

**SUPPORTING STATEMENT FOR AN
INFORMATION COLLECTION REQUEST (ICR)**

1. IDENTIFICATION OF THE INFORMATION COLLECTION

1(a). Title and Numbers of the Information Collection

Title: Pesticide Program Public Sector Collections (FIFRA Sections 18 & 24(c))

OMB No.: 2070-new

EPA No.: 2311.01

1(b). Short Characterization/Abstract

This Information Collection Request (ICR) covers the paperwork burden under the Paperwork Reduction Act (PRA) associated with two types of pesticide registration requests made by states, U.S. Territories, or Federal agencies. Specifically, this ICR covers emergency exemption requests, which allow for an unregistered use of a pesticide, and requests by states to register a pesticide use to meet a special local need (SLN). Section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizes the Environmental Protection Agency (EPA) to grant emergency exemptions to states, U.S. Territories, and Federal agencies to allow an unregistered use of a pesticide for a limited time if EPA determines that emergency conditions exist. Section 18 requests include unregistered pesticide use exemptions for specific agricultural, public health, and quarantine purposes. Section 24(c) of FIFRA authorizes the EPA to grant permission to a particular state to register additional uses of a federally registered pesticide for distribution and use within that state to meet a SLN.

These information collection activities are ongoing and this ICR combines the following currently approved ICRs: "Applications and Summary Report for Emergency Exemption," (EPA No. 0596.08, OMB No. 2070-0032) approved by OMB and scheduled to expire July 31, 2012 and the "Notice of Pesticide Registration by States to meet a Special Local Need" (EPA No. 0595.08, OMB No. 2070-0055,) approved by OMB and scheduled to expire March 31, 2013. These ICRs are being combined into one document because the programs they represent share similar respondent populations, state governments and other federal agencies seeking exemptions or other modifications to the federal pesticide registration program defined in FIFRA. The Agency believes combining these ICRs into one ICR will increase the clarity of review for the public and will streamline Agency review of the information collection activities and related burdens for such programs.

Applications and Summary Report for Emergency Exemption (FIFRA §18)

Section 18 of FIFRA authorizes EPA to grant emergency exemptions to states and Federal agencies to allow an unregistered use of a pesticide for a limited time if EPA determines that emergency conditions exist. Generally, a Section 18 emergency exemption is requested when growers encounter an agricultural pest problem on a site for which there is either no registered pesticide available or for which there is a registered pesticide that would be effective but is not yet

approved for use on that particular site. Section 18 also allows EPA to grant unregistered pesticide use exemptions for other specific purposes such as protecting endangered species, the environment, public health, or for quarantine purposes.

Most requests for emergency exemptions are made by state lead agricultural agencies, although federal agencies such as the United States Departments of Agriculture (USDA), Defense (DOD) and Interior (USDI) also request exemptions. Most of the requests are related to an agricultural pest problem, so the process is often initiated when growers in a particular region identify an urgent, non-routine situation that registered pesticides will not alleviate. When this happens, the growers contact their state lead agency (usually a state's department of agriculture) and request that the state agency make a request to EPA for a Section 18 emergency exemption. The state agencies evaluate the requests and submit requests to EPA for emergency exemptions they believe are warranted. The uses are requested for a limited period of time to address the emergency situation only.

Notice of Pesticide Registration by States to Meet a Special Local Need (FIFRA §24(c))

Section 24(c) of FIFRA authorizes the States to register additional uses of federally registered pesticides for distribution and use within the State to meet a special local need (SLN). A State-issued registration under FIFRA Section 24(c) is deemed a federal registration for the purposes of the pesticide's use within the State's boundaries. A State must notify EPA, in writing, of any action it takes, i.e., when it issues, amends, or revokes a State registration. The Agency has 90 days to disapprove the registration. In such cases, the State is responsible for notifying the affected registrant.

2. NEED FOR AND USE OF THE COLLECTION

2(a). Need/Authority for the Collection

Applications and Summary Report for Emergency Exemption (FIFRA §18)

This information collection allows the Agency to collect the necessary data to expeditiously make statutory determinations to grant or deny a Section 18 request. Unexpected changes in climatic conditions, development of pest resistance, and/or importation of pests are some of the unpredictable situations that could necessitate a Section 18 emergency exemption request. In these situations, there is sometimes an urgent need for the use of a pesticide, a use that may be unregistered and for which there is insufficient time to obtain registration.

Requests for Section 18 emergency exemptions, i.e., the submission of applications, are made at the discretion of a state, U.S. territory, or Federal agency. Should one of these entities apply for an emergency exemption, EPA requests the information and data identified under Section 4(b) "Information Requested" of this supporting statement. If EPA determines that conditions exist which warrant an exemption and that the risks are acceptable, EPA typically approves the emergency exemption request. EPA will deny an emergency exemption request if the pesticide use may cause unreasonable adverse effects to human health or the environment, or if emergency criteria are not met. A state may withdraw an exemption request at any point in the process.

