Attachment C – (2)

FFDCA 408(p) Order Template for Pesticide Registrants

As of April 10, 2009

NOTE: This template was developed by EPA to provide guidance to EPA staff and managers who will be preparing the Tier 1 Orders that will be issued under the Endocrine Disruptor Screening Program (EDSP), as well as for the recipients of the Tier 1 Orders. This template is not a rule or regulation, nor does it create or confer legal rights or impose any legally binding requirements on EPA or any party. In preparing a final Tier 1 Order, EPA may depart from the guidance presented in this template where circumstances warrant and without prior notice. Orders will be generated individually for each chemical and each order recipient. EPA will insert the information in blue type and brackets when the order is generated.

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Summary Information about this Order and the Order Recipient:

Order/DCI #: [Insert sequential number as assigned by the system.]
Chemical Common Name: [Insert chemical name.]
Chemical #: [Insert number assigned to identify the chemical named.]

Date Issued: [Insert date of signature. This serves as the issuance date.]
Due Date for Initial Response: [Insert date, calculated as 90 calendar days from issuance + 10 calendar days for final processing and mailing.]
Due Date for Consortia Documentation: [Insert date, calculated as 150 calendar days from issuance + 10 calendar days for final processing and mailing.]
Due Date for Progress Report: [Insert date, calculated as 12 months from issuance.]
Due Date for Final Submission: [Insert date, calculated as 24 months from issuance].

Company Name: [Insert name.]
Company #(s): [Insert number assigned to identify the company in the system.]
Address: [Insert address where Order will be directed to.]
Contact Person: [Insert the name of the contact person.]

Dear Sir or Madam:

This Order requires you and other registrants of pesticide products containing the chemical named above to submit certain data or otherwise respond as noted herein to the U. S. Environmental Protection Agency (EPA, the Agency). This chemical is identified as a pesticide active ingredient. Pursuant to section 408(p)(3) of the Federal Food, Drug and Cosmetic Act, which mandates that all pesticide chemicals be tested under the Endocrine Disruptor Screening Program ("EDSP") these data are necessary to maintain the continued registration of your product(s) containing the listed pesticide active ingredient(s). [21 U.S.C. 346a (p)(3), (5)].

If you do not respond to this Order, or if you fail to otherwise comply with its requirements, then the registration of product(s) subject to this Order will be subject to suspension, pursuant to FFDCA section 408 (p)(5)(C)(i) and FIFRA section 3(c)(2)(B)(iv).

Introduction

This Order is issued pursuant to sections 408(p)(3) and (5) of the Federal Food Drug and Cosmetic Act (FFDCA) [21 U.S.C. 346a(p)(3) and (5)] and FIFRA section 3(c)(2)(B) [7 U.S.C. 136a(c)(2)(B)]. FFDCA Section 201(q)(1) 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)].

To facilitate the formation of consortia to develop the required data, and to the extent that the information is not protected as confidential business information, we have provided each Order recipient with a list of the other recipients of orders for this chemical. (See Enclosure A). EPA intends to publish the list of all order recipients in the **Federal Register** and will then post the list on the Agency's website, along with the status of the Orders, including recipients' responses. EPA intends to update the list with subsequent publication(s) and posting(s) as appropriate. You are encouraged to join a consortium and can check on the status of responses from the other order recipients for this chemical on the Web site.

The information collection requirements described in this document have been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.* The Information Collection Request (ICR) document prepared by EPA is identified under EPA ICR No. 2249.01, and OMB Control No. 2070-[# will be inserted when obtained]. The public reporting burden for this collection of information is estimated to average [# will be inserted when ICR is approved] hours per order.

This Order is organized as follows:

Section I. The Authority for this Order

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 the 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) 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, to conduct testing in accordance with the screening program, and submit information obtained from the testing to the Administrator, within a reasonable time period that the Administrator determines is sufficient for the generation of the information.

Section 3(c)(2)(B) of the 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) 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.

Section II. Why You Are Receiving This Order

On [insert date of FR publication], 2009, EPA published a final list of the chemicals to undergo EDSP Tier 1 screening ([inert FR citation]). The pesticide active ingredient identified on page 1 of this Order is included on that list, and you are receiving this Order because you are identified as a registrant of a pesticide product that contains that ingredient. As such, pursuant to section 408(p)(3) of the FFDCA, you are subject to this Order.

