examining the thyroid axis in both sexes provides the opportunity to detect potential gender differences in response to treatment at a relatively early life stage.

b. *Amphibian metamorphosis assay*. The amphibian metamorphosis assay (AMA) is an *in vivo* screening assay intended to identify substances which interfere with the normal function of the HPT axis. The AMA represents a generalized vertebrate model based on the conserved structure and function of thyroid systems among species. The AMA is based on the principle that the dramatic morphological changes that occur during post-embryonic development are dependent upon the normal functioning of the HPT axis, and that interference with these processes leads to measurable effects. During tadpole metamorphosis, thyroid hormone (TH) influences virtually every tissue in the body initiating diverse morphological, physiological and biochemical changes that include cell proliferation, differentiation and death. The result is *de novo* organ formation, organ loss, and extensive tissue remodeling. Given the dependence of metamorphosis on TH and the strict biochemical control under which these processes occur, the transformations that occur can serve as endpoints representative of thyroid axis function. The primary endpoints in the AMA are the hindlimb length during the developmental stage and the thyroid histology. Each endpoint can be affected by chemicals that interact with the HPT axis. For example, antagonists of thyroid production, iodination and action have been shown to delay development and induce diagnostic lesions in the thyroid gland. Thyroid agonists (e.g., native thyroid hormone) will accelerate development. Additionally, unlike the mammalian assays that have been developed to detect interactions along the HPT axis, the AMA has the ability to detect chemicals that act on peripheral tissues. For example, inhibition of monodeiodinases that transform T4 to T3 can cause asynchronous development, detected by an inability to assign a developmental stage to a tadpole. Knowledge of this mechanism is important because development can be affected without concomitant effects on thyroid histology or circulating thyroid hormone concentrations. Although post-embryonic development is different between mammals and most amphibians (i.e., metamorphosis), there is a high level of evolutionary conservation of the thyroid system and underlying molecular and cellular pathways among vertebrates. Hence, the AMA, particularly with the use of Anurans, is a general model for evaluating the interaction of chemicals with the HPT axis in the EDSP Tier 1 screening battery. In addition, the results can be used to complement or corroborate results in the pubertal male and female assays (Table 2 of this unit).

VI. Test Guidelines for EDSP Tier 1 Screening Battery

EPA is also announcing the availability of the test guidelines for conducting the assays included in the EDSP Tier 1 Screening Battery (Table 1 in Unit V.A.).

The Androgen Receptor Binding, Aromatase, Estrogen Receptor Binding (Rat Uterine Cytosol), Female Pubertal, Male Pubertal, and Steroidogenesis assays were developed and validated by the Agency.

The Amphibian Metamorphosis, Estrogen Receptor Transcriptional Activation, Fish Short-term Reproduction, Hershberger and Uterotrophic assays were developed and validated using a collaborative process involving EPA's Office of Science Coordination and Policy (OSCP), Office of Research and Development (ORD), and Office of Pesticide Programs (OPP) as well as OECD as previously outlined in a **Federal Register** notice of July 13, 2007 (72 FR 38577) (FRL–8138–4). The process took into account the harmonized testing strategy for the screening and testing of potential endocrine disrupting chemicals and consequences of such a strategy on the development and validation of test guidelines involving regulatory systems for new and existing substances according to OECD's Endocrine Disrupter Testing and Assessment (EDTA) Task Force in 1998.

In both cases, the draft protocols (and all related materials) were made available as part of the independent peer review. The draft protocols were revised to reflect comments received during the peer review process, and have been incorporated into the OPPTS compendium of harmonized test guidelines, under *Series 890–Endocrine Disruptor Screening Program Test Guidelines* as follows:

- 890.1100–Amphibian Metamorphosis (Frog)
- 890.1150–Androgen Receptor Binding (Rat Prostate Cytosol)
- 890.1200–Aromatase (Human Recombinant)
- 890.1250–Estrogen Receptor Binding (Rat Uterine Cytosol)
- 890.1300–Estrogen Receptor Transcriptional Activation (Human Cell Line — HeLa-9903)
- 890.1350–Fish Short-term Reproduction
- 890.1400–Hershberger (Rat)
- 890.1450–Female Pubertal (Rat)
- 890.1500–Male Pubertal (Rat)
- 890.1550–Steroidogenesis (Human Cell Line — H295R)
- 890.1600–Uterotrophic (Rat)

For information on accessing these guidelines see Unit I.B.2.

