section 408(p)(5)(B) provides none of the indicia that Congress intended to expand the current expectation as to which data are compensable. For example, FFDCA section 408(p)(5)(B) is silent on a reimbursement period, processes and acceptable arbitration organizations, EPA's role in the process, penalties for non-compliance, and exemptions. Not only does EPA believe that FFDCA section 408(p)(5) fails to provide EPA with the authority to establish unique procedures for the EDSP, but EPA believes that this provision does not authorize EPA to modify existing data compensation rights established under FIFRA section 3 or FFDCA section 408(i).

By contrast, FIFRA, TSCA, and FFDCA section 408(i) all provide specific directions to the Agency on all of these issues. FIFRA section 3(c)(1)(F) establishes an elaborate set of criteria and procedures governing the rights of data submitters to obtain either ''exclusive use'' over or data compensation for data they submit to EPA. TSCA section 4 has similarly detailed provisions. [See also 7 U.S.C. 136a (c)(1)(F)(ii)–(iii); 15 U.S.C. 2603(c)(3)–(4)]. Similarly, section 408(i) of FFDCA, which extends FIFRA data compensation rights to data submitted ''in support of a tolerance or tolerance exemption,'' effectively provides guidance on all of these issues, providing that such data ''shall be entitled to. . .exclusive use and data compensation to the same extent provided by [section 3 of FIFRA].''

In summary, EPA interprets FFDCA section 408(p)(5)(B)'s direction to require EPA to develop procedures that will promote cost sharing among test order recipients and to provide for compensation for data submitted pursuant to a FFDCA section 408(p) test order, but only to the extent either FIFRA section 3 or FFDCA section 408(i) provide for cost sharing or data compensation. As explained more fully in the remainder of this unit, however, EPA believes that its approach to minimizing duplicative testing will not only promote joint data development, but also encourage cost sharing among all test order recipients. In addition, EPA believes that most EDSP data developed in response to FFDCA section 408(p) test orders will be

compensable under FIFRA, or pursuant to FFDCA section 408(i).

As discussed in Unit IV.C.1., EPA intends to adopt procedures implementing FFDCA section 408(p) screening that will minimize duplicative testing; these measures will 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 would be 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. What data are compensable 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 belief 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. 136a(b)(2)(D)(viii)]. Thus, EDSP data on active and inert ingredients for which there is a tolerance or tolerance exemption will be 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 (2)(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 would be compensable as outlined in FIFRA section 3(c)(1)(F) if the data are submitted by a pesticide registrant.

In summary, most EDSP data will be compensable under FIFRA or FFDCA section 408(i). Data for active and inert ingredients that have a tolerance or tolerance exemption or are the subject of a pending petition will be compensable regardless of what companies submit the data. Other active ingredients will also be 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 will be compensable under FIFRA or FFDCA section 408(i), some EDSP data will be generated by chemical manufacturers and importers of inert ingredients that have neither a tolerance nor tolerance exemption and are not the subject of a pending 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 would not be 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, data submitted to EPA in response to a FFDCA section 408(p) order by a person who is neither a registrant nor an applicant would not become compensable under FIFRA. However, although data on a non-food use 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 a registrant to support continued registration of a pesticide product. In addition, EPA believes that the internal procedures it intends to adopt would effectively provide manufacturers and importers with the same opportunity for cost sharing/compensation available to all other order recipients.

Given EPA's belief that FFDCA section 408(p)(5)(B) does not give EPA the authority to modify FIFRA data compensation rights, the fact that much EDSP data will also potentially be 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. 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 is considering issuing orders to registrants to conduct EDSP testing pursuant to both FIFRA section 3(c)(2)(B) and FFDCA section 408(p).

Although EPA believes there are ways to make all EDSP data generated on 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 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 an inert ingredient after an original data submitter has provided EDSP data on the 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 those manufacturers or importers of a substance for which EDSP data had previously been submitted who subsequently enter the market, 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), EPA may issue a test order to a manufacturer or importer who begins to sell an inert ingredient 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. 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. In furtherance of the goal of ''fair and equitable sharing of test costs,'' the Agency would accept citation of existing data only if the recipient 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 could not readily identify new entrants in the market. EPA would largely rely 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 could issue the FFDCA section 408(p) catch-up orders.

An issue arising under this approach is whether to send FFDCA section 408(p) test orders to subsequent entrants into the marketplace indefinitely or only to send them for a limited period of time. EPA is proposing to only send ''catch-up'' FFDCA section 408(p) test orders to subsequent entrants into the marketplace within 15 years—a time frame matching the period of compensability under FIFRA section 3(c)(1)(F). An additional issue that will need to be resolved is whether manufacturers of inert ingredients who do not themselves market the ingredients for use in pesticide products should be required to generate data in response to a 408(p) test order. See Unit IV.F.1. for further discussion of this topic. The Agency invites public comment on these issues.

b. Who will provide compensation? Although the procedures described should result in having all companies that manufacture or import an 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 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 pesticide chemical ingredients except non-food use inerts, the Agency interprets the formulator's exemption to be applicable. Under FIFRA section 3(c)(2)(D), an applicant for registration of a product may be excused from submitting or citing data pertaining to registered products that the applicant has purchased from another person. EPA has also taken the position that this principle extends to a FIFRA applicant's purchase of food use inert ingredients, when all applicable inert ingredient data requirements have been satisfied by the inert ingredient manufacturer.

The formulator's exemption under FIFRA section 3(c)(2)(D) is not applicable to EDSP data generated on non-food use inerts (unless 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 inert ingredients. The policy rationale underlying FIFRA's formulator's exemption is equally applicable in the case of non-food use 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 inert ingredients they purchase to make their products. [See 49 FR 30892, August 1, 1984]. As a result, EPA is considering adopting the following procedures to determine whether the end-use formulators had met their obligations to submit EDSP screening data.

c. *How will EPA determine 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 on the owners of the data. This is the Data Submitters List. Product registrants 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). Product registrants typically cite the data submitted on the active ingredients to support a technical registration. The citation is accompanied by either a claim that the registrant is eligible for a formulator's exemption or proof 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 issues of reasonable compensation. If the applicant or registrant fails to fulfill the agreement, the owner of the data may petition the Agency to cancel the registration. These procedures would also be applicable to EDSP data that are subject to FFDCA section 408(i).

