SUPPORTING STATEMENT FOR AN INFORMATION COLLECTION REQUEST (ICR)

1. Identification of the Information Collection

1(a). Title of the Information Collection

Title: **Data Requirements for Antimicrobial Pesticides (Proposed Rule)**

EPA ICR No. **2318.01** OMB Control No. **2070-(new)**

1(b). Short Characterization/Abstract

This Information Collection Request (ICR) covers the information collection activities contained in the proposed rule entitled: "**Data Requirements for Antimicrobial Pesticides,"** identified in the Regulatory Agenda under RIN 2070-AD30. In the proposed rule, EPA is:

- Proposing newly codified data requirements, which are not currently established in part 161, but are routinely considered in current practice.
- Proposing changes to some of the existing data requirements such as a change from conditionally-required to required, a change in the number of test species, or expanding the number of use patterns for which the test is required.
- Proposing new data requirements, which have never been required or has rarely been required on a case-by-case basis, and has not been routinely considered during the Agency's evaluation of the data needed for the purpose of risk assessment.
- Proposing to eliminate the requirement for the chronic nonrodent study currently established in part 161.

You may access the proposed rule and related supporting information in Docket ID No. EPA–HQ–OPP–2008-0110 at www.regulations.gov.

The information collection activities related to the submission of data to EPA in order to register, amend or retain a new or existing pesticide product or obtain a tolerance for that product are already approved by OMB under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq*. As such, this ICR only addresses the proposed *changes* that impact the information collection activities related to antimicrobial pesticides. The procedures for submitting data to EPA under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug, and Cosmetic Act (FFDCA) are not changing in this proposal, and are already approved by OMB as follows:

1. Data Submission Activities Associated With Tolerance Actions (currently approved under OMB Control No. 2070-0024 (EPA ICR No. 0597));
2. Data Submission Activities Associated With The Application For A New Or Amended Registration Of A Pesticide (currently approved under OMB Control No. 2070-0060 (EPA ICR No. 0277));
3. Data Submission Activities Associated With The Generation Of Data For

Reregistration (currently approved under OMB Control No. 2070-0107 (EPA ICR No. 1504)); and

4. Data Submission Activities Associated With The Generation Of Data For Special Review Or Registration Review (currently approved under OMB Control No. 2070-0057 (EPA ICR No. 0922)).

Since the revised data requirements in the proposed rule may result in changes to each of these ICRs when this rule is finalized, EPA is providing this ICR to discuss those changes and the Agency's burden estimates related to the changes. EPA is seeking comment on these estimates, along with the proposed rule. At the final rule stage, after considering comments received and revising the ICR to reflect the final rule, EPA will submit a revised ICR to OMB for review and approval. Once approved by OMB, the burden estimate in this ICR will be apportioned among the existing ICRs as appropriate.

The following is a brief description of each of the currently approved ICRs that are listed above.

1(b)(i). Tolerance Actions. The submission of data in support of a petition to establish, revoke or amend a tolerance or an exemption from the requirement to have a tolerance, which is currently covered by the existing ICR entitled "Tolerance Petitions for Pesticides on Food/ Feed Crops and New Inert Ingredients" (OMB Control No. 2070-0024 (EPA ICR No. 0597)). Under the FFDCA, EPA is responsible for ensuring that the maximum residue levels likely to be found in or on food/feed are safe for human consumption through a careful review and evaluation of residue chemistry and toxicology data. In addition, EPA must ensure that adequate enforcement of the tolerance can be achieved through the testing of submitted analytical methods. If the data are adequate for EPA to determine that there is a reasonable certainty that no harm will result from aggregate exposure, the Agency will establish the tolerance or grant an exemption from the requirement of a tolerance.

1(b)(ii). Registration Actions. The submission of data in support of an application for a new or amended registration of a pesticide product as required under FIFRA section 3, and FFDCA, which is currently covered by the existing ICR entitled "Application for New and Amended Pesticide Registration" (OMB Control No. 2070-0060 (EPA ICR No. 0277)). EPA is required to 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. 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.

1(b)(iii). *Re*registration Actions. The submission of data necessary to support the continued registration of any pesticide active ingredient originally registered before November 1, 1984, as mandated by Section 4 of FIFRA, which is currently covered by the existing ICR entitled "Data Generation for Pesticide Reregistration" (OMB Control No. 2070-0107 (EPA ICR No. 1504)). Section 3(c)(2)(B) of FIFRA authorizes EPA to require that pesticide registrants generate and submit to the Agency any such data needed to make this assessment. Section 4 of FIFRA also establishes a process for the development of information needed to make reregistration decisions. Pesticide registrants seeking reregistration must generate and report the required data according to specific time tables. For the most part, EPA is in Phase 4 of the process prescribed in FIFRA section 4.

