



Summary of the Workshop on the Endocrine Disruptor Screening Program

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Appendix A: Workshop Agenda

PREFACE

Eastern Research Group, Inc. (ERG), a contractor to the U.S. Environmental Protection Agency (EPA), prepared this summary report. Meeting minutes were not prepared and a transcript was not recorded. The intent of this report is to provide an overview of the discussions that occurred on the draft policies and procedures the Agency has developed for the Endocrine Disruptor Screening Program (EDSP).

No attempt has been made to analyze or evaluate any portion of the discussions. The discussions presented in this summary reflect individual opinions of the participants and should not be considered to be the opinion or belief of EPA.

1.0 INTRODUCTION

This report summarizes remarks and comments made during the Workshop on the Endocrine Disruptor Screening Program, organized by the U.S. Environmental Protection Agency (EPA). The workshop was announced in a Federal Register notice (72 FR 65732, 23 November 2007) and took place in Arlington, Virginia on December 17, 2007, at the Environmental Protection Agency Conference Center.

The workshop featured presentations and a question and answer session pertaining to the draft policies and procedures for completing the initial screening and testing under EPA's Endocrine Disruptor Screening Program (EDSP) and the burden and cost estimates for the related information collection activities. Appendix A presents the workshop agenda.

The workshop brought together over 50 representatives from industry, academia, non-governmental organizations, and government to focus on the draft EDSP policies and procedures, specifically:

- The procedures that EPA is considering using 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; and
- Other related procedures and/or policies.

The workshop Web site (http://www.epa.gov/scipoly/oscpendo/meetings/mtg_121707.htm) provides access to additional workshop materials, including the workshop presentations, the Federal Register notice on the draft policies and procedures, and the Federal Register notice on the draft Information Collection Request (ICR).

1.1 Background and Purpose

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. 346a et. seq.], [[Page 65733]] 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].

EPA currently is implementing its EDSP in three major parts that are being developed in parallel and with substantial work on each well underway. The three parts are briefly summarized as follows:

1. **Assay validation.** Under FFDCA §408(p), EPA is required to use “appropriate validated test systems and other scientifically relevant information” to determine whether substances may have estrogenic effects in humans. EPA is validating assays that are candidates for inclusion in the Tier 1 screening battery and Tier 2 tests, and will select the appropriate screening assays for the Tier 1 battery based on the validation data. Validation is defined as the process by which the reliability and relevance of test methods are evaluated for the purpose of supporting a specific use. The status of each assay can be viewed on the EDSP website in the Assay Status table: <http://www.epa.gov/scipoly/oscpendo/pubs/assayvalidation/status.htm>. In addition, on July 13, 2007, EPA published a Federal Register document that outlined the approach EPA intends to take for conducting the peer reviews of the Tier 1 screening assays and Tier 2 testing assays and EPA's approach for conducting the peer review of the Tier 1 battery (72 FR 38577) (FRL-8138-4). EPA also announced the availability of a “list server” (Listserv) that will allow interested parties to sign up to receive e-mail notifications of EDSP peer review updates, including information on the availability of peer review materials to be posted on the EDSP website.
2. **Priority setting.** EPA described its priority setting approach to select pesticide chemicals for initial screening on September 27, 2005 (70 FR 567449) (FRL-7716-9), 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) (FRL-8129-3). The Agency expects to finalize this initial list of chemicals before screening is initiated 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/prioritysetting>.
3. **Policies and procedures.** EPA described the draft policies in a Federal Register Notice published on December 13, 2007 (72 FR 70842) (FRL-8340-3) relating to:
 - The procedures that EPA is considering using 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 and/or policies.

In addition, EPA has developed an ICR to obtain the necessary approval under the Paperwork Reduction Act (PRA) for the related paperwork activities. The ICR document, which describes the information collection activities and related estimated

paperwork burden and costs, was announced for public review and comment in (72 FR 70842) (FRL-8340-3).

The workshop focused on the item 3 listed above, the draft EDSP Policies and Procedures, and the ICR.

1.2 **Key Questions**

In the Federal Register Notice for the draft EDSP Policies and Procedures, EPA outlined several key questions that need to be resolved before the policies and procedures are finalized. Answers to these questions could help guide the Agency in decisions regarding outstanding issues.

