

Future Technological Trends Resulting GE Plants, Implementation, Comment Period Ends: 08/27/2007, Contact: Michael J. Wach 301-734-0485.

*EIS No. 20070292, Final EIS, COE, CA, San Luis Rey Flood Control Project, Operation and Maintenance of the Vegetation and Sediment Management, from College Blvd to the Pacific Ocean, San Diego County, CA, Wait Period Ends: 08/13/2007, Contact: Tiffany Kayama 213-452-3845.*

*EIS No. 20070293, Final EIS, SFW, 00, Light Goose Management Plan, Reducing and Stabilizing Specific Populations "Light Geese" in North America, Implementation, Wait Period Ends: 08/13/2007, Contact: James R. Kelley 612-713-5409.*

*EIS No. 20070294, Final EIS, APH, 00, ADOPTION—Resident Canada Goose Management Plan, Evaluate Alternatives Strategies to Reduce, Manage, and Resident Canada Goose Population, Implementation, within the Conterminous U.S., Contact: David Reinhold 301-734-7921.*

U.S. DOA, APH has adopted the U.S. DOI/SFW Final EIS 20050479 filed 11/09/2005. APH was a cooperating agency on the project. Recirculation of the document is not necessary under 1506.3(b) of the CEQ Regulations.

#### Amended Notices

*EIS No. 20070119, Draft EIS, NOA, AK, PROGRAMMATIC—Outer Continental Shelf Seismic Surveys in the Beaufort and Chukchi Seas, Proposed Offshore Oil and Gas Seismic Survey, AK, Comment Period Ends: 07/30/2007, Contact: William T. Hogarth 301-713-1632.*

Revision of FR Notice Published 05/18/2007; Review Period extended to 07/30/2007.

*EIS No. 20070185, Draft EIS, FHWA, GA, Northwest I-75/I-575 Corridor Project, Transportation Improvements, Funding, Cobb and Cherokee Counties, GA, Comment Period Ends: 08/13/2007, Contact: Wayne Fedora 404-562-3651.*

Revision of FR Notice Published on 05/18/2007; Review Period extended to 08/13/2007.

Dated: July 10, 2007.

**Robert W. Hargrove,**

Director, NEPA Compliance Division, Office of Federal Activities.

[FR Doc. E7-13670 Filed 7-12-07; 8:45 am]

BILLING CODE 6560-50-P

## ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPPT-2007-0493; FRL-8138-4]

### Endocrine Disruptor Screening Program; Assay Peer Review Process

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice.

**SUMMARY:** The purpose of this notice is to announce the approach EPA intends to take for conducting peer reviews of the Tier 1 screening assays and Tier 2 testing assays that are being validated by the Agency's Endocrine Disruptor Screening Program (EDSP), as well as EPA's approach for conducting the peer review of the Tier 1 battery. EPA is also announcing the availability of a listserver (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. These materials may include the documents to be peer reviewed, background documents, the charge to the peer reviewers, and reports that summarize the results of peer reviews.

#### FOR FURTHER INFORMATION CONTACT:

Linda Phillips, Office of Science Coordination and Policy (7203M), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 564-1264; e-mail address: [phillips.linda@epa.gov](mailto:phillips.linda@epa.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. General Information

###### A. Does this Action Apply to Me?

This action is directed to the public in general. You may be potentially affected by this action if you produce, manufacture, use, consume, work with, or import commercial or pesticide chemicals. To determine whether you or your business may be affected by this action, you should carefully examine section 408(p) of FFDC, 21 U.S.C. 346a(p). Potentially affected entities, using the North American Industrial Classification System (NAICS) codes to assist you and others in determining whether this action might apply to certain entities, may include, but are not limited to:

- Chemical Manufacturers, Importers and Processors (NAICS code 325), e.g., entities who manufacture, import or process chemical substances.
- Pesticide, Fertilizer, and Other Agricultural Chemical Manufacturing (NAICS code 3253), e.g., entities who manufacture, import or process

pesticide, fertilizer and agricultural chemicals.

- Scientific Research and Development Services (NAICS code 5417), e.g., persons who conduct testing of chemical substances for endocrine effects.