As previously noted, compensation for data on inert ingredients has not been an issue to date so implementation of data compensation for EDSP data on inert ingredients would involve new procedures. The approach outlined here is also being considered for administering the formulator's exemption for all food use inert data; EPA intends that the procedures ultimately adopted for the EDSP will be consistent with (if not the same as) those adopted generically for all food use inert data, as there is no reason for creating separate procedures for EDSP inert data and all other food use inert data.

First, for each inert ingredient on which EPA receives EDSP data, EPA would identify the data submitter on an ''Inerts Suppliers List.'' This list would contain the names of every company that had either submitted the required EDSP data or fulfilled its obligation under a FFDCA section 408(p) test order by offering to share the cost of testing with other data developers. Second, EPA would need to require pesticide applicants and registrants to identify the source of every inert ingredient for which there are compensable EDSP data. Then, EPA would consider that the end-use formulator had adequately complied with FFDCA section 408(p)(3)'s requirement to conduct EDSP screening only if the person identified as the source for the inert ingredient appeared on the ''Inerts

Suppliers List'' for that inert ingredient. If the applicant or registrant of the end-use product chose to use a source for the inert ingredient that is not on the ''Inerts Suppliers List,'' EPA would issue an order to the manufacturer of the inert ingredient, and/or to the applicant or registrant, requiring the manufacturer and/or applicant or registrant to generate the EDSP test data.

The Agency could take the following possible approaches for applying these procedures to determine whether the end-use formulators had met their obligations to conduct EDSP screening:

i. *Determine compliance in conjunction with applications for new and amended registrations.* EPA could apply these procedures as part of the routine processing of applications for new and amended registrations. Under FIFRA section 3(c)(1)(F), the action of submitting an application would trigger the obligation to identify the source of an inert ingredient for which there were EDSP data. If the source cited by the applicant was not on the ''Inerts Suppliers List,'' the applicant would have the choice of either offering to pay compensation to a source on the list or of changing sources to a supplier already on the list. Should the applicant choose neither option, EPA would require the applicant to generate EDSP data in order to obtain its registration.

ii. *Determine compliance both in conjunction with applications for registration, and during registration review.* In addition to relying on existing procedures under FIFRA section 3(c)(1)(F), EPA could also use the registration review program authorized under FIFRA section 3(g). Under registration review, EPA reexamines all previously registered pesticide products approximately once every 15 years and, as necessary, requires the registrants to take steps necessary to come into compliance with the applicable statutory and regulatory requirements. As part of such updating, EPA could require registrants to comply with FIFRA section 3(c)(1)(F) with respect to the right to cite and rely on EDSP data pertaining to an inert ingredient in their products. Thereafter, the registrants would proceed as under the first option.

iii. *Issue test orders to end-use formulators.* This option is similar to the second, except that EPA would issue test orders under either FFDCA section 408(p) or FIFRA section 3(c)(2)(B) to end-use formulators whose products contain a particular inert ingredient, rather than waiting until registration review. Under this approach, EPA would continue to determine compliance in conjunction with applications for registration, and would also issue test orders shortly after submission of the EDSP data for a particular inert ingredient, to all registrants whose products contain a particular inert ingredient. The test orders would require the registrants either to provide the EDSP data, to cite and offer to pay compensation for existing EDSP data, or to demonstrate that the registrant purchased its product from a company on the ''Inerts Suppliers List.'' Under this approach, EPA would also determine compliance in conjunction with applications for new or amended registrations.

Among these three options, EPA prefers the first whereby data compensation would be triggered as registrants sought new or amended registrations. (As long as a registrant did not amend its registration, it would not have to make an offer to pay compensation.) This is because EPA believes that the registration and amended registration processes should effectively capture all new and existing products. EPA recognizes that although each of these procedures would make the registration process more complex and require additional resources from both the regulated community and EPA, the first seems to involve the smallest increase in administrative burden. However, EPA requests comment on the merits of the various approaches.

The alternatives differ primarily by how quickly the original data submitters could be assured that pesticide formulators are either offering to pay compensation or are buying only from a supplier on the ''Inerts Suppliers List.'' Under the third option, this accounting would occur shortly after submission of the EDSP data when all affected registrants would receive test orders shortly after the submission of the EDSP data and orders would require affected registrants to comply within a short time period. The second option would require registrant responses only as EPA reviewed products containing a particular active ingredient. At the end of 15 years, however, all registrants would have been required to comply with FIFRA section 3(c)(1)(F). While these differences may seem significant, the Agency thinks that, in reality, there is little difference between the options. If all manufacturers and importers were parties to the initial submission, and so long as EPA promptly issues ''catch up'' orders under FFDCA section 408(p) to new manufacturers and importers of the inert ingredient as they enter the marketplace, a product registrant should always discover that its supplier is already on the list.

As discussed, the requirements for instituting such procedures could be onerous and would become more onerous over time as more inert ingredients go through the EDSP. Registrants would eventually have to identify the source of all inert ingredients, many of which can pass through multiple packaging, wholesale, and retail steps before being purchased by a formulator. Any time the registrant, or an actor in the supply chain, changed sources, an amendment would be necessary along with a new claim of exemption or offer to pay compensation. This would discourage registrants from changing sources, even between suppliers on the ''Inerts Suppliers List,'' potentially limiting competition and leading to higher costs for producers and consumers of pesticide products. EPA would have to process all changes, verify that exemptions are valid, and maintain the ''Inerts Suppliers List,'' as well as distinguish between compensable data and non-compensable data.

