Supporting Statement for an Information Collection Request (ICR)

1. Identification of the Information Collection

1(a) Identification of the Information Collection:

1(a)(i) Title: Tier 1 Screening of Certain Chemicals Under the Endocrine Disruptor Screening Program (EDSP).

1(a)(ii) EPA ICR No.: 2249.03
OMB Control No.: 2070-0176
Docket ID No.: EPA–HQ–OPPT–2011–0966

1(b) Short Characterization/Abstract

This is a renewal of an existing information collection request (ICR) under the Paperwork Reduction Act (PRA),[1] covering the information collection activities associated with Tier 1 screening of chemicals under the EPA's Endocrine Disruptor Screening Program (EDSP). The EDSP is established under section 408(p) of the Federal Food, Drug, and Cosmetic Act (FFDCA),[2] which requires the EPA to develop a chemical screening program using appropriate validated test systems and other scientifically relevant information to determine whether certain substances may have hormonal effects. The EDSP consists of a two-tiered approach to screen chemicals for potential endocrine disrupting effects. The purpose of Tier 1 screening is to identify substances that have the potential to interact with the estrogen, androgen, or thyroid hormone systems using a battery of assays.[3] Substances that have the potential to interact with estrogen, androgen or thyroid systems may proceed to Tier 2, which 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. Additional information about the EDSP is available through the agency's Web site at http://www.epa.gov/endo.

This ICR addresses the information collection activities for the initial list of chemicals screened under Tier 1 of the EDSP, and covers the full range of information collection activities associated with the issuance of and response to Tier 1 EDSP orders issued by the EPA. The initial list was established in 2009, and consists of 67 pesticide active ingredients (PAIs) and pesticide inerts.[4] As the renewal of an ongoing information collection activity approved under the PRA, this ICR addresses the paperwork burden associated with the continuation of these activities over the next three (3) years. As such, the paperwork burdens are adjusted to reflect the planned progression associated with the information collection activities covered by the ICR.

Under the existing ICR, the EPA issued the Tier 1 EDSP orders to the identified pesticide registrant and inert manufacturers, and received the initial responses from those order recipients. However, as stated in

[1] 44 USC 3501 *et seq*.
[2] See Attachment A.
[3] Nothing in the identification of chemicals for Tier 1 screening under the EDSP provides a basis to infer that 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 identified for screening under Tier 1 of the EDSP should not be construed as a list of known or likely endocrine disruptors.
[4] See Attachment G.

the EDSP policies and procedures document (Attachment B), the EPA will continue to issue "catch-up" orders for a period of 15 years to companies who enter the marketplace after the issuance of the initial orders in 2010. An up to date matrix with information on the status of the orders issued and responses received for those chemicals is available on the agency's Web site at http://www.epa.gov/endo. To facilitate consortia formation, the EPA also makes a list of the order recipients for each chemical publicly available at the Web address above.

Although the information collection activities are not being changed by this ICR renewal, the burden estimates reflect the planned progression of the collection activities associated with the initial list of chemicals to be screened under the EDSP. At this stage of the program, the remaining ongoing information collection activities relate primarily to data submission, and to those activities associated with "catch-up" orders. In calculating the overall burden, the EPA assumes that all future "catch-up" order recipients will join existing data submitters, and will not elect to become independent data generators.

Finally, the EPA has also reviewed the cost estimates for the eleven assays, including the analytical chemistry costs, and adjusted the costs for inflation. As before, the total costs of the tests are used to calculate the paperwork burdens and costs for this ICR.

2. Need for and Use of the Collection

2(a) Need/Authority for the Collection

The agency's authority for the information collection activities associated with the EDSP includes authorities under the FFDCA, the Safe Drinking Water Act (SDWA), the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), and the Toxic Substances Control Act (TSCA). This information collection activity fulfills a direct statutory mandate and is needed in order to provide information that will allow the agency to identify substances that have the potential to interact with the estrogen, androgen, or thyroid hormone systems.

The EDSP was established in 1998 to carry out the mandate in section 408(p) of the FFDCA (see Attachment A), which directs the 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 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 the 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 the 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 the 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 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, the 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 the 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), the 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]."

FIFRA section 3(c)(1)(F) provides certain protections for people who submit data to the EPA in connection with decisions under the 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 entity 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 SDWA provides the 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(b) Use/Users of the Data

In general, the 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.[5] 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 fact that a substance may interact with a hormone

[5] To access an overview of the endocrine system go to http://www.epa.gov/endo/pubs/edspoverview/primer.htm.

system, however, does not mean that when the substance is used, it will cause adverse effects in humans or ecological systems.

Subsequently, when used with the Tier 2 testing data[6] and other available information,[7] the Tier 1 screening data obtained through this information collection activity will be used by the EPA and others as part of the hazard characterization of a chemical that is regulated by FIFRA, FFDCA, TSCA and SDWA.

More specifically, the data collected under Tier 1 will allow the agency to evaluate the potential interaction of a chemical with the endocrine system. The 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 to address the potential of chemicals to cause adverse effects as a consequence of interaction with the endocrine system. In fact, the EPA has considered the potential interaction of a chemical with the endocrine system in making certain pesticide registration decisions. For example, the 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[8] and vinclozolin.[9]

The agency intends to take a weight-of-evidence approach to evaluate the available Tier 1 data for a particular chemical to determine its potential to interact with the endocrine system, and if so, whether additional data are 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 the 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 for risk assessment.

In addition to helping determine whether 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 are appropriate, and whether or not similar substances might share common mechanisms. Subsequently, Tier 1 screening data may be used to qualitatively characterize the risk of pesticides.

The tiered approach for screening (Tier 1) and testing (Tier 2) that the 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 in the initial list of chemicals 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, the 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.

[6] The collection of Tier 2 data is not part of this information collection activity.
[7] This refers to other information that is available to EPA at the time of its analysis, including information that is not covered by this ICR.
[8] To access the procymidone decision, go to http://www.epa.gov/pesticides/reregistration/procymidone/.
[9] To access the vinclozolin decision, go to http://www.epa.gov/pesticides/reregistration/vinclozolin/.

The paperwork related requirements imposed on the respondents as part of Tier 1 screening under the EDSP allow the 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 Chemical Safety and Pollution Prevention (OCSPP), the Office or Pollution Prevention and Toxics (OPPT), the Office of Pesticide Programs (OPP), and the Office of Science Coordination and Policy (OSCP) will be responsible for the EPA activities 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. The review of Tier 1 screening data received and resulting determinations related to the subject chemical will be based on a coordinated EPA effort that will also include other EPA offices, *e.g.*, Office of Research and Development (ORD), etc.

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

3. Non-Duplication, Consultation, and 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 the EPA. FFDCA specifically assigns this task to the EPA. 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 enactment of FFDCA section 408(p) and initiation of EDSP, there were no validated methods to screen or test chemicals for their potential to affect the endocrine system.

In addition, the agency has a strong commitment to avoiding potential duplication in all of its testing programs, as well as in its implementation of the EDSP. The EPA also 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), the 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. The EPA is using validated methods or assays to identify and characterize the endocrine activity of pesticides and inert ingredients 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 the 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 the EPA. In addition, order recipients and other interested stakeholders may 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 policies and procedures document (Attachment B).