In some emergency situations, there is insufficient time for a formal Section 18 application to be made by the state and reviewed by the Agency. In such cases, a state agency may temporarily bypass the normal Section 18 application process and declare a “crisis exemption” which allows for the immediate use of an unregistered pesticide for no longer than 15 days, unless a specific exemption request has been submitted to EPA. The state declaring the crisis exemption must coordinate the declaration with EPA prior to releasing it to the users of the pesticide. EPA performs a cursory review of the use to ensure there are no concerns. If any concerns are noted, EPA confers with the state and under extreme cases may not allow a crisis to be declared. If the state follows up the crisis with, or has already submitted, an emergency exemption request, the use may continue under the crisis until EPA has made a decision on the request. EPA must establish the appropriate time-limited tolerance(s) required by the Federal Food, Drug and Cosmetic Act (FFDCA) for any pesticide uses to commercial agricultural items under emergency exemptions, including crisis exemptions.

Producers of minor crops are especially reliant on the emergency exemption program. Agricultural pests of national importance that are controlled largely through Section 18s include zebra mussels and varroa mites. Most recently, the Section 18 emergency exemption program is also supporting the stink bug invasive species agricultural initiative. Less frequently, emergency exemption requests are submitted in order to combat pests which pose a threat to public health.

On January 27, 2006, EPA published a final rule (71 FR 4495) revising the regulations governing emergency exemptions, which became effective on March 28, 2006. The final rule, 40 CFR Part 166, contains two primary revisions to the application, review and approval process for specific exemptions. The first major revision was to create a streamlined recertification application for eligible repeat emergency exemption requests. The second major revision was to clarify the definition of significant economic loss and revision of data requirements for documenting loss.

Section 18 of FIFRA (see **Attachment A-1**) states in part that, "The Administrator may, at [his/her] discretion, exempt any federal or state agency from any provision of this Act if [s]he determines that emergency conditions exist that require such exemption." Under this provision, EPA may temporarily authorize federal or state agencies to allow use of pesticide products under emergency conditions. Detailed regulations regarding the procedures for emergency exemptions are codified at 40 CFR Part 166 (see **Attachment B-1**).

Section 408 of the Federal Food, Drug, and Cosmetic Act (see **Attachment A-3**) requires that EPA establish tolerances, maximum legal limits for all pesticide residues in food, including those resulting from Section 18 emergency uses. Tolerances established for emergency exemptions are time-limited to correspond to the use season or multiple use seasons. Thus, data collected under this collection also allows the Agency establish tolerances or tolerance exemptions for Section 18 emergency uses. When the Agency establishes a tolerance, there must be a finding that there is “reasonable certainty that no harm” will result to human health from aggregate and cumulative exposure to the pesticide, as required by the health-based standard. For Section 18 actions, these Agency tolerance setting activities must be undertaken in a timely manner. Their expiration dates are established by a final rulemaking published in the *Federal Register*. The time-limited tolerances for pesticide emergency exemptions are codified at 40 CFR 176, see **Attachment C**.

Notice of Pesticide Registration by States to Meet a Special Local Need (FIFRA §24(c))

EPA requires this information to ensure that the States do not issue any registrations that might conflict with other requirements in FIFRA, or with Section 408 of FFDCA, which require that a tolerance exist for any pesticide used on a food or feed commodity (**Attachment A-3**). FIFRA Section 24(c)(3) mandates that if the Administrator determines that a registration issued by a State is inconsistent with the FFDCA or if the use of a pesticide registered by the State constitutes an imminent hazard, the Administrator may disapprove the registration.

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

The data collected by the Agency under FIFRA Section 18 for the temporary use of a pesticide product for an unregistered use allows EPA to evaluate whether such use will mitigate an emergency situation. Generally, the data submitted must support the Agency's evaluation of whether: 1) an emergency exists; 2) use of the pesticide under the exemption will be protective of human health and the environment; and 3) the requested product's effectiveness in allaying the emergency. Information contained in the application and follow-up reporting is essential for gauging the emergency nature of the situation, the effectiveness of the product, the risks of the treatment program, and the economic loss based on the new tiered thresholds for significant economic loss determination.

The potential respondents to the SLN information collection activity are the States, which FIFRA Section 2(aa) defines to include Washington, D.C., Puerto Rico, the U.S. Virgin Islands, Guam and the islands of the Pacific Territory, and American Samoa. The information "users" are the Agency decision makers at the U.S. EPA Office of Pesticide Programs (OPP). The information is used to ensure conformity with FIFRA and FFDCA. The States are required to collect, from the manufacturer or grower groups, adequate information to support the Section 24(c) application for registration or amendment. Both the State and the manufacturer or grower group are required to keep records.

3. NON DUPLICATION, CONSULTATIONS, AND OTHER COLLECTION CRITERIA

3(a). Non duplication

This information collection activity is unique and is administered by EPA pursuant to FIFRA. There is no possibility of duplication by any other federal agency.

3(b). Public Notice and Opportunity to Comment

In preparing this consolidation ICR, EPA published a notice in the Federal Register (73 FR 65846) on November 5, 2008 which provided a 60-day public notice and comment period on the draft combined ICR. The Agency did not receive any public comments on the draft combined ICR.

3(c). Consultations

Applications and Summary Report for Emergency Exemption (FIFRA §18)

Consultation and/or dialogue between states and the Agency during the submission and review of an application are frequent and ongoing. Questions or consultations pertaining to a particular submission are addressed in meetings or telephone conversations with the applicant and do not necessarily occur at specified intervals. In addition to communications regarding specific exemption requests, members of Agency staff participate in stakeholder training workshops with state pesticide regulatory representatives. These communications permit an exchange of information regarding problems and questions on the program in general and other relevant issues. For example, OPP staff members conducted a series of training workshops at headquarters and several regional locations for stakeholders.