Section III. Data Required By This Order

This Order identifies the screening assays that will identify substances that have the potential to interact with the endocrine system. These screening assays are part of Tier 1 screening under the EDSP. The purpose of Tier 1 screening (also referred to as "screening") is to identify substances that have the potential to interact with the estrogen, androgen, or thyroid hormone systems using a battery of assays. The fact that a substance may interact with a hormone system, however, does not mean that when the substance is used, it will cause adverse effects in humans or ecological systems.

Although this Order only identifies the Tier 1 screening assays, upon examining the screening data submitted, EPA may issue a subsequent Order to require additional testing of this chemical under Tier 2 of the EDSP to:

- Determine whether a substance may cause endocrine-mediated effects through or involving estrogen, androgen, or thyroid hormone systems, or such other endocrine effect as the Administrator may designate;

- Determine the consequences to the organism of the activities observed in screening assays; and

- Establish the relationship between doses of an endocrine-active substance administered in the test and the effects observed.

III.A. Data Required – The Tier 1 Battery

[NOTE: The availability of the final Tier 1 screening battery will be announced in the Federal Register before any 408(p) orders will be issued. Until that is done, the list of assays presented in this template is only a list of the assays that **are expected to be** in the battery based on the proposed Tier 1 screening battery that underwent peer review by the FIFRA Scientific Advisory Panel (SAP) in March 2008. When the orders are issued, the order will reflect the final Tier 1 Battery.]

On [insert date of FR publication], 2009, ([inert FR citation]), EPA announced the final Tier 1 screening battery. The following is a list of the endocrine disruptor screening battery data that you must submit to the Agency in response to this Order:

Amphibian Metamorphosis (Frog) - The Amphibian Metamorphosis assay involves the use of tadpoles to determine if chemicals affect the hypothalamic-pituitary-thyroid (HPT) axis during metamorphosis and consequently result in developmental effects.

Androgen Receptor Binding (Rat Prostate) - The androgen receptor (AR) is involved in the development of male sexual characteristics. The AR Binding assay identifies chemicals that affect the endocrine system by binding to hormone receptors to either mimic the action of the

natural hormone or block access of the hormone to the site and thus block hormone controlled activity.

Aromatase (Human Recombinant) - Aromatase is an enzyme complex responsible for estrogen biosynthesis that converts androgens into estrogens, estradiol, and estrone. The Aromatase in vitro assay focuses on this portion of the steroidogenic pathway to detect substances that inhibit aromatase activity.

Estrogen Receptor Binding - The estrogen receptor (ER) is involved in female maturation and reproductive function. The ER Binding assay measures the ability of a chemical to bind to the estrogen receptor.

Estrogen Receptor Transcriptional Activation (Human Cell Line (HeLa-9903)) - The estrogen receptor (ER) is involved in female maturation and reproductive function. The ER Transcriptional Activation is a cell-based assay that measures the ability of a chemical to bind to the ER and activate transcription resulting in the synthesis of the enzyme luciferase.

Fish Short-term Reproduction - The Fish Short-term Reproduction assay screens for disturbances in the hypothalamic-pituitary-gonadal (HPG) axis including (anti-)estrogenic, (anti-)androgenic, aromatase inhibition, and steroid modulating effects. The assay examines abnormalities associated with survival, reproductive behavior, secondary sex characteristics, histopathology, and fecundity (i.e., number of spawns, number of eggs/spawn, fertility, and development of offspring) of fish exposed to test chemicals.

Hershberger (Rat) - The Hershberger assay is designed to detect androgenic and anti-androgenic effects. In this in vivo assay, the weight of several androgen-dependent tissues, including accessory sex glands, are measured in castrated or immature male rats.

Female Pubertal (Rat) - The Pubertal Female assay involves the use of rats to screen for estrogenic and thyroid activity in females during sexual maturation. This assay examines abnormalities associated with sex organs and puberty markers, as well as thyroid tissue.

Male Pubertal (Rat) - The Pubertal Male assay involves the use of rats to screen for androgenic, anti-androgenic, and thyroid activity in males during sexual maturation. This assay examines abnormalities associated with sex organs and puberty markers, as well as thyroid tissue.