D. What Procedures Can EPA 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 III.C. are equally relevant to EPA's implementation of this directive. EPA is therefore adopting 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 also does not believe 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 will consider 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 data would be 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 would be considered as part of the registration process, and would therefore be considered to be data submitted in support of a registration. As such that information would be directly subject to

FIFRA section 10. However covered, data subject to FIFRA section 10 would be 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 would consider 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 would only be 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 Will 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 generally 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 Notice to include registrants who use an integrated system to 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; (2) registrants whose products are produced using an integrated system, as defined in 40 CFR 158.1539(g); and (3) registrants who use an unregistered technical active ingredient to manufacture their pesticide product.

• *End-use registrants (customers)* – Registrants whose products contain an active ingredient or an inert ingredient. The registrant does not necessarily manufacture or import the active pesticide ingredient or inert.

• *Manufacturers/importer* – Entities who manufacture or import an inert ingredient that do not necessarily have to hold an EPA registration for the sale of pesticide products. This would also include 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. *Technical registrants and manufacturers/importers vs. all registrants and manufacturers/importers.* 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.'' Registrants are entities that hold a license for the sale of pesticide products. Pesticide products contain multiple substances, including both active and inert ingredients. EPA thinks that this language gives EPA the discretion to send FFDCA section 408(p) test orders to:

a. Persons who manufacture or import an active ingredient or inert ingredient.

b. Registrants whose products contain an active ingredient or an inert ingredient.

c. People in both groups.

Thus, the universe of recipients of FFDCA section 408(p) test orders is potentially very large. In most cases, however, the Agency expects that only one or a few companies would actually take the lead in organizing and conducting required EDSP studies. For pesticide active ingredients, the data developers are likely to be the companies that manufacture the substances subject to test orders (or who import the substances from a foreign manufacturer), as opposed to those who purchase the ingredient from a manufacturer or importer and mix it to make a pesticide product.

For pesticide active ingredients, EPA believes sending FFDCA section 408(p) test orders both to the technical registrant and to the end-use registrant (their customers) would lead to unnecessary administrative costs for EPA and the regulated industry. Similarly for inert ingredients, EPA believes sending FFDCA section 408(p) test orders to both the manufacturers/importers of the inert ingredient and to the end-use registrants (whose pesticide product contains that inert ingredient and the manufacturer's/importer's customer) would also be unduly burdensome to the Agency and the regulated community. Issuing FFDCA section 408(p) test orders to all registrants of pesticide products containing the chemical would also serve to increase the number of recipients, making the formation of data development groups more challenging administratively. Further, issuing FFDCA section 408(p) test orders to all registrants of pesticide products containing the chemical is unnecessary to promote fair and equitable sharing of test costs. Product registrants, which are often small businesses, would be quite unlikely to directly contribute to the actual conduct of the required testing and may simply reformulate their products in response to an order. Accordingly, EPA is considering an approach that limits the issuance of FFDCA section 408(p) orders only to the technical registrant of an active ingredient and to the manufacturer/importer of the inert ingredients rather than to all registrants whose products contain the ingredient.

2. *Pesticide active ingredients.* The Agency can easily identify the technical registrants of active ingredients. As previously noted, a technical registrant holds a registration for a specific active ingredient that the technical registrant formulates into end-use (or retail) products they produce or that the technical registrant sells to other companies 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 larger companies, have historically been responsible for generating the data to support theend-use 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). In addition, there is a subset of registrants that do not purchase a substance for use as an active ingredient, but produce it themselves through an integrated process. These registrants cannot rely on the formulator's exemption to satisfy data requirements, but must generate data themselves or offer to pay for relevant data that were previously generated by another registrant (such as a technical registrant).

As noted previously, some active ingredients do not have a separate technical registration because a single company manufactures the chemical and formulates it into pesticide products, but does not sell the chemical separately to other formulators. The data to support a technical registration exist, but are incorporated into the data for the product registrations.

Test orders under FFDCA section 408(p) may be sent either to pesticide active ingredient technical registrants, or to both pesticide active ingredient technical registrants and all end-use registrants that utilize that pesticide active ingredient in their registered product. EPA prefers the first approach.

The primary disadvantage to issuing orders solely to technical registrants arises in the (unlikely) event that the technical registrant fails to submit the EDSP data. The penalty for failure to comply with a FFDCA section 408(p) test order is suspension of the technical registrant's registration. However, because EPA had not issued a test order to the end-use registrant, EPA would have no basis for suspending the end-use registrant's registration, and the end-use registrant could legally continue to sell its products, even though, just like the technical registrant, it had not submitted EDSP data. Moreover, even if EPA immediately issued a test order to the end-use registrant, the test order could not compel immediate compliance; the registrant would need to be given adequate time to generate the data.

Nonetheless, EPA believes that this disadvantage is ultimately unlikely to be significant. First, if the technical registration has been suspended, EPA expects that the end-use formulator would be unlikely to find a source for its active ingredient, and consequently would be unable to produce a product even though it could legally sell one. Second, it has been EPA's experience that the technical registrants rarely, if ever, fail to comply with DCIs, and thus, the issue is unlikely to arise in practice.

A second issue is that 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 without specifying its future use, FIFRA does not require registration of the chemical until it appears 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 subject to EPA's authority under the plain language of FFDCA section 408(p)(5).

EPA requests comment on whether or not to send FFDCA section 408(p) test orders to producers of commodity chemicals that do not hold a pesticide registration for a product containing the substance to be tested.

3. *Inert ingredients.* For inert ingredients, test orders under FFDCA section 408(p) may be sent to manufacturers/importers only, or to both manufacturers/importers and one or more pesticide registrants who use the inert ingredient in their pesticide product. For inert ingredients, manufacturers/importers include any company that manufactures or imports the inert chemical regardless of whether they are a registrant and regardless of whether they directly sell the chemical for use as a pesticide inert.

