SUPPORTING STATEMENT
FOR AN INFORMATION COLLECTION REQUEST (ICR)

1. IDENTIFICATION OF THE INFORMATION COLLECTION

1(a) Title of the Information Collection

TITLE: Application for New and Amended Pesticide Registration

OMB No. 2070-0060 EPA No. 0277.16

1(b) Short Characterization/Abstract

This data collection program is designed to provide the Environmental Protection Agency (EPA) with necessary data to evaluate an application of a pesticide product as required under Section 3 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act (FQPA) of August 3, 1996 (see Attachment A). Under FIFRA, EPA must evaluate pesticides thoroughly before they can be marketed and used in the United States to ensure that they will not pose unreasonable adverse effects to human health and the environment. Pesticides that meet this test are granted a license or "registration" which permits their distribution, sale and use according to requirements set by EPA to protect human health and the environment.

In evaluating a pesticide registration application, EPA assesses a wide variety of potential human health and environmental effects associated with use of the product. The producer of the pesticide must provide data from tests done according to EPA guidelines or other test methods that provide acceptable data. These tests must determine whether a pesticide has the potential to cause adverse effects on humans, wildlife, fish and plants, including endangered species and non-target organisms, as well as possible contamination of surface water or groundwater from leaching, runoff and spray drift. Potential human risks include short-term toxicity and long-term effects such as cancer and reproductive system disorders. EPA also must approve the language that appears on each pesticide label. A pesticide product can only be used according to the directions on the labeling accompanying it at the time of sale, through its use and disposal. Following labeling instructions carefully and precisely is necessary to ensure safe use.

An individual or entity wanting to obtain a registration for a pesticide product must submit an application package consisting of information relating to the identity and composition of the product, proposed labeling, and supporting data (or compensation for others' data) for the product, as outlined in 40 CFR part 158. The EPA bases registration decisions for pesticides on its evaluation of a battery of test data provided primarily by applicants for registration. Required studies include testing to show whether a pesticide has the potential to cause unreasonable adverse human health or environmental effects. The Agency currently collects data on physical chemistry, toxicology, environmental fate, ecological effects, worker exposure, residue chemistry, environmental chemistry, and product performance. All or part of this information may be required depending on use and type of product. If EPA's evaluation of the data shows that the statutory requirements of FIFRA are met, a registration is approved.

Registrants of EPA-registered pesticide products at times become subject to regulations or guidance that includes labeling revisions. The revised labeling is submitted as an amendment to the

Agency along with the completed application form (EPA Form 8570-1 and other forms as needed, see Attachment B). Generally, data are not required for revised labeling regulations or guidance; however, EPA must review and approve the revised labeling. This review is most often accomplished by a Product Manager, or Team Leader, in one of the three regulatory divisions within EPA's Office of Pesticide Programs (OPP) responsible for pesticide registration: the Registration Division, the Antimicrobial Division, and the Biopesticides and Pollution Prevention Division. These divisions ensure that revisions comply with the applicable labeling requirement or guidance.

The Agency has added to its basic registration information collection of additional information from registrants. This allows the implementation of the Reduced-Risk Initiative (PR Notice 97-3, "Guidelines for Expedited Review of Conventional Pesticides under Reduced-Risk Initiative and for Biological Pesticides;" see Attachment C). The guidance in this notice is intended to give expedited review timeframes to those pesticide products that can be expected to accomplish one or more of the following:

(1) Reduce the risks of pesticides to human health.

(2) Reduce the risks of pesticides to nontarget organisms.

(3) Reduce the potential for contamination of groundwater, surface water, or other valued environmental resources.

(4) Broaden the adoption of integrated pest management strategies, or make such strategies more available or more effective.

Applicants for the registration of such products are invited to provide an explanation accompanied by any supporting information on their application with any associated tolerance petitions for special consideration based on these factors. Products that are successfully classified as presenting the potential to reduce risk will receive earlier registration and consequent earlier marketability.

2. NEED FOR AND USE OF THE COLLECTION

2(a) Need/Authority for the Collection

Authorizing legislation is contained in Section 3 of FIFRA, as amended. Governing regulations and guidelines are contained in 40 CFR parts 152, 156, 158 (attachments D, E, and F, respectively), and in PR Notice (PRN) 97-3. Label amendments, 40 CFR 156, may be required to maintain continued registration following a regulatory review (e.g., registration review). Labeling amendments pertaining to groups of products may be implemented through Pesticide Registration Notices (PRN) or Federal Register Notices (FRN).

2(b) Practical Utility/Users of the Data

The information collected under this ICR is used to support registration decisions for new or amended pesticides. Once all data reviews are completed satisfactorily, the labeling is determined to be adequate, and the product is determined to meet the statutory standards of FIFRA, registration is issued to the applicant.

3. NON-DUPLICATION, CONSULTATIONS, AND OTHER COLLECTION CRITERIA

3(a) Non-duplication

Duplication will not occur in this program, as each applicant must submit information unique to the particular product being offered for registration. If the product is not unique, existing data may be referenced by the applicant as described in item 5(c) below. On amended applications, the applicant is able to refer to any information previously submitted, thereby satisfying data requirements without the burden of providing duplicate information or additional data development.

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

In proposing to renew this ICR, EPA provided a 60-day public notice and comment period that ended on February 13, 2012 (76 FR 77817, December 14, 2011). The materials related to the proposed renewal of this ICR, as well as comments submitted during the public comment period may be accessed as described in section 6(f) of this supporting statement.

