SUPPORTING STATEMENT FOR AN INFORMATION COLLECTION REQUEST (ICR)

1. IDENTIFICATION OF THE INFORMATION COLLECTION

1(a) Title of the Information Collection:

Tier 1 Screening of Certain Chemicals Under the Endocrine Disruptor Screening Program (EDSP)
EPA ICR No.: **2249.01;** OMB Control No.: **2070-(tbd)**
Docket ID No.: **EPA-HQ-OPPT-2007-1081**

1(b) Short Characterization/Abstract

This is a new information collection request (ICR) under the Paperwork Reduction Act (PRA), 44 USC 3501 *et seq*., covering the information collection activities associated with Tier 1 screening of the first group of chemicals under the Endocrine Disruptor Screening Program (EDSP). The EDSP is established under §408(p) of the Federal Food, Drug, and Cosmetic Act (FFDCA), which requires endocrine screening of all pesticide chemicals. To view the statutory language, see Attachment A.

The Agency first proposed the basic components of the EDSP on August 11, 1998 (Ref. 1). After public comments, external consultations and peer review, EPA provided additional details about the EDSP on December 28, 1998 (Ref. 2). The EDSP consists of a two-tiered approach to screen all pesticide chemicals for potential endocrine disrupting effects. 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. Additional information about the EDSP is available through the Agency's Web site at http://www.epa.gov/scipoly/oscpendo/index.htm.

The focus of this ICR is on the information collection activities associated with the Tier 1 screening of the first group of chemicals identified for initial screening under the EDSP. The list of chemicals was produced using the approach described in a **Federal Register** notice issued on September 27, 2005, and includes chemicals that the Agency, in its discretion, has decided should be tested first based upon exposure potential (Ref. 3). Nothing in the approach for generating the initial list provides a basis to infer that by simply being on this list these chemicals are suspected to interfere with the endocrine systems of humans or other species, and it would be inappropriate to do so. As such, the list of chemicals resulting from the application of this approach should not be construed as a list of known or likely endocrine disruptors.

After considering comments on the draft list of chemicals issued on June 18, 2007 for public review and comment (Ref. 4), EPA finalized the list of chemicals to be the first to undergo Tier 1 screening on April 3, 2009 (Ref. 5). The first group of

chemicals identified for testing includes pesticide active ingredients and High Production Volume (HPV) chemicals used as pesticide inerts. For purposes of the public review draft of this ICR, the Agency used the draft list of chemicals to calculate the burden and cost estimates. Since the final list is now available, this ICR uses the final list of chemicals (see Attachment G). More information on the EPA's priority setting approach and the list of chemicals is available at http://www.epa.gov/scipoly/oscpendo/prioritysetting.

On April 3, 2009, after considering comments on a draft Policy and Procedures Document that was issued on December 13, 2007 (Ref. 6), EPA signed a document describing the specific details of the policies and procedures that EPA generally intends to adopt for initial screening under the EDSP, including the statutory requirements associated with and format of the Orders that will be used to request the Tier 1 data, as well as EPA's procedures for fair and equitable sharing of test costs and handling confidential data (Ref. 7). The Policy and Procedures Document (see Attachment B) describes the administrative policies and procedures that EPA generally intends to use in implementing the EDSP for initial screening, and serves as the general source for the information collection activities associated with the issuance of Orders for Tier 1 screening under the EDSP, which are covered by this ICR.

While the requirements in the statutes and the individual Tier 1 Orders are binding on EPA and the Order recipients, the Policy and Procedures Document does not impose any binding requirements. The policies and procedures described in the Policy and Procedures Document are not intended to be binding on either EPA or any outside parties, and EPA may depart from them where circumstances warrant and without prior notice. The Tier 1 Order, however, is binding on the Order recipient and non-compliance with the provisions in the Order will result in penalties as described in the Order.

This ICR only covers the information collection activities related to Tier 1 screening of the chemicals on the final list in Attachment G. It does NOT cover the information collection activities related to Tier 2 testing. EPA will prepare a separate ICR to address the information collection activities associated with Tier 2 testing. In addition, subsequent Tier 1 screening of additional chemicals not identified in Attachment G will be addressed separately, either in a separate ICR or in an amendment to this ICR. In either case, EPA will follow the notice and comment process prescribed by the PRA to first seek public comment on the new or revised ICR before submitting it to OMB for review and approval under the PRA.

2. NEED FOR AND USE OF THE COLLECTION

2(a) Need/Authority for the Collection

2(a)(i) Authority

The EDSP was established in 1998 to carry out the mandate in §408(p) of the FFDCA (see Attachment A), which directs EPA "to develop a screening program . . . to

determine whether certain substances may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or such other endocrine effect as the Administrator may designate." If a substance is found to have an effect, section 408(p)(6) directs the administrator to take action under available statutory authority to ensure protection of public health. That is, the ultimate purpose of the EDSP is to provide information to the Agency that will allow the Agency to evaluate the risks associated with the use of a chemical and take appropriate steps to mitigate any risks. The necessary information includes identifying any adverse effects that might result from the interaction of a substance with the endocrine system and establishing a dose-response curve.

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)].

FFDCA section 408(p)(3) expressly requires that EPA "shall provide for the testing of all pesticide chemicals." FFDCA section 201 defines "pesticide chemical" as "any substance that is a pesticide within the meaning of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), including all active and pesticide inert ingredients of such pesticide." [FFDCA section 201(q)(1), 21 U.S.C. 231(q)(1)]. 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." [21 U.S.C. 346a(p)(3)].

FFDCA section 408(p)(5)(A) provides that the Administrator "shall issue an order to a registrant of a substance for which testing is required [under FFDCA section 408(p)], or to a person who manufactures or imports a substance for which testing is required [under FFDCA section 408(p)], 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 Agency determines is sufficient for the generation of the information."

FFDCA section 408(p)(5)(B) requires that, "to the extent practicable, the Administrator shall minimize duplicative testing of the same substance for the same endocrine effect, develop, as appropriate, procedures for fair and equitable sharing of test costs, and develop, as necessary, procedures for handling of confidential business information. . . ." [21 U.S.C. 346a (p)(5)(B)].

If a registrant fails to comply with an Order issued under FFDCA section 408(p)(5), the Administrator is required to issue "a notice of intent to suspend the sale or distribution of the substance by the registrant. Any suspension proposed under this paragraph 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 fully with this paragraph." [21 U.S.C. 346a

(p)(5)(C)]. Any hearing is required to be conducted in accordance with section 554 of the Administrative Procedures Act (APA). [5 U.S.C. 554]. FFDCA section 408(p) explicitly provides that "the only matter for resolution at the hearing shall be whether the registrant has failed to comply with a test order under subparagraph (A) of this paragraph." [21 U.S.C. 346a (p)(5)(C)(ii)]. A decision by the Administrator after completion of a hearing is considered to be a final Agency action. [21 U.S.C. 346a (p)(5)(C)(ii)]. The Administrator shall terminate a suspension issued with respect to a registrant if the Administrator determines that the registrant has complied fully with FFDCA section 408(p)(5). [21 U.S.C. 346a (p)(5)(C)(iii)].

FFDCA section 408(p)(5)(D) provides that any person (other than a registrant) who fails to comply with an order issued under FFDCA section 408(p)(5) shall be liable for the same penalties and sanctions as are provided for under section 16 of the Toxic Substances Control Act (TSCA). [21 U.S.C. 346a (p)(5)(D)]. Such penalties and sanctions shall be assessed and imposed in the same manner as provided in TSCA section 16. Under section 16 of TSCA, civil penalties of up to $25,000 per day may be assessed, after notice and an administrative hearing held on the record in accordance with section 554 of the APA. [15 U.S.C. 2615(a)(1)–(2)(A)].

FFDCA section 408(f) establishes procedures that the Agency "shall use" to require data to support the continuation of a tolerance or exemption that is in effect. The provision identifies three options:

- Issuance of a notice to the person holding a pesticide registration under FIFRA section 3(c)(2)(B) [FFDCA section 408(f)(1)(A)].
- Issuance of a rule under section 4 of TSCA [FFDCA section 408(f)(1)(B)].
- Publication of a notice in the **Federal Register** requiring submission, by certain dates, of a commitment to generate the data "by one or more interested persons." [FFDCA section 408(f)(1)(C)].

Before using the third option, however, EPA must demonstrate why the data "could not be obtained" using either of the first two options. FFDCA section 408(f)(1) expressly provides that EPA may use these procedures to "require data or information pertaining to whether the pesticide chemical may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen or other endocrine effects." Finally, FFDCA section 408(f)(1)(B) provides that, in the event of failure to comply with a rule under TSCA section 4 or an order under FFDCA section 408(f)(1)(C), EPA may, after notice and opportunity for public comment, modify or revoke any tolerance or exemption to which the data are relevant.

In addition, FFDCA section 408(i) provides that "[d]ata that are or have been submitted to the Administrator under this section or FFDCA section 409 in support of a tolerance or an exemption from a tolerance shall be entitled to confidential treatment for reasons of business confidentiality and to exclusive use and data compensation to the same extent provided by section 3 and section 10 of [FIFRA]."

A number of other statutory provisions are discussed in this document and, consequently, are also described in this section.

FIFRA section 3(c)(1)(F) provides certain protections for people who submit data to EPA in connection with decisions under EPA's pesticide regulatory program. Specifically, FIFRA section 3(c)(1)(F) confers “exclusive use” or “data compensation” rights on certain persons (“original data submitters”) who submit data (in which they have an ownership interest), in support of an application for registration, reregistration, or experimental use permit, or to maintain an existing registration.

Applicants who cite qualifying data previously submitted to the Agency by the original data submitter must certify that the original data submitter has granted permission to the applicant to cite data or that the applicant has made an offer of compensation to the original data submitter. In the case of “exclusive use” data, the applicant must obtain the permission of the original data submitter and certify to the Agency that the applicant has obtained written authorization from the original data submitter. (Data are generally entitled to “exclusive use” for 10 years after the date of the initial registration of a pesticide product containing a new active ingredient.) If data are not subject to exclusive use but are compensable, an applicant may cite the data without the permission of the original data submitter, so long as the applicant offers to pay compensation for the right to rely on the data. (Data are “compensable” for 15 years after the date on which the data were originally submitted.) If an applicant and an original data submitter cannot agree on the appropriate amount of compensation, either may initiate binding arbitration to reach a determination. If an applicant fails to comply with either the statutory requirements or the provisions of a compensation agreement or an arbitration decision, the application or registration is subject to denial or cancellation. [See also 7 U.S.C. 136a (c)(1)(F)(ii)–(iii)].

FIFRA section 3(c)(2)(B) provides that “. . .[i]f the Administrator determines that additional data are required to maintain in effect an existing registration of a pesticide, the Administrator shall notify all existing registrants of the pesticide to which the determination relates and provide a list of such registrants to any interested person.” [7 U.S.C. 136a(c)(2)(B)]. Continued registration of a pesticide requires that its use not result in “unreasonable adverse effects on the environment” (defined as “(1) any unreasonable risk to man or the environment, taking into account the economic, social, and environmental cost and benefits of the use of any pesticide, or (2) a human dietary risk from residues that results from a use of a pesticide in or on any food inconsistent with the standard under section 408 of the [FFDCA].” [7 U.S.C. 136(bb)].

FIFRA section 3(c)(2)(B) contains a mechanism by which recipients of notices of data requirements (referred to as “Data Call-In notices” or “DCI notices”) may jointly develop data and provides that “[a]ny registrant who offers to share in the cost of producing the data shall be entitled to examine and rely upon such data in support of maintenance of such registration.” The section establishes procedures to allow registrants who received DCI notices to use binding arbitration to resolve disputes about each person's fair share of the testing costs.

Further, FIFRA section 3(c)(1)(F) makes clear that data submitted under FIFRA section 3(c)(2)(B) are also “compensable” when cited in support of an application for a registration. In other words, a pesticide company that chooses to rely on such data

rather than develop its own data must offer compensation to the original data submitter – usually the data generator. Lastly, the Agency may suspend the registration of a pesticide if the registrant fails to take appropriate steps to provide data required under a DCI notice in a timely manner.

Finally, FIFRA section 3(c)(2)(D) contains a provision, referred to as the "formulator's exemption" that is intended to simplify and promote equity in the implementation of the data compensation program under FIFRA section 3(c)(1)(F). This exemption relieves an applicant of the obligation to submit a study, or to cite and obtain permission or offer to pay data compensation to cite the results of a study if the study is relevant to the safety assessment of a registered product that the applicant buys from another person and uses to make the applicant's product. Congress' rationale for this exemption is that the seller will recover any data generation costs through the purchase price of its product. Thus, if a pesticide formulator applies to register a product containing an active ingredient that the formulator purchased from the basic manufacturer of the active ingredient, the formulator does not need to submit or cite and offer to pay compensation for any data specifically relevant to the purchased product. The Agency has extended the principles of the formulator's exemption to data requirements under FIFRA section 3(c)(2)(B). Consequently, if the formulator received a DCI notice requiring data on the active ingredient, the formulator could comply by providing documentation that it bought the active ingredient from another registrant.

In addition, section 1457 of the Safe Drinking Water Act (SDWA) provides EPA with discretionary authority to require testing, under the FFDCA section 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." [42 U.S.C. 300j–17].

2(a)(ii) Need

In addition to fulfilling a direct statutory mandate, the collection of information under this ICR is needed in order to provide information to the Agency that will allow the Agency 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.

