EDSPICR-draft-2007-12-05

SUPPORTING STATEMENT FOR AN INFORMATION COLLECTION REQUEST (ICR)

1. IDENTIFICATION OF THE INFORMATION COLLECTION

1(a) Title of the Information Collection:

Tier 1 Screening of Certain Chemicals Under the Endocrine Disruptor Screening Program (EDSP)
OMB Control No.: **2070-(tbd)**
EPA ICR No.: **2249.01**

1(b) Short Characterization/Abstract

This is a new information collection request (ICR) under the Paperwork Reduction Act (PRA), 44 USC 3501 *et seq*., covering the information collection activities associated with Tier 1 screening of the first group of chemicals under the Endocrine Disruptor Screening Program (EDSP). The EDSP is established under §408(p) of the Federal Food, Drug, and Cosmetic Act (FFDCA), which requires endocrine screening of all pesticide chemicals and was established in response to growing scientific evidence that humans, domestic animals, and fish and wildlife species have exhibited adverse health consequences from exposure to environmental chemicals that interact with their endocrine systems. (See Attachment A).

The Agency first proposed the basic components of the EDSP on August 11, 1998 (63 FR 42852) (Ref. 1). After public comments, external consultations and peer review, EPA provided additional details about the EDSP on December 28, 1998 (63 FR 71541) (Ref. 2). The EDSP consists of a two-tiered approach to screen all pesticide chemicals for potential endocrine disrupting effects. The purpose of Tier 1 screening (referred to as "screening") is to identify substances that have the potential to interact with the estrogen, androgen, or thyroid hormone systems using a battery of assays. The purpose of Tier 2 testing (referred to as "testing"), therefore, is to identify and establish a dose-response relationship for any adverse effects that might result from the interactions identified through the Tier 1 assays. Additional information about the EDSP is available through the Agency's Web site at http://www.epa.gov/scipoly/oscpendo/index.htm.

EPA is currently implementing its EDSP in three major parts that are being developed in parallel and with substantial work on each well underway. This ICR is related to the third component of the EDSP, i.e., implementation of Tier 1 screening. The three parts are briefly summarized as follows:

1. *Assay Validation.* Under FFDCA §408(p), EPA is required to use "appropriate validated test systems and other scientifically relevant information" to determine

whether substances may have estrogenic effects in humans. EPA is validating assays that are candidates for inclusion in the Tier 1 screening battery and Tier 2 tests, and will select the appropriate screening assays for the Tier 1 battery based on the validation data. Validation is defined as the process by which the reliability and relevance of test methods are evaluated for the purpose of supporting a specific use (Ref. 2). In addition, on July 13, 2007, EPA published a **Federal Register** document that outlined the approach EPA intends to take for conducting the peer reviews of the Tier 1 screening assays and Tier 2 testing assays and EPA's approach for conducting the peer review of the Tier 1 battery (72 FR 38577) (Ref. 3). The status of each assay can be viewed on the EDSP Web site in the Assay Status table: http://www.epa.gov/scipoly/oscpendo/pubs/assayvalidation/status.htm.

2. *Priority Setting.* On June 18, 2007 (72 FR 33486), EPA issued the draft list of the first group of chemicals that will be screened in the Agency's EDSP (Ref. 4). The draft list was produced using the approach described in a **Federal Register** notice issued on September 27, 2005 (70 FR 56449), and includes chemicals that the Agency, in its discretion, has decided should be tested first based upon exposure potential (Ref. 5). This list should not be construed as a list of known or likely endocrine disruptors. Nothing in the approach for generating the initial list provides a basis to infer that by simply being on this list these chemicals are suspected to interfere with the endocrine systems of humans or other species, and it would be inappropriate to do so. The first group of chemicals identified for testing includes pesticide active ingredients and High Production Volume (HPV) chemicals used as pesticide inerts. After considering comments on this draft list of chemicals, EPA will issue a second **Federal Register** notice containing the final list of chemicals to be the first to undergo Tier 1 screening. For purposes of this ICR, the Agency used the draft list, which consists of 73 chemicals, to calculate the burden and cost estimates. More information on the EPA's priority setting approach and the draft list of chemicals is available at http://www.epa.gov/scipoly/oscpendo/prioritysetting.

3. *Procedures.* In a recently published **Federal Register** document (Ref. 6), EPA announced the availability of and is seeking public comment on the draft policies and procedures and the draft template for the test orders that EPA intends to use for Tier 1 screening under the EDSP of the initial list of chemicals. This ICR addresses the information collection activities described in these draft documents, which are also attached to this ICR. (See Attachment B and C).

The focus of this ICR is on the information collection activities associated with the Tier 1 screening of the 73 chemicals identified for initial screening under the EDSP. A separate ICR will be developed to address the information collection activities associated with Tier 2 testing. In addition, subsequent Tier 1 screening of additional chemicals not selected for the initial round will be addressed separately, either in a separate ICR or in an amendment to this ICR. In either case, EPA will follow the notice and comment process prescribed by the PRA to first seek public comment on the new ICR before submitting it to OMB for review and approval under the PRA.

2. NEED FOR AND USE OF THE COLLECTION

2(a) Need/Authority for the Collection

2(a)(i) Authority.

The EDSP was established in 1998 to carry out the mandate in §408(p) of the FFDCA [21 U.S.C. §346a et. seq.], which directed EPA "to develop a screening program . . . to determine whether certain substances may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or such other endocrine effect as the Administrator may designate." If a substance is found to have an effect, section 408(p)(6) directs the administrator to take action under available statutory authority to ensure protection of public health. That is, the ultimate purpose of the EDSP is to provide information to the Agency that will allow the Agency to evaluate the risks associated with the use of a chemical and take appropriate steps to mitigate any risks. The necessary information includes identifying any adverse effects that might result from the interaction of a substance with the endocrine system and establishing a dose-response curve. (Attachment A).

Under FFDCA § 408(p), EPA is required to test all pesticide chemicals and may test any other substance that may have an effect that is cumulative to an effect of a pesticide chemical, if EPA determines that a substantial population may be exposed to the substance, 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. The EDSP potentially will encompass a broad range of chemicals, and EPA has a number of authorities at its disposal to require testing of these types of chemicals. However, the scope of this ICR focuses only on the first 73 chemicals identified for Tier 1 screening.

In addition, section 1457 of the Safe Drinking Water Act (SDWA) also authorizes EPA to screen substances that may be found in sources of drinking water, and to which a substantial population may be exposed, for endocrine disruption potential. [42 U.S.C. §300j-17]

2(a)(ii) Need.

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

FFDCA), included a mandate for EPA to set up the EDSP using validated methods to test all pesticide chemicals (and other substances that may have cumulative effect of a pesticide or a substantial population is exposed) for their potential to interact with the endocrine system. EPA has been working to validate Tier 1 screening assays and Tier 2 tests to be used for this purpose. To access an overview of the endocrine system and information on endocrine disruptors go to http://www.epa.gov/scipoly/oscpendo/pubs/edspoverview/primer.htm.

2(b) Use/Users of the Data

Under the tiered approach for screening and testing that EPA is using to determine whether a substance may have an effect in humans that is similar to an effect produced by naturally occurring hormones, the Tier 1 screening data will be used to identify substances that have the potential to interact with the endocrine system. Chemicals that go through Tier 1 screening and are found to exhibit the potential to interact with the estrogen, androgen, or thyroid hormone systems will proceed to Tier 2 for testing. More rigorous Tier 2 testing data will be collected to determine whether the substance causes adverse endocrine-related effects, identify the adverse endocrine-related effects caused by the substance, and establish a quantitative relationship between the dose and the adverse endocrine-related effect. This ICR applies to Tier 1 screening. A subsequent ICR will address Tier 2.

The paperwork related requirements imposed on the respondents as part of Tier 1 screening under the EDSP allow EPA to ensure that the necessary testing data will be developed, that the results meet basic scientific standards of acceptability and adequacy, that unforeseen complications or issues can be promptly addressed, and that the testing is progressing on schedule.