Steroidogenesis (Human Cell Line – H295R) - The Steroidogenesis in vitro assay detects interference with the body's production of male and female steroid sex hormones. This assay is a cell-based assay using the H295R human adrenocortical carcinoma cell line which can detect inducers of enzymes responsible for steroid synthesis as well as chemicals that inhibit it.

Uterotrophic (Rat) - The Uterotrophic assay involves the use of female rats to screen for estrogenic effects. In this in vivo assay, uterine weight changes are measured in ovariectomised or immature female rats.

III.B. Conducting the Battery - Testing Protocols

Pursuant to section 408(p)(1), testing conducted for the EDSP must be based on "validated test systems and other scientifically relevant information." 21 U.S.C. § 346a (p)(1). "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). OSRI 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. See also the discussion in Section IV. of this Order.

The assays identified in Section III.A. of this Order must be conducted using the test protocols that have been validated and made available for use by the Order recipients that are completing the assays to generate new data to respond to this Order. All of the applicable testing protocols have been validated and are available on the Agency's web site at: [insert URL to website, which will include a list of the Protocols and links to the appropriate documents in the Docket].

If you choose to generate the data to respond to this Order, you may not deviate from an approved testing protocol unless you first consult with the Agency and obtain Agency approval of any deviation. If you wish to use a protocol that differs from those identified in this Order, you must submit a detailed description of the proposed protocol (including a precise description of any deviations from the protocol attached to this Order) and your reason for wishing to use it. Because section 408(p)(1) of the FFDCA requires that the screening be conducted with validated tests, in order for EPA to approve the use of your proposed protocol, you must demonstrate that the protocol has been scientifically validated or the deviation is such that the final study is nonetheless properly considered to have been scientifically validated . If the Agency rejects your protocol you will be notified in writing. Moreover, you should be aware that rejection of a proposed protocol will not be a basis for extending the deadline for submission of data.

If you choose to cite or submit existing data, including other scientifically relevant information, you must indicate whether the information provided follows an accepted scientific methodology or protocol, including but not limited to those presented in EPA's harmonized test guideline compendium (see http://www.epa.gov/oppts and select "Test Methods & Guidelines" on the left), and provide a cogent and complete rationale for why you believe the information is sufficient to satisfy part or all of this Order. EPA's decisions about whether the information satisfies part or all of the Tier 1 Order will be based on the weight of evidence from all relevant information available to the Agency. See the instructions for submitting your response, which appear in Section IV.

You must also adhere to the good laboratory practice (GLP) standards described in 40 CFR part 160, which require you to follow certain practices when conducting studies, and when you submit data to EPA you must provide a GLP compliance statement indicating a) that the data

were generated using GLPs; or b) describe in detail "all differences" between the GLPs and the practices used; or c) confirm that you did not sponsor or conduct the study and do not therefore know whether the study was conducted in accordance with the GLPs.

III.C. Generating the Data – Applicable Timeframes

You are required to submit the data or otherwise satisfy the data requirements specified in this Order and submit them to EPA no later than [Insert date, calculated as 24 months from issuance]. The Agency set this due date after considering the amount of time one might reasonably expect each assay to complete, including the planning activities before beginning the test, actual performance of the test, analyzing test results, and completing the final study report for that assay (see Table 1). EPA also included several months for overall planning, and several months after the last test is completed to allow ample time for the Order recipients to prepare the final report for submission to EPA.

Table 1 – Estimated Timeframes for Completing the Individual Assay Reports

Assay	Timeframes
Amphibian Metamorphosis (Frog)	15 months
Androgen Receptor Binding (Rat Prostate)	6 months
Aromatase (Human Recombinant)	6 months
Estrogen Receptor Binding	6 months
Estrogen Receptor Transcriptional Activation (Human Cell Line (HeLa-9903))	6 months
Fish Short-term Reproduction	12 months
Hershberger (Rat)	9 months
Female Pubertal (Rat)	15 months
Male Pubertal (Rat)	15 months
Steroidogenesis (Human Cell Line – H295R)	6 months
Uterotrophic (Rat)	9 months

There is no set sequence for completing these assays, and the due date for submitting the final report to EPA provides you with ample flexibility for Order recipients to join forces and complete this battery within the timeframe provided.