In the last two decades there has been a growing awareness of the possible adverse effects in humans and wildlife from exposure to chemicals that can interfere with the endocrine system. These effects can include developmental malformations, interference with reproduction, increased cancer risk, and disturbances in the immune and nervous system function. Clear evidence exists that some chemicals cause these effects in wildlife, but limited evidence exists for the potential of chemicals to cause these effects in humans at environmental exposure levels. Very few chemicals have been tested as to their potential to interfere with the endocrine system, and it has been recognized that current standard test methods do not provide adequate data to identify potential endocrine disruptors (EDs) or to assess their risks to humans and wildlife. In light of these concerns, the 1996 Food Quality Protection Act (FQPA) amended FFDCA

to include a mandate for EPA to set up the EDSP using validated methods to test all pesticide chemicals (and other substances that may have cumulative effect of a pesticide or a substantial population is exposed) for their potential to interact with the endocrine system. To access an overview of the endocrine system and information on endocrine disruptors go to http://www.epa.gov/scipoly/oscpendo/pubs/edspoverview/primer.htm.

2(b) Use/Users of the Data

In general, EPA intends to use the data collected under the EDSP, along with other information, to determine if the chemical may pose a risk to human health or the environment due to disruption of the endocrine system. The determination that a chemical does or is not likely to have the potential to interact with the endocrine system (i.e., disruption of the estrogen, androgen, or thyroid hormone systems) will be made on a weight-of-evidence basis taking into account data from the Tier 1 assays and/or other scientifically relevant information.

The data collected under Tier 1 will allow the Agency to evaluate the potential interaction of a chemical with the endocrine system. EPA has extensive experience in using data from multiple sources to develop integrated assessments of hazard, modes of action / mechanisms of toxicity, and overall potential for risk. EPA scientists will continue to use such experience, together with insights from the validation process for Tier 1 assays, to address the potential of chemicals to cause adverse effects as a consequence of interaction with the endocrine system. In fact, EPA has considered the potential interaction of a chemical with the endocrine system in making certain pesticide registration decisions. For example, EPA considered data from prototypes of the assays included in the current EDSP Tier 1 screen, along with other existing data, in preparing the risk assessments of procymidone[1] and vinclozolin[2].

The Agency intends to take a weight-of-evidence approach to evaluate the available data for a particular chemical to determine whether the potential endocrine disrupting effects associated with the use of the chemical can be ascertained with the data available, or whether additional data is needed. Chemicals that go through Tier 1 screening and are found to have the potential to interact with the estrogen, androgen, or thyroid hormone systems will proceed to the next stage of the EDSP where EPA will determine which, if any, of the Tier 2 tests are necessary based on the available data. Tier 2 testing is designed to identify any adverse endocrine-related effects caused by the substance, and establish a quantitative relationship between the dose and that endocrine effect.

In addition to helping determine whether or not Tier 2 testing is necessary for a particular substance, the Tier 1 screening data may also be used to determine what kind of Tier 2 data is appropriate, and whether or not similar substances might share common mechanisms. Subsequently, when used with the Tier 2 testing data, the Tier 1

1 To access the procymidone decision, go to http://www.epa.gov/pesticides/reregistration/procymidone/.
2 To access the vinclozolin decision, go to http://www.epa.gov/pesticides/reregistration/vinclozolin/.

screening data will become a part of the risk characterization of a pesticide that is intrinsic to FIFRA and FFDCA decisions.

The tiered approach for screening (Tier 1) and testing (Tier 2) that EPA is using under the EDSP is the most cost-effective and least burdensome approach for complying with the statutory mandate to screen all pesticides for endocrine disruptor effects. Instead of requiring that all pesticides undergo the testing that would be necessary to determine (a) whether the substance causes adverse endocrine-related effects, (b) identify the adverse endocrine-related effects caused by the substance, and (c) establish a quantitative relationship between the dose and the adverse endocrine-related effect, EPA determined that it would be more efficient (and would use fewer animals) to conduct the less expensive and less complex Tier 1 screening to identify those substances that have the potential to interact with the estrogen, androgen and thyroid hormone systems.

The paperwork related requirements imposed on the respondents as part of Tier 1 screening under the EDSP allow EPA to ensure that the identified screening data will be developed, that the results will meet basic scientific standards, that unforeseen complications or issues can be promptly addressed, and that the screening is progressing on schedule so that the data will be available for consideration in time for anticipated regulatory decisions as required under FIFRA and FFDCA.

Within the Office of Prevention, Pesticides and Toxic Substances (OPPTS), the Office of Pesticide Programs (OPP) and the Office of Science Coordination and Policy (OSCP) will be responsible for issuance of the Orders, receiving, processing and maintaining records of responses to the Orders, as well as other administrative functions related to the Orders. OSCP and OPP will coordinate the review of Tier 1 screening data received and resulting determinations related to the subject chemical.

As indicated previously, this ICR only applies to Tier 1 screening. A subsequent ICR will address Tier 2 testing. Tier 2 is discussed here only in the context of the use of Tier 1 data.

3. NON-DUPLICATION, CONSULTATION, & OTHER COLLECTION CRITERIA

3(a) Non-duplication

The information collected under this program is collected by no other federal agency or any other office within EPA. FFDCA specifically assigns this task to EPA. As described above, this information is required for EPA's evaluation of endocrine disrupting effects and of the health and environmental effects and economic benefits associated with the use of chemicals and pesticides that are shown to have ED effects. The EDSP is the only program in the United States mandated to validate assays and require testing of chemicals for their potential to disrupt the endocrine system. Prior to the passage of the FQPA and initiation of EDSP, there were no validated methods to screen or test chemicals for their potential to affect the endocrine system.

The Agency has a strong commitment to avoiding potential duplication in all of its testing programs, and actively promotes efficiency through its harmonized test guidelines and active participation in the rigorous scientific effort to identify data needs for risk assessments, develop testing protocols, and develop new methods for testing chemicals that minimize potential duplication, create greater efficiencies in testing, and minimize the use of animals in testing.

As a charter member of the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM), EPA is working in a manner consistent with the interagency validation framework in the development and refinement of assays to reduce animal use, refine procedures involving animals to make them less stressful, and replace the use of animals in tests where scientifically appropriate. When complete, EPA will use these validated methods or assays to identify and characterize the endocrine activity of pesticides, commercial chemicals, and environmental contaminants, specifically in relation to estrogen, androgen, and thyroid hormones.

The Agency considered these goals in developing the procedures for the EDSP, both those procedures used within EPA and those that might be used by the respondents. For example, when a chemical is manufactured by several companies, the procedures encourage the companies to join together to develop and submit the requested data to EPA. In addition, Order recipients and other interested stakeholders will be able to cite existing or submit other scientifically relevant data that they believe meet the screening requirements defined in the Order. This is described in more detail in the Policy and Procedures Document (Attachment B).

3(b) Public Notice Required Prior to ICR Submission to OMB

On December 13, 2007, EPA published a notice in the **Federal Register** to provide a 60-day public notice and comment period on the draft ICR (Ref. 8). EPA received comments from 11 entities, and has prepared a Response to Comment document that can be found in Attachment H. Several changes were made to the ICR in response to public comments, ranging from language changes to increase overall understanding to specific changes in the burden activities and estimates. The substantive changes are highlighted in this section.

Several commenters felt that the ICR needed to include the cost and burden for the potential need to conduct analytical chemistry tests on the substance to be tested. Recognizing that this test is a standard prerequisite to conducting any tests on a particular substance because it is used to define the substance being tested, EPA has added this element and the related cost and burden to this ICR.

Several commenters asserted that the estimated test costs used to calculate data generation burden appeared to be low because it is not clear whether the estimates considered the final protocols. Since the Tier 1 screens are still new and are not yet provided by the commercial laboratories, more refined cost estimates are simply not available at this time. Nevertheless, EPA has increased the estimated test costs

used to calculate data generation burden, and intends to conduct a thorough evaluation of the test costs as part of its evaluation of the Tier 1 process established for the initial screening of chemicals under the EDSP.

To facilitate completion of the initial response within the 90 days, EPA revised the Initial Response Form to more clearly identify the response options for the two different kinds of entities that might receive an Order, and created a new Initial Response Form for the Consortium. There are now two Forms (see Attachment D) - One form is for use by the Individual Order recipient and the other is for use when a Consortium provides their group's response. EPA intends to include both of the Initial Response Forms in the EDSP Order Packet that is sent to the recipients.

Other changes are identified within the Agency's responses to the comments (see Attachment H).

3(c) Consultations

Since the establishment of EDSP in 1998, EPA has consulted with various stakeholders throughout its development and implementation efforts, including: agrichemical and commodity chemical industries, environmental organizations, public health organizations, academia, animal welfare organizations, state governments, and federal agencies, including consultation with the Department of Health and Human Services. A historical overview of the external consultations and public comment opportunities provided since 1996 is available at http://www.epa.gov/scipoly/oscpendo/pubs/edspoverview/index.htm.

In addition to the solicitation of public comment on the Agency's draft policy and procedures for implementing the EDSP (Ref. 6), the draft List (Ref. 4), and the draft ICR (Ref. 8), EPA held two public workshops with interested parties. The workshops provided an opportunity for the Agency and stakeholders to discuss comments and questions about the draft policy, procedures and this ICR, as well as share ideas and information about potential improvements. These workshops contributed to improvements in this ICR.

3(d) Effects of Less Frequent Collection

Once per chemical substance is the statutory minimum, because FFDCA section 408(p)(3) specifically requires that EPA "shall provide for the testing of all pesticide chemicals," unless the Agency can determine that the chemical qualifies for the statutory exemption—i.e., that it is not anticipated to interact with the endocrine system.

In addition, a recipient of an Order for Tier 1 screening may provide an initial response that could justify delaying Tier 1 screening or, although expected to be rare for the initial group of chemicals, allowing the company to go directly to Tier 2. The Agency will consider any such requests on a case-by-case or chemical-by-chemical basis and will provide a written response that will be made publicly available. In some cases, the

Agency's response to an individual requester may be applicable to all Order recipients for that chemical or could otherwise provide insight to recipients of Orders for other chemicals.

For purposes of this ICR, the Agency assumes that all recipients of an Order for Tier 1 screening will provide an initial response and either generate the data or join a consortium to generate the data, while the submission of a progress report and the data will occur only once per chemical.

3(e) General PRA Guidelines

The one general PRA guideline that is exceeded by this collection is the time period for retaining records. When data are generated to support a pesticide registration under FIFRA, EPA requirements in 40 CFR 169.2(k) apply, which state that records containing research data relating to registered pesticides be retained for as long as the registration is valid and the producer remains in business. Registrations are valid until they are either voluntarily cancelled or withdrawn by the registrant or until EPA has cause to suspend or cancel the registration. Since the average period of marketability of a pesticide ranges from 15 to 30 years, the PRA guidelines specifying that data other than health, medical or tax records not be required to be retained for more than three years will be exceeded in this ICR.

In those regulatory cases where the Agency's action may be challenged, it is imperative that all records, raw data, and specimens be available. Recognizing this, the recordkeeping requirements in 40 CFR part 169 were authorized to exceed the PRA general guidelines when they were established. Those requirements are being adopted unchanged under the EDSP for these chemicals because the data submitted would be used to support pesticide registration related decisions under FIFRA and FFDCA.

3(f) Confidentiality

In general, most health and safety data submitted by registrants, manufacturers, and importers under FFDCA are considered to contain no Confidential Business Information (CBI). Although FFDCA §408(p)(5)(B) requires that EPA develop, to the extent practicable and as necessary, procedures for the handling of confidential business information, it does not provide the authority for the Agency to either create new rights or to modify existing rights to confidentiality. Rather, EPA believes that this provision directs the Agency to create procedures that operate within the existing confines of FIFRA §10, the Freedom of Information Act (FOIA), and the Trade Secrets Act.

As discussed in more detail in the Policy and Procedures Document (Attachment B), because the data would support a tolerance or exemption from the requirement of a tolerance, FFDCA §408(i) provides that much of the data submitted in response to an Order issued under FFDCA §408(p) would be subject to the protections in FIFRA §10. In addition, CBI submitted by pesticide registrants in response to an Order issued under

FFDCA §408(p) would be considered as part of the registration process, and would therefore be considered to be data submitted in support of a registration. However covered, data subject to FIFRA §10 would be provided certain protections that go beyond those authorized by FOIA. For example, FIFRA §10(g) generally prohibits EPA from releasing information submitted by a registrant under FIFRA to a foreign or multinational pesticide producer, and requires the Agency to obtain an affirmation from all persons seeking access to such information that they will not disclose the information to a foreign or multinational producer. FFDCA §408(i) extends the protection available under FIFRA §10 for data submitted in support of a tolerance or tolerance exemption.

All other confidential business information submitted in response to an Order issued under FFDCA §408(p) (i.e., data not in support of a registration or tolerance/tolerance exemption) is only protected by the provisions of FOIA and the Trade Secret Act. 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]. Note that substantive criteria must be met to claim confidentiality of business information, as specified in 40 CFR §2.208.

EPA would consider that data submitted jointly with a registrant, or as part of a consortium in which pesticide registrants participate, to be data submitted in support of a tolerance/tolerance exemption or registration, and therefore entitled to protection under FIFRA §10. However, if a non-registrant chooses not to partner with a registrant, such data would only be subject to the protections available under FOIA and the Trade Secrets Act.

