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

Response to Comments on the DRAFT Endocrine Disruptor Screening Program (EDSP): Policies & Procedures for Initial Screening and Testing

[72 FR 70842, December 13, 2007 (FRL–8340–3)]

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

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1.0 Overview of Response to Comments Paper

1.1 Introduction

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

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

1.2 Background

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

The Agency first proposed the basic components of the EDSP on August 11, 1998 (63 FR 42852) (FRL–6021–3). After public comments, external consultations and peer review, EPA provided additional details on December 28, 1998 (63 FR 71542) (FRL–6052–9). The design of the EDSP was based on the recommendations of the Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC), which was chartered under the Federal Advisory Committee Act (FACA) [5 U.S.C. App.2, 9(c)]. The EDSTAC was comprised of members representing the commercial chemical and pesticides industries, Federal and State agencies, worker protection and labor organizations, environmental and public health groups, and research scientists. EDSTAC recommended that EPA's program address both potential human and ecological effects; examine effects on estrogen, androgen, and thyroid hormone-related processes; and include non-pesticide chemicals, contaminants, and mixtures in addition to pesticides. Based on EDSTAC recommendations, EPA developed a two-tiered approach, referred to as the EDSP. The purpose of Tier 1 screening (referred to as ''screening'') is to identify substances that have the potential to interact with the estrogen, androgen, or thyroid hormone systems using a battery of assays. The fact that a substance may interact with a hormone system, however, does not mean that when the substance is used, it will cause adverse effects in humans or ecological systems.

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

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

Tier 1 screening assays and Tier 2 testing assays and EPA's approach for conducting the peer review of the Tier 1 battery (72 FR 38577) (FRL–8138–4). EPA also announced the availability of a ''list server'' (Listserv) that will allow interested parties to sign up to receive e-mail notifications of EDSP peer review updates, including information on the availability of peer review materials to be posted on the EDSP website. The Agency js publishing a final list of assays that will comprise the initial EDSP Tier 1 Screening Battery before EPA begins issuing orders in 2009.

- **Priority setting.** EPA described its priority setting approach to select pesticide chemicals for initial screening on September 27, 2005 (70 FR 567449), and announced the draft list of initial pesticide active ingredients and pesticide inerts to be considered for screening under FFDCA on June 18, 2007 (72 FR 33486). Inclusion on the initial list is solely based on potential pathways of exposure to that chemical and not on any potential for that chemical to interact with the endocrine system. The Agency js publishing a final list of chemicals that will be subject to initial screening before EPA begins issuing orders to require testing in 2009. 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.

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

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

1.3 Overview of Public Comments

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

Table 1: Docket Submission Information

DCN	Commenter	Affiliation
EPA-HQ-OPPT-2007-1080-0008	C. Pierce	
EPA-HQ-OPPT-2007-1080-0013	Holly Carpenter	American Nurses Association (ANA)
EPA-HQ-OPPT-2007-1080-0018	Klaus L.E. Kaiser	TerraBase Inc.
EPA-HQ-OPPT-2007-1080-0019.1	Thomas W. Curtis, Deputy Executive Director	American Water Works Association (AWWA)
EPA-HQ-OPPT-2007-1080-0020	John D. Gordon, Director of Research	Xenobiotic Detection Systems, Inc.
EPA-HQ-OPPT-2007-1080-0021.1	Steven J. Goldberg, Vice President and Associate General Counsel, Regulatory Law and Government Affairs	BASF Corporation
EPA-HQ-OPPT-2007-1080-0022.2	Michael P. Walls, Managing Director	Regulatory and Technical Affairs, American Chemistry Council (ACC)
EPA-HQ-OPPT-2007-1080-0024.1	Dee Ann Staats, Environmental Science Policy Leader	CropLife America
EPA-HQ-OPPT-2007-1080-0025.1	Susan Ferenc, President	Chemical Producers and Distributors Association (CPDA)
EPA-HQ-OPPT-2007-1080-0026.1	Catherine Willett, Science Policy Advisor, Regulatory Testing Division	People for the Ethical Treatment of Animals (PETA)
EPA-HQ-OPPT-2007-1080-0027.1	Beth L. Law, Assistant General Counsel	Consumer Specialty Products Association (CSPA)
EPA-HQ-OPPT-2007-1080-0028.1	Alan J. Olson, Director of Technology and Product Stewardship	Ferro Corporation