3(b) Consultations

In addition to the notice and comment requirement, the EPA is required under 5 CFR 1320.8(d)(1) to consult with potential respondents and data users about specific aspects of an ICR before submitting it to OMB for review and approval, regardless of whether changes have or have not been made to the collection activity. The EPA identified eight entities based on previous interactions related to the existing ICR and consulted with them about the information collection activities and related burden estimates provided in the public review draft for this ICR. The details of that consultation, including specific information about the entities, questions posed, and responses received, is provided in Attachment H of this document. The following is a summary of the consultation and the agency's response.

Publicly Available Data: Most respondents indicated that the submission of "other scientifically relevant information" (OSRI) was expensive and time consuming. It was stated that the agency was too strict in its review of the OSRI. Respondents stated that by not accepting OSRI, portions of the EDSP Tier 1 battery were duplicative.

Frequency of Collection: Most participants responded that the frequency of the data collection was fine given the fact that Tier 1 EDSP orders would only be issued "once" per chemical (except in rare situations). One consultation participant noted the lack of practical utility for the one-year progress report that is required of order recipients to be submitted to the EPA.

Clarity of Instructions: All respondents indicated that instructions could be improved in terms of clarity. However, most respondents indicated that the forms that needed to be submitted were clear and easy to understand.

Electronic Reporting and Record Keeping: All respondents encouraged the EPA to move to electronic reporting and record keeping as quickly as possible.

Burden and Costs: All respondents felt that the costs associated with the EDSP Tier 1 Battery were underestimated. Most respondents also felt that the EPA could do a better job explaining exactly how the ICR is calculated and where specific figures are "pulled" from. CropLife America stated that they felt the current cost estimate for the EDSP Tier 1 Battery is 15% lower than "real world" costs. CropLife America also indicated that the labor categories (currently managerial, technical, and clerical) should be expanded to include legal and consultant categories.

EPA Response to Consultation Feedback: Because of the similarity in comments received during the consultation process and the public comment period and the general overlap of participants, please refer to the section 3(c) of this document.

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

The EPA received four responses to the 60-day public notice and comment period for the draft ICR renewal (77 FR 47640, August 9, 2012):

Commenter#[1]	DCN[2]	Commenter Name[3]	Affiliate
1	EPA-HQ-OPPT-2011-0966-0012	Bayer CropScience Endocrine Drive Team	Bayer CropScience LP
2	EPA-HQ-OPPT-2011-0966-0013	Clare Thorpe, Senior Director Human Health Policy	CropLife America (CLA) and Endocrine Policy Forum (EPF)
3	EPA-HQ-OPPT-2011-0966-0014	Scott Slaughter	Center for Regulatory Effectiveness (CRE)
4	EPA-HQ-OPPT-2011-0966-0015	Patricia L. Bishop, Research Associate, Regulatory Testing Division and Kristie Sullivan, Director, Regulatory Testing Issues	People for the Ethical Treatment of Animals (PETA) and Physicians Committee for Responsible Medicine (PCRM)

Key:
(1) This is the number that is used in this document to refer to this particular commenter.
(2) This is the number that is used to identify this comment in the docket at http://www.regulations.gov,
(3) This is the name of the individual or entity that submitted the comments, along with their affiliation, if provided.

A complete *Response to Public Comments Document* is in Attachment I, and is also in the docket at http://www.regulations.gov under Docket ID number EPA-HQ-OPPT-2011-0966.

3(d) Effects of Less Frequent Collection

Once per chemical substance is the statutory minimum, because FFDCA section 408(p)(3) specifically requires that the 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. For the purposes of this ICR renewal, the agency assumes that the only additional new work will be that associated with the issuance of new "catch-up" orders.

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, the 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 the 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.

It is important to note that the same record retention requirements do not apply to non-pesticides.

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 section 408(p)(5)(B) requires that the 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, the EPA believes that this provision directs the agency to create procedures that operate within the existing confines of FIFRA section 10, the Freedom of Information Act (FOIA), and the Trade Secrets Act.

As discussed in more detail in the policies and procedures document (Attachment B), because the data would support a tolerance or exemption from the requirement of a tolerance, FFDCA section 408(i) provides that much of the data submitted in response to an order issued under FFDCA section 408(p) would be subject to the protections in FIFRA section 10. In addition, CBI submitted by pesticide registrants in response to an order issued under FFDCA section 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 section 10 would be provided certain protections that go beyond those authorized by FOIA. For example, FIFRA section 10(g) generally prohibits the 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 section 408(i) extends the protection available under FIFRA section 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 section 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.

As indicated in the policies and procedures document (Attachment B), the 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 section 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 section 408(p) by the agency to collect Tier 1 screening data under the EDSP. Under FFDCA section 408(p)(5)(A), the 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" [emphasis added]. As such, the potential respondent universe as described in the existing ICR remains the same.

Identification of Order Recipients: The EPA generally identified the following categories of potential recipients of the Tier 1 orders:

- *Pesticide 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 has 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 and 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.

As stated earlier, for a duration of 15 years after the issuance of the initial orders in 2010, the EPA intends to issue a "catch-up" order to any company who subsequently enters the marketplace to manufacture or import the substance that was the subject of an EDSP order. Specifically, in addition to the order recipients identified by the agency, the EPA may issue an order under FFDCA section 408(p)(5) to a manufacturer or importer who enters the marketplace after the issuance of the initial orders, *i.e.*, 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 section 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.

Grouping Respondents by Information Collection (IC) Activities: The agency has divided the two identified respondent groups into the following distinct information collection (IC) categories:

- *Order Recipients*. This category includes everyone that could receive an EDSP order for one or more of the chemicals on the initial list, but has not already received an EDSP order.
- *Data Generators/Submitters*. This category includes one company for each chemical because the EPA expects companies to work together to provide the required data so that they do not duplicate efforts.
- *Consortium Participants*. This category includes the order recipients that are not in the Data Generators/Submitters category. These companies will actively participate in consortia activities, and includes the recipient of a subsequent "catch-up" order that is expected to join the ongoing activities.

Calculating the Number of Respondents: To date, the EPA has already issued the initial Tier 1 EDSP orders for the 67 chemicals, and those order recipients have already provided their initial responses. This is specifically reflected in the estimated number of respondents for the different IC categories.

In terms of estimating the potential number of **order recipients** for purposes of estimating the burden in this ICR, the EPA is assuming the potential issuance of up to 20 additional orders each year (15 involving pesticide active ingredients and 5 involving pesticide inert ingredients). Based on the agency's experience with "catch-up" orders to date, this appears to be a reasonable approach for estimating the number of potential catch-up orders. The EPA also assumes that all "catch-up" order recipients will join an existing data generator (*i.e.*, a consortium).

In terms of estimating the potential number of **data generators/submitters** for purposes of estimating the burden in this ICR, the EPA assumed that there would be one for each of the 67 chemicals. The EDSP process is longer than three years, the term of an ICR. All of the orders have been issued, with the

exception of catch-up orders. Therefore, for this ICR, the agency knows that Tier 1 data are being generated only once for each of the 52 chemicals of the original 67. Of the 52 remaining chemicals, 22 are supported by a single respondent, while a group of respondents that have formed a consortia for 30 chemicals. The orders for the remaining 15 chemicals were satisfied through cancellation in the case of (8) pesticides and withdrawn as a pesticidal inert for the 7 remaining (formerly) inert chemicals.