3(g) Sensitive Questions

No information of a sensitive or private nature is requested in conjunction with this information collection activity. Further, this information collection activity complies with the provisions of the Privacy Act of 1974 and OMB Circular A-108.

4 THE RESPONDENTS AND THE INFORMATION REQUESTED

4(a) Respondents

Respondents to this ICR consist of those individuals and companies that receive an Order issued under FFDCA §408(p) by the Agency to collect Tier 1 screening data under the EDSP. Under FFDCA §408(p)(5)(A), EPA "shall issue" Orders "to **a registrant** of a substance for which testing is required . . . **or to a person who manufactures or imports** a substance for which testing is required." EPA has generally identified the following categories of potential recipients of the Tier 1 Orders:

- Registrants - Entities who manufacture or import a pesticide active ingredient or inert ingredient and hold an active EPA registration for that substance. In the pesticide universe, there are *Technical Registrants (basic manufacturers)* and *End-Use Registrants (customers).* A *Technical Registrant* manufactures or imports the active ingredient or inert ingredient that is, in most cases, used in the formulation of other pesticide products. An *End-Use Registrant* manufactures or imports the end-use product that contains an active ingredient or an inert ingredient that they obtain from a technical registrant. Although the *Technical Registrant* can also be an *End-Use Registrant*, the Agency's focus for purposes of the Tier 1 Orders is on the *Technical Registrant*.

- *Manufacturers/Importer* – Persons who manufacture or import a chemical substance but do NOT hold an EPA registration for that substance. For the most part, the chemical substances may be used as an inert ingredient in a pesticide, but also have other non-pesticidal uses.

The Agency used the following North American Industrial Classification System (NAICS) codes to obtain publicly available information about potential respondents that informed the estimates presented in this ICR:

- Chemical Manufacturers 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. This includes Producers & Formulators of Pesticide Products (NAICS code 32532); Producers of Antifouling Paints (NAICS code 32551); Producers of Antimicrobial Pesticides (NAICS code 32561); and Producers of Nitrogen Stabilizers (NAICS code 32531).

- Scientific research and development services (NAICS code 5417), e.g., persons who conduct testing of chemical substances for endocrine effects. These entities will not receive Orders, but their potential involvement in responding to paperwork activities did inform the estimates presented in this ICR.

Although final identification of all the specific individual recipients for the Tier 1 Order for each of the initial chemicals will not be finalized until the Orders are being prepared for final issuance, the Agency has updated the preliminary searches completed for the draft ICR in 2007. Specifically, the Agency searched internal data sources to identify potential recipients, or respondents for the purposes of estimating the burden in this ICR. For example, the Agency used internal OPP data sources to identify the technical registrants and the end-use product registrants for pesticide active ingredients on the initial list, and used the data from the TSCA Inventory Update Rule (IUR) database to identify manufacturers and importers of the HPV chemicals identified as inert ingredients on the initial list. It is important to note that the IUR data are based on reports from companies that domestically manufacture or import the chemical in quantities greater than 10,000 lbs/yr at a single site in 1998 and 2002 and in quantities greater than 25,000 lbs/yr at a single site in 2006. Since such thresholds do not exist

for EDSP, the use of IUR data may not have identified everyone that should receive a Tier 1 Order. As such, when the Agency identifies the final recipients of the Tier 1 Order, it intends to also search a few external public sources of information in an attempt to identify other manufacturers and importers of the listed chemicals. For this same reason, the Agency has increased the number of potential respondents used for calculating the burden and cost in this ICR, as discussed later in this section.

For purposes of calculating the number of potential respondents for this ICR, the Agency divided the respondents into three categories: 1) Order Recipients; 2) Data Generators/Submitters; and 3) Consortium Participants. The Order Recipients category includes everyone that could receive an Order issued under FFDCA §408(p) for these chemicals; the Data Generators/ Submitters category includes one company for each chemical; and the Consortium Participants category includes the Order recipients that are not in the Data Generators/Submitters category. Table 1 presents the estimated number of respondents based on the Agency's efforts to date to identify potential Order recipients.

In addition to the Order recipients identified by the Agency, EPA may issue an Order under FFDCA §408(p)(5) to a manufacturer or importer who enters the marketplace after the issuance of the initial Orders and when they begin to sell an inert ingredient following the submission of required EDSP data on the ingredient by manufacturers or importers who were in the marketplace when the initial Orders were issued. The Agency refers to these as "catch-up" Orders. As with the initial Order issued under FFDCA §408(p), recipients of a "catch-up" Order could fulfill the testing requirement either by submitting the results of a new study or by citing the data submitted by another person. In furtherance of the goal of "fair and equitable sharing of test costs," the Agency would accept citation of existing data only if the recipient either had the original data submitter's permission or the recipient had made an appropriate offer to pay compensation to the original data submitter that also determined how disputes would be resolved.

At this time the Agency has no way to predict or estimate the number of potential recipients for these "catch-up" Orders. For purposes of estimating the burden in this ICR, the Agency is estimating that up to 20 entities might receive such "catch-up" Orders in any one year. Since such Orders will be issued after the original Orders have been issued, the recipients of such Orders will probably either join an existing consortium or provide data compensation to the data generator, rather than generate and submit the data on their own. EPA will monitor the issuance of such "catch-up" Orders and the corresponding responses during the approval of this ICR. If it appears necessary to increase this estimate during that period, EPA will submit an Information Correction Worksheet to OMB to adjust the total approved burden accordingly.

Table 1 - Estimated Number of Potential Order Recipients (Respondents)

Potential Respondent Category	Estimated Number of Respondents			
	Pesticide Registrants	Manufacturers/ Importers	Catch-Up Orders	Total
Order Recipients	207	163	20	390
Data Generators/Submitters	58	9	0	67
Consortium Participants	149	154	20	323

The estimated total number of potential respondents is 390.

4(b) Respondent Activities

Each respondent, or recipient of an Order issued under FFDCA §408(p), is expected to engage in the following activities:

(1) *Read instructions* – Each recipient of an Order issued under FFDCA §408(p) will need to read the Order to understand what they must do to comply with the Order, what deadlines are associated with those activities and the details of how and who to respond to. Depending on the recipients familiarity with the EDSP, the respondent may also want to read other information about the EDSP, such as the Policy and Procedures Document that formed the basis for the requirements in the Order and describes the specific details of the policies and procedures that EPA generally intends to adopt for initial screening under the EDSP, including the statutory requirements associated with and format of the Orders issued under FFDCA §408(p), as well as EPA's procedures for fair and equitable sharing of test costs and handling confidential data.

To illustrate what an Order recipient might expect to receive in terms of instructions that they must follow to comply with the Order, the Agency provided draft templates for the two different kinds of Orders that the Agency intended to use. After considering public comment on the related procedures and the changes made to it to address comments, EPA revised the two templates. (See Attachment C). The two templates, one for Pesticide Registrants, and the other for Manufacturers/Importers, are similar in most respects, differing only to the extent necessary to reflect the necessary differences as articulated in the Policy and Procedures Document. Although the Agency intends to use these templates as presented in Attachment C, the individual Orders will contain the necessary requirements for the subject chemical. As such, the final individual chemical Orders may vary.

(2) *Plan activities* – After reading the Tier 1 Order they received, the recipient will need to plan the activities necessary to comply with the Order based on their determination regarding their intended response and whether they are interested in forming a consortia with other manufacturers of the chemical or conducting the tests themselves.

(3) Submit an initial response to EPA – The Tier 1 Order will direct each recipient to provide an initial response to EPA within 90 days of the issuance of the Order that indicates how they intend to comply with the Order. To simplify completion of this initial response within the 90 days, EPA has created an **Initial Response Form for Individual Order Recipients** (See Attachment D – (1)). EPA intends to include this form in the Order packet, pre-populated with the basic information about the recipient, the chemical covered, and the applicable test data sought. The recipient of the Order packet would complete the form by checking the appropriate boxes to indicate their intentions with regard to each assay listed in the Order, and, if applicable, attach appropriate documentation to provide a rationale and/or supporting documentation for

their response. The response is assay specific to provide maximum flexibility to the recipients who may wish to choose different response options for the individual assays identified in the Order. An Order recipient may elect any of these options for one or more of the assays in the Order, and is not limited to electing a single response for all assays, nor are they required to elect different options for each assay. For simplicity, however, the Response Form is structured so that recipients indicate their responses on an assay-by-assay basis – even if the response is the same for more than one of the assays. For example, the recipient may submit or cite existing data to address one or more assay, indicate that they will generate the data for one or more assay, and/or indicate that the intend to form or join a consortia to provide the data for one or more of the other assays identified in the Order.

If the recipient intends to form or join a consortium (or task force) with other manufacturers of the chemical to provide the data for one or more of the assays identified in the Order, each consortium participant or potential participant is expected to submit an **Initial Response Form for Individual Order Recipients** within 90 calendar days. Within 150 calendar days of issuance of the Order, or as part of their initial response, the designated lead for the consortium is expected to submit the **Initial Response Form for Consortium /Task Force** (Attachment D – (2)) 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 various response options available to a recipient, along with related activities they may engage in that are specific to that response option are described in section 4(c)(i) of this ICR.

(4) *Read and discuss the protocol* – The Order recipients will need to read the protocols for the assays identified in the Order and may have questions or may need to modify one or more of the protocols for the subject chemical. An Order recipient wishing to deviate from any of the protocols identified in the Order, may do so only after consultation with EPA. Such requests should be submitted to EPA with a clear rationale and explanation of the deviation. All protocol variations will be reviewed by EPA and a response will be sent to the specific Order recipient in a timely fashion. These procedures are consistent with current EPA practices regarding pesticide test guidelines and the data requirements in 40 CFR parts 158 and 161. Although this activity is expected to be primarily performed by the data generating entity, other participants in a consortium may also participate in these discussions.

If the Order recipient chooses to submit or cite existing data, including other scientifically relevant information, this discussion would be focused on whether the data provided or cited 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). Such recipients will be expected to provide a cogent and complete rationale for why they

believe the information is sufficient to satisfy part or all of the 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.

In addition, the Order recipient is expected to comply with the Agency's good laboratory practice (GLP) standards described in 40 CFR part 160, which require entities to follow certain practices when conducting studies, and, with the submission of data to EPA, to 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.

(5) *Generate the data* – As indicated by the initial response, some recipients will conduct the research or administer the tests to generate the data requested in the Order.

For the purposes of calculating paperwork burden hours and costs in this ICR, EPA assumed that the data generation will not be directly performed by the Order recipient. Instead, EPA assumes that data generation will be performed by a contract laboratory at the request of the Order recipient or a consortium. The Agency has no information to estimate how many recipients might use a contract laboratory and how many might generate the data in house. Assuming that data will always be generated by a contract laboratory is consistent with the assumption used in other ICRs that involve data generation. In addition, as indicated by one of the commenters on the ICR, many companies now outsource toxicology testing because it is less expensive than maintaining that function in-house (Ref. 9, p.5). Nevertheless, only those activities imposed by the information collection request are attributable to this ICR. For example, the travel time and costs for the contract laboratory staff to travel to meet with the contracting company is not an activity imposed by the information collection request and is therefore not attributable to the ICR. Nor are any costs or burden related to mistakes made by the contract laboratory, such as failure to properly follow an applicable protocol, which then requires the contract laboratory to redo the screening assay.

(6) *Report progress, compile and review the data* – Unless EPA has notified a recipient in writing that the requirements of the Order have been satisfied, the Order recipient will be expected to submit a progress report to EPA within 12 months after the issuance of the Order. The progress report should provide a brief description of the status of the 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.

(7) *Complete paperwork to assemble the submission package* - Those Order recipients that generate the data or serve as the consortium lead will be expected to compile the data results from performing the assay(s), review the data for completeness and compliance with GLPs, and assemble the submission package in accordance with the instructions provided in the Order. In general, these are the same submission procedures as those that are currently used for submitting other data in support of a pesticide registration, with only a few modifications – such as the mailing address.

(8) *Submit final data to EPA* – The final data package is then submitted to EPA following the specific instructions provided in the Order, which will also specify the due date for final compliance with the Order's request for data. Although the Order specifies a final due date for submission of all of the data specified in the Order, an Order recipient may either submit the data for each individual assay as it is completed, or submit the data from all of the assays at one time. The Order recipient may also submit the data before the due date specified in the Order.

(9) *Maintain records* - Recipients will be asked to maintain a record of their initial response for three (3) years, and recipients who submit data will be asked to maintain records pursuant to 40 CFR 169.2(k), i.e., containing research data relating to a registered pesticides for as long as the registration is valid and the producer remains in business.

For purposes of estimating the potential respondent paperwork burden and costs associated with these activities, the Agency identified three separate categories of duties: 1) managerial; 2) technical; and 3) clerical. Each activity identified above may involve one or more duty category. In Table 2, the Agency identifies the assumed recipient activities divided between the three duty categories.