- 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 §408(p), under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) §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 §408(p), under FIFRA §3(c)(2)(B), or under both authorities?

- B) **Cost Sharing**
 - 1) 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 §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 §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 §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 §3(c)(1)(F) only, FIFRA §3(c)(1)(F) and FIFRA §3(g), or FIFRA §3(c)(1)(F) and FIFRA §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 §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 §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 §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 §408(p) test order recipients to facilitate the formation of consortia?
- H) Due Process Options
- 1) EPA requests comment on whether the informal administrative review procedures 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) Confidential Business Information (CBI)
 - 1) Provide comments on how best to address CBI concerns associated with notifying high production volume (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 percent of the test costs represent the paperwork burden?

2.0 PRESENTATIONS AND QUESTIONS FROM THE PUBLIC

A summary of workshop presentations and questions asked from the public during the workshop is provided below. Note that the workshop presentations are available on the workshop Web site (http://www.epa.gov/scipoly/oscpendo/meetings/mtg_121707.htm).

2.1 EPA Presentations

A brief summary of the topics discussed during the presentations given by EPA is provided below.

2.1.1 Welcome & Introductory Remarks

Elizabeth Resek (Acting Director of the Office of Science Coordination & Policy (OSCP), Office of Prevention, Pesticides and Toxic Substances (OPPTS)) welcomed the group and briefly reviewed the agenda for the workshop.

2.1.2 Overview of the EDSP

Linda Phillips (Director of the Exposure Assessment Coordination & Policy Division (EACPD), OSCP, OPPTS) provided an overview of the EDSP. This included a brief overview of EPA's statutory authorities and a recap of the program's history. Dr. Phillips also reviewed the two-tiered system recommended by the Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC). She described the three current EDSP activities including:

- Assay Validation,
- Priority Setting, and
- Policies and Procedures.

Details on the three activities are included in Section 1.0 above.

2.1.3 Introduction to EDSP Policies & Procedures

Bill Wooge (EACPD, OSCP, OPPTS) introduced the draft EDSP policies and procedures. This included a brief discussion of the FFDCA §408(p)(5) directive, EPA's policy goals, and EPA's proposal for issuing test orders.

2.1.4 Legal Authorities for EDSP Policies & Procedures

Laurel Celeste (EDSP Legal Counsel, Office of General Counsel) reviewed the legal authority for EDSP policies and procedures. This included discussion on the following authorities:

- FFDCA §408(p) – Authority for EDSP Testing;
- FFDCA §408(i) – Extension of “FIFRA Protection”;
- FIFRA §3(c)(2)(B) – Authority to Require Data;

- FIFRA §3(c)(1)(F) – Data Compensation;
- FIFRA §3(c)(2)(D) – “Formulators’ Exemption”; and
- FIFRA §10(b) & FIFRA §10(g) – Confidential Business Information.

A brief question and answer session followed Ms. Celeste’s presentation. A summary of the session follows.

Larry Hammond (Industry Task Force II on 2,4-D Research Data) requested clarification between an intent letter to offer to pay versus certifying actual payment. Ms. Celeste stated that the Agency is not making any changes to FIFRA and that all existing procedures remain the same. Mr. Hammond noted that often times a registrant could receive a registration before actually paying. Ms. Celeste confirmed that a registrant can receive a registration before paying and that EPA would confirm the registrant met its obligation as part of EPA’s follow-up activities.

Mr. Hammond asked how a technical registrant would ask EPA to cancel a registration if it did not feel it had been adequately compensated. Ms. Celeste indicated that if a registrant felt they did not receive a fair offer to pay, they would follow existing petition procedures under FIFRA to request cancellation of the registration of the person who had not offered adequate payment.

Mr. Hammond asked EPA to expand on the statement “all registrants will receive a data call-in (DCI) notice.” He specifically inquired about end-use registrants. Ms. Celeste stated that the Agency’s preferred approach was not to send orders to end-use registrants.

Terry Quill (Quill Law Group LLC) provided clarification on a statement made by Ms. Celeste regarding Toxic Substances Control Act (TSCA) penalties: the Notice stated a penalty of \$25,000, per day, rather than the \$15,000 stated by Ms. Celeste. He stated that under TSCA, both criminal and civil penalties would apply. He added that that in reality, the fines would total to about \$32,000 per day.