In terms of estimating the potential number of **consortium participants** for purposes of estimating the burden in this ICR, the EPA assumed that the recipients of a catch-up order would join the ongoing consortium. Based on the initial responses received already, there are 30 consortia currently underway that include a total of 213 participants.

Table 1 presents the estimated number of respondents for each IC category, which is used subsequently as a multiplier for the per response burden in order to calculate the total annual burdens.

Table 1 – Estimated Number of Potential Respondents

IC #	IC Category Name	Estimated Number of Respondents
1.	**Order Recipients**	**60**
1(a).	– Registrants	0
	Catch-Up Orders	45
1(b).	– Manufacturers/Importers	0
	Catch-Up Orders	15
2.	**Data Generators/Submitters**	**52**
2(a).	– Registrants	50
	Catch-Up Orders	0
2(b).	– Manufacturers/Importers	2
	Catch-Up Orders	0
3.	**Consortium Participants**	**273**
3(a).	– Registrants	207
	Catch-Up Orders	45
3(b).	– Manufacturers/Importers	6
	Catch-Up Orders	15
	Total Respondents	**385**

4(b) Respondent Activities

Respondent activities vary based on the IC category and the respondent group. Although identified under the applicable IC category, the activities are numbered sequentially to allow for cross-referencing.

IC #1: Order Recipients:

In general, these respondents will receive individual orders that are prepared by the EPA using the order templates identified in Attachment C(1), entitled "*FFDCA 408(p) Order Template for Pesticide Registrants (As of September 16, 2009)*" or in Attachment C(2), entitled "*FFDCA 408(p) Order Template for Pesticide Inert Ingredients (As of September 16, 2009)*." The order will specify the data that must be submitted (*i.e.*, based on the eleven Tier 1 assays as discussed later in this section), and outline the timeframes for responding to the order, including providing an initial response, annual status reports, if applicable, and for submitting the data responsive to the order.

The order will direct the recipient to provide an initial response within 90 days of receiving the order using the currently approved form identified as EPA Form No. 6300-05, entitled "*FFDCA section 408(p) Order/FIFRA section (3)(c)(2)(B) Data Call-In (DCI) - Initial Response Form for Individual Order Recipients*," in attachment D(1). The EPA will continue to include a copy of this form in the order packet sent to the recipient, and will continue to pre-populate it with the basic information about the recipient, the chemical covered, and the applicable test data sought.

Since the agency assumes that there is already an existing consortium, it is also assumed that the consortium has already provided an initial response using the currently approved form identified as EPA Form No. 6300-05-C, entitled "*FFDCA section 408(p) Order/FIFRA section (3)(c)(2)(B) Data Call-In (DCI) - Initial Response Form for Consortium/ Task Force*," in attachment D(2).

At this stage of the program, as discussed previously in section 4(a), those entities previously identified as respondents have already received the order, so the respondents for this IC category are now only those that will receive a catch-up order, *i.e.*, order recipients. Nevertheless, the activities for these respondents remain the same. Specifically, these respondents will engage in the activities identified and described later in this section as items (1) through (5).

IC #2: Data Generators/Submitters:

In general, the order recipients that are included in this IC category are those respondents that have indicated an intention to generate and submit the data requested, either individually or on behalf of a consortium. As such, these respondents will engage in the activities identified and described later in this section as items (4) through (9).

IC #3: Consortium Participants:

In general, the order recipients that are included in this IC category are those respondents that will actively participate in consortia activities, and includes recipients of a subsequent "catch-up" order because they are expected to join the ongoing activities. These respondents will be a participant in, but not fully responsible for, the activities identified and described later in this section as items (4) and (6), as well as maintain records related to their participant and compliance with the order as described in item (9).

Overview of Covered Activities:

Each recipient of an order (aka respondent) is expected to engage in the following information collection related activities:

(1) *Read instructions* – Each recipient will 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 recipient's familiarity with the EDSP, the recipient may also read other information about the EDSP, such as the policies and procedures document (Attachment B) that explain the agency's rationale for the requirements in the order and which describes the specific details of the policies and procedures that the 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 section 408(p), as well as the 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 an order under the EDSP, the agency has developed order templates for the two different kinds of potential order recipients:

- An Order Template for Pesticide Registrants, entitled "*FFDCA 408(p) Order Template for Pesticide Registrants (As of September 16, 2009)*." Attachment C(1).

- An Order Template for Pesticide Inert Chemicals, entitled "*FFDCA 408(p) Order Template for Pesticide Inert Ingredients (As of September 16, 2009).*" Attachment C(2).

Although the agency generally intends to use these templates, the individual orders will contain the necessary recipient specific details and requirements for the subject chemical. As such, the final individual orders that a recipient might receive may vary from these templates, as well as from other orders issued for a chemical.

(2) *Plan activities* – After reading the Tier 1 order they received, the recipient will plan the activities necessary to comply with the order based on their intended response to the order.

(3) *Submit an initial response to the EPA* – The Tier 1 orders will direct each recipient to provide an **initial response** to the EPA within 90 calendar days of issuance of the order that indicates how they intend to comply with the order. The response options available to the recipient will vary depending on whether the subject chemical is a pesticide active ingredient or pesticide inert chemical. The various response options available to a recipient, along with the related additional activities that they may engage in specific for that response option are described in section 4(c)(i) of this ICR.

To simplify completion of this initial response within the 90 days, the EPA has created an *Initial Response Form for Individual Order Recipients* [see Attachment D(1)]. The 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 will 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 form allows for assay specific responses 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 the response 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. OSRI may also be submitted for consideration in satisfying all of the assays in the order, the initial response form includes a separate line item to indicate whether OSRI is being cited or submitted to address either (A) a particular assay (*i.e.*, in part 2.1.C. of the form), or (B) to satisfy the order as a whole (*i.e.*, in part 2.2. of the form). The response option involving the submission of OSRI is described in section 4(c)(i) of this ICR.

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* [Attachment D(1)] 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.

In the context of this renewal ICR, the respondents in the IC category for order recipients are only expected to submit an individual response form, because the EPA is assuming that the recipients of catch-up orders will join an ongoing consortium, rather than form a new one or generate data.

(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 the EPA. Such requests should be submitted to the EPA with a clear rationale and explanation of the deviation. All protocol variations will be reviewed by the 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 the EPA's harmonized test guideline compendium.[10] 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. The 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 the 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 purposes of this renewal ICR, however, recipients of the catch-up order are not expected to engage in such activities because they are expected to join with whoever has already committed to do this.

[10] http://www.epa.gov/ocspp/pubs/frs/home/testmeth.htm.

For the purposes of calculating paperwork burden hours and costs in this ICR, the EPA assumed that the data generation will be performed by a contract laboratory at the request of an individual order recipient or a consortium. The agency has no information upon which 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 industry, many companies now outsource toxicology testing because it is less expensive than maintaining that function in-house (Reference 8, p. 5.). Nevertheless, only those activities imposed by the information collection request are attributable to this ICR. For example, the 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 study.