Section IV. Responding to the Order

You must respond to this order within the timeframes established pursuant to section IV.A., and the specific applicable dates as identified on page 1 of this Order. If you do not respond to this Order, or if you fail to otherwise comply with its requirements, then the registration of the product(s) subject to this Order will be subject to suspension, pursuant to FFDCA section 408 (p)(5)(C)(i) and FIFRA section 3(c)(2)(B)(iv).

To comply with this Order, you are expected to engage in the following activities:

(1) Read this Order.
(2) Determine and plan activities necessary to respond to the order.

(3) Submit an Initial Response Form to EPA, identifying the response option you intend to use. See section IV.B.
(4) If you decide to generate the data, Read and, if applicable, discuss the protocols. See section III.B.
(5) Submit a Progress Report. See section VI.
(6) Generate the data.
(7) Compile and review the data for submission. See section V.
(8) Complete paperwork to assemble the submission package. See section V.
(9) Submit Final Report/Data to EPA. See section V.
(10) Maintain records. See section VII.

IV.A. Schedule for Responding to the Order

Your schedule for responding may vary based on the response options discussed in more detail in the next section. Please note that in calculating the due date for the Initial Response, the Agency has included an additional 10 calendar days to account for processing the final order package for delivery to the Post Office. In general, your basic schedule is summarized on page 1 of this Order and is based on the timeframes identified in Table 2, which are discussed elsewhere in this Order:

Table 2 – Basis for Establishing the Due Dates in this Order

Timeframes for Due Dates:	**What is Due:**
Within 90 calendar days of the Order's issuance (+ 10 calendar days for processing)	Individual Recipient's Initial Response
Within 150 calendar days of the Order's issuance (+ 10 calendar days for processing)	Consortia Documentation & Consortia's Initial Response
Within 12 months from Order's issuance	A Progress Report describing the status of an Order Recipient's compliance with the Order.
24 months from Order's issuance	Final Study Report and submission of the data to EPA

In general, the Agency will not consider any requests for extending the deadlines for the Initial Response or Progress Report. However, the Agency will consider extending the final report due date when the circumstances warrant it. If you cannot submit the data/reports to the Agency in the time frame required by this Order and intend to seek additional time to meet the requirement, you must submit a written request to the Agency before the applicable deadline. Your written request must include: (1) a detailed description of the expected difficulty and (2) proposed schedule including alternative dates for meeting such requirements on a step-by-step basis. You must explain any technical or laboratory difficulties and provide documentation from the laboratory performing the testing. While EPA is considering your request, the original deadline remains. The Agency will respond to your request in writing; extensions can only be granted in writing. If EPA does not grant your request, the original deadline remains. Normally, extensions can be requested only in cases of extraordinary testing problems beyond the expectation or control of the registrant, manufacturer, or importer. Extensions will not be considered if the request for extension is not made in a timely fashion; in no event shall an extension request be considered if it is submitted at or after the lapse of the subject deadline.

IV.B. Options for Responding to the Order

You have several options for responding to this order. To report your commitment to act in response to the test order, you must submit an Initial Response to EPA within 90 days of the issuance of this Order.

Please complete the **Initial Response Form for Individual Order Recipients** (Enclosure B), which EPA has pre-populated with basic information about this Order, the chemical and your contact information. Follow the mailing instructions in section V.D. of this Order to submit this form to EPA by the due date for the initial response that is indicated on page 1 of this Order.

You have several potential response actions from which to choose, each response option involves specific procedures that you must follow:

Option 1: Generate Data

If you choose to individually generate new data for each test specified in this Order, you must comply with the procedures prescribed in this Order. All data generated and submitted must comply with the Good Laboratory Practice (GLP) rule (40 CFR part 160) and the tests must be conducted according to protocol requirements identified in Section III.B. In submitting the data, you must follow the procedures described in this Order.

Option 2: Submit or Cite Existing Data

If you choose to submit or cite an existing study in response to this Order (including data previously submitted to the Agency), your Initial Response must include either the data or a reference to the data for each test that is required, along with a rationale that explains how the study you cited or submitted satisfies part or all of this Order. Existing studies are studies that predate issuance of this Order. In order to be accepted as satisfaction of the requirements imposed in this Order, the Agency expects that any such hazard-related data would be of high quality and achieves the objective of Tier 1 assays to provide reasonable assurance that a chemical does or does not have the potential to interact with the estrogen, androgen, or thyroid systems. EPA's decisions about whether the data cited or submitted satisfies part or all of the Tier 1 Order will be based on the weight of evidence from all relevant information available to the Agency.