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

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

1. *Docket.* Materials cited in this notice are available in docket number EPA-HQ-OPPT-2007-0493. All documents in the docket are listed in the regulations.gov index. To access the electronic docket, go to <http://www.regulations.gov>, select "Advanced Search," then "Docket Search." Insert the docket ID number where indicated and select the "Submit" button. Follow the instructions on the regulations.gov website to view the docket index or access available documents. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available electronically at <http://www.regulations.gov>, or, if only available in hard copy, at the OPPT Docket. The OPPT Docket is located in the EPA Docket Center (EPA/DC) at Rm. 3334, EPA West Bldg., 1301 Constitution Ave., NW., Washington, DC. The EPA/DC Public Reading Room hours of operation are 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding Federal holidays. The telephone number of the EPA/DC Public Reading Room is (202) 566-1744, and the telephone number for the OPPT Docket is (202) 566-0280. Docket visitors are required to show photographic identification, pass through a metal detector, and sign the EPA visitor log. All visitor bags are processed through an X-ray machine and subject to search. Visitors will be provided an EPA/DC badge that must be visible at all times in the building and returned upon departure.

2. *Electronic access.* You may access this **Federal Register** document electronically through the EPA Internet

under the “**Federal Register**” listings at <http://www.epa.gov/fedrgstr/>.

## II. Introduction

### A. What Action is the Agency Taking?

EPA is announcing its approach for conducting peer reviews of Tier 1 screening assays and Tier 2 testing assays that are being validated by the Agency’s Endocrine Disruptor Screening Program (EDSP), as well as its approach for conducting the peer review of the Tier 1 battery. EPA is also announcing the availability of a listserv (Listserv). To subscribe to the EDSP Listserv send a blank e-mail message to: [join-edsp@lists.epa.gov](mailto:join-edsp@lists.epa.gov) from the location at which you normally send or receive mail. For more information on the listserv, go to <http://www.epa.gov/scipoly/oscpendo>. Using the Listserv, interested parties may sign up to receive e-mail notifications of EDSP peer review updates, including information on the availability of peer review materials to be posted at the EDSP website. These materials may include the documents to be peer reviewed, background documents, the charge to the peer reviewers, and reports that summarize the results of peer reviews. EPA is not at this time soliciting public comment on the individual Tier 1 assays. Rather, EPA will solicit comments on the Tier 1 battery once the individual peer reviews have been completed as discussed in Unit IV.D.

### B. What is the Agency’s Authority for Taking this Action?

Section 408(p) of FFDCA requires EPA “to develop a screening program, using appropriate validated test systems and other scientifically relevant information, to determine whether certain substances may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or such other endocrine effect as [EPA] may designate.” (FFDCA 21 U.S.C. 346a(p)). These test systems are being validated under EPA’s EDSP. EPA’s validation process includes peer review as its final step.

## III. Background

EPA initially set forth the EDSP in the August 11, 1998, **Federal Register** notice (63 FR 42852) (FRL–6021–3) and solicited public comment on the program in the December 28, 1998, **Federal Register** notice (63 FR 71541) (FRL–6052–9). The program set forth in these notices 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, section 9(c). The EDSTAC was comprised of members representing the commercial chemical and pesticides industries, Federal and State agencies, worker protection and labor organizations, environmental and public health groups, and research scientists.

EDSTAC recommended that EPA’s program address both potential human and ecological effects; examine effects on estrogen, androgen, and thyroid hormone-related processes; and include non-pesticide chemicals, contaminants, and mixtures in addition to pesticides (Ref. 1). Based on these recommendations, EPA developed a two tiered approach, referred to as the EDSP. The purpose of Tier 1 is to identify substances that have the potential to interact with the estrogen, androgen, or thyroid hormone systems using a battery of relatively short-term screening assays. The purpose of Tier 2 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. The Tier 2 tests are multi-generational assays that will provide the Agency with more definitive testing data. EDSTAC also recommended that EPA establish a priority-setting approach for choosing chemicals to undergo Tier 1 screening.

EPA currently is implementing its EDSP in three major parts that are being developed in parallel and with substantial work on each well underway. This document deals only with the peer review component of the validation process (item 3 in the following discussion). EPA is addressing the other aspects of the EDSP in separate documents published in the **Federal Register**. The three parts are briefly summarized as follows:

1. *Priority setting.* EPA is prioritizing chemicals to undergo screening in the battery of Tier 1 assays. EPA described its priority setting approach for the first 50-100 chemicals to be tested in the **Federal Register** of September 27, 2005 (70 FR 56449) (FRL–7716–9). The draft initial list of chemicals to undergo Tier 1 screening was published in the **Federal Register** for public review on June 18, 2007 (72 FR 33486) (FRL–8129–3). The Agency expects to finalize this initial list of chemicals before screening is implemented in 2008. More information on EPA’s priority setting approach for the EDSP is available at <http://www.epa.gov/scipoly/oscpendo/prioritysetting>.