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

Table 2: Number of Comments per Topic:

Subject/Topic	Number of Comments
Minimizing Duplicative Testing	21
Cost Sharing	3
Data Compensation	17
Confidential Business Information	5
Test Order Recipients	17
Identification of Test Order Recipients	10
Responding to Test Orders	25
Procedural Issues	20
Due Process Options	3

Estimated Test Costs and Paperwork Burden	5
Statutory Authorities	9
Order Templates	0
Other Topics	122
Total	**257**

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

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

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

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

2.0 Response to Comments

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

2.1.1 General Goal

Submitted Comment(s):

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

EPA Response:

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

2.1.2 General Problems with EPA's Proposed Approach

Submitted Comment(s):

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

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

EPA Response:

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

EPA considered the possibility that a company might refuse to develop data jointly in the hopes that a competitor would be forced from the market if the rival lacked the resources to generate the data alone. However, EPA only requires an *offer* to develop data jointly to fulfill the order, thereby rendering such action futile. At the same time, such an offer must agree to some binding authority to insure that all sides will

abide by current and future agreements for cost sharing. Thus, the requirements of the order mimic the statutory requirements of FIFRA.

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

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

Submitted Comment(s):

EPA appears to consider the goal of minimizing duplicative testing only in the context of reducing the number of screening tests of the same chemical, rather than whether such a screening test is needed at all.

EPA Response:

"Duplicative testing" (as used by the commenters) appears to mean the repetition of assays that would not bring additional information to the EDSP assessments. To reiterate, EPA defines "duplicative testing" as testing the same chemical using the same test. Nevertheless, even though EPA does not interpret the statute in the manner suggested by the commenter, EPA has adopted procedures intended to address the substance of the commenter's concern: that assays should not be required where the assay would not result in the submission of additional information needed for the EDSP assessment. Elsewhere in this Response to Comments document, and in Section IV.C.1.c. and IV.F.1.b. of the Policies and Procedures Federal Register Notice, EPA discusses the process by which order recipients and other stakeholders may submit other scientifically relevant information that they believe can be used to satisfy part or all of the Tier 1 Order and/or otherwise inform the determination as to whether the substance may have an effect that is similar to an effect produced by a substance that interacts with the estrogen, androgen and/or thyroid hormonal systems.

EPA does recognize the goal of eliminating unnecessary testing and has, under FIFRA, long followed the policy of allowing order recipients to submit or cite alternative or additional data that they believe addresses a particular request for information. EPA has adopted a similar policy for the EDSP, as shown by the response options available to order recipients.

Implicit in the comment is the idea that EPA should bear the responsibility for making a determination of whether existing data are adequate for the EDSP prior to issuing an order. However, both FIFRA and FFDCA clearly indicate that it is the responsibility of the manufacturer and/or registrant to demonstrate that their chemical

and/or product can be used safely. Moreover, EPA believes that manufacturers/registrants are better placed to identify data specific to their chemical/product that addresses the chemical's potential to interact with the endocrine system. Finally, EPA believes that it is in the interest of both the Agency and industry that orders be issued and responses documented so that all parties can clearly demonstrate that the obligations imposed by FFDCA §408 have been met.