The submitted or cited study must have been conducted in accordance with accepted scientific methodology or protocol, including but not limited to those presented in EPA's harmonized test guideline compendium (see http://www.epa.gov/oppts and select "Test Methods & Guidelines" on the left). Deviations from the protocols validated for the Tier 1 assays, must be identified, along with an explanation for the deviations, including an explanation as to why, notwithstanding the deviations, the protocol used should still be considered as providing an accepted scientific methodology or protocol, and any other information you think the Agency should consider in deciding whether to accept the data in satisfaction of this Order.

If EPA has previously reviewed a protocol for a study you are submitting or citing, you must identify any action taken by the Agency on the protocol and must indicate the manner in which all Agency comments, concerns or issues were addressed in the final protocol and study.

If you choose to cite a study that has been previously submitted to EPA, that study must have been previously classified by EPA as acceptable (i.e., the study was not rejected by the Agency for any reason related to completeness or quality) or it must be a study which has not yet been reviewed by the Agency. With respect to any studies for which you wish to select this option you must provide EPA with a copy of the title page along with the identification number of the study you are citing (MRID number), and, if the study has been reviewed by the Agency, you must provide the Agency's classification of the study. **Do not resubmit a study that has previously been submitted to EPA for another purpose.**

EPA will review any existing study submitted or cited in response to this Order to determine whether the study is acceptable and whether the study satisfies the requirements of this Order. The Agency will notify you in writing of its determination. If the Agency determines that the study is acceptable, the Initial Response Form is the only response you are required to complete to satisfy this Order and EPA will notify you in writing that the Order is satisfied. If, however, EPA determines that the study is not acceptable, you must still satisfy the requirements of this Order. You should be aware that if the Agency determines that the study is not acceptable, the Agency will require you to comply with this Order, normally without an extension of the required date of submission. The Agency may determine at any time that a study is not valid and needs to be repeated.

If you are citing a study of which you are not the original data submitter, you may need to submit an offer to pay compensation to the original data submitter. Consequently, you should simultaneously include an offer to pay [in accordance with 40 CFR § 152.93] [which includes an offer to resolve any dispute over the recipients' shares of the test costs by submitting the dispute to a neutral third party with authority to bind the parties (e.g., through binding arbitration or through a state or federal court action)], unless you have received confirmation from EPA that no such compensation is necessary.

Option 3: Form a Task Force or Offer to Join a Task Force

If you choose to form a task force or consortium to share in the cost of producing the required data, all participants of the task force or consortium must submit their own **Initial Response Form for Individual Order Recipients** providing the name of the party who will be submitting the data on your behalf.

The designated lead for the task force or consortium must complete the **Initial Response Form for Consortium /Task Force** (Enclosure C) to provide the primary contact for the task force or consortium, the list of participants, and an indication of the task force or consortium's planned response for each assay, along with documentation of its formation (such as a copy of the joint agreement or a written statement by all the parties that an agreement exists). The joint agreement to produce the data need not specify all of the terms of the final arrangement between the parties or the mechanism to resolve the terms. The designated lead for the task force or consortium must follow the mailing instructions in section V.D. of this Order to submit this form

and accompanying information to EPA by the due date for the consortia response that is indicated on page 1 of this Order.

Once the task force or consortium submits the data and EPA has completed its initial review to accept the data in satisfaction of this Order, EPA will provide written notification to the contact for the task force or consortium that this Order has been satisfied, which in turn will close out the Orders for each of the participants.

If you are unable to join a task force or consortium, you must provide EPA with documentary evidence that you made a reasonable offer to join or share in the testing costs. Such evidence may be (1) your letter offering to join in an agreement, or (2) your letter that contains a legally binding offer to join in an agreement and provide a reasonable share of the test costs, and that includes a reasonable process for resolving any disputes of the appropriate share of the test costs.

If the task force or consortium fails to submit the data or meet the requirements of the Order in a timely and adequate manner, you will normally be subject to penalties of up to $25,000 per day, unless you commit to submit, and do submit, the required data by the dates specified in this Order. In such cases, the Agency will generally not grant time extensions for the submission of data. Thus, if you agree to jointly submit the data, each Order recipient is still subject to penalties of up to $25,000 per day, unless some party with whom you are in agreement makes a commitment to generate the data and submits the data in accordance with the deadlines and all other requirements set forth in this Order.