The Office of Pesticide Programs (OPP) and the Office of Science Policy and Coordination (OSCP) will be responsible for receiving, processing and maintaining records of responses to the 408(p) orders. OSCP and OPP will coordinate the review of Tier 1 screening data received and will determine whether Tier 2 testing should be required.

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

3(a) Non-duplication

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

the passage of the FQPA and initiation of EDSP, there were no validated methods to screen or test chemicals for their potential to affect the endocrine system.

The Agency has a strong commitment to avoiding potential duplication in all of its testing programs, and actively promotes efficiency through its harmonized test guidelines and active participation in the rigorous scientific effort to identify data needs for risk assessments, develop testing protocols, and develop new methods for testing chemicals that minimize potential duplication, create greater efficiencies in testing, and minimize the use of animals in testing. As a charter member of the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM), EPA is working in a manner consistent with the interagency validation framework in the development and refinement of assays to reduce animal use, refine procedures involving animals to make them less stressful, and replace animals where scientifically appropriate. When complete, EPA will use these validated methods or assays to identify and characterize the endocrine activity of pesticides, commercial chemicals, and environmental contaminants, specifically in relation to estrogen, androgen, and thyroid hormones.

The Agency considered these goals in developing the procedures for the EDSP, both those procedures used within EPA and those that might be used by the respondents. For example, when a chemical is manufactured by several companies, the procedures encourage the companies to join together to develop and submit the requested data to EPA.

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

This is the draft ICR that is being issued for public review and comment before submission to OMB for review and approval under the PRA. Prior to submission to OMB, EPA will amend this section of the ICR to reference that effort and how the Agency amended the ICR after considering any comments received.

*[Placeholder for revised ICR: On [date will be inserted], EPA published a notice in the **Federal Register** to provide a 60-day public notice and comment period on the draft ICR. (72 FR [insert page citation]). EPA received [insert #] comments. [Insert summary of PRA issues raised by comments, and EPA's response.]]*

3(c) Consultations

Since the establishment of EDSP in 1998, EPA has consulted with various stakeholders throughout its development and implementation efforts, including: agrichemical and commodity chemical industries, environmental organizations, public health organizations, academia, animal welfare organizations, federal agencies, and state governments. As indicated previously, EPA is currently implementing its EDSP in three parts: 1) Assay development and validation, 2) Priority setting, and 3) Development of a framework for testing and data submission. A historical overview of

the external consultations and public comment opportunities provided since 1996 is available at http://www.epa.gov/scipoly/oscpendo/pubs/edspoverview/index.htm. The following is a summary of some of the ongoing consultations related to the Agency's EDSP implementation process.

Assay development and validation – After EPA published its 1998 Proposed Statement of Policy, the Agency, as directed by statute, asked the SAB/SAP to form a Joint Subcommittee to review the scientific issues related to the development of EDSP. The Joint Subcommittee met publicly on March 30 through April 1, 1999 and produced a report entitled, *Review of the EPA's Proposed Environmental Endocrine Disruptor Screening Program* (EPA-SAB-EC-99-013), published in July 1999 (Ref. 7). EPA's charge to the Joint Subcommittee was broad and complex, posing 18 major questions within four broad areas: 1) scope of the program; 2) priority setting; 3) the high throughput pre-screening (HTPS) approach; and 4) the proposed endocrine disruptor screening program. The Subcommittee offered several recommendations and identified a few areas of concern, but generally supported EPA's program as outlined in the December 1998 **Federal Register** notice (Ref. 2).

In 2001, EPA established an Endocrine Disruptor Methods Validation Subcommittee (EDMVS) under the National Advisory Council for Environmental Policy and Technology (NACEPT), in accordance with FACA, to assist its EDSP implementation activities (Ref. 8). EDMVS met nine times from late 2001 through 2003 and provided advice and counsel to EPA on topics including the development and choice of initial screening and testing protocols, prevalidation study designs, and validation study designs. EDMVS members worked to ensure that scientifically-sound assays were developed for animal- and non-animal-based ED screens and tests during the validation process. The subcommittee also ensured that people and organizations had the opportunity to comment and express their concerns on issues associated with the assays and processes. EDMVS played a purely advisory role to EPA, and did not conduct any official scientific peer reviews of EDSP methods.

In May 2004, the Endocrine Disruptor Methods Validation Advisory Committee (EDMVAC) was chartered to replace EDMVS. The EDMVAC continued to function like EDMVS by providing advice and recommendations to EPA on scientific and technical aspects of the Tier 1 screens and Tier 2 assays being considered for EDSP. The committee will evaluate relevant scientific issues, protocols, data, and interpretations of the data for the assays during the validation process. EDMVAC also provided advice on the composition of the Tier 1 screening battery. To access more information about EDVMS and EDMVAC, go to http://www.epa.gov/scipoly/oscpendo/pubs/assayvalidation/edmvac.htm.

On July 13, 2007, EPA published a **Federal Register** document that outlined the approach EPA intends to take for conducting the peer reviews of the Tier 1 screening assays and Tier 2 testing assays and EPA's approach for conducting the peer review of the Tier 1 battery (72 FR 38577) (Ref. 3). The mechanism that will be used to peer review Tier 1 assays will be an external letter review organized under an EPA peer

review contract. The procedures used for peer review of the Tier 1 assays will be in accordance with EPA's Peer Review Handbook. For each assay, a balanced peer review panel consisting of three to ten peer reviewers will be selected from a pool of qualified peer review candidates identified from academia, government, and the private sector, based on their subject matter expertise, availability, and lack of conflict of interest or past involvement in the project.

In July 2007, EPA also announced the availability of a "Listserv" or mailing group that allows interested parties to sign up to receive e-mail notifications of EDSP peer review updates, including information on the availability of peer review materials to be posted on the EDSP website. These materials may include the documents to be peer reviewed, background documents, the charge to the peer reviewers, and reports that summarize the results of peer reviews.

Chemical Selection Process - In addition to public comment on its planned approach for selecting the first group of chemicals to be screened in EDSP (Ref. 9), which was issued in final form in September 2005 (Ref. 5), the Agency issued a draft list of 73 pesticide chemicals for public review and comment (Ref. 4). These chemicals are the first to be considered for screening under the EDSP and should not be construed to be a list of known or likely endocrine disruptors. Nothing in the approach for generating the initial list provides a basis to infer that any of the chemicals selected interfere with or are suspected to interfere with the endocrine systems of humans or other species. Additional information about the draft list is available at http://www.epa.gov/scipoly/oscpendo/pubs/prioritysetting/listfacts.htm.

EDSP Policy and Procedures - A recently issued **Federal Register** notice outlines the Agency's draft policy and procedures for public comments (Ref. 6). This ICR is also being made available to the public for comment and any comments received will be given consideration prior to submitting this ICR to OMB for final review and approval under the PRA.

Public Workshop – During the public comment period for this ICR and the related draft policy and procedures document, the Agency intends to hold a public workshop with interested parties. This workshop will allow the Agency and stakeholders to discuss comments and questions about the draft policy, procedures and this ICR, as well as share ideas and information about potential improvements.

3(d) Effects of Less Frequent Collection

Under this ICR, the Tier 1 screening will occur only once per chemical substance. This is the statutory minimum, because FFDCA section 408(p)(3) specifically requires that EPA "shall provide for the testing of all pesticide chemicals," unless the Agency can determine that the chemical qualifies for the statutory exemption—i.e., that it is not anticipated to interact with the endocrine system. In addition, a recipient of a 408(p) order for Tier 1 screening may provide an initial response that could justify delaying Tier 1 screening or 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 in response to individual response submissions. For purposes of this ICR, the Agency assumes that all recipients of a 408(p) order for Tier 1 screening will provide an initial response and either generate the data or join a consortium to generate the data.

3(e) General PRA Guidelines

The one general PRA guideline that is exceeded in this collection is the time period for retaining records. When data are generated to support a pesticide registration under FIFRA, EPA requirements in 40 CFR 169.2(k) apply, which state that records containing research data relating to registered pesticides be retained for as long as the registration is valid and the producer remains in business. Registrations are valid until they are either voluntarily cancelled or withdrawn by the registrant or until EPA has cause to suspend or cancel the registration. Since the average period of marketability of a pesticide ranges from 15 to 30 years, the PRA guidelines specifying that data other than health, medical or tax records not be required to be retained for more than three years will be exceeded in this ICR. In those regulatory cases where the Agency's action may be challenged, it is imperative that all records, raw data, and specimens be available to support the Agency's decision. 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 73 chemicals because the data submitted would be used to support the pesticide registrations under FIFRA.

