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.: 0277.17

Docket ID No.: EPA-HQ-OPP-2015-0332

1(b) Short Characterization/Abstract

This information collection is designed to provide the Environmental Protection Agency (EPA) with the necessary information to evaluate an application for the registration of a pesticide product, as required under Section 3 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA) (see **Attachment A**). Under FIFRA, EPA must evaluate pesticides comprehensively 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, the EPA assesses a wide range of potential human health and environmental effects associated with use of the product. The producer of the pesticide must provide data from tests conducted 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. The assessments involve short-term toxicity and long-term effects such as cancer and reproductive system disorders. The 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. Labeling instructions must be carefully and precisely followed in order 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.

Under FFDCA, EPA sets tolerances, or maximum residue limits, for pesticide residues on foods. In the absence of a tolerance for a pesticide residue, a food containing such a residue is subject to seizure by the government. In setting tolerances, EPA must make a finding that the tolerance is "safe." Safe is defined as meaning that there is a "reasonable certainty that no harm will result from aggregate exposure to the pesticide residue." To make the safety finding, EPA considers, among other things: the toxicity of the pesticide and its break-down products, aggregate exposure to the pesticide in foods and from other sources of exposure, and any special risks posed to infants and children. Some pesticides are exempted from the requirement to have a tolerance. EPA may grant exemptions in cases where the pesticide residues do not pose a dietary risk under reasonably foreseeable circumstances. Information collection activities associated with the tolerance petition process, including generation of residue chemistry data required in 40 CFR part 158 with registration applications for a new food use of a registered pesticide active ingredient, are covered separately under OMB Control No. 2070-0024 (EPA ICR No. 0597).

Pursuant to FIFRA Section 33--Pesticide Registration Service Fees, the Consolidated Appropriations Act of 2004 established the Pesticide Registration Improvement Act, or PRIA (see **Attachment B**). This statute created a registration service fee system for applications specific to pesticide registrations, amended registrations, and associated tolerance actions. Since its approval, PRIA has been reauthorized twice (2007, and 2013). Under PRIA, the EPA is required to make a determination on pesticide registration applications within specified decision time frames. The paperwork burden associated with PRIA fees is covered under a separate ICR, OMB Control No. 2070-0179 (EPA ICR No. 2330).

Registrants may seek, at their discretion, to amend a registration by submitting data and revised, proposed labeling to EPA. Also, registrants of EPA-registered pesticide products at times become subject to regulations or guidance which necessitate labeling revisions. The revised labeling is submitted to the Agency as an amendment along with the completed application (EPA Form 8570-1 and other forms as needed; see **Attachment C**).

In the context of its conventional pesticide registration activities, EPA operates a reduced risk program that offers an incentive through a shortened regulatory review schedule for proposed uses that might be beneficial to the public and the environment owing to their risk profile, compared to alternatives for pest control. The reduced risk program is described in a policy notice known as~~,~~ 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 D**). The guidance in this PR Notice is intended to give expedited review timeframes to new registrations of 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 non-target 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 provide an explanation accompanied by relevant supporting information, including 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.

Although this ICR covers the majority of the information collection activities associated with the pesticide application process, which includes the generation of data under 40 CFR part 158, it is important to note that there are also other ICRs that address registration related information collection activities. For example, the paperwork burden for tolerance petitions is not included in the estimates for this ICR. They are covered in a separate ICR under OMB No. 2070-0024, **Tolerance Petitions for Pesticides on Food/Feed Crops and New Inert Ingredients** (EPA ICR No. 0597).

2. NEED FOR AND USE OF THE COLLECTION

2(a) Need/Authority for the Collection

Authorizing legislation is contained in Section 3 of FIFRA (7 USC 136a7 USC 136a) and section 408 of FFDCA (21 USC 346a). Governing regulations and guidelines are contained in 40 CFR parts 152, 156, 158 (**Attachments E**, **F** and **G**, respectively), and in **PR Notice (PRN) 97-3**. Label amendments under 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 a PRN or notice in the **Federal Register** (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 unit 5(c) of this ICR, entitled "Small Entity Flexibility." On amended applications, the applicant is able to refer to any previously submitted information, thereby satisfying data requirements without the burden of providing duplicate information or additional data development. In fact, EPA's registration program encourages a collaborative approach to developing data whenever relevant, facilitating data citation and ensuring that original data generators/submitters are compensated when their data are cited in another application.

To avoid potential overlap between the requirement of study data in support of an application for the registration for a new food use pesticide active ingredient under FIFRA, and developing data to support a tolerance petition, the EPA allows the use of data required to support a tolerance petition that are already archived in EPA records for use as part of a FIFRA registration of a pesticide to be used in a like manner and in the same use pattern. Information collection activities to establish tolerance limits are covered under the Tolerance ICR (OMB Control No. 2070-0024), and therefore not included in this ICR.

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

Pursuant to 5 CFR 1320.8(d), in proposing to renew this ICR, the EPA published a **Federal Register** Notice (80 FR 34153; June 15, 2015) providing a 60-day public comment period. The Agency received comments from two registrants: the American Chemical Council's Biocides Panel (ACC, or the Panel) and Bayer CropScience LP (Bayer). The comments and EPA's responses are discussed in **Attachment M**, and changes made to the ICR are summarized in this unit of the ICR.

In general, both commenters raised different concerns about whether other registration related activities were properly included in the ICR, and whether EPA's estimated burden and costs significantly underestimated the PRA burden associated with this information collection.

Some of the activities mentioned by the commenters are already covered by other ICRs and are purposely excluded from this one. For example, the burden and costs from archiving data as required under 40 CFR 158 is covered by a separate ICR (see OMB Control No. 2070-0028, Recordkeeping Requirements for Producers of Pesticides under Section 8 of FIFRA). That information collection includes the paperwork burden associated with the storage of study documents developed in accordance with Good Laboratory Practice Standards. Likewise, the paperwork burden for tolerance petitions is not included in the estimates for this ICR because they are covered in a separate ICR (see OMB Control No. 2070-0024, Tolerance Petitions for Pesticides on Food/Feed Crops and New Inert Ingredients). That ICR includes the paperwork burden or costs for studies required under 40 CFR 158, i.e., the cost of residue data, which EPA has chosen to include in the Tolerance Petitions ICR in order to avoid double counting. This includes studies that are submitted with an application for registration of a new food use for a registered pesticide active ingredient. The paperwork burden hours and costs associated with the pesticide registration fee programs are covered under a separate information collection titled Pesticide Registration Fees Program (OMB Control No. 2070-0179).