List of Subjects

Environmental protection, Chemicals, Chemical testing, Endocrine disruptors, Pesticides, Test guideline.

Dated: October 14, 2009.

Stephen A. Owens,

Assistant Administrator, Office of Prevention, Pesticides and Toxic Substances.

[FR Doc. E9–25348 Filed 10–20–09; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPP–2009–0634; FRL–8434–8]

Endocrine Disruptor Screening Program; Tier 1 Screening Order Issuing Announcement

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This action announces the Agency's initiation of the Endocrine Disruptor Screening Program (EDSP) Tier 1 screening for the first group of 67 chemicals by issuing orders between October 29, 2009, and February 26, 2010, pursuant to the authority provided to EPA under section 408(p)(5) of the Federal Food, Drug, and Cosmetic Act (FFDCA). The EDSP Tier 1 screening data required to satisfy an order are due within 2 years of the date of issuance of the order. This action also provides information for pesticide registrants, manufacturers and importers of inert chemicals used in pesticide products, and the public on how to obtain details about the orders (such as the date of issuance and the recipients), the ''Pesticide Inert Ingredients Data Submitters and Suppliers List'' (PIIDSSL), and how interested persons other than recipients of test orders may submit other scientifically relevant information on the chemicals subject to the orders.

DATES: Order recipients must respond according to the schedules contained in the order they receive. Persons other than order recipients who wish to submit other scientifically relevant information related to one of the chemical-specific orders should submit

that information within 90 days of the order issuance date.

ADDRESSES: Persons other than order recipients should submit their information identified by docket identification (ID) number EPA–HQ–OPP–2009–0634, by one of the following methods:

- *Federal eRulemaking Portal*: *http://www.regulations.gov*. Follow the on-line instructions for submitting comments.
- *Mail*: Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.
- *Delivery*: OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket Facility's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305–5805.

Instructions: Direct your comments to docket ID number EPA–HQ–OPP–2009–0634. EPA's policy is that all comments received will be included in the docket without change and may be made available on-line at *http://www.regulations.gov*, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through regulations.gov or e-mail. The regulations.gov website is an ''anonymous access'' system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through regulations.gov, your e-mail address will be automatically captured and included as part of the comment that is placed in the docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: All documents in the docket are listed in the docket index available at *http://www.regulations.gov*. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either in the electronic docket at *http://www.regulations.gov*, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The hours of operation of this Docket Facility are from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Jane Scott Smith, Pesticide Re-evaluation Division (7508P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–0048; fax number: (703) 308–8090; e-mail address: *smith.jane-scott@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you manufacture, use, or import pesticide/agricultural chemicals and other chemical substances; or if you are or may otherwise be involved in the testing of chemical substances for potential endocrine effects. Potentially affected entities may include, but are not limited to:

- Chemical manufacturers, importers and processors (NAICS code 325), e.g., persons who manufacture, import or process chemical substances.
- Pesticide, fertilizer, and other agricultural chemical manufacturing (NAICS code 3253), e.g., persons who manufacture, import or process pesticide, fertilizer and agricultural chemicals.
- Scientific research and development services (NAICS code 5417), e.g., persons who conduct testing of chemical substances for endocrine effects.

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

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

1. *Docket*. EPA has established a docket for this action under docket ID number EPA–HQ–OPP–2009–0634. Publicly available docket materials are available either in the electronic docket at *http://www.regulations.gov*, or, if only available in hard copy, at the Office of Pesticide Programs (OPP) Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The hours of operation of this Docket Facility are from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

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?