1(b)(iv). Special or Registration Review Actions. The submission of data necessary to assess whether the continued registration of an existing pesticide causes an unreasonable adverse effect on human health or the environment, which is currently covered by the existing ICR entitled "Data Call-Ins for the Special Review and Registration Review Programs" (OMB Control No. 2070-0057 (EPA ICR No. 0922)). Section 3(c)(2)(B) of FIFRA authorizes EPA to require that pesticide registrants generate and submit to the Agency any such data needed to make this assessment.

The Special Review process is set in motion when EPA has reason to believe that the use of a pesticide may result in unreasonable adverse effects to human health or the environment. The goal of this process is to reduce the risks posed by a pesticide to an acceptable level while taking into consideration the benefits provided by the use of the pesticide.

The Registration Review process ensures that the Agency will periodically review all existing pesticide registrations as required by FIFRA Section 3(g), with a goal of reviewing a pesticide's registration once every 15 years and to ensure continued protection of human health and the environment throughout the "life" of each pesticide's registration.

2. Need For and Use of the Collection

2(a). Need/Authority for the Collection

The proposed rule is issued under the authority of sections 3, 4, 5, 10, 12, and 25 of FIFRA and section 408 of FFDCA. The data required for a registration, reregistration, experimental use permit, or tolerance are listed in 40 CFR parts 158 and 161, and once finalized the data requirements in this proposed rule will also be codified in 40 CFR part 158. The collection of information covered by this ICR is needed to ensure that the statutory requirements related to the registration of antimicrobial pesticides can be met by the public and EPA.

For additional information about the statutory and historical framework, see Unit III. of the preamble in the proposed rule. In addition, the following is an overview of the

distribution of this authority with regard to the existing ICRs.

2(a)(i). Tolerance Actions. The tolerances for pesticide residues in food or feed are set primarily under the authority of section 408 of FFDCA, as amended. The Agency takes these tolerance actions either on its own initiative pursuant to FFDCA §408(e) or in response to a petition filed pursuant to FFDCA §408(d). The regulations covering tolerances are contained in Title 40 of the Code of Federal Regulations (CFR) Part 180. Actual listings of individual tolerances by chemical are also found in Part 180.

Under FFDCA §408(d), any person may file a petition with EPA, proposing the issuance of a regulation establishing, modifying, or revoking (a) a tolerance for a pesticide chemical residue in or on food, or (b) an exemption from the requirement to have a tolerance for such residue. The Agency publishes a notice of receipt for such petitions in order to provide an opportunity for public comment on the request, and then either issues a final regulation, or a notice denying the petitioner's request. FFDCA §408(d)(4) directs the Agency to issue a final regulation establishing, modifying, or revoke a tolerance for the pesticide chemical residue or an exemption of the pesticide chemical residue from the requirement of a tolerance, or issue an order denying the petition.

Under FFDCA §408(e), at any time the Agency may issue a regulation establishing, modifying, suspending, or revoking (a) a tolerance for a pesticide chemical residue in or on food, or (b) an exemption from the requirement to have a tolerance for such residue. When initiating such actions, FFDCA §408(e)(2) requires the Agency to issue a notice of proposed rulemaking to provide an opportunity for public comment.

The Food Quality Protection Act of 1996 (FQPA), which amended the two primary statutes regulating pesticides, i.e., FFDCA and FIFRA, requires that tolerances be set at a level to ensure that there be "a reasonable certainty that no harm will result from aggregate exposure." Among other things, FQPA requires EPA to consider a number of factors when setting such tolerances or registering pesticide products, including:

(1) special protection for infants and children;
(2) aggregate exposure and risk from foods and other known sources, such as drinking water and household pesticide use;
(3) consideration of common mechanisms of toxicity (some chemicals have different molecular structures but cause deleterious effects in the same manner); and,
(4) consideration of endocrine disruptor effects.

The collection of information covered by this ICR is needed to ensure that the statutory requirements related to tolerances can be met by the public and EPA. Food or feed commodities found to contain residues of a pesticide without or in excess of established tolerances are considered adulterated, and are subject to seizure by FDA, and may result in civil penalties.