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

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

In addition, Unit IV.E.3.c. discusses the special considerations that arise when an inert ingredient is contained within a mixture whose composition is both proprietary and unknown by the registrant who purchases it for use in a registered pesticide product; EPA refers to this as an ''inert in a proprietary mixture.''

a. *Food-use inerts.* If an inert 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 inert ingredients, EPA's preferred option is to issue FFDCA section 408(p) test orders only to manufacturers and importers. Limiting the universe of FFDCA section 408(p) test order recipients should reduce the resources needed to issue the test order (EPA) and to comply with the test order (regulated community) and facilitate joint data submissions and cost sharing.

Another approach would be to issue test orders to both manufacturers and importers and to all registrants (both technical and end-use) of products containing the inert(s). While this approach would use the procedures familiar to registrants under FIFRA section 3(c)(2)(B), this advantage does not outweigh the added administrative burdens associated with the process of identifying and notifying all registrants using an inert ingredient in their pesticide formulations, and the requirement for all of these registrants to respond to the FFDCA section 408(p) test orders and DCI notices, without compromising CBI. Moreover, many product registrants may simply reformulate their products in response to such an order, which would require altering their registrations. EPA would like to avoid such disruptions if there are no data to indicate that the current formulation poses any risks.

However, as discussed in Unit IV.C., issuing FFDCA section 408(p) test orders to both end-use registrants and manufacturers and importers of food use inerts would have implications for the timing of the accounting with respect to registered end-use pesticide products. In other words, issuing orders would assure that EPA determined shortly after receiving the data that all end-use formulators either purchased their ingredient from a company on the ''Inert Suppliers List''; made an offer to pay; or received a test order to generate data. EPA's preferred approach is to address compensation obligations as registrants apply for or amend registrations. Unit IV.C., however, discusses in more detail two other alternatives.

b. *Non-food use inerts.* EDSP data submitted on non-food use 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. In recognition of this fact, EPA has identified two possible options with regard to who receives the FFDCA section 408(p) test orders and under what legal authority the orders are issued. The options differ in administrative complexity and in the extent to which the resulting data

receive protections under FIFRA section 3 and section 10.

First, EPA could send the FFDCA section 408(p) test orders only to manufacturers/importers of the substance used as a non-food use inert ingredient. This option has the principal advantage of simplicity (compared to the other options) and it limits the administrative resources required for implementation by both the regulated community and EPA. Under this option, however, data generators may not receive added protections under FIFRA for proprietary information or compensation from applicants and registrants that used the inert ingredient to formulate their pesticide products. Even if FIFRA's compensation provisions would not apply, the procedure whereby companies entering the market after submission of the EDSP data would receive ''catch-up'' FFDCA section 408(p) test orders would most likely lead to the manufacturers and importers subject to the initial FFDCA section 408(p) test orders receiving offers to share test costs equitably.

The second option would involve sending FFDCA section 408(p) test orders to both manufacturers and importers and sending both FFDCA section 408(p) test orders and DCI notices under FIFRA section 3(c)(2)(B) to registrants whose products contain the inert ingredient (end-use registrant). This option has one principal disadvantage over the first option—assuming at least one registrant participated in the data development, this option would basically double the administrative burden to EPA and the regulated community and have the same significant disadvantages as discussed in connection with sending FFDCA section 408(p) test orders to all registrants of products containing a food use inert. (See Unit IV.E.3.a.).

After weighing the advantages and disadvantages of these options, EPA believes that the first option represents the best balance. In large measure, this is based on the Agency's judgment that the burden to both the Agency and the recipients associated with issuing test orders to all end-use registrants cannot be justified by the slight advantages offered by issuing orders to end-use registrants. EPA expects that manufacturers generally know who purchases their products, and thus do not need EPA to identify them. Thus, manufacturers who wish to partner with a registrant would still be able to do so, without the need for EPA to also issue a test order to the end-use registrant.

c. *Inert ingredients in a proprietary mixture.* The Agency faces unique and particularly complex issues when dealing with a registrant whose pesticide product contains an inert ingredient that is present only because the registrant purchases a ''proprietary mixture.'' A proprietary mixture is a product that contains one or more inert ingredients and for which the exact composition is not known by the purchaser. EPA requires the manufacturer of proprietary mixtures to identify the ingredients in the product, and EPA considers this information in deciding whether to approve the registration of the product. But because the manufacturer of the proprietary mixture considers its composition a trade secret, EPA is prohibited from disclosing this confidential information to the registrant or others.

For example, an end-use pesticide product may contain ''Super Surfactant Ultra'' as an inert chemical component, but the formulator of theend-use pesticide product does not know the exact contents of ''Super Surfactant Ultra.'' The Agency would face a difficult (if not impossible) dilemma if EPA determined that it was necessary to obtain EDSP data on one of the ingredients in ''Super Surfactant Ultra,'' and EPA had chosen a procedure that involved sending FFDCA section 408(p) test orders and/or DCI notices to all registrants whose product contained that ingredient. In such a case, EPA may be prohibited from disclosing information that could divulge the contents or nature of the inert ingredients in ''Super Surfactant Ultra'' to the pesticide end-use registrant. Since the very issuance of the test order could divulge confidential proprietary information (the fact that ''Super Surfactant Ultra'' contains a particular inert ingredient) to the recipient (the registrant who purchases ''Super Surfactant Ultra'' but does not know its composition), EPA may not be able to include the registrants who purchase ''Super Surfactant Ultra'' among the recipients of the test orders. If EPA does not send test orders to the registrants whose products contain a proprietary mixture from the list of recipients, these registrants would unfairly escape the obligation to respond to the test order. On the other hand, if EPA does send test orders to generate data on a specific inert ingredient to registrants whose products contain a proprietary mixture, EPA would potentially violate the prohibitions against disclosing CBI.