3(f) Confidentiality

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

As discussed in more detail in the Policy and Procedures Document (Attachment B), because the data would support a tolerance or exemption from the requirement of a tolerance, FFDCA §408(i) provides that much of the data submitted in response to FFDCA §408(p) test orders would be subject to the protections in FIFRA §10. In addition, CBI submitted by pesticide registrants in response to a FFDCA §408(p) test order would be considered as part of the registration process, and would therefore be considered to be data submitted in support of a registration. However covered, data subject to FIFRA §10 would be provided certain protections that go beyond those authorized by FOIA. For example, FIFRA §10(g) generally prohibits EPA from releasing

information submitted by a registrant under FIFRA to a foreign or multinational pesticide producer, and requires the Agency to obtain an affirmation from all persons seeking access to such information that they will not disclose the information to a foreign or multinational producer. FFDCA §408(i) extends the protection available under FIFRA §10 for data submitted in support of a tolerance or tolerance exemption.

All other confidential business information submitted in response to a FFDCA §408(p) test order (i.e., data not in support of a registration or tolerance/tolerance exemption) is only protected by the provisions of FOIA and the Trade Secret Act. FOIA requires agencies to make information available to the public upon request, except for information that is "specifically made confidential by other statutes" or data that are "trade secrets and commercial or financial information obtained from a person and is privileged or confidential." [5 U.S.C. §552]. Note that substantive criteria must be met to claim confidentiality of business information, as specified in 40 CFR §2.208.

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

3(g) Sensitive Questions

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

4 THE RESPONDENTS AND THE INFORMATION REQUESTED

4(a) Respondents

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

- 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 408(p) orders is on the *Technical Registrant*.

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

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

- Chemical Manufacturers and Processors (NAICS code 325), e.g., persons who manufacture or process chemical substances.

- Pesticide, Fertilizer, and Other Agricultural Chemical Manufacturing (NAICS code 3253), e.g., persons who manufacture or process pesticide, fertilizer and agricultural chemicals. This includes Producers & Formulators of Pesticide Products (NAICS code 32532); Producers of Antifouling Paints (NAICS code 32551); Producers of Antimicrobial Pesticides (NAICS code 32561); Producers of Nitrogen Stabilizers (NAICS code 32531); and Producers of Wood Preservatives (NAICS code 32519).

Although final identification of all the specific order recipients for the Tier 1 screening of the initial 73 chemicals is still underway, the Agency has conducted a preliminary search of internal data sources to identify potential recipients, or respondents for the purposes of estimating the burden in this ICR. For example, the Agency used internal OPP data sources to identify the technical registrants and the end-use product registrants for 64 of the 73 chemicals on the initial list, and used the 2002 data from the Inventory Update Rule database to identify manufacturers and importers of the remaining 9 HPV chemicals identified as inert ingredients for pesticides on the list of 73 chemicals. It is important to note that the IUR data are based on reports from companies that domestically manufacture or import the chemical in quantities greater than 10,000 lbs/yr at a single site in 2002. When the Agency identifies the final recipients of the order, it intends to also search external sources of information in an attempt to identify all of the manufacturers and importers of the listed chemicals.

For purposes of calculating the number of potential respondents for this ICR, the Agency divided the respondents into three categories: 1) Order Recipients; 2) Data Generators/Submitters; and 3) Consortium Participants. The Order Recipients category includes everyone that could receive an order, the Data Generators/ Submitters category includes one company for each chemical; and the Consortium Participants

category includes the order recipients that are not in the Data Generators/Submitters category. Table 1 presents the estimated number of respondents based on the Agency's initial efforts to identify potential respondents. These figures will be adjusted as appropriate to reflect the final order recipients, but any adjustment is not expected to have a significant impact on the final burden estimate in this ICR.

Table 1 - Estimated Number of Potential Respondents

Potential Respondent Category	Estimated Number of Respondents			
	Pesticide Registrants	Manufacturers/ Importers	Catch-Up Orders	Total
Order Recipients	280	160	5	445
Data Generators/Submitters	64	9	0	73
Consortium Participants	216	151	0	367

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

At this time the Agency has no way to predict or estimate the number of potential recipients for these "catch-up" orders. For purposes of estimating the burden in this ICR, the Agency is estimating that up to 5 entities might receive such "catch-up" orders in any one year.

4(b) Respondent Activities

As described in more detail in the Policy and Procedures Document (Attachment B), a recipient of a 408(p) order is expected to engage in the following activities:

(1) *Read instructions* – Each order recipient will need to read the 408(p) 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. A draft template of the 408(p) order is also available for review and comment. (See Attachment C.)

(2) *Plan activities* – After reading the order, the recipient will need to plan the activities necessary to comply with the 408(p) order, including determining their intentions, forming a consortia with other manufacturers of the chemical, identifying a lead for the laboratory work, conducting the tests, etc.

(3) *Submit an initial response to EPA* - The EDSP test order will direct each recipient to provide an initial response to EPA within 90 days of the issuance of the order that indicates how they intend to comply with the order. To simplify completion of this initial response within the 90 days, EPA has created an Order Response Form (See Attachment D). 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 order packet recipient would only need to indicate their intentions to complete the form for submission to EPA. The response options available to a recipient are described in section 4(c)(i) of this ICR.

(4) *Read and discuss the protocol* – Since the protocols are currently being developed through the assay validation process described earlier, the order recipients will need to read the protocols accompanying the order and may have questions. Although this activity is expected to be primarily performed by the data generating entity, other participants in a consortium may also participate in these activities.

(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 EDSP test order, using the test protocols attached to the order and complying with the good laboratory practice (GLP) standards described in 40 CFR part 160. An order recipient wishing to deviate from the required protocol, may do so only after consultation with EPA. Such requests should be submitted to EPA with a clear rationale. All protocol variations will be reviewed by EPA and a response will be sent to the specific order recipient in a timely fashion. EPA does not expect to receive such requests, but these procedures are consistent with current EPA practices regarding pesticide test guidelines and 40 CFR part 158. In addition, for the purposes of calculating paperwork burden hours and costs in this ICR, EPA assumed that the data generation will not be directly performed by the 408(p) order recipient. Instead, EPA assumes that data generation will be performed by a contract laboratory at the request of the 408(p) order recipient. The Agency has no information to estimate how many recipients might use a contract laboratory and how many might generate the data in house. By assuming that data will always be generated by a contract laboratory, which is consistent with the assumption used in other ICRs that involve data generation, the Agency includes additional activities and burden that may not otherwise have been included. As such, using this assumption to calculate the potential paperwork burden for data generation is likely to result in an overestimate of total potential burden.

(6) *Compile and review the data submission* – Those order recipients that generate the data, will also compile the data results for submission to EPA, reviewing the data for completeness.

(7) *Complete paperwork to assemble the submission package* - Those order recipients that generate the data, will also assemble the submission package. In doing so, the recipient should follow 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, which are described further below.

(8) *Submit final data to EPA* – The final data package is then submitted to EPA following the specific instructions specified in the order (see also below).