EPA received three comments during the comment period, all of which asked to extend the comment period for review of the draft ICR. A response to the three comments was placed in the docket, stating that an extension could not be granted, as the ICRs would expire. The commenters had further generally stated that EPA's estimates of cost and burden were low compared to their experience, however none of the commenters provided any specific information to EPA for review and analysis in consideration of these estimates. EPA did review its burden estimate, based on actual tracking at 2011 year-end, and revised burden estimates to reflect best possible data on the number of responses. This resulted in an upward change in the estimated number of responses, which led to an overall increase in burden estimate, reflected in this supporting statement, rather than a decrease in burden statement that was originally estimated. That increase is an adjustment.

3(c) Consultations

Under 5 CFR 1320.8(d)(1), agencies are required to consult with potential ICR respondents and data users about specific aspects of ICRs before submitting an original or renewal ICR to OMB for review and approval. In accordance with this regulation, EPA pursued additional consultations with interested parties during the development of the renewal of this collection. Consultation questionnaires were sent to the following stakeholders:

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Biopesticide Industry Alliance
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McFarland, WI 53558-0465
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Dr. Ray S. McAllister, Director, Regulatory Affairs
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One stakeholder responded. (See Attachment H for a copy of the stakeholder's response, and Attachment G for a sample copy of the ICR questionnaire provided to industry representatives.) The respondent indicated that increased ability to submit data and applications electronically would reduce burden, save cost, and improve the overall application process. While some electronic submission is already permitted (see section 3(e) General Guidelines, subtitle Electronic Submissions of this supporting statement), EPA acknowledges that additional opportunities for electronic submission, including secure transmission of Confidential Business Information, would be more efficient for registrants and the Agency. In addition, the Agency recognizes that e-submission forms that facilitate application to regulatory agencies in other countries, such as aligning with Canada's Pest Management Regulatory Agency (PMRA), facilitate registrants' abilities to meet registration requirements. For example, EPA is currently developing as the Confidential Statement of Formula e-form that could also be used to satisfy PMRA requirement. While not available for this renewal, EPA will continue to explore ways to increase availability of electronic submissions and will amend this ICR to create electronic forms as possible.

The stakeholder also commented that while the 194 hours estimate for a registration application seemed correct, the split between management and technical time may be different for the area of "compile and review;" however, given the generally used 2-to-1 ratio of technical to management, and the commenter's statement that management may spend 30-40 hours on "compile and review," the Agency was unable to reconcile the numbers and stay within the 194 hours estimate. The Agency also believes that 30-40 hours of management time to "compile and review" is an overestimate. The Agency believes that since the overall burden estimate is considered correct by the one commenter, the mix between technical and management is likely also correct and would not make a significant difference if we were to reallocate within the table.

Finally, the commenter pointed out that wage rates did not reflect the going rates for technical consultants. EPA reviewed the rates for technical consultants with the Bureau of Labor Statistics (BLS) data, which is consistently used by EPA to estimate burden cost in ICRs. The hourly rate of $60.85 for technical and $120.28 for management is an average and is consistent with BLS data.

3(d) Effects of Less Frequent Collection

Not applicable. The Section 3 information collection activity is initiated by applicants for registration. Information is submitted in conjunction with the application. There is no set means by which the EPA can reduce the frequency. If the information were not submitted, EPA would be unable to fulfill its statutory responsibilities relative to the review and registration of pesticides and protection of human health and the environment.

3(e) General Guidelines

Pesticide label In accordance with a determination made by the Office of Management and Budget (OMB) in 1995, the third party disclosure requirement involving the registrant's disclosure of product specific information to potential users and the general public through the pesticide label, is not a

collection of information because the information that must be included as the product labeling has been approved and provided to the registrant by EPA as part of the original registration (5 CFR 1320.3(c)(2)). As such, this ICR does not include any third party burden or cost estimates specifically associated with the labeling activities that are a part of the original registration. Please note, however, that EPA must seek OMB concurrence whenever any general labeling changes initiated by the Agency result in an estimated burden of more than 5,000 burden hours. In such cases, EPA must provide OMB with a brief description of the general labeling change, along with the estimated burden and costs. OMB has agreed to notify EPA of any comments or questions within 10 days of receiving the information, after which EPA may proceed with the labeling change.

Long-term recordkeeping The recordkeeping activities briefly described in this ICR exceed OMB's guideline that agencies not require that records be retained for more than 3 years (5 CFR 1 320.5(d)(2)(iv)). As authorized under FIFRA section 8, EPA regulations require that registrants retain records containing research data relating to registered pesticides (including all data submitted to EPA in support of a registration - see 40 CFR 169.2(k)) for as long as the registration is valid and the producer is in business. However, the burden related to the recordkeeping requirements is covered under another ICR (see OMB Control No. 2070-0028, Recordkeeping Requirements for Producers of Pesticides under Section 8 of FIFRA).

Electronic submissions OMB regulations require agencies to provide a statement indicating whether the proposed collection of information involves the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses, and an explanation of the decision (5 CFR 1320.5(a)(iii)(E)). At this time, OPP is not offering a fully electronic submission option. Electronic-Submissions (or "e-Submissions) are available for Section 3 New Applications and Section 3 Amendments. There are two methods by which companies can assemble the e-submission discs. In both methods, the files to be submitted along with an XML data file containing information about the files and the submission itself are "zipped" into a single file and placed on a disc (CD/DVD) for submission to the EPA. The first is a new method introducing the use of a "builder" application. The second, introduced in July 2008, requires the manual editing of the XML file. Additional information on both of e-submission methods can be accessed at: http://www.epa.gov/pesticides/regulating/registering/submissions/.