If an inert ingredient appears in a pesticide product only as a constituent of a proprietary mixture, there appears to be no practicable way to minimize duplicative testing or to extend data compensation and data confidentiality protections to data submitted for the purposes of the EDSP unless the inert manufacturer is willing to disclose the confidential composition of the mixture to at least one pesticide registrant. EPA believes that a manufacturer might give EPA permission to disclose to a registrant the fact that a proprietary mixture contains a particular inert ingredient in order to ensure that the registrant complied with the data compensation procedures to identify the source of an inert ingredient. As previously discussed, EPA cannot issue test orders or DCI notices to pesticide registrants unless EPA can identify the substance to be tested. Consequently, because of confidentiality issues (among other reasons), EPA's preference would be to issue FFDCA 408(p) test orders involving inert ingredients in confidential mixtures only to manufacturers/importers and to registrants whose production, sale, or use of the inert ingredient can be determined by publicly available information. Another alternative would be to issue test orders to the manufacturer/importer of the confidential mixture, rather than for its individual components. This would not involve any disclosure of CBI, but it could lead to duplicative testing in that an ingredient may already have been tested separately. In addition, this option raises difficult scientific issues involved in testing mixtures. EPA will continue to explore this issue, and would welcome commenters' suggestions.

4. *Summary of who would receive orders under EPA's preferred approaches.* Specifically under EPA's preferred approach, EPA would take the following actions to maximize joint data development, data compensation, data confidentiality protections, and resource efficiency:

- Pesticide active ingredients. Test orders issued pursuant to FFDCA section 408(p) and FIFRA section 3(c)(2)(B) would be sent to technical registrants of the pesticide active ingredient.
- Inert ingredients. Test orders issued pursuant to FFDCA section 408(p) would be sent to current manufacturers and importers; ''catch-up'' FFDCA section 408(p) test orders would be sent to manufacturers and importers who subsequently enter the marketplace after the original orders had been issued.

5. *How will EPA identify order recipients*? For FFDCA section 408(p) test orders involving pesticide active ingredients, the Agency will 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.

For FFDCA section 408(p) test orders involving inerts, the Agency will use OPPIN (where applicable) 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. The Agency is interested in public comment on the Agency's approach to identify FFDCA section 408(p) test order recipients for inert ingredients.

EPA generally plans to make public the list of recipients of FFDCA section 408(p) test orders and DCI notices and to invite comments from the public identifying additional persons who should have received the data requirements notices. Commenters could either identify themselves or another person as additional candidates (with proper substantiation) for receipt of a FFDCA section 408(p) test order. Although not the Agency's preferred approach, if EPA sends test orders to pesticide registrants for EDSP data on inert ingredients, the Agency may not be able to release a complete list of test order recipients that includes the names of all affected registrants because this list could effectively disclose proprietary information about the composition of their formulations. (As discussed in Unit IV.C., EPA would have to give affected registrants the option of identifying an agent to represent them in matters relating to the test order, including being listed on the list of recipients of the test order.) The list of recipients could be published in the **Federal Register**, or posted on the Agency's website. For example, the Agency is considering posting the status of the orders on the website so that both recipients and the public can check on the status of responses to the orders, and the list of recipients could be part of that posting. The Agency seeks comment on the mechanism for making the list of recipients public.

6. *How will order recipients be notified*? Order recipients would be notified through their direct receipt of a FFDCA section 408(p) test order via registered mail. They would receive an order packet that will contain the instructions, background materials, and forms needed to comply with the order. (See the draft order template in the docket).

F. How Should Recipients Respond to a Test Order?

The following procedures would be used by recipients who are responding 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 an inert ingredient after EDSP data on a substance had been submitted to EPA. These options would also be appropriate for responding to test orders issued jointly under the authority of FFDCA section 408(p) and FIFRA section 3(c)(2)(B).

1. *Initial response*. Each recipient would be directed to provide a response to EPA within 90 days of the issuance of the order. This response is intended to allow the recipient to provide EPA with its intended response. To simplify completion of this initial response within the 90 days, EPA has created a simple Order Response Form. EPA intends to include the form in the order packet, pre-populated with the basic information to connect it to the specific order. A copy of the draft form is available in the public docket for your review and EPA encourages your comments and suggestions.

The recipients of a test order would have several potential response actions from which they could choose. The 90–day response options include:

a. *Recipient indicates that they intend to generate new data.* The recipient would choose this option to indicate that they agree to individually generate new data for each test specified to meet the requirements of the order. In the case of data pertaining to an inert ingredient for which there is no tolerance or exemption, the recipient may negotiate an agreement to have a registrant of a product containing the inert ingredient submit the data so that the data qualify for compensation under FIFRA—the data generator and the registrant could work out among themselves how actual compensation would be apportioned.

b. *Recipient indicates that they intend to enter (or offer to enter) into an agreement to form a consortium to generate the data.* The recipient would choose this option to indicate that they are forming a task force or consortium to comply with the test order. Recipients would identify who is part of the consortium, as well as indicate for which tests data will be generated. Alternatively, recipients may provide EPA with documentation that they have made an offer to 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 or through a state or federal court action). Note: 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.

c. *Recipient indicates that they intend to rely on existing data.* The recipient would choose this option to indicate that they intend to submit or cite existing data that satisfies the request in the test order. The recipient's response would include either the data or a reference to the data for each test that are being cited. Data compensation procedures may apply. If the study is not exactly as specified in the protocols attached to the test order, the recipient should provide an explanation as to why the data should be accepted as satisfaction of the test order. The Agency would expect that any such hazard-related data would be scientifically comparable to data that would be generated by the EDSP.

For the initial screening, EPA expects that opportunities for order recipients to respond in this manner will be limited. As mandated by the statute, EPA has developed and validated appropriate assays and it is unlikely that other studies would be acceptable under data quality standards. During the validation process, however, a chemical on the initial list might have been a test subject for a study listed in the order. Order recipients may be able to cite these data if protocols, which were modified over the course of validation, are sufficiently similar. EPA intends to provide recipients with information about the availability of validation studies along with the orders.