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

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

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

Activity	Managerial Duties	Technical Duties	Clerical Duties
(1)	Read EPA's Policy and Procedures Document	Read EPA's Policy and Procedures Document	
	Review the EDSP Order	Review the EDSP Order	
(2)	Identify timeframe for response		
	Identify & evaluate response options	Evaluate response options	
	Plan activities		
	Negotiate/establish consortium/ task force agreements	Participate in consortium/ task force discussions	
(3)	Determine response	Recommend a response	
	Oversee employee activities		Complete response form
	Sign initial response forms		Send to EPA
(4)	Communicate with EPA	Review of protocol	
(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	
	Communicate with EPA, as appropriate	Maintain records and procedures during testing period in accordance with the GLPs	Assist in preparing files
(6)	Review final draft report(s)	Proof draft final data reports	
(7)	Approve final submission package	Draft summary of the data for cover letter	Prepare final submission to EPA
		Review final submission package	
(8)	Approve/sign submission		Send submission to EPA
(9)		Prepare data for files	Prepare file & maintain records

4(c) Information Requested

The 408(p) order will identify the specific Tier 1 screening data being requested, and all 408(p) order recipients are expected to provide an initial response that identifies how the recipient intends to respond to the order. The specific information requested from each order recipient may vary based on the respondent's initial response. This section of the ICR describes the possible responses, and related information associated with that response. For purposes of this ICR, however, it is important to clarify that many of the initial response options already exist within the pesticide program, e.g., for Data-Call-Ins under FIFRA 3(c)(2)(B). In providing the option as described in more detail in the Policy and Procedures Document (Attachment B), the Agency is adopting those existing procedures unchanged for use under the EDSP. Under those existing procedures, a registrant may engage in additional activities associated with the response option they choose. 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 ICRs. The Agency believes that any additional activities related to the EDSP do not impact the estimated burden and that the burden is covered by the existing ICRs.

4(c)(i) Initial Response.

As indicated previously, EPA intends to include the Initial Response Form (see Attachment D) with the order that is sent to the recipient and pre-populate the Form with basic information about the chemical covered, data requested, and other information to connect the Form to the specific order. The only additional data elements that this form will collect are those related to the respondent's intentions. As described in more detail in the Policy and Procedures Document (Attachment B), the recipient of a test order will have several potential response options. The following is a description of each of these options, and a detailed workflow in Attachment E illustrates how these would work based on the procedures currently in use for data collections under FIFRA.

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

(2) 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 test order. Recipients would identify who is part of the consortium. Alternatively, recipients may provide EPA with documentation that they have made a judicially enforceable offer to enter into agreement to develop data jointly with one or more recipients of the order and that they

have offered to pay a reasonable share of the test costs, and have developed a process for resolving disputes with regard to the appropriate share of test costs. Note: 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.

(3) Cite Existing Data. The recipient would choose this option to indicate that they intend to submit or cite existing data that satisfies the request in the test order. Recipients would include the data or a reference to the data for each test that is being cited. If the study is not exactly as specified in the protocols attached to the test order, recipients should provide an explanation as to why the data should be accepted as satisfaction of the test order. The Agency would expect that any such data would be scientifically comparable to data that would be generated by the order. EPA recognizes that for the initial screening, opportunities for order recipients to respond in this manner will be limited. As mandated by the statute, EPA is developing and validating the appropriate assays – which are forming the basis for the protocols. Since these are new tests, it is unlikely that other studies would be scientifically comparable. During the validation process, however, a chemical on the initial list might have been a test subject for a study listed in the order. Order recipients may be able to cite these data if protocols, which were modified over the course of validation, are sufficiently similar.

(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) they are not or are no longer a pesticide registrant, or (ii) they do not or no longer manufacture or import the chemical identified in the order. An explanation of the basis for the claim, along with appropriate information to substantiate that claim, would be submitted with the response to allow EPA to evaluate the claim.

(5) Intend to Voluntarily Cancel or Reformulate the Product Registration or Discontinue the Manufacture/Importation of the Chemical. 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 408(p) order. In the case of manufacturers/importers of both active and inert ingredients, the recipient would choose this option to indicate that they intend to agree to cease manufacture or importation of the chemical and products. This is all accomplished through the submission of an application to amend the registration following the established procedures. In general, EPA's draft policy does not include the issuance of 408(p) orders to registrants of end-use products.

(6) Claim a Formulators' Exemption. A product registrant who receives an order to test a chemical who purchases the chemical from another recipient who has agreed to generate the data may be eligible for a formulators' exemption, but exercise of this

option may depend on the authority under which the order is issued. If EPA were to rely solely on FIFRA 3(c)(2)(B), the option would not be available for orders to test an inert ingredient since manufacturers and importers would not be subject to a FIFRA order. Such a claim would initiate the existing procedures for formulators' exemption. EPA will confirm claims of eligibility. A formulators' exemption would become invalid if the supplier of the chemical were not to submit the data either individually or jointly with other recipients.

4(c)(ii) Extension Requests.

The FFDCA §408(p) test order would identify a due date for completing the data specified and submitting it to EPA. If an order recipient would like to request an extension of time to complete the testing, the request should be submitted with a rationale for the extension and any supporting material, in order to allow the Agency to properly assess the request. All such requests would be reviewed by EPA and a response would be sent to the requester in a timely fashion.

4(c)(iii) Data Generation.

The 408(p) order will request specific data on how the chemical substance interacts with the estrogen, androgen, or thyroid hormone systems using a battery of assays. Recipients of the 408(p) order will generate the data using the test protocols attached to the order, unless the recipient discusses and EPA approves an alternative test protocol. As indicated previously, EPA is currently developing and validating the *in vitro* and *in vivo* assays that will be used in determining the potential for chemicals to cause endocrine disruption in humans or wildlife. The Tier 1 screening battery, as proposed by EPA, is based on the Endocrine Disruptor Screening and Testing Advisory Committee's (EDSTAC) recommendations and is intended to identify chemicals affecting the estrogen, androgen, or thyroid hormone systems through any of several recognized modes of action.

Specifically, the EDSTAC recommended that a Tier-1 battery be comprised of a suite of complementary screening assays. The primary assays recommended by EDSTAC for inclusion in the battery are as follows:

Estrogen receptor (ER)
Androgen receptor (AR)
In vitro steroidogenesis
Uterotropic (rat)
Hershberger (rat)
Pubertal female (rat)
Frog metamorphosis
Fish screen

In addition, EDSTAC recognized there were other screening assays that may be suitable for a Tier-1 battery and, therefore, recommended that the EPA also validate the following alternative screening assays:

In vitro aromatase
Pubertal male (rat)
Adult male (rat)

The primary Tier-1 screening battery and two alternative batteries that were recommended by EDSTAC are shown in Table 3.

Table 3. EDSAC's recommended *in vitro* and *in vivo* screening assays

Primary Tier-1 Screening Battery	**Alternate Tier-1 Screening Battery No. 1**	**Alternate Tier-1 Screening Battery No. 2**
***In vitro* assays**	***In vitro* assays**	***In vitro* assays**
ER binding	ER binding	ER binding
AR binding	AR binding	AR binding
Steroidogenesis assay	Placental/Recombinant Aromatase	Placental/Recombinant Aromatase
***In vivo* assays**	***In vivo* assays**	***In vivo* assays**
Uterotropic (rat)	Uterotropic (rat)	Uterotropic (rat)
Hershberger (rat)		
	Intact adult male (rat)	
		Pubertal male (rat)
Pubertal female (rat)		
Frog metamorphosis	Frog metamorphosis	Frog metamorphosis
Fish screen	Fish screen	Fish screen

As indicated previously, the statute requires EPA to validate the assays. As such, EPA is validating each assay, and will select the appropriate screening assays for the Tier 1 battery based on the validation data. The status of each assay can be viewed in the Assay Status table at:
http://www.epa.gov/scipoly/oscpendo/pubs/assayvalidation/status.htm.

The following is a brief description of the assays that are candidates for the Tier 1 screening battery:

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

2. *Receptor Binding in vitro Assays* - Chemicals can 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. The androgen receptor (AR) is involved in the development of male sexual characteristics and the estrogen receptor (ER) is involved in female maturation and reproductive function. Several receptor binding assays are being considered, including:

a. An AR binding assay that utilizes rat prostate cytosol to examine the ability of a test chemical to bind with androgen receptors;
b. An AR binding assay that utilizes a rat recombinant AR to examine the ability of a test chemical to bind with androgen receptors;
c. An ER binding assay that utilizes rat uterine cytosol to examine the ability of a test chemical to bind with estrogen receptors; and
d. An ER binding assay utilizes the alpha isoform of the human recombinant ER to examine the ability of a test chemical to bind with estrogen receptors.

3. *Aromatase* - 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. *Fish Screen* - The Fish Screen assay screens for estrogenic and androgenic 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.