2(a)(ii). Registration Actions. 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 E, F, and G, 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(a)(iii). *Re*registration Actions. EPA implements the reregistration program pursuant to the authority in section 4 of FIFRA, as amended. EPA is required to collect additional information, as necessary, to determine whether active pesticide ingredients initially registered before November 1, 1984, are eligible for reregistration.

2(a)(iv). Special or Registration Review Actions. FIFRA §3(a) and §12(a)(1) require a person to register a pesticide product with the EPA before the pesticide product may be lawfully sold or distributed in the United States. A pesticide registration is a license that allows a pesticide product to be sold and distributed for specific uses under specified terms and conditions such as use instructions and precautions. The proponent of initial or continued registration always bears the burden of demonstrating that a pesticide product meets the statutory standard for registration. A pesticide product may be registered or remain registered only if it meets the statutory standard for registration given in FIFRA §3(c)(5), which is as follows:

(A) Its composition is such as to warrant the proposed claims for it.
(B) Its labeling and other material required to be submitted comply with the requirements of this Act.
(C) It will perform its intended function without unreasonable adverse effects on the environment.
(D) When used in accordance with widespread and commonly recognized practice it will not generally cause unreasonable adverse effects on the environment.

FIFRA §2(bb) defines “unreasonable adverse effects on the environment" as (1) “any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide, or (2) a human dietary risk from residues that result from a use of a pesticide in or on any food inconsistent with the standard under section 408 of the Federal Food Drug and Cosmetic Act."

The authority for the information collection activities contained in this ICR can be found in FIFRA §3(c)(2)(B), which allows EPA to require pesticide registrants to generate and submit data to the Agency when data is needed to assess whether the existing pesticide registration poses an unreasonable risk to human health or the environment.

Whenever EPA has reason to believe that the use of a registered pesticide may result in unreasonable adverse effects to people or the environment, the Agency initiates a Special Review of the registration for that pesticide to determine whether it must take any action under FIFRA §6(b) to cancel or change the registration of that pesticide. Special Review is an intensive and systematic examination process that offers opportunities for interested parties to comment and present evidence on the risks

and benefits of a pesticide. EPA uses the authority under FIFRA §3(c)(2)(B) to request additional information from the registrant that is necessary for its review.

FIFRA §3(g) requires EPA to periodically assess the registration of each pesticide and assess all information/data necessary to determine whether the intended use(s) of the pesticide presents unreasonable adverse effects on human health or the environment. Continued registration of some pesticides may require that the Agency obtain additional information under FIFRA §3(c)(2)(B) necessary to complete the Registration Review.

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

Registration related activities involving antimicrobial pesticide products are reviewed within the Antimicrobial Division (AD) of the Office of Pesticide Programs (OPP). 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, as well as the action that has triggered the review (tolerance action, new or amended registration, reregistration action, special review, or registration review).

2(b)(i). Tolerance Actions. EPA must make the statutory determination that the pesticide residues in food or feed will result in a reasonable certainty of no harm effects of human health from aggregate exposure through dietary, non-occupational, and drinking water routes of exposure before establishing the tolerance. To allow for the most efficient processing and review of tolerance petitions, the Agency provided a description of the types of information that EPA considers helpful in the appendices to Pesticide Registration (PR) Notice No. 97-1 (Attachment D).[1] EPA uses the data to make decisions about the tolerance petitions. The Agency's risk managers review, among other things, the regulatory aspects of each petition and coordinate scientific review of the supporting data. Agency residue chemists and toxicologists review all the applicable data. As a result of these reviews, EPA is able to make the statutory determination that the resulting pesticide residues in food or feed will not cause unreasonable adverse dietary effects on human health.

2(b)(ii). Registration Actions. 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.

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

[1] PR Notice 97-1 applies to most applicants with registration applications, non-crop-destruct experimental use permit applications, and tolerance or tolerance exemption petitions pending within the Agency. It also applies to most future applicants seeking new or amended pesticide registrations and all actions involving synthetic chemicals, antimicrobial, biochemical and microbial pesticides.

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 (as defined in PRNs 97-3 and 98-7) 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.

2(b)(iii). *Re*registration Actions. Under the FIFRA section 4 reregistration program, EPA examines health and safety data for pesticide active ingredients initially registered before November 1, 1984, and determines whether they are eligible for reregistration. To be eligible, a pesticide must have a substantially complete set of data, and the Agency must assess all the information/data necessary to determine whether products containing the pesticide present unreasonable risks to man or the environment when used in accordance with approved label directions.