2. *Procedures.* EPA intends to commence Tier 1 screening of the first group of pesticide chemicals by issuing test orders under FFDCA section 408(p)

to chemical companies identified as the manufacturer or processor of the identified chemicals, including the pesticide registrant. EPA is developing a draft implementation policy that will describe the procedures that EPA will use to issue orders, the procedures that order recipients would use to respond to the order, how data protection and compensation will be addressed in the test orders, and other related procedures or policies. In addition, EPA is developing a draft template for the test order and a draft information collection request (ICR) to obtain the necessary clearances under the Paperwork Reduction Act (PRA). The Agency expects to seek public comment on the draft implementation policy and related documents in late summer 2007, and after considering those comments, EPA expects to finalize the policy by the end of 2007.

3. *Assay validation.* EPA is validating assays that are candidates for inclusion in the Tier 1 screening battery, selecting the appropriate screening assays for the screening battery based on the validation data, and developing and validating Tier 2 tests. Validation is defined as the process by which the reliability and relevance of test methods are evaluated for a specific use (Ref. 2). EPA has implemented the validation process in several phases (Ref. 3), including the following:

- Preparation of detailed review papers (DRPs) that involve a search of the relevant scientific literature and development of a document that discusses the scientific basis of each assay and critically evaluates candidate protocols.
- Conduct of pre-validation studies that demonstrate and optimize the assay, with the end result being a standardized protocol for use in the multi-laboratory validation phase.
- Conduct of validation studies in multiple laboratories. The purpose of this phase is to demonstrate the transferability of the protocol, measure lab-to-lab variability, and help establish final performance characteristics for the assay.
- Peer review of the data to determine strengths and weaknesses of the assays. Peer review is the critical evaluation of scientific and technical work products by independent experts. Its purpose is to improve the quality, credibility, and acceptability of regulatory decisions. According to EPA’s Peer Review Handbook (Ref. 4), peer review is an important component of the scientific process. It provides a focused, objective evaluation of a research proposal, publication, risk assessment, health advisory, guidance

or other document submitted for review. The criticisms, suggestions and new ideas provided by the peer reviewers ensure objectivity, stimulate creative thought, strengthen the reviewed

document and confer scientific credibility on the product. Comprehensive, objective peer review leads to good science and product

acceptance within the scientific community.

EPA plans to peer review the following EDSP work products:

Tier 1 Assays	Tier 1 Assay Battery	Tier 2 Assays
Adult Male Androgen Receptor Binding Aromatase Estrogen Receptor Binding Female Pubertal Fish Screen Frog Metamorphosis Hershberger <sup>1</sup> Male Pubertal Steroidogenesis H295R Uterotrophic <sup>2</sup>	Battery To be Determined	Amphibian Growth and Reproduction Two-generation Avian Two-generation Fish Two-generation Mysid

<sup>1</sup>The Hershberger assay has been peer reviewed by the Organization for Economic Cooperation and Development (OECD). EPA will not conduct a separate peer review of this assay.

<sup>2</sup>The Uterotrophic assay has been peer reviewed by OECD. EPA will not conduct a separate peer review of this assay.

The primary product to be peer reviewed for each assay will be an Integrated Summary Report (ISR) that summarizes and synthesizes the information compiled from the validation process (i.e., DRPs, pre-validation studies, and inter-lab validation studies, with a major focus on inter-laboratory validation results).

#### IV. Peer Review Process

The approaches that EPA intends to use for conducting peer reviews of the Tier 1 and Tier 2 assays, and the Tier 1 battery are described in the following sections.

##### A. Tier 1 Assays

The mechanism that will be used to peer review Tier 1 Assays will be an external letter review organized under an EPA peer review contract. The procedures used for peer review of the Tier 1 assays will be in accordance with EPA's Peer Review Handbook (Ref. 4). For each assay, the contractor will compile a list of qualified peer review candidates who are independent of those who performed the work or who have been involved in the development or refinement of the protocol, including those who have provided EPA with expert advice throughout the validation process. The potential peer reviewers will be identified from among academia, government, and the private sector, based on their subject matter expertise, availability, and lack of conflict of interest or past involvement in the project. From this pool of candidate reviewers, the contractor will establish a balanced peer review panel consisting of 3 to 10 peer reviewers. EPA will be notified of the identity of the peer

reviewers, but will not have contact with them before or during the peer review process to ensure that an independent review is performed. The contractor will provide the reviewers with the ISR for the assay to be reviewed and any supporting documentation that is needed for the peer review, along with a list of charge questions that will be developed by EPA. The ISR will summarize and synthesize the information compiled from the validation process (i.e., DRPs, pre-validation studies, and inter-lab validation studies), with a major focus on inter-laboratory validation results. The charge to the reviewers will be designed to address the following types of issues:

1. Clarity of the stated purpose of the assay.
2. Clarity, comprehensiveness, and consistency of the data interpretation with the stated purpose of the assay.
3. Biological and toxicological relevance of the assay as related to its stated purpose.
4. Clarity and conciseness of the protocol in describing the methodology of the assay such that the laboratory can:
  - a. Comprehend the objective;
  - b. Conduct the assay;
  - c. Observe and measure prescribed endpoints;
  - d. Compile and prepare data for statistical analyses; and
  - e. Report the results.
5. Strengths and/or limitations of the assay.
6. Impacts of the choice of:
  - a. Test substances,
  - b. Analytical methods, and
  - c. Statistical methods in terms of demonstrating the performance of the assay.

7. Repeatability and reproducibility of the results obtained with the assay, considering the variability inherent in biological and chemical test methods.

The panel will review and comment on the assay, and the contractor will compile the peer review record. The peer review record will include the peer review document and all supporting materials given to the peer reviewers; the instructions/charge to the peer reviewers; all comments, information, and materials received from the peer reviewers; and names, affiliations, qualifications of the peer review panel members. EPA will use the peer review record to make a final determination as to a Tier 1 assay's suitability for use in the screening program, and finalize the assay for consideration for inclusion in the Tier 1 battery. EPA plans to begin peer reviewing Tier 1 assays by mid-2007. This schedule is dependent upon the successful completion of studies that are currently underway.

##### B. Tier 1 Battery

As recommended by the Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC), EPA's EDSP testing strategy will consist of a battery of Tier I assays. The battery is expected to be comprised of screening assays that, when used in combination, will identify substances that have the potential to interact with the estrogen, androgen, and thyroid hormone systems.

Prior to initiating testing, EPA intends to propose a battery of Tier 1 screening assays. The battery will be peer reviewed by the Scientific Advisory Panel (SAP) established under the Federal Insecticide, Fungicide, and

Rodenticide Act (FIFRA). The FIFRA SAP is structured to provide scientific advice, information and recommendations to EPA on pesticides and pesticide-related issues as to the impact of regulatory actions on health and the environment. The FIFRA SAP is a Federal advisory committee established in 1975 under FIFRA that operates in accordance with requirements of the FACA. The FIFRA SAP is composed of a permanent panel consisting of seven members who are appointed by the EPA Administrator from nominees provided by the National Institutes of Health and the National Science Foundation. In addition, FIFRA, as amended by the FQPA of 1996, established a Science Review Board consisting of at least 60 scientists who are available to the FIFRA SAP on an ad hoc basis to assist in reviews conducted by the Panel. As a peer review mechanism, the FIFRA SAP provides comments, evaluations and recommendations to improve the effectiveness and quality of analyses made by Agency scientists. Members of the FIFRA SAP are scientists who have sufficient professional qualifications, including training and experience, to provide expert advice and recommendation to the Agency. More information about the FIFRA SAP is available at <http://www.epa.gov/scipoly/sap>.

The proposed battery along with the materials supporting its composition will be provided to a panel of approximately 15 to 20 SAP reviewers. Some of the panel members may be individuals who participated in review of one or more Tier 1 assays, and some individuals will be new to the EDSP peer review process. Use of some of the same reviewers for both the Tier 1 assays and the Tier 1 battery is intended to ensure that individuals familiar with the individual assays are represented when the battery is discussed. This should not present a conflict of interest because the context of the review and the questions being asked of the battery reviewers will differ from what is asked of the reviewers for the individual Tier 1 assays (e.g., questions posed to the SAP reviewers would pertain to whether the proposed battery adequately covers the endpoints of interest for estrogen, androgen, and thyroid while questions posed to the Tier 1 assay reviewers would focus on the strengths and weaknesses of individual assays.

#### C. Tier 2 Assays

The peer review strategy for the Tier 2 assays will follow a pattern similar to that used for Tier 1 battery. These assays

will be peer reviewed by the FIFRA SAP.