The Panel's comments focused on the inclusion of adequate burden and costs and activities associated with the 2013 final rule that established 40 CFR part 158 Subpart W to consolidate the data requirements for antimicrobial pesticides in one place. Some comments echoed concern raised for the proposed rule that were addressed in the final rule. For example, consultation on studies or protocols is not required; it remains a long standing practice for EPA to provide assistance whenever circumstances warrant or the registrant requests it. This practice occurs on a case-by-case basis and is not an information collection activity.

Regarding the costs to generate the required studies, the EPA believes Bayer's method of calculating the burden of new A.I. development significantly overestimates the cost. The EPA believes Bayer simply added the cost of all tests for each of the science disciplines (ecological effects, environmental fate, health effects, product chemistry, and residue chemistry) without regard to the use patterns. Since data may or may not be required for a particular use pattern, as indicated in the data requirement tables, the cost for data generation must first be estimated for each use pattern, and then averaged over the use patterns. As reflected in 40 CFR 158, the use patterns the EPA used are terrestrial (food, feed, nonfood), aquatic (food, nonfood), greenhouse (food, nonfood), forestry, residential (indoor, outdoor), indoor (food, nonfood), and industrial uses (the parenthesis represent further granulation, e.g., a greenhouse food use is considered separately from greenhouse nonfood use).

The test costs are periodically updated and represent the study cost that would be sought by an independent laboratory hired to conduct the study. Laboratories consulted are provided with study protocols and asked to provide a high and low estimate. Without comparable information that can be reproduced and is reliable, EPA did not change these estimates.

Prior to submitting comments, Bayer asked EPA to provide additional information supporting a statement in unit 3(e) of the draft supporting statement, which indicated that general OMB guidelines for third party disclosure requirements did not apply to labeling of pesticide products. The Agency has revised relevant sections of this ICR, including unit 3(e), to clarify the basis for the conclusion that the third party disclosure provision do not apply to displaying specific product information on pesticide labeling. Pesticide labels must meet EPA requirements, contain specifically established language, and be approved by EPA. The burden and cost associated with labeling aspects of the application are accounted for in this ICR, but the provision of a label on the product for the intended user is not because the later does not qualify as a collection of information under the terms of the PRA. The EPA has posted Bayer's request and our response email in the docket (**Attachment L**).

The discussion in unit 3(e) of this ICR (the *Electronic submissions* sub-**s**ection) has also been updated to more fully describe both the anticipated overall burden decrease and the recent changes in the electronic data submission portal.

As discussed in the Response to Comment document, although EPA did not incorporate the significant increases in burden estimate that were suggested by the commenters, the Agency is interested in exploring those areas and in the context of developing a revised ICR at the next renewal cycle, using the 3 years from approval of this ICR to explore and discuss alternatives with the registrants and other stakeholders.

3(c) Consultations

Under 5 CFR 1320.8(d)(1), agencies are required to consult with respondents about specific aspects of information collection before submitting approval requests to OMB. In accordance with this regulation, EPA staff contacted representatives from a cross section of stakeholders to seek feedback on the burden estimates in this ICR, and on the clarity of the information collection process. The following three of several companies contacted agreed to receive consultations questions for their responses:

John J. Arthur
BASF Corp.

George Katsigas
Baker Petrolite, LLC

Michael Sarli
United Industries

United Industries provided responses, and agreed with the Agency's burden estimates. See **Attachment H** for contact information for those consulted, the questions asked, and United Industries' responses.

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

Third-party disclosure of label information: Labeling regulations under 40 CFR 156 require registrants to display product specific information to potential users and the general public through the pesticide label that is approved by EPA. The required information for the label is gathered and prepared by the registrant and submitted as part of the application for registration. The burden and cost of preparing and submitting the label information to EPA are included in this ICR as part of the burden associated with preparing the application for registration. The information that must be included as the product labeling is approved and provided to the registrant by EPA as part of the original registration.

This ICR does not, however, include any third party burden or cost estimates for providing the pesticide label on each product so as to disclose use and safety information to potential users and the general public. The use of the pesticide label to accomplish this disclosure, is not a collection of information as defined by the PRA and OMB implementing regulations (5 CFR 1320.3(c)(2)). This determination was made by OMB in the context of implementing the 1995 PRA amendments and related OMB final regulations of 1995. In general, OMB explained that the new 3rd party disclosure provision added to the PRA in 1995 was not intended to require agencies to estimate burden for the required disclosure of important health and safety information on product labels, in particular if the label or language for the label is specifically provided by law (e.g., the Surgeon General warnings required to be on the labels of alcohol or tobacco products), or required to be approved by an agency (e.g., EPA labels on pesticide products or PCB containing transformers).

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 1320.5(d)(2)(iv)). As authorized under FIFRA section 8, EPA regulations under 40 CFR 169.2(k) require that registrants retain records containing research data relating to a registered pesticide, including all data submitted to EPA in support of a registration, 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: While mechanisms and guidance are under development, EPA encourages electronic submissions for the following types of regulatory actions:

- New pesticide active ingredients.
- New pesticide products containing already-registered pesticide active ingredients.
- Amendments to registered pesticide products.

- Experimental use permits.
- Petitions for food tolerance.
- Distributor products.
- Endocrine Disruptor Screening Program (EDSP) Orders.

The Government Paperwork Elimination Act required agencies to make available to the public electronic reporting alternatives to paper-based submissions by 2003, unless there is a strong reason for not doing so. In the past, the Agency was unable to ensure the security of CBI material that might be transmitted over the Internet. Starting in September, 2015, the EPA started offering the Pesticide Submission Portal (PSP), a fully electronic alternative as an option for submitting registration forms electronically, as well as the ability to sign and submit confidential information using Central Data Exchange (CDX) technology. The development of a web-based submission portal is a critical step in the realization of EPA's long-term vision for secure data exchange between registrants and the Agency. (See Attachment N for screen shots of PSP, along with available online instructions and guidance).

The new electronic submission process is a combination of document file uploads and providing information online that is equivalent to existing OMB approved forms that would otherwise be filled out, printed, and mailed to EPA. The PSP leverages the Agency's existing Central Data Exchange (CDX) to provide a secure method of submitting these documents and information within a secure online environment. CDX does require initial user registration for which the paperwork burden estimate is covered under "*Cross-Media Electronic Reporting Rule*" ICR,OMB No. 2025-0003; EPA No. 2002.26.