Table 2 – Expected Order Recipient Activities by Burden Categories
(assumes initial response is to generate the data)

Activity	Managerial Duties	Technical Duties	Clerical Duties
(1)	Read EPA's Policy and Procedures Document	Read EPA's Policy and Procedures Document	
	Review the EDSP Order	Review the EDSP Order	
(2)	Identify timeframe for response		
	Identify & evaluate response options	Evaluate response options	
	Plan activities		
	Negotiate/establish consortium/ task force agreements	Participate in consortium/ task force discussions	
(3)	Determine response	Recommend a response	
	Oversee employee activities		Complete response form
	Sign initial response forms		Send to EPA
(4)	Communicate with EPA	Review of protocol (deviations)	Arrange logistics for calls or meetings with EPA
		Review GLPs (deviations)	
		Identify & discuss other scientifically relevant information & related protocol &/or GLP deviations	
(5)	Plan/oversee employee and contract activities	Plan the data collection activities using the approved protocols	
	Secure contract lab services and approve statement of work (SOW)	Conduct the tests, using protocols & GLPs	
	Communicate with EPA, as appropriate	Maintain records and procedures during testing period in accordance with the GLPs	Assist in preparing files
(6)	Review final report(s)	Compile & review data	

Activity	Managerial Duties	Technical Duties	Clerical Duties
		Prepare final data reports	
(7)	Approve final submission package	Draft summary of the data for cover letter	Prepare final submission package
		Review final submission package	
(8)	Approve/sign submission		Send submission to EPA
(9)		Prepare data for files	Prepare final file folders
			Maintain records

4(c) Information Requested

This section of the ICR describes the information that an Order recipient is expected to provide the Agency. In general, all Order recipients are expected to provide an initial response (with information associated with that response when applicable), and those recipients that generate data, either individually or as part of a consortium, are expected to provide a 1 year progress report and submit data to EPA.

The Order will identify the specific Tier 1 data being requested and will provide the specific instructions for complying with the Order. All Order recipients are expected to provide an initial response that identifies how the recipient intends to respond to the Order. The specific information requested with the initial response from each Order recipient will vary based on the respondent's initial response – the options for which are described in section 4(c)(i) of this ICR. For purposes of this ICR, however, it is important to clarify that many of the initial response options already exist within the pesticide program, e.g., for Data-Call-Ins under FIFRA 3(c)(2)(B). In providing the option as described in more detail in the Policy and Procedures Document (Attachment B), the Agency is adopting those existing procedures unchanged for use under the EDSP. Under those existing procedures, a registrant may engage in additional activities associated with that response option. For example, a respondent/registrant could choose to reformulate the product or seek a formulator's exemption. Both of these initial response options involve established procedures, and additional activities that are already approved by OMB under separate existing ICRs. The Agency believes that any additional use of those existing procedures related to the EDSP do not impact the estimated burden covered by the existing ICRs. As such, this ICR does not duplicate the burden associated with the response options that involve existing procedures that are already covered by another ICR.

4(c)(i) Order Recipient's Response Options

As described in more detail in the Policy and Procedures Document (Attachment B), the recipient of an Order will have several potential response options, as specified within the Order itself. The recipient uses the **Initial Response Form for Individual Order Recipients** (see Attachment D – (1)) to indicate which option they intend to use to respond to the data request for each assay. The response is assay specific to provide maximum flexibility to the recipients who may wish to choose different response options for the individual assays identified in the Order. An Order recipient may elect any of these options for one or more of the assays in the Order, and is not limited to electing a single response for all assays, nor are they required to elect different options

for each assay.

The recipient of the Order packet would complete the form by checking the appropriate boxes to indicate their intentions with regard to each assay listed in the Order, and, if applicable, attach appropriate documentation to provide a rationale and/or supporting documentation for their response.

The following is a description of each of the available response options (see also Attachment E, which provides an overview of the response options in a workflow format):

(1) I Will Generate New Data. The recipient would choose this option to indicate that they agree to individually generate new data for each test specified to meet the requirements of the Order. In the case of data pertaining to an inert ingredient for which there is no tolerance or exemption, the recipient may identify a "cooperating registrant/agent" for EPA (e.g., to whom EPA could send a DCI notice under FIFRA §3(c)(2)(B) or identify on the recipient list). The cooperating registrant/agent would then become jointly responsible for generating and submitting the data. This is different from a consortium, which is discussed later.

(2) I Am Citing or Submitting Existing Data. The recipient would choose this option to submit or cite existing data (including other relevant scientific information) that they believe can be used to satisfy part or all of the Tier 1 Order. Existing data may be of several types. An example may be an *in vitro* assay for transcriptional activation that is conducted with a different cell line and by a different protocol. But more generally, existing data may be "other scientifically relevant information." Other scientifically relevant information can include data from studies other than the EDSP Tier 1 assays, e.g., studies conducted to satisfy a 40 CFR part 158 or part 161 data requirement, data from other studies conducted to address an identified issue, or data from studies found in the scientific literature. In addition to the Tier 1 Order recipient, anyone can submit other scientifically relevant information. To allow EPA to review the submission of other scientifically relevant information in a timely fashion, the submitter of the information should consider providing a scientifically sound rationale that explains how the submitted or cited data provides the information needed to satisfy part or all of the Tier 1 Order and/or otherwise inform the Agency's Tier 1 determination.

The submitted or cited study should 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, will need to 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 the submitter thinks the Agency should consider in deciding whether to accept the data in satisfaction of the Order.

If EPA has previously reviewed a protocol for a study that is being submitted or cited, the submitter needs to 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 a study that has been previously submitted to EPA is cited, that study must have been 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. When citing something that was previously submitted, the Agency needs a copy of the title page along with the identification number of the study cited (MRID number), and, if the study has been reviewed by the Agency, the Agency's classification of the study. **The Agency specifically asks that a study that has previously been submitted to EPA NOT be resubmitted for another purpose.**

EPA will review any existing study submitted or cited in response to the Order to determine whether the study is of sufficient quality and can be used to satisfy the Order. The Agency intends to notify submitters in writing of its determination, as well as make the determination publicly available.

If the individual citing a study is not the original data submitter, that individual may need to submit an offer to pay compensation to the original data submitter. Consequently, such individuals are encouraged to 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 the individual has received confirmation from EPA that no such compensation is necessary.

(3) I Will Enter (or Offer to Enter) Into an Agreement to Form a Consortium to Generate the Data. The recipient would choose this option to indicate that they are forming a task force or consortium to comply with the Order. In such cases, each participant or potential participant is expected to submit an **Initial Response Form for Individual Order Recipients** within 90 calendar days. Within 150 calendar days of issuance of the Order, or as part of their initial response, the designated lead for the consortium is expected to submit the **Initial Response Form for Consortium /Task Force** (Attachment D – (2)) 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.

Alternatively, an Order recipient may provide EPA with documentation that they made a judicially enforceable offer to enter into an agreement to develop data jointly with one or more recipients of the Order and that they offered to pay a reasonable share of the test costs (or developed a process for resolving disputes with regard to the appropriate share of test costs). If the required data are not generated by the person(s) to whom the offer is made, all parties, including those that have made offers to pay or

otherwise joined the consortium, would be responsible for generating and submitting the data.

(4) Claim Not to be Subject to the Test Order. The recipient would choose this option to indicate that they are not subject to the Order because:

(i) In the case of a Tier 1 Order involving a pesticide active ingredient, the recipient is not a pesticide registrant, or

(ii) In the case of an initial Tier 1 Order that involves a pesticide inert ingredient, the recipient does not currently manufacture or import the chemical, or

(iii) In the case of a "catch-up" Order, the recipient obtains the chemical solely from persons who are either (1) the original data submitter; (2) a person who has complied with a Tier 1 Order by offering compensation; or (3) a person who is otherwise an approved source for the pesticide inert ingredient.

The recipient's initial response would include an explanation and documentation supporting their claim to allow EPA to evaluate the claim. If EPA can not verify the claim, the recipient is still subject to the Order and the deadline(s) for responding remain.

(5) I Intend to Voluntarily Cancel or Reformulate the Product Registration. This option is only available for pesticide registrants. Registrants may request voluntary cancellation of their product's pesticide registration pursuant to FIFRA section 6(f). Doing so would initiate the existing procedures for a voluntary cancellation. Under those procedures, the registrant may either adopt the standard procedures for sale or use of existing stocks of their pesticide, or may propose an alternative procedure. Alternatively, in the case of an inert ingredient, a registrant of an end-use product may submit an application to amend the formulation of its product by removing the ingredient that is the subject of the Tier 1 Order. This is all accomplished through the submission of an application to amend the registration following the established procedures. In general, EPA's policy does not include the issuance of orders under FFDCA §408(p) to registrants of end-use products.

(6) I Claim a Formulators' Exemption. A product registrant who receives an Order to test a chemical who purchases the chemical from another recipient who has agreed to generate the data may be eligible for a formulators' exemption, but exercise of this option may depend on the authority under which the Order is issued. If EPA were to rely solely on FIFRA 3(c)(2)(B), the option would not be available for Orders to test an inert ingredient since manufacturers and importers would not be subject to a FIFRA order. Such a claim would initiate the existing procedures for formulators' exemption. EPA will confirm claims of eligibility. A formulators' exemption would become invalid if the supplier of the chemical were not to submit the data either individually or jointly with other recipients.

(7) I Have or Am in the Process of Discontinuing the Manufacture/Importation of the Inert Ingredient. This option is only available for pesticide inert ingredients. The recipient of an Order for a pesticide inert ingredient (i.e., manufacturer/importer) would

choose this option to indicate that they have already or are in the process of discontinuing the manufacture or import of the chemical. The recipient's initial response would include an explanation and documentation supporting their claim. EPA intends to verify such a claim. If EPA confirms the claim, the Initial Response Form is the only response required to satisfy the Order. If, however, EPA determines that the claim is false, the recipient must comply with the Order.

(8) I Will Not Sell the Chemical for Use in Pesticide Products. This option is only available for pesticide inert ingredients. The recipient of an Order for a pesticide inert ingredient (i.e., manufacturer/importer) would choose this option to indicate that they do not currently or agree to no longer sell their chemical for use in the pesticide market. To elect this option, the Order recipient would indicate, as part of its initial response, that they commit to discontinue, on or before a date six months after the issuance of the Tier 1 Order, all sale and distribution of the chemical to any person who the recipient knows, or reasonably should know, intends to use the chemical in the formulation of a pesticide product. The Order recipient would also indicate that it will include in all contracts for sale or distribution of the material a provision that contractually prohibits the purchaser from using the substance in the formulation of a pesticide product. As part of its initial response, the Order recipient would be asked to provide a copy of the contract provision and a certification to include this contractual provision in any contracts entered into on or after a date six months after the issuance of the Tier 1 Order.

(9) Request an exemption under FFDCA section 408(p)(4). FFDCA section 408(p)(4) provides that "the Administrator may, by order, exempt from the requirements of this section a biologic substance or other substance if the Administrator determines that the substance is anticipated not to produce any effect in humans similar to an effect produced by a naturally occurring estrogen." For the initial screening, EPA is not aware of sufficient data that would allow the Agency to confidently determine that a chemical meets the statutory standard for an exemption--i.e., that it is not anticipated to interact with the endocrine system. Although a relatively broad range of toxicity data are available for pesticide active ingredients regulated under FIFRA, in most cases EPA has not yet established how the available data might be confidently used to predict the endocrine disruption potentials of these chemicals. This may be due to the non-specific nature of an effect or effects observed, questions related to whether the mode of action in producing a given effect or effects is or are endocrine system-mediated in whole or in part, or the lack of relevant data to make a judgment altogether.

However, if an Order recipient believes that this showing can be made for its chemical, the Agency would consider requests to issue such an exemption order on a case-by-case or chemical-by-chemical basis in response to individual submissions. In order for the Agency to make the necessary statutory finding to issue the exemption, the request would need to provide any hazard-related information that you believe would allow EPA to determine that your chemical is anticipated to not be an endocrine disruptor, i.e., is not anticipated "to produce any effect in humans similar to an effect produced by a naturally occurring estrogen."

(10) Other initial responses. a). Pre-enforcement challenges to a Tier 1 Order. A recipient may wish to challenge the Tier 1 Order. The Order will describe the informal

process by which a recipient may raise, and EPA may review, objections to the issuance of an Order or to specific provisions in the Order. For EPA to be able to respond to the objections in a timely manner, the recipient would need to state with particularity the scope and basis of the objection, providing sufficient detail to allow the Agency to evaluate the objection.

b). Additional EDSP screening is unnecessary because the chemical is an endocrine disruptor or was used as a "positive control" in the EDSP validation effort. If an Order recipient chooses to ask EPA to reconsider some or all of the testing specified in the Tier 1 Order, EPA would review the request, along with the appropriate information supporting the claim that additional EDSP screening of the chemical is unnecessary because the chemical is an endocrine disruptor or was used as a "positive control" in the EDSP validation effort, on a case-by-case basis. Based on the information currently available, EPA generally expects that if the chemical was used by EPA as a ''positive control'' to validate one or more of the screening assays, only the data submitted related to those assays for which the chemical was used to complete the testing as part of the validation effort would be sufficient to satisfy the Tier 1 Order.

4(c)(ii) Progress Report

Unless EPA has notified the Order recipient in writing that the requirements of the Order have been satisfied, the Order recipient must submit a progress report to EPA within 12 months of the issuance of the Order (the specific due date will be identified in the Order). The progress report should provide a brief description of the status of the respondent's 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.

4(c)(iii) Extension Requests

If a recipient cannot comply with the time frame established in the Order (see section 5(d) of this ICR), they may seek additional time by submitting a written request to the Agency before the applicable deadline. The written request must include: (1) a detailed description of the expected difficulty and (2) a proposed schedule including alternative dates for meeting the requirements of the Order. If the delay is based on technical or laboratory difficulties, recipients are expected to explain any technical or laboratory difficulties and provide documentation from the laboratory performing the testing.

While EPA is considering any such request, the original deadlines in the Order remain unchanged. The Agency will respond to such requests in writing because extensions can only be granted in writing. If EPA does not grant the 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.

