SUPPORTING STATEMENT FOR AN INFORMATION COLLECTION REQUEST (ICR)

1. IDENTIFICATION OF THE INFORMATION COLLECTION

1(a) Title of the Information Collection

Title: **Experimental Use Permits (EUPs) for Pesticides**

OMB No. 2070-0040 EPA No. 0276.14

1(b) Short Characterization/Abstract

This Information Collection Request (ICR) is a renewal of an existing ICR that is currently approved by OMB and is due to expire November 30, 2010. The information collection provides EPA with the data necessary to determine whether to issue an experimental use permit (EUP) under section 5 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (Attachment A, pp. 58-59). FIFRA requires that before a pesticide product may be distributed or sold in the U.S., it must be registered by EPA. However, FIFRA section 5 authorizes EPA to issue an EUP to allow pesticide companies to temporarily ship pesticide products for experimental use for the purpose of gathering data necessary to support the application for registration of a pesticide product. In general, EUPs are issued either for a pesticide not registered with the Agency or for a new use of a registered.

The information collected and reported under an EUP is a summary of that which is routinely submitted in connection with registration. The EUP allows for large scale field testing, if necessary, in order to collect sufficient data to support registration. An EUP is not required if the person conducting the tests does not expect to receive benefits in pest control.

The prospective registrant files EPA Form 8570-17, Application for An Experimental Use Permit to Ship and Use a Pesticide for Experimental Purposes Only (see Attachment B) for a permit to generate information or data necessary to register a pesticide under Section 3 of FIFRA. This information from the applicant is necessary in order to grant and effectively monitor the EUP. The applicant must also provide the Agency with a final report on the results of the experimental program which includes information such as: amount of the product applied; the crops or sites treated; any observed adverse effects; any adverse weather conditions which may have inhibited the program; the goals achieved; and the disposition of containers, unused pesticide material, and affected food/feed commodities.

If the food/feed treated under the terms of an EUP is to be shipped in commerce, the applicant must also submit a petition for temporary tolerance pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA) (21 U.S.C. 346a). The information collection activities associated with tolerances are addressed in a separate ICR (EPA ICR #597), which is approved by OMB under OMB Control Number 2070-0024. As such, tolerance related activities are not described in this ICR.

2. NEED FOR AND USE OF THE COLLECTION

2(a). Need/Authority for the Collection

As required by section 5 of FIFRA, and Part 172 of Title 40 of the Code of Federal Regulations (40 CFR Part 172), the information collected and reported is necessary to evaluate the potential hazard of the product and to make certain that the permit was issued for genuine experimental purposes rather than as a form of temporary registration. (See Attachment C for a link to the regulations). To ensure compliance, the final report is compared with the objectives of the testing program. The information also enables EPA to identify whether the treated food or feed crops will be used in a commercial market. Such use would require issuance of a temporary tolerance or destruction of the crop because the use was for research purposes only. Since it is common for applicants to request extensions of EUPs, it is imperative that the Agency has reports in hand in order to judge the need for such extensions.

Exemptions from EUP requirements:

Under the existing EUP regulations, small-scale experimental uses of pesticides are presumed exempt from the EUP requirements. EPA will not require an EUP for a substance or mixture of substances being put through laboratory or greenhouse tests, or fewer than one surface acre per pest for terrestrial tests or fewer than ten acres per pest for aquatic tests, in which the sole purpose under the following small scale field testing scenarios:

Land-Pesticide testing on plots of land ten acres or less in size:

Test plots may be as large as ten acres per pest if the effect of each pesticide on several pests is being investigated at a different time for each pest. However, if pesticide effects on more than one pest are being investigated all at the same time, the test plot may not exceed ten acres in size. Furthermore, any food or feed crops involved in or affected by the tests must be destroyed or consumed only by experimental animals unless a tolerance or exemption from a tolerance has been established.

Aquatic Uses-Pesticide testing on water bodies one surface acre or less in size:

Water bodies may be as large as one acre per pest if the effect of each pesticide on several pests is being investigated at a different time for each pest. However, if pesticide effects on more than one pest are being investigated all at the same time, the water body may not exceed one acre in size. Bodies of water involved in or affected by the tests may not be used for irrigation, drinking water supplies, or body contact through recreational activities. In addition, pesticides may not be tested in waters that contain or which affect any fish, shellfish or other plants or animals which may be taken for food or feed unless a tolerance or exemption from tolerance exists for the test product.

Animal Treatment Uses:

Tests may be conducted only in cases where experimental animals will not be used for food or feed unless a tolerance or exemption from tolerance exists for the test product.

Other Uses:

In instances where testing operations do not accurately reflect whether the testing is to be considered small-or large-scale acreage limits, the Agency will determine on a case-by-case basis whether an exemption from the requirement from an EUP is appropriate.