Application packages and files for pesticide registration can be submitted via PSP. This includes forms, studies, and draft product labeling. Applicants need not submit multiple electronic copies of any pieces of their applications. In PR Notice 2011-3, EPA made clear that the requirement to submit multiple copies of data is applicable only to paper submissions. Similarly, EPA interprets the requirement to submit five copies of draft labeling in 40 CFR 152.50(e) to apply only to applications made on paper. As electronic submissions are easily reproducible, EPA will accept electronic applications containing one electronic copy of all the required elements.

EPA will continue to accept paper applications but encourages applicants to take advantage of this new, more efficient option and forego the courier costs to send to EPA. For electronic submissions, applicants do not need to submit multiple copies of any pieces of their application, the requirement for multiple copies of data and five copies draft labeling only applies to paper submissions.

Whereas existing registration application forms require an ink signature, the web-based portal uses EPA's Central Data Exchange (CDX) to allow applicants to electronically sign and securely submit the required information. The use of CDX is intended to save registrants' and the Agency's time and resources by simplifying data submissions, receipt confirmation, information access and reporting. The electronic reporting option for CBI-related data through EPA's CDX reporting site has only been in place for a few months. Therefore, the Agency has not yet

evaluated whether respondents are more inclined to use the new submission portal, PSP, for that purpose.

While it is too early to be able to quantify any change in burden, the Agency's pesticide program, along with the pesticide industry, recognizes the advantages in terms of accuracy, speed, cost and personnel from electronic data transfer technologies. The Agency believes that the ability to electronically submit information required for registration reduces the burden of sending, receiving, and archiving paper submissions, minimizes errors, and eliminates the need for multiple data entries across forms.

Additional benefits of using the Portal include a status indicator that allows registrants to track the movement of their submissions and automatically generated MRID numbers. Extensive guidance regarding available electronic submission options is available to registrants via OPP's website at http://www2.epa.gov/pesticide-registration/electronic-submissions-pesticide-applications.

Overall, the EPA is continuing to investigate opportunities for technological improvements which focus on information collection using fully electronic tools. OPP continues to consult with industry associations and other federal agencies and is participating in an Agency-wide workgroup to develop electronic reporting standards. One of OPP's priority areas in developing such electronic tools is related to electronic submission of data and labels. Some of the tools discussed in this ICR under this initiative are the electronic Confidential Statement of Product Specifications (CSPS) form (to be used in lieu of the Confidential Statement of Formula or CSF) the SmartLabel, and the web-based PSP.

The web-based submission portal initiative is expected to leverage existing collaboration between Canada and the US toward a harmonized single portal usable for electronic submissions to either Agency. In 2014, under the joint U.S. - Canada *Regulatory Cooperation Council*'s (RCC) *Crop Protection Products Initiative*, OPP and Canada's Pest Management Regulatory Agency (PMRA) developed a joint product specification form (see **Attachment I**). The Confidential Statement of Product Specifications (CSPS) form is intended to provide an optional, fully electronic alternate to the Confidential Statement of Formula, or CSF (EPA Form 8570-4). The proposed joint form (CSPS) is a combined and harmonized version of the CSF form and Canada's Statement of Product Specification Form (SPSF).

The harmonized form reflects a baseline level of information already submitted to either agency in the registration application. While there are some differences between PMRA and EPA information requirements, many CSPS data elements are overlapping. Some data elements on the form are specific to EPA or PMRA requirements, and PMRA requirements that do not overlap with EPA's will not be required for a US registration application. A guidance document as well as detailed form instructions are available to help the applicant determine which fields are required to be completed based on their product type, and the types of content for those fields. For the electronic version of the CSPS, 'tool tips,' help text and validation tools will be available while using the electronic wizard module.

The existing EPA Form 8570-4 (CSF) is currently submitted only on paper, and as a result, no structured data are collected. Each time any change is needed, some of the common

data must be re-entered and submitted on a different form. Because the CSPS would collect structured data, submitters who opt to use the electronic version would be able to access information already stored in the data system to partially complete their submissions such that the data would not need to be reentered for every submission. As most CSF forms submitted to EPA are modifications to previously submitted versions, adoption of an electronic reporting option is anticipated to result in significant time savings for the applicant and the reviewing agency or agencies.

In addition, the electronic wizard module would perform error checks and validations, flagging issues that registrants may need to address before being permitted to advance to the next step in a given submission. One of the error checks performed in the CDX module is CBI claims. If the submitter of the CSPS checks a box to indicate a response includes CBI, the field provided for substantiation of that claim cannot be left blank. This technology is expected to provide significant improvement in data accuracy by reducing common errors such as mathematical calculations. The electronic wizard module would also greatly enhance registrants' ability to correctly designate information for pesticide product types and for food use applications (e.g., with antimicrobial and inert ingredients).

Other information submission methods: With paper submissions, ordinarily, registrants would be required to submit three paper copies of study data to EPA, or two paper copies if they submit the required study data in Adobe Acrobat Portable Document Format (PDF) on a compact disc.

Alternatives to paper-based records and data submissions include the use of "web forms"/XML based submissions via the Agency's Internet site, magnetic media-based submissions (e.g., diskette, CD-ROM, etc.), and now through EPA's new Pesticide Submissions Portal (PSP).

There are two non-CDX based methods by which companies can assemble the e-submission discs for electronic-Submission (or "e-Submissions). 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 newer method introducing the use of a "builder" application. The second, introduced in July 2008, requires the manual editing of the XML file. The XML method of information exchange from industry to EPA is based on a harmonized XML schema used by Canada's PMRA, which OPP has adapted. This harmonization assures industry that a documentation package submitted to one participating regulatory agency can also be submitted to the other participating agency, increasing standardization and decreasing the burden on industry. Additional information about both e-submission methods can be accessed at: http://www2.epa.gov/pesticide-registration/assembly-electronic-packages-and-discs.

3(f) Confidentiality

Although the EPA urges the submitter to minimize the amount of claimed Confidential Business Information (CBI), in accordance with FIFRA Section 10 and 40 CFR Part 2, Subpart B, the EPA will protect from disclosure all data and/or information brought to the Agency in

conjunction with this information collection that may be claimed as trade secret, commercial, or financial information.

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: *The agency is required to display the OMB Control Number and inform respondents of its legal significance in accordance with 5 CFR 1320.5(b).* This was accomplished shortly after approval, and EPA has addressed these terms in **Attachment C**.