5. *Hershberger* - The Hershberger assay is designed to detect androgenic and anti-androgenic effects. In this *in vivo* assay, accessory sex gland weights, including several androgen-dependent tissues, are measured in castrated or immature male rats.

6. *Pubertal Female* - 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.

7. *Pubertal Male* - 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.

8. *Steroidogenesis* - The Steroidogenesis *in vitro* assay detects interference with the body's production of male and female steroid sex hormones. A version of the assay using sliced testis as a source of steroidogenic enzymes was optimized by EPA to detect chemicals that inhibit synthesis of steroid hormones, but continued concerns about being able to distinguish between compounds that inhibit steroid hormone synthesis and chemicals that kill the cells responsible for testosterone synthesis led to a halt in further work on validating this assay. This assay is being replaced by a cell-based assay using the H295R human adrenocortical carcinoma cell line. The H295R cell line also holds promise in being able to

detect inducers of enzymes responsible for steroid synthesis in addition to chemicals that inhibit it.

9. *Uterotrophic* - 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.

10. *15-day Adult Intact Male* - The Adult Male assay involves the use of rats to screen primarily for anti-androgenic and thyroid activity. The assay will screen for abnormalities associated with primary and secondary sex organs, systemic hormone concentrations, and thyroid.

For purposes of estimating the potential burden for the Tier 1 screening information collection activities covered by the ICR, the Agency is assuming that the battery will include the candidate assays. Although this is highly unlikely, assuming this for the purposes of the draft ICR will ensure that the Agency's total estimate for potential burden and costs are overestimates. Once the battery is known, the estimates can be adjusted downward.

4(c)(iv) Data Submission.

As described in more detail in the Policy and Procedures Document (Attachment B), the data submission content and format under the EDSP is based on that used currently for other pesticide data submissions. Since the 73 chemicals involve pesticides and pesticide inerts, EPA believes that doing this helps to minimize the potential burden because the 408(p) order recipients are likely to be familiar with the existing requirements. As such, the content and format of the data submission package for transmittal to EPA should be consistent with the following requirements.

1. *Format for Data Submission.* As part of a cooperative NAFTA project, EPA and the Canadian Pest Management Regulatory Agency (PMRA) developed standard data evaluation formats, or templates. The templates have been in use by these agencies since 2002 for writing their data evaluation records (DERs) of studies submitted under FIFRA and FFDCA to EPA and the Canadian data codes (DACOs). The DER that the agencies prepare contains a study profile documenting basic study information such as materials, methods, results, applicant's conclusions and the evaluator's conclusions. The templates provide pesticide registrants and the public an opportunity to gain a better understanding of the regulatory science review and decision-making process. The agencies encourage registrants to include study profiles based on these templates in their study documents for all pesticide types. These templates describe the layout and scope of information that should be contained within a study profile and can serve as guides for preparation of study documents. Use of the templates improves the likelihood of a successful submission, since the information necessary for an efficient agency review is outlined. Additional details about these templates are available at: http://www.epa.gov/pesticides/regulating/studyprofile_templates/.

In addition, Pesticide Registration (PR) Notice 86-5, entitled "Standard Format for Data Submitted Under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and Certain Provisions of the Federal Food, Drug, and Cosmetic Act (FFDCA)," describes the requirements for organizing and formatting submittals of data supporting a pesticide registration (http://www.epa.gov/PR_Notices/pr86-5.html). The Agency has begun the process of updating the guidance in PR Notice 86-5 to further clarify the data submission process for pesticide related submissions and will provide the public with an opportunity to comment on the proposed revisions to PR 86-5 consistent with the procedures described in PR Notice 2003-3, entitled "Procedural Guidance for EPA's Office of Pesticide Programs Procedures Concerning the Development, Modification, and Implementation of Policy Guidance Documents" (http://www.epa.gov/PR_Notices/pr2003-3.pdf).

The Agency also encourages FFDCA §408(p) test order recipients to submit completed study profiles and supporting data in an electronic format (PDF) whether submitting one or several studies. For more information, go to the electronic data submissions website at http://www.epa.gov/oppfead1/eds/edsgoals.

2. *Transmittal Document.* Each submission in satisfaction of a FFDCA §408(p) test order must be accompanied by a transmittal document that includes the following information:

(1) Identity of the submitter.
(2) The date on which the submission package was prepared for transmittal to EPA.
(3) Identification of the FFDCA §408(p) test order associated with the submission (e.g., the test order number).
(4) A list of the individual documents included in the submission.

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

(1) A title page including the following information:
  (i) The title of the study, including identification of the substance(s) tested and the test name or data requirement addressed.
  (ii) The author(s) of the study.
  (iii) The date the study was completed.
  (iv) If the study was performed in a laboratory, the name and address of the laboratory, project numbers or other identifying codes.
  (v) If the study is a commentary on or supplement to another previously submitted study, full identification of the other study with which it should be associated in review.
  (vi) If the study is a reprint of a published document, all relevant facts of publication, such as the journal title, volume, issue, inclusive page numbers, and date of publication.

(2) Upon submission to EPA, each document must be accompanied by a signed and dated document containing the appropriate statement(s) regarding any data confidentiality claims as described in the FFDCA §408(p) test order.
(3) A statement of compliance or non-compliance with respect to GLP standards as required by 40 CFR 160.12, if applicable.
(4) A complete and accurate English translation must be included for any information that is not in English.

5. AGENCY ACTIVITIES, COLLECTION METHODOLOGY, & INFORMATION MANAGEMENT

5(a) Agency Activities

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

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

(1) *Prepare instructions.* Prepare procedural steps, guidance & instructions for 408(p) order recipients so that they understand what data are to be submitted, when & how. The Policy and Procedures Document (Attachment B) describes the policies and procedures that EPA intends to use to implement the data collection component of the EDSP. Although that document is non-binding, the Agency will incorporate specific instructions in each order, so that each order recipient receives detailed instructions with the order.

(2) *Identify chemicals to be screened.* EPA has implemented the September 2005 selection approach to identify the chemicals for which Tier 1 screening under the EDSP will be required (Ref. 5). The draft list is currently out for public review, but will be finalized before the EDSP test orders are issued (Ref. 4). This ICR assumes that all 73 chemicals on that draft list will be the subject of an EDSP test order. Should that number change for the final list, the ICR will be adjusted accordingly.

(3) *Identify Recipients.* EPA has identified the potential recipients of the EDSP test orders for the 73 chemicals. For test orders involving pesticide active ingredients, the Agency used the Office of Pesticide Programs Information Network (OPPIN). OPPIN is an internal OPP database for query, input and tracking of pesticide products, ingredients, studies, regulatory decisions and other information about registered products. For test orders involving Inerts, the Agency used OPPIN (where applicable) and other databases and information sources to identify appropriate

manufacturers/importers and end use registrants. These other databases may include other internal EPA databases and publicly available sources like Dun and Bradstreet, online marketing material, etc. EPA is also considering publishing the orders and the list of recipients in the **Federal Register**. However, the identity of some companies is currently protected as CBI and would not be made publicly available.

(4) *Prepare the EDSP Test Orders.* EPA intends to use the draft order template (see Attachment C) to prepare individual orders for each chemical. 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 consortia. Those companies protected as CBI will not be listed in that order, but will still receive the order. In addition, the Agency is considering publishing the chemical specific orders in the **Federal Register**.

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

(6) *Issue the Orders.* The Assistant Administrator for Prevention, Pesticides and Toxic Substances (OPPTS) will issue the orders.

(7) *Process Initial Responses.* OPP will receive the Initial Response Form, document the response, track responses & determine next steps based on the responses. In general, the Agency will review the response to determine if it is complete and whether it satisfies the request in the 408(p) order, if so, the response will be documented accordingly. Depending on the response, the Agency may also need to complete other tasks, e.g., document lead for a consortia, process a voluntary cancellation request or other request for reformulation.

(8) *Provide Assistance & Complete Follow-up, as needed.* The Agency will respond to any questions the recipient may have regarding the 408(p) order in a timely manner, as well as process any requests for extensions or protocol variations.

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

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

(11) *Process Data Submissions.* The Agency will process submissions of data generated under the 408(p) order, including initial review of the data submission for completeness, initial log-in to document receipt, and determining the close out of the order.

