

**SUPPORTING STATEMENT FOR AN  
INFORMATION COLLECTION REQUEST (ICR)**

**1. IDENTIFICATION OF THE INFORMATION COLLECTION**

**1(a). Title of the Information Collection**

Pesticide Data Call-In Program

OMB Nos.: 2070-new

EPA Nos.: 2288.01

**1(b). Short Characterization/Abstract**

This new information collection request (ICR) consolidates and renews 3 currently-approved ICRs. The Environmental Protection Agency's (EPA), Office of Pesticide Programs (OPP) is consolidating the following existing ICRs into this new ICR:

- Data Call-Ins for the Special Review and Registration Review Programs (OMB Control No. 2070-0057; EPA ICR No. 0922.07);
- Data Generation for Pesticide Reregistration (OMB Control No. 2070-0107; EPA ICR No.1504.05); and,
- Data Acquisition for Anticipated Residue and Percent of Crop Treated (OMB Control No. 2070-0164; EPA ICR No.1911.02).

These ICRs enable the EPA to acquire the necessary data in support of the statutorily mandated pesticide reviews under the four program areas to assess whether the continued registration of an existing pesticide causes an unreasonable adverse effect on human health or the environment and/or pursue appropriate regulatory measures. EPA uses data collected under the ICRs that are being consolidated in 4 key program areas:

- Special Review;
- Reregistration;
- Registration Review; and,
- Tolerance assessment.

When these ICRs were last approved, OMB instructed EPA to submit one ICR package to cover all DCI ICRs (i.e., to consolidate them into a single ICR). The ICRs share similar respondent populations, use the same data collection mechanism (a DCI), and employ the same methodology to calculate the related paperwork burden hours and costs.

**2. NEED FOR AND USE OF THE COLLECTION**

**2(a). Need/Authority for the Collection**

EPA's Office of Pesticide Programs (OPP), under the Assistant Administrator for Prevention, Pesticides and Toxic Substances, uses the information collected under this ICR to



expected of a pesticide being registered today for the first time. Section 4 directs EPA to use Section 3(c) (2) (B) authority to obtain the required data. While, Reregistration Eligibility Decisions are expected to be completed by 2006 for food-use pesticide ingredients and 2008 for non-food use pesticide ingredients, the Agency may still need to issue DCIs after FY 2008 to close out the program. **(Attachment A)**

- **The Registration Review Program:** Section 3(g) of FIFRA contains provisions to help achieve the goal of reviewing each pesticide every 15 years to assure that the pesticide continues to pose no risk of unreasonable adverse effects on human health or the environment. Section 3(g) instructs EPA to use the section 3(c)(2)(B) authority to obtain the required data. **(Attachments B and C)**
- **The Special Review Program:** Though rare, EPA may conduct a Special Review if EPA believes that a pesticide poses risks of unreasonable adverse effects on human health or the environment. Section 3(c) (2) (B) of FIFRA provides a means of obtaining any needed data. **(Attachment B)**
- **Anticipated Residue/Percent Crop Treated Information:** Under section 408 of the Federal Food, Drug and Cosmetic Act (FFDCA), before a pesticide may be used on food or feed crops, the Agency must establish a tolerance for the pesticide residues on that crop or established an exemption from the requirement to have a tolerance. Section 408(b)(2)(E) and (F) of FFDCA authorize the use of anticipated or actual residue (ARs) data and percent crop treated (PCT) data to establish, modify, maintain, or revoke a tolerance for a pesticide. **(Attachment D)** The FFDCA requires that if AR data are used, data must be reviewed five years after a tolerance is initially established. If PCT data are used, the FFDCA affords EPA the discretion to obtain additional data if any or all of several conditions, including but not limited to the following, are met:
  - the existing data have been found unreliable;
  - exposure estimates underestimate exposures for any significant population group;
  - and
  - dietary exposure must be re-evaluated periodically.
- **Enforcement and Unanticipated Incidents:** In extremely rare instances, a need for a data call-in may arise from changes in the discovery of deficiencies in previously submitted data, or from the discovery of specific attributes of the pesticide or its ingredients. This may give rise to concerns such as observed or suspected adverse human health or environmental effects attributed to the use of a pesticide. Or such data is needed in support of Agency enforcement cases resulting from consumer complaints about the product, its storage stability, the integrity of its container, or exaggerated advertising claims. This type of DCI is needed because the concern and therefore the need for data arise not from a mandated review program like the programs described above, but from unanticipated circumstances. Section 3(c) (2) (B) of FIFRA provides a means of obtaining any needed data.

In order to conduct the required re-evaluation, a Pesticide Registrant may be required to submit specific data necessary to demonstrate that residues do not exceed the residue levels used to establish the tolerance. Under the authority of section 3(c) (2) (B) of FIFRA, the Agency will

issue a DCI to obtain any additional data.

## **2(b). Practical Utility/Users of the Data**

EPA uses the information collected to carry out its statutory responsibilities under sections section 4 of FIFRA, section 3(g) of FIFRA, section 6 (b) of FIFRA, and section 408 of FFDCA. The data collected allows EPA to assess whether the continued registration of an existing pesticide causes an unreasonable adverse effect on human health or the environment.

The Agency issues DCIs as part of one or more statutorily mandated review processes and has determined that more information is needed. Agency decisions requiring additional data are usually “triggered” by the data requirements set forth in 40 CFR parts 150 through 180, with the majority of the data requirements regarding studies captured in 40 CFR part 158.

The Agency uses data requirements to ensure that the statutory standards are met. Some of these standards include, but are not limited to, determining if a pesticide can remain registered because it does not causes an unreasonable adverse effect on human health or the environment, section §3(c) (5) and section 2(bb) of FIFRA, the safety standard of section 408 of FFDCA, as amended, directs the Agency to consider aggregate exposures from dietary and other non-occupational sources when assessing the risks of a pesticide. In addition to dietary exposure, such sources as drinking water and residential use must be considered. Thus, EPA must make the statutory determination that pesticide residues in food or feed will result in a reasonable certainty of no harm to human health from aggregate exposure through dietary, non-occupational, and drinking water routes of exposure. FQPA also directs EPA to consider the cumulative effects of pesticides that share a “common mechanism of toxicity,” consider special sensitivities of infants and children, and consider possible endocrine disruptor effects. EPA must also evaluate the data obtained from registrants to ensure that residues in or on food are not above the residue levels relied on for establishing the tolerance. If the submitted residue data demonstrates that the residue levels are above the levels relied on for establishing the tolerance, EPA will take appropriate action to modify or revoke the tolerance.

### **2(b)(1) Types of Data Collected**

The data that EPA collects and reviews fall into three general categories: confirmatory data, product-specific data, and voluntary data.

*Confirmatory Data.* In making a regulatory decision, additional generic studies sometimes are required to confirm the Agency’s risk assessments, findings, or conclusions about a pesticide, and to help determine whether further use modifications will be necessary to reduce risks of concern.

*Product-Specific Data.* After the existing data supporting a pesticide are evaluated and a regulatory determination is made, EPA’s focus turns to the information and data required to make regulatory decisions at the product-specific level. For every end-use product (that is, every product that contains an active ingredient), registrants are required to submit certain data specific to the product as formulated and sold (including acute toxicity and product chemistry studies),

revised labeling. In certain instances, the Agency requires that the registrant submit a Confidential Statement of Formula. For example: Registrants are required to submit a Confidential Statement of Formula (EPA Form 8570-4) to comply with registration-related requirements under FIFRA section 3, such as when a registrant seeks to add uses for a currently-registered pesticide, or when the registrant changes a registered pesticide's formulation. The requirement is mentioned here since registrants have not always submitted the required information immediately to EPA and the deficiency may remain at the time of the regulatory review. The paperwork burden for the submission of Form 8570-4 is covered under OMB Control No. 2070-0060 (*Application for New/Amended Pesticide Registration*; EPA ICR. No. 0277). Additional information and data are essential to making the final regulatory decision regarding the particulars of a specific product.

*Voluntary Data.* FQPA requires EPA to specifically consider a number of factors when making pesticide reregistration and other types of regulatory decisions. While registrants have historically and voluntarily submitted data to EPA that was not specifically required/requested, EPA issued Pesticide Registration (PR) Notice 97-1 in light of the FQPA requirement to identify areas in which the Agency may need additional data to fully assess risks under FQPA. The PR notice encouraged registrants to supplement their original reregistration submissions with additional information that may permit more accurate estimates of exposure and/or risk. As a result of PR Notice 97-1, EPA received large numbers of voluntarily submitted studies for pesticides in reregistration, particularly for large volume, controversial chemicals. While the reregistration program is near completion, the Agency still anticipates receiving a small number of voluntarily submitted studies from registrants to fulfill other statutory requirements.

### **3(a). Non duplication**

The information collected under these programs is specific to the needs of the federal pesticide law negating the need for similar data by other federal agencies or any other office within EPA. Prior to requesting any information the Agency must review existing records for the availability of the information that it is considering requesting. The Agency maintains files on all pesticide chemicals, which includes all correspondence and information/data submitted. Before any DCI is issued, these files are referenced to determine whether the necessary data are already on hand, thereby eliminating duplicative data requests. For example, a majority of the percent-crop-treated information can currently be obtained internally, thus DCIs will only be issued when more data is necessary. The data for anticipated residues, on the other hand, is unique to the requirements of FIFRA, and, therefore, must be submitted to the Agency. EPA also provides for public comment periods for all the review programs which may modify the DCI requirements if warranted by information provided by registrants or the public.

OPP publishes a list of data submitters and encourages the registrants to act cooperatively in the development of data or in its use. OPP encourages cost-sharing agreements among manufacturers of specific pesticide chemicals in order to minimize the duplication of laboratory tests and reduce the costs for developing the data. All DCI notices explain the statutory provisions for cost-sharing agreements under FIFRA.

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

Pursuant to 5 CFR 1320.8(d), EPA published a Federal Register (FR) notice (See 73 FR 2907; January 16, 2008) notice soliciting comment on this information collection activity and the Agency's intent to renew, consolidate and request OMB approval of this ICR. The Agency received only one public comment on this consolidated renewal ICR from William M. Mahlburg, Director Government Affairs, Nufarm Americas, Inc. Mr. Mahlburg suggested that the Agency re-evaluate the timing set for registrant response to DCIs to provide more time for registrants to respond because technical registrants for numerous active ingredients will be affected by multiple DCIs that are simultaneous or overlapping. Mr. Mahlburg stated that due to a multitude of end-use product registrations that Nufarm submits large volumes of studies termed "low burden" and that companies with more than 25 end-use product registrations with the same active ingredient were constrained by the Agency's set DCI response time line and needed additional DCI response time to help eliminate the response process burdens associated with high volume registration companies.

The Agency does not expect that a given technical registrant will typically receive simultaneous DCIs for multiple active ingredients. However, in situations where a large number of studies are required, the Agency has responded to requests for time extensions by staggering when responses are due. In its comment, Nufarm did not submit any new burden data for the Agency to consider. Therefore, there are no new data for the Agency to evaluate. In addition, submissions to the Agency from 1996-2004 of voluntary data not required by the Agency but which are submitted by registrants to supplement an active ingredient database show that most are considered by the Agency to be "low burden." At this time, the Agency does not anticipate changing the low burden hour study projections documented in this ICR. Overall, in developing paperwork burden estimates, EPA assumed that responses (including ones to end-use product-specific data) from registrants would not include the following: data already generated at registration, submitted under a previous DCI, resubmissions because the original data were not complete or did not meet submission requirements, or preexisting data that can be found in published, peer reviewed literature. Since the commenter did not offer any new burden numbers for the Agency to consider, the Agency did not change the burden numbers in the final document.