4. THE RESPONDENTS AND THE INFORMATION REQUESTED

4(a) Respondents - NAICS Codes

The information collection under this ICR affects individuals or entities engaged in activities related to the registration of pesticide products. There are approximately 1,751 pesticide respondents 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

Application Materials

- Forms for pesticide registration applications.
- Supporting data may be required as part of the submission.
- Draft labeling that meets the regulatory requirements set out in 40 CFR 152.50.

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). These have been described as Types A and B, respectively. In “Type A” activities, applicants for new active ingredients will be required to submit administrative forms, product labeling, a CSF, as well as a full complement of physical chemistry, toxicology, environmental fate, ecological effects, worker exposure, residue chemistry, environmental chemistry, and product performance data, as identified in 40 CFR 158. (Note: Residue chemistry study development is accounted for in a separate ICR for tolerance petitions, as explained in Sections 1(b), 3(a) and 6 of this ICR.)

"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 less data and complexity than "Type A" activities. “Type B” activities include a range of actions from Fee for Service to the less involved label amendments and notifications. 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. There are several types of amendments, or “Type B” activities, 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, has contacted the appropriate company (owning the data that the applicant is referencing), and offered to pay reasonable compensation for the use of the data.

In addition to the two main categories, as described in Section 1(b) of this ICR, the EPA operates a reduced risk program that offers an incentive through an expedited review timeframe for new ingredients or proposed new uses of conventional pesticides that might be beneficial to the public and the environment owing to their risk profile, compared to alternatives for pest control. These activities are described as “Type C” in this ICR.

"Type C" 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. In addition to the registration application itself, “Type C” activities require that the registrant provide a “reduced risk” rationale document addressing risk reduction parameters described in PR Notice 97-3. The items required to be submitted in applications for “reduced risk” chemicals include generic data, product specific data, administrative forms, product labeling, and a CSF. Administrative forms usually include the application for registration, data compensation form, a data matrix, the CSF, and copies of the complete labeling. Applicants for “Type C” registrations provide an explanation accompanied by relevant supporting information, including associated tolerance petitions for special consideration based on these factors. (The paperwork burden for tolerance petitions is covered in a separate ICR under OMB No. 2070-0024.) Products that are successfully classified as presenting potentially reduced risk will receive earlier registration and consequent earlier marketability.

Response Type	**Description/Example**
Type A	**Description:** “Type A” activities support the registration of new active ingredients and

New A.I.s & New Uses	new uses. They 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, as specified in 40 CFR 158. Administrative forms usually include the application for registration and the data compensation forms, a data matrix, the CSF, and copies of the complete labeling. EPA encourages electronic submission of these application types.
	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. The applicant would format the complete data and submit 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 less data and complexity than "Type A" activities. “Type B” activities include both Fee for Service actions, as well as less involved label amendments and notifications. Individually, “Type B” activities often present low burden, but the number of such submissions is high, translating to a large work load for the Agency. 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, the CSF, and copies of the complete labeling. EPA encourages electronic submission of these application types.
	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 support the registration of new active ingredients and new uses that may qualify as "reduced risk" and be given expedited processing. "Type C" 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, the CSF, and copies of the complete labeling. In addition to the registration application itself, “Type C” activities require that the registrant provide a “reduced risk” rationale document addressing risk reduction parameters described in PR Notice 97-3. EPA encourages electronic submission of these application types.
	Example: An example of a "Type C" activity would be an application for registration of a new active ingredient (a.i.) where a “reduced risk” rationale per PR Notice 97-3 is also submitted with the registration application. All of the data requirements and administrative forms described under “Type A” applications must be addressed for “Type C” applications, and in addition the “reduced risk” rationale document must be provided. A new a.i. or new use associated with “Type C” activity is less likely to have risk concerns that would require refined risk assessment on the Agency’s part, or require additional information on the registrant’s part to address risk concerns. An application determined by the Agency to be "reduced risk” is provided an expedited decision time frame under PRIA. This kind of application is of equal complexity to the "Type A" activity, but more complex than "Type B."

The completion and submission of the following forms is necessary to register a pesticide product (see **Attachment C**):

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. 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;
4. Create information	If submitting study data, arrange for testing of any physical chemistry, toxicological, environmental fate, ecological effects, worker exposure, residue chemistry, environmental chemistry, product performance, and

	efficacy data required by germane regulations to support registration.
5. Compile and review	Assemble data, evaluate for accuracy, appropriateness, and completeness;
6. Complete paperwork	Complete all appropriate application documents;
7. Submit registration information (application-related material)	Using preferred option for registration applications, submit required information to the EPA.
8. Store/maintain data	File and maintain copies of all registration data submitted to the Agency.

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

5(a) Agency Activities

In general, the degree and level of Agency activities in the review of data submissions will depend on the complexity of the product being registered, 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.

New Registrations

A product containing a new active ingredient will 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 Antimicrobials 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.

Reduced Risk Registrations

Registrants submitting registration applications for new 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.

Amendments

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

Notifications are registration modifications, 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.

Label Approvals

Label reviews are 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 Antimicrobials Division, and the Biopesticides and Pollution Prevention Division. These divisions ensure that revisions comply with the applicable labeling requirement or guidance.

A general category of OPP's activities related to the information collection described in this ICR is summarized below:

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 OPP's central tracking database system, called OPPIN. 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

The regulatory divisions, based on the registration action, assign the packages for appropriate evaluation. Each scientific discipline reviews the data and may develop a Data Evaluation Report (DER) and appropriate risk assessments that summarize the data review.

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.

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 food use is sought, a tolerance or exemption 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. If the label amendment is approved, a stamped master label is sent to the registrant.

5. Store and Maintain Data

   OPP stores, files, and maintains copies of any registration notices and labeling information.

5(b) Collection Methodology and Management

All registration actions are entered into OPP's central database system, called OPPIN, to track progress toward registration. Registration actions accompanied by data (e.g., products containing new active ingredients or new uses) are also entered into the 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 submission of this information to EPA.

6. ESTIMATING BURDEN AND COST OF THE COLLECTION

The paperwork burden from pesticide registration comes from two sources: the burden that results from preparing and filing the registration application and the PRA burden associated with scientific study data generation. Previous versions of this ICR did not contain estimates of burden associated with data generation. Estimates of the paperwork burden hours and costs from both sources are provided in this section. Tables 1-A and 1-B show the total annual paperwork burden estimates (hours) for this information collection. It should be noted that the number of responses for the application process paperwork burden do not directly correlate with the number of responses for the data generation burden.