(6) *Report progress, compile and review the data* – Unless the 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 the 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. Compiling and reviewing the data can include such activities such as Data Entry Spreadsheet Templates (DESTs). DESTs for the EDSP Tier 1 Battery can be found at http://www.epa.gov/endo/pubs/toresources/seps.htm#dests.

(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 having performed the applicable 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 the EPA* – The final data package is then submitted to the 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. Recipients who submit data in support of a pesticide registration will also be asked to maintain records of that data pursuant to 40 CFR 169.2(k), *i.e.*, containing research data relating to a registered pesticide for as long as the registration is valid and the producer remains in business.

Distribution of Activities by Labor Categories:

For purposes of estimating the potential respondent paperwork burden and costs associated with these activities, the agency identified three separate labor categories: 1) managerial; 2) technical; and

3) clerical. Each activity identified above may involve one or more labor or duty category. In Table 2, the agency identifies the assumed recipient activities divided between the three labor categories.

Table 2 – Expected Respondent Activities by Labor Categories

Activity	Managerial Duties	Technical Duties	Clerical Duties
(1)	Read the EPA's policies and procedures document	Read the EPA's policies and procedures document	
	Review the EDSP order	Review the EDSP order	
(2)	Identify timeframe for response		
	Identify and 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 the EPA
(4)	Communicate with the EPA	Review of protocol (deviations)	Arrange logistics for calls or meetings with the EPA
		Review GLPs (deviations)	
		Identify and discuss other scientifically relevant information and 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 and GLPs	
	Communicate with the 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 and review data	
		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 the EPA
(9)		Prepare data for files	Prepare final file folders
			Maintain records

4(c) Information Requested

This section of the ICR renewal describes the information that an order recipient is expected to provide the agency. The order will identify the Tier 1 data being requested and will provide the specific instructions for complying with the order. In general, all order recipients are expected to provide an individual initial response that identifies how the recipient intends to respond to the order. The specific information required to be provided with the individual initial response from each order recipient will vary based on the respondent's initial response – the options for which are described in the order, the applicable procedure documents, and are summarized in section 4(c)(i) of this ICR. Those recipients that generate data, either individually or as part of a consortium, are expected to provide a 1-year progress report, and then submit the data to the EPA.

For purposes of this ICR, it is important to note that many of the initial response options adopted for EDSP 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 policies and procedures document (Attachment B), the agency adopted the 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 those other 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

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 order recipient 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 provides a brief overview of the available response options for orders involving pesticide active ingredients and pesticide inert ingredients (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 the EPA (*e.g.*, to whom the EPA could send a DCI notice under FIFRA section 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 the 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.

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 the EPA NOT be resubmitted in its entirety.**

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 the EPA that no such compensation is necessary.

The 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.

(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 [*see 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 the 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.

Although catch-up order recipients are most likely to select this option, these respondents are generally expected to join a consortium that has already been formed, or otherwise join with an individual who has already committed to generate 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 a Tier 1 order involving 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) an original data submitter; (2) a person who has complied with an EDSP 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 the EPA to evaluate the claim. If the EPA cannot 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, the EPA's policy does not include the issuance of orders under FFDCA section 408(p) to registrants of end-use products.

(6) *I Claim a Formulators' Exemption*. A pesticide 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 the 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. The 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 Chemical*. 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. The EPA intends to verify such a claim. If the EPA confirms the claim, the Initial Response Form is the only response required to satisfy the order. If, however, the 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."

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 or requests for such consideration. 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 the recipient believes would allow the EPA to determine that the 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*. There are two other response options available to all order recipients.

a) *Pre-enforcement challenges to the Tier 1 Order*. If a recipient wishes to challenge the Tier 1 order, the order will describe the informal process by which a recipient may raise, and the EPA may review, objections to the issuance of an order or to specific provisions in the order. For the 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 the EPA to reconsider some or all of the testing specified in the Tier 1 order, the 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, the EPA generally expects that if the chemical was used by the 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 the 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 the 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 for an extension to the agency. The written request must be submitted before the applicable deadline and 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 the EPA is considering any such request, the original deadlines in the order remain unchanged. The agency will respond to such requests in writing because time extensions can only be granted in writing. If the EPA does not grant the request, the original deadline remains. Normally, time extensions can be requested only in cases of extraordinary testing problems beyond the expectation or control of the registrant, manufacturer, or importer. Time extensions will not be considered if the request for extension is not made in a timely fashion; in no event shall a time 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 from 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 following is a list and brief description of each of the assays that are 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

The order itself will specify the data submission content and format that the recipient should use. For pesticide active ingredients and pesticide inert ingredients the content and format is based on that used currently for other pesticide data submissions. Since the initial chemicals involve pesticides and pesticide inerts, the 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 the EPA should be consistent with the following existing standards:

1. *Format for Data Submission*. As part of a cooperative project, the EPA and the Canadian Pest Management Regulatory agency (PMRA) developed standard data evaluation formats, or templates. The templates have been in use by the agencies since 2002 for writing their data evaluation records (DERs) of studies submitted under FIFRA and FFDCA to the 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 agencies encourage recipients to include study profiles based on these templates, which 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/.

   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).

   In addition, the agency 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 the 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 the 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, *e.g.*, such as those 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, and Information Management

5(a) Agency Activities

The functions and responsibilities associated with the EDSP under FFDCA section 408(p) have been assigned to the EPA's OCSPP.[11] Within OCSPP, 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.

OCSPP's OSCP will coordinate the review of Tier 1 screening data received, posting of information on the agency's Website, and the preparation of resulting determinations related to the subject chemical. Data received by the EPA will first be reviewed for completeness and then routed to an agency team of scientists and analysts for technical review. Although the technical review teams will consist mostly of staff from the offices in OCSPP, it will also include staff from other EPA offices, as appropriate.

In general, the agency is expected to engage in the following general activities related to the information collection activities under this ICR renewal:

(1) Prepare instructions. Prepare procedural steps, guidance and instructions for order recipients so that they understand what data are to be submitted, when and how. The policies and procedures document (Attachment B) describes the policies and procedures that the EPA intends to use to implement the data collection component of the EDSP. Although that document is non-binding, the

[11] Prior to April 22, 2010, this office was known as the Office of Prevention, Pesticides and Toxic Substances (OPPTS).

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. The list of the chemicals covered by this ICR is provided in Attachment G. For purposes of this renewal ICR, since all of the remaining 52 chemicals on the final list have been the subject of a Tier 1 order issued under FFDCA section 408(p), the agency assumes that they could also be the subject of a catch-up order.

(3) Identify order recipients. As indicated previously, the EPA has already issued Tier 1 orders to those identified for the remaining 52 chemicals as described in the existing ICR. As such, this ICR renewal involves potential recipients of catch-up orders. Recipients of catch-up orders will only be identified if a new registration application is received by the agency for one of the chemicals on the initial list, or if a company is otherwise identified. See the discussion on respondents in section 4(a) of this ICR renewal.

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, the 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 is maintained up to date on the agency's EDSP Web site, along with the status of the order (including recipients' responses received by the EPA). These reports can be accessed at http://www.epa.gov/endo/pubs/toresources/index.htm.