The exemptions described above are not definitive, but 40 CFR 172.3 gives EPA discretionary authority to exempt particular testing operations from the EUP requirements under other conditions. 40 CFR 172.3 also allows EPA discretionary authority to require EUPs for testing operations even when the exemption conditions of 40 CFR 172.3(b) and (c) are met.

EUP for Small-scale Field Testing of Microbial Pesticides:

The Agency may require an EUP for small scale field testing of certain unique microbial pesticides (i.e., genetically-altered and non-indigenous microbial pest control agents) because of the potential concern for microorganisms to reproduce and multiply in the environment and the potential for these microbial pesticides to cause unforeseen adverse impacts. Prior to the initiation of any small scale field testing involving genetically-altered or non-indigenous microbial pest control agents, the research organization, company, or individual must submit a notification to the Agency so that a determination can be made as to whether an EUP is required. The requirements for a EUP for field testing of microbial pesticides are found in 40 CFR 172.43-172.59. These requirements differ significantly from the EUP requirements for testing other pesticides.

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

The information collected and reported under an EUP will enable the Agency to:

- Determine whether a new request for an EUP or a renewal, extension or amendment of an EUP, if requested, is justified;
- allow for adequate monitoring of the EUP program; and
- ascertain the cause/effect relationship when a pesticide is registered and later found to have adverse effects (as in the case of phytotoxicity); and
- allow the Agency to review efficacy data which may contain important health data.

3. NON DUPLICATION, CONSULTATIONS, AND OTHER COLLECTION CRITERIA

3(a). Non duplication

The respondent is not required to submit EUP-related information or data to any other Federal agency or to any other EPA program offices. FIFRA section 7, however, does require annual pesticide production reports from all persons who produce pesticides (see Attachment A, p. 65). The pesticide material produced in conjunction with an EUP would be included in these

annual production reports; however, annual production information is not required as a condition of the EUP, only total production in the final report.

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

Pursuant to 5 CFR 1320.8(d), EPA published a Federal Register (FR) Notice announcing this proposed information collection activity and providing a 60-day public comment period (75 FR 9594; March 3, 2010) (a copy of this FR document is available in the docket for this ICR). The Agency did not receive any public comments.

3(c). Consultations on this Renewal ICR

In the context of an individual EUP, consultation and/or dialogue between the respondent and EPA occurs on an informal, ongoing "as needed" basis, primarily during the submission and review of the application for an EUP. Historically, when technical, administrative or other problems arise, the respondent is given ample opportunity to inform the agency and vice versa. This communication between both parties may take place either in a telephone conversation or in a meeting setting, but not necessarily by a prescribed schedule.

In addition, as required under 5 CFR 1320.8(d)(1), EPA staff contacted several representatives of pesticide registrants by e-mail to seek feedback on the EUP information reporting requirements and the regulatory burden estimates expressed by the Agency in this ICR. The list of representatives and the questions posed is provided in Attachment D.

The Agency received responses from Monsanto Company and Syngenta Biotechnology, Inc. (see Attachment E). Monsanto indicated that, based on their experience with the time needed to assemble and format the data to fulfill Pesticide Registration (PR) Notice 86-5 requirements (Attachment F), their EUP paperwork burden is significantly higher both for chemical pesticides and for plant-incorporated protectants (PIPs) than the estimates provided in the first public review draft of this ICR. In response to this feedback, the burden estimates provided by Monsanto for chemical pesticides have been incorporated into the estimates provided in section 6 of this ICR, to derive the current paperwork burden estimates per EUP application.

In addition to their overall higher paperwork burden estimates for EUP applications, Monsanto's estimates for PIP EUP applications involving PIPs, are notably higher than those for chemical pesticides. PIPs are pesticidal substances produced by plants and the introduced genetic material with the desired pesticidal trait necessary for the plant to produce the substance (for more information about PIPs, go to http://www.epa.gov/oppbppd1/biopesticides/pips/#science). Monsanto's estimates for PIP EUP applications involving PIPs, include the time it takes them to prepare and format the different combinations of acreage and active ingredient calculations that they say are required to be broken down in different ways (i.e., by protocol tables, by PIP tables, etc.).

As PIP EUPs have increased in complexity due to the testing of multiple stacked traits under a single EUP, EPA has not required an EUP for each trait combination, but has allowed individual and trait combinations related to the development of novel trait or use to be lumped under one EUP. This approach has actually provided a cost-savings for EUP applicants,

allowing them to submit one EUP when EPA could require ten or more times that amount (33 in one case). Therefore, Monsanto's increased time estimates for this particular activity are not necessary representative of typical burdens for EUP applications per PIP trait.

