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. 0277.15

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 Federal Food, Drug, and Cosmetic Act (FFDCA) as amended (see Attachment A). Under FIFRA as amended, 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.

Registration of a pesticide is a scientific, legal and administrative process through which EPA examines the ingredients of the pesticide; the particular site or crop on which it is to be used; the amount, frequency and timing of its use; and storage and disposal practices. 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. 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. If EPA's evaluation of the data shows that the statutory requirements of FIFRA are met, then 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). Normally, data are not required or reviewed 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 (PM), or Team Leader (TL), 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 who ensure that revisions comply with the applicable labeling requirement or guidance.

The Agency has added to its basic registration information collection 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 scheduling priority in registration consideration 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 (rationale) 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 priority treatment in the scheduling of scientific reviews with resulting potential benefit of 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., reregistration). Labeling

amendments pertaining to groups of products may be implemented through Pesticide Registration (PR) or Federal Register (FR) notices.

2(b) Practical Utility/Users of the Data

For conventional pesticides, the application is reviewed by the Information Technology and Resources Management Division (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 the Biopesticides and Pollution Prevention Division (BPPD). Applications for antimicrobial pesticide products are reviewed within the Antimicrobial Division (AD). 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") may require only a minimal review for completeness of the application, the adequacy of the labeling, and the satisfaction of data compensation requirements. However, 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, other OPP Divisions such as the Heath and Effects Division (HED), the Biological and Economic Analysis Division (BEAD), Special Review and Reregistration Division (SRRD), and the Environmental Fate and Effects Division (EFED) are actively involved in the data analysis and agency determination of OPP registration actions.

An application that is incomplete or that is found to be deficient in data or labeling is rejected, and the applicant is permitted to correct the deficiencies and resubmit the application. When 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, then registration is issued to the applicant.

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.. 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 because it presents the opportunity for risk reduction. 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 application review priority. This policy specifies the standard format for registrants to use when providing justification for a reduced-risk pesticide to allow efficient processing within OPP.

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 also is able to refer to any appropriate information previously submitted, thereby satisfying data requirements, if any data is needed, without the burden of providing duplicate information or additional data development.

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

Pursuant to 5 CFR 1320.8(d), ICR, EPA published a Federal Register (FR) Notice (73 FR 17973; April 2, 2008). The Agency did not receive any public comments.

3(c) Consultations

Consultation and/or dialogue between the respondent and EPA occurs on an informal, ongoing "as needed" basis, primarily during the submission and review of the application for an experimental use permit. Historically, when technical, administrative, or other problems arise, the respondent has ample opportunity to inform the agency and vice versa. It has been the Agency's experience that registrants do not hesitate to inform OPP staff when problems or questions arise, and we welcome those contacts, as well as suggestions for improvement in the process. This communication between both parties may take place either in a telephone conversation or in a meeting setting, but not necessarily by a prescribed schedule.

During the preparation of this ICR renewal, EPA staff contacted several representatives of pesticide registrants by e-mail to seek feedback on the information reporting requirements and process. A sample copy of the ICR questionnaire provided to industry representatives is in Attachment J. The Agency received no comments from the representatives listed below during the consultation period.

Amy Roberts,
Regulatory Consultant
Technology Science Group, Inc.
aroberts@tsgusa.com

Dr. Ray S. McAllister
Director Regulatory Affairs
CropLife
rmcallister@croplifeamerica.org

Mr. Eric Maurer
Valent Corporation
Eric.Maurer@valent.com

Robin G. Todd PhD BCE
Director
ICR, Inc.
1330 Dillon Heights Avenue
Baltimore, MD 21228-1199

3(d) Effects of Less Frequent Collection

Not applicable. This 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, wildlife, and the environment, including endangered species.

3(e) General Guidelines

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.

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 the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)).

Also, OMB 's 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. Additionally, OPP is not yet prepared to accept the electronic submission of any forms listed in this ICR. Forms-based submissions likely would be transmitted via the World Wide Web and neither OPP nor the Agency's Office of Environmental Information have developed the information technology approaches that would adequately protect FIFRA Confidential Business Information submitted in this way. Therefore, the public should note that the electronic submission option currently applies only to the submission of studies and supplemental files.

Ordinarily, registrants would be required to submit 3 paper copies of study data to EPA. However, as a option registrants need only submit 2 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 the associated regulation as contained in 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.