(4) *Prepare the EDSP Tier 1 Orders*. The EPA intends to use the appropriate order template (as discussed in section 4(b) of this ICR) 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, 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, the EPA intends to maintain an up to date list of order recipients on the agency's EDSP Web site.

Along with preparation of the orders, the 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, the EPA is maximizing the available resources and efficiencies related to the administrative components of Tier 1 screening under the EDSP.

(5) *Review and 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 OCSPP 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.

(7) *Process Initial Responses*. The agency will receive the Initial Response Form, document the response, track responses and 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 complete other tasks, *e.g.*, document lead for a consortia, process a voluntary cancellation request or request for reformulation, etc. The agency will 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 and 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, OCSPP will determine appropriate action (*i.e.*, whether to initiate cancellation procedures, refer the case to the EPA's Office of Enforcement and Compliance Assurance (OECA) for enforcement, etc.).

(10) *Issue "Catch-up" Orders*. The EPA may issue a so called "catch-up" order to a manufacturer or importer who begins to sell a pesticide ingredient (active or inert) 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.

(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, OPPT 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 policies and procedures document (Attachment B).

(12) *Analyze Data*. OCSPP will implement the agency's internal standard review procedures to review the data. For example, what do 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 are needed. For more background information on the weight-of-evidence approach, please go to http://www.regulations.gov, specifically under docket EPA-HQ-OPPT-2010-0877.

(13) *Incorporate/Use the Data*. The agency will incorporate the data into a risk assessment and make a regulatory decision as necessary and appropriate. The 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 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 the 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. For pesticide active and inert ingredients, the data will be stored in OPPIN. 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, the 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 section 10) may request copies of non-confidential studies through FOIA.

In addition, OPP's Information Technology and Resource Management Division (ITRMD) has enhanced the agency's tracking database (PRISM) to provide the necessary information to accomplish the Tier 1 goal. PRISM was used for issuance and tracking of EDSP orders related to the initial list of chemicals.

To meet the goals of the EDSP, the system allows for the creation of orders for each chemical. For pesticide active ingredients, the system will manage information associated with the company, product or pesticide active ingredients, requirement information, and information related to the responses. For inert ingredients, the system manages the associated companies only, since these companies may not have any registered products. In addition, the system allows for the submission of studies through registrant consortiums, in addition to individuals. This will ensure that the companies who received orders are given credit for the submissions when the consortium is identified as the study owner. For every inert there is 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 manages response extensions and identifies 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 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 policies 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 that document, the 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 happens to manufacture one of the chemicals and therefore receives a Tier 1 test 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. The 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.

The 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, which will be calculated based on the date the order is issued. In general, the basic schedule the 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 and 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 the 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 policies and procedures document (Attachment B).

The timing of the activities covered by this ICR is not specific enough to accurately divide them by year. For purposes of estimating the potential paperwork burden in this ICR, the EPA therefore 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 the 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. 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 the 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 the 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 May 2011 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, and 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 29.6% of total labor cost, based on benefits for all private industry workers from http://www.bls.gov/schedule/archives/ecec_nr.htm.[12] 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]	Wages	$57.42	$28.32	$17.02
Benefits Percentage of Total Labor[2]	Benefits%	29.6%	29.6%	29.6%
Loaded Hourly Rate (LHR)	Wages / 1-Benefits%	$81.56	$40.23	$24.18
Overhead Percentage[3]		50%	50%	50%
Overhead Per Hour (OPH)	LHR*Overhead%	$40.78	$20.12	$12.09
Fully Loaded Hourly Rate	**LHR + OPH**	**$122.34**	**$60.35**	**$36.27**

1. Data Source: http://www.bls.gov/oes/current/naics4_325300.htm
2. Fringe benefits/wage per hour.
3. U.S. EPA, *EPA Air Pollution Control Cost Manual, Sixth Edition*, EPA-452-02-001, January 2002, pp. 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 = $122.34, Technical = $60.35; and Clerical = $36.27.

[12] DOL, Bureau of Labor, September 11, 2012 Announcement of June 2012 Data http://www.bls.gov/news.release/archives/ecec_09112012.htm

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, the EPA calculated the paperwork burden as a percentage of the testing costs; and 2) For the rest of the paperwork activities, the 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 the EPA's overall experience with such activities.

1. *Method Used to Calculate the Burden and Costs for Data Generation*. The 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.

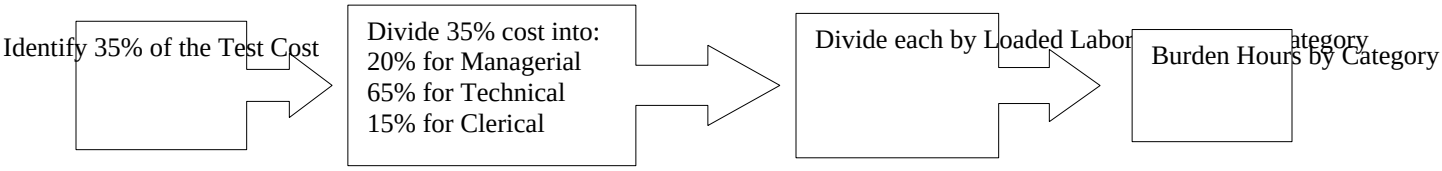
   To calculate the burden associated with the paperwork activities involved in conducting the tests, the agency starts with the cost of the test, typically the market price for the test as identified by laboratories that offer testing services. The agency used estimated costs for 2 assays that were based on estimates provided by the EPA scientist overseeing the validation effort for those 2 assays. Since the 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 (References 8 and 9). The EPA believes that these estimates are still valid as adjusted for inflation. Our basis for being comfortable with these cost estimates is a peer-reviewed article that appeared in *Toxicological Sciences* entitled, "Application of an Integrated Testing Strategy to the U.S. EPA Endocrine Disruptor Screening," which estimated the costs for the eleven assays to be $572,913.[13] As indicated in Attachment F, the estimate provided by the EPA is slightly higher at $637,184.

   Based on the existing methodologies, the 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.

[13] The total in the article of $544,397 was in 2010 dollars, which were adjusted for 2012 using the inflation calculator at http://www.bls.gov/data/inflation_calculator.htm.

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, the 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.

6(b) Estimating Respondent Burden and Cost

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

6(b)(i) Estimated Burden and Costs

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

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 the EPA[(b)]	24	21	2	**47**
4) Read and discuss the protocol	36	145	0	**181**
---> Activities related to the submission of OSRI[(c)]	40	201	37	**278**
5) Participate in Consortium	24	145	2	**171**
6) Generate the data[(d)]	397	2,612	1,003	**4,012**
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 submission package	5	20	7	**32**
10) Submit final data to the EPA	3	0	2	**5**
11) Maintain records	0	24	62	**86**
Total Burden:	**630**	**3,433**	**1,134**	**5,197**

(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) Hours required for OSRI Submission from CLA/EPF Report (Reference 9).
(d) Burden estimate is a percentage of the total test cost, which is calculated in Attachment F.