4(c)(iv) Data Generation

The Tier 1 Order will request specific data on how the chemical substance interacts with the estrogen, androgen, or thyroid hormone systems using a battery of assays. The Tier 1 screening battery is intended to identify chemicals affecting the estrogen, androgen, or thyroid hormone systems through any of several recognized modes of action. The proposed Tier 1 screening battery underwent peer review by the FIFRA Scientific Advisory Panel (SAP) in March 2008. The SAP concluded that the proposed battery of assays was adequate to begin screening chemicals to detect the potential for interaction with the estrogen, androgen or thyroid (EAT) hormonal systems. For more information about the FIFRA SAP review of the Tier 1 screening battery, go to http://www.epa.gov/scipoly/sap/meetings/2008/032508_mtg.htm.

The availability of the final Tier 1 screening battery will be announced in the Federal Register before any Tier 1 Orders will be issued. Until that is done, this ICR and the Order Templates in Attachment C only provide the list of assays that **are expected to be** in the battery. In doing so, the Agency has identified the universe of assays that might be included in the final Tier 1 battery. The Agency may, however, not include all of these assays in the final Tier 1 battery, or may otherwise decide to only include a subset of these assays in an individual Tier 1 Order that is issued under the EDSP for a particular chemical and respondent. For example, the Agency may determine that only a subset of the assays are necessary to inform the Agency's Tier 1 determination for a particular chemical. In the event that the Order does not include all of these assays, it will always include a subset of these assays. In other words, the Tier 1 Order would not include assays that are not identified on this list.

In addition, recipients of the Tier 1 Order will generate the data using the test protocols identified in the Order or provided by EPA, unless the recipient discusses and EPA approves an alternative test protocol. This is already discussed previously in this ICR.

The following is a list and brief description of each of the assays that are expected to be part of the final Tier 1 battery:

1. *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.

2. *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.

3. *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.

4. *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.

5. *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.

6. *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.

7. *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.

8. *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.

9. *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.

10. *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.

11. *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.

For purposes of estimating the potential burden for the Tier 1 screening information collection activities covered by the ICR, the Agency is assuming that each Tier 1 Order will include all of the above listed assays. By assuming that each Order

will include all of these assays, the ICR provides coverage for those cases where the Order may not include all of the assays.

4(c)(v) Data Submission

As described in more detail in the Policy and Procedures Document (Attachment B), the data submission content and format under the EDSP is based on that used currently for other pesticide data submissions. Since the initial chemicals involve pesticides and pesticide inerts, EPA believes that doing this helps to minimize the potential burden because the Order recipients are likely to be familiar with the existing requirements. As such, the content and format of the data submission package for transmittal to EPA should be consistent with the following existing standards, which are expected to be incorporated into the individual Orders:

1. *Format for Data Submission.* As part of a cooperative NAFTA project, EPA and the Canadian Pest Management Regulatory Agency (PMRA) developed standard data evaluation formats, or templates. The templates have been in use by these agencies since 2002 for writing their data evaluation records (DERs) of studies submitted under FIFRA and FFDCA to EPA and the Canadian data codes (DACOs). The DER that the agencies prepare contains a study profile documenting basic study information such as materials, methods, results, applicant's conclusions and the evaluator's conclusions. The templates provide pesticide registrants and the public an opportunity to gain a better understanding of the regulatory science review and decision-making process. The agencies encourage registrants to include study profiles based on these templates in their study documents for all pesticide types. 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 the requirements for organizing and formatting submittals of data supporting a pesticide registration (http://www.epa.gov/PR_Notices/pr86-5.html). The Agency has begun the process of updating the guidance in PR Notice 86-5 to further clarify the data submission process for pesticide related submissions and will provide the public with an opportunity to comment on the proposed revisions to PR Notice 86-5 consistent with the procedures described in PR Notice 2003-3, entitled "Procedural Guidance for EPA's Office of Pesticide Programs Procedures Concerning the Development, Modification, and Implementation of Policy Guidance Documents" (http://www.epa.gov/PR_Notices/pr2003-3.pdf).

The Agency also encourages Order recipients to submit completed study profiles and supporting data in an electronic format (PDF) whether submitting one or several

studies. For more information about electronic submissions, go to http://www.epa.gov/pesticides/regulating/registering/submissions/index.htm.

2. *Transmittal Document.* Each submission in satisfaction of a Tier 1 Order must be accompanied by a transmittal document that includes the following information:

(1) Identity of the submitter.
(2) The date on which the submission package was prepared for transmittal to EPA.
(3) Identification of the Tier 1 Order associated with the submission (e.g., the number assigned to the Order).
(4) A list of the individual documents included in the submission.

3. *Individual Study or Test Result Documents.* Unless otherwise specified by the Agency, each submission must be in the form of individual documents or studies. Previously submitted documents should not be resubmitted unless specifically requested by the Agency. Instead previously submitted documents should be cited with adequate information to identify the previously submitted document. Each study or document should include the following:

(1) A title page including the following information:
  (i) The title of the study, including identification of the substance(s) tested and the test name or data requirement addressed.
  (ii) The author(s) of the study.
  (iii) The date the study was completed.
  (iv) If the study was performed in a laboratory, the name and address of the laboratory, project numbers or other identifying codes.
  (v) 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.
  (vi) 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.
(2) 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 the Tier 1 Order.
(3) A statement of compliance or non-compliance with respect to GLP standards as required by 40 CFR 160.12, if applicable.
(4) A complete and accurate English translation must be included for any information that is not in English.

5. AGENCY ACTIVITIES, COLLECTION METHODOLOGY, & INFORMATION MANAGEMENT

5(a) Agency Activities

The functions and responsibilities associated with the EDSP under FFDCA section 408(p) have been assigned to OPPTS. Within OPPTS, OPP will be primarily responsible for the administrative functions related to the issuance of the Orders, receiving, processing and maintaining records of responses to the Orders, as well as

other administrative functions related to the Orders. OSCP and OPP will coordinate the review of Tier 1 screening data received and resulting determinations related to the subject chemical.

In addition to preparing and issuing the Orders, the data collected under FFDCA section 408(p) will be received by OPP, where the data will first be reviewed for completeness and then routed to the appropriate Agency team of scientists and analysts for technical review. Although the technical review teams will consist mostly of staff from OPP and OSCP, it will also include staff from other EPA offices, e.g., Office of Pollution Prevention and Toxics (OPPT), Office of Water (OW), Office or Research and Development (ORD), and other EPA offices as appropriate.

In general, the Agency is expected to engage in the following general activities under this ICR:

(1) *Prepare instructions.* Prepare procedural steps, guidance & instructions for Order recipients so that they understand what data are to be submitted, when & how. The Policy and Procedures Document (Attachment B) describes the policies and procedures that EPA intends to use to implement the data collection component of the EDSP. Although that document is non-binding, the Agency will incorporate specific instructions into each Order, so that each Order recipient receives detailed instructions on what they must do to comply with the Order.

(2) *Identify chemicals to be screened.* EPA has implemented the September 2005 selection approach to identify the chemicals for which Tier 1 screening under the EDSP will be required (Ref. 3). After considering public comments on the draft list (Ref. 4), EPA recently issued a final list (Ref. 5). This ICR assumes that all of the chemicals on the final list will be the subject of a Tier 1 Order issued under FFDCA §408(p).

(3) *Identify Recipients.* EPA has identified the potential recipients of the Tier 1 Orders for the chemicals identified on the final list of initial chemicals to be screened under the EDSP. See the discussion on respondents in section 4(a) of this ICR.

For Tier 1 Orders involving pesticide active ingredients, the Agency used the Office of Pesticide Programs Information Network (OPPIN). OPPIN is an internal OPP database for query, input and tracking of pesticide products, ingredients, studies, regulatory decisions and other information about registered products.

For Tier 1 Orders involving inerts, the Agency used OPPIN (where applicable) and other databases like the TSCA Inventory Update Reporting (IUR) database and other public information sources to identify appropriate manufacturers/importers. These other databases may include other internal EPA databases and publicly available sources like Dun and Bradstreet, online marketing material, etc.

In addition, to facilitate the formation of consortia to develop the data requested in an Order, and to the extent that the information is not protected as confidential business information, EPA will provide each Order recipient with a list of the other recipients of the Order for the subject chemical. The list of Order recipients will also be

published in the Federal Register and posted on the Agency's EDSP Web site, along with the status of the Order (including recipients' responses). EPA intends to update the list with subsequent publication(s) and posting(s) as appropriate.

This ICR also assumes that other entities that should receive an Order might be identified after the first set of Orders are issued, either by EPA or by someone else. In those cases, EPA intends to issue "catch-up" Orders as appropriate.

(4) *Prepare the EDSP Tier 1 Orders.* EPA intends to use the appropriate Order template (see Attachment C) to prepare individual Orders for each chemical and Order recipient. The Order will identify all of the non-CBI protected recipients so that the recipients may more easily identify the potential participants to include in a consortium, and it will indicate how many recipients could not be listed. Those companies protected as CBI will not be listed in that Order, but will still receive an Order and will have an opportunity to designate an agent for purposes of the List of Order Recipients. As indicated previously, EPA intends to publish the List of Order Recipients for chemical specific Orders in the Federal Register, and will maintain an up to date list on the Agency's EDSP Web site.

Along with preparation of the Orders, EPA will prepare the pre-populated Initial Response Form for each Order recipient. The Agency intends to accomplish this through a semi-automated process using the same database that will track the Orders, initial responses, and data submissions. This system is discussed in more detail in section 5(b) of this ICR. In using this approach, EPA is maximizing the available resources and efficiencies related to the administrative components of Tier 1 screening under the EDSP.

(5) *Review & Approve Orders.* The EDSP Tier 1 Orders will be reviewed and approved by a senior Agency official(s) for completeness before they are issued.

(6) *Issue the Orders.* The appropriate authorized OPPTS senior official will sign each Order, which will then be processed for issuance as appropriate. Orders will then be mailed to each recipient using certified and return receipt mailing options offered by the U.S. Postal Service (Ref. 10).

(7) *Process Initial Responses.* OPP will receive the Initial Response Form, document the response, track responses & determine next steps based on the responses. In general, the Agency will review the response to determine if it is complete and whether it satisfies the request in the Tier 1 Order, if so, the response will be documented accordingly. Depending on the response, the Agency may also need to complete other tasks, e.g., document lead for a consortia, process a voluntary cancellation request or request for reformulation, etc. The Agency will also need to verify claims and review data cited or submitted and provide a written response to the Order recipient that accepts or rejects their claim(s).

(8) *Provide Assistance & Complete Follow-up, as needed.* The Agency will respond to any questions the recipient may have regarding the Tier 1 Order in a timely manner, as well as process any requests for extensions or protocol variations.

(9) *Address Non-responders.* Once identified, the Agency will determine appropriate action (i.e., whether to initiate cancellation procedures, refer the case to the Office of Enforcement and Compliance Assurance (OECA) for enforcement, etc.).

(10) *Issue "Catch-up" Orders.* EPA may issue a so called "catch-up" Tier 1 Order to a manufacturer or importer who begins to sell an inert ingredient following the submission of required EDSP data on the ingredient by manufacturers or importers who were in the marketplace when the initial Tier 1 Orders were issued.

(11) *Process Data Submissions.* The Agency will process submissions of data generated under the Tier 1 Order, including initial review of the data submission for completeness, initial log-in to document receipt, and determining the close out of the Order. As indicated previously, this will be coordinated by OPP and OSCP. Although each Order will need to be addressed individually, the Agency may determine that the satisfaction of the Order for a particular chemical by one Order recipient can be used to determine that all of the Orders for that chemical are also satisfied. However, satisfaction of an Order by one Order recipient, may not affect the need for the other Order recipients to comply at all. For more information, see the Policy and Procedures Document (Attachment B).

(12) *Analyze Data.* OPP will implement the Agency's internal standard review procedures to review the data. For example, what does the data tell us about the chemical's potential to interact with E, A, and/or T?

In general, the Agency intends to take a weight-of-evidence approach to evaluate the available data for a particular chemical to determine whether the potential endocrine disrupting effects associated with the use of the chemical can be ascertained with the data available, or whether additional data is needed.

(13) *Incorporate/ Use the Data.* The Agency will incorporate the data into a risk assessment and make a regulatory decision as necessary and appropriate. EPA has extensive experience in using data from multiple sources to develop integrated assessments of hazard, modes of action / mechanisms of toxicity, and overall potential for risk. EPA scientists will continue to use such experience, together with insights from the validation process for Tier 1 assays, to address the potential of chemicals to cause adverse effects as a consequence of interaction with the endocrine system. For example, do we know enough to determine whether or not we should take any regulatory action to prevent or mitigate the exposures that might lead to the interaction identified? Should the chemical be considered for Tier 2 testing?

In addition, chemicals that go through Tier 1 screening and are found to have the potential to interact with the estrogen, androgen, or thyroid hormone systems will proceed to the next stage of the EDSP where EPA will determine which, if any, of the Tier 2 tests are necessary based on the available data. Tier 2 testing is designed to identify any adverse endocrine-related effects caused by the substance, and establish a quantitative relationship between the dose and that endocrine effect.

(14) *Store Data in Retrievable System.* The Agency will index and store the data in the Agency's files. Primarily the data will be stored in OPPIN, because the initial group of chemicals to be screened are pesticides or chemicals used as inerts in pesticide products. This system is discussed in more detail in section 5(b) of this ICR.