### **3(c). Consultations**

Consultation and/or dialogue between registrants and the Agency concerning data requirements, need for particular information and the protocol to be used to conduct the study are frequent and ongoing.

Generally, all programs discussed in this DCI Program ICR are intrinsically woven with the Agency's public participation review process. Stakeholders and the public have a number of opportunities for input, consultation and involvement throughout the process, including but not limited to issues such as the need for additional data. Significant public comments will be addressed prior to issuing DCIs. Until the DCI is issued, registrants are not required to submit data. This integrated public participation framework provides consistent, predictable opportunities for public and stakeholder involvement through public comment periods at regular

intervals to help inform EPA's regulatory decision making. EPA's formalized public participation process for reregistration and tolerance reassessment (See 69 FR 26819, May 14, 2004; also <http://www.epa.gov/oppsrrd1/public.htm>) recognizes that all pesticides do not present the same degree of risk or complexity of issues, and accordingly describes the ways in which the Agency tailor the public participation process to the uses and risks of each pesticide and to obtain public input as needed while still making timely decisions and meeting statutory deadlines and program goals. The process for registration review, including public participation, is described in the procedural rule for registration review (40 CFR part 155) and is summarized on the Agency's web site at [http://www.epa.gov/oppsrrd1/registration\\_review/public\\_involvement.htm](http://www.epa.gov/oppsrrd1/registration_review/public_involvement.htm)

If appropriate to resolve scientific questions, the Agency may also seek peer review and/or advice from the FIFRA Science Advisory Panel SAP. The FIFRA SAP is a Federal advisory committee established in 1975 under FIFRA that operates in accordance with requirements of the Federal Advisory Committee Act. The FIFRA SAP is composed of a permanent panel consisting of seven members who are appointed by the EPA Administrator from nominees provided by the National Institutes of Health and the National Science Foundation. FIFRA, as amended, established a Science Review Board consisting of at least 60 scientists who are available to the FIFRA SAP on an ad hoc basis to assist in reviews conducted by the Panel.

EPA consulted with a variety of respondents regarding the information collection activities for this ICR during the renewal and consolidation process. A list of the respondents contacted is below:

Ray McAlister, Vice President  
Science and Regulatory Affairs  
CropLife America  
[ray@croplife.us](mailto:ray@croplife.us)

Susan Little, Executive Director  
Consumer Specialty Products Association  
900 17th Street N. W..  
Washington, DC 20005  
[slittle@cspa.org](mailto:slittle@cspa.org)

Daniel Botts, Director  
FFDA's Environmental &  
Pest Management Division  
Minor Crop Farmer Alliance  
Technical Committee (Chairman)  
Florida Fruit & Vegetable Assoc.  
[daniel.botts@ffva.com](mailto:daniel.botts@ffva.com)

Rebeckah Freeman Adcock,  
Director, Congressional Relations  
American Farm Bureau  
600 Maryland, Ave., S.W.  
Suite 1000W  
Washington, DC 20024  
[rebeckah@fb.org](mailto:rebeckah@fb.org)

The consultation questions and any responses received are included in the docket as attachments E-1 through E-4 for this action. Generally, the questions and discussions with respondents included whether the labor rate estimates in the ICR are accurate and whether the estimates of burden and methodology for arriving at the estimate are correct, and whether respondents would consider submitting the information electronically, such as through web forms and whether the consolidation document was easy to read. To date, one respondent,

Rebeckah F. Adcock, American Farm Bureau Federation noted that the document was clearly written and concisely laid out. The Agency did not received any comments regarding the burden.

### **3(d). Effects of Less Frequent Collection**

Information is collected under this ICR only when the Agency has identified a need for the specific data, and only on a one-time basis. AR or PCT information is collected one time within the five years preceding the reliance on such data. The AR or PCT information collection is required by sections 408(b)(2)(E)(I) and 408(b)(2)(F) of the FFDCA and cannot be collected less frequently.

### **3(e). General Guidelines**

The only guideline established under the Paperwork Reduction Act (PRA) that is exceeded in this collection is the time period for retaining records. Pursuant to FIFRA §8, EPA recordkeeping requirements in 40 CFR 169.2(k) state that records containing research data relating to registered pesticides be retained as long as the registration is valid and the producer remains in business. Registrations are valid until they are either voluntarily canceled 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 collection activity.

#### **3(e)(1). Forms**

The forms associated with this ICR may also be used for other information collection activities that are approved under other OMB Control numbers, e.g., 2070-0060. Specifically:

- Confidential Statement of Formula, (EPA Form 8570-4)
  - also approved under OMB Control Number 2070-0060
- Formulator's Exemption Statement, (EPA Form 8570-27)
  - also approved under OMB Control Number 2070-0060
- Certification of Compliance with Data Gap Procedures, (EPA Form 8570-28)
- Certification of Attempt to Enter into an Agreement with Registrants for Development of Data (EPA Form 8570-32)
- Certification with Respect to Citation of Data (in Pesticide Registration (PR) Notice 98-5) (EPA Form 8570-34)
  - also approved under OMB Control Number 2070-0060
- Data Matrix (also in PR Notice 98-5) (EPA Form 8570-35)
  - also approved under OMB Control Number 2070-0060



- Summary of the Physical/Chemical Properties (EPA Form 8570-36)
  - also approved under OMB Control Number 2070-0060
- Self-Certification Statement for the Physical/Chemical Properties (EPA Form 8570-37)
  - also approved under OMB Control Number 2070-0060
- Requirements Status and Registrant's Response (EPA Form 6300-3)
- Data Call-In Response Form (EPA Form 6300-4)

Forms 6300-3 and 6300-4 are automatically generated by EPA's computer databases and are pre-populated with information that is specific to each individual registrant that receives a Data Call-In notice for a given pesticide. These forms are not widely accessible to general public. Instead, EPA will continue to generate the pre-populated, registrant-specific forms through the Agency's computer system when preparing to issue Data Call-In notices.

In the past, under the separate renewals for these ICRs and in accordance with 5 CFR 1320.5(a)(1)(iii)(C), EPA discontinued the display of expiration dates on these forms because the forms had not changed after many years of use and were not expected to change in the future. The OMB approved prior ICR requests, and EPA will continue to omit the expiration dates on these forms. See **Attachment F** for accessibility to forms.

### **3(e)(2). OMB Review of Specific DCIs**

When OMB last approved these ICRs in 2005, OMB directed EPA, via the terms of clearance, to seek OMB clearance before issuing a given DCI. Specifically, the terms of clearance provided that:

*EPA must provide OMB with notice and an opportunity to review the DCI. The information sent to OMB shall include basic information on the pesticide, the total number of respondents, the planned schedule for issuance and data submission, a list of required studies, the practical utility of the data, and an estimate of the paperwork burden and testing costs.*

### **3(f). Confidentiality**

Except as provided in FIFRA section 10(d)(1)(A), (B) or (C), health and safety data submitted by registrants under FIFRA must be made available by the Agency upon request from anyone not affiliated with a multi-national pesticide firm. These exceptions, however, specifically prohibit disclosure of the inert ingredients in a pesticide or of its manufacturing, quality control processes, sales and production data, or trade secrets.

Registrants may claim at the time of submission that specific data are subject to treatment as confidential for reasons other than falling within the exclusions for mandatory release. All data subject to such claims, or falling within FIFRA section 10(d)(1)(A), (B), or (C) are handled strictly in accordance with the provisions of the FIFRA Confidential Business Information Security Manual. The manual requires that all CBI must be marked or flagged as such, all CBI must be kept in secure (double-locked) areas, and all CBI intended to be destroyed must be cleared by a Document Control Officer and shredded.

**3(g). Sensitive questions**

No information of a sensitive or private nature is requested in conjunction with this information collection activity, and 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/NAICS Codes**

Respondents to the information collection activities related to this ICR consist of pesticide Registrants identified by the North American Industrial Classification System (NAICS) code **325320** (Pesticide and Other Agricultural Chemical Manufacturing).

**4(b). Information Requested**

*Reregistration*

Over the next three years, EPA expects to issue 137 DCIs for active ingredients and the pesticide products that contain them. The breakdown of the regulatory decisions for the Reregistration Program that EPA expects to make over the next 3 years is as follows:

<b>Type of Decision</b>	<b>No. of Pesticide Ingredients</b>
Reregistration Eligibility Decisions (REDs) and efficacy data	107
Import tolerances (ingredients with no U.S. registrations)	30
<b>Total</b>	<b>137</b>

*Special Review and Registration Review*

Special Reviews, though rare, are conducted when the Agency determines such a review is warranted. For the sake of the analyses presented in Section 6 of this ICR, EPA assumes that it will issue one DCI per year. Over the next 3 years EPA expects to issue 121 DCIs (41 annually) for the Registration Review Program.

*Anticipated Residue and Percent Crop Treated (AR/PCT) Reviews*

Over the next 3 years, EPA expects to issue 4 AR-related DCIs and 1 PCT-related DCI per year. The breakdown of the annual number and type of DCIs is as follows:

<b>Type of DCI</b>	<b>Number of DCIs per year</b>
<i>Anticipated Residue</i>	
Generation and submission of base set of AR data (“Type 1”)	2
Submission of minimal verification-of-use information (“Type 2”)	1
Submission of AR data from publicly available sources (“Type 3”)	1
<i>Percent Crop Treated</i>	
Submission of PCT data using existing information (“Type 4”)	1
<b>Total</b>	<b>5</b>

*Enforcement and Unanticipated Incidents*

As explained in section 2 of this ICR, DCIs related to enforcement cases and unanticipated incidents are extremely rare. For the sake of the analyses presented in Section 6 of this ICR, EPA assumes that it will issue only one DCI for this purpose over the next 3 years.