Mr. Quill requested clarification on the differences between the options for due process to challenge orders. He noted that one approach described in the Notice appears to create a situation where one would be in violation of a test order, risking civil and criminal penalties, prior to allowing review. Doing so would not provide adequate due process. Ms. Celeste stated that no penalties would be assessed until after a hearing, thus not violating due process. She added that EPA does not want to force people to fail to comply with an order before they can challenge the order. In practice, if an order recipient disagreed with a component or requirement of the order, they could come to the Agency and request a review or discussion. Ms. Celeste explained that EPA needed to lay out both options; however, the Agency prefers the approach where EPA would interpret the statute such that the same procedures are applicable to both registrants and other test order recipients.

2.1.5 Procedures for EDSP Test Orders

Angela Hofmann (Director, Regulatory Coordination Staff, OPPTS) reviewed the procedures for EDSP test orders. Ms. Hofmann discussed who would receive the EDSP test orders, how recipients should respond to the test orders, and the consequences of non-compliance.

A brief question and answer session followed Ms. Hofmann's presentation. A summary of the session follows.

Julie Spagnoli (FMC Corporation) asked for clarification on who would receive a test order for registrants whose products are produced using an integrated system or registrants who use an unregistered technical active ingredient to manufacture their pesticide product. Ms. Hofmann indicated that these types of registrants would be treated as technical registrants as described in the Federal Register Notice. EPA's preferred approach is to issue test orders to technical registrants of pesticide active ingredients.

Ms. Spagnoli asked if the recipients of the test order will be able to view other test order recipients and notify EPA of any recipients EPA may have inadvertently overlooked. Ms. Hofmann indicated that a list of other test order recipients would be included with the test order and that EPA would welcome a notification of any registrants left off the list.

Ms. Spagnoli asked how EPA planned to notify formulators if a technical registrant canceled their registration (i.e., would EPA provide the formulators an opportunity to generate the data to fulfill the test order). William Jordan (Senior Policy Advisor, Office of Pesticide Programs (OPP), OPPTS) stated that the Agency's preferred approach is to only send test orders to technical registrants. If the technical registration is 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. Reformulation would then be required. However, if even one registrant chooses to do the data and stay in business, then end-use registrants would be required to change their supplier.

Mr. Jordan also commented on another related issue where some active ingredients are "commodity chemicals" (i.e., 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.

Ms. Spagnoli asked if the test order will go to manufacturers based on the use of the product. Mr. Jordan indicated that EPA is considering whether to also issue test orders to a person who manufactures a chemical for which testing is required, even if they manufacture the chemical for non-pesticidal uses. Mr. Jordan stated that if a company received an order and chose to comply with the order by ceasing manufacture

of the chemical, they would have to cease manufacturing the chemical entirely (not just the pesticide uses).

Arlean Rohde (ExxonMobile Chemical Company) requested clarification on the statement “inerts maybe handled differently” in relation to cancelling a registration. Ms. Hofmann clarified that the Agency would need to rely on TSCA authorities to assess penalties. Ms. Hofmann asked the participants to submit comments on this topic.

Sarah Brozena (American Chemistry Council (ACC)) asked whether EPA had proposed a time period during which a manufacturer had to cease manufacturing an inert ingredient. Ms. Hofmann indicated that EPA has not established a time frame and noted that the Agency is requesting comment on what would be an appropriate time frame.

Joseph Colosi (Desales University) asked if a company who received an order could choose what tests they would perform. Ms. Hofmann stated that the test orders would specify which tests were required. Mr. Colosi asked if there was an option for a company to pay EPA to do the testing. Ms. Celeste stated that that the statute requires EPA to issue an order to an entity and that entity is required to generate the data; therefore, there is no option to pay the Agency to generate the data.

2.1.6 Contesting, Cost Sharing, Compensation, and CBI

William Jordan described the procedures for contesting a §408(p) order, the Agency’s goal to minimize duplicative testing, promote cost sharing and data compensation, and appropriately handle CBI.

A brief question and answer session followed Mr. Jordan’s presentation. A summary of the session follows.