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) They are not a pesticide registrant, or (ii) they do not currently manufacture or import a chemical that anyone uses as a pesticide active or inert ingredient. An explanation of the basis for the claim, along with appropriate information to substantiate that claim, would be required to allow EPA to evaluate the claim.

e. *Recipient indicates that they intend to voluntarily cancel or reformulate the product registration or discontinue the manufacture/importation of the chemical.* Registrants may request voluntary cancellation of their product's pesticide registration pursuant to FIFRA

section 6(f). Doing so would initiate the existing procedures for a voluntary cancellation. Under those procedures, the registrant may either adopt the standard procedures for sale or use of existing stocks of their pesticide, or may propose an alternative procedure. Alternatively, in the case of an inert ingredient, (if EPA issues orders to end-use registrants) a registrant may submit an application to amend the formulation of its product by removing the ingredient. In the case of manufacturers/importers of both inert ingredients and commodity chemical active ingredients, the recipient would choose this option to indicate that they intend to agree to cease manufacture or importation of the chemical.

An additional option that EPA is considering would allow the manufacturer/importer to continue production of the chemical, but would involve their commitment to cease supplying the chemical for use in pesticide products. EPA does not prefer this alternative because of the practical difficulties in enforcing such agreements, given that there may not be a direct link between the manufacturer and the ultimate consumer. For example, if Company A receives the order and commits to sell that product only for non-pesticidal uses, it is unclear how Company A could enforce that agreement on its customers. Thus, Company A may agree not to sell it to Company B for use as a pesticide, but if Company B sells it to Company C for use as a pesticide inert, it is unlikely that EPA would discover it. Moreover, the most that EPA could do in that circumstance would be to send an order to Company B requiring testing. Further, tracking such agreements by reviewing the source of the end-use registrant's inert ingredient would be extremely complicated and burdensome for both the Agency and the end-use registrant.

If, as a result of comments or further analysis, EPA determines that orders will be sent to pesticide product registrants (end-use registrants), recipients may have an additional response option of claiming a formulator's exemption as discussed in the next section.

f. Claim a formulator's exemption. A product registrant who receives an order to test a chemical who purchases the chemical from another recipient who has agreed to generate the data may be eligible for a formulator's exemption. EPA will confirm claims of eligibility. A formulator's exemption would become invalid if the supplier of the chemical were not to submit the data either individually or jointly with other recipients.

g. 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 will 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.''

In addition, the Agency does not expect an FFDCA section 408(p) test order recipient to submit a request to bypass Tier 1 screening as part of their response to the test order. As indicated in the September 2005 **Federal Register** notice announcing the Agency's chemical selection approach and again in the June 2007 **Federal Register** notice announcing the availability of the draft list of chemicals for initial screening under the EDSP, any company subject to a testing requirement under Tier 1 may assert during the comment period for the draft list that the chemical is an endocrine disruptor and that the Tier 1 EDSP screening is unnecessary. EPA does not intend to permit chemicals on the draft list to bypass Tier 1 screening and move directly to Tier 2 testing without appropriate data to support such an action. As such, EPA expects that this issue will be addressed in finalizing the list of chemicals for initial screening, which will occur before any FFDCA section 408(p) test orders are issued.

2. *Generate the data specified in the test order.* As indicated in their Initial Response Form, the recipient's next step would be to generate the data specified in the FFDCA section408(p) test order. EPA currently anticipates that the tests would need to be conducted using the test protocols that would be attached to the order as background materials because of the statutory requirement that the test method be validated. If, however, an order recipient believes a deviation from the required protocol is needed, they should first consult the Agency before deviating from the test protocol. All requests should be submitted with a clear rationale to allow the Agency to evaluate the request in a timely manner. All protocol variations would be reviewed by EPA and a response would be sent to the specific order recipient in a timely fashion.

In addition, 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 the data specified in the test order.* The Agency intends to adopt 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. The orders will include requirements on how the data should be formatted. If EPA were issuing orders today, it is likely the Agency would require that the submission be

consistent with the following requirements.

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 should 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 the requirements for organizing and formatting 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 will 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 encourages FFDCA section 408(p) test order recipients to submit completed study profiles and supporting data in an electronic format (PDF) whether submitting one or several studies. For more information, go to the electronic data submissions website at *http://www.epa.gov/oppfead1/eds/edsgoals.htm*.

b. *Transmittal document.* In order for EPA to track the compliance of each order recipient, each submission in satisfaction of a FFDCA section 408(p) test order must 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.
- Identification of the FFDCA section 408(p) test order associated with the submission (e.g., the test order number).
- A list of the individual documents included in the submission.

c. *Individual study or test result documents.* Unless otherwise specified by the Agency, each submission must be in the form of individual documents or studies. EPA does not anticipate requiring 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 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 should 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, each document must be accompanied by a signed and dated document containing the appropriate statement(s) regarding any data confidentiality claims as described in the FFDCA section 408(p) test order.

iii. A statement of compliance or non-compliance with respect to GLP standards as required by 40 CFR 160.12, if applicable.

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

4. *Request an extension.* The FFDCA section 408(p) test order would identify a due date for completing the data specified and submitting it to EPA. If an order recipient would like to request an extension of time to complete the testing, the request should be submitted with a clear rationale for the extension, and any supporting material, in order to allow the Agency to properly and timely assess the request. All such requests would be reviewed by EPA and a response would be sent to the requester in a timely fashion.

5. *Maintaining records.* The FFDCA section 408(p) test order would identify the records that the recipient should maintain. In general, the Agency expects recipients to maintain copies of the data and other information submitted to the Agency. 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 otherwise submit their data in support of a pesticide registration would be held to the recordkeeping standards in 40 CFR part 169. Recipients who are not a registrant would also be asked to maintain records related to the generation of the data as specified in the order. 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. These records shall be retained as long as the registration is valid and the producer is in business, and made available to EPA or its agent for inspection.

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) allows 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 inert ingredient manufacturers/importers, FFDCA section 408(p)(5)(D) allows 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, or believes the time frame for completing the study is too short). 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. 136a(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. 136a(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.