(12) *Analyze Data.* Implement the Agency's internal standard review procedures to review the data and determine next steps, i.e., should the chemical be considered for Tier 2 testing?

(13) *Incorporate Data.* The Agency will incorporate the data into a risk assessment and make a regulatory decision as necessary and appropriate.

(14) *Store Data in Retrievable System.* The Agency will index and store the data in the Agency's files. Primarily the data will be stored in OPPIN, because the 73 chemicals are pesticides or inerts used in pesticide products.

5(b) Collection Methodology and Management

For each of the 73 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 408(p) 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 408(p) order. For example, as with other pesticide data related submissions, EPA intends for a record of each study submitted to be maintained in the Agency's Pesticide Document Management System (PDMS), and public access to the PDMS bibliography may be made through the National Pesticides Information Retrieval System (NPIRS). NPIRS supports searches of the PDMS database by chemical, subject, submission date, laboratory, guideline number, and document type. The public, after satisfying any applicable requirements (e.g., FIFRA §10) may request copies of non-confidential *studies* through the Freedom of Information Act (FOIA).

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

To meet the goals of the EDSP, the system will allow for the creation of orders for each active ingredient and inert ingredient. For the active ingredients, the system will manage associated company, product, and requirement information. For inert ingredients, the system will manage the associated companies only, since these companies may not have any registered products. In addition, the system needs to allow for the submission of studies through registrant consortiums. It needs to be able to give the member companies (who received orders) credit for the submissions when the consortium is identified as the study owner. For every inert there shall be a subsection for its Battery, results and comments. The system will track the milestones

associated with the drafting, concurrence, mail-out, 90-day response, submission receipts, and reviews. Also, the system shall manage response extensions and identify and manage all non-responsive companies.

In addition to tracking the previously mentioned elements related to each specific order, the Agency will track the following: submission type, submission date, submission comment, review sent and completed dates, requirement status and requirement status comment. These elements are needed in order to track the responses submitted by each company, the submitted studies, study reviews, study status and requirement status. The Agency will produce several reports to facilitate tracking, etc. For example, a 90-day company response status report is needed to determine whether companies have responded, and to identify their intentions. An option to display only overdue responses will be included. It should include all chemicals and be sorted by company (and product if applicable). A requirement status report by requirement across all chemicals, sorted by company is needed in order to present overall progress and allow management to directly identify delays.

5(c) Small Entity Flexibility

In developing the Policy and Procedures Document (Attachment B), the Agency considered alternatives for small businesses to the extent practical within the mandate in FFDCA. The procedures are intended to minimize potential duplicative testing, and emphasize collaborative efforts to generate the requested data. For example, as described in more detail in EPA's policy statement, EPA does not intend to issue 408(p) orders to registrants of end-use products or reformulators. 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 will not be responsible for supplying endocrine data on a chemical they use in their end-use product or formulation.

If there is a small business that does happen to manufacture one of the 73 chemicals, they may minimize potential burden by fulfilling their responsibilities by either joining a testing consortium or task force. Participation in a testing consortium may relieve the business of direct responsibility for generating or submitting the data. In addition, EPA can accommodate requests for extensions of time from small entities, and provide other assistance, as needed.

5(d) Collection Schedule

There is no periodic schedule for the collections under this ICR. This information collection activity only involves a one-time, two step collection activity per chemical. In response to the 408(p) order, the Agency will collect an initial response from the recipient, followed subsequently by the collection of the data. Some respondents will only submit the initial response, while other respondents will submit an initial response and the required data. In either case, the Agency expects a respondent to submit no more than two responses per chemical, unless they request an extension.

The submission due date is based on the standard time required to conduct the tests according to the validated protocols provided with the order, with the potential for the recipient to request an extension from EPA. The time period for Tier 1 screening level testing may take longer than one year depending on the composition of the screening battery. For purposes of estimating the annual potential paperwork burden in this ICR, EPA assumed that the data would be submitted within 2 or 3 years of receiving the 408(p) order. Although the activities are expected to occur over the three year approval period for the ICR, the timing of these activities is not specific enough to accurately divide them by year. To calculate an annual burden, the Agency has assumed a three year duration of equal annual effort.

6. ESTIMATING THE BURDEN AND COST OF THE COLLECTION

The PRA requires EPA to estimate the "paperwork burden" i.e., the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal Agency. OMB will not approve a "collection" until EPA provides an ICR that describes the information collection activities in detail and provides an estimate of the paperwork burden hours and costs. Under the PRA, "burden" means the "time, effort, or financial resources expended by persons to generate, maintain, or provide information to or for a Federal Agency." This can include the resources to: review instructions; develop, acquire, install, and use technology and systems; search data sources; collect, review, validate, and verify information/data; process and maintain information/data; disclose and transmit/submit information/data; change/adjust the existing ways of complying with any previously applicable instructions and requirements to now comply with new requirements; and, train personnel. The Agency is also required to estimate the paperwork costs, which includes 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.

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

6(a) Methodology for Estimating Respondent Burden and Cost

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

Average wage data for the relevant sectors of respondents are available in the National Industry-Specific Occupational Employment and Wage Estimates from the Bureau of Labor Statistics (BLS) at http://www.bls.gov/oes/current/oes_nat.htm. We used the NAICS codes to obtain the estimated loaded labor rates used in this ICR, i.e., NAICS 325300, Pesticide, Fertilizer, & Other Agricultural Chemical Manufacturing http://www.bls.gov/oes/current/naics4_325300.htm. Within that sector, the wage data are provided by Standard Occupational Classification (SOC). The SOC system is used

by Federal statistical agencies to classify workers into occupational categories for the purpose of collecting, calculating, or disseminating data. Each broad occupation includes detailed occupation(s) based on similar job duties, skills, education, or experience. For more information on SOC and what is included in each SOC, see http://www.bls.gov/oes/current/oes_stru.htm. The SOCs used for the following labor types are listed below in Table 4 and apply to all of the sectors identified above.

Table 4 - Respondent SOCs Used in this ICR

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

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

Table 5 – Respondent Loaded Labor Rates Used in this ICR

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

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

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

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

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

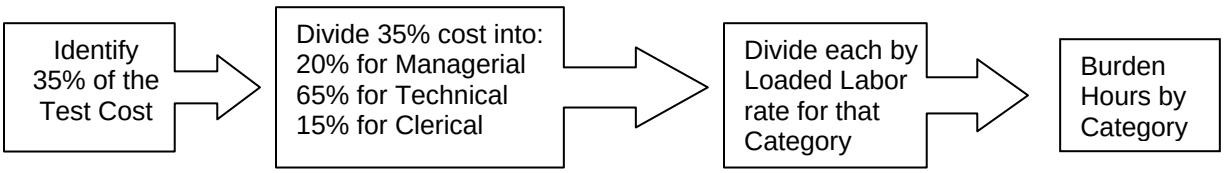
The Agency then used two basic approaches to calculate the potential burden and costs for this ICR: 1) For the data generation activities, EPA calculated the paperwork burden as a percentage of the testing costs; and 2) For the rest of the paperwork activities, EPA estimated the average amount of time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

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

To calculate the burden associated with the paperwork activities involved in conducting the tests, the Agency started with the cost of the test. Since the tests that will be used are still undergoing validation, market costs for these tests are not available. The Agency therefore used a Cost Estimate Survey of commercial laboratories for the estimated costs related to the assays undergoing validation (Ref. 10). The estimated costs for the other 2 assays were based on estimates provided by the EPA scientist overseeing the validation effort for those 2 assays. Since EPA is funding the assay validation effort, these estimates are reasonable surrogates for actual market prices at this time and for the purposes of this ICR. Once these tests are available on the market, these costs will be adjusted as appropriate.

Based on the existing methodologies, EPA used 35% of the estimated total test cost to calculate the total potential cost for the paperwork activities related to data generation. The 35% of test cost is disaggregated by labor category, and then burden hours are extrapolated by using the loaded labor rates. See Figure 1 below for an illustrated outline of the Agency burden calculation process for data generation.

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 408(p) 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.

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. The results are presented in section 6(b) of this ICR.