However, since requirements for field testing of pesticides are substantially different for PIP EUP applications and tend to be more intensive than for chemical pesticides, they can require more time to prepare and to submit the information. In addition, over the past ten years, the Agency has increasingly received a higher percentage of EUP applications for PIP (on a trait-by-trait basis) than for chemical pesticides. As a result, in this ICR, applications for PIP EUPs have been treated as a separate response type from those for chemical EUPs. For the 2010 renewal cycle of this ICR, the second response type (PIP) will use Monsanto's estimates as these are the only numbers available to the Agency at this time.

Another part of the response from Monsanto also pointed out that the fully loaded labor rates provided in the ICR are too low. However, they provided no further details. In section 6 of this ICR, the same fully loaded labor rates for NAICS code 325300 has been used both for chemical and biological pesticide manufacturers.

Syngenta commented in general terms on the complexity of the PIPs application process but did not give specific explanations.

3(d). Effects of Less Frequent Collection

There is only one submission required in conjunction with each request for EPA approval to conduct testing on certain pesticides. Therefore, the frequency of the collection cannot be reduced, except to eliminate the collection altogether. The Agency then would have no means by which to evaluate the potential human health risks and environmental hazard presented by a proposed test.

3(e). General Guidelines

The only guideline 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 as long as the registration is valid and the manufacturer remains in business. Pesticide 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 program.

3(f). Confidentiality

When trade secret information or Confidential Business Information (CBI) is provided to the Agency, such information is protected from disclosure under FIFRA Section 10, as amended and EPA's confidentiality regulation in 40 CFR Part 2, Subpart B. Data submitted to the Agency are handled strictly in accordance with the FIFRA CBI Security Manual. This manual contains instructions relative to all contact with confidential documents, including responsibility of EPA

employees; physical security measures; CBI materials within EPA, such as CBI typing procedures (documents typed internally or on contract); and division internal procedures. The manual dictates that: (1) all CBI must be marked or flagged as such, (2) all CBI must be kept in secure, double-locked areas, and (3) all CBI for destruction must be cleared by a document control officer and placed in the Office of Chemical Safety and Pollution Prevention paper shredder.

3(g). Sensitive Questions

No information of a sensitive or private nature is requested in conjunction with this information collection activity. Further, 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

The North American Industrial Classification System (NAICS) code for respondents participating in this data collection is 325300 (Pesticide Registrants).

4(b). Information Requested

4(b) (i) Data Items

Form 8570-17 must be submitted to EPA with each EUP application. The type of information to be submitted with the application depends on whether the product is already registered and whether a tolerance is required for the testing covered under the EUP. 40 CFR 172.4 lists the information that is required.

An application for an EUP may be submitted by any company or person wishing to generate the information necessary as required by section 3 of FIFRA in accordance with the regulations found in 40 CFR 172.2(a). The applicant may be a potential registrant, an independent researcher or testing laboratory, or any similar agent or consultant of a manufacturer. Applications must be submitted to the following address:

Document Processing Desk (EUP)
U.S. Environmental Protection Agency
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
1200 Pennsylvania Ave. NW
Washington, D.C. 20460

Information Required in All EUP Applications:

Each EUP application must contain the following information together with a completed copy of 8570-17:

- Applicant's name and address;
- The registration number of the product, if it has been registered (information requirements for unregistered products are listed below in a separate section);
- Purpose or objectives of the proposed testing;
- Detailed description of the proposed testing program including the following test parameters:
    - Pest organism(s) involved;
    - Amount of pesticide proposed to be used;
    - Crops, fauna, and flora involved;
    - Sites and modes of pesticide applications;
    - Pesticide dosage rates;
    - Location of test site, including States;
    - Number of acres in test site;
    - Number of structural sites or number of animals by State to be included in the testing;
    - Proposed dates of the testing; and
    - How the testing will be supervised.
- Name, street address, telephone number and qualifications of program participants, including those not employed by the applicant;
- Names and street addresses of cooperators (persons owning or controlling application sites and granting permission to permittees to use these sites);
- Results of prior testing of product by applicant to determine:
    - toxicity and effects in or on target organisms;
    - toxicity and effects in or on non-target plants, animals and insects at or near the application site; and
    - adverse effects to the environment from application of this product; and
    - how the applicant intends to store and dispose of unused pesticide and containers from the proposed experimental use.

<u>Information Required When the Product to be Tested is Not Already Registered:</u>

New data required to be submitted for EUP applications for field testing of both unregistered chemical and plant-incorporated pesticides (PIP) to show that the pesticide during testing will not cause an unreasonable adverse effect to man and the environment are substantially greater than registered pesticides that have already met these requirements of FIFRA for their labeled uses.