The paperwork burden from the application process and from data generation varies by the type of application. For the burden from the application process, applications are grouped into three types—Type A, Type B, and Type C—as previously described. Estimates of the burden and cost from the application process is described for each of these three categories in Section 6(a).

The paperwork burden from study data generation does not occur with all types of registrations, only those that require submission of data. Only new active ingredients (AI), new uses, new products, and some label amendments require such data. The majority of data required for registration of new uses are limited to residue chemistry studies necessary to establish a new tolerance. As indicated in Sections 1(b) and 3(a) of this ICR, the Agency has chosen to account for the burden for generation of residue chemistry data used for tolerances in the tolerance petition ICR, whether the data is submitted with an application for a new food use of a pesticide active ingredient or as part of a petition seeking a tolerance. The EPA believes that is the best place for it – as most of that data is generated with petitions and not for the initial application.

Therefore, the paperwork burden from generation study data for new uses would be covered by the Tolerance ICR (OMB Control No. 2070-0024) and is not discussed in this ICR. Estimates of the paperwork burden and the costs of data generation associated with new AIs and new products is discussed in Section 6(b).

Annual aggregate paperwork burden for all respondent Section 3 activities is estimated to be 15 million hours: 145,213 hours for application activities and 1.38 million hours from data generation. There are currently an estimated 1,751 pesticide registrants holding at least one pesticide registration. The number of pesticide registrants has increased since the last ICR renewal from 1,683 to 1,751, an increase of 68 registrants.

The total annual costs associated with paperwork burden from the application process are estimated to be approximately $12.47 million per year.

- “Type A” activities are estimated to cost approximately $2.76 million per year.
- “Type B” activities are estimated to cost approximately $9.32 million per year.
- “Type C” activities are estimated to cost approximately $389 thousand per year.

Table 1-A: Annual Information Collection Paperwork Burden Estimates for Registration Application Process

Application Category	Number of registrants (respondents)	Average annual responses	Average annual responses per respondent	Burden per response (hours)	Average annual burden per respondent	Average annual burden (hours)
Type A	1,751	197	0.113	194	22	38,218
Type B	1,751	7,273	4.154	14	58	101,827
Type C	1,751	8	0.005	646	3	5,168
All Types	**1,751**	**7,478**	**4.271**		**83**	**145,213**

The total annual costs associated with the paperwork burden from data generation are estimated to be approximately $96.25 million per year.

- The paperwork burden from data generation for new active ingredients (AI) is estimated to cost approximately $62.59 million per year.
- The paperwork burden from data generation for new products is estimated to cost approximately $33.66 million per year.

Table 1-B: Annual Information Collection Paperwork Burden Estimates for Data Generation

Registration Type	Number of registrants (respondents)	Average annual responses	Average annual responses per respondent	Average Burden per response (hours) [1]	Average annual burden per respondent (hours)	Average annual burden (hours) [2]
New AI	1,751	30	0.017	37,078	628	897,149
New Product	1,751	695	0.397	625	248	482,531
All Types	**1,751**	**725**	**0.414**		**876**	**1,379,680**

[1] Average burden hours per response across the three registering divisions. See Tables 6-A and 6-B for details.
[2] Average annual burden hours are calculated as the sum of average annual burden hours for each registration type and cannot be computed from the values in this table. See Tables 6-B and 7-B for details.

To calculate the costs of the paperwork burden from the application process and from data generation, the burden hours were multiplied by current wages. Agency economists revised the estimated wages, benefits and overhead for all labor categories for the affected industry 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 wage rates and overhead costs for this ICR renewal are presented in **Attachment J.** Cost estimates are provided in the following sections.

6(a) Respondent Paperwork Burden Hours and Cost from Application Process

This section describes the methodologies and provides estimates of respondent paperwork burden hours and costs from the application process. The reporting and recordkeeping burden associated with the Section 3 application process for registering 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).

To determine the appropriate number of applications (responses) for each category, the EPA averaged data on pesticide registration activities from 2012-2014. When the Agency receives applications for registrations and amendments to registrations, these actions are tracked in OPP's 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 registration-related applications in greater detail. Information from the central database and supplemental divisional tracking is used as the basis of the burden estimates.

The average number of responses annually has changed since the last ICR renewal from 8,136 to 7,478, a decrease of about eight percent. Table 2 shows the average number of applications per year by type and division. Across all registering divisions, there were 7,478 Section 3 registration actions annually, on average, during the years 2012-2014. These included an average of 197 "Type A" activities, 7,273 "Type B" activities, and 8 "Type C" activities.

Table 2: Average Annual Number of Actions by Type and Division, 2012-2014 Average

	AD	BPPD	RD	All Divisions
Type A	16	22	159	197
Type B	2,254	575	4,444	7,273
Type C	0	0	8	8
All Action Types	2,270	597	4,612	7,478

Table 3-A presents estimates for burden hours and costs per "Type A" registration application. Each "Type A" application is estimated to require 26 management hours, 128 technical hours, and 40 clerical hours for a total of 194 hours per application at a cost of 14,019.

Table 3-A: Estimated Burden/Cost per "Type A" Registration Application

Collection Activities, Type A	Burden Hours			Total	
	Mgmt.	Technical	Clerical	Hours	Costs
	$121.72/hr	$72.01/hr	$40.93/hr		
Read Instructions	18	0	0	18	$2,191
Plan activities	4	0	0	4	$487
Gather/create information	0	120	0	120	$8,641
Compile and review	4	8	0	12	$1,063
Complete paperwork	0	0	30	30	$1,228
Submit information					
Store/maintain data	0	0	10	10	$409
Third party disclosure					
TOTAL	26	128	40	**194**	**$14,019**

Table 3-B presents the total annual burden hours and costs by division for "Type A" registration applications. Registrants spend a total of 3,104 burden hours at a cost of $224 thousand to prepare and submit "Type A" applications to the Antimicrobial Division, 4,203 burden hours at a cost of $304 thousand to prepare and submit "Type A" applications to the Biopesticides and Pollution Prevention Division, and 30,911 hours at a cost of $2.234 million to prepare and submit "Type A" applications to the Registration Division. The total paperwork burden and cost associated with preparing and submitting "Type A" registration applications to EPA is estimated at $2.762 million per year.