The estimated per chemical cost for each of the paperwork activities is presented in Table 7. 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 to the existing ICR. The following loaded labor rates were used to calculate these costs:
Managerial = $122.34; Technical = $60.35; and Clerical = $36.27.

Table 7 – Estimated Per Chemical Costs by Activity

Activity [(a)]	Managerial $122.34	Technical $60.35	Clerical $36.27	Total
1) Read instructions	$1,468	$724	$0	**$2,192**
2) Plan activities	5,872	2,535	0	**8,407**
3) Submit an initial response to the EPA[(b)]	2,936	1,267	73	**4,276**
4) Read and discuss the protocol	4,404	8,751	0	**13,155**
---> Activities related to the submission of OSRI[(c)]	4,894	12,130	1,342	**18,366**
5) Participate in Consortium	2,936	8,751	73	**11,760**
6) Generate the data[(d)]	48,569	157,634	36,379	**242,582**
7) Submit Progress Report	612	1,207	254	**2,073**
8) Compile and review the final data for submission	4,404	11,527	435	**16,366**
9) Complete paperwork to assemble submission package	612	1,207	254	**2,073**
10) Submit final data to the EPA	367	0	73	**440**
11) Maintain records	0	1,448	2,249	**3,697**
12) Delivery costs				**$10.55**
Total Cost:	**$77,074**	**$207,181**	**$41,132**	**$325,398**

(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) Hours required for OSRI Submission from CLA/EPF Report (Reference 9).
(d) Burden cost estimate is a percentage of the total test cost, which is calculated in 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 U.S. Postal Service rate is $10.55 from the west coast to the east coast (Reference 7).

6(b)(ii) Estimating Burden and Costs by IC Category

As discussed earlier, all respondents are not expected to engage in the same basic activities, their activities will be based on their initial response to the order. For the purposes of this ICR renewal, the estimated burden and costs for the two respondent groups are divided into distinct "IC" categories as presented in Table 1. Using the estimated number of respondents in Table 1 and the estimated per chemical burden and costs from Tables 6 and 7 for the various activities, the estimated respondent burden and costs for the different IC categories is presented in the following tables.

IC #1: Order Recipients

For this IC category, the agency assumed that all respondents are expected to engage in the activities identified in Table 6 and 7 as activities 1-3, and 11, which are all associated with receipt of the order and submission of the required initial response.

Table 8 – IC #1: Estimated Burden and Costs for Order Recipients – Registrants of Pesticide Active Ingredients

Activity[a]	Total # Responses[b]	Per Response		Total	
		Burden (hrs)[c]	Cost ($)[d]	Burden (hrs.)[e]	Costs ($)[f]
1) Read instructions	45	24	$2,192	1,080	$98,640
2) Plan activities		90	8,407	4,050	378,315
3) Submit an initial response to the EPA		47	4,276	2,115	192,420
11) Maintain records[g]		43	3,697	1,935	166,365
Total:		**204**	**$18,572**	**9,180**	**$835,740**

Key:
(a) Activities are described in more detail in section 4(b) of this ICR.
(b) From Table 1, catch-up orders.
(c) See Activity listing in Table 6.
(d) See Activity listing in Table 7.
(e) Total = (b) x (c)
(f) Total = (b) x (d)
(g) Maintaining records of the initial response is estimated to be ½ of the totals in Tables 6 and 7.

Table 9 – IC #1: Estimated Burden and Costs for Order Recipients – Manufacturers and Importers of Pesticide Inert Ingredients

Activity[a]	Total # Responses [b]	Per Response		Total	
		Burden (hrs)[c]	Cost ($)[d]	Burden (hrs.)[e]	Costs ($)[f]
1) Read instructions	15	24	$2,192	360	$32,880
2) Plan activities		90	8,407	1,350	126,105
3) Submit an initial response to the EPA		47	4,276	705	64,140
11) Maintain records[g]		43	3,697	645	55,455
Total:		**204**	**$18,572**	**3,060**	**$278,580**

Activity[a]	Total # Responses [b]	Per Response		Total	
		Burden (hrs)[c]	Cost ($)[d]	Burden (hrs.)[e]	Costs ($)[f]

Key:
(a) Activities are described in more detail in section 4(b) of this ICR.
(b) From Table 1, catch-up orders.
(c) See Activity listing in Table 6.
(d) See Activity listing in Table 7.
(e) Total = (b) x (c)
(f) Total = (b) x (d)
(g) Maintaining records of the initial response is estimated to be ½ of the totals in Tables 6 and 7.

The total IC #1 burden and costs is therefore a total of 12,240 hours (9,180 hrs + 3,060 hrs) and $1,114,320 ($835,740 + $278,580).

IC #2: Data Generators/Submitters:

This IC category of respondents is intended to capture the additional burden and costs expected for a subset of the order recipients who are generating and submitting the requested data to the agency. As discussed previously, the EPA assumes that for each chemical, the data will be submitted only once, either by an individual order recipient or a consortium. For this IC category, the agency assumes that these respondents will engage in the activities identified in Table 6 and 7 as activities 4 and 6 through 12, which are all associated with generating and submitting the data. Please note that participation in a consortium is addressed in the next group of ICs.

Table 10 – IC #2: Estimated Burden and Costs for Data Generators and Submitters – Registrants of Pesticide Active Ingredients

Activity[a]	Total # Responses[b]	Per Response		Total	
		Burden (hrs)[c]	Cost ($)[d]	Burden (hrs.)[e]	Costs ($)[f]
4) Read and discuss the protocol	50	181	$13,155	9,050	$657,750
6) Generate the data[h]		4,012	242,582	200,600	12,129,100
7) Submit Progress Report		32	2,073	1,600	103,650
8) Compile and review the final data for submission		239	16,366	11,950	818,300
9) Complete paperwork to assemble the submission package		32	2,073	1,600	103,650
10) Submit final data to the EPA		5	440	250	22,000
11) Maintain records [g]		43	3,697	2,150	184,850
12) Delivery Costs			11		528
	Total:	**4,544**	**$280,397**	**227,200**	**$14,019,828**

Key:
(a) Activities are described in more detail in section 4(b) of this ICR.
(b) From Table 1, includes catch-up orders.
(c) See Activity listing in Table 6.
(d) See Activity listing in Table 7.
(e) Total = (b) x (c)
(f) Total = (b) x (d)
(g) Maintaining records of the initial Response is estimated to be ½ of the totals in Tables 6 and 7.
(h) Burden cost estimate is a percentage of the total test cost, which is calculated in Attachment F.

Table 11 – IC #2: Estimated Additional Burden and Costs for Data Generators and Submitters – Manufacturers and Importers of Pesticide Inert Ingredients

Activity[a]	Total # Responses[b]	Per Response		Total	
		Burden (hrs)[c]	Cost ($)[d]	Burden (hrs.)[e]	Costs ($)[f]
4) Read and discuss the protocol	2	181	$13,155	362	$26,310
6) Generate the data[h]		4,012	242,582	8,024	485,164
7) Submit Progress Report		32	2,073	64	4,146
8) Compile and review the final data for submission		239	16,366	478	32,732
9) Complete paperwork to assemble the submission package		32	2,073	64	4,146
10) Submit final data to the EPA		5	440	10	880
11) Maintain records[g]		43	3,697	86	7,394
12) Delivery Costs			11		21
	Total:	**4,544**	**$280,397**	**9,088**	**$560,793**

Key:
(a) Activities are described in more detail in section 4(b) of this ICR.
(b) From Table 1, includes catch-up orders.
(c) See Activity listing in Table 6.
(d) See Activity listing in Table 7.
(e) Total = (b) x (c)
(f) Total = (b) x (d)
(g) Maintaining records of the initial Response is estimated to be ½ of the totals in Tables 6 and 7.
(h) Burden cost estimate is a percentage of the total test cost, which is calculated in Attachment F.