In conducting the reregistration program, when the need for additional information or data arises, OPP is authorized to issue a data call-in notice (DCI) pursuant to FIFRA section 3(c)(2)(B) (see attachment B) to obtain the data, and when necessary, the registrant may be required to certify compliance with data compensation requirements under the authority of FIFRA section 3(c)(2)(D).

Agency scientists and analysts integrate the new data received from registrants with the existing data in EPA's files. EPA reviews all relevant information to assess the potential risks associated with the use of the pesticide, to determine whether the pesticide should be reregistered. If a determination is made that a pesticide is eligible for reregistration, and the registrant submits acceptable product specific data and revised labeling, products containing the pesticide shall be reregistered within a specified time period. However, if after a review of the data, it is determined that a pesticide should not be reregistered, the Agency will take appropriate regulatory action.

2(b)(iv). Special or Registration Review Actions. OPP will use the information/data obtained from registrants to assess whether unreasonable adverse effects are associated with the use of the chemical in the pesticide products. Agency scientists and analysts integrate the new data received from registrants with the existing data in EPA's files. The information is then reviewed to assess the potential risks and benefits associated with the use of the pesticide. If it is determined that regulatory actions are needed, the Agency will act accordingly.

A record of each study submitted is maintained in the Agency's Pesticide Document Management System (PDMS), and public access to the PDMS bibliography may be made through the National Pesticides Information Retrieval System (NPIRS). NPIRS supports searches of the PDMS database by chemical, subject, submission date, laboratory, guideline number, and document type. The public may request copies of non-confidential studies through the Freedom of Information Act (FOIA), after satisfying FIFRA section 10.

3. Non Duplication, Consultations, and Other Collection Criteria

3(a). Non duplication

Duplication is not an issue because these records are generally unique to the requirements of the federal pesticide law (FIFRA) and to specific pesticide products. EPA is the primary Federal agency that regulates pesticide chemicals, pesticide containers and disposal. To the extent that companies may already retain these records as part of its management practices, any potential duplication will facilitate their compliance with the regulation. Therefore, there is no duplication of effort.

In addition, EPA maintains files on all pesticide chemicals, as well as correspondence and information/data submitted. These files are referenced to determine whether the necessary data are already on hand, thereby eliminating duplicative data requests. The list of data submitters that EPA publishes enables the industry to act cooperatively in the development and/or use of data. Further, EPA allows cost-sharing agreements among manufacturers of specific pesticide chemicals in order to minimize the duplication of laboratory tests conducted for this program.

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

The notice of proposed rulemaking will serve as the public notice for this ICR. At the final rule stage, EPA will amend this ICR to reflect the Agency’s consideration of any comments received on the proposed rule and this draft ICR.

3(c). Consultations

The determination of what data or information are needed for making the critical decisions related to the registration of a pesticide relies on a scientifically rigorous process that includes extensive stakeholder involvement and consultations, public review and comment, and peer review by the FIFRA Scientific Advisory Panel (SAP). Stakeholders have been involved in the context of SAP deliberations.

The Agency has been developing this proposal for a number of years and it is widely anticipated by the regulated community. Stakeholders have been involved in the deliberations related to these proposed revisions on a case-by-case basis, and have received updates through forums such as the American Chemistry Council (ACC) Biocides Panel and the antimicrobial workshops conducted periodically by OPP’s Antimicrobials Division.

3(d). Effects of Less Frequent Collection

Not applicable. Information is collected under this ICR only when the Agency has identified a need for the specific data, and only on a one-time basis. 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

The only general guideline established under the Paperwork Reduction Act (PRA) that is exceeded in this collection is the time period for retaining records. EPA requirements in 40 CFR 169.2(k) state that records containing research data relating to registered pesticides be retained for as long as the registration is valid and the producer remains in business. Registrations are valid until they are either voluntarily canceled or withdrawn by the registrant or until EPA has cause to suspend or cancel the registration. Since the average period of marketability of a pesticide ranges from 15 to 30 years, the PRA guidelines specifying that data other than health, medical or tax records not be required to be retained for more than three years will be exceeded in this collection activity.

The forms associated with this ICR are already approved for use for the same purposes as those described in this ICR because they are also used for the four other information collection activities identified previously. When EPA submitted the previous ICR to OMB for review in 2000, the Agency requested permission, in accordance with 5 CFR 1320.5(a)(1)(iii)(C), to discontinue the display of expiration dates on these forms in the future because the forms had not changed after many years of use and/or were not expected to change in the future. OMB approved that request and EPA has therefore continued to omit the expiration dates from these forms.