The Agency is initiating the EDSP Tier 1 screening for the first group of 67 chemicals by issuing test orders from October 29, 2009, through February 26, 2010. Details on the status of the orders will be provided on EPA's website at *http://www.epa.gov/endo* with information, including the order issuance date, the recipient(s) of the order, each order recipient's response and the order due date. EPA intends to update the list with subsequent publications and postings as appropriate. This public listing is provided to invite the public to identify additional entities who should receive the FFDCA section 408(p) test order. The commenters could either identify themselves or another person as additional candidates (with proper substantiation) for receipt of a FFDCA section 408(p) test order by contacting the person listed under **FOR FURTHER INFORMATION CONTACT**.

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

FFDCA section 408(p)(1) requires EPA ''to develop a screening program, using appropriate validated test systems and other scientifically relevant information to determine whether certain substances may have an effect in humans that is

similar to an effect produced by a naturally occurring estrogen, or such other effects as [EPA] may designate.'' (21 U.S.C. 346a(p)). Section 408(p)(3) specifically requires that the Administrator ''shall provide for the testing of all pesticide chemicals.'' (21 U.S.C. 346a(p)(3)).

Section 201 of FFDCA defines ''pesticide chemical'' as ''any substance that is a pesticide within the meaning of [FIFRA], including all active and inert ingredients of such pesticide.'' (21 U.S.C. 231(q)(1)).

Section 408(p)(5) of FFDCA provides that the Administrator shall 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. The order shall require the recipient to conduct testing in accordance with the screening program, and to submit information obtained from the testing to the Administrator, within a reasonable time period that the Administrator determines is sufficient for the generation of the information.

Section 3(c)(2)(B) of FIFRA provides that registrants must submit additional data, upon notification that the Administrator has determined that additional data are required to maintain an existing pesticide registration. (7 U.S.C. 136a(c)(2)(B)). In light of the directive in section 408(p)(3) of FFDCA that EPA is to provide for the endocrine screening of all pesticide chemicals, EPA considers that such data have been statutorily determined to be necessary to maintain an existing pesticide registration.

III. Background

EPA developed the EDSP in response to the Congressional mandate in section 408(p) of FFDCA 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 effects as [EPA] may designate'' (21 U.S.C. 346a(p)). When carrying out the program, the statute requires EPA to ''provide for the testing of all pesticide chemicals.'' The statute also provides EPA with discretionary authority to ''provide for the testing of any other substance that may have an effect that is cumulative to an effect of a pesticide chemical if the Administrator determines that a substantial population may be exposed to such a substance.'' In addition, section 1457 of the Safe Drinking Water Act (SDWA) provides EPA with discretionary authority to provide for testing, under the FFDCA 408(p) screening program, ''of any other substances that may be found in sources of drinking water if the Administrator determines that a substantial population may be exposed to such substance.''

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 71542) (FRL–6052–9). The program initiated 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. Based on these recommendations, EPA developed a two-tiered assessment approach for these chemicals, 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 purpose of Tier 2 testing (referred to as ''testing'') is to identify and establish a dose-response relationship for any adverse effects that might result from the interactions identified through the Tier 1 assays. EDSTAC also recommended that EPA establish a priority-setting approach for choosing chemicals to undergo Tier 1 screening.

EPA implemented its EDSP in three major parts.

1. *Assay validation*. Under FFDCA section 408(p), EPA is required to use ''appropriate validated test systems and other scientifically relevant information'' to determine whether substances may have estrogenic effects in humans or other endocrine effects as EPA may designate. 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 EDSP Tier 1 screening assays were peer reviewed by independent experts and by the FIFRA Scientific Advisory Panel (SAP) during a public meeting on March 25–27, 2008. Details on the validation and peer review process for the assays as well as the peer review reports can be found on EPA's website at *http://www.epa.gov/scipoly/oscpendo/pubs/assayvalidation/index.htm*. The FIFRA SAP report is available at *http://www.epa.gov/scipoly/sap/meetings/2008/march/minutes2008-03-25.pdf*. Elsewhere in this issue of the **Federal Register**, EPA is issuing the final Tier 1 battery composed of the validated assays. The Tier 1 battery protocols can be found in the corresponding docket EPA–HQ–OPPT–2009–0634 or the website at *http://www.epa.gov/oppts* (select ''Test Methods & Guidelines''). EPA is also in the process of developing and validating Tier 2 tests. The status of each assay can be viewed on the EDSP website in the Assay Status table: *http://www.epa.gov/scipoly/oscpendo/pubs/assayvalidation/status.htm*.