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. 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 little or no data (e.g., “me-too” products) for currently registered chemicals and use patterns. 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 chemistry, toxicology, environmental fate, ecological effects, worker exposure, residue chemistry, environmental chemistry, product performance, and perhaps efficacy data 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 being registered 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	**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	**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	**Description: “**Type C" activities involve registration of new conventional active ingredients or uses that may qualify as "reduced risk" chemicals and/or OP replacements that are given expedited processing. An applicant must prepare an application that includes specific information as described in PR notice 97-3 and/or 98-7 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 or OP replacement, the Agency will accept the application as "reduced risk” and/or OP replacement 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

The pesticide registration application package, complete with the required forms, necessary data, and labels, is mailed to OPP, where it 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 then refers both 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 microfilming and for inputting into the tracking database. After this is completed, the data package is routed to the PM or TL for processing.

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 PM or TL. If its similarity to a pesticide currently registered by the EPA is questionable, it may be sent for a short interdisciplinary review. The PM or TL 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 the PM or TL logs in and routes 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. The PM or TL 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 the final decision to register a pesticide.

If the registration action is for revised labeling in response to a PR Notice, the revised labeling submitted along with appropriate EPA forms will be reviewed by a PM or TL for compliance with the applicable Notice and, following the registration decision, entered into the tracking database.

Rationales with supporting information that propose to present a reduced-risk product for registration are reviewed by senior OPP scientists and risk managers who determine whether the product does indeed warrant the priority treatment accorded to reduced-risk pesticide applications. Pesticide applications with any associated tolerance petitions for pesticides successfully classified as offering opportunities for risk reduction will receive priority treatment in the scheduling of scientific reviews.

The Agency sometimes allows registration to be altered in some way via notification or "minor" amendment. Notifications are registration modifications without need of extensive data

review (e.g., product chemistry and labeling) that require the registrant to inform the EPA but do not require the Agency's approval. Notifications for conventional pesticides are screened in the RD Registration Support Branch to ensure they are not beyond the scope of the notification process. Biological/biopesticide notifications are reviewed by the BPPD; antimicrobial notifications are reviewed by AD.

Agency Activity	Description
1. Receive Application	In the case of new registration applications, the Front-End Processing Unit reviews the application for administrative completeness and routes complete applications to the appropriate regulatory division;
2. Plan activities	Registration actions accompanied by data to support registration are routed to a contractor for loading into the tracking database. The action then is routed to the appropriate PM/TL. Registration actions not accompanied by data are loaded into the tracking database by ITRMD. Following that, actions are routed to the PM/TL who routes them for review. In the case of revised labeling amendments such as those submitted in support of requirements under the Worker Protection Standard (WPS), ITRMD will screen the application for completeness and submit it to the appropriate regulatory division for examination.
3. Create information	In the case of new active ingredient or new use applications, the Agency scientists (or contractors) review all submitted data and forward DERs and risk assessments to the PM/TL that summarize the results of their reviews and presents their evaluation;
4. Gather information	The DERs and risk assessments from the scientific disciplines are routed to a PM or TL;
5. Compile and review	The PM or TL reviews the data summaries and risk assessments For new active ingredients and new uses, decision packages are prepared and routed to the Director of OPP for the final decision. For all other actions, the PM/TL makes a determination whether to register a new or amended product.
6. Complete paperwork	Complete and send 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.
7. Store/maintain data	Store, file, and maintain copies of any registration notices and labeling information.

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) also are 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, 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's 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). Total aggregate burden for all respondent registration activities is estimated to be 76,180 hours.

The annual burden for all respondents completing "Type A" activities is estimated to be 27,160 hours, based on 140 responses at 194 hours per response.

The annual burden for all respondents completing "Type B" activities is estimated to be 42,560 hours, based on 3,040 responses at 14 hours per response.

The annual burden for all respondents completing "Type C" activities is estimated to be 6,460 hours, based on roughly 10 responses at 646 hours per response.

6(b) Estimating Respondent Costs

There are currently an estimated 1,725 pesticide registrants holding at least one pesticide registration. The number of pesticide registrants has decreased since the last ICR renewal from

2,100 to 1,725, a difference of 375. For purposes of determining the appropriate number of responses for each activity, EPA averaged respondent data for registration activities submitted to EPA from 2005-2007; EPA has averaged almost 3,200 annual responses. Thus, average number of responses annually has also changed from the last ICR renewal from 7,021 to 3,190, a reduction of over 50%.

The annual costs associated with these activities are estimated to be approximately $5,528,542 per year.

- "Type A" activities are estimated to cost about $1,768,193 per year.
- "Type B" activities are estimated to cost about $3,339,318 per year.
- "Type C" activities are estimated to cost $421,030 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 G**

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 2006 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/oes_nat.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 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 http://www.bls.gov/oes/current/oes_stru.htm).
Loaded Wage Rate	Unless stated otherwise, all benefits represent 43% of unloaded wage rates, based on benefits for all civilian non-farm workers, from http://www.bls.gov/news.release/ecec.t01.htm. 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.