Table 3-B: Total Annual Burden and Cost by Division for "Type A" Registration Applications [1]

Labor Category [2]	AD		BPPD		RD		Total	
	Hrs.	Cost	Hrs.	Cost	Hours	Cost	Hours	Cost
Management	416	$50,636	563	$68,569	4,143	$504,245	5,122	$623,450
Technical	2,048	$147,476	2,773	$199,708	20,395	$1,468,620	25,216	$1,815,804
Clerical	640	$26,195	867	$35,473	6,373	$260,861	7,880	$322,528
TOTAL	3,104	$224,307	4,203	$303,749	30,911	$2,233,726	**38,218**	**$2,761,782**

[1] Hours are calculated by multiplying hours per labor category from Table 3-A by the average number of applications for that division from Table 2. For example, 416 management hours for AD is calculated as 26 management hours per "Type A" application multiplied by 16 "Type A" applications in AD per year.
[2] Hours and wages used to calculate the totals for each labor category are from Table 3-A.

Table 4-A presents estimates for burden hours and costs per "Type B" applications/notifications. Each "Type B" application is estimated to require 8 management hours, 2 technical hours, and 4 clerical hours for a total of 14 hours per application at a cost of 1,282.

Table 4-A: Estimated Burden/Cost per "Type B" Registration Application/Notification

Collection Activities, Type B	Burden Hours			Total	
	Mgmt.	Technical	Clerical	Hours	Costs
	$121.72/hr	$72.01/hr	$40.93/hr		
Read Instructions	7	0	0	7	$852
Plan activities	0.5	0	0	0.5	$61
Gather/create information	0	1.5	0	1.5	$108
Compile and review	0.5	0.5	0	1	$97
Complete paperwork	0	0	3	3	$123
Submit information					
Store/maintain data	0	0	1	1	$41
Third party disclosure					
TOTAL	8	2	4	**14**	**$1,282**

Table 4-B presents the total annual burden hours and costs by division for "Type B" applications/notifications. Registrants spend a total of 31,551 burden hours at a cost of $2.888 million to prepare and submit "Type B" applications to the Antimicrobial Division, 8,055 burden hours at a cost of $737 thousand to prepare and submit "Type B" applications to the Biopesticides and Pollution Prevention Division, and 62,221 hours at a cost of $5.695 million to prepare and submit "Type B" applications to the Registration Division. The total paperwork burden and cost associated with preparing and submitting "Type B" applications to EPA is estimated at $9.321 million per year.

Table 4-B: Total Annual Burden and Cost by Division for "Type B" Registration Applications [1]

Labor Category [2]	AD		BPPD		RD		Total	
	Hrs.	Cost	Hrs.	Cost	Hrs.	Cost	Hours	Cost
Management	18,029	$2,194,530	4,603	$560,237	35,555	$4,327,714	58,187	$7,082,481
Technical	4,507	$324,573	1,151	$82,860	8,889	$640,073	14,547	$1,047,505
Clerical	9,015	$368,970	2,301	$94,194	17,777	$727,626	29,093	$1,190,790
Total	31,551	$2,888,074	8,055	$737,290	62,221	$5,695,413	**101,827**	**$9,320,777**

[1] Hours are calculated by multiplying hours per labor category from Table 4-A by the average number of applications for that division from Table 2. For example, 18,029 management hours for AD is calculated as 8 management hours per "Type B" application multiplied by 2,254 "Type B" applications in AD per year.
[2] Hours and wages used to calculate the totals for each labor category are from Table 4-A.

Table 5-A presents estimates for burden hours and costs per "Type C" reduced risk application. Each "Type C" application is estimated to require 102 management hours, 448 technical hours, and 96 clerical hours for a total of 646 hours per application at a cost of $49 thousand.

Table 5-A: Estimated Burden/Cost per "Type C" Reduced Risk Registration Application

Collection Activities, Type C	Burden Hours			Total	
	Mgmt.	Technical	Clerical	Hours	Costs
	$121.72/hr	$72.01/hr	$40.93/hr		
Read Instructions	22	0	0	22	$2,678
Gather Information	0	368	0	368	$26,500
Process, Compile, and Review Info	80	80	0	160	$15,498
Record and Report Info	0	0	72	72	$2,947
Store, File, and Maintain Info	0	0	24	24	$982
TOTAL	102	448	96	**646**	**$48,605**

Table 5-B presents the total annual burden hours and costs for "Type C" reduced risk applications. Registrants spend a total of 5,168 burden hours at a cost of $389 thousand to prepare and submit "Type C" applications to the Registration Division. The Antimicrobial Division and the Biopesticides and Pollution Prevention Division do not receive "Type C" applications.

Table 5-B: Total Annual Burden and Cost for "Type C" Reduced Risk Registration Applications [1]

Labor Category [2]	RD	
	Hours	**Cost**
Management	816	$99,324
Technical	3,584	$258,084
Clerical	768	$31,434
Total	**5,168**	**$388,842**

[1] Hours and costs are calculated using the same method as Tables 3-B and 4-B.
[2] Hours and wages used to calculate the totals for each labor category are from Table 5-A.

6(b) Respondent Paperwork Burden Hours and Cost from Data Generation

To calculate the burden and costs associated with the paperwork activities involved in data generation, the Agency starts with the cost of the test, typically the market price for the test as identified by laboratories that offer testing services. The Agency maintains an archive of the basic FIFRA study cost estimates that were developed through surveys of independent testing laboratories, Agency economic analyses, and registrant comments during ICR renewal periods. To the greatest extent possible, EPA uses multiple sources to provide test cost estimates, which are updated as needed.

EPA uses 35% of the estimated total test cost to calculate the total potential cost for the paperwork activities related to data generation. The 35% of test cost is disaggregated by labor category, and then burden hours are extrapolated by using the loaded labor rates. To disaggregate by labor category, the Agency considered the estimated distribution of paperwork activity across the labor categories represented and the existing methodology assumption that paperwork activities for data generation mostly involve the technical staff to perform the tests, with fewer activities related to management and clerical staff.

Figure 1 illustrates the method for calculating the paperwork burden of data generation.

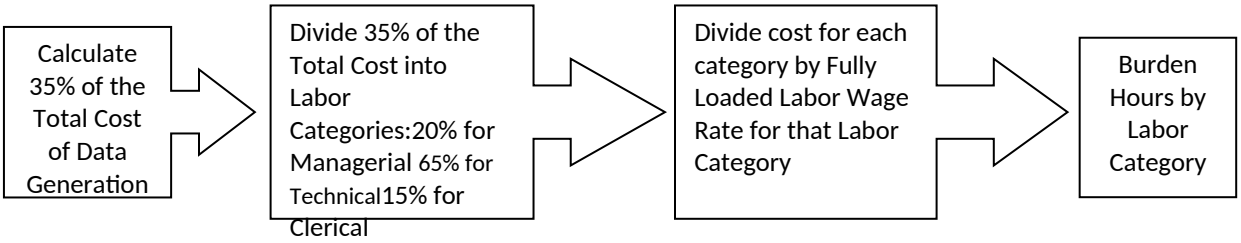

Figure 1: Method for Calculating Paperwork Burden from Test Costs

Similar to the data call-in or DCI ICR (OMB Control No. 2070-0174), this approach assumes and incorporates the following core considerations:

(1) Registrants generate all of the data as specified in the CFR without any changes, and none of the data is waived.