(i) Data Items, Including Record Keeping Requirements

Considering the potential variation in the specific need identified for the individual pesticide under review, the specific data items that may be collected for the individual pesticides under this ICR are also likely to vary from pesticide to pesticide. However, based on the specific need identified for the pesticide, the Agency may request, or the registrant may voluntarily submit several types of data, including, but not limited to:

- Product Chemistry
- Residue Chemistry
- Environmental Fate
- Toxicology
- Reentry Protection
- Spray Drift
- Wildlife and Aquatic Organisms
- Plant Protection
- Nontarget Insect
- Product Performance
- Biochemical Pesticides
- Microbial Pesticides
- Exposure Studies
- Dermal Absorption/Penetration Studies
- Acute and Subchronic Neurotoxicity Studies

Cholinesterase Determination  
Biomonitoring Studies (in Children)  
Monte Carlo Probabilistic Assessments/Acute and Chronic Dietary Exposure Analyses  
Historical Water Monitoring Data  
Field Monitoring Studies and Evaluations  
Runoff and Drift Monitoring Studies  
Pesticide Removal Studies using Vegetative Filter Strips  
Retrospective Analyses of Surface Water Contamination  
Analyses of Use Patterns  
Research Studies of Applications and Use in Professional Markets  
Comparative Formulations/Application Methods/Resulting Crop Residue Studies  
Mechanistic Studies for Carcinogenicity  
Studies on Potential to React with DNA  
Monitoring data (States, special monitoring, market basket, single serving, etc.)  
Field trials,  
Processing studies,  
Reduction in residue data (washing, peeling, cooking, etc.),  
Livestock feeding studies  
Metabolism studies  
Percent crop treated data

These categories, which are defined in greater detail in 40 CFR Part 158, basically consist of the criteria for information and/or data that are necessary to make a regulatory finding. (See guidelines and policies to assist registrants with responding to DCIs; see science policy at <http://www.epa.gov/pesticides/science/policies.htm> and test guidelines at <http://www.epa.gov/opptsfrs/home/guidelin.htm>.) In addition to the categories identified above, the Agency may also require that a special study be conducted to provide critical information about the risks and benefits of the pesticide in support of continued registration. Agency requests for special studies would be based on the particular characteristics of the chemical, and the Agency's need for such information to make the required statutory finding.

(ii) Respondent Activities

A pesticide registrant who receives a DCI will generally engage in the following activities under this ICR:

- |                              |   |
|------------------------------|---|
| <b>1. read instructions</b>  | read the DCI letter to understand what data are to be submitted   |
| <b>2. plan activities</b>    | plan the activities necessary to comply with the DCI, or develop options to avoid having to submit data (e.g., exemption/waiver), submit 90-day response to EPA |
| <b>3. create information</b> | conduct research, administer tests, analyze data to develop studies, perform laboratory analysis, write study documents   |

- |                              |   |
|------------------------------|---|
| <b>4. gather information</b> | search for existing data that will satisfy the DCI                                      |
| <b>5. compile and review</b> | assemble and evaluate data for accuracy and appropriateness for compliance with the DCI |
| <b>6. complete paperwork</b> | prepare necessary correspondence, documents and packages for submitting data to EPA     |
| <b>7. maintain and file</b>  | maintain the data and other information submitted to the Agency                         |

Registrants who receive a DCI notice from EPA must notify the Agency how they intend to comply with the terms of the DCI notice within 90 days of receipt of the notice. Registrant options for complying with the DCI notice vary greatly and thus the per respondent burden can also vary greatly. A summary of the registrant compliance options are listed below:

(iii) Reducing the PRA Burden: Variation of Response to A DCI

Voluntary Cancellation - Registrants opting to voluntarily cancel their products containing the active ingredient that is subject to the DCI must submit a completed Data Call-In Response Form. If a product is voluntarily cancelled, further sale and distribution of that product after the effective date of cancellation must be in accordance with the existing stocks provision of the individual DCI notice.

Deletion of Uses - Registrants choosing to amend their registration to delete the uses of their product to which the requirements apply must submit the Requirements Status and Registrant's Response Form, a completed application for amendment, a copy of their proposed amended labeling, and all other information required for processing the application. They must also complete a Data Call-In Response Form. If registrants choose to delete the use(s) subject to the DCI notice or uses subject to specific data requirements, further sale, distribution, or use of their product after one year from the due date of their 90-day response must bear an amended label.

Generic Data Exemption - Registrants are entitled to apply for a generic data exemption from the requirement to submit or cite generic data concerning an active ingredient if the active ingredient in the product is derived exclusively from purchased, registered pesticide products containing the active ingredient. To qualify for a generic data exemption, a product must meet all of the following requirements:

- The active ingredient(s) in the registered product must be present solely because of incorporation of another registered product which contains the subject active ingredient(s) and be purchased from a source not connected with the registrant; and,

- Every registrant who is the ultimate source of the active ingredient(s) in the product subject to the DCI notice must be in compliance with the requirements of the notice and must remain in compliance; and
- The registrant of the product that is the subject of the DCI notice must have provided to EPA an accurate and current "Confidential Statement of Formula" for each of the products to which the Notice applies.

Registrants applying for the Generic Data Exemption complete and submit a Data Call-In Response Form along with all supporting documentation. If a generic data exemption is claimed, the registrant is not required to complete the Requirements Status and Registrant's Response Form. Generic data exemption cannot be selected as an option for product specific data.

Registrants who are granted a Generic Data Exemption rely on the efforts of other persons to provide the Agency with the required data. If the registrant(s) who have committed to generate and submit the required data fail to take appropriate steps to meet the requirements, the Agency will consider that both the submitting and exempted registrants are not in compliance and will normally initiate proceedings to suspend the registrations of both registrants' products unless the registrant who was granted the generic data exemption commits to submit and does submit the required data within the specified time. In such cases the Agency generally will not grant a time extension for submitting the data.

Submission of Required Data - Registrants choosing this option must agree to either: submit the data required by the notice within the specified time frame; enter into an agreement with one or more other registrants to develop data jointly; make offers to cost-share; submit an existing study that has not been submitted previously to the Agency by anyone; submit or cite data to upgrade a study classified by EPA as partially acceptable and upgradeable; or cite an existing study that EPA has classified as acceptable or an existing study that has been submitted but not reviewed by the Agency.

Submission of Data Waiver Request - A registrant may request either a low volume/minor use waiver or a waiver based on the registrant's belief that the data requirement(s) do not apply to their product. In addition to the Requirements Status and Registrant's Response Form, registrants requesting low volume/minor use waivers must submit the following information:

- Total company sales (pounds and dollars) of all registered product(s) containing the active ingredient(s). If applicable to the active ingredient(s), include foreign sales for those products that are not registered in this country but are applied to sugar (cane or beet), coffee, bananas, cocoa, and other such crops, by year for each of the past five years.
- An estimate of the sales (pounds and dollars) of the active ingredient(s) for each major use site, by year for each of the past five years.

- Total direct production cost of product(s) containing the active ingredient(s) by year for the past five years, including information on raw material cost, direct labor cost, advertising, sales and marketing, and any other significant costs, listed separately.
- Total indirect production cost (e.g. plant overhead, amortized plant and equipment) charged to product(s) containing the active ingredient(s) by year for the past five years. Exclude all non-recurring costs that were directly related to the active ingredient(s), such as costs of initial registration and any data development.
- A list of each data requirement for which the registrant is requesting a waiver.
- The type of waiver sought and the estimated cost to the registrant (listed separately for each data requirement and associated test) of conducting the testing needed to fulfill each of these data requirements.
- A list of each data requirement for which the registrant is not seeking any waiver and the estimated cost (listed separately for each data requirement and associated test) of conducting the testing needed to fulfill each of these data requirements.
- For each of the next ten years, a year-by-year forecast of company sales (pounds and dollars) of the active ingredient(s), direct production costs of product(s) containing the active ingredient(s) (following the parameters in item c above), indirect production costs of product(s) containing the active ingredient(s) (following the parameters in item d above), and costs of data development pertaining to the active ingredient(s). In addition, the registrant must provide a description of the importance and unique benefits of the active ingredient(s) to users and discuss the use patterns and the effectiveness of the active ingredient(s) relative to registered alternative chemicals and non-chemical control strategies. Registrants should provide information on any of the following factors in order to assist EPA in making a determination about the importance of an Active ingredient's benefits:
  - documentation of the usefulness of the active ingredient(s) in Integrated Pest Management;
  - description of the beneficial impacts on the environment of use of the active ingredient(s), as opposed to its registered alternatives;
  - information on the breakdown of the active ingredient(s) after use and on its persistence in the environment, and description of the product's usefulness against pest(s) of public health significance.

Failure to submit sufficient information for the Agency to make a determination regarding a request for a low volume minor use waiver will result in denial of the request for a waiver.

Request for Waiver of Data - A registrant may also request a waiver if they believe that a particular data requirement should not apply because the corresponding use is no longer

registered or the requirement is inappropriate. In addition to the Requirements Status and Registrant's Response Form, registrants requesting a waiver of data requirements must submit a rationale explaining why the registrant believes the data requirements should not apply, as well as copies of current product labels and a current copy of the Confidential Statement of Formula for each product. If the Agency determines that a registrant does not qualify for a waiver and that the data are required for the product(s), the registrant must choose a method of meeting the requirements of the notice within the 90-day time frame provided by the notice. Within 30 days of the registrant's receipt of the Agency's written decision, the registrant must submit a revised Requirements Status and Registrant's Response Form indicating the option chosen.

**5. THE INFORMATION COLLECTED - AGENCY ACTIVITIES, COLLECTION METHODOLOGY, AND INFORMATION MANAGEMENT**

**5(a). Agency Activities**

The following Agency activities are necessary to conduct a DCI under this ICR:

develop DCI correspondence	prepare the DCI letter identifying all the data needed
answer registrants' questions	respond to any questions the registrant may have regarding the DCI
review data submissions	review data submissions for completeness and appropriateness
record DCI submissions	record submissions in tracking system for internal review
analyze data	conduct scientific reviews of data
store data	index data and store it in Agency files

**5(b). Collection Methodology and Management**

After initiating a statutorily mandated pesticide review whether a Special Review, closeout of a Reregistration Review, a Registration Review or a AR or PCT Review and determining that additional data is needed, the Agency will issue a DCI when the need for additional data has been identified.

OPP tracks DCIs and all registrant responses through the Office of Pesticide Programs Information Network (OPPIN), OPP's general purpose action tracking system. Additionally, the Reference Files System (REFS) is used if the registrant voluntarily cancels a product in response to a DCI. The Pesticide Data Management System (PDMS) lists the bibliography of data submitters for the DCI and OPPIN tracks the submissions. All correspondence associated with the issuance and response to the DCI is filed in the master registration file or 'registration jacket' of affected products. Data submitted in response to a DCI is processed, catalogued and archived in the PDMS. Failures to comply with DCI requirements are referred to EPA's Office of Enforcement and Compliance Assurance for appropriate follow-up actions.



Although the Agency does not publish the submitted information, and public access to the PDMS bibliography is 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 may request copies of non-confidential studies through FOIA.

OPP continues to investigate the possibility of providing optional electronic data transfer services to the industry as a means of minimizing the burden of registration activities. The Agency's pesticide program, along with the pesticide industry, recognizes the advantages in terms of accuracy, speed, cost and personnel from electronic data transfer technologies. In addition, OPP continues to consult with industry associations and other federal agencies, and is participating in an Agency-wide workgroup to develop electronic reporting standards intended to facilitate the submission and use of information about pesticides.

### **5(c). Small Entity Flexibility**

Currently, pesticide registrants may be divided into two groups. Approximately 10 percent of the total: manufacture or import chemical active ingredients intended for use as pesticides, sell these active ingredients to other firms for formulation into pesticide products, and/or make the end-products themselves. The second, and by far the larger, group of registrants purchase the active ingredients in their pesticide products from members of the first group, and combine them with pesticide inert ingredients or sometimes simply repackage them to make their end-use products.

This second group is primarily comprised of small businesses. When small businesses use a registered source of the active ingredient to formulate their products, they generally are exempt from generating health and safety data for pesticide active ingredients ("generic data"). Consequently, they usually need only respond to a DCI for active ingredient data by claiming the "generic data exemption" (for more detail, see section 4(b)(iii) "Reducing the PRA Burden" Variation of Response to a DCI" of this document). They do not incur any other information burden associated with the data call-in.