In the preparation of this ICR, EPA also consulted by telephone and e-mail with representatives of three state agencies that have experience with submitting Section 18 emergency exemption requests to obtain feedback on the burden estimates in the ICR, the clarity of instructions provided, the feasibility of reporting the data by electronic means, and other questions pertaining to the requirements of the emergency exemption program. The consultation included state representatives from the Wisconsin Department of Agriculture, Trade and Consumer Protection; the California Department of Pesticide Regulation, Pesticide Registration Branch; and the Nebraska Department of Agriculture, Animal and Plant Health Division.

All three states basically agreed that the new streamlined process for re-certified Section 18 applications, first implemented in 2006, has reduced the amount of time needed to submit an emergency exemption request. The streamlined process eliminates the need to submit a full application every year. Two of the three states, California and Nebraska, stated that the Agency's burden and cost estimates for typical Section 18 emergency requests were accurate but pointed out that there had been rare instances of pest management challenges, e.g., Asian soybean rust, which were national in scope and required significant resources for the two lead states. The Wisconsin Dept. of Agriculture found it difficult to estimate burden hours per application for technical labor because the technical expert, who does not work for the state, prepares the emergency exemption application materials. As such, for recertification requests, the burden hours for technical labor seemed high. All three states have submitted applications electronically and agree that it saves time and money and facilitates a quicker response when sharing information with other states and agencies. EPA notes that there will always be some variance of burden hours and costs between state programs because of the differences of how the programs are administered in each state. At this time, the Agency does not believe the variance between the states' burden hours and costs and the Agency's estimated burden hours and costs warrants readjustment. Thus, no changes to the estimated burden hours per response have been made for this ICR. The changes in total annual burden hours come from the reduced number of Section 18 requests per year and the changes in total estimated cost come from the change in the number of requests plus the updated wage rates. The details of consultant contacts and the comments received in the consultation process for emergency exemptions are in **Attachment D**.

Notice of Pesticide Registration by States to Meet a Special Local Need (FIFRA §24(c))

In addition to informal consultation between states and EPA during the submission and review of SLN registration applications, which occurs on an ongoing basis, EPA contacted several stakeholders to consult them on their assessment of the regulatory burden estimates expressed by the Agency in this ICR. One stakeholder responded.

Mr. John R. Lake
Pennsylvania Department of Agriculture
Phone: (717) 772-5211

The single consultation response indicated that the burden and cost estimates were on the higher end of a reasonable range. Additionally, the respondent indicated that the Agency should focus on improving the management and accessibility of publically available data. The respondent also commented on the need to improve the guidelines for submittal of information. The full response for SLN notices is contained in **Attachment E**.

3(d). Effects of Less Frequent Collection

As discussed above, there is no collection schedule for these information collection activities, per se. This activity is conducted only once per application for a FIFRA Section 18 or Section 24(c) registration. Therefore, it is not possible for EPA to reduce the frequency of the collection.

3(e). General Guidelines

Applications and Summary Report for Emergency Exemption (FIFRA §18)

EPA requires the states to maintain records of the first food use of a pesticide under an emergency exemption for two years following the date of expiration. Generally, an applicant for an emergency exemption is not required to maintain data beyond the date that the summary report has been received by the Agency. The OMB guidelines codified in 5 CFR 1320.6 indicate that data, other than health, medical, or tax records, need not be retained for more than three years; therefore, this time limit will not be exceeded in this program.

OMB regulations require agencies to provide a statement indicating whether the proposed collection of information involves the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses, and an explanation of the decision (5 CFR 1320.5(a)(iii)(E)). OPP does offer the option of electronic submission of emergency exemption requests, or Section 18 applications. States may e-mail applications to OPP in Word or pdf format.

Notice of Pesticide Registration by States to Meet a Special Local Need (FIFRA §24(c))

The recordkeeping activities briefly described in this program exceed OMB's guideline that agencies not require that records be retained for more than 3 years (5 CFR 1320.5(d)(2)(iv)). As

authorized under FIFRA Section 8, EPA regulations 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)*(EPA ICR No. 0143)).

In addition, this information collection does not include any estimated burden or costs related to the third party activities associated with pesticide product labeling. In 1995, OMB determined, in the context of OMB Control No. 2070-0060, *Application for New and Amended Pesticide Registration* (EPA ICR No. 0277), that the Agency does not need to estimate burden or costs for the third party disclosure requirement involving the registrant's disclosure of product specific information to potential users and the general public through the pesticide labeling. This activity is not considered to be a collection of information subject to approval under the PRA because the information that must be included as the product labeling has been approved and provided by EPA. (5 CFR 1320.3(c)(2)).

Although a pilot project to develop a fully electronic SLN submission option is underway, OPP is not offering a fully electronic SLN submission option at this time. Extensive guidance regarding the SLN submission process is available to states via the OPP Internet site at: <http://www.epa.gov/opprd001/24c/>.