In addition to the information listed immediately above, when the product to be tested has not been registered, the applicant must provide the following information:

- A complete confidential statement of composition giving the composition of the formulation to be tested as a tabulation of the names and percentage by weight of each ingredient, both active and inert;
- Chemical and physical properties of each active ingredient of the formulation being tested including the analytical methods to be used to determine these;
- Available data on the rate of decline of residues on the treated crop or site together with other information relevant to determining when workers can safely re-enter treated areas; and

- Available toxicity and exposure data, including human epidemiological data, relevant to assessing the potential of the product to cause injury to users and other people who may be exposed.

When Testing May Result in Pesticide Residue on Food:

When the product to be tested is to be used in such a manner to leave residue on food or feed, the applicant has three options for determining that treated crops are not used for food or feed use without a tolerance:

- The applicant may submit evidence that a tolerance or a tolerance requirement exemption has been established under Section 408 of the FFDCA;

- The applicant may submit a petition for a new tolerance or for an exemption from the requirement for a tolerance established under Section 408 of the FFDCA (Chapter 7 of this document, Tolerance Petitions, describes this process in detail); and

- The applicant may certify that the food or feed derived from the experimental program will be destroyed or will be fed only to experimental animals which will be destroyed. Alternatively, the applicant may certify that the food or feed derived from the experimental program will be disposed of in another manner which does not endanger man or the environment; the permit application shall specify the means of such disposal.

EUP applications should be submitted to EPA as far in advance as possible of the first shipping date, at least six months in advance. FIFRA section 5(a) requires EPA to complete EUP reviews within 120 days, and failure to provide the appropriate information or data may delay processing of the EUP beyond this date.

Labeling Requirements:

All pesticides shipped or used under an EUP must be labeled with directions and conditions for use including the following:

- The prominent statement “For Experimental Use Only”;
- The Experimental Use Permit Number;
- The statement “Not for sale to any person other than a participant or cooperator of the EPA-approved Experimental Use Program”;
- The name, brand or trademark;
- The name and address of the permittee, producer, or registrant;
- The net contents;
- An ingredient statement;
- Warning or caution statements;
- Any limitations on entry of persons into treated areas;
- The establishment registration number, except in those cases where application of the pesticide is made solely by the producer; and
- The directions for trial use.

Extensions or renewal of EUPs:

EUPs and associated temporary tolerances are usually issued for a period of one or two years. The permit and any associated temporary tolerances, may be extended, renewed, or amended upon written request to the Agency, if circumstances warrant.

Fee Requirements:

If an application for an EUP is accompanied by a petition for a tolerance, temporary tolerance, an exemption from the requirement of a tolerance, or a temporary tolerance exemption, the petition is subject to fee requirements. An extension or renewal request for a temporary tolerance is also subject to a fee requirement. In March 2004, the Pesticide Registration Improvement Act (PRIA) of 2003 became effective. The goal of this Act is to create a more predictable evaluation process for affected pesticide decisions, and couple the collection of individual fees with specific decision review periods. The legislation also promotes shorter decision review periods for applications including reduced-risk. Certain submitted EUP actions are included under PRIA and the burden hours and costs associated with these activities are estimated in the Pesticide Registration Fee Waivers ICR, (OMB Control No.: 2070-0167, EPA ICR No.: 2147), and are not duplicated in this ICR.

Use of an EUP Product on Food or Feed Crops:

A product may only be used on food or feed crops if the Agency has issued tolerances or exemptions from requirements for tolerances for all inert ingredients, metabolites, and degradation products, as well as active ingredients. If the proposed labeling bears instructions for use of the product on food or feed crops, or if the intended use of the product results or may be expected to result, directly or indirectly, in pesticide residues in or on food or feed, applicants must submit a statement indicating whether a tolerance or an exemption from the requirement of a tolerance has been issued by the Agency under section 408 of the FFDCA.

If a tolerance, exemption from the requirement of a tolerance has not been issued for such residues, applicants must include with the application a petition for establishment of appropriate tolerances, exemptions from the requirement of a tolerance, or food additive regulation in accordance with 40 CFR 180. Alternatively, applicants may certify that the food or feed derived from the experimental program will be destroyed or fed only to experimental animals for testing purposes, or otherwise disposed of in a manner which will not endanger man or the environment.

Suggested Format for an EUP Application:

The following format is an example of an acceptable EUP application. Not all of the items are necessary in every case. Depending on whether the product being tested is already registered with EPA, and whether a tolerance is necessary because treated crops will be used as food or feed, several of these entries may not be necessary.

Section A - This section should include a data sheet detailing the chemical and physical properties of the test chemical along with a complete statement of the names and percentages by weight of each active and inert ingredient in the formulation to be shipped.

Section B - This section should include a copy of the proposed experimental label. The minimum labeling requirements are set forth in 40 CFR 172.6.

Section C - This section should include toxicity data, including LD50 values, eye and skin irritation data for the formulated product, and subacute, teratology (one species), mutagenicity, and possibly chronic and reproduction data on the active ingredient. Data on the product's toxicity to fish and wildlife may also be included in Section C as appropriate.