The following tables present the estimated registration annual burden and cost estimates:

Table 1-A: Est. Burden/Cost per "Type A" Antimicrobial Registration Application (AD)

Collection Activities	Burden Hours			Total	
	Mgmt. $103.62/hr	Tech. $67.05/hr	Cler. $33.85/hr	Hours	Costs $
Read Instructions	18	0	0	18	1,865.16
Plan activities	4	0	0	4	414.48
Gather/create information	0	120	0	120	8,046.00
Compile and review	4	8	0	12	950.80
Complete paperwork	0	0	30	30	1,015.50
Store/maintain data	0	0	10	10	338.50
TOTAL	26	128	40	194	$12,630.52

Annual Costs: 194 hours x 16 responses per year = 3,104 hours

(a) Management: 26 hours x $103.62 x 16 Responses = $ 43,105.92
(b) Technical: 128 hours x $67.05 x 16 Responses = $137,318.40
(c) Clerical: 40 hours x $33.85 x 16 Responses = $ 21,664.00
Total = $202,008.32

Table 1-B: Est. Burden/Cost per "Type A" Antimicrobial Registration Application (BPPD)

Collection Activities	Burden Hours			Total	
	Mgmt. $103.62/hr	Tech. $67.05/hr	Cler. $33.85/hr	Hours	Costs $
Read Instructions	18	0	0	18	1,865.16
Plan activities	4	0	0	4	414.48
Gather/create information	0	120	0	120	8,046.00
Compile and review	4	8	0	12	950.80
Complete paperwork	0	0	30	30	1,015.50
Store/maintain data	0	0	10	10	338.50
TOTAL	26	128	40	194	$12,630.52

Annual Costs: 194 hours x 35 responses per year = 6,790 hours

(a) Management: 26 hours x $103.62 x 35 Responses = $ 94,294.20
(b) Technical: 128 hours x $67.05 x 35 Responses = $300,384.00
(c) Clerical: 40 hours x $33.85 x 35 Responses = $ 47,390.00
Total = $442,068.20

Table 1-C: Est. Burden/Cost per "Type A" Registration Application (RD)

Collection Activities	Burden Hours			Total	
	Mgmt. $103.62/hr	Tech. $67.05/hr	Cler. $33.85/hr	Hours	Costs $
Read Instructions	18	0	0	18	1,865.16
Plan activities	4	0	0	4	414.48
Gather/create information	0	120	0	120	8,046.00
Compile and review	4	8	0	12	950.88
Complete paperwork	0	0	30	30	1,015.50
Store/maintain data	0	0	10	10	338.50
TOTAL	26	128	40	194	$12,630.52

Annual Costs: 194 hours x 89 responses per year = 17,266 hours

(a) Management: 26 hours x $103.62 x 89 Responses = $239,776.68
(b) Technical: 128 hours x $67.05 x 89 Responses = $763,833.60
(c) Clerical: 40 hours x $33.85 x 89 Responses = $120,506.00
Total = $1,124,116.28

Table 1-D: "Type A" Annual Activity Burden/Cost Subtotals

Processing Division	Responses	Burden	Cost
AD	16	3,104 hours	$202,008.32
BPPD	35	6,790 hours	$442,068.20
RD	89	17,266 hours	$1,124,116.28
"Type A" Subtotal	140	27,160 hours	$1,768,192.80

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

Collection Activities	Burden Hours			Total	
	Mgmt. $103.62/hr	Tech. $67.05/hr	Cler. $33.85/hr	Hours	Costs $
Read Instructions	7.0	0.0	0.0	7.0	725.34
Plan activities	0.5	0.0	0.0	0.5	51.81
Gather/create information	0.0	1.5	0.0	1.5	100.58
Compile and review	0.5	0.5	0.0	1.0	85.34
Complete paperwork	0.0	0.0	3.0	3.0	101.55
Store/maintain data	0.0	0.0	1.0	1.0	33.85
TOTAL	8.0	2.0	4.0	14.0	1,098.47

Annual Costs: 14 hours x 1,727 responses per year = 24,178 hours

(a) Management: 8 hours x $103.62 x 1,727 responses = $1,431,613.92
(b) Technical: 2 hours x $ 67.05 x 1,727 responses = $ 231,590.70
(c) Clerical: 4 hours x $ 33.85 x 1,727 responses = $ 233,835.80
Total = $1,897,040.42