### **5(d). Collection Schedule**

There is not a collection schedule per se. DCIs are issued when the need is identified. The time frame in which the respondents must then submit the requested material is specifically established for each DCI based on the individual circumstances surrounding the particular DCI and applicable review. For a variety of reasons, most manufacturers wait to generate new data and/or submit new/existing data until EPA issues the DCI. One of the most important reasons for this is that EPA's issuance of a DCI is a public statement that the data is needed, and will be relied on, thus "triggering" the data compensation provisions of section 3(g)(1)(B) of FIFRA.

As part of the consultation and public participation process, EPA generally works with respondents to ensure that sufficient time is built into the individual DCIs to allow for respondents to gather and submit the requested information. However, the timing of AR/PCT-related DCIs and respondent data submissions is somewhat different.

AR DCIs will generally be issued whenever ARs data is relied upon, either to establish new tolerances or reassess existing tolerances. Registrants have five years before data must generally be submitted in support of the ARs used. Data must also be periodically reviewed when PCT estimates are relied upon, but in most cases the Agency will be able to internally collect or generate this data. EPA will issue PCT DCIs in cases where the Agency is unable to obtain the information on its own. In these cases, the registrant must submit data within five years of the use of PCT estimates. Additional time is provided for development of new studies appropriate to the nature of the studies required.

## **6. ESTIMATING THE BURDEN AND COST OF THE COLLECTION**

### **Methodology Used To Estimate the Burden for DCIs**

To estimate the burden and costs for the paperwork related activities for respondents to comply with DCIs notices issued under any of the review programs, EPA estimates PRA activities to be 35% of the cost to generate new data. This methodology is based on using the average cost estimates for the specific studies requests in each DCI and is only applicable to DCI related data generation. This approach was adopted because it allows the Agency to consider the potential for there to be greater burden related to a more complex study. The premise is that a more expensive study probably causes the respondent to incur more burden hours and costs than generating a less expensive study. The public, registrants, key stakeholders, and OMB developed this percentage from numerous sources of information including agency expertise, consultation with industry, and repeated review on the Agency's information collection activities.

To help calculate the PRA costs, the Agency maintains an archive of the basic FIFRA study cost estimates that were developed through surveys of independent testing laboratories, Agency economic analyses, and registrant comments during ICR renewal periods. To the extent possible, EPA uses multiple sources to provide test cost estimates, which are updated as needed.

This methodology assumes all recipients of a DCI generate all of the data as specified in the DCI notice. Using this assumption however, the Agency has chosen to overestimate the burden because not all DCI recipients engage in all of the DCI activities. The Agency is aware that DCI recipients who engage in a taskforce for data generation, voluntarily cancel the product or affected uses, submit or cite existing data, or are granted a waiver incur fewer burden hours and cost. The Agency actively encourages cost-sharing agreements among manufacturers of specific pesticide chemicals to minimize the duplication of laboratory tests conducted and to minimize costs for DCI recipients.

Common to developing the burden estimates for all DCIs, EPA uses the following general assumptions:

- studies were submitted by registrants (not grower groups, or other agencies, etc.);
- studies had not been requested under a previous DCI;
- studies were not a request to resubmit because the original study submitted was not complete or did not meet the data submission requirements; and

- studies submitted that are based on preexisting data and can be found in published, peer reviewed literature were not included.

A detailed discussion of the Agency’s “*Methodology Used to Estimate Paperwork Burden Hours and Costs by the Office of Pesticide Programs for Submission of Required Data/Information for Responding to a Data Call-In Notice*” is available at **Attachment G** to this document.

### Updating Labor Rates

The Agency has updated the estimated wages, benefits and overhead for all labor categories for affected industries, state government, and EPA employees based on publicly available data from the US Bureau of Labor Statistics. The formulas used to estimate the labor rates and formulas used to derive the fully loaded rates and overhead costs for this ICR renewal are listed in **Attachment H**

Methodology	The methodology uses data on each sector and labor type for an <i>Unloaded wage rate</i> (hourly wage rate), and calculates the <i>Loaded wage rate</i> (unloaded wage rate + benefits), and the <i>Fully loaded wage rate</i> (loaded wage rate + overhead). Fully loaded wage rates are used to calculate respondent costs. This renewal uses 2003 base data.
Unloaded Wage Rate	Wages are estimated for labor types (management, technical, and clerical) within applicable sectors. The Agency uses average wage data for the relevant sectors available in the National Industry-Specific Occupational Employment and Wage Estimates from the Bureau of Labor Statistics (BLS) at <a href="http://www.bls.gov/oes/current/oes_nat.htm">http://www.bls.gov/oes/current/oes_nat.htm</a> .
Sectors	The specific North American Industry Classification System (NAICS) code and website for each sector is included in that sector’s wage rate table (see Attachment G). Within each 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 (see <a href="http://www.bls.gov/oes/current/oes_stru.htm">http://www.bls.gov/oes/current/oes_stru.htm</a> ).
Loaded Wage Rate	Unless stated otherwise, all benefits represent 43% of unloaded wage rates, based on benefits for all civilian non-farm workers, from <a href="http://www.bls.gov/news.release/ecec.t01.htm">http://www.bls.gov/news.release/ecec.t01.htm</a> . However, if other sectors are listed for which 43% is not applicable, the applicable percentage will be stated.
Fully Loaded Wage Rate	We multiply the loaded wage rate by 50% (EPA guidelines 20-70%) to get overhead costs.

### Format

For reader clarity this consolidation document contains four separate parts which discuss “Section 6 - Estimating The Burden And Cost Of The Collection.” For this section only, discussions regarding PRA burden and costs for each of the review programs have been

restructured into separate parts which allow the reader/reviewer to readily identify the burden activities associated with a particular review program. The parts are labeled as follows:

Part 1 – Section 6: Estimating the Burden and Cost of the Collection for the Reregistration Review program (including reassessing import tolerances).

Part 2 – Section 6: Estimating the Burden and Cost of the Collection for the Special Review and Registration Review Programs

Part 3 – Section 6: Estimating the Burden and Cost of the Collection for the Anticipated Residue and Percent Crop Treated Review Programs

Part 4 – Section 6: Estimating the Burden and Cost of the Collection for Enforcement and Unanticipated Incidents

**Bottom-line Summary of Annual DCI-Related Respondent Paperwork Burdens and Costs**

Collection Activity	Burden Hours	Costs
<i>Reregistration Program DCIs</i>		
Confirmatory DCIs	27,213	\$1,883,612
Product Specific DCIs	125,414	\$2,900,584
Voluntarily Submitted Low Burden Studies	3,159	\$218,641
Voluntarily Submitted High Burden Studies	9,565	\$786,567
<i>Special Review and Registration Review DCIs</i>		
Special Review DCIs	919	\$56,202
Registration Review DCIs	65,374	\$4,595,587
<i>Anticipated Residue/Percent Crop Treated DCIs</i>		
AR DCIs: Base Set of Data	27,272	\$1,828,886
AR DCIs: Verification-of-use Data	690	\$52,940
AR DCIs: Updated Public Source Monitoring Data	548	\$39,644
DCIs for Percent Crop Treated Estimates	59	\$3,966
<i>Enforcement And Unanticipated Incident DCIs</i>		
Enforcement And Unanticipated Incident DCIs	2,088	\$140,097
<b>Total</b>	<b>262,301</b>	<b>\$12,506,726</b>

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 regulations, planning the necessary data collection activities, conducting tests, analyzing data, generating reports and completing other required paperwork, and storing, filing, and maintaining the data. The 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. The OMB control number for this information collection appears at the beginning and the end of this document. In addition OMB control numbers for EPA’s regulations, after initial display in the final rule, are listed in 40 CFR part 9.

The Agency has established a public docket for this ICR under Docket ID No. **EPA-HQ-OPP-2007-0923**, which is available for online viewing at [www.regulations.gov](http://www.regulations.gov), or in person viewing at the OPP Regulatory Public Docket in Rm. S-4400, One Potomac Yard (South Building), 2777 S. Crystal Drive, Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305-5805. You may submit comments regarding 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.

Comments may be submitted to EPA electronically through <http://www.regulations.gov> or by mail addressed to Director, Collection Strategies Division, U.S. Environmental Protection Agency (2822T), 1200 Pennsylvania Ave., NW, Washington, D.C. 20460. 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. Include docket ID No. **EPA-HQ-OPP-2007-0923** and OMB control numbers 2070-0057; 2070-0107; and 2070-0164 in any correspondence but do not submit any DCI or other related information (e.g., forms, reports, etc.) to these addresses.

September 10, 2008

**Part 1- Section 6:**  
Estimating the Burden and Cost of the Collection for the Reregistration Review program  
(including reassessing import tolerances).

**Part 1** describes the burden activities associated with the Reregistration review program, which also includes the burden activities associated with import tolerance reassessment. While the final regulatory decisions for the Reregistration program are scheduled for completion in 2008, the Agency will still issue Reregistration DCIs for the life of this ICR.

**6(a) Estimating Respondent Burden – Reregistration**

The total estimated *annual* burden hours for respondents to comply with the information collection activity for the Reregistration Program to be **165,351 hours**, with the total *annual* respondent burden cost estimated to be **\$5,789,404**.

The burden estimate is dependent upon the type or class of chemical under review and whether there is a high, medium or low burden that are directly related to the complexity of studies, and the cost of such studies required for a particular chemical. Reregistration review burden estimates are based only on Phase 5 (completion) activities and for reassessing existing import tolerances. EPA examined the historical data for confirmatory, product specific and voluntary data that have been submitted for representative pesticides in this program. This information was used to project the estimates in this ICR. As a result of the review, EPA will not adjust the estimated hourly burden per response for any of the respondents for the renewal of this ICR.

Over the next three years, EPA expects to issue 137 DCIs for active ingredients and the pesticide products that contain them. The breakdown of the regulatory decisions for the Reregistration Program that EPA expects to make over the next 3 years is as follows:

<b>Type of Decision</b>	<b>No. of Pesticide Ingredients</b>
Reregistration Eligibility Decisions (REDs) and efficacy data	107
Import tolerances (ingredients with no U.S. registrations)	30
Total	137

**6(a)(1). Paperwork Burden Related to the Submission of Confirmatory Data – Reregistration**

Confirmatory data are required of registrants to complete registrant databases and to assist in the evaluation of risk findings. For DCIs involving confirmatory studies, EPA also assumed that only one respondent – the manufacturer of the active ingredient – will provide the data requested (i.e, one registrant will submit an average of 9.8 “confirmatory” studies per DCI, and therefore, there will be only one response submitted to EPA per DCI involving confirmatory data. EPA expects to issue 137 confirmatory DCIs over the next 3 years, which equals an average of 45.66 confirmatory DCIs annually. See Table 1 below for burden activity details.