5(b) Collection Methodology and Management

For each of the chemicals identified for Tier 1 screening as part of the EDSP, the specific data requested, the testing necessary to generate that data, along with the validated protocols to conduct the tests, the time frame for completing the testing, and the date by which the requested data must be submitted to the Agency will be established in the Tier 1 Order. As indicated previously, the Agency intends to utilize the systems and procedures already established and in use for Data-Call-In activities under FIFRA to collect and manage the data submitted in response to the Tier 1 Order. For example, as with other pesticide data related submissions, EPA will maintain a record of each study submitted in the Agency's Pesticide Document Management System (PDMS), and public access to the PDMS bibliography may be made through the National Pesticides Information Retrieval System (NPIRS). NPIRS supports searches of the PDMS database by chemical, subject, submission date, laboratory, guideline number, and document type. The public, after satisfying any applicable requirements (e.g., FIFRA §10) may request copies of non-confidential studies through FOIA.

In addition, OPP's Information Technology & Resource Management Division (ITRMD) is enhancing the Agency's tracking database (PRISM) to provide the necessary information to accomplish the Tier 1 goal; specifically capturing information regarding a chemical's active and inert ingredients. Currently, the system has the capability to handle active ingredient information. The complete management of active ingredients can be accomplished with the DCI (Data Call-In) module within PRISM; however, the management of inert ingredients had to be developed.

To meet the goals of the EDSP, the system will allow for the creation of Orders for each active ingredient and inert ingredient. For the active ingredients, the system will manage associated company, product, and requirement information. For inert ingredients, the system will manage the associated companies only, since these companies may not have any registered products. In addition, the system needs to allow for the submission of studies through registrant consortiums. It needs to be able to give the member companies (who received Orders) credit for the submissions when the consortium is identified as the study owner. For every inert there shall be a subsection for its Battery, results and comments. The system will track the milestones associated with the drafting, concurrence, mail-out, 90-day response, submission receipts, and reviews. Also, the system shall manage response extensions and identify and manage all non-responsive companies.

In addition to tracking the previously mentioned elements related to each specific Order, the Agency will track the following: submission type, submission date, submission comment, review sent and completed dates, requirement status and requirement status comment. These elements are needed in order to track the

responses submitted by each company, the submitted studies, study reviews, study status and requirement status. The Agency will produce several reports to facilitate tracking, etc. For example, a 90-day company response status report is needed to determine whether companies have responded, and to identify their intentions. An option to display only overdue responses will be included. It should include all chemicals and be sorted by company (and product if applicable). A requirement status report by requirement across all chemicals, sorted by company is needed in order to present overall progress and allow management to directly identify delays.

5(c) Small Entity Flexibility

In developing the Policy and Procedures Document (Attachment B), the Agency considered alternatives for small businesses to the extent practical within the mandate in FFDCA. For example, as described in more detail in EPA's policy statement, EPA does not intend to issue Tier 1 Orders to registrants of end-use products or formulators, primarily because most small entities potentially impacted under the EDSP are end-use product registrants or formulators and are not basic manufacturers or registrants. As such, small businesses are not expected to be responsible for supplying endocrine data on a chemical they use in their end-use product or formulation.

In addition, the procedures are intended to minimize potential duplicative testing, and emphasize collaborative efforts to generate the requested data. If there is a small business that does happen to manufacture one of the chemicals and therefore receives a Tier 1 Order, the small business may minimize potential burden by joining a consortium or task force, which may relieve the small business of direct responsibility for generating or submitting the data. EPA has further facilitated this collaborative approach by including the list of Order recipients for a particular chemical in the original Order package that the entity will receive. Participants in a consortium are free to negotiate the terms of the agreement, including the level of participation expected from each member. Typically, that level of participation, which may be based on time or money, is based on the entity's market share for that chemical.

EPA can accommodate requests for extensions of time from small businesses, and provide other assistance, as needed. In fact, OPP has established small business liaisons that are available to provide a broad range of assistance to small businesses. An extension in time may help a small business because other manufacturers who received an Order for that same chemical may submit the data sooner. Since an entity may demonstrate that they made a reasonable offer to contribute towards the costs for generating that data, a small entity in this case would only be responsible for their fair share of the costs, and the time an effort involved in making a reasonable offer.

5(d) Collection Schedule

There is no periodic schedule for the collections under this ICR. This information collection activity only involves a one-time, three step collection activity per chemical. The Order will identify the applicable due dates for the collections under the Order. In

general, the basic schedule EPA intends to use in the Order is based on the timeframes identified in Table 3:

Table 3 – General Basis for Establishing the Due Dates in the 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's Documentation & 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 calculating the due date for the Initial Response, the Agency has included an additional 10 calendar days to build in extra time for the Agency to process the final Order package after signature, i.e., to add all the due dates that will be calculated from the signature date, and for physical delivery of the package to the Post Office for mailing. In general, the Agency does not expect to consider requests for extending the deadlines for the Initial Response. However, the Agency will consider extending the final report due date when the circumstances warrant it. The Agency's policy regarding time extensions is presented in the Policy and Procedures document (Attachment B).

The time period for Tier 1 screening is expected to take longer than one year from commencement based on the anticipated composition of the screening battery, but respondents will not be expected to commence screening as soon as they receive the Orders, or complete the individual assays in any particular sequence. Although the activities are expected to occur over the three year approval period for the ICR, the timing of these activities within that three year period is not specific enough to accurately divide them by year. For purposes of estimating the potential paperwork burden in this ICR, EPA assumed that the data would be submitted within 2 or 3 years of receiving the Tier 1 Order, i.e., within the 3 year approval period for this ICR. To calculate an annual burden, the Agency assumed a 3 year duration of equal annual effort.

6. ESTIMATING THE BURDEN AND COST OF THE COLLECTION

The PRA requires EPA to estimate the "paperwork burden" i.e., the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal Agency. OMB will not approve a "collection" until EPA provides an ICR that describes the information collection activities in detail and provides an estimate of the paperwork burden hours and costs.

Under the PRA, "burden" means the "time, effort, or financial resources expended by persons to generate, maintain, or provide information to or for a Federal Agency." This can include the resources to: review instructions; develop, acquire, install, and use technology and systems; search data sources; collect, review, validate, and verify information/data; process and maintain information/data; disclose and transmit/submit information/data; change/adjust the existing ways of complying with

any previously applicable instructions and requirements to now comply with new requirements; and, train personnel. The Agency is also required to estimate the paperwork costs, which include both the costs associated with the paperwork burden hours, and any additional costs not tied to a burden hour, but incurred under the PRA nonetheless (e.g., the cost for mailing the forms to EPA).

In this section of the ICR, the Agency discusses the methodology and assumptions used to calculate the potential paperwork burden and costs for both respondents and EPA.

6(a) Methodology for Estimating Respondent Burden and Cost

6(a)(i) Method Used to Calculate the Loaded Labor Rates

Average wage data for the relevant sectors of respondents are available in the National Industry-Specific Occupational Employment and Wage Estimates from the Bureau of Labor Statistics (BLS) at http://www.bls.gov/oes/current/oes_nat.htm. We used the NAICS codes to obtain the estimated loaded labor rates used in this ICR, i.e., NAICS 325300, Pesticide, Fertilizer, & Other Agricultural Chemical Manufacturing http://www.bls.gov/oes/current/naics4_325300.htm. Within that sector, the wage data are provided by Standard Occupational Classification (SOC). The SOC system is used by Federal statistical agencies to classify workers into occupational categories for the purpose of collecting, calculating, or disseminating data. Each broad occupation includes detailed occupation(s) based on similar job duties, skills, education, or experience. For more information on SOC and what is included in each SOC, see http://www.bls.gov/oes/current/oes_stru.htm. The SOCs used for the following labor types are listed below in Table 4 and apply to all of the sectors identified above.

Table 4 - Respondent SOCs Used in this ICR

Labor Category	SOC #	Standard Occupational Classification
Management	11-0000	Management Occupations
Technical	19-0000	Life, Physical, and Social Science Occupations
Clerical	43-0000	Office and Administrative Support Occupations

For purposes of calculating a loaded labor rate, we used the mean average hourly wage rate and assumed that benefits are 43% of wage rates, based on benefits for all civilian non-farm workers from http://www.bls.gov/news.release/ecec.t01.htm. We then multiply the loaded wage by 50% to get overhead costs. Overhead costs are added to the loaded wage rate to get the fully loaded wage rate.

Table 5 – Respondent Loaded Labor Rates Used in this ICR				
Labor Category	**Formula Used**	**Managerial**	**Technical**	**Clerical**
Unloaded Hourly Rate[1]	W	$ 48.31	$ 35.86	$ 15.78
Benefits Percentage[2]	Lb = B/W	43%	43%	43%
Benefits per hour	B = W*Lb	$ 20.77	$ 15.42	$ 6.62
Loaded Hourly Rate	Wb = W+B (= W(1+Lb))	$ 69.08	$ 51.28	$ 22.40
Overhead Percentage[3]	Lo = OH/Wb	50%	50%	50%
Overhead per hour	OH = Wb*Lo	$ 34.54	$ 25.64	$ 11.20
Fully Loaded Hourly Rate	Wf = Wb+OH (= W+B+OH)	**$ 103.62**	**$ 76.92**	**$ 33.60**

1. Data Source: http://www.bls.gov/oes/current/naics4_325300.htm.
2. Fringe benefits/wage per hour.
3. U.S. Environmental Protection Agency, *EPA Air Pollution Control Cost Manual, Sixth Edition*, EPA-452-02-001, January 2002, pg. 2-34. The loading for indirect costs used in this ICR (i.e., 50%) is within the range of 20-70% of the load labor rate (wage + benefits) suggested in this EPA guidance.

For this ICR, the Agency therefore uses the following labor rates for the respondents: Managerial = $103.62; Technical = $76.92; and Clerical = $33.60.

6(a)(ii) Method Used to Calculate the Burden and Costs

The specific activities used for estimating the potential burden and costs are identified in section 4(b) of this ICR. Paperwork burden hours and costs are subdivided into the managerial, technical, and clerical duty labor categories, which are also described in more detail in section 4(b) of this ICR.

The Agency then used two basic approaches to calculate the potential burden and costs for this ICR: 1) For the data generation activities, EPA calculated the paperwork burden as a percentage of the testing costs; and 2) For the rest of the paperwork activities, EPA estimated the average amount of time required to complete the specific activity, considering estimates provided in other approved ICRs involving the same activity, feedback from stakeholders, and EPA's overall experience with such activities.

1. *Method Used to Calculate the Burden and Costs for Data Generation.* EPA calculated the paperwork burden for the data generation activities as a percentage of the testing costs. This percent-based estimate of paperwork associated with conducting a test was initially established in consultation with OMB in the 1980's in an effort to provide a reasonable estimate of the burden associated with the paperwork component of data generation, which may vary based on the complexity of the test performed. This appears to be a reasonable and fair alternative to simply setting a single estimate for data generation burden or perhaps using some set criteria like high, medium or low burden, neither of which may fairly reflect potential differences in burden. For purposes of this ICR, the Agency has adopted this established methodology for estimating the paperwork burden for data generation, which is explained further in this section of the ICR.

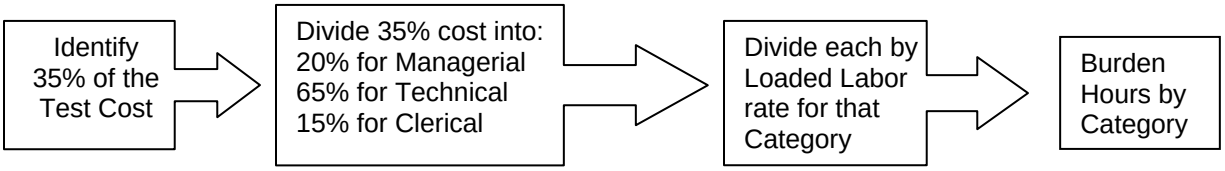
To calculate the burden associated with the paperwork activities involved in

conducting the tests, the Agency starts with the cost of the test, typically the market price for the test as identified by laboratories that offer testing services. Since the tests that will be used in the EDSP are not yet offered by the laboratories, market costs for these tests are not available. The Agency therefore used estimated costs for 2 assays that were based on estimates provided by the EPA scientist overseeing the validation effort for those 2 assays. Since EPA is funding the assay validation effort, we believe that these estimates are reasonable surrogates for actual market prices at this time and for the purposes of this ICR. For the other assays, the Agency used the Cost Estimate Survey of commercial laboratories and other information provided by industry representatives (Ref. 9 & 10). Once these tests are available on the market, these costs will be adjusted as appropriate.

Based on the existing methodologies, EPA used 35% of the estimated total test cost to calculate the total potential cost for the paperwork activities related to data generation. The 35% of test cost is disaggregated by labor category, and then burden hours are extrapolated by using the loaded labor rates. To disaggregate by labor category, the Agency considered the estimated distribution of paperwork activity across the labor category represented and the existing methodology assumption that paperwork activities for data generation mostly involve the technical staff to perform the tests, with a few activities related to management and clerical.

See Figure 1 for an illustrated outline of the Agency burden calculation process for data generation. The results from using this method are presented in section 6(b) of this ICR.