Ordinarily, registrants would be required to submit three paper copies of study data to EPA; however, registrants need only submit two paper copies if they submit the required study data in Adobe Acrobat Portable Document Format (PDF) on a compact disc. Extensive guidance regarding the electronic submission option is available to registrants via the OPP Internet site at http://www.epa.gov/oppfead1/eds/esr_guidance.htm.

3(f) Confidentiality

Although the EPA urges the submitter to minimize the amount of claimed Confidential Business Information (CBI), all data and/or information brought to the Agency in conjunction with this rule that may be claimed as trade secret, commercial, or financial information, will be protected from disclosure by EPA under FIFRA Section 10 and 40 CFR Part 2, Subpart B.

3(g) Sensitive Questions

Not applicable. No information of a sensitive or private nature is requested in conjunction with this collection activity. In addition, this information collection activity complies with the provisions of the Privacy Act of 1974 and OMB circular A-108.

3(h) OMB Terms of Clearance

Upon approval of the expiring ICR, OMB issued the following terms of clearance:

> *This request to renew information collection is approved for three years. Prior to resubmission of this information collection, the Agency should describe the data sources used to identify and count the respondents and responses and confirm that these data sources provide best available information with which to estimate burden.*

EPA has addressed these terms in section 6(a) of this supporting statement.

4. THE RESPONDENTS AND THE INFORMATION REQUESTED

4(a) Respondents - NAICS Codes

Respondents affected by the collection activities under this ICR are individuals or entities engaged in activities related to the registration of pesticide products, i.e., pesticide registrants. There are 1,683 pesticide registrants holding at least one pesticide registration. The North American Industrial Classification System (NAICS) assigned to the parties responding to this information are as follows:

Category	NAICS codes	Examples of potentially affected entities
Pesticide and other agricultural chemical manufacturing	32532	Individuals or entities engaged in activities related to the registration of a pesticide product.

4(b) Information Requested

(i) Data items, including recordkeeping requirements

There are two main categories of applicants for registration: those requiring submission of a full complement of supporting data (e.g., new active ingredients); and those requiring submission of less data (e.g., amendments, for currently registered chemicals). There are several types of amendments, including “me-too” products that require little or no data. Applicants for “me-too” products (i.e., pesticide products claimed to be identical or substantially similar in composition and use to a product currently registered by the EPA) may be required only to use the forms listed below to certify that the applicant intends to rely on data previously submitted to the EPA by another producer, the applicant has contacted the appropriate company (owning the data that the applicant is referencing) and the applicant has offered to pay reasonable compensation for the use of the data.

Applicants for new active ingredients will be required to submit a full complement of physical chemistry, toxicology, environmental fate, ecological effects, worker exposure, residue chemistry, environmental chemistry, and product performance, as identified in 40 CFR 158.

In addition to the annual reporting and record keeping burden associated with a Section 3 registration, the Agency may promulgate guidance that encourages registrants to submit amended labeling for their pesticide products. The combined burden for such labeling guidance may be considered representative of the additional labeling burden placed on registrants by the Agency, and may enable EPA to create a "generic" new labeling burden.

The completion and submission of the following forms, see Attachment B, are necessary in order to register a pesticide product:

1. EPA Form 8570-1, Application for Pesticide Registration, Amendment, Other;
2. EPA Form 8570-4, Confidential Statement of Formula (CSF)
3. EPA Form 8570-27, Formulator's Exemption Statement
4. EPA Form 8570-34, Certification With Respect to Citation of Data
5. EPA Form 8570-35, Data Matrix
6. EPA Form 8570-36, Summary of the Physical/chemical Properties
7. EPA Form 8570-37, Self-certification Statement for the Physical/Chemical Properties

(ii) Respondent Activities

Respondent Paperwork Activity	**Description**
1. Read instructions	Read germane FIFRA legislation, 40 CFR regulations, application form instructions, the Reduced-Risk policy, applicable guidance and correspondence, and germane labeling PR and FR notices;
2. Plan activities	Decide whether pesticide seeking registration is a "me-too" pesticide, as this will determine succeeding activities;
3. Create information	Arrange for testing of any physical chemistry, toxicological, environmental fate, ecological effects, worker exposure, residue chemistry, environmental chemistry, product performance, and efficacy data that appear to be required by germane regulations to support registration.
4. Gather information	Canvass/contact other chemical firms holding EPA registrations, if any, to determine whether it would be appropriate to share or rely on testing data already submitted by another company;
5. Compile and review	Assemble data, evaluate for accuracy, appropriateness, and completeness;
6. Complete paperwork	Complete all appropriate application documents;
7. Store/maintain data	File and maintain copies of all registration data submitted to the Agency.