EPA has considered two alternative interpretations to resolve this ambiguity. Under one approach, EPA would interpret the statute such that the same procedures are applicable to both registrants and other test order recipients. EPA prefers this approach because it would simplify the process for both EPA and order recipients. The other approach would result in different procedures for pesticide registrants and all other test order recipients based on the disparate requirements established by FFDCA section 408(p)(5)(C) and (D).

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. 136a(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. 136a(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 in the appropriate district court *at the time the order is issued. [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 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. [5 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 preferred interpretation of the statutes and existing regulations would be 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. Moreover, EPA believes that, in general, it would simplify matters to have a single set of procedures for all test order recipients. Accordingly, pre-enforcement judicial review of the test order would 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 would interpret 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 would be consistent with the issues listed in TSCA section 16(a)(2)(B), which do not expressly relate to the validity of the underlying requirement.

Alternatively, EPA could interpret the legal status of the order to differ between registrants and non-registrants, based on the procedural distinctions created by FFDCA section 408(p)(5)(C) and (D). Under this approach, FFDCA section 408(p) test orders would constitute final agency action only for pesticide registrants, and only those test orders would be subject to pre-enforcement review in federal district courts. Accordingly, non-registrants would only be able to challenge the provisions of the order in an enforcement proceeding, and would not be entitled to pre-enforcement review in district court.

I. Informal Administrative Review Procedure

EPA intends to include a provision in the FFDCA section 408(p) test order that requires the order recipients to raise any questions or challenges concerning the issuance of the test order to the Agency in response to the order. EPA would review the issues presented and provide a written response within a specified time frame. The Agency understands that it would 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. EPA requests comment on whether such a provision would be appropriate, and on the appropriate parameters for such a requirement, including the deadline for order recipients to initially provide their concerns, and the time frame for the Agency's response.

J. 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 should instead submit the necessary information to cite to the previously submitted information as described earlier in this document.

V. Specific Topics for Commenters

While interested person are invited to comment on any issue discussed in this notice, the Agency would find it particularly helpful if interested commenters address the general issues and specific questions, set forth below. If, for example, commenters have ideas on how the Agency could minimize duplicative testing that are not captured in the questions below, the Agency welcomes comments on the general issue itself.

A. Minimizing Duplicative Testing

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

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

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

B. Cost Sharing

What evidence of a willingness to share the cost of generating EDSP data should EPA require?

C. Data Compensation

1. What evidence of a willingness to pay compensation for previously submitted EDSP data should EPA require?

2. Should EPA issue ''catch-up'' FFDCA section 408(p) test orders to people who begin to manufacture or import an inert ingredient after required EDSP data have been submitted?

3. If so, at what point (e.g., during registration review) and for how long should EPA issue such ''catch-up'' test orders?

4. What alternatives should EPA consider for the 15–year period proposed, and why?

D. Who Should Receive Test Orders?

1. If EPA relies on FIFRA section 3(c)(2)(B) as an authority to require data for an active ingredient, should EPA send the DCI only to technical registrants or to all registrants whose products contain the active ingredient?

2. Should EPA send FFDCA section 408(p) test orders to producers of commodity chemicals that do not hold a pesticide registration for a product containing the substance to be tested?

3. How should EPA address the issuance of test orders for an inert ingredient that is contained in a ''proprietary mixture''?

4. After EPA has received compensable EDSP data on an inert ingredient, which authority should EPA use to ensure that pesticide registrants are buying their inert ingredient only from sources on the ''Inert Suppliers List'': FIFRA section 3(c)(1)(F) only, FIFRA section 3(c)(1)(F) and FIFRA section 3(g), or FIFRA section 3(c)(1)(F) and FIFRA section 3(c)(2)(B)?

E. How to Identify Potential Recipients of Test Orders

1. Please suggest an efficient approach to identify potential recipients of FFDCA section 408(p) test orders for inert ingredients. Please identify any databases that will provide the best information.

2. Please comment on the preferred mechanism for making the list of recipients of FFDCA section 408(p) test orders public.

3. Please comment on a mechanism to identify entities that should have received a test order, but that were not initially identified.

4. How should EPA evaluate requests for exemptions under FFDCA section 408(p)(4)?

F. How to Respond to Test Orders

1. Is 90 days sufficient time for recipients of a test order to respond with their intentions for complying with the order?

2. Should EPA allow a person to ''fulfill'' the requirements of a test order by promising not to manufacture or import an active ingredient? An inert ingredient?

3. Should EPA allow a person to ''fulfill'' the requirements of a test order

on an inert ingredient by promising not to manufacture or import the inert ingredient for use in a pesticide product? If so, how would EPA enforce such an agreement?

G. Procedural Issues

1. When should a recipient of a test order for EDSP data on an inert ingredient be able to judicially challenge the issuance of the order?

2. Should EPA include an optional or mandatory informal administrative review procedure by which a person who wishes to judicially challenge the validity of a test order would raise the objections first with the Agency?

3. Should the 90–day response form be mandatory or optional?

4. Should test protocols be attached to the order and/or posted on a website?

5. Should the Agency establish a website of FFDCA section 408(p) test order recipients to facilitate the formation of consortia?

H. Due Process Options

EPA requests comment on whether the informal administrative review procedures (as outlined in this document) would be appropriate. Please also comment on the appropriate parameters for such a requirement, including the deadline for order recipients to initially provide their concerns, and the time frame for the Agency's response.

I. CBI

Provide comments on how best to address CBI concerns associated with notifying HPV inert manufacturers, including the difficulty of informing registrants, without disclosing the identity of the inert.

J. Estimated Test Costs and Paperwork Burden

1. Please provide comments on the estimated test costs and burden hours presented in the draft ICR. Explain the basis for your estimates in sufficient detail to allow EPA to reproduce the estimates.

2. Provide comments on the methodology used by EPA to estimate the burden for data generation, which is based on the total estimated test costs.