Figure 1: Method for Calculating Paperwork Burden from Test Costs



This approach assumes and incorporates the following:

1) Recipients generate all of the data as specified in the Tier 1 Order.
2) All data generation is performed by an independent laboratory.
3) Paperwork burden is disaggregated by labor category as follows:
   a. Managerial (20%)
   b. Technical (65%)
   c. Clerical (15%)
4) Labor rates are fully loaded, meaning that they include the estimated costs of wages, overhead, and benefits paid to an employee. See section 6(a)(i) of this ICR.

2. *Method Used to Calculate the Burden and Costs for Other Activities.* For the other activities, EPA estimated the burden hours by considering the activities themselves and the expected amount of time that the activity involves on average. These estimates consider the Agency's experience with similar data collection activities

and direct experience in conducting the assays for validation. The costs are calculated using the loaded labor rates for the labor categories that are identified in section 6(a)(i) of this ICR.

As indicated previously, almost all of the response options provided to recipients of Tier 1 Orders are the same as those afforded to pesticide registrants in response to DCIs. Although other ICRs already address the paperwork burden associated with the activities involved in those options, the Agency has provided a general estimate for the burden associated with providing the supporting materials related to the various options based on its general experience with the pesticide program. At this time, it is not possible to estimate how many respondents may choose which option.

Regardless of the response option that recipients of Tier 1 Orders choose, the Agency has assumed that the data will be generated for each chemical with all manufacturers participating in a consortium or task force, and with only one Order recipient engaged in actually generating and submitting the data. This means that all of the potential recipients of Orders will experience a base set of burden associated with the initial receipt, response activities and subsequent burden related to consortium participation, and that one recipient for each of the chemicals will experience the burden associated with generating the data, submitting a one-time progress report and eventually submitting the data. The results of this method are presented in section 6(b) of this ICR.

Until the Agency has some experience with this new collection activity, it is impossible to provide a more refined estimate. At this time, it is important to note that the estimated total burden for this ICR is based on several assumptions that are intended to be biased towards providing conservative estimates. These estimates should not, however, be interpreted as providing an accounting for all of the paperwork activities associated with the EDSP Tier 1 screening for the initial chemicals. Once all of the protocols for the Tier 1 assays are finalized and the Orders are issued for the first group of chemicals to be screened under the EDSP, the Agency intends to conduct a more thorough evaluation of the screening costs and related activities.

6(b) Calculating Respondent Burden and Costs

This section explains how the Agency calculated the estimated respondent burden and costs for this ICR.

6(b)(i) Respondent Burden Estimates

The estimated respondent burden for each of the paperwork activities described in Table 2 in section 4(b) of this ICR, disaggregated by the labor category listed in Table 4, are presented in Table 6 below.

Table 6 – Estimated Per Chemical Burden Hours for the Activities				
Activity (a)	**Managerial**	**Technical**	**Clerical**	**Total**
1) Read instructions	12	12	0	24
2) Plan activities	48	42	0	90
3) Submit an initial response to EPA (b)	24	21	2	47
4) Read and discuss the protocol	36	145	0	181
5) Participate in Consortium	24	145	2	171
6) Generate the data (c)	273	1196	632	2101
7) Submit Progress Report	5	20	7	32
8) Compile and review the final data for submission	36	191	12	239
9) Complete paperwork to assemble the submission package	5	20	7	32
10) Submit final data to EPA	3	0	2	5
11) Maintain records	0	24	62	86
Total burden:	466	1816	726	3008

(a) Activities described in more detail in section 4(b) of this ICR, which are disaggregated based on labor category.
(b) This estimate includes an estimated burden to provide additional material with the response.
(c) Burden estimate is a percentage of the total test cost, which is calculated in Attachment F (rounded).

As discussed earlier, all respondents are not expected to engage in the same basic activities. Using the respondent categories and numbers presented in Table 1, Tables 7-9 present the estimated respondent burden for each category of respondent. Sorting the potential burden this way will facilitate the Agency's completion of separate information collection (IC) forms for each category of respondent, which is now required in the ICR submission and tracking electronic system that is being used.

Table 7 – Estimated Burden Hours by Activity for Pesticide Registrant			
Activity (a)	**Estimated Burden (b)**	**Estimated # Respondents (c)**	**Total Burden Hours (d)**
1) Read instructions	24	207	4,968
2) Plan activities	90	207	18,630
3) Submit an initial response to EPA (b)	47	207	9,729
4) Read and discuss the protocol	181	58	10,498
5) Participate in Consortium	171	149	25,479
6) Generate the data (c)	2101	58	121,858
7) Submit Progress Report	32	58	1,856
8) Compile and review the final data for submission	239	58	13,862
9) Complete paperwork to assemble the submission package	32	58	1,856
10) Submit final data to EPA	5	58	290
11) Maintain records	86	207	17,802
Total burden:	3008		226,828

(a) Activities described in more detail in section 4(b) of this ICR, which are disaggregated based on labor category.
(b) Per chemical burden taken from the total column in Table 6.
(c) Number of potential respondents from Table 1, pesticide registrant column.
(d) Total = (b) x (c)

Table 8 – Estimated Burden Hours by Activity for Manufacturers/Importers			
Activity (a)	**Estimated Burden (b)**	**Estimated # Respondents (c)**	**Total Burden Hours (d)**
1) Read instructions	24	163	3,912
2) Plan activities	90	163	14,670
3) Submit an initial response to EPA (b)	47	163	7,661
4) Read and discuss the protocol	181	9	1,629
5) Participate in Consortium	171	154	26,334
6) Generate the data (c)	2101	9	18,909
7) Submit Progress Report	32	9	288
8) Compile and review the final data for submission	239	9	2,151
9) Complete paperwork to assemble the submission package	32	9	288
10) Submit final data to EPA	5	9	45
11) Maintain records	86	163	14,018
Total burden:	3008		89,905

(a) Activities described in more detail in section 4(b) of this ICR, which are disaggregated based on labor category.
(b) Per chemical burden taken from the total column in Table 6.
(c) Number of potential respondents from Table 1, manufacturer/importer column.
(d) Total = (b) x (c)

As indicated previously, EPA intends to issue "catch-up" Orders to those companies that enter the market place after the initial Order recipients have responded. These respondents will not be expected to generate data. Instead, the respondents will need to join an existing consortia (or offer to join), or otherwise compensate (or make an offer to compensate) those who have already done so.

Table 9 – Estimated Burden Hours by Activity for "Catch-up" Orders			
Activity (a)	**Estimated Burden (b)**	**Estimated # Respondents (c)**	**Total Burden Hours (d)**
1) Read instructions	24	20	480
2) Plan activities	90	0	0
3) Submit an initial response to EPA (b)	47	20	940
4) Read and discuss the protocol	181	0	0
5) Participate in Consortium	171	20	3,420
6) Generate the data (c)	2101	0	0
7) Submit Progress Report	32	0	0
8) Compile and review the final data for submission	239	0	0
9) Complete paperwork to assemble the submission package	32	0	0
10) Submit final data to EPA	5	0	0
11) Maintain records	86	20	1,720
Total burden:	3008		6,560

(a) Activities described in more detail in section 4(b) of this ICR, which are disaggregated based on labor category.
(b) Per chemical burden taken from the total column in Table 6.
(c) Number of potential respondents from Table 1, Catch-up Orders column.
(d) Total = (b) x (c)

Table 10 presents the total estimated respondent burden.

Table 10 – Estimated Total Respondent Burden Hours by Activity			
Activity (a)	**Estimated Burden (b)**	**Estimated # Respondents (c)**	**Total Burden Hours (d)**
1) Read instructions	24	390	9,360
2) Plan activities	90	390	35,100
3) Submit an initial response to EPA (b)	47	390	18,330
4) Read and discuss the protocol	181	67	12,127
5) Participate in Consortium	171	323	55,233
6) Generate the data (c)	2,101	67	140,767
7) Submit Progress Report	32	67	2,144
8) Compile and review the final data for submission	239	67	16,013
9) Complete paperwork to assemble the submission package	32	67	2,144
10) Submit final data to EPA	5	67	335
11) Maintain records	86	390	33,540
Total burden:	3,008		325,093

(a) Activities described in more detail in section 4(b) of this ICR, which are disaggregated based on labor category.
(b) Per chemical burden taken from the total column in Table 6.
(c) Number of potential respondents from Table 1.
(d) Total = (a) x (b)

Since there is expected to be some overlap between the potential recipient categories, the number of potential respondents used for this estimate may be reduced once the final list of Order recipients is complete. The Agency also expects that a single potential respondent might receive more than one Tier 1 Order if they manufacture or import more than one of the listed chemicals, and that there are multiple potential respondents for each chemical. For example, the Agency estimates that an Order recipient might receive as many as 4 Orders (i.e., covering 4 chemicals), with the average company receiving 2 Orders (i.e., covering 2 chemicals). There may be as many as 56 recipients for an individual Order, with an average of less than 5 recipients for most of the Orders. As indicated previously, these estimates cannot be further refined until the Agency identifies all of the specific Order recipients for the final list of chemicals that will undergo Tier 1 screening under this ICR, which will cannot occur until the Orders are ready to be issued. As such, the number of potential individual Order recipients in Table 1 represents the best available estimate of potential respondents at this time.

6(b)(ii) Respondent Cost Estimates

The estimated respondent cost for each of the paperwork activities is presented in Table 11. The burden costs are calculated by multiplying the burden hours in Table 6 by the loaded labor rate for the different labor categories, with the costs for generating the data coming from Attachment F.

In addition to the burden costs, the costs of delivering the data to the Agency are added to arrive at the total estimated per respondent cost. Delivery costs were calculated using the Agency's experience with data submissions for pesticide deliveries, which assumes the delivery of a paper copy and a CD-Rom using special delivery. Although not required, nor used by everyone, the Agency is using special delivery for

the calculation to provide a conservative estimate that would account for expected variations in delivery costs. Based on the 2-day delivery rate for a large envelope up to 2 lbs. in weight, the US Postal Service rate is $10.55 from the west coast to the east cost (Ref. 11). Total delivery costs ($10.55 x 67 submissions = $706.85) was then added to the estimated cost in Tables 11 & 12.

Table 11 – Estimated per Chemical Costs by Activity

Activity (a)	Managerial $103.62/hr.	Technical $76.92/hr.	Clerical $33.60/hr.	Total $
1) Read instructions	1243.44	923.04	0	2,166.48
2) Plan activities	4973.76	3230.64	0	8,204.40
3) Submit an initial response to EPA (b)	2486.88	1615.32	67.20	4,169.40
4) Read and discuss the protocol	3730.32	11153.40	0	14,883.72
5) Participate in Consortium	2486.88	11153.40	67.20	13,707.48
6) Generate the data (c)	28302	91982	21227	141,511.00
7) Submit Progress Report	518.10	1538.40	235.20	2,291.70
8) Compile and review the final data for submission	3730.32	14691.72	403.20	18,825.24
9) Complete paperwork to assemble the submission package	518.10	1538.40	235.20	2,291.70
10) Submit final data to EPA	310.86	0	67.20	378.06
11) Maintain records	0	1846.08	2083.20	3,929.28
12) Delivery Costs	0	0	0	10.55
Total costs:	$48,300.66	$139,672.40	$24,385.40	$212,369.01

(a) Activities described in more detail in section 4(b) of this ICR, which are disaggregated based on labor category.
(b) This estimate includes an estimated burden to provide any additional burden requested for an option.
(c) Burden cost estimate is a percentage of the total test cost, which is calculated in Attachment F (rounded).

Table 12 presents the estimated total respondent costs for the initial group of chemicals expected to undergo Tier 1 screening under the EDSP.

Table 12 – Estimated Total Respondent Costs by Activity

Activity	Estimated Costs ($)	Estimated Respondents	Total $ (rounded)
1) Read instructions	2,166.48	390	844,927
2) Plan activities	8,204.40	390	3,199,716
3) Submit an initial response to EPA (b)	4,169.40	390	1,626,066
4) Read and discuss the protocol	14,883.72	67	997,209
5) Participate in Consortium	13,707.48	323	4,427,516
6) Generate the data (c)	141,511.00	67	9,481,237
7) Submit Progress Report	2,291.70	67	153,544
8) Compile and review the final data for submission	18,825.24	67	1,261,291
9) Complete paperwork to assemble the submission package	2,291.70	67	153,544
10) Submit final data to EPA	378.06	67	25,330
11) Maintain records	3,929.28	67	263,262
12) Delivery Costs	10.55	67	707
Total costs:	$212,369.01		$22,434,349

As discussed previously, the total respondent burden hours and costs calculated for this ICR involves activities that are expected to occur over the 3 year approval period for the ICR, as opposed to annually for each of the 3 years. Since the timing of these activities is not specific enough to accurately divide them by year, the Agency has

assumed a 3 year duration of equal annual effort. As such, the **total annual respondent burden and costs for this ICR is simply divided by 3 to get an estimated annual burden of approximately 108,364 hours** (325,093 hours ÷ 3) **and a cost of approximately $7,478,116** ($22,434,349 ÷ 3).

6(c) Methodology for Estimating Agency Burden and Cost

6(c)(i) Method Used to Calculate the Loaded Labor Rates

To calculate the Agency's loaded labor rate, we used the average wage data available in the National Industry-Specific Occupational Employment and Wage Estimates from the Bureau of Labor Statistics (BLS) at http://www.bls.gov/oes/current/oes_nat.htm. Specifically, we used the NAICS code 999100 to obtain the estimated loaded labor rates used in this ICR for the Federal Executive Branch (http://www.bls.gov/oes/current/naics4_999100.htm). As was done for the respondents, we used the wage data provided by SOC (see Table 13). For purposes of calculating a loaded labor rate, we used the mean average hourly wage rate and assumed that benefits are 43% of wage rates, based on benefits for all civilian non-farm workers from http://www.bls.gov/news.release/ecec.t01.htm. We then multiply the loaded wage by 50% to get overhead costs. Overhead costs are added to the loaded wage rate to get the fully loaded wage rate.