As under FIFRA, EPA provides the recipients of FFDCA §408(p) test orders with the option of submitting or citing existing data, along with a rationale that explains how the cited or submitted study satisfies part or all of the Tier 1 Order. Existing data may include data that has already been generated using the assay(s) specified in the Order, or "other scientifically relevant information." Other scientifically relevant information is information that informs the determination as to whether the substance may have an effect that is similar to an effect produced by a substance that interacts with the estrogen, androgen, and/or thyroid hormonal systems (e.g., information that identifies substances as having the potential to interact with the estrogen, androgen, and/or thyroid system(s); information demonstrating whether substances have an effect on the functioning of the endocrine system). Other scientifically relevant information may either be functionally equivalent to information obtained from the Tier 1 assays—that is, data from assays that perform the same function as EDSP Tier 1 assays—or may include data that provide information on a potential consequence or effect that could be due to effects on the estrogen, androgen or thyroid systems. Some "other scientifically relevant information" may be sufficient to satisfy part or all the Tier 1 Order. The submission or citation of other scientifically relevant information in lieu of the data specified in the Order is discussed in Unit IV.F.1.b. of the revised Policies and Procedures document.

In addition, the Agency has written a paper entitled "EPA's Approach for Considering Other Scientifically Relevant Information (OSRI) under the Endocrine Disruptor Screening Program." This paper was developed by EPA to provide guidance to EPA staff and managers who will be reviewing the responses to Tier 1 Orders issued under the EDSP, and may also be of interest to parties considering whether to submit other scientifically relevant information to EPA. This paper provides general guidance and is not binding on either EPA or any outside parties. Anyone may provide other scientifically relevant information, and the Agency will assess the information for appropriateness on a case-by-case basis, responding to the submitter in writing, and making EPA's determination publicly available. A copy of the approach paper has been placed in Docket ID number EPA–HQ–OPPT–2007–1080.

Submitted Comment(s):

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

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

EPA Response:

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

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

Consistent with all of the comments on this issue, EPA generally believes that it would be appropriate to provide data use protections for those who submit data relevant to pesticide inert ingredients for 15 years following the date on which the data

were submitted. This time frame corresponds to the duration of protection afforded "compensable" data submitted under FIFRA. EPA received only positive feedback on the 15 year timeframe as proposed.

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

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

2.2.1 To Whom Should EPA Issue Test Orders

Submitted Comment(s):

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

EPA Response:

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

Submitted Comment(s):

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

EPA Response:

The Agency agrees that it should issue test orders to all manufacturers and importers of a pesticide inert ingredient. The Agency thinks that it would not be practical

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

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

Submitted Comment(s):

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

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

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

importer was keeping its commitment by checking the Confidential Statement of Formula (CSF) filed by a registrant.

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

EPA Response:

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

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

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

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

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

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

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

EPA would also take steps to try to prevent companies from inadvertently subverting the commitment made by order recipients. For example, the FR notice would inform companies who sell the pesticide inert ingredient (other than test order recipients) that they may become subject to receipt of an FFDCA § 408(p) order if they obtain the pesticide inert ingredient (either directly or indirectly) from a source who has not committed to generate the EDSP data and then sell the pesticide inert ingredient into the pesticide market. EPA would also inform manufacturers who agree to generate the data that EPA will rely on them to bring to EPA's attention information indicating that a pesticide registrant appears to be obtaining the pesticide inert ingredient from an "unapproved" source.

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

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

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

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

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

2.3 Procedural Issues

2.3.1 Additional Procedures Needed

Submitted Comment(s):

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

EPA Response:

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

2.4 Due Process Options

2.4.1 Pre-Enforcement Review & Informal Administrative Review

Submitted Comment(s):

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

EPA Response:

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

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

Submitted Comment(s):

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

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

EPA Response:

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

2.5 Estimated Test Costs and Paperwork Burden

The notice of the availability for public comment of the proposed EDSP Draft Proposed Policies & Procedures for Initial Screening and Testing was published in the **Federal Register** on December 13, 2007 (72 FR 70842) (FRL–8340–3). On the same day, December 13, 2007, a notice of the availability for public comment of the Draft Information Collection Request (ICR) covering the information collection activities associated with the Tier 1 screening of the first group of chemicals under the Endocrine Disruptor Screening Program (EDSP) was also published in the **Federal Register** (72 FR 70839) (FRL–8155–8). Comments related to the ICR were submitted under Docket ID # EPA-HQ-OPPT-2007-1081. Comments related to the estimated test costs and

paperwork burden received on the policies and procedures were duplicative of those submitted for the ICR. For clarity, these comments have been comprehensively addressed in the Agency's response to public comments document for the ICR. Please refer to the response to public comments document that will be placed in the docket under Docket ID # EPA-HQ-OPPT-2007-1081.

2.6 Statutory Authorities

2.6.1 Legal Authority

Submitted Comment(s):

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

EPA Response:

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

> [t]he Agency considers any data generated in response to requirements under FFDCA §408(p) on a pesticide chemical for which there is an existing tolerance, tolerance exemption, or pending petition to establish a tolerance or an exemption to be data submitted in support of a tolerance or an exemption. In fact, FFDCA §408(b)(2)(D)(viii) explicitly requires EPA to consider ''such information as the Administrator may require on whether the pesticide chemical may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen or other endocrine effects,'' as part of its determination that a substance meets the safety standard. [21 U.S.C. §136a(b)(2)(D)(viii)]. Thus, EDSP data on active and pesticide inert ingredients for which there is a tolerance or tolerance exemption will be compensable as outlined under FIFRA §3(c)(1)(F). (72 FR at 70850)

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

data, as the information could have been collected through either of those mechanisms.

Submitted Comment(s):

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

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

The commenter questioned whether this outcome is consistent with Congressional intent. The history of FFDCA §408(p), which was initially part of the bill that became the Safe Drinking Water Act amendments of 1996, indicates that Congress expected EPA to use "enforceable consent agreements" (ECAs). Since ECAs are a part of the process by which EPA has imposed data requirements under TSCA (but not under FIFRA), the commenter argued therefore that Congress meant EPA to use TSCA when dealing with non-registrants. The commenter also argued that Congress laid out a process in FFDCA §408(f) that EPA is to use in requiring endocrine data to support the continuation of a tolerance or tolerance exemption. This indicates that EPA should use TSCA if it cannot use FIFRA.

EPA Response:

EPA disagrees that its decision to rely on FFDCA §408(p) order authority to collect EDSP data is in any way inconsistent with Congressional intent, or otherwise insufficiently justified. FFDCA §408(p), the section that obliges EPA to establish and

collect EDSP data, explicitly mandates that EPA "*shall* issue an order to a registrant…or *to a person who manufactures or imports a substance* for which testing is required under this subsection." [21 USC 346a(p)(5) (emphasis added)]. This represents clear Congressional direction to proceed as EPA has chosen to do, and use the order authority established by §408(p).

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

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

In large measure, the commenter's concern stems from a perception that manufacturers and importers of non-food use pesticide inerts will necessarily receive a lesser degree of data use protection than other order recipients. As noted elsewhere in this response to comments document, this is inaccurate. Through the adoption of internal procedures, and through the exercise of agency discretion to determine compliance with the 408(p) order, EPA has developed a system that will effectively provide the same *substantive* data compensation as is statutorily provided to registrants and manufacturers and importers of pesticide inerts. The commenter has not identified any particular areas in which the data compensation or CBI protections are substantively deficient. Rather, the commenter seems primarily concerned that the procedures EPA has developed will not function effectively.

The confusion may have stemmed from the Agency's explanation of its rationale for failing to adopt a set of procedures that are unique to the EDSP. Because existing statutory authorities distinguish between manufacturers of non-food use pesticide inerts and between manufacturers of food use pesticide inerts and registrants, both the Agency's procedures and the rationale for those procedures will necessarily vary. But that is distinct from whether the substantive degree of protection that is achieved through those procedures essentially differs, or necessarily provides lower data protections. Whether it be through the processes available under FIFRA §3(c)(1)(F) or

FFDCA § 408(i), which are applicable to active ingredients and food use pesticide inerts, or through the internal procedures EPA adopts, order recipients will be able to fulfill their obligations by joining a consortium to share data development costs or by offering to pay compensation to those who have previously generated data.