Response Type	Description/Example
Type A **New A.I.s & New Uses**	**Description:** "Type A" activities support the registration of new active ingredients and new uses. "Type A" activities involve a registrant or applicant assembling and submitting an application for registration of a new active ingredient or a new use for a currently registered active ingredient. The items required to be submitted in this application include generic data, product specific data, administrative forms, product labeling, and a CSF. The generic and product specific data specified in 40 CFR 158 must be generated by the registrants, formatted properly, and submitted with the correct number of copies. Administrative forms usually include the application for registration, data compensation form, a data matrix, and a CSF. Five copies of the complete labeling must be submitted as well.
	Example: An example of a "Type A" activity would be an application for registration of a new active ingredient (a.i.). Typically, for new a.i.'s, applications must be submitted for at least two new products -- the manufacturing use product (either imported or made in the U.S. that may be formulated into end-use products) and at least one end-use product (that bears directions for the intended end uses). An applicant would need to determine generic and product specific data required by 40 CFR 158 for the new a.i. (taking into account the use patterns sought), generate those data, and submit them with the application. For a new a.i., the generic data consists of certain acute, sub-chronic, and chronic toxicology; environmental fate; ecological effects (birds, fish, invertebrates); and product chemistry. When the data are completed, the applicant would format and submit the studies along with the other items required for an application, as described above.
Type B **New or Amended Products Using Currently Registered A.I.s**	**Description:** "Type B" activities involve a registrant or applicant assembling and submitting an application for registration of a new or amended product that contains a currently registered active ingredient. Generally, "Type B" activities involve far less data and complexity than "Type A" activities. The items that must be submitted or cited in this application include product specific data, administrative forms, product labeling, and a CSF. The product specific data specified in 40 CFR 158 must be generated by the registrant/applicant or cited from an identical or substantially similar product. If submitted, the data must be formatted properly and with the correct number of copies. Administrative forms usually include the application for registration, data compensation form, a data matrix, and a CSF. Five copies of the complete labeling must be submitted as well.
	Example: An applicant might seek registration of a new product containing an active ingredient that is already registered. Often, the formulation of this product is identical or substantially similar to that of a currently registered end-use product. This is called a "me-too" registration. In this case, the applicant only needs to cite data from another product (selective method) or from all products containing that a.i. (cite-all method) to support the new product. The applicant also submits the labeling and other administrative forms without submitting any data. If a product is not substantially similar to another product, the applicant must submit product specific data (acute toxicity and product chemistry) for that product. Nevertheless, this kind of application is far less complicated than a "Type A" application.
Type C **Reduced Risk A.I.s & Uses**	**Description: "**Type C" activities involve registration of new conventional active ingredients or uses that may qualify as "reduced risk" chemicals that are given expedited processing. An applicant must prepare an application that includes specific information as described in PR notice 97-3 to explain why the new conventional a.i. or use has inherently lower risk than currently registered products.
	Example: A new a.i. may have a lower toxicity, exposure and risk profile than a currently registered a.i. for the same conventional commodity. If the applicant can document and explain why the new a.i. or new use should be a reduced risk, the Agency will accept the application as "reduced risk" and will process it expeditiously, presuming that all required data have been submitted. This kind of application is less complex than the "Type A" activity, but more complex than "Type B."

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

5(a) Agency Activities

OPP activities in conjunction with receipt of information in this ICR are summarized by the following steps:

1. Receive Application

- The pesticide registration application package, complete with the required forms, necessary data, and proposed labels, is received by the Front-End Processing Unit in the Information Technology and Resources Management Division (ITRMD). After screening the application for administrative completeness, ITRMD refers the complete application and any accompanying data to the appropriate regulatory division. ITRMD is responsible for entering the registration action into the appropriate database for tracking purposes. If the application form is accompanied by data to support the registration application (e.g., new active ingredients and new uses), ITRMD will forward the registration data package to a contractor for inputting into the tracking database. After this is completed, the data package is routed to the appropriate regulatory division for processing.

2. Review Application

- If the registration application is clearly for a "me-too" pesticide product or use, then the product may be registered on an expedited basis by the reviewer. If its similarity to a pesticide currently registered by the EPA is questionable, it may be sent for a short interdisciplinary review. The Program Manager or Team Leader ensures that the database is updated by identifying where it is sent for review.

- If the registration action is clearly not for a "me-too" pesticide product or use, then action is taken to correct the assignment of the registration action and to route the data to the appropriate scientific evaluation group for full data reviews. Each scientific discipline reviews the data and may develop a Data Evaluation Report (DER) and appropriate risk assessments that summarize the data review.

3. Make Registration Decision

- The Program Manager or Team Leader examines all of the scientific reviews and proposed labeling and determines whether the product may be registered. If the product contains an active ingredient not currently registered by EPA, the review summary is included as part of a decision package and referred to the Director of OPP for a final decision on whether or not to register a pesticide. When a new tolerance is established for an already registered active ingredient (e.g., new use), the final decision is made by the Division Director of the registering division.

- If the registration action is for revised labeling in response to a Pesticide Registration Notice, the revised labeling submitted along with appropriate EPA forms will be reviewed by a Program Manager or Team Leader for compliance with the applicable Pesticide Registration Notice and, following the registration decision, entered into the tracking database.

4. Notify Applicant
- OPP sends a Notice of Registration to the applicant informing the applicant that the product has been registered and specifying any conditions of registration. For labeling amendments, a letter is sent to the applicant stating approval/disapproval with comments.

5. Store and Maintain Data
- OPP stores, files, and maintains copies of any registration notices and labeling information.

The degree and level of the review will depend on the complexity of the product, and whether it is identical or substantially similar to other products already registered. Products containing active ingredients present in currently registered products and proposed for uses currently registered ("me-too" registrations) may require only a minimal review for completeness of the application, the adequacy of the labeling, and the satisfaction of data compensation requirements.