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

Collection Activities	Burden Hours			Total	
	Mgmt. $103.62/hr	Tech. $67.05/hr	Cler. $33.85/hr	Hours	Costs $
Read Instructions	7.0	0.0	0.0	7.0	725.34
Plan activities	0.5	0.0	0.0	0.5	51.81
Gather/create information	0.0	1.5	0.0	1.5	100.58
Compile and review	0.5	0.5	0.0	1.0	85.34
Complete paperwork	0.0	0.0	3.0	3.0	101.55
Store/maintain data	0.0	0.0	1.0	1.0	33.85
TOTAL	8.0	2.0	4.0	14.0	1,098.47

Annual Costs: 14 hours x 251 responses per year = 3,514 hours

(a) Management: 8 hours x $103.62 x 251 Responses =$208,068.96
(b) Technical: 2 hours x $67.05 x 251 Responses = $ 33,659.10
(c) Clerical: 4 hours x $33.85 x 251 Responses = $ 33,985.40
Total = $275,713.46

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

Collection Activities	Burden Hours			Total	
	Mgmt. $103.62/hr	Tech. $67.05/hr	Cler. $33.85/hr	Hours	Costs $
Read Instructions	7.0	0.0	0.0	7.0	725.34
Plan activities	0.5	0.0	0.0	0.5	51.81
Gather/create information	0.0	1.5	0.0	1.5	100.58
Compile and review	0.5	0.5	0.0	1.0	85.34
Complete paperwork	0.0	0.0	3.0	3.0	101.55
Store/maintain data	0.0	0.0	1.0	1.0	33.85
TOTAL	8.0	2.0	4.0	14.0	1,098.47

Annual Costs: 14 hours x 1,062 responses per year = 14,868 hours

(a) Management: 8 hours x $103.62 x 1,062 Responses = $880,355.52
(b) Technical: 2 hours x $67.05 x 1,062 Responses = $142,414.20
(c) Clerical: 4 hours x $33.85 x 1,062 Responses = $143,794.80
Total = 1,166,564.52

Table 2-D: Type B Activity Burden/Cost Subtotals

Processing Division	Responses	Burden	Cost
AD	1,727	24,178 hours	$1,897,040.42
BPPD	251	3,514 hours	$275,713.46
RD	1,062	14,868 hours	$1,166,564.52
"Type B" Subtotal	3,040	42,560 hours	$3,339,318.40

Table 3: Est. Burden/Cost per "Type C" Reduced Risk Application (RD only)

Collection Activities	Burden Hours			Total	
	Mgmt. $103.62/hr	Tech. $67.05/hr	Cler. $33.85/hr	Hours	Costs $
Read Instructions	22	0	0	22	2,279.64
Gather Information	0	368	0	368	24,674.40
Process, Compile and Review Information	80	80	0	160	13653.60
Record and Report Information	0	0	72	72	2,437.20
Store, File and Maintain Information	0	0	24	24	812.40
TOTAL	102	448	96	646	$43,857.24

Annual Costs: 646 Hours x 10 responses per year = 6,460 Hours

(a) Management: 102 hours x $103.62 x 10 responses = $105,692.40
(b) Technical: 448 hours x $67.05 x 10 Responses = $300,384.00
(c) Clerical: 96 hours x $33.85 x 10 Responses = $ 32,496.00
Total = $421,030.40

6(c) Estimating Agency Burden and Cost

For this ICR renewal, the Agency is using a new data source to estimate the Agency burden. The projected burden figures use 2007 data, which includes burden hours from internal OPP Divisions that provide significant support and analysis for the FIFRA Section 3 ICR registration program.

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. In the past, the Agency burden calculations reflected only the Section 3 ICR FTE activities for the Registration Division (RD), the Biopesticides and Pollution Prevention Division (BPPD), and the Antimicrobial Division (AD) as used in the last renewal. The 2008 renewal now also includes the appropriate FTE activity data from the Heath and Effects Division (HED), the Biological and Economic Analysis Division (BEAD), Special Review and Reregistration Division (SRRD), Field and External Affairs Division (FEAD) and the Environmental Fate and Effects Division (EFED). Thus, eight (8) OPP Divisions work together to complete the activities related to OPP registration actions.[1] The Agency believes using this new 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.

[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.

Using this new source of data the estimated number of Agency FTE's dedicated to Section 3 registration and registration support activities is approximately 22 managerial FTEs as shown in Table 1, 190 technical FTEs as shown in Table 2, and 15 clerical FTEs as shown in Table 3. The aggregated Agency estimated FTE dedicated to Section 3 activities is 227 and the burden hours are 472,160.