The Data Call-In Response Form and the Requirements Status and Registrant's Response Form have been approved by OMB for several years under OMB Control No. 2070-0060, although with no official EPA Form number. These forms are automatically generated by EPA's computer databases and are pre-populated with information that is specific to each individual registrant that receives a Data Call-In notice for a given pesticide. These forms will not be widely accessible to general public through EPA's Internet site. Instead, EPA will continue to generate the pre-populated, registrant-specific forms through the Agency's computer system when preparing to issue Data Call-In notices. EPA is currently assigning official numbers for these forms to help clarify their OMB approval status. As discussed above, EPA will also continue to omit expiration dates for these forms.

In addition, OMB's regulations require agencies to provide a statement indicating whether the 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)). EPA is leaving the choice of an information storage method for the records to the regulated community. The records must be made available on request by EPA or its representatives, and may be stored by means of

automated, electronic, mechanical or other forms of information technology.

With regard to the use of information technology to allow for the submission of the data electronically, EPA has developed standard data evaluation formats, or templates for writing its data evaluation records (DERs) of studies submitted under FIFRA and FFDCA to EPA. These templates describe the layout and scope of information that should be contained within a study profile and can serve as guides for preparation of study documents. Use of the templates improves the likelihood of a successful submission, since the information necessary for an efficient agency review is outlined. Additional details about these templates are available at: *http://www.epa.gov/pesticides/regulating/studyprofile_templates/*. In addition, Pesticide Registration (PR) Notice 86–5, entitled *Standard Format for Data Submitted Under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and Certain Provisions of the Federal Food, Drug, and Cosmetic Act (FFDCA)*, describes EPA's preferred method for organizing and formatting submittals of data supporting a pesticide registration (*http://www.epa.gov/PR_Notices/pr86-5.html*). Providing standard templates will also facilitate electronic submission.

Prior to December 2001, registrants were required to submit as many as seven (7) paper copies of study data to EPA. Under the 2001 hybrid option, registrants only needed to submit two (2) paper copies if they also submitted the required study data in Adobe Acrobat Portable Document Format (PDF) on a compact disc. This established PDF as the standard file format for the electronic submission of required studies, using compact disks as the transport medium.

In addition, OPP recently announced an e-Submission initiative to help EPA move toward a more paperless environment. The information exchange from industry to EPA is based on a harmonized eXtensible Markup Language (XML) schema used by Canada's PMRA, which has been adapted by EPA. This harmonization assures industry that a documentation package submitted to one participating regulatory agency can likewise be submitted to the other participating agency, thus increasing standardization and decreasing the burden on industry. EPA also believes that information submitted to EPA in the XML schema format is intended to improve data quality and allow for a more efficient pesticide registration process. To assist pesticide registrants with the creation of the e-Submission XML packages, EPA has established an e-Submission XML help desk. For more information about electronic submissions, go to *http://www.epa.gov/pesticides/regulating/registering/submissions/index.htm*.

3(f). Confidentiality

Trade secret or confidential business information (CBI) is frequently submitted to the EPA under the pesticide program because submissions usually include the manufacturing process, product formulation, and supporting data. Health and safety data submitted by registrants under FIFRA are considered by EPA to contain no CBI. However, some data items identified in Section 4(b)(ii) of this supporting statement, such as sales and production data, trade secrets, and/or commercial information are protected from disclosure under FIFRA section 10 and the associated regulation as contained in 40 CFR Part 2, Subpart B. Such data submitted to this Agency are handled strictly in accordance with the provisions of the FIFRA Confidential Business

Information Security Manual. This manual contains instructions relative to all contact with confidential documents, including: responsibilities of EPA employees; physical security measures; CBI copying and destruction procedures; transfer of CBI materials within EPA to contractors or other government offices; computer security; CBI typing procedures; and procedures internal to OPP. The manual dictates that all CBI must be marked or flagged as such, all CBI must be kept in secure (double-locked) areas, and all CBI intended to be destroyed must be cleared by a document control officer and shredded.

3(g). Sensitive Questions

Not applicable. No information of a sensitive or private nature is requested in this information 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

Using the North American Industrial Classification System (NAICS) codes, the Agency has identified the following entities as being potentially impacted by this proposed rule:

- Producer of pesticide products (NAICS 32532), antifoulants (NAICS 32551), antimicrobial pesticides (NAICS 32561) or wood preservatives (NAICS 32519).
- Importers of such products, or any person or company who seeks to register an antimicrobial, antifoulant coating, ballast water treatment, or wood preservative pesticide.
- Any person who seeks to obtain a tolerance for such pesticides.