Section D - This section should include residue data, including when appropriate, data on: (1) food or feed commodities; (2) non-food crops such as tobacco; or (3) foliage or other sites where the product may be used and on which remaining residues of the product may pose a risk to man or the environment. Section D also includes a description of the analytical methods used, a summary of the residue data acquired, and when appropriate, environmental fate data.

Section E - This section should include product performance information demonstrating that the product is useful for the purposes proposed. Because EPA has waived the requirement for submitting efficacy data for all products except those with public health uses, Section E need not contain actual efficacy data, but should include a summary of the results of all efficacy testing performed on the product.

Section F - This section should include a statement explaining whether a tolerance exists or is being requested, especially if the product is to be tested in a manner that may result in residues in food or feed. If a tolerance is being requested, the temporary tolerance petition must be provided with the EUP application. Given the occurrence whenever all food or feed derived from the experimental program is to be destroyed or fed to experimental animals, a statement of explanation must be included.

Section G - The section should include details concerning the proposed experimental program, including:

- qualifications, names, addresses and telephone numbers of all EUP participants, including cooperators, i.e., persons who grant permission for an experimental use pesticide to be used on application sites which they own or control;
- names of states in which the product will be used, along with the amount of active ingredient and acreage (or other appropriate measures) to be used in each state, and the names of states in which the pesticide may be shipped for further distribution;
- details of the proposed EUP program, including types of pests or organisms targeted; the crops, animals, surface, or sites to be treated; the geographical areas where the material is to be used; the use patterns, intended plot sizes, number of plots, number of replicates, and other test parameters to be used;
- information on prior testing, including a description and the specific results of any appropriate prior testing of the product conducted by the applicant to determine, toxicity and effects in or on any target organisms at the site of application; phytotoxicity and other forms of toxicity or effects on nontarget plants, animals and insects, at or near the site of application ; or any adverse effects on the environment;
- objectives of the EUP program, including a statement specifying the type of data to be collected and the intended gain from conducting the program;

- justification for the quantity (volume) of active ingredient proposed to be used under the EUP, including a statement specifying the various parameters used to determine the quantity of active ingredient;
- a statement proposing a suitable duration for the EUP commensurate with the program objectives; and
- details concerning the method of disposing of unused materials at the conclusion of the testing program.

Program Surveillance and Data Reporting Requirements for an EUP:

Once the permit is issued and the pesticide testing is underway, the applicant is required to track the results at each test site and submit a final report to EPA which shall include (40 CFR 172.8):

- All data gathered during the testing program. Although field notes need not be included in this report, they must be kept available for EPA review upon request.
- A report of how pesticide containers and unused pesticides were disposed of, including the quantity disposed of, disposal sites and disposal methods.
- In the case where meat-producing animals or birds are treated by or exposed to an experimental use pesticide, the applicant must report the name and location where the animals will be processed to the U.S. Department of Agriculture, Animal and Plant Health Inspection Service, Washington, DC, 20250.
- The applicant must also report any adverse effects from use of or from exposure to the pesticide being tested.

EPA may require advance notice from the applicant of the intended test dates, sites and times. The applicant must also allow EPA access to the testing site to determine whether the testing complies with the terms and conditions of the permit.

4(b) (ii) Respondent Activities

The following are the activities to be conducted by a respondent (applicant) in order to comply with the provisions of EPA Form 8570-17.

Activity	Explanation
read FIFRA Section 5 and 40 CFR 172.8(b)	become familiar with the legislation and regulations and determine the requirements as they pertain to a proposed experimental use of a pesticide
plan activities	plan the actions necessary to comply with the legislation and regulations
create information	develop information required for notification
gather information	gather information required for the notification or containment records
process, compile, and review information	check information for accuracy and completeness
complete paperwork	prepare notification document or containment record
record, disclose, and display information	submit notification to OPP
store, maintain, and file information	retain copies of all submissions

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

5(a). Agency Activities

The following are activities necessary to evaluate a submitted request for an EUP:

Activity	Explanation
review submitted application package	review application form and package for completeness and appropriateness
record submission	record submission in tracking system
analyze submission	conduct scientific reviews of data
file submission	store and maintain submission information in Agency's file system

5(b). Collection Methodology and Management

A submitted EUP package usually includes three parts: an EPA Application Form 8570-17, the product label, and, in most cases, supporting data. The application form and the product label are pin-punched by date by the Front-End Application Processing Unit for initial screening. If everything is found to be complete, the proposed EUP is given a file symbol, entered into the appropriate tracking system, and a registration jacket is created identifying the document by the appropriate Product Manager (PM) for the chemical being employed. The accompanying data is identified and processed for review.