The total IC #2 burden and costs is therefore a total of 236,288 hours (227,200 hours + 9,088 hours) and $14,580,621 ($14,019,828 + $560,793).

IC #3: Consortium Participants

This IC category is intended to capture the additional burden and costs expected for a subset of the order recipients who are participating in a consortium. As discussed previously, the EPA assumes that when there are more than one order recipients for a particular chemical, the recipients will join forces to generate and submit the data in response to the order. If the order recipient is not the lead, they are assumed to be participants in that effort. For this IC category, the agency assumes that these respondents will also engage in the activities identified in Tables 6 and 7 as activity 5, which is associated with participating in a consortium.

Again, the EPA has issued all orders for the 67 chemicals on the initial list of chemicals and is assuming that there will be no more new data generators or submitters (*i.e.*, no new consortium) for this IC category. However, the EPA is making the assumption that 60 "catch-up" order recipients (45 pesticide active ingredients and 15 pesticide inert ingredients over a 3 year period) will join an existing consortium to generate data.

Table 12 – IC #3: Estimated Additional Burden and Costs for Consortium Participants – Registrants of Pesticide Active Ingredients

Activity[a]	Total # Responses[b]	Per Response		Total	
		Burden (hrs)[c]	Cost ($)[d]	Burden (hrs.)[e]	Costs ($)[f]
5) Participate in Consortium	252	171	$11,760	43,092	$2,963,520
	Total:	**171**	**$11,760**	**43,092**	**$2,963,520**

Key:

Activity[a]	Total # Responses[b]	Per Response		Total	
		Burden (hrs)[c]	Cost ($)[d]	Burden (hrs.)[e]	Costs ($)[f]

(a) Activities are described in more detail in section 4(b) of this ICR.
(b) From Table 1, includes catch-up orders.
(c) See Activity listing in Table 6.
(d) See Activity listing in Table 7.
(e) Total = (b) x (c)
(f) Total = (b) x (d)

Table 13 – IC #3: Estimated Additional Burden and Costs for Consortium Participants – Manufacturers and Importers of Pesticide Inert Ingredients

Activity[a]	Total # Responses [b]	Per Response		Total	
		Burden (hrs)[c]	Cost ($)[d]	Burden (hrs.)[e]	Costs ($)[f]
5) Participate in Consortium	21	171	$11,760	3,591	$246,960
Total:		**171**	**$11,760**	**3,591**	**$246,960**

Key:
(a) Activities are described in more detail in section 4(b) of this ICR.
(b) From Table 1, includes catch-up orders.
(c) See Activity listing in Table 6.
(d) See Activity listing in Table 7.
(e) Total = (b) x (c)
(f) Total = (b) x (d)

The total IC #3 burden and costs is therefore a total of 46,683 hours (43,092 hrs + 3,591 hrs) and $3,210,480 ($2,963,520 + $246,960).

6(c) Estimating Agency Burden and Cost

For the agency activities, the 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, the EPA has multiplied this burden by the total number of chemicals (667 hours x 52 chemicals = 35,204 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 and 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) Provide assistance and follow-up, as needed	0	36	0	**36**
9) Identify non-responders	0	0	1	**1**
10) Process Data Submissions	0	8	1	**9**
11) Analyze data[c]	0	440	0	**440**
12) Incorporate data into risk assessments[d]	0	88	0	**88**
13) Store data in retrievable system	0	4	8	**12**
Total Burden:	**9**	**637**	**31**	**677**

(a) Activities described in more detail in section 5(a) of this ICR.

Activity[a]	Managerial	Technical	Clerical	Total

(b) This estimate includes an estimated burden to provide any additional burden requested for an option.
(c) Assumes 40 hrs per assay (40 x 11).
(d) Assumes 8 hrs per assay (8 x 11).

The costs are calculated using the U.S. Department of Labor, Bureau of Labor Statistics data[14] and the methods identified in section 6(a)(i) of this ICR based on the NAICS 999100, Federal Executive Branch. The resulting loaded labor rates were used to calculate these costs: Managerial = $118.62; Technical = $76.74; and Clerical = $43.43. The estimated burden hour costs for the agency are presented in Table 15. To calculate the total potential agency costs over the three years, the EPA has multiplied the per chemical cost in Table 14 by the total number of chemicals ($51,297 x 52 chemicals = $2,667,444).

Table 15 – Estimated Agency Per Chemical Burden Hour Costs

Activity[a]	Managerial $118.62	Technical $76.74	Clerical $43.43	Total
1) Prepare instructions	$237	$921	$87	$1,245
2) Identify chemicals to be screened	237	1,612	87	1,936
3) Identify recipients	237	1,228	0	1,465
4) Prepare the 408(p) order packages	0	307	434	741
5) Review and approve the orders	237	307	0	544
6) Issue the orders	0	0	261	261
7) Process initial responses[b]	119	307	43	469
8) Provide assistance and follow-up, as needed	0	2,763	0	2,763
9) Identify non-responders	0	0	43	43
10) Process Data Submissions	0	614	43	657
11) Analyze data	0	33,766	0	33,766
12) Incorporate data into risk assessments	0	6,753	0	6,753
13) Store data in retrievable system	0	307	347	654
Total Cost:	**$1,067**	**$48,885**	**$1,345**	**$51,297**

Key:
(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 the ICR (Bottomline)

The total estimated burden and costs for the information collection activities associated with the renewal of the ICR for the initial list of chemicals to be screened under the EDSP is presented in Table 16.

[14] http://www.bls.gov/oes/current/naics4_999100.htm

Table 16 – Estimated TOTAL Respondent Burden and Costs for ALL Activities

Respondent Category[a]	Total # Responses[b]	Per Response[c]		Total[d]	
		Burden (hrs)	Cost ($)	Burden (hrs)	Costs ($)
Registrants of PAIs					
IC #1(a) - Order Recipients	45	204	$18,572	9,180	$835,740
IC #2(a) - Data Generators/Submitters	50	4,544	$280,397	227,200	$14,019,828
IC #3(a) - Consortium Participants	252	171	$11,760	43,092	$2,963,520
Subtotal for Pesticide Active Ingredients:				***270,472***	***$17,819,088***
Manufacturers/Importers of Pesticide Inert Ingredients					
IC #1(b) - Order Recipients	15	204	$18,572	3,060	$278,580
IC #2(b) - Data Generators/Submitters	2	4,544	$280,397	9,088	$560,793
IC #3(b) - Consortium Participants	21	171	$11,760	3,591	$246,960
Subtotal for Pesticide Inert Ingredients:				***15,739***	***$1,086,333***
Total:[e]	**385**	**9,838**	**$621,458**	**295,211**	**$18,905,421**

Key:
(a) Grouped by respondents and according to IC category as presented in section 6(b) of this renewal ICR.
(b) From Table 1, includes catch-up orders.
(c) See totals from Tables in section 6(b) of this renewal ICR.
(d) Total = (b) x (c)
(e) Calculated by adding the column.