Based on the industry profile provided in the Economic Analysis for the proposed rule, all companies having one or more FIFRA Section 3 or FIFRA Section 24(c) antimicrobial pesticide registrations were identified by EPA's OPPIN database in 2007, and companies with the same parent companies were consolidated. EPA estimates that there are about 750 unique parent antimicrobial firms. For purposes of estimating the number of potential respondents for this ICR, EPA used 750.

4(b). Information Requested

4(b)(i). Data Items, Including Record Keeping Requirements

First promulgated in 1984, EPA's pesticide data requirements codified in 40 CFR part 158 and 161 outline the kinds of data and related information typically needed to register a pesticide. In this proposal, the data requirements are organized by scientific discipline (e.g., toxicology), just as the existing data requirements in part 158 for conventional, and biochemical and microbial pesticides and those in part 161 for antimicrobials.

A significant change in this proposal from the existing data requirements in part 161 is the introduction of 12 use patterns specific to antimicrobials. Since there is much variety in pesticide chemistry, exposure, and hazard, the requirements are designed to be flexible. Test notes to the data requirements tables explain the conditions under which data are typically needed. Essentially, the data requirements identify the questions that the applicant will need to answer regarding a pesticide product before the Agency can register it.

Data requirements address both components of a risk assessment, i.e., the hazards that the pesticide presents, and the estimated level of exposure to humans or nontarget species. Having the appropriate information enables the Agency to understand when those hazards pose risks. The answer to one question may inform the kind of information needed to answer other questions. For example, a pesticide that is persistent and toxicologically potent may require more extensive exposure data to help establish a safe level of exposure. In addition, because a number of antimicrobials are used for public health purposes (for example, disinfectants, sterilants, or sanitizers), there are product performance data requirements to assure that the antimicrobial product works as intended.

As described in the proposed rule, the Agency is proposing to adopt specific use patterns that are designed to make it easier to determine which requirements apply to which antimicrobial products. Specifically, the Agency proposes to structure its data requirements for antimicrobial products by using a system of 12 use patterns based on similarity of use, purpose, pesticidal function, the nature of the exposure, and, in some cases, application methods.

In addition to retaining most current data requirements for antimicrobials (which are already approved under the existing ICRs), the proposed rule incorporates nine (9) new data requirements and revises other existing data requirements. Two (**developmental neurotoxicity** and **immunotoxicity**) are the same new data requirements as promulgated in the final rule for conventional chemicals (72 FR 60934). (See Unit VIII. of the preamble to the proposed rule), which are covered by the existing ICRs for conventional pesticides. While **photodegradation in soil** studies have been routinely required for conventional chemicals, this study would be a new data requirement for wood preservatives. (See Unit XII. of the preamble to the proposed rule). Similarly, two new exposure data requirements (**soil residue dissipation** and **non-dietary ingestion exposure**) are today proposed for antimicrobials. (See Unit IX.D. of the preamble to the proposed rule).

Four new data requirements (**activated sludge sorption isotherm study**; **ready biodegradability study; porous pot study;** and **modified activated sludge, respiration inhibition test**) are proposed today for antimicrobials that are not included in the final rule for conventional pesticides. This is due to the nature of antimicrobial pesticides, which includes many down-the-drain uses, i.e. those discharged to public treatment systems, and is discussed in Unit XII.B. and C. of the preamble to the proposed rule.

The existing recordkeeping requirements are not being changed with this proposal. Specifically, 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)*).

4(b)(ii). Respondent Activities

In general, the respondent activities described in the existing ICRs are not being changed with this proposed rule. The only difference in the activities is that the respondents will perform specific tests to gather the data for submission. All other activities remain identical.

5. The Information Collected - Agency Activities, Collection Methodology, and Information Management

5(a) EPA Activities

The Agency activities described in the existing ICRs will not change with this proposed rule, except that EPA will now have the information needed to make decisions.

5(b). Collection Methodology and Management

The Agency's collection methodologies and management of data submitted that is described in the existing ICRs will not change with this proposed rule.

5(c). Small Entity Flexibility

The small entity flexibility described in the existing ICRs will not change with this proposed rule.