2. *Priority setting*. EPA described its priority setting approach for the first group of pesticide chemicals to be tested under the EDSP in the **Federal Register** of September 27, 2005 (70 FR 56449) (FRL–7716–9), and proposed the draft list of initial chemicals for review and public comment in the **Federal Register** notice of June 18, 2007 (72 FR 33486) (FRL–8129–3). The public comments and Agency responses can be found in the associated docket EPA–HQ–OPPT–2004–0109. In April 2009, EPA published in the **Federal Register** its final list of the first group of chemicals to be screened under EDSP. The first group of 67 chemicals identified for screening includes pesticide active ingredients and high production volume (HPV) chemicals used as pesticide inert ingredients (also known as other ingredients). This list should not be construed as a list of known or likely endocrine disruptors. More information on EPA's priority setting approach for selection of the first group of chemicals for the EDSP is available at *http://www.epa.gov/scipoly/oscpendo/prioritysetting*.

The first group of chemicals to be screened consists of chemicals that section 408(p) of FFDCA requires be screened, i.e., pesticide active ingredients and chemicals used as pesticide inert ingredients (also known as other ingredients). EPA anticipates that it may, in the future, modify its approach to selecting chemicals for screening. Information and factors that EPA may consider in selecting chemicals could include: Public input; the results of testing chemicals on the initial list; management considerations to increase the integration of screening with other regulatory activities within the Agency; implementation considerations flowing from a decision

to extend screening to additional categories of chemicals (e.g., non-pesticide chemical substances); and the availability of new priority setting tools (e.g., High Throughput Pre-screening or Quantitative Structure Activity Relationships models). More information on EPA's priority setting approach is available at *http://www.epa.gov/scipoly/oscpendo/pubs/prioritysetting*.

3. *Procedures*. EPA published a document in the **Federal Register** of December 13, 2007 (72 FR 70842) (FRL–8340–3), that describes the proposed procedures that EPA would use to issue orders, the proposed procedures that order recipients would use to respond to the order, how data protection and compensation would be addressed in the test orders, and other related proposed procedures or policies. In addition, EPA developed 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). On April 15, 2009, the Agency published the final policies and procedures and related documents in the **Federal Register** ((74 FR 17560) (FRL–8399–9), (74 FR 17579) (FRL–8399–7), and (74 FR 17477) (FRL–8412–2)). EPA generally intends to adopt these procedures for initial screening of chemicals under the EDSP, including the statutory requirements associated with and format of the test orders, as well as EPA's procedures for fair and equitable sharing of test costs and handling of confidential data (docket number EPA–HQ–OPPT–2007–1080).

IV. Order Issuance Schedule

The Agency intends to initiate the EDSP Tier 1 screening for the first group of 67 chemicals by issuing test orders listed in the following table.