A product containing a new active ingredient may require multiple data reviews related to physical chemistry, toxicology, environmental fate, ecological effects, worker exposure, residue chemistry, environmental chemistry, and product performance prior to approval. Therefore many divisions may be actively involved in the data analysis and agency determination of OPP registration actions. For conventional pesticides, the application is reviewed by ITRMD, the Registration Division (RD), the Health Effects Division (HED), and the Environmental Fate and Effects Division (EFED), and Biological and Economic Analysis Division (BEAD). For biological/biopesticide pesticides, the application is reviewed by ITRMD, and the Biopesticides and Pollution Prevention Division (BPPD). Applications for antimicrobial pesticide products are reviewed by ITRMD and the Antimicrobial Division (AD). The Agency notifies an applicant when an application is incomplete or is found to be deficient. The applicant is permitted to correct the deficiencies and submit the corrections.

Once issued, a registration also may be amended in various ways, such as adding or deleting uses, modifying the labeling, or altering the product composition in minor ways. To request these changes, the registrant is required to submit an application for amended registration on EPA Form 8570-1, along with all appropriate additional forms, labeling and supporting data.

Notifications are registration modifications, typically without need of data review, that require the shortest review and approval or denial time. Unlike a new active ingredient or a new use, Notifications are reviewed only by the division responsible for registering the product.

Registrants submitting registration applications for pesticide products that may fall within the scope of the Reduced-Risk Initiative may provide a written rationale with any supporting information on why their pesticide may qualify for special consideration. This rationale with supporting information will be reviewed and evaluated and, if the pesticide demonstrates the opportunity for risk reduction, the EPA uses this finding as a factor in determining a shorter review time. This policy specifies the standard format for registrants to use when providing justification for a reduced-risk pesticide to facilitate efficient processing within OPP.

5(b) Collection Methodology and Management

All registration actions are entered into the database to track progress toward registration. Registration actions accompanied by data (e.g., products containing new active ingredients or new uses) are also entered into OPP's database to track progress toward registration. Once a product has been registered, pertinent status information regarding the product is revised in the tracking database. The system contains the following types of information: new or amended product registrations, suspensions, cancellations, product active ingredients, product uses, and use deletions. ITRMD maintains official registration file jackets, in which copies of the application, EPA's reviews, registration approvals, correspondence, label, the CSF and other related information are all retained.

5(c) Small Entity Flexibility

EPA Form 8570-27 ("Formulator's Exemption Statement") reduces the data submission burden on an applicant for registration of a product that uses an EPA-registered pesticide product as the source of its active ingredient. This form exempts the applicant from furnishing the generic data that already were submitted by the company registering the source product.

The Agency also has cataloged and computerized its pesticide data base so that one can easily determine whether a particular study has been submitted, and by whom it was submitted. This identifies, by chemical and site(s), each item of data in the EPA files. As a result, applicants encounter little difficulty in identifying available data needed to support an application for registration.

5(d) Collection Schedule

Not applicable. The activity is conducted only as a registration application is received for consideration. There is no set schedule for the collection of this information.

6. ESTIMATING BURDEN AND COST OF THE COLLECTION

6(a) Estimating Respondent Burden

The reporting and recordkeeping burden associated with Section 3 registration of pesticides may be thought of in terms of three general categories of burden (including most registration actions except those pertaining to setting tolerances and inert ingredients). Annual aggregate burden for all respondent registration activities is estimated to be 168,204 hours, as further illustrated in section 6(b).

Table 1: Annual Information Collection Burden Estimates for Each General Category

Information Collection	No. of Registrants (respondents)	Avg. no. of annual responses/respondent	Avg. no. of Annual Responses	Estimated Burden/Response	Avg. Annual Burden
"Type A" activities	1683	0.15	249	194 hours	48,306 hours
"Type B" activities	1683	4.7	7,872	14 hours	110,208 hours
"Type C" activities	1683	0.009	15	646 hours	9,690 hours

When the Agency receives applications for registrations and amendments to registrations it immediately enters them into the Office of Pesticide Program central database system, called OPPIN.

From this system, the Agency can provide reporting on actual numbers of applications, broken down by several major types. Each registering division further tracks applications in greater detail. Information from the central database and supplemental divisional tracking is used at the end of the year as the basis of the burden estimates.

6(b) Estimating Respondent Costs

There are currently an estimated 1,683 pesticide registrants holding at least one pesticide registration. The number of pesticide registrants has decreased since the last ICR renewal from 1,725 to 1,683 - a difference of 42. For purposes of determining the appropriate number of responses for each activity, EPA averaged respondent data for registration activities submitted to EPA from 2008-2010; The average number of responses annually has changed from the last ICR renewal from 3,190 to 8,136 an increase of about 155%.

The annual costs associated with these activities are estimated to be approximately $13,435,600 per year.

- "Type A" activities are estimated to cost about $3,087,800 per year.
- "Type B" activities are estimated to cost about $9,701,400 per year.
- "Type C" activities are estimated to cost about $646,400 per year.

Agency economists revised 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 I.**

(i) Methodology

The methodology uses data on each sector and labor type for an *Unloaded wage rate* (hourly wage rate), and calculates the *Loaded wage rate* (unloaded wage rate + benefits), and the *Fully loaded wage rate* (loaded wage rate + overhead). Fully loaded wage rates are used to calculate respondent costs. This renewal uses 2010 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 http://www.bls.gov/oes/current/oessrci.htm

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 I). 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 http://www.bls.gov/oes/current/oes_stru.htm).