Submitted Comment(s):

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

EPA Response:

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

Nevertheless, working within the confines of the authority conferred upon the Agency by existing statutes, EPA has developed *procedures* that will effectively promote joint data development and cost sharing and provide confidentiality. As discussed elsewhere in this response to comments document, and in EPA's final FR notice, EPA believes that the internal procedures it has adopted would effectively provide manufacturers and importers of all pesticide inerts with the same opportunity for joint data development, as well as cost sharing, and compensation available to all other order recipients

Submitted Comment(s):

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

EPA Response:

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

2.6.2 Need for Rulemaking to Establish Implementation Policies and Procedures

Submitted Comment(s):

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

EPA Response:

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

2.7 Order Templates

No comments on the order templates were received.

2.8 Other Topics

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

Submitted Comment(s):

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

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

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

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

EPA Response:

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

Submitted Comment(s):

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

- Under what authority to require testing of inert ingredients;
- Which entities should receive test orders for inert ingredients;
- How to provide for cost sharing and how to ensure compensation for data generated on such ingredients;
- How to address mixtures of inert ingredients – both scientifically and in terms of data use & confidentiality procedures;
- Whether to allow a manufacturer or importer to commit not to sell into the pesticide market as an alternative to generated required data on an inert ingredient, and if so, how to enforce that commitment;
- Has not developed a process for identifying recipients of "catch-up" orders; and
- Whether FFDCA §408(p) orders to manufacturers and importers of inert ingredients are subject to pre-enforcement review.

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

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

EPA Response:

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

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

Submitted Comment(s):

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

EPA Response:

The individual assays that will be included in the final screening battery will have undergone validation with a range of compounds. Moreover, the particular choice of assays included in the screening battery has also undergone independent external scientific peer review by the FIFRA Scientific Advisory Panel (Please go to http://www.epa.gov/scipoly/sap/meetings/2008/032508_mtg.htm for more details). For assays that will be included in Tier 1, EPA will ensure that neither this public comment nor any of the expert scientific peer reviews of the assays or battery have concluded that the assays and battery have not met the validation criterion with respect to inert

ingredients. The Agency therefore concludes that the assays will be appropriate for use in screening inert ingredients as active ingredients.

Submitted Comment(s):

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

EPA Response:

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

2.8.2 EPA Gave Inadequate Time for Public Comment

Submitted Comment(s):

Several comments were received stating that EPA has not allowed adequate time for public comment on the complex issues arising out of the proposed procedures for inert ingredients. Furthermore, because of the many complex issues involving the application of this new program to inert ingredients, EPA should set up a stakeholder meeting where these issues are discussed and recommendations made. While such a meeting might delay implementation, the meeting could produce a more streamlined process, better understanding in the regulated community and greater compliance.

EPA Response:

The Agency has provided ample opportunity for the public to understand and to comment on its draft procedures. EPA issued a notice in the **Federal Register** explaining its proposal and giving the public 60 days to submit comments (72 FR 70842) (FRL–8340–3). At the request of several stakeholders, EPA extended the comment period for an additional 30 days ((73 FR 6963) (FRL–8351–2)). During the public comment period, EPA held two public meetings (December 17, 2007 and February 28, 2008) at which staff described the proposed procedures and answered questions from the public. In addition, in response to specific requests, EPA has held other meetings with individual stakeholders. This record demonstrates that there has

been adequate time for public comment. Finally, while the Agency does not think that there is any need for an additional public meeting before it begins to send test orders under FFDCA §408(p), EPA is willing to meet with stakeholders to explain its plans.