The three-part EUP package is sent to the designated PM who is responsible for managing the registration action. The testing program and labeling program are reviewed by the PM while the data portion is routed for scientific review to the appropriate discipline. On completion of the scientific review, the PM receives a written analysis of the data. If the data is found to be acceptable, an EUP is issued. If not, the EUP request is rejected and the PM then notifies the applicant in writing of the deficiencies before the EUP request can be resubmitted. The file is then updated in the tracking system to reflect the latest status and the registration jacket is stored in the file room.

5(c). Small Entity Flexibility

The Agency recognizes that many small businesses are involved in research and development activities with pesticides. In setting forth the notification requirements, EPA has sought to minimize the regulatory burden on research and development activities. Toward this end, the Agency has identified the minimum amount of data to be submitted to permit a scientific assessment of the proposed research. Much of this information already would be available to the respondent as part of the normal information developed during the research and development stage. These data requirements are flexible and may be adjusted as appropriate to the specific product under review. As an alternative to submitting a Notification, an applicant may apply for, and obtain an EUP before conducting a field test with a pesticide. Because the notification requirements have been designed from the outset to minimize the burden on respondents, as a

result, there are no special measures taken for small businesses since the burden is considered to be at a minimal level.

5(d). Collection Schedule

Not applicable. This activity is conducted only when an EUP request is made.

6. ESTIMATING THE BURDEN AND COST OF THE COLLECTION

6(a). Estimating the Respondent Burden

Consultations responses and a review of the Agency process for EUP data submissions indicate that the paperwork burden can be significantly higher both for chemical pesticides and for plant-incorporated protectants (PIP) than previous estimates. In response, this ICR has made changes (an increase in the overall burden, and the creation of a second response type for plant-incorporated protectants or PIP) based on respondent's experience with the time needed to assemble and format the data to fulfill PR Notice 86-5 requirements (Attachment F).

Burden estimates provided through consultations responses for chemical pesticides have been incorporated to derive an average figure for the current paperwork burden estimates per EUP application for that response type.

The respondent's estimates for PIP EUP applications include the time it takes them to prepare and format the different combinations of acreage and active ingredient calculations that they say are required to be broken down in different ways (i.e., by protocol tables, by PIP tables, etc.).

As PIP EUPs have increased in complexity due to the testing of multiple stacked traits under a single EUP, EPA has not required an EUP for each trait combination, but has allowed individual and trait combinations related to the development of novel trait or use to be lumped under one EUP. This approach has actually provided a cost-savings for EUP applicants, allowing them to submit one EUP when EPA could require ten or more times that amount (33 in one case). Therefore, Monsanto's increased time estimates for this particular activity are not necessary representative of typical burdens for EUP applications per PIP trait.

However, as detailed in sections 3(c) and 4(b)(i) of this ICR, requirements for field testing of PIP tend to be more intensive than for chemical pesticides, resulting in more time to prepare and submit the information. Moreover, over the past ten years, the Agency has increasingly received a higher percentage of PIP EUP applications than EUPs for chemical pesticides (on a trait-by-trait basis). As a result, in this ICR, PIP EUP applications have been treated as a separate response type from chemical EUPs. For the 2010 renewal cycle of this ICR, the second response type (PIP) will use Monsanto's estimates as these are the only numbers available to the Agency at this time.

Based on the number of EUP applications received in fiscal years 2007, 2008 and 2009, the estimated annual number of respondents for chemical pesticides is 10.3 and the estimated number of EUP applications for plant-incorporated protectants is 10.7 for each year of the three

year renewal cycle. Total respondent burden hours are estimated at 32.8 hours per response for chemical pesticides at a cost of $1,942.53 and 147 hours per response for plant-incorporated protectants at a cost of $8,858.76. The total annual respondent burden of the EUP program is estimated to be 1,907 hours and $114,566.

6(b) Estimating Respondent Costs

To determine respondent costs, the Agency used the Bureau of Labor Statistics estimates of labor rates for the North American Industry Classification System (NAICS) code for the Pesticide Registrants (NAICS 325300). The managerial labor rate is based on the Standard Occupational Code (SOC) for management occupations; the technical labor rate is based on the SOC for life, physical and social science occupations; and the clerical labor rate is based on the SOC for office and administrative support occupations. The labor rates are fully loaded and indexed to 2009 dollars. (See Attachment G.) The fully loaded hourly mean wage rate estimate for managerial occupations is $118.32 per hour. For technical occupations, the fully loaded mean wage rate is $60.88 per hour, and for occupations the fully loaded mean wage rate is $37.40 per hour. (See Worksheet for Pesticide Registrants, NAICS: 325300).

Using the Agency's burden estimate and the fully-loaded labor rates, the Agency estimates the applicant labor costs to be approximately $1,942.53 per chemical pesticide EUP response, and $8,858.76 per PIPs EUP response. The total labor cost associated with the paperwork burden of the EUP program is estimated to be $114,566.