Loaded Wage Rate

Unless stated otherwise, all benefits represent 43.6% of unloaded wage rates, based on benefits for all civilian non-farm workers, from June 2010 data from http://www.bls.gov/news.release/ecec.t01.htm.

Fully Loaded Wage Rate

We multiply the loaded wage rate by 50% (EPA guidelines 20-70%) to get overhead costs.

(ii) Analysis

The following tables present estimated annual burden and cost estimates for this ICR. Since costs are displayed as rounded to nearest ten or hundred dollars, they may not calculate exactly.

Table 2-A: Est. Burden/Cost per "Type A" Antimicrobial Registration Application (AD)

Collection Activities Type A	**Burden Hours**			**Total**	
	Mgmt	Technical	Clerical	Hours	Costs
	$120.28 per hour	$60.85 per hour	$37.11 per hour		
Read Instructions	18	0	0	18	$2,200
Plan activities	4	0	0	4	$500
Gather/create information	0	120	0	120	$7,300
Compile and review	4	8	0	12	$1,000
Complete paperwork	0	0	30	30	$1,100
Store/maintain data	0	0	10	10	$400
TOTAL	26	128	40	194	$12,400
Annual Burden/Cost	**Hours per response**	**x Responses per year**	**= Hours per year**	**x Wage per hour**	**= Costs per year**
(a) Management:	26	25	650	$120.28	$78,200
(b) Technical:	128	25	3,200	$60.85	$194,700
(c) Clerical:	40	25	1,000	$37.11	$37,100
Total	194	25	4,850		$310,000

Table 2-B: Est. Burden/Cost per "Type A" Biopesticide Registration Application (BPPD)

Collection Activities Type A	Burden Hours			Total	
	Mgmt	Technical	Clerical	Hours	Costs
	$120.28 per hour	$60.85 per hour	$37.11 per hour		
Read Instructions	18	0	0	18	$2,200
Plan activities	4	0	0	4	$500
Gather/create information	0	120	0	120	$7,300
Compile and review	4	8	0	12	$1,000
Complete paperwork	0	0	30	30	$1,100
Store/maintain data	0	0	10	10	$400
TOTAL	26	128	40	194	$12,400
Annual Burden/Cost	**Hours per response**	**x Responses per year**	**= Hours per year**	**x Wage per hour**	**= Costs per year**
(a) Management:	26	22	572	$120.28	$68,800
(b) Technical:	128	22	2,816	$60.85	$171,400
(c) Clerical:	40	22	880	$37.11	$32,700
Total	194	22	4,268		$272,800

Table 2-C: Est. Burden/Cost per "Type A" Registration Application (RD)

Collection Activities Type A	Burden Hours			Total	
	Mgmt	Technical	Clerical	Hours	Costs
	$120.28 per hour	$60.85 per hour	$37.11 per hour		
Read Instructions	18	0	0	18	$2,200
Plan activities	4	0	0	4	$500
Gather/create information	0	120	0	120	$7,300
Compile and review	4	8	0	12	$1,000
Complete paperwork	0	0	30	30	$1,100
Store/maintain data	0	0	10	10	$400
TOTAL	26	128	40	194	$12,400
Annual Burden/Cost	**Hours per response**	**x Responses per year**	**= Hours per year**	**x Wage per hour**	**= Costs per year**
(a) Management:	26	202	5,252	$120.28	$631,700
(b) Technical:	128	202	25,856	$60.85	$1,573,400
(c) Clerical:	40	202	8,080	$37.11	$299,900
Total	194	202	39,188		$2,505,000

Table 2-D: "Type A" Annual Activity Burden/Cost Subtotals

Processing Division	Responses	Burden	Cost
AD	25	4,850	$310,000
BPPD	22	4,268	$272,800
RD	202	39,188	$2,505,000
"Type A" Subtotal	249	48,306	$3,087,800

Table 3-A: Est. Burden/Cost per "Type B" Application/Notification (AD)

Collection Activities Type B	**Burden Hours**			**Total**	
	Mgmt	Technical	Clerical	Hours	Costs
	$120.28 per hour	$60.85 per hour	$37.11 per hour		
Read Instructions	7	0	0	7	$840
Plan activities	0.5	0	0	0.5	$60
Gather/create information	0	1.5	0	1.5	$90
Compile and review	0.5	0.5	0	1	$90
Complete paperwork	0	0	3	3	$110
Store/maintain data	0	0	1	1	$40
TOTAL	8	2	4	14	$1,230
Annual Burden/Cost	**Hours per response**	**x Responses per year**	**= Hours per year**	**x Wage per hour**	**= Costs per year**
(a) Management:	8	2,924	23,392	$120.28	$2,813,600
(b) Technical:	2	2,924	5,848	$60.85	$355,900
(c) Clerical:	4	2,924	11,696	$37.11	$434,100
Total	14	2,924	40,936		$3,603,500

Table 3-B: Est. Burden/Cost per "Type B" Application/Notification (BPPD)