3(f). Confidentiality

Applications and Summary Report for Emergency Exemption (FIFRA §18)

Although EPA urges submitters to minimize the amount of Confidential Business Information (CBI) contained in Section 18 requests, some data and/or information submitted to the Agency in conjunction with this rule may be claimed as trade secret or commercial or financial information and will be protected from disclosure by EPA under FIFRA Section 10 and the associated regulations codified at 40 CFR Part 2, Subpart B. In general, EPA works to make information relative to Section 18 decisions and supporting data easily available to the public (e.g. web site postings of program information, and public distribution of decision documents). Growers and industry stakeholders need to be made aware of Section 18 exemptions. Thus, as a rule, claims of confidentiality are not made on emergency exemption applications. On certain rare occasions, the manufacturer of the requested producer may have product formulation information that is necessary to protect CBI.

Trade secret information and CBI are handled strictly in accordance with the FIFRA CBI Security Manual. This manual contains instructions relative to all contact with confidential documents, including the responsibilities of EPA employees; physical security measures; CBI materials within EPA, such as CBI typing procedures (documents typed internally or on contract); and internal division procedures. The manual dictates that: (1) all CBI must be marked or flagged as such by the submitter of that information, (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 shredded.

Notice of Pesticide Registration by States to Meet a Special Local Need (FIFRA §24(c))

The Agency estimates that less than 0.1% of the 24(c) registrations are for new products, thereby requiring the submission of a Confidential Statement of Formula. In addition, any data and/or information brought to the Agency in conjunction with the submission of 24(c) registrations may be claimed as trade secret, commercial or financial information and must be protected from disclosure by EPA under FIFRA Section 10 and the associated regulation as contained in 40 CFR Part 2, Subpart B. All CBI data submitted to EPA under FIFRA is handled strictly in accordance with the provisions of the FIFRA CBI Security Manual.

3(g). Sensitive Questions

No information of a sensitive or private nature is requested in conjunction with this ICR. 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

Respondents affected by the collection activities under this ICR include federal and state agencies which regulate pesticides or pesticide products, with the vast majority done by states, as well as pesticide registrants for the Section 24(c) applications. Section 2(aa) of FIFRA defines state to include any of the 50 states, the District of Columbia, the Commonwealth of Puerto Rico, the United States Virgin Islands, Guam, the Trust Territory of the Pacific Islands, and American Samoa. The North American Industrial Classification System (NAICS) code assigned to the states and federal government agencies responding to this information collection is 999200, State Government. The NAICS code used for registrants is 325300, Pesticide, Fertilizer, and Other Agricultural Chemical Manufacturing.

4(b)(i). Information Requested

Applications and Summary Report for Emergency Exemption (FIFRA §18)

To apply for an exemption, an application must be submitted in writing by the head of a federal or state agency, the Governor of the state involved, or their official designee. If a designee has been delegated authority to request exemptions, written authorization of such delegation must accompany the request or be on file with EPA (See **Attachment A-1**).

Applications for specific, quarantine, or public health exemptions must contain the following information:

Data Item	Description
Identity of contact person(s)	Name and telephone number of one or more qualified experts who may be contacted if questions arise concerning the application.

Data Item	Description
Description of the pesticide	<p>Description of pesticide(s) proposed for the use under the exemption.</p> <p><i>For a federally registered pesticide:</i></p> <ul style="list-style-type: none"> ▪ registration number and name of pesticide product (if a specific product is requested), or formulation(s) requested (if a specific product is not desired), and ▪ copy of any additional labeling proposed for the emergency exemption. <p><i>For an unregistered pesticide product, copy of:</i></p> <ul style="list-style-type: none"> ▪ EPA Form No. 8570-4 Confidential Statement of Formula (or reference to one already submitted to the Agency), and ▪ Complete labeling to be used in connection with proposed use.
Description of the proposed use	<p>Application must identify all of the following:</p> <ul style="list-style-type: none"> ▪ sites to be treated, including locations within the state, ▪ method of application, ▪ rate of application of active ingredient and product, ▪ total acreage or other appropriate unit proposed to be treated, ▪ total amount of pesticide proposed to be used (active ingredient and product), and ▪ all applicable restrictions and requirements concerning proposed use and qualifications of applicators using the pesticide.
Alternative methods of control	<p>Detailed explanation of why the pesticide(s), currently registered for the particular use proposed in the application, is not available in adequate supplies and/or effective to the degree needed to control the emergency. If the applicant states that an available registered pesticide is ineffective for the given situation, the statement must be supported by field data that demonstrate this, or if such data are unavailable, statements by qualified agricultural experts, extension personnel, university personnel or other persons similarly qualified in the field of pest control. In addition, a detailed explanation must be provided of why alternative practices, if available, either would not provide adequate control or would not be economically or environmentally feasible.</p>
Effectiveness of proposed use	<p>Application must contain data, discussion of field trials, and other evidence that provide the basis for the conclusion that the proposed pesticide treatment will be effective in dealing with the emergency.</p>
Discussion of residues for food uses	<p>If proposed use is expected to result in residues of the pesticide in or on food or feed, application must list the food likely to contain such residues and must contain an estimate of the maximum amount of the residue likely to result from the proposed use, together with the information on which such estimates are based.</p>
Discussion of risk information	<p>Potential risks to human health, endangered species, beneficial organisms, and the environment expected to result from the proposed use, together with references to data and other supporting information.</p>
Coordination with other affected state or federal agencies	<p>If the proposed pesticide use is likely to be of concern to other Federal or state agencies, application must indicate that such agencies have been contacted prior to submission of the application, and any comments received from such agencies must be submitted to EPA.</p>

Data Item	Description
Notification of registrant or basic manufacturer	Statement that the registrants of all pesticide products proposed for use or, if appropriate, the basic manufacturer, support the request for a specific, quarantine, or public health exemption.
Description of proposed enforcement program	Explanation of the authority of the applicant or related state or federal agency for ensuring that use of the pesticide under the proposed exemption would comply with any special requirements imposed by EPA and a description of the program and procedures for assuring such compliance.
Progress toward registration	Prior to submitting an application for a repeat specific or public health exemption, the federal or state agency must contact the registrant regarding the progress being made toward registration of the proposed use and include this information in the Section 18 application. This information must also include a summary of study deficiencies and data gaps, and registrant's timetable for completing requirements for registration.