TABLE 1-LIST OF CHEMICALS AND ORDER ISSUANCE DATES FOR TIER 1 SCREENING IN THE EDSP

Chemical Name	CAS Number	Pesticide Active Ingredient (x) or as Noted	Order Issuance Time Frame
Abamectin	71751–41–2	x	January 2010
Acephate	30560–19–1	x	November 2009
Acetone	67–64–1	HPV/Inert	February 2010
Atrazine	1912–24–9	x	October 2009
Benfluralin	1861–40–1	x	October 2009
Bifenthrin	82657–04–3	x	November 2009
Butyl benzyl phthalate	85–68–7	HPV/Inert	January 2010
Captan	133–06–2	x	January 2010
Carbamothioic acid, dipropyl-, S-ethyl ester	759–94–4	x	November 2009
Carbaryl	63–25–2	x	November 2009
Carbofuran	1563–66–2	x	November 2009
Chlorothalonil	1897–45–6	x	December 2009
Chlorpyrifos	2921–88–2	x	November 2009
Cyfluthrin	68359–37–5	x	November 2009
Cypermethrin	52315–07–8	x	November 2009
2,4-D	94–75–7	x	October 2009
DCPA (or chlorthal-dimethyl)	1861–32–1	x	October 2009
Diazinon	333–41–5	x	November 2009
Dibutyl phthalate	84–74–2	HPV/Inert	January 2010
Dichlobenil	1194–65–6	x	December 2009
Dicofol	115–32–2	x	December 2009
Diethyl phthalate	84–66–2	HPV/Inert	January 2010
Dimethoate	60–51–5	x	November 2009
Dimethyl phthalate	131–11–3	HPV/Inert	January 2010
Di-sec-octyl phthalate	117–81–7	HPV/Inert	January 2010
Disulfoton	298–04–4	x	November 2009

TABLE 1-LIST OF CHEMICALS AND ORDER ISSUANCE DATES FOR TIER 1 SCREENING IN THE EDSP—Continued

Chemical Name	CAS Number	Pesticide Active Ingredient (x) or as Noted	Order Issuance Time Frame
Endosulfan	115–29–7	x	December 2009
Esfenvalerate	66230–04–4	x	November 2009
Ethoprop	13194–48–4	x	November 2009
Fenbutatin oxide	13356–08–6	x	October 2009
Flutolanil	66332–96–5	x	December 2009
Folpet	133–07–3	x	January 2010
Gardona (cis-isomer)	22248–79–9	x	November 2009
Glyphosate	1071–83–6	x	January 2010
Imidacloprid	138261–41–3	x	January 2010
Iprodione	36734–19–7	x	January 2010
Isophorone	78–59–1	HPV/Inert	January 2010
Linuron	330–55–2	x	December 2009
Malathion	121–75–5	x	November 2009
Metalaxyl	57837–19–1	X	December 2009
Methamidophos	10265–92–6	X	November 2009
4,7-Methano-1H-isoindole-1,3(2H)-dione, 2-(2-ethylhexyl)-3a,4,7,7a-tetrahydro-	113–48–4	x	January 2010
Methidathion	950–37–8	x	November 2009
Methomyl	16752–77–5	x	November 2009
Methyl ethyl ketone	78–93–3	HPV/Inert	January 2010
Methyl parathion	298–00–0	x	November 2009
Metolachlor	51218–45–2	x	December 2009
Metribuzin	21087–64–9	x	December 2009
Myclobutanil	88671–89–0	X	December 2009
Norflurazon	27314–13–2	X	October 2009
o-Phenylphenol	90–43–7	x	January 2010
Oxamyl	23135–22–0	x	November 2009
Permethrin	52645–53–1	x	November 2009
Phosmet	732–11–6	x	November 2009
Piperonyl butoxide	51–03–6	x	November 2009
Propachlor	1918–16–7	x	December 2009
Propargite	2312–35–8	x	October 2009
Propiconazole	60207–90–1	x	December 2009
Propyzamide	23950–58–5	x	January 2010
Pyridine, 2-(1-methyl-2-(4-phenoxyphenoxy)ethoxy)-	95737–68–1	x	January 2010
Quintozene	82–68–8	x	December 2009

TABLE 1-LIST OF CHEMICALS AND ORDER ISSUANCE DATES FOR TIER 1 SCREENING IN THE EDSP—Continued

Chemical Name	CAS Number	Pesticide Active Ingredient (x) or as Noted	Order Issuance Time Frame
Resmethrin	10453–86–8	x	November 2009
Simazine	122–34–9	x	December 2009
Tebuconazole	107534–96–3	x	December 2009
Toluene	108–88–3	HPV/Inert	February 2010
Triadimefon	43121–43–3	x	December 2009
Trifluralin	1582–09–8	x	January 2010

Details on the status of the orders will be provided on EPA's website at *http://www.epa.gov/endo* with information, including the order issuance date, the recipient(s) of the order, the order recipient's response to the order, and the order due date.