**Table 1. Annual Respondent Burden for DCIs Involving Confirmatory Studies**

Collection Activities	Burden Hours			Total	
	Mgmt. \$103.62/hr	Tech. \$67.05/hr	Cler. \$33.85/hr	Hours	Costs
1. Read and discuss test requirements	12	0	0	12	\$1,243.44
2. Discuss test and protocol with Agency	6	6	0	12	\$1,024.02
3. Plan activities	24	6	0	30	\$2,889.18
4. Create information	18	299	36	353	\$23,131.79
5. Gather information	0	30	0	30	\$2,011.50
6. Process, compile, review information for accuracy	35	48	0	83	\$6,845.10
7. Complete written forms	0	0	12	12	\$406.20
8. Record, disclose, display information	11	0	24	35	\$1,952.22
9. Store, file, or maintain information	11	0	18	29	\$1,749.12
<b>Total</b>	<b>117</b>	<b>389</b>	<b>90</b>	<b>596</b>	<b>\$41,252.57</b>

Estimated Total Annual Respondent Burden & Costs for DCIs Involving Confirmatory Studies:  
 Burden: 596 hours per response x 1 response per DCI x 45.66 DCIs = 27,213.36 burden hours.  
 Costs: \$41,253 per response x 1 response per DCI x 45.66 DCIs = \$1,883,611.90

#### **6(a) (2). Paperwork Burden Related to Voluntarily Submitted Data - Reregistration**

Voluntary data consist of studies not required by the Agency but are submitted by registrants to supplement a pesticide database. To account for the burden attributed to voluntarily submitted data, the Agency inventoried the types of voluntarily submitted data for a range of chemicals. Based on a sampling of Reregistration Eligibility Decisions (REDs) affected by FQPA tolerance reassessment submitted over an eight year period (1996- 2004), the Agency received 67 voluntary data submissions. This averages to 8.375 submissions annually.

In the past, many of voluntarily submitted studies have been existing studies, e.g., studies found in existing literature, or studies that were slightly modified and resubmitted, or studies of lower cost. Some may be special studies such as a Monte Carlo, or limited market basket survey, or other studies to provide the Agency with actual exposure data. Regardless of the voluntarily submitted status, the Agency has categorized these data as high, medium or low burden and averaged the burden for these studies as if they represented a cross section of typical data requirements.

For the next ICR renewal period, EPA recognizes that some registrants will continue to submit voluntary data to support the activities for the completion of the reregistration review program as well as and the other review programs. EPA expects to receive 25 voluntary such submissions over the next three years; 16 of which are expected to be “low burden” submissions



and 9 of which are expected to be “high burden” submissions. Thus, EPA expects to receive about 8 voluntary submissions annually; 5.3 of which are expected to be “low burden” submissions and 3 of which are expected to be “high burden” submissions. For the details of the burden hours and costs see Table 2.A and Table 2. B.

**Table 2. A. Annual Respondent Burden for Submissions of Voluntary Low Burden Studies**

Total	117	389	90	596	\$41,252.57
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Estimated Total Annual Respondent Burden & Costs for DCIs Involving Voluntary Low Burden:

Burden: 596 hours x 5.3 responses = 3,159 hours

Costs: \$41,253 x 5.3 responses = \$218,640.90

**Table 2. B. Annual Respondent Burden for Submission of Voluntary High Burden Studies**

Collection Activities	Burden Hours			Total	
	Mgmt. \$103.62/hr	Tech. \$67.05/hr	Cler. \$33.85/hr	Hours	Costs
1. Read and discuss test requirements	72	0	0	72	\$7,460.64
2. Discuss test and protocol with Agency	36	36	0	72	\$6,144.12
3. Plan activities	144	36	0	180	\$17,339.40
4. Create information	108	1,791	215	2,114	\$145,833.03
5. Gather information	0	179	0	179	\$12,001.95
6. Process, compile, review information for accuracy	215	287	0	502	\$41,521.65
7. Complete written forms	0	0	72	72	\$2,437.20
8. Record, disclose, display information	72	0	144	216	\$12,335.04
9. Store, file, or maintain information	72	0	108	180	\$11,116.44
<b>Total</b>	<b>719</b>	<b>2,329</b>	<b>539</b>	<b>3,587</b>	<b>\$256,189.43</b>

Estimated Total Annual Respondent Burden for DCIs Involving Voluntary High Burden:

Burden: 3,587 hours x 3 responses = 9,565 hours

Costs: \$256,189 x 3 responses = \$768,567

### **6(a)(3). Paperwork Burden Related to the Submission of Product-Specific Data – Reregistration**

Product-specific data is generally comprised of toxicity and product chemistry data. In the past for DCIs involving *product-specific data* (sometimes referred to as PDCIs), EPA examined several typical reregistration cases with a typical number of batches and EPA's estimate of the number and type of PDCI studies required. EPA noted that while the number pesticide products captured by a RED for an active ingredient (and, therefore, the number of responses per PDCI associated with a RED) vary greatly from 1 to more than 100, the average number of responses per PDCI was three (3). It is a common industry practice where the manufacturer of the active ingredient and the companies that use that active ingredient in their products share their financial and scientific resources in order to provide EPA with a complete DCI response. This helps industry avoid a duplication of effort and thereby minimize the burden and cost impacts on each individual company.

The industry practice regarding the citation of data on similar products and the citation of existing data previously submitted to the Agency could also be the reason that the number of studies called in under the PDCI typically differs significantly from the number of new studies actually generated in response to the PDCI. For example, in 2004 the Agency evaluated a sampling of 95 pesticide product reviews (PDCIs) related to 5 randomly selected pesticide

chemicals to determine the number of new Acute Toxicity and Product Chemistry studies generated in response to a DCI. Based on this evaluation, it was determined that approximately 18% of the Acute Toxicity data requirements and approximately 10% of the Product Chemistry data requirements were newly generated data. Among the six Acute Toxicity requirements surveyed, (acute oral, acute dermal, acute inhalation, acute eye irritation, acute dermal irritation and dermal sensitization), the Acute eye irritation (870.2400), and Acute dermal irritation (870.2500) studies accounted for as much as 50% of the new data produced (in equal proportions). The other 50% of the new data is equally distributed between the remaining four study requirements. Among the ten Product Chemistry requirements surveyed, (Storage Stability (830.6317), Corrosion Characteristics (830.6320), Viscosity (830.7100) and the Analytical Methods (830.1800) guidelines accounted for approximately 90% of the new data produced (in equal proportions). The remaining 10% of the new data was equally distributed between the Flammability (830.6315), pH (830.7000), Density (830.7300), and various requirements for technical/pure active ingredients including Preliminary analysis (830.1700), Water solubility (830.7840 or 830.7860), and Vapor pressure (830.7950).

The Agency projects 49 PDCIs (16.33 annually) will be called-in over the next three years. This equates to about 28% of the 137 DCIs to be issued for this ICR renewal. The Agency will again predict each PDCI will generate about three (3) responses. Table 3 provides the detail for these burden activities.

**Table 3. Annual Respondent Burden Estimates for Product Specific DCI Activities**

Collection Activities	Burden Hours			Total	
	Mgmt. \$103.62/hr	Tech. \$67.05/hr	Cler. \$33.85/hr	Hours	Costs
1. Read and discuss test requirements	51	0	0	51	\$5,284.62
2. Discuss test and protocol with Agency	26	26	0	52	\$4,437.42
3. Plan activities	102	26	0	128	\$12,312.54
4. Create information	77	1,280	154	1,511	\$99,015.64
5. Gather information	0	128	0	128	\$8,582.40
6. Process, compile, review information for accuracy	154	204	0	358	\$29,635.68
7. Complete written forms	0	0	51	51	\$1,726.35
8. Record, disclose, display information	51	0	102	153	\$8,737.32
9. Store, file, or maintain information	51	0	77	128	\$7,891.07
<b>Total</b>	<b>512</b>	<b>1,664</b>	<b>384</b>	<b>2,560</b>	<b>\$177,623.04</b>

Estimated Total Annual Respondent Burden for Product Specific DCI Activities:

Burden: 2,560 hours x 3 responses per DCI x 16.33 DCIs = 125,414.40 hours.

Costs: \$177,623 x 3 responses per DCI x 16.33 DCIs = \$2,900,583.50

**6(b). Estimating Respondent Costs - Reregistration**

The total annual cost for all respondents is estimated to be \$5,789,404. Respondent costs are based on managerial, technical and clerical burden hours estimated at \$103.62, \$67.05, and \$33.85 per hour, respectively.

**6(c). Estimating Agency Burden and Cost - Reregistration**

The Agency’s **annual** burden hours and costs for developing DCI correspondence, communication with registrants, developing documents, tracking and storing the evaluation of the data submissions, and other DCI processing activities is detailed in Table 4 below. For this renewal, EPA projects a slight decrease in the burden hours and costs associated with the performance of the duties issuing and processing DCIs. The decrease is attributable to the reduction of the number of DCIs, from 142 to 137, the Agency plans to issue over the next three years.

**Table 4. Annual Agency Burden Estimates - Reregistration**

Collection Activities	Burden Hours			Total	
	Mgmt. \$101.16/hr	Tech. \$66.88/hr	Cler. \$39.23/hr	Hours	Costs
a. Develop DCI correspondence	948	9,480	948	11,376	\$766,915.97
b. Answer DCI questions from	119	4,740	0	4,859	\$329,049.24
c. Review, evaluate data submission	238	138,029	0	138,267	\$9,231,379.52
d. Record DCI submissions	0	0	1,896	1,896	\$74,380.08
e. Store data	0	0	238	238	\$9,336.74
<b>Total Annual Agency Burden</b>	<b>1,305</b>	<b>152,249</b>	<b>3,082</b>	<b>156,636</b>	<b>\$10,411,061.55</b>

**6(d). Bottom Line Hours and Cost Tables – Reregistration**

The total **annual** estimated burden hours and costs for the Reregistration review program for the next three years is represented in Table 5 below.

**Table 5. Annual Bottom Line Hours And Costs / Master Table**

Collection Activity	Burden Hours	Costs
DCI Involving Confirmatory Studies	27,213	\$1,883,612
Voluntary Low Burden Studies	3,159	\$218,641
Voluntary High Burden Studies	9,565	\$786,567
Product Specific DCIs	125,414	\$2,900,584
<b>Total Annual Respondent Burden and Costs</b>	<b>165,351</b>	<b>\$5,789,404</b>
<b>Total Annual Agency Burden</b>	<b>156,636</b>	<b>\$10,411,061.55</b>

**6(e). Reasons for Change in Burden - Reregistration**

In the ICR renewal, EPA projects a slight decrease in the estimated number of DCIs the Agency will issue annually, from 47.33 to 45.66, compared to the last ICR. Consequently, EPA expects that the associated burden will decrease because less DCI responses will be submitted to the Agency each year. Part of this reduction is also attributable to the reduction of DCI responses for product specific data, 16.33 instead of 30.33, as reported in the last ICR. However, EPA is projecting it will receive about the same number of voluntarily submitted data of 8 responses (5.3 low burden and 3 high burden) annually. EPA's estimate of the burden breakdown for each individual respondent for each labor category (management, technical and clerical) remains unchanged from the previous ICR. The overall adjustments in the burden for this ICR result in a net decrease hours annually from 275,063 to 165,351 which is directly related to the decrease in the number of DCIs to be issued. Part of the reduction in the estimated costs, for respondents and Agency personnel is attributable to EPA's methodology which re-estimated labor rates for industry and the Agency. The decrease is a program adjustment.