A participant asked what would happen if a company transferred a registration. Mr. Jordan replied that the existing transfer rules under FIFRA remain the same and would apply. For example, if Company A holds a registration and retains data rights and they transfer the registration to Company B, then Company B is eligible for a formulators’ exemption and is not required to pay compensation to other companies. Company B would only be obligated to pay compensation if it amends its registration. The participant asked who would receive the FFDC A §408(p) test order in the scenario described. Mr. Jordan indicated that the test order would be issued to the holder of the technical registration.

Andrew M. Jaques (ACC) inquired about a chemical that initially was used as an inert ingredient in pesticide products that may now (or in the future) no longer be used an inert ingredient. Mr. Jordan reminded participants that EPA has other authorities under FFDC A §408(p) and the SWDA that authorize EPA to require testing of substances that are not pesticide chemicals. Specifically, FFDC A 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]. In those instances, the Agency could issue a §408(p) test order and policies and procedures would be similar to those proposed for non food-use inert ingredients. Mr. Jordan noted that none of these types of chemicals were included in the first group of 73 and that there are no current plans to issue test orders for those types of substances.

Ray McAllister (CropLife America) remarked that an inert manufacturer may not know where his product is being used and asked if EPA was proposing to stop all commodity uses of chemicals. Mr. Jordan explained that EPA is considering (and requested comment on) whether to issue a test order to all manufacturers and importers of the chemical, including companies who are selling to non-pesticide product companies. If an order recipient chose to comply with the order by discontinuing manufacture of the chemical, they would be required to cease manufacture of both pesticide and non-pesticide uses of the chemical.

Mr. McAllister asked whether EPA would be monitoring all confidential statements of formulations (CSFs) for compliance (i.e., to ensure end-use formulators are purchasing their inert ingredients from a source that appeared on the “Inerts Supplier List”). Mr. Jordan agreed that monitoring CSFs could be used to determine compliance. However, the Agency will also be relying on industry to help EPA with enforcement (i.e., self-policing within the market).

Mr. McAllister asked for clarification regarding use of the term “unregistered” related to food-use inerts and how the Agency would distinguish between foreign and domestic unregistered chemicals. Mr. Jordan stated that “unregistered” means that the chemical does not appear in a CSF (i.e., if an import tolerance exists but there are no U.S. manufacturers). EPA indicated that this is likely a theoretical situation that, in practice, would not occur.

Mr. McAllister asked EPA how the Agency can implement this program without a rulemaking. Ms. Celeste stated that the Administrative Procedures Act (APA) requires rulemaking in a number of circumstances, but it also has exemptions. The Agency believes that the draft EDSP policies and procedures are exempt from rulemaking, as the draft policies and procedures are largely internal to the Agency. FFDCA only requires EPA to issue an order.

Mr. Quill questioned whether EPA has thought through the problems that may arise, and noted that many issues will have to be settled in court. He noted that if EPA had promulgated a rule, all the issues may have been worked out at one time. Ms. Celeste stated that the Agency did not want to codify immature procedures and that the Agency preferred to monitor how the procedures functioned in practice. If changes to procedures are required to streamline things based on experience gained with the first group of chemicals, the Agency could codify them in the future after the procedures and policies have been proven to work well. Mr. Jordan explained that the procedures were patterned after DCI procedures that were produced under FIFRA §3(c)2(B), which the

Agency agrees work well. This same logic is being applied to develop FFDCA §408(p) orders. Mr. Jordan also commented, in regards to sorting out matters through meetings, that the current pesticide licensing process involves an extensive dialogue between EPA and the regulated community.

Mr. Quill commented that he appreciated the difficulty of implementing this program and asked if the Agency believed it could not require data on inert ingredients by using a FIFRA DCI. Mr. Jordan stated that EPA has the legal authority to send DCIs to registrants who have products that contain inerts, but that the Agency does not believe that approach makes the most sense because many of those companies are only formulators. They are smaller producers and are less sophisticated. EPA thinks it is better to work with the larger companies who are familiar with the process and can afford to generate data.

Mr. Quill remarked that for a number of years a system existed where there were registered pesticide manufacturers under FIFRA and chemical manufacturers under TSCA, but now the Agency is putting “non-registrants” in a position of having to test a pesticide chemical. He asked if the Agency had thought about fairness issues regarding putting non-registrants in registrants’ shoes. Ms. Celeste explained that §408(p)(5) purposely includes “non-registrants” by requiring the Agency to “... issue an order to a registrant of a substance for which testing is required under this subsection, **or** to a person who manufactures or imports a substance for which testing is required under this subsection.”