In addition, the following information must be provided:

Data Item	Description
For a specific exemption	<p>All of the following, as appropriate, must be provided concerning the nature of the emergency:</p> <ul style="list-style-type: none"> ▪ scientific and common name of the pest or pest complex; ▪ events that brought about the emergency condition; ▪ anticipated risks to endangered or threatened species, beneficial organisms, or the environment that would be remediated by the proposed use of the pesticide; and ▪ anticipated significant economic loss that would occur without the use of the requested registered pesticide, together with data and other supporting information, that addresses the historical net and gross revenues for the site, the estimated net and gross revenues for the site without use of the proposed pesticide, and the estimated net and gross revenues for the site with use of the proposed pesticide.
For a quarantine exemption	<p>A quarantine exemption may be authorized in an emergency condition to control the introduction or spread of any pest new to and therefore known to be widely prevalent or distributed within and throughout the United States and its territories. The application for the quarantine exemption must include the following information:</p> <ul style="list-style-type: none"> ▪ scientific and common name of the pest or pest complex; ▪ origin of the introduced pest and the means of its introduction and spread into the area, if known. ▪ economic impact of controlling versus not controlling the pest via the proposed pesticide treatment.
For a public health exemption	<ul style="list-style-type: none"> ▪ Scientific and common name of pest or pest complex; if the pest is a vector, a description of the disease it is expected to transmit; and ▪ magnitude of the health problems that are expected to occur without the pesticide use; and availability of medical treatment for the health problem.
For a crisis exemption, <u>only</u> the following information must be provided:	<p><i>The state or federal agency issuing the crisis exemption must coordinate any crisis declaration in advance with EPA prior to initiating the use. The notice must include:</i></p> <ul style="list-style-type: none"> ▪ <i>name of active ingredient authorized for the crisis use, including the common name and the Chemical Abstracts Service (CAS) number;</i> ▪ <i>crop or site on which the pesticide is to be used;</i> ▪ <i>use pattern (method, number, and rate of applications);</i> ▪ <i>dates that applications started or will begin and end;</i> ▪ <i>an estimate of the level or residues of the pesticide expected to result from use under the crisis exemption (for food crops); and</i> ▪ <i>discussion of the emergency situation and any other pertinent information available at the time, including why time was insufficient to request a specific or quarantine exemption, and intentions with respect to requesting a specific exemption for this use.</i>

Notice of Pesticide Registration by States to Meet a Special Local Need (FIFRA §24(c))

Application for a 24(c) registration: Applicants for State registrations under FIFRA Section 24(c) to meet a special local need (typically pesticides manufacturers and grower groups) must submit the

following information directly to the state using EPA Form 8570-25, Application for/Notification of State Registration of a Pesticide to Meet a Special Local Need (**Attachment G**), and EPA Form 8570-4, Confidential Statement of Formula (**Attachment F**), when applicable:

Data Item	Description
Identity of contact person(s)	Name and address of the applicant and any other person whose name will appear on the labeling or in the directions for use.
Description of the pesticide	The name of the pesticide product, and, if the application is for an amendment to a federally registered product the EPA registration number of that product.
Proposed product labeling	A copy of the proposed labeling, including all claims made for the product as well as directions for its use to meet the special local need, consisting of: <ul style="list-style-type: none"> ▪ For a new product, a copy of the complete proposed labeling; or, ▪ For an additional use of a federally registered product, a copy of proposed supplemental labeling and a copy of the labeling for the federally registered product. ▪ If a State classifies for restricted use a product or use, which is not required to be so classified under FIFRA, supplemental labeling for the product or use containing additional appropriate precautions, and a statement that the product or use is for restricted use within the State may be required.
Proposed product formulation	The complete formula of the product, if the application is for a new product registration.
Other relevant information about product	Any other information that is required to be reviewed prior to registration.

Information following the issuance of a 24(c) registration: As soon as practical after a registration is issued, the following information must be provided:

Data Item	Description
Copy of the final printed labeling	New product labeling must contain: <ul style="list-style-type: none"> ▪ A statement identifying the State where registration is to be valid. ▪ The special local need registration number assigned by the State. ▪ For an additional use of a federally registered product, the State must require that at the time of sale, labeling from the federally registered product be accompanied by supplemental labeling.

Information Requested by EPA to verify an SLN registration: Within ten working days from the date a State issues, amends or revokes a registration, the State is required to notify EPA, in writing, of the action. Using EPA Form 8570-25 where applicable, notification of State registration or amendments thereto, must include the following:

Data Item	Description
Effective Date	<ul style="list-style-type: none"> ▪ Effective date of the registration or amendment. ▪ Notification of revocation of a registration by a State shall indicate the effective date of revocation, and shall state the reasons for revocation.
Product Information	<ul style="list-style-type: none"> ▪ Confidential statement of the formula of any new product, and

Data Item	Description
	<ul style="list-style-type: none"> ▪ A copy of the draft labeling reviewed and approved by the State, provided that labeling previously approved by the Administrator as part of a federal registration need not be submitted.
Final Product Labeling	State must send EPA a copy of the final printed labeling approved by the State within 60 days after the effective date of the registration or amendment.
Other relevant information	The Agency may request, when appropriate, that a State submit any data used by the State to determine that unreasonable adverse effects will not be caused.