2. *Method Used to Calculate the Burden and Costs for Other Activities.* For the other activities, EPA estimated the burden hours by considering the activities themselves and the expected amount of time that the activity involves on average. These estimates consider the Agency's experience with similar data collection activities and direct experience in conducting the assays for validation. The costs are calculated using the loaded labor rates for the labor categories that are identified in section 6(a)(i) of this ICR.

As indicated previously, this ICR assumes that the Tier 1 screening battery will include all of the candidate assays identified in section 4(c)(iii) of this ICR, and that the respondents will perform the entire battery. Should the final battery not include all of the candidate assays that are undergoing validation, which is highly unlikely at this point, the estimated total burden for this ICR would be reduced by the removal of the test cost and burden associated with any assay not included in the final battery.

Regardless of the response option that recipients of 408(p) 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, with only one order recipient engaged in actually generating and submitting the data. This means that all of the potential recipients of orders for the 73 chemicals will experience a base set of burden associated with the initial receipt and response activities, and subsequent burden related to consortium participation, and that one recipient for each of the 73 chemicals will experience the burden associated with generating and submitting the data. The results are presented in section 6(b) of this ICR.

6(b) Calculating Respondent Burden and Costs

This section explains how the Agency calculated these estimates.

6(b)(i) Respondent Burden Estimates

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

Table 6 – Estimated Per Chemical/Respondent Burden Hours for the Activities

Activity (a)	Managerial	Technical	Clerical	Total
1) Read instructions	12	12	0	24
2) Plan activities	48	42	0	90
3) Submit an initial response to EPA (b)	24	18	2	44
4) Read and discuss the protocol	36	72	0	108
5) Participate in Consortium	24	72	2	98
6) Generate the data (c)	253	1108	585	1946
7) Compile and review the data submission	36	181	12	229
8) Complete paperwork to assemble the submission package	3	10	6	19
9) Submit final data to EPA	3	0	2	5
10) Maintain records	0	24	62	86
Total burden:	439	1539	671	2649

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

As discussed earlier, all respondents are not expected to engage in the same activities. Using the respondent categories established in Table 1, Table 7 below presents the estimated total respondent burden for the 73 chemicals:

Table 7 – Estimated Total Respondent Burden Hours by Activity

Activity (a)	Estimated Burden	Estimated Respondents	Total
1) Read instructions	24	445	10,680
2) Plan activities	90	445	40,050
3) Submit an initial response to EPA (b)	44	445	19,580
4) Read and discuss the protocol	108	73	7,884
5) Participate in Consortium	98	367	35,966
6) Generate the data (c)	1946	73	142,058
7) Compile and review the data submission	229	73	16,717
8) Complete paperwork to assemble the submission package	19	73	1,387
9) Submit final data to EPA	5	73	365
10) Maintain records	86	73	6,278
Total burden:	2649		280,965

Since there is expected to be some overlap between the potential recipient categories, the number of potential respondents used for this estimate may be reduced once the final list of order recipients is complete. The Agency also expects that a single potential respondent might receive more than one 408(p) order if they manufacture or import more than one of the 73 listed chemicals, and that there are multiple potential respondents for each chemical. For example, the Agency estimates that an order

recipient might receive as many as 4 orders, with the average company receiving 2 orders. There may be as many as 76 recipients for an individual order, with the an average of less than 5 recipients for most of the orders. As indicated previously, these estimates will be updated when the Agency identifies all of the specific order recipients for the final list of chemicals that will undergo Tier 1 screening under this ICR.

6(b)(ii) Respondent Cost Estimates

The estimated respondent cost for each of the paperwork activities is presented in Table 8 below. The 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.

Table 8 – Estimated per Chemical/Respondent Burden Hour Costs

Activity (a)	Managerial $103.62/hr.	Technical $76.92/hr.	Clerical $33.60/hr.	Total $
1) Read instructions	1243.44	923.04	0	2,166.48
2) Plan activities	4973.76	3230.64	0	8,204.4
3) Submit an initial response to EPA (b)	2486.88	1384.56	67.20	3,938.64
4) Read and discuss the protocol	3730.32	5538.24	0	9,268.56
5) Participate in Consortium	2486.88	1384.56	67.20	3,938.64
6) Generate the data (c)	26218.01	85208.53	19663.51	131,090.05
7) Compile and review the data submission	3730.32	13922.52	12403.20	30,056.04
8) Complete paperwork to assemble the submission package	310.86	769.20	201.6	1,281.66
9) Submit final data to EPA	310.86	0	67.20	378.06
10) Maintain records	0	1846.08	2083.20	3,929.28
11) Delivery Costs	0	0	0	10.55
Total costs:	$43,004.45	$112,822.81	$34,485.91	$194,262.36

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

Table 9 below presents the estimated total respondent burden costs for the 73 chemicals:

Table 9 – Estimated Total Respondent Burden Costs by Activity			
Activity	**Estimated Costs ($)**	**Estimated Respondents**	**Total $ (rounded)**
1) Read instructions	2,166.48	445	964,084
2) Plan activities	8,204.40	445	3,650,958
3) Submit an initial response to EPA (b)	3,938.64	445	1,752,695
4) Read and discuss the protocol	9,268.56	73	676,605
5) Participate in Consortium	3,938.64	367	1,445,481
6) Generate the data (c)	131,090.05	73	9,569,574
7) Compile and review the data submission	30,056.04	73	2,194,091
8) Complete paperwork to assemble the submission package	1,281.66	73	93,561
9) Submit final data to EPA	378.06	73	27,598
10) Maintain records	3,929.28	73	286,837
11) Delivery Costs	10.55	73	770
Total burden:	$194,251.81		$20,662,254

In addition to the burden costs, the costs of delivering the data to the Agency are added to arrive at the total estimated per respondent cost. Delivery costs were calculated using the Agency's experience with data submissions for pesticide deliveries, which assumes the delivery of a paper copy and a CD-Rom using special delivery. Although not required, nor used by everyone, the Agency is using special delivery for the calculation to provide a conservative estimate that would account for expected variations in delivery costs. Based on the 2-day delivery rate for a large envelope up to 2 lbs. in weight, the US Postal Service rate is $10.55 from the west coast to the east cost (Ref. 11). Total delivery costs ($10.55 x 73 submissions = $770.15) was then added to the total respondent cost from Table 9 to calculate the total potential per respondent cost ($20,661,484 + $770 = $20,662,254).

The total respondent burden hours and costs calculated for this ICR involves activities that are expected to occur over the three year approval period for the ICR, as opposed to annually for each of the three years. Since the timing of these activities is not specific enough to accurately divide them by year, the Agency has assumed a three year duration of equal annual effort. As such, the **total annual respondent burden and costs for this ICR is simply divided by 3 to get an estimated annual burden of 93,655 hours** (280,965 hours ÷ 3) **and a cost of $6,887,418** ($20,662,254 ÷ 3).

6(c) Methodology for Estimating Agency Burden and Cost

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

To calculate the Agency's loaded labor rate, we used the average wage data available in the National Industry-Specific Occupational Employment and Wage Estimates from the Bureau of Labor Statistics (BLS) at http://www.bls.gov/oes/current/oes_nat.htm. Specifically, we used the NAICS code

999100 to obtain the estimated loaded labor rates used in this ICR for the Federal Executive Branch (http://www.bls.gov/oes/current/naics4_999100.htm). As was done for the respondents, we used the wage data provided by SOC (see Table 10). For purposes of calculating a loaded labor rate, we used the mean average hourly wage rate and assumed that benefits are 43% of wage rates, based on benefits for all civilian non-farm workers from http://www.bls.gov/news.release/ecec.t01.htm. We then multiply the loaded wage by 50% to get overhead costs. Overhead costs are added to the loaded wage rate to get the fully loaded wage rate.

Table 10 - Agency Loaded Labor Rates Used in this ICR

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

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

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

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

For the Agency activities, EPA estimated the burden hours by considering the activities themselves and the expected amount of time that the activity may involve on average. These estimates consider the Agency's experience with similar data collection activities. The estimated per chemical/respondent burden hours for the Agency are presented in Table 11. To calculate the total potential Agency burden over the three years, EPA has multiplied this burden by the total number of chemicals (773 hours x 73 chemicals = 56,429 hours).