**6(f). Burden Statement - Reregistration**

The annual respondent burden for DCIs and voluntary data submissions under the Reregistration program is estimated to be 165,351, with a 3-year respondent burden of 496,053 hours.

**Part 2 – Section 6:**  
Estimating the Burden and Cost of the Collection  
for the Special Review and Registration Review Programs

**Part 2** describes the burden activities associated with the Special Review and Registration Review programs.

### **6(a) Estimating Respondent Burden – Special Review**

#### Special Review Program

Special Reviews, though rare, are conducted when the Agency determines such a review is warranted. In the Special Review Program, EPA focuses on specific hazards or uses of a pesticide. Special Reviews are not intended to be comprehensive evaluations of the pesticide, instead the DCIs are to address the specific hazard or exposure concerns that are at issue.

The total estimated annual respondent burden hours and costs for Special Review is estimated at 919 burden hours with the total annual respondent cost estimated at \$56,202.

The potential number of Special Review DCIs required, the type of data, and the number of respondents affected is quite variable. Thus, a Special Review DCI may request data on more than one pesticide, and may involve two or more respondents who are encouraged to join together to provide the needed data. The annual burden estimate is based on the following assumptions: (a) that the Agency would issue one DCI under the Special Review program in any given 12-month period, and (b) for each Special Review DCI issued there would be one response. The Agency has also assumed an average total test cost of \$500,000 per Special Review DCI.

Over a three-year ICR approval period, three responses would be expected and the total respondent burden for Special Review related activities is estimated to be 2,757 hours. This estimate remains unchanged from the previous ICR. Because of the variability inherent in each Special Review DCI, the estimates serve as a proxy for what the actual burdens are likely to be. Although the Agency estimated that an average of 1 respondent per Special Review DCI is expected because historically, a majority of the Special Review DCIs has only affected 1 or 2 respondents, on rare occasions, some previous Special Review DCIs have exceeded this. In recent years, the Agency has not issued one Special Review DCI each year over a three-year period. Table 1A details the estimated annual respondent burden hours and costs for Special Review DCIs



**Table 1A: Estimated Annual Burden hours and Cost Estimates for Special Review DCIs per Respondent**

COLLECTION ACTIVITIES	BURDEN HOURS (per year)			TOTALS	
	Mgmt. \$103.62/h r	Tech. \$67.05/ hr	Cler. \$33.85/ hr	Hrs	Cost
1) Read and discuss test requirements	18	0	0	18	\$1,865.16
2) Discuss test and protocol with Agency	9	9	0	18	\$1,536.03
3) Plan activities	0	0	0	0	\$0
4) Create information	37	9	0	46	\$4,437.39
5) Gather information	28	460	0	488	\$29,617.74
6) Process, compile, review information for accuracy	0	46	0	46	\$3,084.30
7) Complete written forms	55	74	55	184	\$12,522.55
8) Record, disclose, display information	0	0	18	18	\$609.30
9) Store, file, or maintain information	36	0	65	166	\$5,930.57
<b>TOTAL</b>	<b>183</b>	<b>598</b>	<b>138</b>	<b>919</b>	<b>\$56,201.85</b>

**Special Review** Estimated Annual Respondent Burden hours and Cost  
Hours: 919 hours per response X 1 response X 1 DCI= 919 hours  
Costs: \$56,202 per response X 1 response X 1 DCI= \$56,202

**6(a)(1) Estimating the Respondent Burden – Registration Review**

Registration Review

While the agency projected burden hours and cost of issuing DCI for the Registration Review program in the last ICR, no DCI could be issued until the final procedural rules for the registration review program were issued. The final rules were published August 9, 2006 (71 FR 45719) and became effective October 10, 2006. The first dockets for registration review cases

were opened in February 2007 and a majority of dockets opened to date have identified the need for additional data in order to complete the preliminary risk assessment. The Agency is actively developing the internal protocols necessary to issue DCIs under this program. Estimates include additional activities anticipated by the reauthorization of the Pesticide Registration Improvement Act amendments of October 9, 2007.

The total estimated **annual** burden hours for respondents to comply with this information collection activity is 65,374 hours with the total **annual** respondent cost estimated to be \$4,595,587.

During *Registration Review*, EPA will, among other things, update the databases of pesticides to obtain data that were not required when the pesticide was registered or reregistered, but which are now required and determined necessary. Like the *Special Review* program, the potential number of Registration review DCIs that will be issued, the type of data, and the number of respondents affected will be quite variable.

Over the next 3 years EPA expects to issue 121 DCIs (41 annually) for the Registration Review Program. The Agency assumes that one respondent “registrant” will provide the data requested. The Agency estimates one registrant will submit an average of 1.5 studies per DCI. A detailed illustration of the estimated annual respondent burden hours and costs is listed in Table 1B.

**Table 1B: Estimated Annual Respondent Burden Hours and Costs for Registration Review DCIs**

COLLECTION ACTIVITIES	BURDEN HOURS (per year)			TOTALS	
	Mgmt. \$103.62/hr	Tech. 67.05/hr	Cler. \$33.85/hr	Hrs	Cost
1) Read and discuss test requirements	22	0	0	22	\$2,279.64
2) Discuss test and protocol with Agency	11	11	0	22	\$1,877.37
3) Plan activities	44	11	0	55	\$5,296.83
4) Create information	33	544	33	610	\$41,011.71
5) Gather information	0	54	0	54	\$3,620.70
6) Process, compile, review information for accuracy	65	87	0	152	\$12,568.65
7) Complete written forms	0	0	22	22	\$744.70
8) Record, disclose, display information	22	0	44	66	\$3,769.04
9) Store, file, or maintain information	22	0	38	60	\$3,565.94
<b>TOTAL</b>	<b>219</b>	<b>707</b>	<b>137</b>	<b>1,063</b>	<b>\$74,724.58</b>

**Registration Review** Estimated Annual Respondent Burden Hours and Cost  
Hours: 1063 hours per response X 1.5 responses X 41 DCIs = 65,374.5 hours  
Costs: \$74,725 per response X 1.5 responses X 41 DCIs = \$4,595,587.5

**6(b). Estimating Respondent Costs - Special Review and Registration Review**

The estimated *annual* cost for all respondents for Special Review and Registration review is estimated to be \$3,418,827. Respondent costs are based on managerial, technical and clerical burden hours estimated at \$103.62, \$67.05, and \$33.85 per hour, respectively.

**6(c). Estimating Agency Burden and Cost - Special Review Registration Review**

**Special Review – Agency Burden**

In this ICR, the estimated average number of Agency burden hours per response for Special Review is the same as in the previous ICR; i.e., 1,348 hours. Over a three-year ICR approval period, 3 responses are expected and the total Agency burden hour and cost is estimated at 4,044 (1,348 x 3) hours. See Table 2A for the detail of the Agency burden hours and costs for processing Special Reviews.

**Table 2A: Estimated Annual Agency Burden and hours Cost for Special Review DCIs**

Collection Activities	Burden Hours			Total	
	Mgmt. \$101.16/hr	Tech. \$66.88/hr	Cler. \$39.23/hr	Hours	Cost
Develop DCI correspondence needed	32	160	60	252	\$16,291.72
Answer registrants' questions regarding the DCI	4	160	0	164	\$11,105.44
Review and analyze data submissions	4	880	0	884	\$59,259.04
Record DCI submissions	0	0	40	40	\$1,569.20
Store Data	0	0	8	8	\$313.40
<b>TOTAL</b>	<b>40</b>	<b>1,200</b>	<b>108</b>	<b>1,348</b>	<b>\$88,539.24</b>

Hours: 1348 per response X 1.5 responses X 1 DCIs = 2,022 Hours  
 Costs: \$88,539 per response X 1.5 responses X 1 DCIs = \$132,808.5

**Registration Review – Agency Burden**

The annual estimated Agency burden hours and costs for Registration Review are illustrated in Table 2B below.

**Table 2B: Estimated Annual Agency Burden Hours and Costs for Registration Review DCIs**

Collection Activities	Burden Hours			Total	
	Mgmt. \$101.16/hr	Tech. \$66.88/hr	Cler. \$39.23/hr	Hours	Cost
Develop DCI correspondence needed	64	320	120	504	\$32,583.94
Answer registrants' questions regarding the DCI	4	160	0	164	\$11,105.44
Review and analyze data submissions	4	0	0	4	\$404.64
Record DCI submissions	0	0	80	80	\$3,138.40
Store Data	0	0	8	8	\$265.84
<b>TOTAL</b>	72	480	208	760	\$47,497.76

**Registration Review** Estimated Agency Annual Burden Hours and Costs

Hours: 760 per response x 1.5 responses x 41 DCIs = 46,740 hours

Costs: \$47,498 per response x 1.5 responses x 41 DCIs = \$2,921,127

**6(d). Bottom Line Burden Hours and Cost Tables/ Master Table for Special Review and Registration Review**

The estimated total and annual Respondent burden hours and costs are illustrated in Table 3, while the estimated total and annual Agency burden hours and costs are illustrated in Table 4.

**Table 3: Bottom Line Respondent Burden Hours and Costs/ Master Table**

	Per Response		Number of Responses	Totals	
	Hours	Cost		Hours	Cost
<b>Special Review</b>	919	\$56,202	1	919	\$56,202
<b>Registration Review</b>	1,063	\$74,725	61	65,374	\$4,595,587
<b>TOTAL ANNUAL BURDEN</b>	1,982	\$130,937	62	66,293	\$4,651,789

<b>TOTAL 3 YEAR BURDEN</b>	5,946	\$392,811	186	198,879	\$13,955,367
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**Table 4: Bottom Line Agency Burden Hours and Costs/Master Table**

	Per Response		Number of Responses	Totals	
	Hours	Costs		Hours	Cost
<b>Special Review</b>	1,348	\$88,539	1	1,348	\$88,539
<b>Registration Review</b>	760	\$47,498	61	47,740	\$2,921,127
<b>TOTAL ANNUAL BURDEN</b>	2,108	\$136,037	62	49,088	\$3,009,666
<b>TOTAL 3 YEAR BURDEN</b>	6,324	\$416,340	186	140,844	\$9,028,998

**6(e). Reasons for Change in Burden - Special Review and Registration Review**

This ICR renewal request will result in a slight increase in the annual respondent burden of 675 hours, i.e., from 64,699 to 65,374 hours, when compared with the previous ICR. Most of the burden increase can be attributed to the increase in the number of DCIs (41 DCIs verses 40 DCIs) to be issued under the Registration review program that is now underway. This is a program adjustment.

**6(f). Burden Statement - Special Review and Registration Review**

The annual respondent burden for the information collection activities under this ICR is estimated to average 919 hours for Special Review DCIs and 65,374 hours for Registration Review DCIs.

**Part 3 – Section 6**  
Estimating the Burden and Cost of the Collection for  
the Anticipated Residue and Percent Crop Treated Review Programs

**Part 3** describes the burden activities associated with the Anticipated Residue and Percent Crop Treated (AR/PCT) review programs. The AR/PCT review program requires the Agency to re-evaluate of previous Agency decisions regarding the establishment of a tolerance (maximum residue limit) for pesticide residues on food or feed crops. The law also requires that tolerance decisions based on ARs or PCT data be verified to ensure that residues in or on food are not above the residue levels relied on for establishing the tolerance.