RESPONSE BURDEN AND COST ESTIMATES PER EUP APPLICATION FOR CHEMICAL PESTICIDES

COLLECTION ACTIVITIES	BURDEN HOURS (PER YEAR			TOTAL	
	Management $118.32/hr.	Technical $60.88/hr.	Clerical $37.40/hr.	Hours	Costs
Read regulations	1.3	1.3	-	2.5	$224.01
Plan activities	-	2.5	-	2.5	$152.21
Create information	-	3.0	2.0	5.0	$257.44
Gather information	-	4.3	4.0	8.3	$408.34
Compile and review	2.0	6.0	2.0	10.0	$676.74
Complete paperwork	0.3	0.8	2.0	3.1	$155.95
Store/maintain data	-	0.5	1.0	1.5	$67.84
TOTAL BURDEN	3.6	18.3	11.0	32.8	$1,942.53

ANNUAL BURDEN: 32.8 Hours Per Response x 10.3 Responses Per Year = 338.9(339 rounded) Hours
ANNUAL COSTS

(a) Management: 3.6 hours x $118.32 x 10.3 Respondents	$4,340
(b) Technical: 18.3 hours x $60.88 x 10.3 Respondents	$11,482
(c) Clerical: 11.0 hours x $37.40 x 10.3 respondents	$4,251
Total	$20,073

RESPONSE BURDEN AND COST ESTIMATES PER EUP APPLICATION FOR PLANT-INCORPORATED PROTECTANTS

COLLECTION ACTIVITIES	BURDEN HOURS (PER YEAR			TOTAL	
	Management $118.32/hr.	Technical $60.88/hr.	Clerical $37.40/hr.	Hours	Costs
Read regulations	2.0	4.0	0.0	6.0	$480.18
Plan activities	0.0	20.0	0.0	20.0	$1,217.68
Create information	0.0	40.0	4.0	44.0	$2,584.94
Gather information	0.0	6.0	8.0	14.0	$664.47
Compile and review	4.0	40.0	4.0	48.0	$3,058.23
Complete paperwork	1.0	8.0	4.0	13.0	$754.98
Store/maintain data	0.0	1.0	1.0	2.0	$98.28
TOTAL BURDEN	7.0	119.0	21.0	147.0	$8,858.76

ANNUAL BURDEN: 147.0 Hours Per Response x 10.7 Responses Per Year = 1,568 Hours
ANNUAL COSTS

(a) Management: 7.0 hours x $118.32 x 10.7 Respondents	$8,835
(b) Technical: 119.0 hours x $60.88 x 10.7 Respondents	$77,282
(c) Clerical: 21.0 hours x $37.40 x 10.7 respondents	$8,377
Total	$94,493

6(c) Estimating Agency Burden and Costs

For this ICR renewal, the Agency is using data on internal OPP Divisions that provide significant support and analysis for the EUP ICR program. This data is taken from the Time and Attendance Information System (TAIS), which archives the Agency's Full Time Equivalents (FTEs) for most OPP program activities. The Agency believes that using data from the TAIS reflects the changes to the internal operations for implementing and administering EUP 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 new source of data the estimated number of Agency FTE's dedicated to EUP activities is 0.18 managerial FTE, 1.77 technical FTEs, and 0.11 clerical FTE. Greater detail is given in the below tables. The aggregated Agency estimated FTEs dedicated to EUP activities is 2.05 and, based on 2,080 hours per FTE, the burden hours are 4,271.

Distribution of Agency Managerial FTEs Supporting EUP Activities

AD	BPPD	EFED	HED	RD
0.01	0.08	0.02	0.06	0.02
Agency total				0.18

Distribution of Agency Technical FTEs Supporting EUP Activities

AD	BPPD	EFED	HED	RD
0.05	0.85	0.13	0.52	0.21
Agency total				1.77

Distribution of Agency Clerical FTEs Supporting FIFRA EUP Activities

AD	BPPD	EFED	HED	RD
0.01	0.06	0.01	0.02	0.02
Agency total				0.11

To determine Agency costs, the Agency used the Bureau of Labor Statistics estimates of labor rates for the North American Industry Classification System (NAICS) code for the Federal Executive Branch (NAICS 999100). The managerial labor rate is based on the Standard Occupational Code (SOC) for management occupations; the technical labor rate is based on the SOC for life, physical and social science occupations; and the clerical labor rate is based on the SOC for office and administrative support occupations. The labor rates are fully loaded and indexed to 2009 dollars. (See Attachment H.) The fully loaded hourly mean wage rate estimate for managerial occupations is $112.36 per hour. For technical occupations, the fully loaded mean wage rate is $74.47 per hour, and for occupations the fully loaded mean wage rate is $42.41 per hour. (See Attachment H, Worksheet for NAICS 999100 EPA or Federal Government)

To calculate the Agency's estimated annual cost of EUP activities, the number of FTEs allocated to EUP activities is multiplied by the cost per FTE. This represents the Agency's estimate of its cost that will result from EUP activities for each of the next three years.