Mr. Quill acknowledged the language, but questioned EPA’s interpretation of the language indicating one interpretation could have been to require registrants to perform testing on “pesticide chemicals” and manufacturers or importers to require testing of “other substances.” Mr. Jordan stated that the Agency realized they had a choice and they decided, for the inert ingredients, it made the most sense to send orders to manufacturers and importers who were likely to be more sophisticated and fewer in numbers (i.e., those who would likely generate the data). He also noted that registrants could perceive unfair penalties of \$32,000 per day for manufacturers/importers versus registration cancellations (based on profit/loss statements). Mr. Jordan acknowledged that EPA realizes it will be dealing with new stakeholders and is making every effort to listen to concerns and find reasonable solutions.

Mr. Hammond asked if all orders for the first list would be issued at the same time. Ms. Hofmann stated that the orders will likely be issued over the course of a few months to allow EPA time to physically process the orders. She indicated that the Agency has not discussed the order for distribution (e.g., by CAS number or alphabetical by chemical name). Ms. Hofmann indicated that, depending on the convergence of finalizing the screening battery, the procedures, and the draft list, EPA intends to issue the first orders in fall of 2008.

Ms. Brozena asked if data compensation and cost sharing only apply to order recipients, or if protections are also afforded to others that may be interested (i.e., formulators). Mr. Jordan stated that data compensation protections will only apply to order recipients. Regarding “catch up” orders, EPA will be sending orders to

manufacturers and importers and protections would then be afforded to them. However, Mr. Jordan explained that all data submitted under FIFRA §3(c)2(B) and FFDCA §408(i) would be considered “relevant” to pesticide registrations and therefore compensable.

2.1.7 Information Collection Request

Ms. Hofmann briefly reviewed the Information Collection Request associated with the EDSP. She described the methods and key assumptions the Agency used to calculate paperwork and data generation cost burdens.

A brief question and answer session followed Ms. Hofmann’s presentation. A summary of the session follows.

Richard Becker (ACC) commented that ACC had funded the 2003 survey that EPA used to develop a portion of its estimates, and he noted that there were still many uncertainties with the protocols when the survey was conducted. Based on that survey and new information, he stated that the testing costs estimated may be quite low in relation to actual test costs. Mr. Becker estimated that the ICR may be underestimating test costs, and that test costs are likely to be on the order of \$250,000 to \$300,000 for the complete battery for a single chemical. He asked EPA what the timeframe was for finalizing the ICR and if it would allow the Agency to account for changes based on the final protocols. Ms. Hofmann responded that orders cannot be issued without having an approved ICR in place. The Office of Management and Budget (OMB) is required to act within 60 days following submission of the ICR to OMB by EPA, but cannot act until a 30-day public comment period concludes. Ms. Hofmann explained that the screening battery is expected to be complete in March and the ICR will be updated based on the final battery. She noted that additional information on test costs is welcome.

Mr. Becker remarked that analytical chemical costs were also excluded from the 2003 survey, but he thinks they should be reflected. He also commented that some assays were included as alternative assays, and suggested that test costs could be presented as a range. Ms. Hofmann stated that the best approach may be to include all assays in the ICR because OMB does not allow ranges. She agreed that the 2003 study was not complete and encouraged stakeholders to submit comments on components that should be accounted for when calculating costs.

Mr. Becker also emphasized the importance in understanding whether the protocols would require the use of positive and negative control chemicals along with the test chemical. Such a requirement will also affect the costs for the ICR.

2.1.8 Questions Posed in the Policies & Procedures Document

Mr. Wooge briefly reviewed the questions the Agency posed to the public regarding the draft EDSP policies and procedures (see Section 1.2 Key Questions).

Mr. Wooge reminded participants that this was not the official forum to provide comments and that stakeholders should officially submit their comments through the Docket using the instructions outlined in the Federal Register Notice.

2.2 General Questions from the Public

Following EPA presentations, the floor was opened to workshop participants for questions. A summary of questions and answers follows.