V. Submission of Other Scientifically Relevant Information by Interested Parties

The Agency published the final policies and procedures and related documents in the **Federal Register** of April 15, 2009 ((74 FR 17560), (74 FR 17579), and (74 FR 17477)); as part of those documents, EPA discussed its policies relating to the submission of other scientifically relevant information in satisfaction of a test order. As explained at greater length in those documents, if recipients of the FFDCA section 408(p) test orders choose to cite or submit existing data, (i.e., other scientifically relevant information (OSRI)), along with a rationale that explains how the cited or submitted study satisfies the Tier 1 test order in lieu of developing new data, EPA will determine whether the information can be used to satisfy part or all of the Tier 1 order and/or otherwise inform the Tier 1 determination. 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 of the Tier 1 order and/or otherwise inform the Tier 1 determination.

The Agency has written a paper entitled ''EPA's Approach for Considering Other Scientifically Relevant Information (OSRI) under the EDSP'' (see *www.regulations.gov* and search for docket number EPA–HQ–OPPT–2007–1080–0032). This paper was developed to provide guidance to EPA staff and managers who will review the responses to Tier 1 test orders issued under the EDSP, and may also be of interest to parties considering whether to submit OSRI to EPA. This paper is intended only to provide general guidance and is not binding on either EPA or any outside parties. Anyone, including members of the general public, may provide OSRI, and the Agency will assess the information for appropriateness on a case-by-case basis to determine whether the information can be used to satisfy part or all of the Tier 1 order and/or otherwise inform the Tier 1 determination.

Persons other than those receiving testing orders who would like to submit OSRI on chemicals subject to test orders should include the following information:

- The submitter's contact information.
- The name of the program (i.e., Endocrine Disruptor Screening Program (EDSP).
- The name of the chemical to which the information applies.
- The citation of the study and/or a copy of the study, if possible.
- The order number(s) to which the information applies.
- A rationale that explains how the cited or submitted study(ies) satisfies all or some portion of the Tier 1 order.

In order for this information to be given timely consideration, the information should be submitted on the same time frame as the response to orders, i.e. this information should be submitted as a comment to the docket for this action (EPA–HQ–OPP–2009–0634) within 90 days of the issuance date of the orders for a given chemical. The details about the dates of issuance of the orders can be found at *www.epa.gov/endo*.

VI. Pesticide Inert Ingredients Data Submitters and Suppliers List

Currently, EPA maintains a list of all data on pesticide active ingredients that supports registration of products containing the active ingredient, along with contact information for the submitters (i.e., owners) of the data, known as the ''Data Submitters List.'' The Agency published the final policies and procedures and related documents in the **Federal Register** on April 15, 2009 ((74 FR 17560), (74 FR 17579), and (74 FR 17477)) describing EPA's intention to establish a Pesticide Inert Ingredients Data Submitters & Suppliers List (PIIDSSL) which is similar to the ''Data Submitters List.'' The purpose of the PIIDSSL is to identify any entity who has submitted compensable data on a pesticide inert ingredient in response to a test order issued under section 408(p) of FFDCA. Pursuant to FIFRA section 3(c)(1)(F), when a applicant's product contains a pesticide inert ingredient on the PIIDSSL, EPA intends to require the applicant to identify the source of the pesticide inert ingredient. If the applicant's source does not appear on the PIIDSSL, EPA intends to require the applicant either to switch to a source on the PIIDSSL; offer to pay compensation to the original data submitter(s) on the PIIDSSL; or generate

their own data to support their application.

The PIIDSSL can be found on EPA's website at *www.EPA.gov/DataSubmittersList* or a link to it can be found at *www.epa.gov/endo*.

List of Subjects

Environmental protection, Chemicals, Endocrine disruptors, Pesticides.

Dated: October 14, 2009.

Stephen A. Owens,

Assistant Administrator, Office of Prevention, Pesticides and Toxic Substances.

[FR Doc. E9–25352 Filed 10–20–09; 8:45 am]

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