4(b)(ii). Respondent Activities

Applications and Summary Report for Emergency Exemption (FIFRA §18)

EPA Form No. 8570-4, *Confidential Statement of Formula (Attachment F)*, is the single form associated with the application and/or summary reports for an emergency exemption. This form is being used for this ICR but is covered by a different ICR - *Application for New and Amended Pesticide Registration (OMB No. 2070-0060, EPA ICR No. 0277)*. To comply with the reporting and record keeping requirements for specific, quarantine, and public health exemptions, the exemption holder must provide the following data items to EPA:

Data Item	Description
Unexpected adverse effects information	Any unexpected adverse effects resulting from the use of a pesticide under a crisis, specific, quarantine, or public health exemption must be reported immediately to the Agency.
Final reports	<p>A report summarizing the results of pesticide use under a specific, quarantine, and public health exemption must be submitted to EPA within six months of the expiration of the exemption unless otherwise specified by the Agency. The information in this report must include the following:</p> <ul style="list-style-type: none"> ▪ total acreage, amount of commodity or other unit treated and the total quantity of the pesticide used; ▪ discussion of the effectiveness of the pesticide in dealing with the emergency condition; ▪ description of any unexpected adverse effects that resulted from the use of the pesticide under the exemption; ▪ results of any monitoring required and/or carried out under the exemption; ▪ any enforcement actions taken in connection with the exemption; ▪ method(s) of disposition of food crops, if required to be destroyed; and <p>any other information requested by the Administrator.</p>

Records	<p>Records for all treatments involving the first food use of a pesticide will be maintained by the state or federal agency for which an emergency exemption was granted for a minimum of two years following the date of expiration of the exemption. On request by EPA, these records must be made available to the Administrator. Records must include the following:</p> <ul style="list-style-type: none"> ▪ locations where the pesticide was applied; ▪ dates of application (range); and ▪ total quantity of the pesticide used.
----------------	---

To obtain permission to use an unregistered pesticide product under emergency conditions, an applicant must petition EPA in writing, provide information addressing the data items listed above, and commit to the submission of the summary report on the use. Section 18 emergency exemption applications are submitted to the Risk Integration, Minor Use, and Emergency Response Branch (Mail Code 7505P), Registration Division, Office of Pesticide Programs, U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue., N.W., Washington, D.C., 20460.

In order to participate in the program, the applicant must complete the following tasks:

- Read the applicable FIFRA requirements and CFR regulations.
- Process, compile, and review the requested data.
- Generate application correspondence and a follow-up summary report.
- Store, file, or maintain the information.

Notice of Pesticide Registration by States to Meet a Special Local Need (FIFRA §24(c))

Applicant Activities:

Data Item	Description
Gather data	Proposed label, product formulation (if applicable), name of applicant, name of product, federal registration number (if applicable), and any other information required by the State.
Submit materials to the State	Compile necessary data and materials. Complete application for State registration (EPA Form 8570-25) and submit to State
Store, file, and maintain the information	Applicant must maintain records of information submitted to the State for as long as the State registration is active.

State Activities:

Data Item	Description
Compile information	Organize data submitted by registrant (or grower group) to develop the SLN justification. Registrant must maintain records of information submitted to the State.
Review information	Evaluate the data: <ol style="list-style-type: none"> 1. Determine whether there is a special local need for the registration; 2. Determine that use of the product for which registration is sought will not cause unreasonable adverse effects on humans or the

	environment; 3. For use of a product with public health claims, determine that the product warrants the claims made, i.e., efficacy determination; 4. Review the proposed labeling submitted with the application to determine State and federal compliance; 5. Issue or amend State registration.
Notify Federal Government	Complete and submit EPA Form 8570-25 and all accompanying data and materials. Respond to any Agency questions or concerns.
Store, file, and maintain the data	Maintain copies of the information and data submitted to EPA.
Respond to Registrant (if necessary)	Notify registrant if Federal Government disapproves the State's registration.

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

5(a). Agency Activities

Applications and Summary Report for Emergency Exemption (FIFRA §18)

EPA regulations at 40 CFR part 176, entitled “Time-Limited Tolerances for Pesticide Emergency Exemptions,” provide a process to ensure timely decisions on any tolerance-related issue in response to a request for an emergency exemption for a pesticide to be used on food or feed. Time-limited tolerance petitions related to FIFRA Section 18 are evaluated on a case-by-case basis to determine if adequate reliable data are available to make the required safety finding mandated under FFDCA Section 408 and FQPA.

Applications for emergency exemptions are submitted by U.S. states and territories, and federal agencies at their discretion. These applications are received by OPP, Registration Division, Risk Integration, Minor Use, and Emergency Response Branch, where they are reviewed for completeness. The application package is routed to scientists and economists within OPP to determine whether the proposed emergency exemption is warranted, that there is “reasonable certainty of no harm” to human health resulting from aggregate and cumulative exposure, and that it presents no undue hazard to humans or the environment (See **Attachment B-1**). Once the determinations are made, the applicant is notified in writing. The tolerance is published in the Federal Register.