#### **6(a) Estimating Respondent Burden - AR/PCT**

The annual respondent range between 59 and 13,636 burden hours per DCI, depending upon the type of DCI response requested. The total estimated burden for this ICR of 28,569 burden hours is based on the Agency's estimate of the potential burden and number of responses for each of the following four types of potential DCIs:

- Type 1- DCI for anticipated residues requiring a base set of data (13,636 hrs./response);
- Type 2- DCI for anticipated residues requiring minimum data (69 hrs./response);
- Type 3- DCI for anticipated residues collected from publicly available sources (137 hrs./response); and
- Type 4- DCI for percent crop treated using existing information (59 hrs./hrs response).

After re-evaluation the burden hours from the last ICR, the Agency is not changing the burden hour estimates from the last ICR renewal period. The following information presents the Agency's burden estimates for each type of DCI.

#### **AR DCI Type 1 - DCI for anticipated residues requiring a base set of data:**

Respondent burden hours for generating and submitting data in response to a DCI for anticipated residues requiring a base set of data to be submitted are estimated at 13,636 burden hours per response. And one response equals one DCI. EPA also considered the typical burden for reading instructions, planning activities, compiling and reviewing the submission, submitting the data to EPA, and related record keeping in estimating the total per response burden and costs. Using the USDA's Pesticide Data Program (PDP) which generates publicly available monitoring data as the basis, EPA estimated the burden for conducting a monitoring study to gather the necessary data. Portions of the annual respondent burden hours and cost are related to generation of new data for meeting 40 CFR part 158 data requirements for anticipated residues.

In most cases, registrants will be able to get the information from federal and state monitoring programs, thus EPA estimates that no more than two registrants might generate their own monitoring data in response to the DCI. The total annual burden hours for a Type -1 AR DCI is estimated to be 27,272 hours, The Agency projects only two (2) Type 1 AR DCIs will be issued generating one response per DCI.



**TABLE 1****Type 1 AR DCI- Annual Respondent Burden/Cost Estimates for Anticipated Residues Generating Anticipated Residue Data**

ACTIVITIES	BURDEN HOURS (per year)			TOTAL	
	Mgmt. \$103.62	Tech. \$67.05	Cler. \$33.85	Hours	Costs
1) Read instructions	2	0	0	2	207.24
2) Plan activities	4	0	0	4	414.48
3) Create information	0	13,600	0	13,600	911,880.00
4) Gather information	0	16	0	16	1,072.80
5) Compile and review	1	8	0	9	640.02
6) Complete paperwork	2	0	2	4	275.01
7) Maintain and file	0	0	1	1	33.85
<b>TOTAL</b>	<b>9</b>	<b>13,624</b>	<b>3</b>	<b>13,636</b>	<b>\$914,443.40</b>

**Type I AR DCI** Burden: 13,636 per response x 1 response x 2 DCIs = 27,272 hours  
Costs: \$914,443 per response x 1 response x 2 DCIs = \$1,828,886

**Type 2 AR DCI - DCI for anticipated residues verification use information data:**

Minimum data captures the burden for cases in which the respondent verifies that nothing has changed; i.e., the formulation, use rate, geographic distribution of use, etc. have not changed since the ARs were used to establish or reassess the tolerance. The EPA estimates that this verification for updating use information is estimated at 69 burden hours per response. EPA estimates that no more than 10 respondents each year will comply with a DCI by submitting a base set of data for updating use information. As such, the total respondent burden hours per year are estimated at 690 hours. See Table 2.

**TABLE 2****Type 2 AR DCI - Annual Respondent Burden/Cost Estimates for Anticipated Residues Requiring Minimum Data for Verifying Use Information**

Collection Activities	Burden Hours (per year)			Total	
	Mgmt. \$103.62	Tech. \$67.05	Cler. \$ 33.85	Hours	Costs
1) Read Instructions	8	0	0	8	828.96
2) Plan Activities	16	0	0	16	1657.92
3) Create Information	0	0	0	0	0
4) Gather Information	0	16	0	16	1072.80
5) Compile and Review	2	16	0	18	1280.04
6) Complete Paperwork	2	0	8	10	470.04
7) Submit and File	0	0	1	1	33.85
<b>Total</b>	<b>28</b>	<b>32</b>	<b>9</b>	<b>69</b>	<b>\$5,293.61</b>

**Type 2 AR DCI** Burden: 69 per response x 10 responses x 1 DCI = 690 hours  
 Cost: \$5,294 per response x 10 responses x 1 DCI = \$52,940.

**Type 3 AR DCI** - DCI for anticipated residues collected from publicly available sources:

The average respondent burden for submitting a base set of data for updating monitoring information is estimated at 137 burden hours per year. EPA estimates that an average of 4 respondents each year is likely to be able to comply with a DCI by submitting data from publicly available sources. As such, the total annual respondent burden for this type of DCI is estimated to be 548 burden hours. See Table 3.

**TABLE 3****Type 3 AR DCI: Annual Respondent Burden/Cost Estimates for Anticipated Residues Collected from Publicly Available Sources**

Collection Activities	Burden Hours (per year)			Total	
	Mgmt. \$103.62	Tech. \$67.05	Cler. \$33.85	Hours	Costs
1) Read Instructions	8	0	0	8	828.96
2) Plan Activities	16	0	0	16	1,657.96
3) Create Information	0	0	0	0	0
4) Gather Information	0	60	0	60	4,023.00
5) Compile and Review	2	40	0	42	2889.24
6) Complete Paperwork	2	0	8	10	478.04
7) Submit and File	0	0	1	1	33.85
<b>Total</b>	<b>28</b>	<b>100</b>	<b>9</b>	<b>137</b>	<b>9,911.05</b>

**Type 3 AR DCI** Burden: 137 per response x 4 responses x 1 DCI = 548 hours.

Cost: \$9,911 per response x 4 responses x 1 DCI = \$39,644

**Type 4 PCT DCI - DCI for percent crop treated using existing information:**

The annual per respondent burden for generating percent crop treated estimates using existing information is estimated to be 59 burden hours. Percent crop treated estimates are generally conducted within the Agency, and only in rare instances would a registrant need to gather the information; one DCI per year impacting one respondent is probably an overestimation. The estimated costs assume that cost of purchasing or obtaining percent crop treated information derived from existing, contracted data sources. See Table 4.

**TABLE 4****Type 4 PCT DCI - Annual Respondent Burden/Cost Estimates for Percent Crop Treated Using Existing Information**

Activities	Burden Hours (per year)			Total	
	Mgmt. \$103.62	Tech. \$67.05	Cler. \$33.85	Hours	Costs
1) Read Instructions	1	1	0	2	170.67
2) Plan Activities	0	2	0	2	134.1
3) Create Information	0	8	0	8	536.4
4) Gather Information	0	22	0	22	1475.1
5) Compile and Review	1	20	0	21	1444.62
6) Complete Paperwork	1	0	2	3	171.32
7) Submit and File	0	0	1	1	33.85
<b>Total</b>	<b>3</b>	<b>53</b>	<b>3</b>	<b>59</b>	<b>\$3,966.06</b>

**Type 4 PCT DCI -** Burden: 59 hours per response x 1 response x 1 DCI= 59 hours

Cost: \$3,966 per response x 1 response x 1 DCI = \$3,966

**6(b) Estimating Respondent Costs - AR/PCT DCIs**

The total annual cost for all respondents of AR and PCT DCIs is estimated to be \$1,925,436. Respondent costs are based on managerial, technical and clerical burden hours estimated at \$103.62, \$67.05, and \$33.85 per hour, respectively.

**6(c) Estimating Agency Burden and Costs – AR/PCT**

The Agency's *annual* burden hours and costs for developing DCI correspondence, communication with registrants, developing documents, tracking and storing the evaluation of the data submissions, and other DCI processing activities is detailed in Table 5 and Table 6 below. For this renewal, EPA projects the same number of burden hours associated with the performance of the duties issuing and processing AR DCIs as was projected in the last ICR. Thus, like the last ICR, this renewal will project the Agency will process 4 AR DCIs and 1 PCT DCI annually.

**TABLE 5****Annual Estimated Agency Burden Hour and Cost For Processing AR DCIs Types 1-3**

Collection Activities	Burden Hours (per year)			Total	
	Mgmt. \$101.16	Tech. \$66.88	Cler. \$39.23	Hours	Costs
Develop DCI notice	1	0	2	3	179.62
Answer Registrants' questions	0	4	5	9	463.67
IN-process data submissions	0	0	4	4	156.92
Analyze data	1	80	0	81	5451.56
Record and store DCI data	0	0	2	2	78.46
<b>Total</b>	<b>2</b>	<b>84</b>	<b>13</b>	<b>99</b>	<b>\$6,330.23</b>

**AR DCIs Types 1-3**

Annual Estimated Agency Burden: 99 hours x 16 responses = 1,584 hrs

Annual Estimated Agency Cost: \$6,330 x 16 responses = \$101,280.

**TABLE 6****Annual Estimated Agency Burden Hours and Costs for Processing Type 4 - PCT DCIs**

Collection Activities	Burden Hours (per year)			Total	
	Mgmt. \$101.16	Tech. \$66.88	Cler. \$39.23	Hours	Costs
Develop DCI notice	1	0	2	3	140.39
Answer Registrants' questions	0	4	5	9	463.67
IN-process data submissions	0	0	4	4	156.92
Analyze data	1	40	0	41	2776.36
Record and store DCI data	0	0	2	2	78.46
<b>Total</b>	<b>2</b>	<b>44</b>	<b>13</b>	<b>59</b>	<b>\$3615.80</b>

**Type 4 PCT DCIs - Estimated Annual Agency Burden Activities**

Hours: 59 hours x 1 response = 59 hours

Costs: \$3,616 x 1 response = \$3,616

**6(d) Bottom Line Burden Hours and Cost Table**

The total estimated annual respondent burden is 28,569 burden hours (28,509 burden hours for all AR DCI submissions + 59 burden hours for PCT DCI submissions), with an associated cost of \$1,925,436 (\$1,921,471 for all AR DCI submissions + \$3,965 for PCT DCI submissions) see table below.

The total estimated annual Agency burden is 1,643 burden hours (1,584 burden hours for all AR DCI submissions + 59 burden hours for PCT DCI submissions), with an associated cost of \$104,896 (\$101,280 for all AR DCI submissions + \$3,616 for PCT DCI submissions). See Table 7 below.

**Table 7. Annual Bottom Line Hours and Costs/Master Table**

	Key Activities	Hours	Costs
Respondents	Type 1- DCI: generating anticipated residue data.	27,272	\$1,828,886
	Type 2- DCI for submitting minimal verification of use information	690	\$52,940
	Type 3- submitting anticipated residue data from publicly available sources	548	\$39,644
	Type 4- submitting percent crop treated data using existing information.	59	\$3,966
Total estimated respondent burden/costs.		28,569	\$1,926,436
Agency	Type 1-3 AR DCIs for managing anticipated residue DCI's	1,584	101,280
	Type -4 PCT DCIs for managing percent crop treated DCI's.	59	\$3,616
Total Agency burden/costs.		1,643	\$104,896

**6(e) Reasons for Change in Burden - AR/PCT**

For this ICR renewal the annual estimated respondent burden hours are 28,569 hours at a cost of \$1,925,436. There is no increase in the burden hours over the last ICR renewal. However, the costs have decreased slightly due to the adjustment attributable to EPA's re-estimation of labor rates for industry and the Agency. This is a program adjustment.