3. Is it reasonable to continue to assume that as much as 35% of the test costs represents the paperwork burden?

VI. 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 policy statement is considered to be a ''significant guidance document'' under the terms of the amended Executive Order because this policy 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 notified the Office of Management and Budget (OMB) and submitted a draft of this policy to OMB 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 described in this document have been submitted for review by the OMB under the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.* Elsewhere in today's **Federal Register** is a separate document that announces the availability of the draft Information Collection Request (ICR) document that has been prepared by EPA, identified by EPA ICR No. 2249.01). Pursuant to the PRA, the Agency is seeking public review and comment on the ICR before it submits the ICR to OMB for approval under the PRA. The following is a brief summary of the ICR document, which describes the information collection activities and EPA's estimated burden in more detail.

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. The OMB control numbers for EPA's regulations codified in Chapter 40 of the CFR, after appearing in the preamble of the final rule, are listed in 40 CFR part 9, are displayed either by publication in the **Federal Register** or by other appropriate means, such as on the related collection instrument or form, if applicable. The display of OMB control numbers in certain EPA regulations is consolidated in 40 CFR part 9. 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.

Burden under the PRA means the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

Under the EDSP, the information collection activities include reviewing the order and related instructions, providing the initial response, participating in a consortia, generating the data, 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 2,649 hours, with an estimated cost of $194,252. The total annualized estimated paperwork burden for this ICR is 93,655 hours, with an estimated total annual cost of $6,887,418. The Agency believes that this is an over estimate because this estimate assumes that the respondent actively participates in all potential activities, including developing a consortia, generating all of the potential data, requesting an extension and submitting the data. The Agency also assumed that all of the potential tests currently scheduled for validation would be used for each chemical. It is highly unlikely that any one respondent would need to participate at this level, or that all of the tests would be performed for each respondent.

Direct your comments on the Agency's need for this information, the accuracy of the provided burden estimates, and any suggested methods for minimizing respondent burden, including the use of automated collection techniques, to EPA using the public docket that has been established for the ICR (Docket ID No. EPA–HQ–OPPT–2007–1081). The Agency will consider and address comments received on the ICR as it develops the final policy and related final ICR.

VII. References

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.

List of Subjects

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

Dated: December 7, 2007.

James B. Gulliford,

Assistant Administrator for Prevention, Pesticides and Toxic Substances.

[FR Doc. E7–24166 Filed 12–12 ndash;07; 8:45 am]

BILLING CODE 6560–50–S

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR Part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The application also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 4 of the BHC Act (12 U.S.C. 1843). Unless otherwise noted, nonbanking activities will be conducted throughout the United States. Additional information on all bank holding companies may be obtained from the National Information Center website at *www.ffiec.gov/nic/*.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than January 4, 2008.

A. Federal Reserve Bank of Atlanta (David Tatum, Vice President) 1000 Peachtree Street, N.E., Atlanta, Georgia 30309:

1. Summerville/Trion Bancshares, Inc., Summerville, Georgia; to acquire 100 percent of the voting shares of Dunnellon State Bank, Dunnellon, Florida.

B. Federal Reserve Bank of Dallas (W. Arthur Tribble, Vice President) 2200 North Pearl Street, Dallas, Texas 75201–2272:

1. First National Bank Group, Inc., Edinburg, Texas; to acquire 9.90 percent of the voting shares of Southside Bancshares, Inc., Tyler, Texas, and thereby indirectly acquire voting shares of Southside Delaware Financial Corporation, Dover, Delaware, and Southside Bank, Tyler, Texas.

Board of Governors of the Federal Reserve System, December 6, 2007.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc. E7–23930 Filed 12–12–07; 8:45 am]

BILLING CODE 6210–01–S

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR Part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The application also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 4 of the BHC Act (12 U.S.C. 1843). Unless otherwise noted, nonbanking activities will be conducted throughout the United States. Additional information on all bank holding companies may be obtained from the National Information Center website at *www.ffiec.gov/nic/*.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than January 7, 2008.

A. Federal Reserve Bank of Atlanta (David Tatum, Vice President) 1000 Peachtree Street, N.E., Atlanta, Georgia 30309:

1. Floridian Financial Group, Inc., Daytona Beach, Florida; to acquire 100 percent of the voting shares of Orange Bank of Florida, Orlando, Florida.

B. Federal Reserve Bank of Chicago (Burl Thornton, Assistant Vice President) 230 South LaSalle Street, Chicago, Illinois 60690–1414:

1. Black River BancVenture, Inc., Memphis, Tennessee; to become a bank holding company by acquiring 42 percent of the voting shares of Michigan Community Bancorp, Ltd., and thereby indirectly acquire voting shares of Lakeside Community Bank, both of Sterling Heights, Michigan.

2. Black River BancVenture, Inc., Memphis, Tennessee; to acquire 15 percent of the voting shares of Community Shores Bank Corp., and thereby indirectly acquire voting shares of Community Shores Bank, both of Muskegon, Michigan.

3. Black River BancVenture, Inc., Memphis, Tennessee; to acquire 15 percent of the voting shares of Allegiance Bank of North America, Bala Cynwood, Pennsylvania.

4. Black River BancVenture, Inc., Memphis, Tennessee; to acquire 15 percent of the voting shares of Bay Commercial Bank, Walnut Creek, California.

5. Capitol Bancorp LTD, and Capital Development Bancorp Limited VII, both of Lansing, Michigan; to acquire 51 percent of the voting shares of Pisgah Community Bank, Asheville, North Carolina (in organization).

6. Capitol Bancorp LTD, and Capital Development Bancorp Limited VII, both of Lansing, Michigan; to acquire 51 percent of the voting shares of Colonia Bank, Phoenix, Arizona (in organization).

7. Capitol Bancorp LTD, and Capital Development Bancorp Limited VII, both of Lansing, Michigan; to acquire 51 percent of the voting shares of Reidsville Community Bank, Reidsville, North Carolina (in organization).

C. Federal Reserve Bank of Dallas (W. Arthur Tribble, Vice President) 2200 North Pearl Street, Dallas, Texas 75201–2272:

1. CSB Financial Corporation; to become a bank holding company by acquiring 100 percent of the voting shares of Citizens State Bank, both of Miles, Texas.