The Agency has provided a list of the other manufacturers and/or importers, to the extent permitted by confidentiality requirements that have received an EDSP Order for this chemical. (Enclosure A). This list is intended to help order recipients identify other companies with whom they could form agreements to develop data jointly.

Option 4: Claim Not Subject To the Order

You may claim that you are not subject to this order if you do not manufacture or import the chemical identified on page 1 of this Order or you believe the order was otherwise sent to you in error. An explanation of the basis for the claim, along with appropriate information to substantiate that claim, must accompany your Initial Response so that EPA can evaluate the claim. The Agency intends to make a determination and respond to your request in writing within 90 days of receipt. If EPA can not verify your claim, the original requirements and deadlines in this Order remain. If your claim is verified, EPA will consider your response to be satisfaction of the Order and will close out this Order.

Option 5: Voluntarily Cancel the Pesticide Registration(s)

In place of submitting the data required in this Order, you may request the voluntary cancellation of your product(s) containing the pesticide active ingredient(s) that is the subject of this Order. If you wish to voluntarily cancel your product, you must submit a request for voluntary cancellation under FIFRA section 6(f). You must submit your request within 90 days

of the issuance of this Order using the Agency's existing procedures for a voluntary cancellation (see 40 CFR 152.99).

In response to your request to voluntary cancel your product(s) registrations, EPA will initiate the standard process for voluntary cancellation, which includes publication of a Federal Register notice announcing the proposed voluntary cancellation, as required by FIFRA section 6(f). The Agency has standard provisions for sale or use of existing stocks of a pesticide, but you may propose an alternative. If you propose alternative provisions for sale or use of existing stocks, EPA will review your proposal and respond in writing, prior to publication of the FIFRA section 6(f) notice.

If you choose this option and cancel your registrations, the Initial Response Form is the only response you are required to complete to satisfy this Order. When the product's pesticide registration(s) is cancelled, the Agency will notify you in writing that you have satisfied the Order.

Option 6: Reformulate the Product(s) to Exclude this Chemical from the Formulation

In place of submitting the data required in this Order, you may submit an application to amend the formulation of your registered product by removing as an ingredient of your product the chemical that is the subject of this Order. Submitting such an application will initiate the existing procedures for reformulation. If you choose this option, the Initial Response Form is the only response required to satisfy the Order as long as you complete the procedures and reformulate your product(s). When you product's formulation has been changed, the Agency will notify you in writing that you have satisfied the Order.

Option 7: Claim a *Formulators' Exemption*

If you are a product registrant who purchases the chemical from another recipient that has agreed to generate the data, you may be eligible for a formulator's exemption. EPA will confirm claims of eligibility. A response asserting the formulator's exemption would no longer be considered an appropriate response to a test order if the supplier of the chemical fails to comply with the test order (i.e., it fails to submit the data either individually or jointly with other recipients or it fails to comply with the terms of a compensation agreement or the binding decision of a neutral third party regarding the terms of compensation). If EPA confirms your eligibility for this option, the Initial Response Form is the only response you are required to complete to satisfy this Order. If, however, EPA determines that you are not eligible, you must comply with the Order and the original deadline remains.

Option 8: Other Response Options

As part of your Initial Response, you may also ask EPA to reconsider some or all of the testing specified in this Order if:

a) You can demonstrate (supported by appropriate data) that the chemical is an endocrine disruptor and that additional screening or testing under the EDSP is unnecessary.

b) You can demonstrate (supported by appropriate data) that the chemical meets the standard for an exemption under FFDCA section 408(p)(4) (*i.e.*, "that the substance is not anticipated to produce any effect in humans similar to an effect produced by a naturally occurring estrogen").

c) Your chemical was used by EPA as a ''positive control'' to validate one or more of the screening assays. EPA will only accept these data in satisfaction of that part of the test order related to those assays for which the chemical was used to complete the testing as part of the validation effort.

The Agency intends to make a determination on your claim and respond to you in writing within 90 days of receipt. If EPA can not verify your claim, the original requirements and deadlines in this Order remain. If your claim is verified, EPA will consider your response to be satisfaction of the Order and will close out this Order.