ANNUAL BURDEN: 2.05 FTE x 2,080 hours per FTE = 4,271 Hours
ANNUAL COSTS

(a) Management: 378 hours (0.18 FTE) x $112.36 =	$42,432
(b) Technical: 3,673 hours (1.77 FTE) x $74.47 =	$273,544
(c) Clerical: 220 hours (0.11 FTE) x $42.41 =	$9,348
Total	$325,325

6(d) Bottom Line Hours and Costs / Master Table

MASTER TABLE

	TOTAL	
	Hours	Costs
Respondent Burden/Cost Estimates:	1,907	$114,566
Agency Burden/Cost Estimates:	4,271	$325,325

6(e) Reasons For Changes in Burden

Annual respondent burden is estimated in this renewal to be 1,907 hours. This is an increase from the ICR approved by OMB, which is 757 hours. This increase is an adjustment as a result of consultations with EUP program participants, and an increase in the portion of EUP applications that are for plant-incorporated protectants (PIPs) compared to chemical pesticides. Estimated respondent costs have also increased from $48,327 to $114,566.

The corresponding estimated Agency burden and total costs has also been adjusted upwards from 1,125 hours to 4,271 hours, and from $75,199 to $325,325. This is a result of an improvement in the data and method used to calculate Agency burden.

6(f) Burden Statement

The total annual "respondent" (applicant) burden for the renewal ICR entitled Experimental Use Permit (EUP) for Pesticides is estimated to be 1,907 with an average potential per respondent burden of between 32.8 hours for chemical pesticides and 147 hours for plant-incorporated protectants. "Burden" is defined in 5 CFR 1320.3(b). The agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB control numbers for certain EPA regulations in title 40, after initial display in the final rule, are listed in 40 CFR part 9 and appear on the information collection instrument as applicable, i.e., form or instructions, and in the Federal Register.

The Agency has established a public docket for this ICR under Docket ID No. EPA-HQ-OPP-2009-0883, which is available for online viewing at www.regulations.gov, or in person viewing at the OPP Regulatory Public Docket in Rm. S-4400, One Potomac Yard (South Building), 2777 S. Crystal Drive, Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305-5805. You may submit comments regarding the Agency's need for this information, the accuracy of the provided burden estimates and any suggested methods for minimizing respondent burden, including the use of automated collection techniques.

Comments may be submitted to EPA electronically through http://www.regulations.gov or by mail addressed to OPP Regulatory Public Docket (7502P), Office of Pesticide Programs (OPP), Environmental Protection Agency, 1200 Pennsylvania Ave., NW, Washington, DC 20460–0001. You can also send comments to the Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th Street, NW, Washington, DC 20503, Attention: Desk Office for EPA. Include docket ID No. EPA-HQ-OPP-2006-0632 and OMB control number 2070-0040 in any correspondence but do not submit EUP applications and any related information (e.g., forms, reports, etc.) to these addresses. The information described in this ICR is to be submitted to the address identified in section 4(b) of this supporting statement.

7. ATTACHMENTS to this SUPPORTING STATEMENT

All of the attachments listed below can be found in the docket for this ICR, identified as Docket ID Number, **EPA-HQ-OPP-2009-0883**, which is accessible electronically through **www.Regulations.gov**. On the main page, select **Advanced Search** from the menu bar at the top and select **Docket Search**. Enter the Docket ID Number in the **Docket ID** field. Click on the **Submit button**. From the results page, you will be able to link to the docket view or directly open select documents found in the docket.

Attachment A: Federal Insecticide Fungicide Rodenticide Act (FIFRA), 7 U.S.C. 136 *et seq*.
http://agriculture.senate.gov/Legislation/Compilations/Fifra/FIFRA.pdf

Attachment B: EPA Form 8570-17 - Application for an Experimental Use Permit to Ship and Use a Pesticide for Experimental Purposes Only
http://www.epa.gov/opprd001/forms/8570-17.pdf

Attachment C: 40 CFR Part 172 - Experimental Use Permits
(e-CFR: http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=f13a0ae0044f899ce60dffaad0eedc89&rgn=div5&view=text&node=40:23.0.1.1.22&idno=40)

Attachment D: Renewal Consultations (List of Representatives and Questions Posed)

Attachment E: Consultations Responses

Attachment F: Pesticide Registration (PR) Notice 86-5: Standard Format for Data Submitted Under FIFRA and Certain Provisions of FFDCA
http://www.epa.gov/PR_Notices/pr86-5.html

Attachment G: Work Sheet used to Calculate Registrant Labor Costs

Attachment H: Work Sheet used to Calculate EPA Labor Costs