(2) All data generation is performed by an independent laboratory.

(3) Paperwork burden is disaggregated by labor category as follows:

a. Managerial (20%)
b. Technical (65%)
c. Clerical (15%)

(4) Labor rates are fully loaded, meaning that they include the estimated costs of wages, overhead, and benefits paid to an employee. See **Attachment J**.

Using this methodology, Tables 6-A and 6-B below estimate the paperwork burden associated with registering a new AI and a new product for each of the three registering divisions: the Antimicrobial Division (AD), the Biopesticides and Pollution Prevention Division (BPPD), and the Registration Division (RD). The costs of registering a new AI vary depending on use parameters, e.g., food or non-food use, indoor or outdoor use pattern. The data costs used to calculate paperwork burden are an average of total costs across different types of uses that might be registered in that division.

Table 6-A shows that the average cost of data for registering a new AI ranges from an average of $4.65 million for a new biopesticide to an average of $8.97 million for a new conventional chemical. The paperwork burden, 35% of the cost of data generation, ranges from $1.63 million to $3.14 million or between 23 thousand and 45 thousand hours of burden.

Table 6-A: Estimates of Paperwork Burden Hours from Data Generation for New AIs

Division	Data Cost ($000s)	Paperwork Cost ($000s)	Managerial		Technical		Clerical		Total	
			Hours	FTEs	Hours	FTEs	Hours	FTEs	Hours	FTEs
AD	$8,550	$2,993	4,918	2.4	27,016	13.0	10,969	5.3	42,903	20.6
BPPD	$4,645	$1,626	2,672	1.3	14,677	7.1	5,959	2.9	23,308	11.2
RD	$8,973	$3,141	5,161	2.5	28,352	13.6	11,511	5.5	45,024	21.6

Table 6-B shows the calculation of average annual burden hours and costs from paperwork from data generation for new AIs. The burden per registration is taken from Table 6-A. Average annual burden hours is calculated from the average annual responses and burden per registration. Average annual costs is calculated from the average annual responses and average paperwork cost from Table 6-A.

Table 6-B: Estimates of Annual Paperwork Burden Hours and Cost from Data Generation for New AIs

	Burden per Registration [1]	Average Annual Responses	Average Annual Burden Hours	Average Annual Cost [2]
Antimicrobial	42,903	2	85,806	$5,986,000
Biochemical	23,308	20	466,156	$32,520,000
Conventional	45,024	8	345,187	$24,081,000
TOTAL		30	897,149	$62,587,000

[1] Burden per registration for New AIs from Table 1-B is the average of these values.
[2] Numbers do not compute due to rounding.

Table 7-A shows that the cost of data for registering a new product ranges from $115 thousand to $155 thousand. The paperwork burden, 35% of the cost of data generation, ranges from $36 thousand to $54 thousand or between 520 and 777 hours of burden.

Table 7-A: Estimates of Paperwork Burden Hours from Data Generation for New Products

Division	Data Cost[1]	Paperwork Cost[1]	Managerial		Technical		Clerical		Total	
			Hours	FTEs	Hours	FTEs	Hours	FTEs	Hours	FTEs
AD	$103,800	$36,300	60	0.03	328	0.16	133	0.06	520	0.25

BPPD	$115,400	$40,400	66	0.03	365	0.18	148	0.07	579	0.28
RD	$155,000	$54,200	89	0.04	489	0.24	199	0.10	777	0.37

[1] Rounded to nearest hundred.

Table 7-B shows the calculation of average annual burden hours and costs from paperwork from data generation for new AIs. The burden per registration is taken from Table 7-A. Average annual burden hours is calculated from the average annual responses and burden per registration. Average annual costs is calculated from the average annual responses and average paperwork cost from Table 7-A.

Table 7-B: Estimates of Annual Paperwork Burden Hours and Cost from Data Generation for New Products

	Burden per Registration [1]	Average Annual Responses	Average Annual Burden Hours	Average Annual Cost [2]
Antimicrobial	520	172	89,325	$6,231,500
Biochemical	579	68	39,187	$2,733,733
Conventional	777	456	354,019	$24,697,133
TOTAL		695	482,531	$33,662,367

[1] Burden per registration for New Products from Table 1-B is the average of these values.
[2] Numbers do not compute due to rounding.

The costs used to estimate paperwork burden of data generation in this analysis are conservative because they assume that all new active ingredients generate and submit all data required in 40 CFR Part 158 when, in practice, some of the data requirements may be waived based on specific use patterns or label restrictions. Data waivers would make the average cost of data generation (and the resulting paperwork burden) lower for both new active ingredients and new products. Also, all new products in this analysis are assumed to require toxicology data and product chemistry data to register. In cases where products are substantially similar to other products, they can cite other data rather than generating data. Again, this approach returns conservative estimates of paperwork burden for data generation.

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 2012-2014 data, which include 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 FTEs dedicated to Section 3 registration and registration support activities is approximately 26 managerial FTEs, 171 technical FTEs, and 7 clerical FTEs as shown in Table 8 below. The aggregated Agency estimated FTE dedicated to Section 3 activities is 205 and the burden hours are 426,400.

To determine Agency costs, the Agency used the Bureau of Labor Statistics estimates of 2014 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 $121.79 for managerial occupations, $80.02 for technical occupations, and $45.56 for clerical occupations. (See **Attachment J** for wage calculations.)

To calculate the Agency's estimated annual cost of Section 3 activities, the number of FTE's allocated to registration activities (Table 8) is multiplied by these fully loaded labor rates and by 2,080 hours per FTE, which is estimated to be about $6.70 million for management; $28.44 million for technical; and $703 thousand for clerical. The total estimated Agency cost is $35.84 million.