IV.D. Procedures for Challenging this Order

If you wish to challenge the validity of any of the provisions of this Order, including the requirement to conduct any test or use the specific test protocols required by this Order, you must submit to the Agency a detailed explanation of the basis for your challenge that provides sufficient information for the Agency to evaluate the issue. While EPA is considering your submission, the original deadline remains. The Agency intends to respond to your request in writing within 90 days of receipt. If EPA does not grant your request, the original deadline remains.

IV.E. Procedures for Cost Sharing

Cost sharing is the process by which two or more recipients of a test order contribute to the generation of data (or the compensation for existing data). Contributions may be in cash or in kind and apportionment of costs is subject to negotiation between the participants. EPA encourages all recipients of testing orders for a particular substance to jointly submit data and share data generation costs. All other parties who are also subject to this Order are listed in Enclosure A, unless that information is protected as confidential business information.

EPA has not established specific coordination procedures by which you must collectively generate data. You may therefore determine the procedures that are best suited to your individual circumstances, and the most acceptable approach to sharing test costs.

If you are aware of another manufacturer of any of the products listed on Enclosure A who has not received an order, and you provide EPA with this information, and EPA intends to send that manufacturer an order within 90 days of your notification.

IV.F. Procedures for Data Protection

FOIA requires agencies to make information available to the public upon request, except for information that is "specifically made confidential by other statutes" or data that are "trade secrets and commercial or financial information obtained from a person and is privileged or confidential" [5 U.S.C. § 552]. Any information that you wish to have EPA protect as confidential business information should be clearly identified as such. Note that substantive criteria must be met to support a claim confidentiality of business information, as specified in 40 CFR § 2.208.

Section V. Procedures for Submitting Data to the Agency

V.A. Format for Submissions

EPA has developed standard data evaluation formats, or templates for writing its data evaluation records (DERs) of studies submitted under FIFRA and FFDCA to EPA. These templates describe the layout and scope of information that should be contained within a study profile and can serve as guides for preparation of study documents. Use of the templates improves the likelihood of a successful submission, since the information necessary for an efficient agency review is outlined. Additional details about these templates are available at: *http://www.epa.gov/pesticides/regulating/studyprofile_templates/*.

In addition, Pesticide Registration (PR) Notice 86–5, entitled *Standard Format for Data Submitted Under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and Certain Provisions of the Federal Food, Drug, and Cosmetic Act (FFDCA)*, describes EPA's preferred method for organizing and formatting submittals of data supporting a pesticide registration (*http://www.epa.gov/PR_Notices/pr86-5.html*).

The Agency also encourages FFDCA section 408(p) test order recipients to submit completed study profiles and supporting data in an electronic format (PDF) whether submitting one or several studies. For more information, go to the electronic data submissions website at *http://www.epa.gov/pesticides/regulating/registering/submissions/index.htm*.

V.B. Transmittal Document

In order for EPA to effectively track the compliance of each order recipient, each submission in satisfaction of a FFDCA section 408(p) test order must be accompanied by a transmittal document that includes the following information:

- Identity of the submitter.
- The date on which the submission package was prepared for transmittal to EPA.
- The FFDCA section 408(p) test order number.
- A list of the individual documents included in the submission.

V.C. Submitting Individual Study or Test Result Documents

Unless otherwise specified by the Agency, each submission must be in the form of individual documents or studies. Do not resubmit any documents that you previously submitted to EPA. Instead, as part of your Initial Response Form, please provide a citation or reference to the previously submitted documents with sufficient information to allow the Agency to identify the previously submitted document.

Each study or document submitted to EPA must include the following:

i. A title page including the following information:

- The FFDCA section 408(p) test order number
- The title of the study, including identification of the substance(s) tested and the test name or data requirement addressed.
- The author(s) of the study.
- The date the study was completed.
- If the study was performed in a laboratory, the name and address of the laboratory, project numbers or other identifying codes.
- If the study is a commentary on or supplement to another previously submitted study, full identification of the other study with which it should be associated in review.
- If the study is a reprint of a published document, all relevant facts of publication, such as the journal title, volume, issue, inclusive page numbers, and date of publication.

ii. Upon submission to EPA, each document must be accompanied by a signed and dated document containing the appropriate statement(s) regarding any data confidentiality claims as described in PR-Notice 86-5.

iii. A statement of compliance or non-compliance with respect to GLP standards as required in 40 CFR part 160, as applicable.