Collection Activities Type B	**Burden Hours**			**Total**	
	Mgmt	Technical	Clerical	Hours	Costs
	$120.28 per hour	$60.85 per hour	$37.11 per hour		
Read Instructions	7	0	0	7	$840
Plan activities	0.5	0	0	0.5	$60
Gather/create information	0	1.5	0	1.5	$90
Compile and review	0.5	0.5	0	1	$90
Complete paperwork	0	0	3	3	$110
Store/maintain data	0	0	1	1	$40
TOTAL	8	2	4	14	$1,230
Annual Burden/Cost	**Hours per response**	**x Responses per year**	**= Hours per year**	**x Wage per hour**	**= Costs per year**
(a) Management:	8	231	1,848	$120.28	$222,300
(b) Technical:	2	231	462	$60.85	$28,100
(c) Clerical:	4	231	924	$37.11	$34,300
Total	14	231	3,234		$284,700

Table 3-C: Est. Burden/Cost per "Type B" Application/Notification (RD)

Collection Activities Type B	Burden Hours			Total	
	Mgmt	Technical	Clerical	Hours	Costs
	$120.28 per hour	$60.85 per hour	$37.11 per hour		
Read Instructions	7	0	0	7	$840
Plan activities	0.5	0	0	0.5	$60
Gather/create information	0	1.5	0	1.5	$90
Compile and review	0.5	0.5	0	1	$90
Complete paperwork	0	0	3	3	$110
Store/maintain data	0	0	1	1	$40
TOTAL	8	2	4	14	$1,230
Annual Burden/Cost	**Hours per response**	**x Responses per year**	**= Hours per year**	**x Wage per hour**	**= Costs per year**
(a) Management:	8	4,717	37,736	$120.28	$4,538,900
(b) Technical:	2	4,717	9,434	$60.85	$574,100
(c) Clerical:	4	4,717	18,868	$37.11	$700,300
Total	14	4,717	66,038		$5,813,200

Table 3-D: Type B Activity Burden/Cost Subtotals

Processing Division	Responses	Burden	Cost
AD	2,924	40,936	$3,603,500
BPPD	231	3,234	$284,700
RD	4,717	66,038	$5,813,200
"Type B" Subtotal	7,872	110,208	$9,701,400

Table 4: Est. Burden/Cost per "Type C" Reduced Risk Application (RD only)

Collection Activities Type C	Burden Hours			Total	
	Mgmt	Technical	Clerical	Hours	Costs
	$120.28 per hour	$60.85 per hour	$37.11 per hour		
Read Instructions	22	0	0	22	$2,600
Gather Information	0	368	0	368	$22,400
Process, Compile and Review Information	80	80	0	160	$14,500
Record and Report Information	0	0	72	72	$2,700
Store, File and Maintain Information	0	0	24	24	$900
TOTAL	102	448	96	646	$43,100
Annual Burden/Costs	**Hours per response**	**x Responses per year**	**= Hours per year**	**x Wage per hour**	**= Costs per year**
(a) Management:	102	15	1,530	$120.28	$184,000
(b) Technical:	448	15	6,720	$60.85	$408,900
(c) Clerical:	96	15	1,440	$37.11	$53,400
Total	646	15	9,690		$646,400

6(c) Estimating Agency Burden and Cost

The Agency is using FIFRA Section 3 registration activity data from the Time and Attendance Information System (TAIS), which archives the Agency's Full Time Equivalents (FTEs) for most OPP program activities. The projected burden figures use 2008 – 2010 data, which includes burden hours from internal OPP Divisions that provide significant support and analysis for the FIFRA Section 3 ICR registration program including the Registration Division (RD), the Biopesticides and Pollution Prevention Division (BPPD), the Antimicrobial Division (AD), the Health and Effects Division (HED), the Biological and Economic Analysis Division (BEAD), and the Environmental Fate and Effects Division (EFED). Thus, six OPP Divisions work together to complete the activities related to OPP registration actions. The Agency believes using this data source reflects the changes to the internal operations for implementing and administering the FIFRA Section 3 registration activities. The major impetus for internal program realignment was to implement the requirements of the Food Quality Protection Act of 1996 and the Pesticide Registration Improvement Act of 2003 (PRIA) as reauthorized.

Using this source of data, the estimated number of Agency FTE's dedicated to Section 3 registration and registration support activities is approximately 25 managerial FTEs, 198 technical FTEs, and 7 clerical FTEs as shown in Table 5. The aggregated Agency estimated FTE dedicated to Section 3 activities is 230 and the burden hours are 478,400.

Table 5 – Distribution of Agency FTEs Supporting FIFRA Section 3 Registration and Registration Support Activities[1]

Division:	BEAD	RD	EFED	HED	AD	BPPD	Total	Wage/ hr	Cost
Managerial	2.7	7.2	3.1	6.1	2.9	3.2	**25.1**	**$119.85**	**$6,248,800**
Technical	19.2	61.1	21.1	42.9	24.8	28.7	**197.9**	**$71.58**	**$29,459,500**
Clerical	0.7	2.0	0.9	1.3	1.0	1.3	**7.1**	**$43.21**	**$636,600**
Total Sec 3	**22.5**	**70.3**	**25.1**	**50.3**	**28.6**	**33.1**	**230.0**		**$36,344,900**

Annual Agency burden hours were calculated using the number of hours per FTE multiplied by the number of FTE's (2080 hours/FTE x 230 FTE=478,400 hours).

To determine Agency costs, the Agency used the Bureau of Labor Statistics estimates of 2010 labor rates for the North American Industry Classification System (NAICS) code for the Federal Executive Branch (NAICS 999100). The managerial labor rate is based on the Standard Occupational Code (SOC) for management occupations; the technical labor rate is based on the SOC for life, physical and social science occupations; and the clerical labor rate is based on the SOC for office and administrative support occupations. The fully loaded hourly mean wage rate estimate is $119.85 for managerial occupations, $71.58 for technical occupations, and $43.21 for clerical occupations. (Please see Attachment J - Worksheet for NAICS 999100 EPA or Federal Government Worksheet.)