#### D. Public Comment

The formal peer review process described above is intended to ensure a systematic and unbiased review of the scientific basis for including an assay in the EDSP. Although the Agency recognizes that other qualified scientists may also wish to offer opinions to the Agency on the merits of the assays, EPA is not soliciting public comments during the period in which the individual Tier 1 assays are being peer reviewed. Instead, the Agency will accept comments on the overall Tier 1 battery from the public when the composition of the Tier 1 battery is being peer reviewed by the SAP. A separate **Federal Register** notice will announce the SAP review of the Tier 1 battery and provide information on opportunities for public comment.

#### V. Listserv

The EDSP has created a listserv (Listserv) or "mailing group." A Listserv is an electronic mailing list that makes it possible to reach all individuals in a mailing group with a single e-mail message sent over the Internet. By adding your name to the EDSP Listserv, you will periodically receive an e-mail announcing the availability of materials on the EDSP website and other timely information. To subscribe to the EDSP Listserv send a blank e-mail message to: [join-edsp@lists.epa.gov](mailto:join-edsp@lists.epa.gov) from the location at which you normally send or receive mail.

#### VI. References

The following is a list of the documents that are specifically referenced in this document. These references are available in the docket as identified under **ADDRESSES**.

1. U.S. EPA. Endocrine Disruptor Screening and Testing Advisory Committee Final Report. August 1998. Available at: <http://www.epa.gov/scipoly/oscpendo/edspoverview/finalrpt.htm>.
2. National Institute of Environmental Health Sciences (NIEHS). Validation and Regulatory Acceptance of Toxicological Test Methods, A Report of the ad hoc Interagency Coordinating Committee on the Validation of Alternative Methods. Research Triangle Park, NC. NIH Report 97-3981. March 1997.
3. U.S. EPA. Validation of Screening and Testing Assays Proposed for the EDSP, Draft Version 5.3. October 23, 2006. Available at: <http://www.epa.gov/scipoly/sap/meetings/2007/february/edsp-validation-paper.pdf>.
4. U.S. EPA. Science Policy Council Handbook: Peer Review, 3rd Edition. Office of Science Policy, U.S. Environmental Protection Agency, Washington, DC. EPA/100/B-06/002. Available at: [http://www.nheerl.epa.gov/nheerl\\_science/peer/about\\_peer/files/3rd\\_Edition\\_PR\\_Handbook.pdf](http://www.nheerl.epa.gov/nheerl_science/peer/about_peer/files/3rd_Edition_PR_Handbook.pdf).

#### List of Subjects

Environmental protection, Chemicals, Endocrine disruptors, Pesticides.

Dated: July 2, 2007.

**James B. Gulliford,**

*Assistant Administrator for Prevention, Pesticides and Toxic Substances.*

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**BILLING CODE 6560-50-S**

#### ENVIRONMENTAL PROTECTION AGENCY

[Docket Nos. EPA-R04-SFUND-2007-0542; FRL-8439-3]

#### Georgia-Pacific Hardwood Site, Plymouth, Washington County, NC; Notice of Settlement

**AGENCY:** Environmental Protection Agency.

**ACTION:** Notice of settlement.

**SUMMARY:** Under Section 122(h) of the Comprehensive Environmental Response, Compensation and Liability Act (CERCLA), the United States Environmental Protection Agency has entered into a settlement for reimbursement of past response concerning the Georgia-Pacific Hardwood Site located in Plymouth, Washington County, North Carolina.

**DATES:** The Agency will consider public comments settlement until August 13, 2007. The Agency will consider all comments received and may modify or withdraw its consent to the settlement if comments received disclose facts or considerations which indicate that the settlement is inappropriate, improper, or inadequate.

**ADDRESSES:** Copies of the settlement are available from Ms. Paula V. Batchelor. Submit your comments, identified by Docket ID No. EPA-R04-SFUND-2007-0542 or Site name Georgia-Pacific Hardwood Superfund Site by one of the following methods:

- <http://www.regulations.gov>: Follow the online instructions for submitting comments.
- *E-mail:* [Batchelor.Paula@epa.gov](mailto:Batchelor.Paula@epa.gov).
- *Fax:* 404/562-8842/Attn Paula V. Batchelor.
- *Mail:* Ms. Paula V. Batchelor, U.S. EPA Region 4, SD-SEIMB, 61 Forsyth Street, SW., Atlanta, Georgia 30303. "In