**6(f) Burden Statement - AR/PCT**

The estimated total respondent burden for this ICR over the next three years is 85,707 hours with the annual burden hours ranging from 59 hours to 13,636 hours per response, depending on the type of DCI.

**Part 4 - Section 6:**  
Estimating the Burden and Cost of the Collection for the Enforcement and Unanticipated Incidents

**Part 4** describes the burden activities associated with the Enforcement and Unanticipated Incident DCI activities.

#### **6(a) Estimating Respondent Burden – Enforcement and Unanticipated Incident**

The total estimated annual respondent burden hours and costs for Enforcement and Unanticipated Incident DCI is estimated at 6,266 burden hours for the life of the ICR.

The potential number of DCIs required, the type of data, and the number of respondents potentially affected is quite variable. Thus, a this type of DCI may request data on more than one pesticide, and may involve two or more respondents who are encouraged to join together to provide the needed data. The variability inherent in this type of DCI means the estimates serve only as a proxy for what the actual burdens are likely to be. The annual burden estimate is based on the following assumptions: (a) that the Agency would issue only one DCI for this type of activity and only once during the life cycle of the ICR and (b) for the DCI issued there would be one response. The Agency has also assumed an average total test cost of \$500,000 per Enforcement and Unanticipated Incident DCI.

Historically, there is very little information documenting the need for this type of DCI but such events have occurred. For example one of the worst cases occurred in 1976 when the Food and Drug Administration (FDA) conducting a routine inspection uncovered deficiencies in the manner in which studies were being conducted at Industrial Biotech Laboratories, Inc., (IBT) one of the largest independent laboratories in the U.S. at the time. By 1978 EPA and FDA were conducting joint audits of two other IBT facilities and uncovered similar problems and the case had been referred to the Department of Justice. This turned out to be a massive undertaking. Of the 1205 IBT studies identified by EPA, 801 studies, or approximately 66%, were considered significant to regulatory decisions such as the induction of tumors, birth defects, genetic mutations, neurotoxicity and other chronic reproductive effects. Of the 801 studies considered significant to regulatory decisions, 594 were found to be invalid by EPA and Canada. By 1983, EPA warned pesticide product registrants that products supported by invalid health effects studies conducted by IBT faced suspension action unless replaced by other tests or a commitment to further testing. (*EPA Releases Report on IBT Lab Studies; Warns of Suspension Action*, Environmental News EPA Press Release, Monday July 11, 1983) (see also House of Representatives, Committee on Agriculture, Washington, DC, Improving Data- Pesticide Decisions, July 27 1983; Statement of Edwin Johnson, Director, Office of Pesticide Programs, Environmental Protection Agency)

The estimate of respondent burden hours per response for Enforcement and Unanticipated Incident Activities is 6,266 hours and is based on the same burden hour break down projected in the 2001 ICR OMB 2070-0122; EPA No. 1503.04 which the Agency allowed to expire 12/31/04. The estimated Agency burden hours is based on Agency estimates similar to the burdens projected for the special review program, 1348 burden hours. While the Agency does not anticipate using any of these burden hours, the Agency will project a one time burden estimate for the three year life cycle of ICR. Table 1 lists the potential respondent burden hours



and costs and Table 2 lists the potential Agency burden hours and costs and Table 3, lists the potential three year bottom line totals for Enforcement and Unanticipated Incident Activities.

**6(b). Estimating Respondent Costs - Enforcement Unanticipated Incident Activities**

The estimated *three year* cost for all respondents for Enforcement Unanticipated Incident Activities is estimated to be \$420,291. Respondent costs are based on managerial, technical and clerical burden hours estimated at \$103.62, \$67.05, and \$33.85 per hour, respectively.

**TABLE 1. TOTAL RESPONDENT BURDEN/COST ESTIMATES**  
Enforcement and Unanticipated Incident DCI

Burden Hours (per year)				Totals	
Collection Activities	Mgmt. \$103.62	Tech. \$67.05	Cler. \$33.85	Hours	Costs
1)Read Instructions	2	0	0	2	207.24
2)Plan Activities	2	0	0	2	207.24
3)Create Information	0	6,249	0	6,249	418,6995.45
4)Gather Information	0	3	0	3	201.15
5)Compile and Review	1	4	0	5	371.82
6)Complete Paperwork	2	0	2	4	274.94
7)Submit and File	0	0	1	1	33.85
<b>Total</b>	7	6,256	3	6,266	420,291.69

TOTAL BURDEN HOURS: 6,266 hours x 1 response = 6,266 hours

TOTAL BURDEN COSTS: \$420,291 x 1 response = \$420,291

**6(c). Estimating Agency Burden and Cost - Enforcement Unanticipated Incident Activities**

**TABLE 2: TOTAL AGENCY BURDEN AND HOURS COST**  
Enforcement And Unanticipated Incident DCI

Collection Activities	Burden Hours			Total	
	Mgmt. \$101.16/hr	Tech. \$66.88/hr	Cler. \$39.23/hr	Hours	Cost
Develop DCI correspondence needed	32	160	60	252	16,291.72
Answer registrants' questions regarding the DCI	4	160	0	164	11,105.44
Review and analyze data submissions	4	880	0	884	59,259.04
Record DCI submissions	0	0	40	40	1569.20
Store Data	0	0	8	8	313.84
<b>TOTAL</b>	<b>40</b>	<b>1,200</b>	<b>108</b>	<b>1,348</b>	<b>88,539.24</b>

Hours: 1348 per response X 1 responses X 1 DCI = 1348 Hours  
Costs: \$88,539 per response X 1 responses X 1 DCI = \$88,539

**6(d). Bottom Line Burden Hours and Cost Tables/ Master Table for Enforcement and Unanticipated Incident DCI**

**Table 3: Bottom Line Burden Hours and Costs/ Master Table**

Enforcement and Unanticipated Incidents			Number of Responses
	Hours	Cost	
<b>Respondents</b>	6,266	\$420,291	1
<b>Agency</b>	1348	\$88,539	1

**6(e). Reasons for Change in Burden - Enforcement and Unanticipated Incident DCIs**

This new ICR burden will result in a increase in the total estimated respondent burden of 6,266 hours for the three year life cycle of this ICR (or 2,088 burden hours annually). This is a new program activity.

**6(f). Burden Statement - Enforcement and Unanticipated Incident DCIs**

The total respondent burden for the information collection activities for the three year life cycle of this ICR is estimated to average 6,266 burden hours for Enforcement and Unanticipated Incident activities. The annualized burden for a single DCI is 2,088 hours.

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 regulations, planning the necessary data collection activities, conducting tests, analyzing data, generating reports and completing other required paperwork, and storing, filing, and maintaining the data. The 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. The OMB control number for this information collection appears at the beginning and the end of this document. In addition OMB control numbers for EPA’s regulations, after initial display in the final rule, are listed in 40 CFR part 9.

The Agency has established a public docket for this ICR under Docket ID No. **EPA-HQ-OPP-2007-0923**, which is available for online viewing at [www.regulations.gov](http://www.regulations.gov), or in person viewing at the OPP Regulatory Public Docket in Rm. S-4400, One Potomac Yard (South Building), 2777 S. Crystal Drive, Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305-5805. You may submit comments regarding 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.

Comments may be submitted to EPA electronically through <http://www.regulations.gov> or by mail addressed to Director, Collection Strategies Division, U.S. Environmental Protection Agency (2822T), 1200 Pennsylvania Ave., NW, Washington, D.C. 20460. 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. Include docket ID No. **EPA-HQ-OPP-2007-0923** and OMB control numbers 2070-0057; 2070-0107; and 2070-0164 in any correspondence but do not submit any DCI or other related information (e.g., forms, reports, etc.) to these addresses.

## ATTACHMENTS TO THE SUPPORTING STATEMENT

Attachments to the supporting statement are available in the public docket established for this ICR under docket identification number **EPA-HQ-OPP-2007-0923**. These attachments are available for online viewing at [www.regulations.gov](http://www.regulations.gov) or otherwise accessed as described in this section 6(f) of the supporting statement.

- Attachment A:** 7 U.S.C. 136a-1 - **Section 4 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)**. Also available at online at the US House of Representatives' [US Code website](#)
- Attachment B:** 7 U.S.C. 136a – **Section 3 of FIFRA**. Also available at online at the US House of Representatives' [US Code website](#)
- Attachment C:** 71 FR 45719 – **Pesticides; Procedural for Regulations for Registration Review; Final Rule**. Also available online at <http://edocket.access.gpo.gov/2006/pdf/E6-12904.pdf>
- Attachment D:** 21 U.S.C. 346a – **Section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA)**. Also available at online at the US House of Representatives' [US Code website](#)
- Attachment E:** **Public comment received from William M. Mahlburg, Director, Government Affairs, Nufarm, Americas, Inc.**
- E-1:* Consultation questions and comment received from Rebeckah Freeman Adcock, Director, Congressional Relations, American Farm Bureau
  - E-2:* Consultation questions for Ray McAlister, Vice President Science and Regulatory Affairs, CropLife America
  - E-3:* Consultation questions for Susan Little, Executive Director, Consumer Specialty Products Association
  - E-4:* Consultation questions for Daniel Botts, Director, FFDA's Environmental & Pest Management Division, Minor Crop Farmer Alliance Technical Committee (Chairman), Florida Fruit & Vegetable Association
- Attachment F:** **Forms that are commonly associated with Data Call-ins** – available electronically as a PDF file on the internet at <http://www.epa.gov/opprd001/forms/> except as otherwise noted.
- EPA Form No. 8570-4* - Confidential Statement of Formula
  - EPA Form No. 8570-27* - Formulator's Exemption Statement
  - EPA Form No. 8570-28* - Certification of Compliance with Data Gap Procedures
  - EPA Form No. 8570-32* - Certification of Attempt to Enter into an Agreement with Registrants for Development of Data Form
  - EPA Form No. 8570-34* - Certification with Respect to Citation of Data Form
  - EPA Form No. 8570-35* - Data Matrix Form
  - EPA Form No. 8570-36* - Summary of the Physical/Chemical Properties Form
  - EPA Form No. 8570-37* - Self-Certification Statement for the

Physical/Chemical Properties

*EPA Form No. 6300-3* - Requirements Status and Registrant's Response. This form is computer generated and uniquely pre-populated and sent directly to individual registrants. Blank copies of this form may otherwise only be accessed via the docket for this ICR as described above using the docket identifier EPA-HQ-OPP-2007-0923-0003.

*EPA Form No. 6300-4* - Data Call-In Response Form. This form is computer generated and uniquely pre-populated and sent directly to individual registrants. Blank copies of this form may otherwise only be accessed via the docket for this ICR as described above using the docket identifier EPA-HQ-OPP-2007-0923-0003.

**Attachment G: General Methodology Used to Estimate Paperwork Burden Hours and Costs by the Office of Pesticide Programs for Submission of Required Data/Information for Responding to a Data Call-In Notice.**

**Attachment H: Work Sheets to Calculate Industry and EPA Labor Costs**