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

V. D. Mailing Instructions

Your response to this Order and all related correspondence must be mailed or delivered to EPA as follows:

Mail To: Document Processing Desk (SRRD-EDSP), Office of Pesticide Programs (7504P), U.S. Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, D.C. 20460

Deliver To: Document Processing Desk (SRRD-EDSP), Office of Pesticide Programs (7504P), U.S. Environmental Protection Agency, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays.

Section VI. Submit a Progress Report

Unless EPA has notified you in writing that the requirements of this Order have been satisfied, you must submit a progress report to EPA 12 months after the issuance of this Order (the specific due date for you is identified on page 1 of this Order). Your progress report should provide a brief description of the status of your planned activities for each assay, and, if applicable, a description of any problems encountered or expected difficulties in meeting the schedule for complying with the order. Please include the transmittal document described in section V.B.

Section VII. Recordkeeping Requirements

You must retain copies of the generation of the data and other information documenting your compliance with this Order. This includes all test reports submitted to the Agency in support of a registration or in support of a tolerance petition, *all* underlying raw data, and interpretations and evaluations thereof. Consistent with 40 C.F.R §169.2(k), this includes all test reports submitted to the Agency in support of a registration or in support of a tolerance petition, *all* underlying raw data, and interpretations and evaluations thereof. Under FIFRA section 8, all producers of pesticides, devices, or active ingredients used in producing pesticides subject to FIFRA, including pesticides produced pursuant to an experimental use permit and pesticides, devices, and pesticide active ingredients produced for export, are required to maintain certain records. As such, any recipients who are pesticide registrants or who otherwise submit their data in support of a pesticide registration will be held to the recordkeeping standards in 40 CFR part 169. These records shall be retained as long as the registration is valid and the producer is in business, and made available to EPA or its agent for inspection.

Section VIII. Consequences of Failure to Comply with this Order

FFDCA 408(p)(5)(C)(i) requires EPA to issue to any registrant that fails to comply with a 408(p) testing order "a notice of intent to suspend the sale or distribution of the substance by the registrant." The proposed suspension "shall become final at the end of the 30-day period beginning on the date that the registrant receives the notice of intent to suspend, unless during that period a person adversely affected by the notice requests a hearing or the Administrator determines that the registrant has complied" with the 408(p)testing order. [21 U.S.C. §346a(p)(5)(C)(i)]. If a hearing is requested, the only matter for resolution at the hearing shall be whether the registrant has failed to comply with an order issued under section 408(p)(5)(A). [21 U.S.C. §346a(p)(5)(C)(ii)].

Any suspension issued under FFDCA 408(p)(5)(C)(ii), shall be terminated only upon the Administrator's determination that the registrant has complied fully with the terms of the order. [21 U.S.C. §346a(p)(5)(C)(iii)].

Section IX. Additional Information

Additional information and details about the EDSP may be found on the Agency's Web site at http://www.epa.gov/endo.

If you have any questions about the requirements and procedures established by this Order, please contact one of the following EPA people:

William Wooge
Office of Science Coordination and Policy (OSCP), Mailcode 7201M
Environmental Protection Agency
1200 Pennsylvania Ave., NW., Washington, DC 20460–0001
telephone number: (202) 564–8476; fax number: (202) 564–8482
e-mail address: *wooge.william@epa.gov*

Jane Smith
Office of Pesticide Programs (OPP), Mailcode 7508P
Environmental Protection Agency
1200 Pennsylvania Ave., NW., Washington, DC 20460–0001
telephone number: (703) 308-0048; fax number: (703) 305-8005
e-mail address: *smith.jane-scott@epa.gov*

Section X. Conclusion

Under the authority in FFDCA section 408(p) [21 U.S.C. 346a (p)], and FIFRA section 3(c)(2)(B) [7 U.S.C. 136a(c)(2)(B)], the U.S. Environmental Protection Agency hereby issues this testing Order to take effect on the date of my signature.

Date: _____

Signature: _____
[Insert Name and Title of Authorized Agency Official]
Office of Prevention, Pesticides and Toxic Substances
U.S. Environmental Protection Agency

Enclosures

Enclosure A – List of EDSP Order Recipients for this Chemical
Enclosure B – The Initial Response Form for Individual Responders
Enclosure C – The Initial Response Form for Consortium /Task Force