Catherine Willett (People for the Ethical Treatment of Animals (PETA)) asked how data development consortia would be formed. Mr. Jordan explained that all §408(p) order recipients will be identified by EPA to encourage joint data development. He noted that it is the responsibility of the recipients to form the consortia.

Ms. Willett asked whether EPA would group substances for testing in the future and whether EPA would allow some flexibility regarding submission of data on similar compounds. Mr. Jordan stated that EPA could determine whether existing data may be suitable in the future if a similar compound is selected for screening. Relevant data could be pre-identified and it is possible that additional screening data would not be required if existing data were deemed sufficient.

Ms. Willett asked whether the overall program's policies and procedures would be formally reviewed (with a public comment period) after the first group of 73 chemicals was complete. Dr. Phillips indicated that the process for reviewing the program has not yet been determined. Ms. Hofmann commented that the review of the procedures does not necessarily need to wait until all data are submitted.

Alan Rubin (Envirostrategies, LLC) asked who is responsible for determining the levels of endocrine disrupting compounds (EDCs) that are safe. He asked how the EDSP coordinates with other EPA offices, such as the Office of Water (OW). Mr. Rubin asked if the authority allows the EDSP to collect information on fate and transport of individual EDCs determine if levels are safe in drinking water, fish, biosolids, etc. Ms. Hofmann explained that the EDSP program included an intra-agency working group that included members of OW. She noted that nothing in the EDSP undermines or changes any existing authorities. The draft policies and procedures proposed for the EDSP do not prevent the Agency from issuing a test rule on a particular chemical of concern. Ms. Celeste added that the SDWA provides OW with the authority to issue FFDCA test orders for substances that may be found in sources of drinking water and to which a substantial population may be exposed.

Mr. Rubin urged EPA as a whole to convene its managers to identify data requirements other than toxicity and to identify safe criteria. Elaine Francis (EPA, Office of Research and Development (ORD), National Program Director for Endocrine Disruptors Research Program) described the work EPA is conducting in their laboratories and collaborative efforts with other agencies, such as U.S. Geological Survey (USGS) and industry. EPA is examining EDCs in various environments such as confined animal feeding operations (CAFOs), waste water treatment plants (WWTPs), drinking water plants, and sources of combustion. EPA is also involved in the global

water research strategy. ORD is applying assays in real-world scenarios, including complex environments such as WWTP effluent. Dr. Francis described two inter-agency working groups: one on EDCs and the other on pharmaceuticals in the environment. A draft research strategy will be available in 2008 that identifies the work that has been completed and what work remains on EDCs.

Mr. McAllister asked if additional orders would be issued beyond the current list of 73 chemicals. EPA responded that the current ICR is only valid for the first 73 chemicals and a new ICR would be required to issue additional orders.

Mr. McAllister stated that ACC and CropLife America had asked for an extension of the comment period for the draft list of chemicals. Ms. Hofmann stated that EPA would be granting an extension until February 11, 2008.

Mr. McAllister commented that he has participated on the Inerts Steering Committee since 2001. The Steering Committee discussed issues regarding how to implement §408, specifically in relation to data compensation for non-ED data. A decision was made to forgo a draft Pesticide Registration (PR) Notice and instead pursue rulemaking. Mr. McAllister questioned whether data compensation for inerts for ED data will be different. Ms. Celeste clarified that the Agency is coordinating internally on these procedures with the goal in mind not to put into place something new, but to rely on existing mechanisms.

Karen Bentley (Dupont) noted the draft procedures do not specify a time period for registrants to generate the data. Ms. Celeste explained that the amount of time will be dependent on the final battery; therefore, a timeframe could not yet be established.

Dr. Bentley asked if official test guidelines would be published. Ms. Hoffman explained that the Agency anticipates that the assay protocols will be attached to the test orders.

Mr. Quill asked whether the Agency has the authority to require ED data for non-human species. Ms. Celeste referred Mr. Quill to EPA's response to a petition submitted by PETA.

Mr. Becker asked if EPA was considering eliminating some of the assays and if so, what process would be used to determine which assays would be eliminated. Dr. Phillips stated that EPA is in the process of reviewing peer review comments on the assays and the Agency is not prepared to discuss the final battery. She stated that the final battery may not include all assays because some are alternatives to others. Mr. Becker urged EPA to consider the fact that some alternative assays provide significantly more information with fewer animal test subjects. Dr. Phillips explained that the EDSP would submit a proposed battery to the FIFRA Scientific Advisory Panel (SAP) for their review and recommendations.