The Agency conducts the following activities when responding to an emergency exemption application under FIFRA Section 18:

- Route the application/report to appropriate scientists and economists for review.
- Review information submitted for scientific accuracy.
- Perform a biological, ecological, and economic analysis and a multi-disciplinary risk assessment of the requested use and then forward a regulatory recommendation on the proposed exemption along with a draft notification to EPA management.

- Make the FQPA finding of “reasonable certainty of no harm” to human health resulting from aggregate and cumulative exposure. Establish a time-limited tolerance if required.
- Conduct an assessment of the progress toward registration for the requested use.
- OPP Director (or designee) makes final decision.
- Notify applicant of decision.
- Prepare and publish Federal Register Notice (for applicable food use requests).
- Record electronic data in Agency’s data system and internet cite.

Notice of Pesticide Registration by States to Meet a Special Local Need (FIFRA §24(c))

Activity	Description
Read and record State-submitted information	EPA Form 8570-25 and the application is screened, jacket created, and information is recorded in electronically for tracking purposes.
Review data submissions	Review materials for adherence to federal requirements of label integrity, lack of imminent risk, and the existence of appropriate tolerances.
Publish summary of 24(c)s	Publish, on a regular basis, in the Federal Register, a summary of all State registrations received and those disapproved.
Notify State (if necessary)	Notify the State if the registration is disapproved.
Store/file/maintain the data	Maintains an electronic reference file on all FIFRA Section 24(c) applications received and approved.

5(b). Collection Methodology and Management

Applications and Summary Report for Emergency Exemption (FIFRA §18)

When applications for emergency exemptions are received by EPA, they are jacketed and filed by the name of the state, territory or federal agency, by the date, and by the number of the submission for that entity. The application is tracked in EPA’s data system as an active pending request through the determination process, and subsequent receipt of the summary report, after which the exemption becomes a historical file and the regulatory action is closed.

Notice of Pesticide Registration by States to Meet a Special Local Need (FIFRA §24(c))

The Section 24(c) application form and any supporting materials are received and date-marked to start the 90-day clock. They are screened for completeness, a master file jacket is created for the incoming application, and the case is assigned a unique identifier. Identifying information then is extracted for the required FR Notice of receipt, for the Pesticide Product Information System (PPIS) inventory of all 24(c) actions, and for tracking records.

The file then is reviewed for substantive acceptability, and any scientific data is routed for review by appropriate specialists. When all reviews are completed a decision is made to accept or disapprove the application.

If the decision is to disapprove the application, the State is notified, and a notice of disapproval is published in the FR. The disapproval is recorded in the PPIS data base. If the decision is to accept the application, this is recorded in the master file, and no further action is required.

5(c). Small Entity Flexibility

Small entities are not impacted by this ICR. Sections 18 and 24 of FIFRA apply directly only to State, territorial, and federal government agencies; it does not apply to other entities. States are not “small entities” as defined by the Regulatory Flexibility Act.

While pesticide manufacturers and grower groups may be involved in EPA-State activities under this ICR, any activities they undertake are in response to FIFRA Section 24, which expressly delegates certain pesticide registration authority to States. These entities must comply with State procedures to obtain a special local need registration under FIFRA Section 24(c). Consequently, the Agency cannot offer them any flexibility without intruding on the processes established by each state.

5(d). Collection Schedule

There is no collection schedule associated with this ICR, per se. This information collection activity is initiated by the States or by certain federal agencies when they apply for a FIFRA Section 24(c) registration, or determine that they are confronted with an emergency situation and subsequently submit an emergency exemption application to EPA under FIFRA Section 18.

6. ESTIMATING THE BURDEN AND COST OF THE COLLECTION

The respective burden and cost estimates for PRA activities for the Section 18 and Section 24(c) programs are presented in this section, along with the methodology for developing the estimates.

6(a). Estimating Respondent Burden Hours

The estimates of burden hours per request or application were developed with input from respondents for both programs, and used in the two currently-approved ICRs. EPA believes that these previous burden estimates are still valid, and they were deemed reasonable by those participating in the consultation process during the development of this ICR. Therefore, there is no change in the estimated respondent burden hours per application for either program in this ICR.

The estimated burden hours per response (request or application), for each respondent collection activity, by labor category, is presented in separate tables for Sections 18 and 24(c), in section 6(b) (along with costs per response). The total average respondent burden hours per request is derived by adding the burden for all activities for each labor category, and then summing across labor categories. The total annual respondent burden is calculated as the total burden hours per request times the number of requests (applications) received annually, and is shown in tables for each collection in section 6(b) (along with total annual costs).

The estimated number of applications submitted annually has been updated for this ICR. The numbers of applications received annually for Sections 18 and 24(c) have decreased significantly for both programs since the currently-approved ICRs were developed. The estimates used in this ICR of the number of applications submitted annually under Section 18 and Section 24(c) are based on three-year averages of applications actually received for each program for the years 2009 through 2011.