The **total potential respondent burden and cost** calculated in this renewal ICR involves activities that cannot be divided by year. The agency has calculated the total burden and assumed a 3-year duration of equal effort to calculate the annual burden and cost for this ICR. As such, the total respondent burden and costs for this ICR (as presented in Table 14) is simply divided by 3 to get an estimated annualized burden of **98,403 hours** (295,211 hours ÷ 3) and an estimated annualized cost of **$6,301,807** ($18,905,421 ÷ 3).

Table 17 – Annualized Estimated Total Respondent Burden and Costs for ALL Activities

Respondent Category[a]	Total # Responses[b]	Per Response[c]		Total[d]	
		Burden (hrs)	Cost ($)	Burden (hrs)	Costs ($)
Registrants of PAIs					
IC #1(a) - Order Recipients	**45**	**68**	**$6,191**	**3,060**	**$278,580**
Recording Keeping		54	4,958	2,415	223,125
Reporting		14	1,232	645	55,455
Non-Burden Costs		0	0	0	0
IC #2(a) - Data Generators/Submitters	**50**	**1,515**	**$93,466**	**75,733**	**$4,673,276**
Recording Keeping		1,500	92,230	75,017	4,611,483
Reporting		14	1,232	717	61,617
Non-Burden Costs		0	3.52	0	175.83
IC #3(a) - Consortium Participants	**252**	**57**	**$3,920**	**14,364**	**$987,840**
Recording Keeping		57	3,920	14,364	987,840
Reporting		0	0	0	0
Non-Burden Costs		0	0	0	0
Subtotal for Pesticide Active Ingredients:				***93,157***	***$5,939,696***
Manufacturers/Importers of Pesticide Inert Ingredients					
IC #1(b) - Order Recipients	**15**	**68**	**$6,191**	**1,020**	**$92,860**
Recording Keeping		54	4,958	805	74,375
Reporting		14	1,232	215	18,485

Respondent Category[a]	Total # Responses[b]	Per Response[c]		Total[d]	
		Burden (hrs)	Cost ($)	Burden (hrs)	Costs ($)
Non-Burden Costs		0	0	0	0
IC #2(b) - Data Generators/Submitters		**1,515**	**$93,466**	**3,029**	**$186,931**
Recording Keeping	**2**	1,500	92,230	3,001	184,459
Reporting		14	1,232	29	2,465
Non-Burden Costs		0	3.52	0	7.03
IC #3(b) - Consortium Participants		**57**	**$3,920**	**1,197**	**$82,320**
Recording Keeping	**21**	57	3,920	1,197	82,320
Reporting		0	0	0	0
Non-Burden Costs		0	0	0	0
Subtotal for Pesticide Inert Ingredients:				***5,246***	***$362,111***
Total: [e]	**385**	**3,279**	**$207,152**	**98,403**	**$6,301,807**

Key:
(a) Grouped by respondents and according to IC category as presented in section 6(b) of this renewal ICR.
(b) From Table 1, includes catch-up orders.
(c) Calculated by taking the totals from the Tables in section 6(b) of this renewal ICR (see also Table 16), and dividing by 3. Numbers are rounded.
(d) Total = (b) x (c)
(e) Calculated by adding the column.

To calculate the **total potential agency burden and cost** over the three years, the EPA has multiplied the per chemical burden and cost in Tables 13 and 14 by the total number of chemicals for a total agency burden of **35,204 hours** (677 x 52 chemicals) and a cost of **$2,667,444** ($51,297 x 52 chemicals). Divided by 3 to get an **estimated annualized burden of 11,735 hours** (35,204 ÷ 3) and an estimated annualized cost of **$889,148** ($2,667,444 ÷ 3).

6(e) Reasons for Changes in Burden Estimates

This request represents **a decrease of the annualized burden by 63,012 hours** from that currently in the OMB inventory (from 161,415 hours to 98,403 hours). This change is an adjustment in burden estimates due to the planned progression of the collection activities associated with the initial list of chemicals to be screened under the EDSP. This change is an adjustment.

6(f) Burden Statement for this ICR

The annual public burden for this information collection activity is estimated to range between 204 and 4,919 hours, depending on the respondent category, with an estimated cost between $18,572 and $310,729. Burden is defined in 5 CFR 1320.3(b). An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a current and valid OMB control number. The OMB control numbers for the EPA's regulations in title 40 of the CFR, after appearing in the *Federal Register*, are listed in 40 CFR part 9 and included on the related collection instrument or form, if applicable.

The EPA has established a docket for this ICR under docket ID No. EPA-HQ-OPPT-2011-0966, 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, which 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.

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. 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.
4. 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) http://www.epa.gov/fedrgstr/EPA-PEST/2009/April/Day-15/p8709.pdf.
5. Endocrine Disruptor Screening Program (EDSP); Draft Policies and Procedures Document; Request for Comment; Notice (72 FR 70842, December 13, 2007) http://www.epa.gov/scipoly/oscpendo/pubs/draft_policies_frn.pdf.
6. Endocrine Disruptor Screening Program (EDSP); Policies and Procedures for Initial Screening; Notice (74 FR 17560, April 15, 2009) (see Attachment B to this ICR) http://www.epa.gov/fedrgstr/EPA-PEST/2009/April/Day-15/p8706.pdf.
7. U.S. Postal Service, Online Rate Calculator, as of May 7, 2012. http://postcalc.usps.gov/.
8. EPA Report "Laboratory Testing of Chemicals for Endocrine Disruption Potential - Analysis of Market Factors" (October 14, 2009).
9. Crop Life America, EDSP Tier 1 Screening; Preliminary Burden Report dated November 2010 submitted by Crop Life America's Endocrine Policy Forum.

8. Attachments

All of the attachments listed below can be found in the docket for this ICR (unless otherwise noted); and are accessible electronically through http://www.regulations.gov, under Docket ID Number: EPA-HQ-OPPT-2011-0966.

Attachment	Description
A	FFDCA sections 408(p), 408(i). Available at http://epw.senate.gov/FDA_001.pdf. Paragraph 408(p) begins on page 84. Paragraph 408(i) begins on page 77.
B	Endocrine Disruptor Screening Program (EDSP); Policies and Procedures for Initial Screening; Notice (74 FR 17560, April 15, 2009)

Attachment	Description
	http://www.gpo.gov/fdsys/pkg/FR-2009-04-15/pdf/E9-8706.pdf
C	(1) FFDCA 408(p) Order Template for Pesticide Registrants (As of September 16, 2009). (2) FFDCA 408(p) Order Template for Pesticide Inert Ingredients (As of September 16, 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 (July 30, 2012).
G	Final List of Chemicals for Initial Tier 1 Screening in the EDSP (April 3, 2009).
H	Compendium of Consultation Responses
I	Response to Public Comments Document