Table 11 – Estimated Agency per Chemical Burden Hours

Activity (a)	Managerial	Technical	Clerical	Total
1) Prepare instructions	2	12	2	16
2) Identify chemicals to be screened	2	21	2	25
3) Identify recipients	2	16	0	18
4) Prepare the 408(p) Order Packages	0	4	10	14
5) Review & approve the orders	2	4	0	6
6) Issue the orders	0	0	6	6
7) Process initial responses (b)	1	4	1	6

Table 11 – Estimated Agency per Chemical Burden Hours				
Activity (a)	**Managerial**	**Technical**	**Clerical**	**Total**
8) Provide assistance & 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	520	0	520
12) Incorporate data into risk assessments	0	104	0	104
13) Store data in retrievable system	0	4	8	12
Total burden:	9	733	31	773

(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.
(c) Assumes 40 hrs per assay (40 x 13).
(d) Assumes 8 hrs per assay (8 x 13).

The costs are then calculated using the loaded labor rates for the labor categories that are identified in section 6(c)(i) of this ICR. The estimated burden hour costs for the Agency are presented in Table 12. To calculate the total potential Agency costs over the three years, EPA has multiplied the per chemical cost in Table 12 by the total number of chemicals ($50,921 x 73 chemicals = $3,717,233).

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

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

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

As discussed earlier, the total burden hours for respondents calculated for this ICR involves activities that are expected to occur over the next three years. Since the timing of these activities is not specific enough to accurately divide them by year, the Agency has assumed a three year duration of equal effort to calculate the annual burden and costs for this ICR. The **total annual respondent burden and costs for this ICR is simply divided by 3 to get an estimated annual burden of 93,655 hours** (280,965 hours ÷ 3) **and a cost of $6,887,418** ($20,662,254 ÷ 3). Table 13 presents

the total burden hours and costs for respondents and EPA under this ICR.

Table 13 – Estimated TOTAL Burden Hours & Costs for this ICR

	Per Chemical		# Chemicals	Totals	
	Burden Hrs.	Costs $		Burden Hrs.	Costs $
Respondent (a)	2,649	$195,022	73	280,965	$20,662,254
EPA (b)	773	$50,921	73	56,429	$3,717,233
Annualized Respondent Burden and Costs (c)	883	$65,007	73	93,655	$6,887,418

(a) For total per respondent burden see table 7, and for total per respondent costs see table 9, with the delivery costs added in that are discussed after the tables.
(b) For total per chemical Agency burden see table 11, and for total Agency costs see table 12.
(c) Burden hours and costs are annualized by dividing them by 3.

Table 14 provides a breakdown of the total annualized burden and cost estimate in terms of the grouping required by OMB, i.e., distinct information collections (ICs).

Table 14 – Annualized Information Collections (ICs) for this ICR

IC	Per Chemical (a)		# Chemicals	Totals (b)	
	Burden Hrs.	Costs $		Burden Hrs.	Costs $
Reporting	854	$63,698	73	91,562	$6,791,806
Recordkeeping	29	$1,310	73	2,093	$95,612
Totals:	883	$65,008		93,655	$6,887,418

(a) For total per chemical respondent reporting burden subtract out item 10 in table 6 from total, and for total per respondent costs subtract out item 10 in table 8.
(b) For total respondent recordkeeping burden, subtract out item 10 in table 8 from total, and for total per respondent costs subtract out item 10 in table 9, but add delivery costs to both.
(c) Burden hours and costs are annualized by dividing them by 3.

6(e) Reasons for Change in Burden Estimates

This is a new information collection request, so the burden estimates presented here are all new, and are necessary to fully implement the mandate in FFDCA 408(p). As such, this is considered a program change related to a statutory mandate.

6(f) Burden Statement for this ICR

The total estimated per chemical/per respondent paperwork burden to comply with this information collection activity is 2,649 hours, with an estimated cost of $194,252. The total annualized estimated paperwork burden for this ICR is 93,655 hours, with an estimated total annual cost of $6,887,418. According to the Paperwork Reduction Act, “burden” means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. For this collection, it is the time reading the instructions in the Order, providing an initial response to EPA, planning the necessary data collection activities, conducting tests, analyzing data, generating reports and submitting data, as well as storing, filing, and maintaining the data. An agency may not conduct or sponsor, and a

person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. As a new ICR, the Agency does not yet have an OMB control number for this information collection activity. Once assigned, EPA will announce the OMB control number for this information collection in the Federal Register, and will add it to any related collection instruments or forms used.

To comment on the Agency's need for this information, the accuracy of the provided burden estimates, and any suggested methods for minimizing respondent burden, including the use of automated collection techniques, EPA has established a public docket for this ICR under docket ID No. **EPA-HQ-OPPT-1081**, which is available electronically at http://www.regulations.gov. A hard copy of the docket materials are also available for public viewing at the OPPT Docket. The OPPT Docket is located in the EPA Docket Center (EPA/DC) at Rm. 3334, EPA West Bldg., 1301 Constitution Ave., NW., Washington, DC. The EPA/DC Public Reading Room hours of operation are 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding Federal holidays. The telephone number of the EPA/DC Public Reading Room is (202) 566–1744, and the telephone number for the OPPT Docket is (202) 566–0280. Docket visitors are required to show photographic identification, pass through a metal detector, and sign the EPA visitor log. All visitor bags are processed through an X-ray machine and subject to search. Visitors will be provided an EPA/DC badge that must be visible at all times in the building and returned upon departure.

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

7. LIST OF REFERENCES

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

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

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

3. Endocrine Disruptor Screening Program; Assay Peer Review Process; Notice (72 FR 38577, July 13, 2007) http://www.epa.gov/fedrgstr/EPA-PEST/2007/July/Day-13/p13672.pdf.

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

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

6. Endocrine Disruptor Screening Program (EDSP); Draft Policy and Procedures Document; Request for Comment; Notice (72 FR [insert page], [insert date]) [insert url to the FR notice] (pending publication…. See also Attachment B).

7. *Review of the EPA's Proposed Environmental Endocrine Disruptor Screening Program* (EPA-SAB-EC-99-013, July 1999) http://epa.gov/sab/pdf/ec13.pdf.

8. Endocrine Disruptor Screening Program; Proposed Endocrine Disruptor Methods Validation Subcommittee under the National Advisory Council for Environmental Policy and Technology; Notice of Meeting (66 FR 16466, March 26, 2001).

9. Endocrine Disruptor Screening Program, Proposed Chemical Selection Approach for Initial Round of Screening; Request for Comment; Notice (67 FR 79611, December 30, 2002) http://www.epa.gov/scipoly/oscpendo/pubs/12-02-frnotice.pdf.

10. Cost Estimate Survey: Endocrine Screening Assays, Applied Pharmacology and Toxicology, Inc., May 23, 2003. Available electronically in the docket for this ICR.

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

8. ATTACHMENTS TO THE SUPPORTING STATEMENT

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

Attachment	Description
A	FFDCA sections 408(p), 408(i). Available at http://www.epa.gov/oppfead1/fqpa/ and click on "LAWS," then click on the available PDF file for FFDCA.
B	Endocrine Disruptor Screening Program (EDSP); Draft Policy and Procedures Document; Request for Comment; Notice (72 FR [insert page], [insert date]) *pending publication*. accessible at www.Regulations.gov under Docket ID#: EPA-HQ-OPPT-2007-1080.
C	Draft Template for EDSP Test Orders (08/22/2006)
D	Draft EDSP Order Initial Response Form (08/16/2007)
E	Detailed Workflow for Respondent Activities under the EDSP's Tier 1 Screening For the First 73 Chemicals (November 2007).
F	Calculations for Paperwork Burden and Costs for Data Generation Activities (07/23/2007).
G	List of Agency Activities (07/23/2007).
H	Draft List of Initial Pesticide Active Ingredients and Pesticide Inerts to be Considered for Screening under the Federal Food, Drug, and Cosmetic Act (June 2007) http://www.epa.gov/scipoly/oscpendo/pubs/prioritysetting/draftlist.htm