Table 1 – Distribution of Agency Managerial FTEs Supporting FIFRA Section 3 Registration and Registration Support Activities[2]

BEAD	RD	EFED	SRRD	FEAD	HED	AD	BPPD
2.0	6.6	3.0	<1	<1	4.4	2.7	2.6
Agency total							22

Annual Agency burden hours were calculated using the number of hours per FTE multiplied by the number of FTE's (2080 x 22=45,760).

Table 2 – Distribution of Agency Technical FTEs Supporting FIFRA Section 3 Registration and Registration Support Activities[2]

BEAD	RD	EFED	SRRD	FEAD	HED	AD	BPPD
15.4	59.7	23.2	<1	<1	39.1	23.4	28.9
Agency total							190

Annual Agency burden hours were calculated using the number of hours per FTE multiplied by the number of FTE's (2080 x 190=395,200).

Table 3 – Distribution of Agency Clerical FTEs Supporting FIFRA Section 3 Registration and Registration Support Activities[2]

BEAD	RD	EFED	SRRD	FEAD	HED	AD	BPPD
1.5	4.6	1.7	<1	<1	1.3	3.1	1.9
Agency total							15

Annual Agency burden hours were calculated using the number of hours per FTE multiplied by the number of FTE's (2080 x 15=31,200).

To determine Agency costs, the Agency used the Bureau of Labor Statistics estimates of 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 labor rates are fully loaded and indexed to 2007 dollars. The fully loaded hourly mean wage rate estimate for managerial occupations is $103.32 for an average annual cost of $214,906 (i.e., $103.32/hour x 2080 hours). For technical occupations, the fully loaded mean wage rate is $71.04 for an average annual cost of $147,763. And for clerical occupations, the fully loaded mean wage rate is $40.76 for an average annual cost of $84,871. (Please see Attachment H - Worksheet for NAICS 999100 EPA or Federal Government Worksheet.)

[2] The FTE burden in SRRD and FEAD for each labor category (managerial, technical and clerical) amounted to significantly less than 1 FTE. The estimate for the Agency FTE for each labor category was rounded up to account for the contribution of FEAD and SRRD to the Section 3 FTE burden.

To calculate the Agency's estimated annual cost of Section 3 activities, the number of FTE's is multiplied by this number allocated to registration activities for each year over the next three years, which is estimated to be $4,727,932 for management (i.e., 22 FTE x $214,906/FTE); $28,074,970 annually for technical (i.e., 190 FTE x $147,763/ FTE); and $1,271,715 for clerical (i.e., 15 FTE x $84,781/FTE). The total estimated Agency cost is $34,074,617.

6(d) Bottom Line Burden Hours and Cost

	ANNUAL TOTAL		
	Responses	Hours	Costs
Annual "Type A" Responses	140	27,160	$1,768,192.80
Annual "Type B" Responses	3,040	42,560	$3,339,318.40
Annual "Type C" Responses	10	6,460	$421,030.40
Total Annual Response Burden	3,190	76,180	$5,528,541.60
Agency Burden Estimate		472,160	$34,074,617

6(e) Reasons for Changes in Burden

There is an annual burden reduction of 76,794 hours as a result of 3,831 fewer expected responses across all response types (i.e., Registration Application Types A through C). The reduction in EPA's respondent response estimate is due, in part, to the identification and elimination of double-counting in the Agency's data systems. In addition, due to some industry consolidation and based on registration maintenance fee data, EPA has identified 375 fewer ICR respondents. Therefore, the estimated 76,794 hour decline in annual paperwork burden hours is an adjustment.

6(f) Burden Statement

The annual average reporting and recordkeeping burdens for a registration applicant respondent are estimated to range from 14 hours to 646 hours, depending upon the type of activity. Estimates for the annual applicant respondent burden for collection of information associated with Type "A" and "B" activities 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. 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-2008-0191, which is available for online viewing at 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.

Submit your comments, referencing Docket ID No. EPA-HQ-OPP-2008-0191 and OMB Control No. 2070-0060, to (1) EPA online using www.regulations.gov (our preferred method), or by mail to: Public Information and Records Integrity Branch (PIRIB), Mail Code: 7502P, Office of Pesticide Programs (OPP), Environmental Protection Agency, 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 20503.

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-2008-0191. 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: **Work Sheets used to Calculate Pesticide Registrant Industry Labor Costs**

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

Attachment I: **Time and Attendance Information System (TAIS) Plan Program Accomplishment (PPA) codes used to calculate EPA and Federal Government Burden Hours**

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

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