5(d). Collection Schedule

Not applicable. There is no set schedule for the collection of this information. For example, DCIs are issued when the need is identified. The time frame in which the respondents must then submit the requested material is specifically established for each DCI based on the individual circumstances surrounding the particular DCI and applicable review. EPA usually works with respondents to ensure that sufficient time is built into the individual DCIs to allow for respondents to gather and submit the requested information.

6. Estimating the Burden and Cost of the Collection

6(a). Estimating Regulated Community Burden and Costs

The respondent burden reflected in this ICR is based on the Economic Analyses (EA) prepared for the proposed rule.

6(a)(i). Regulated Community Burden and Costs

The burden on the regulated community considered in this analysis is the administrative burden associated with the time spent to generate the data identified in the proposed rule, and to submit that data to EPA. The burden also includes a review of the new regulations and a determination of how the regulations affect the respondent, which are expected to occur in the first year of compliance with the regulations, but not expected to occur at this same level every year after that.

Table 6-1 summarizes the typical annual paperwork burden and costs to registrants per antimicrobial pesticide registration. This estimate is based on relevant respondent burden data from the current Section 3 Application for New or Amended Pesticide Registration Data ICR (OMB Control No. 2070-0060, EPA ICR No. 0277).

Table 6-1: Antimicrobial Registrant Paperwork Burden & Costs per Registration Action

Burden Activities	Burden Hours (per year)			Total	
	Management $104/hr.	Technical $67/hr.	Clerical $34/hr.	Hours	Costs $
Read Instructions	18	0	0	18	$1,865
Plan Activities	4	0	0	4	$414
Gather/Create Information	0	120	0	120	$8,046
Compile and Review	4	8	0	12	$951
Complete Paperwork	0	0	30	30	$1,015
Store/Maintain Data	0	0	10	10	$338
TOTAL	26	128	40	194	$12,631

Costs may not calculate exactly since the wages are displayed as rounded.
Source: Hours: Application for New or Amended Pesticide Registration (Section 3), OMB Control No. 2070-0060, EPA ICR No. 0277.14.
Source: Wages: http://www.bls.gov/oes/current/naics4_325300.htm

In Section 5 of the EA, the annual number of antimicrobial pesticide registrations was calculated to be 15 (see Table 5-3 in the EA). Multiplied by the paperwork burden and cost per registration, the total annual registrant paperwork burden and costs of the data requirements are estimated to be approximately 2910 hours and $189,465. This cost represents the baseline annual registrant paperwork burden.

The incremental data requirement burden and costs as a result of the proposed rule are estimated to be 35% of the baseline data burden and costs. Assuming that the paperwork burden is proportional to the data requirement costs, the incremental registrant paperwork burden and costs as a result of the proposed rule would be 35% of baseline registrant burden and costs or approximately 1019 hours and $66,150.

In addition to the burden costs, the costs of delivering the data to the Agency are added to arrive at the total estimated costs. Delivery costs were calculated using the Agency's experience with data submissions for pesticide deliveries, which assumes the delivery of a paper copy or a CD-Rom using special delivery. Although not required, nor used by everyone, the Agency is using special delivery for the calculation to provide a conservative estimate that would account for expected variations in delivery costs. Based on the 2-day delivery rate for a large envelope up to 2 lbs. in weight, the US Postal Service rate is $10.55 from the west coast to the east cost. Total delivery costs ($10.55 x 15 submissions = $158.25) was then added to the total respondent cost to calculate the total potential respondent costs.

Total annual registrant burden and costs as a result of the proposed rule would be 3929 hours (2910 + 1019) and $255,773.25 ($158.25 +189,465 + 66,150), which is equal to the sum of the baseline and incremental costs and the delivery costs.

6(b). Estimating EPA Burden and Cost

As indicated in the EA for the proposed rule, EPA is expected to incur new costs in reviewing the additional or modified data that could be required in association with potential changes in data requirements for antimicrobials.

Table 6-2 summarizes the typical baseline paperwork burden and cost to the Agency per antimicrobial pesticide registration. This estimate was based on relevant Agency burden data from the currently approved ICRs.