Table 8: Distribution of Agency FTEs Supporting FIFRA Section 3 Registration Activities [1]

	BEAD	RD	EFED	HED	AD	BPPD	Total FTEs	Hourly wage	Total Annual Cost[2]
Managerial	2.9	7.4	2.4	7.1	3.2	3.4	26.4	$121.79	$6,698,844
Technical	16.5	54.6	14.7	38.1	22.7	24.2	170.9	$80.02	$28,441,551
Clerical	0.7	2.0	0.7	1.5	1.1	1.4	7.4	$45.56	$703,397
Total	**20.2**	**64.1**	**17.8**	**46.7**	**26.9**	**29.0**	**204.7**		**$35,843,792**

[1] Numbers in the table may not add due to rounding.
[2] Total annual cost is calculated using the number of hours per FTE multiplied by the number of FTEs and the hourly wage. For example, total annual cost of managerial FTES is calculated as 2,080 hours/FTE x 26.4 FTEs x $121.79.

6(e) Bottom Line Burden Hours and Cost

Table 9 presents the estimates for total annual hours and cost, for both respondents and the agency, associated with Section 3 activities. The total respondent burden is 1.52 million hours annually at a cost of $108.72 million. The majority of this paperwork burden, 1.38 million hours, is associated with data generation.

Table 9: Estimated Annual Total Hours and Cost

	ANNUAL TOTAL		
	Responses	**Hours**	**Costs**
TOTAL RESPONDENT BURDEN	**8,203**	**1,524,893**	**$108,720,767**
Application Process	**7,478**	**145,213**	**12,471,401**
Annual "Type A" Responses	197	38,218	$2,761,782
Annual "Type B" Responses	7,273	101,827	$9,320,777
Annual "Type C" Responses	8	5,168	$388,842

Data Generation	**725**	**1,379,680**	**96,249,367**
New AIs	30	897,149	$62,587,000
New Products	695	482,531	$33,662,367
TOTAL AGENCY BURDEN		**425,873**	**$35,843,792**

6(f) Reasons for Change in Burden

The annual respondent paperwork burden for the application process has decreased by about 23,000 hours due to fewer applications in each category. There were 52 fewer “Type A” responses, 599 fewer “Type B” responses, and 7 fewer “Type C” responses annually on average in the years 2012-2014 than there were in the years 2008-2010. Agency burden also reflects the lower number of responses in this renewal cycle; agency hours decreased from 478,400 (230 FTEs) to 425,873 (205 FTEs).

The increase in total respondent burden is not a change in paperwork burden per se but rather a change in what is included in this ICR. Paperwork burden from data generation was not previously included in these burden estimates. EPA included estimates of that burden in this renewal; the estimates follow the methodology used to estimate the paperwork burden of data call-ins or DCIs (OMB Control No. 2070-0174).

Overall, there is a difference of 1,356,689 hours in the total estimated respondent burden compared with that identified in the current ICR approved by OMB. This change reflects EPA’s updating of the methodology used to estimate the paperwork burden, and including a previously unaccounted for burden for study data generation. However, there is a decrease of approximately 23,000 hours in the total estimated respondent burden for the registration application process compared with that identified in the ICR currently approved by OMB. This decrease reflects EPA's receipt of fewer number of applications. This change is an adjustment.

6(g) Burden Statement

The annual average reporting and recordkeeping burdens for a registration application are estimated to range from 14 hours to 646 hours, depending upon the type of activity. Estimates for the respondent’s application burden for this 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 burden estimate for “Type C” reduced risk applications, which are handled only by RD, is an average of 646 hours per response.

The annual average reporting and recordkeeping burdens for data generation associated with registration of new active ingredients and new products are estimated to range from 520 hours to 45,000 hours, depending on the type of activity and division. For new active ingredients, estimates for the respondent’s paperwork burden for data generation average 45,024 hours for a new conventional, 42,903 for a new antimicrobial, and 23,308 for a new biopesticide. For new products, estimates for the respondent’s paperwork burden for data generation average 777 hours for a new conventional product, 520 hours for a new antimicrobial, and 579 hours for a new biopesticide.

Burden is defined in 5 CFR 1320.3(b). An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a current and valid OMB control number. The OMB control numbers for EPA's regulations in title 40 of the CFR, after appearing in the Federal Register, are listed in 40 CFR part 9 and included on the related collection instrument or form, if applicable.

6(h) Docket Information

The Agency has established a docket for this ICR under Docket ID No. EPA-HQ-OPP-2015-0332, which is available for online viewing at http://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-2015-0332 and OMB Control No. 2070-0060, to both EPA and OMB as follows:

- To EPA online using http://www.regulations.gov (our preferred method) or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave., NW, Washington, DC 20460, and
- To OMB via email to oira_submission@omb.eop.gov. Address comments to *OMB Desk Officer for EPA.*

7. 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-2015-0332. 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 US Code website
Attachment B:	**7 U.S.C. 136w-8 – Section 33 of FIFRA.** Pesticide registration service fees. Also available online at US Code website.
Attachment C:	**Forms for Pesticide Registration**. http://www.epa.gov/opprd001/forms/

C – 1. *EPA Form 8570-1* - Application for Pesticide, Registration, Amendment, Other **C – 2.** *EPA Form No. 8570-4* - Confidential Statement of Formula **C – 3.** *EPA Form No. 8570-27* - Formulator's Exemption Statement **C – 4.** *EPA Form No. 8570-34* - Certification with Respect to Citation of Data Form **C – 5.** *EPA Form No. 8570-35* - Data Matrix Form **C – 6.** *EPA Form No. 8570-36* - Summary of the Physical/Chemical Properties Form **C – 7.** *EPA Form No. 8570-37* - Self-Certification Statement for the Physical/Chemical Properties	
Attachment D:	**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 E:	**40 CFR 152 – Pesticide Registration and Classification Procedures.** Also available online at the National Archives and Records Administration's Electronic CFR Website
Attachment F:	**40 CFR 156 – Labeling Requirements for Pesticides and Devices.** Also available at: Electronic CFR Website.
Attachment G:	**40 CFR 158 – Data Requirements For Registration.** Also available online at the Electronic CFR Website.
Attachment H:	**Consultation: List of Standard Questions & Responses**
Attachment I:	**Proposed New e-CSF with Instructions and Relevant Information**
Attachment J:	**EPA ICR Number 0277.17 Labor Wage Formulas.** Work Sheets used to Calculate Pesticide Registrant Industry Labor Costs; 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 at: Electronic CFR Website.
Attachment L:	Registrant Communication with EPA (Bayer CropScience LP)
Attachment M	Public Comments & EPA Responses
Attachment N	Pesticide Submission Portal (PSP): Screen Shots, Instructions and Related Guidance