Table 13 - Agency Loaded Labor Rates Used in this ICR

Labor Category	Formula Used	Managerial	Technical	Clerical
Unloaded Hourly Rate[1]	W	$ 47.16	$ 31.18	$ 18.29
Benefits Percentage[2]	Lb = B/W	43 %	43 %	43 %
Benefits per hour	B = W*Lb	$ 20.28	$ 13.41	$ 7.86
Loaded Hourly Rate	Wb = W+B (= W(1+Lb))	$ 67.44	$ 44.59	$ 26.15
Overhead Percentage[3]	Lo = OH/Wb	50 %	50 %	50 %
Overhead per hour	OH = Wb*Lo	$ 33.72	$ 22.30	$ 13.08
Fully Loaded Hourly Rate	Wf = Wb+OH (= W+B+OH)	**$ 101.16**	**$ 66.89**	**$ 39.23**

1. Data Source: http://www.bls.gov/oes/current/naics4_999100.htm
2. Fringe benefits/wage per hour.
3. U. S. Environmental Protection Agency, *EPA Air Pollution Control Cost Manual, Sixth Edition*, EPA-452-02-001, January 2002, pg. 2-34. The loading for indirect costs used in this ICR (i.e., 50%) is within the range of 20-70% of the load labor rate (wage + benefits) suggested in this EPA guidance.

For this ICR, the Agency therefore uses the following labor rates for the Agency: Managerial = $101.16; Technical = $66.89; and Clerical = $39.23.

6(c)(ii) Estimated Agency Burden and Costs

For the Agency activities, EPA estimated the burden hours by considering the activities themselves and the expected amount of time that the activity may involve on average. These estimates consider the Agency's experience with similar data collection activities. The estimated per chemical/respondent burden hours for the Agency are presented in Table 14. To calculate the total potential Agency burden over the three

years, EPA has multiplied this burden by the total number of chemicals (809.5 hours x 67 chemicals = 54,236.5 hours).

Table 14 – Estimated Agency per Chemical Burden Hours

Activity (a)	Managerial	Technical	Clerical	Total
1) Prepare instructions	2	12	2	16
2) Identify chemicals to be screened	2	21	2	25
3) Identify recipients	2	16	0	18
4) Prepare the 408(p) Order Packages	0	4	10	14
5) Review & approve the Orders	2	4	0	6
6) Issue the Orders	0	0	6	6
7) Process initial responses (b)	1	4	1	6
8) Publish & Post List of Recipients	0.5	0.5	2	3
9) Verify claims & Send Written Responses	1	6	1	8
10) Provide assistance & follow-up, as needed	0	36	0	36
11) Identify non-responders	0	0	2	2
12) Process Data Submissions	0	8	1	9
13) Analyze data (c)	0	520	0	520
14) Incorporate data into risk assessments	0	104	0	104
15) Store data in retrievable system	0	4	8	12
16) Identify recipients of Catch-Up Orders	0	1	1	2
17) Prepare and Issue Catch-up Orders	1	6	3	10
18) Amend Recipient List, Publish & Post	0.5	0.5	2	3
19) Process responses to Catch-up Orders	0	2	1	3
20) Process Consortia Documentation	0	0	2	2
21) Close out Order	0.5	2	2	4.5
Total burden:	12.5	751	46	809.5

(a) Activities described in more detail in section 5(a) of this ICR.
(b) This estimate includes an estimated burden to for physically processing the response.
(c) Assumes 40 hrs per assay (40 x 13).
(d) Assumes 8 hrs per assay (8 x 13).

The costs are then calculated using the loaded labor rates for the labor categories that are identified in section 6(c)(i) of this ICR. The estimated burden hour costs for the Agency are presented in Table 15. To calculate the total potential Agency costs over the three years, EPA has multiplied the per chemical cost in Table 15 by the total number of chemicals ($50,921 x 67 chemicals = $3,411,707). The total annual costs to the Agency are estimated to be $1,137,235.60 ($3,411,707 ÷ 3).

Table 15 – Estimated Agency Per Chemical Burden Hour Costs				
Activity (a)	**Managerial**	**Technical**	**Clerical**	**Total**
	$101.16/hr.	**$66.89/hr.**	**$39.23/hr.**	**$**
1) Prepare instructions	202.32	802.68	78.46	1,083.46
2) Identify chemicals to be screened	202.32	1404.69	78.46	1,685.47
3) Identify recipients	202.32	1070.24	0	1,272.56
4) Prepare the 408(p) Order Packages	0	267.56	156.20	423.76
5) Review & approve the Orders	202.32	267.56	0	469.88
6) Issue the Orders	0	0	235.38	235.38
7) Process initial responses (b)	101.16	267.56	39.23	407.95
8) Provide assistance & follow-up, as needed	0	2408.04	0	2,408.04
9) Identify non-responders	0	0	39.23	39.23
10) Process Data Submissions	0	535.12	39.23	574.35
11) Analyze data	0	34782.80	0	34,782.8
12) Incorporate data into risk assessments	0	6956.56	0	6,956.56
13) Store data in retrievable system	0	267.56	313.84	581.4
Total costs:	$910.44	$49,030.37	$980.03	$50,920.84

(a) Activities described in more detail in section 5(a) of this ICR.
(b) This estimate includes an estimated burden to provide any additional burden requested for an option.

6(d) Total Burden Hours and Costs for ICR (Bottomline)

As discussed earlier, the total burden hours for respondents calculated for this ICR involves activities that are expected to occur over the next 3 years. Since the timing of these activities is not specific enough to accurately divide them by year, the Agency has assumed a 3 year duration of equal effort to calculate the annual burden and costs for this ICR.

The total annual respondent burden and costs for this ICR is simply divided by 3 to get an estimated annual burden of approximately 108,364 hours (325,093 hours ÷ 3) and a cost of approximately $7,478,116 ($22,434,349 ÷ 3). Table 16 provides a breakdown of the total annualized burden and cost estimate in terms of the grouping required by OMB, i.e., distinct information collections (ICs).

Table 16 – Annualized Information Collections (ICs) for this ICR (a)				
IC	**Per Chemical (b)**		**Totals (c)**	
	Burden Hrs.	**Costs $**	**Burden Hrs.**	**Costs $**
Reporting	974	$69,480	97,184	$7,390,362
Recordkeeping	29	$1,310	11,180	$87,754
Totals:	1003	$70,790	108,364	$7,478,116

(a) Burden hours and costs are annualized by dividing them by 3.
(b) For per chemical burden see Table 6, i.e., total burden minus line item 11 (3,008-86) ÷ 3, and for costs see Table 11, i.e., total cost minus line item 11 (212369 – 3929) ÷ 3. Line item 11 in both tables represents recordkeeping.
(c) For total respondent burden see Table 10, i.e., total burden minus line item 11 (325093-33540) ÷ 3, and for costs see Table 12, i.e., total cost minus line item 11 (22,434,349-263,262) ÷ 3. Line item 11 in both tables represents recordkeeping.

6(e) Reasons for Change in Burden Estimates

This new information collection request is necessary to fully implement the mandate in FFDCA 408(p). The burden estimates presented here are not currently listed in the OMB Inventory. As such, the total estimated respondent burden in this ICR is considered a program change related to the implementation of a statutory mandate.

6(f) Burden Statement for this ICR

The estimated per chemical/per respondent paperwork burden to comply with this information collection activity is 3,008 hours, with an estimated cost of $212,369. Annualized over three years, the per respondent burden is 1003 hours, and the cost is $70,790. The total annualized estimated paperwork burden for this ICR is 108,364 hours, with an estimated total annual cost of $7,478,116.

According to the Paperwork Reduction Act (PRA), "burden" means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. For this collection, it is the time reading the instructions in the Order, providing an initial response to EPA, planning the necessary data collection activities, conducting tests, analyzing data, generating reports and submitting data, as well as storing, filing, and maintaining the data. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. As a new ICR, the Agency does not yet have an OMB control number for this information collection activity at this time. Once assigned, EPA will announce the OMB control number for this information collection in the Federal Register, and will add it to any related collection instruments or forms used.

Upon submission to OMB for approval, the PRA requires the Agency to provide a 30 day public review and comment opportunity, which is announced in the **Federal Register**. To comment on the Agency's need for this information, the accuracy of the provided burden estimates, and any suggested methods for minimizing respondent burden, including the use of automated collection techniques, EPA has established a public docket for this ICR under docket ID No. **EPA-HQ-OPPT-2007-1081**, which is available electronically at http://www.regulations.gov. A hard copy of the docket materials are also available for public viewing 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.

Submit any comments online at http://www.regulations.gov, following the online instructions for viewing documents and submitting comments. You can also send comments to the Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th Street, NW, Washington, DC 20503, Attention: Desk Office for EPA. Please include the Docket ID No. **EPA-HQ-OPPT-2007-1081**, and the EPA ICR number (2249.01) in any correspondence.

7. LIST OF REFERENCES

The following is a list of the documents that are specifically referenced in this document, along with information about where to access the documents:

1. Endocrine Disruptor Screening Program; Notice (63 FR 42852, August 11, 1998) http://www.epa.gov/scipoly/oscpendo/pubs/081198frnotice.pdf.

2. Endocrine Disruptor Screening Program; Proposed Statement of Policy; Notice (63 FR 71541, December 28, 1998) http://www.epa.gov/scipoly/oscpendo/pubs/122898frnotice.pdf.

3. Endocrine Disruptor Screening Program; Chemical Selection Approach for Initial Round of Screening; Notice (70 FR 56449, September 27, 2005) http://www.epa.gov/fedrgstr/EPA-TOX/2005/September/Day-27/t19260.pdf.

4. Draft List of Initial Pesticide Active Ingredients and Pesticide Inerts to be Considered for Screening under the Federal Food, Drug, and Cosmetic Act; Notice (72 FR 33486, June 18, 2007) http://www.epa.gov/scipoly/oscpendo/pubs/draft_list_frn_061807.pdf.

5. Final List of Initial Pesticide Active Ingredients and Pesticide Inerts to be Considered for Screening under the Federal Food, Drug, and Cosmetic Act; Notice (74 FR 17579, April 15, 2009).

6. Endocrine Disruptor Screening Program (EDSP); Draft Policy and Procedures Document; Request for Comment; Notice (72 FR 70842, December 13, 2007) http://www.epa.gov/scipoly/oscpendo/pubs/draft_policies_frn.pdf.

7. Endocrine Disruptor Screening Program (EDSP); Policies and Procedures for Initial Screening; Notice (74 FR 17560, April 15, 2009) (See Attachment B to this ICR).

8. Agency Information Collection Activities; Proposed Collection; Comment Request; Tier 1 Screening of Certain Chemicals Under the Endocrine Disruptor Screening Program (EDSP); EPA ICR No. 2249.01, OMB Control No. 2070-new; Notice (72 FR 70839, December 13, 2007) http://www.epa.gov/fedrgstr/EPA-TOX/2007/December/Day-13/t24163.htm.

9. Cost Estimate Survey: Endocrine Screening Assays, Applied Pharmacology and Toxicology, Inc., (May 23, 2003) http://www.regulations.gov/fdmspublic/component/main?main=DocumentDetail&d=EPA-HQ-OPPT-2007-1081-0003.

10. Comments (attachment), Applied Pharmacology and Toxicology, Inc., (March 12, 2008), Document ID No.: EPA-HQ-OPPT-2007-1081-0013.1.

http://www.regulations.gov/fdmspublic/component/main?main=DocumentDetail&d=EPA-HQ-OPPT-2007-1081-0008.

11. U.S. Postal Service, Online Rate Calculator, as of July 20, 2007. http://postcalc.usps.gov/.

8. ATTACHMENTS TO THIS SUPPORTING STATEMENT

All of the attachments listed below can be found in the docket for this ICR (unless otherwise noted); and are accessible electronically through www.Regulations.gov , under Docket ID Number: **EPA-HQ-OPPT-2007-1081**.

Attachment	Description
A	FFDCA sections 408(p), 408(i). Available at http://www.epa.gov/oppfead1/fqpa/ and click on "LAWS" then click on the available PDF file for FFDCA.
B	Endocrine Disruptor Screening Program (EDSP); Policies and Procedures for Initial Screening; Notice (74 FR 17560, April 15, 2009)
C	(1) FFDCA 408(p) Order Template for Pesticide Inert Ingredients (As of April 10, 2009). (2) FFDCA 408(p) Order Template for Pesticide Registrants (As of April 10, 2009).
D	(1) Initial Response Form for Individual Order Recipients (As of April 3, 2009). (2) Initial Response Form for Consortium/ Task Force (As of April 3, 2009).
E	Overall Process for EDSP Orders (April 3, 2009).
F	Calculations for Paperwork Burden and Costs for Data Generation Activities (April 3, 2009).
G	Final List of Chemicals for Initial Tier 1 Screening in the EDSP (April 3, 2009).
H	Response to Comments on the Public Review Draft of the Information Collection Request (ICR) entitled: "Tier 1 Screening of Certain Chemicals Under the Endocrine Disruptor Screening Program (EDSP)" (April 10, 2009).