To calculate the Agency's estimated annual cost of Section 3 activities, the number of FTE's allocated to registration activities (Table 5) is multiplied by these fully loaded labor rates and by 2080 hours per FTE, which is estimated to be about $6,248,800 for management; $29,459,500 for technical; and $636,600 for clerical. The total estimated Agency cost is $36,344,900.

6(d) Bottom Line Burden Hours and Cost

Table 6- Estimated Annual Total Hours and Cost

	ANNUAL TOTAL		
	Responses	Hours	Costs
Annual "Type A" Responses	249	48,306	$3,087,800
Annual "Type B" Responses	7,872	110,208	$9,701,400
Annual "Type C" Responses	15	9,690	$646,400
Total Annual Response Burden	8,136	168,204	$13,435,600
Agency Burden Estimate		478,400	$36,344,900

6(e) Reasons for Changes in Burden

There is an annual respondent burden increase of about 92,000 hours as a result of almost 5,000 additional expected responses primarily from "Type B" activities in the RD (Registration Division) and the AD (Antimicrobial Division). The increase reflects the Agency's tracking of information collected under FIFRA section 3 over the past three years, including increased responses for labeling or labeling amendments, and is the Agency's best estimate for the number of responses expected. This change is an adjustment.

[1] The Agency burden related to OPP's Information Technology and Resource Management Division (ITRMD) processing activities are not included in the burden estimate because ITRMD provides the preliminary data processing and tracking for many OPP ICR activities including the FIFRA Section 3 ICR. These systems are integrated for efficient processing, tracking, and maintaining data but they do not readily lend themselves to a clear burden breakdown by ICR activity. The FTE burden in PRD (Pesticide Review Division) and FEAD (Field and External Affairs Division) is significantly less than 1 FTE.

6(f) Burden Statement

The annual average reporting and recordkeeping burdens for a registration applicant respondent are estimated to range from 14 hours to 840 hours, depending upon the type of activity. Estimates for the annual applicant respondent burden for collection of information average 194 hours per application for "Type A" activities, which include new active ingredients and new uses and 14 hours per application for "Type B" activities, which include amendments and notifications. The burdens estimate for "Type C" reduced risk products, which are handled only by RD, is an average of 646 hours per product. However, reduced risk products require both "Type A" and "Type C" for a total of 840 hours for both applications. These estimates include time spent 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 has established a public docket for this ICR under Docket ID No. EPA-HQ-OPP-2011-0886 , which is available for online viewing at www.regulations.gov or in person viewing at the EPA Docket Center Public Reading Room, EPA West Building, Room 3334, 1301 Constitution Avenue, NW, Washington, DC 20004. The EPA/DC is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding federal holidays. The docket telephone number is (202) 566-1744. 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.

Submit your comments, referencing Docket ID No. EPA-HQ-OPP-2011-0886 and OMB Control No. 2070-0060, to (1) EPA online using www.regulations.gov (our preferred method), or by mail to: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), Mailcode: 28221T, 1200 Pennsylvania Ave., NW., Washington, DC 20460., and (2) OMB by mail to: Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), Attention: Desk Officer for EPA, 725 17th Street, NW, Washington, DC

ATTACHMENTS TO THE SUPPORTING STATEMENT

Attachments to the supporting statement are available in the public docket established for this Information Collection Request (ICR) under the docket identification number EPA-HQ-OPP-2011-0886. These attachments are available for online viewing at www.regulations.gov or otherwise accessed as described in the sections below.

Attachment A: **7 U.S.C. 136a – Section 3 of FIFRA**. Also available at online at the US House of Representatives' US Code website

Attachment B: **Forms for Pesticide Registration** – available electronically as a PDF file on the internet at http://www.epa.gov/opprd001/forms/.

EPA Form 8570-1 - Application for Pesticide, Registration, Amendment, Other

EPA Form No. 8570-4 - Confidential Statement of Formula

EPA Form No. 8570-27 - Formulator's Exemption Statement

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

Attachment C: **Pesticide Registration (PR) Notice 97-3 – Guidelines for Expedited Review of Conventional Pesticides under the Reduced-Risk Initiative and for Biological Pesticides.** Also available at online at http://www.epa.gov/PR_Notices/pr97-3.html

Attachment D: **40 CFR 152 – Pesticide Registration and Classification Procedures.** Also available online at the National Archives and Records Administration's Electronic CFR Website

Attachment E: **40 CFR 156 – Labeling Requirements for Pesticides and Devices.** Also available online at the National Archives and Records Administration's Electronic CFR Website

Attachment F: **40 CFR 158 – Data Requirements For Registration.** Also available online at the National Archives and Records Administration's Electronic CFR Website

Attachment G: **Consultation: List of Standard Questions**

Attachment H: **Industry Response to Consultation Questions**

Attachment I: **Work Sheets used to Calculate Pesticide Registrant Industry Labor Costs**

Attachment J: **Work Sheets used to Calculate EPA and Federal Government Labor Costs**

Attachment K: **Display Related to OMB Control #2070-0060 – Listings of Related Regulations in 40 CFR 9.1.** Also available online at the National Archives and Records Administration's Electronic CFR Website