A participant asked what procedures would be used to assess the results of the battery (i.e., to determine whether a chemical moves to Tier 2). Dr. Phillips stated that

EPA would use a weight-of-evidence approach, but noted that the question is somewhat premature and should be saved for the SAP.

Ms. Brozena asked what documentation a manufacturer or importer of an inert ingredient should provide to EPA if they believe their chemical is no longer being used in any pesticide product. Mr. Jordan noted that comments should be submitted for the draft list. The manufacturer or importer should use their discretion in determining the level of documentation required to make their case.

Michael Kelley (toXcel) asked if the Agency would accept the order response option of "cite other data." Ms. Hofmann indicated that EPA did not think there would be instances where existing data could be cited for the initial 73 chemicals. She stated that some studies used to validate the assays may be available if the protocols have not significantly changed. If EPA already has data, additional data would not be required. She noted that the tests Mr. Kelley mentioned (Quantitative structure-activity relationship (QSARs) and structure-activity relationship (SARs)) would not likely be a sufficient replacement.

Mr. Kelley asked if a company would be required to complete the Tier 1 battery if it had completed a Tier 2 test. Ms. Celeste responded that the Agency believes Tier 1 data are useful and provide information not otherwise obtained through Tier 2 testing alone; therefore, EPA does not intend to permit chemicals to bypass Tier 1 screening and move directly to Tier 2 testing without appropriate data to support such an action.

3.0 EPA CLOSING REMARKS

Mr. Wooge closed the workshop by reminding participants of the list of questions at the end of the Federal Register Notice and presentation. He encouraged the participants to look closely at those questions because stakeholder input will be considered in final agency decisions. EPA is very interested in hearing a range of view points and the participants' comments will be influential in the Agency's decisions.

Appendix A
WORKSHOP AGENDA

Public Workshop on the Endocrine Disruptor Screening Program (EDSP); Policies and Procedures for Initial Screening

December 17, 2007 – 9:00 AM to 5:00 PM

Environmental Protection Agency
Conference Center - Lobby Level
One Potomac Yard (South Building)
2777 S. Crystal Drive
Arlington, VA 22202

9:00 AM Welcome & Introductory Remarks

[Elizabeth Resek](#)

[Acting Director, Office of Science Coordination & Policy \(OSCP\), Office of Prevention, Pesticides and Toxic Substances \(OPPTS\)](#)

9:15 AM Overview of the EDSP (Background)

[Linda Phillips](#)

[Director, Exposure Assessment Coordination & Policy Division \(EACPD\), OSCP, OPPTS](#)

- The 3 parts to EDSP (Assay Validation, Priority Setting, Policies & Procedures)

9:30 AM Introduction To EDSP Policies & Procedures

[Bill Wooge](#)

[EACPD, OSCP, OPPTS](#)

9:45 AM Legal Authorities for EDSP Policies and Procedures

[Laurel Celeste](#)

[EDSP Legal Counsel, Office of General Counsel](#)

10:15 AM Break

10:30 AM Procedures for EDSP Test Orders

[Angela Hofmann](#)

[Director, Regulatory Coordination Staff, OPPTS](#)

- Who Would Receive the EDSP Test Orders?
- How Should Recipients Respond to a Test Order?
- What are the Consequences of Non-compliance?

11:15 AM Contesting, Cost Sharing, Compensation, and CBI

[William Jordan](#)

[Senior Policy Advisor, Office of Pesticide Programs \(OPP\), OPPTS](#)

- Contesting a 408(p) Order/Decision
- Minimizing Duplicative Testing
- Promoting Cost Sharing and Data Compensation
- Handling Confidential Business Information

12:00 PM Lunch

- 1:00 PM **Information Collection Request (ICR)**
Angela Hofmann
Director, Regulatory Coordination Staff, OPPTS
- 1:30 PM **Questions Posed in the Policies & Procedures Document**
Bill Wooge
EACPD, OSCP, OPPTS
- 2:00 PM **Questions from the Public**
- 3:00 PM **Break**
- 3:15 PM **Questions from the Public Continued**
- 5:00 PM **Adjourn**