Table 6-2: Antimicrobial Agency Paperwork Burden & Costs per Registration Action

Burden Activities	Burden Hours (per year)			Total	
	Management $101/hr.	Technical $66/hr.	Clerical $39/hr.	Hours	Costs $
Answer registrants' questions	0	14	0	14	$936
In-process data and waiver submissions	0	30	0	30	$2,006
Analyze data and waiver requests	15	217	0	232	$16,031
Record and store information	0	0	16	16	$628
TOTAL	15	261	16	292	$19,601

Costs may not calculate exactly since the wages are displayed as rounded.
Source: Hours: Application for New or Amended Pesticide Registration (Section 3), OMB Control No. 2070-0060, EPA ICR No. 0277.14.
Source: Wages: http://www.bls.gov/oes/current/naics4_999100.htm

In Section 5 of the EA, the annual number of antimicrobial pesticide registrations was calculated to be 15 (see Table 5-3 in the EA). Multiplied by the paperwork cost per registration, the total annual Agency paperwork costs of the data requirements are estimated to be approximately $294,000. These costs represent the baseline annual agency paperwork burden.

The incremental data requirement costs as a result of the proposed rule are estimated to be 35% of the baseline data costs. Assuming that the agency burden is proportional to the data requirement costs, the incremental agency paperwork burden as a result of the proposed rule would be 35% of baseline Agency burden or approximately $103,000.

Total Agency annual paperwork burden as a result of the proposed rule would be approximately $397,000, which is equal to the sum of the baseline and incremental costs.

6(c). Bottom Line Annual Burden Hours and Costs for this ICR

The total annual estimated "bottom line" respondent paperwork burden and costs for this proposed rule are briefly summarized as follows:

- *Estimated total number of potential respondents:* 750.
- *Frequency of response:* On occasion.
- *Estimated total average number of responses for each respondent:* 1.
- *Estimated total average number of responses each year:* 15.
- *Estimated total per response annual burden hours:* 262 hours.
- *Estimated total per response annual burden hour costs:* $17,052. This includes an estimated burden cost of $10.55 for administrative costs associated with copying and delivering the data to EPA.
- *Estimated total respondent annual burden hours:* 3,929 hours.
- *Estimated total respondent annual costs:* $255,780. This includes an estimated burden cost of $158.25 for administrative costs associated with copying and delivering the data to EPA.

(NOTE: These numbers are rounded and may not add up perfectly here. For example, total costs here reflect what the Submission system calculated automatically, rather than the pure total presented earlier.)

The total annual estimated "bottom line" Agency paperwork burden and costs for this proposed rule are approximately $397,000.

6(e). Reasons for Change in Burden for this ICR

This is a new ICR related to a proposed rule. As such, there are no burden hours currently approved in OMB's paperwork burden inventory. However, this proposed rule is estimated to result in an increase of 1019 hours to burden currently approved under other existing ICRs. At the final rule stage, after OMB has approved the final rule's ICR, EPA will incorporate these burdens into the existing ICRs.

6(f). Burden Statement for this ICR

The total estimated annual respondent paperwork burden to comply with the information collection activity related to data requirements for antimicrobial pesticides is 3929 hours, of which 1019 hours represent burden related to new data requirements. The estimated per respondent burden is 194 hours, of which 68 hours represents burden for new data requirements.

As defined by the PRA and 5 CFR 1320.3(b), "burden" means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purpose of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

The OMB control numbers for certain EPA regulations codified in Chapter 40 of the CFR, after appearing in the preamble of the final rule, are listed in 40 CFR part 9, displayed either by publication in the Federal Register or by other appropriate means, such as on the related collection instrument or form, if applicable. For this ICR activity, in addition to displaying the applicable OMB control number in the final rule, the Agency has amended the table in 40 CFR §9.1 to list the OMB control number assigned to this ICR activity.

To comment on the Agency's need for this information, the accuracy of the provided burden estimates, and any suggested methods for minimizing respondent burden, including the use of automated collection techniques, EPA has established a public docket for this ICR under Docket ID No. EPA-HQ-OPP-2008-0110, which is available for public 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. An electronic version of the public docket is available at www.regulations.gov. Use www.regulations.gov to submit or view public comments, access the index listing of the contents of the public docket, and to access those documents in the public docket that are available electronically. Once in the system, input the docket ID number identified above into the "search" box.

List of References for this Supporting Statement:

Reference A **FIFRA Sections 3, 8, 19 and 25**
This information is available electronically at http://www.epa.gov/opp00001/regulating/fifra.pdf.

Reference B **Proposed Rule**
The proposed rule is available in public docket that EPA established for this action (Docket ID No. EPA-HQ-OPP-2008-0110). An electronic version of the docket is available at www.regulations.gov.

Reference C **Economic Analysis for the Proposed Rule**
A copy is available in the public docket for the proposed rule (Docket ID No. EPA-HQ-OPP-2008-0110). An electronic version of the docket is available at www.regulations.gov.