Applications and Summary Report for Emergency Exemption (FIFRA §18)

The estimated average burden of 99 hours per emergency exemption request is presented in Table 1. The total annual response burden associated with submitting applications and summary reports for emergency exemptions is estimated to be 12,672 burden hours per year for the next three years. The number of applications received by EPA has decreased from an average of 494 per year for the years 2004 - 2006 to an average of 128 per year for the years 2009 - 2011. The total annual respondent burden is shown in Table 2 (along with total annual costs). The important trends seen in the applications received in the past three years are:

- successful transition of many widely used, minor crop, Section 18 emergency pesticide uses to full registrations and tolerances under Section 3 labels, thereby eliminating numerous, long-running (repeat) applications from many states;
- continuing pest management challenges that are national in scope that trigger emergency exemption requests, e.g., the use of potassium salt of hop beta acids and fenpyroximate in beehives to control varroa mite; reliance on Section 18 requests to respond to agricultural species threats such as invasive stink bugs and quarantine exemptions to control invasive mussel species.

The Agency expects that some of these factors will persist and expects to receive an average of about 128 applications annually for the next three years. However, the Agency is unable to estimate precisely how many requests will be submitted in the future.

Notice of Pesticide Registration by States to Meet a Special Local Need (FIFRA §24(c))

Registrant Burden

The Agency estimates the average burden for applicants (registrants) for state registrations under FIFRA Section 24(c) to equal approximately 39 hours per application, as presented in Table 3. The Agency expects that approximately 325 applications will be submitted annually during the next 3 years, based on the annual average from 2009-2011. The estimated number of applications has decreased from 693 annually in the currently-approved ICR. The Agency estimates an annual applicant burden of 12,675 hours, shown in Table 4.

State Agency Burden

EPA estimates the state agency burden to average 13 hours per response, as shown in Table 5. The Agency estimates an annual State Agency burden of 4,225 hours (see Table 6).

Overall Burden

The overall respondent burden associated with this collection, which is the sum of registrant and state agency burden, is estimated to be 16,900 hours per year, presented in Table 7. No changes have been made in the requirements for Section 24(c) applications, and no changes have been made to the overall provisions of this information collection activity.

6(b). Estimating Respondent Costs

The costs for respondents to respond to the information collection requirements are calculated by using the estimated burden per response, the number of responses annually, and the appropriate wage rates for each activity. The methodology and sources for wage rates used is presented in the subsection below.

The cost per response (application or request) is calculated by multiplying the burden hours for each respondent collection activity by the wage rate for the affected labor category. The cost for each collection activity per application is summed across labor categories (e.g., managerial, technical, and clerical). Then the total cost for each collection activity is summed for the total cost per application. The applicable wage rates and these costs are presented in separate tables for Sections 18 and 24(c) (along with burden hours) below.

The total annual costs for each labor category are calculated by multiplying the total annual burden hours for that category by the applicable wage rate. Total costs for each labor category are then summed to get the total annual costs for the collection. These costs are presented below in separate tables for each of the two collections.

Methodology for Calculation of Fully Loaded Wage Rates

For this ICR, the Agency revised the estimated wages, benefits, and overhead for all labor categories for affected industry, state government, and EPA employees based on the most recent publicly available data from the US Bureau of Labor Statistics. The methodology for calculating the wage rates is the same for both the emergency exemption and SLN collections, and are based on 2010 wage data (see Attachment H). The calculation of the wage rates uses base wage data for each sector and labor type for an *Unloaded wage rate* (hourly wage rate) and calculates the *Loaded wage rate* (unloaded wage rate + benefits) and the *Fully loaded wage rate* (loaded wage rate + overhead) based on that data. Fully loaded wage rates are used to calculate respondent costs.

Unloaded Wage Rate: Wages are estimated for labor types (management, technical, and clerical) within applicable sectors. The Agency uses average wage data for the relevant sectors available in the National Industry-Specific Occupational Employment and Wage Estimates from the Bureau of Labor Statistics (BLS) (see http://www.bls.gov/oes/current/oes_nat.htm).

Sectors: The specific North American Industry Classification System (NAICS) code and website for each sector is included in that sector's wage rate table in **Attachment H**. Within each sector, the wage data are provided by Standard Occupational Classification (SOC). The SOC system is used by Federal statistical agencies to classify workers into occupational categories for the purpose of collecting, calculating, or disseminating data (see http://www.bls.gov/oes/current/oes_stru.htm).

Loaded Wage Rate: Unless stated otherwise, all benefits represent 44% of unloaded wage rates, based on average rate of benefits for all civilian non-farm workers (see <http://www.bls.gov/news.release/ecec.t01.htm>). If any sectors are listed for which 44% is not applicable; the applicable percentage will be stated.

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

Applications and Summary Report for Emergency Exemption (FIFRA §18)

For Section 18 emergency exemption requests, the state government is the applicant and the only respondent. Table 1 shows the costs per emergency exemption request (or application) of each collection activity, and the total cost per request. The total estimated respondent costs for completing a Section 18 application and summary report are \$5,774 per response.

Table 1. FIFRA §18 – Applicant (State Government) Burden Hours and Cost Estimates per Emergency Exemption Request

COLLECTION ACTIVITY	Burden per application (hours) ¹			Total	
	Managerial \$82.63/hr	Technical \$57.68/hr	Clerical \$39.20/hr	Hours	Costs (\$)
Read FIFRA and FQPA requirements and CFR regulations	4	4	0	8	\$561
Process, compile, and review the requested data for accuracy and appropriateness	0	74	0	74	\$4,269
Generate application correspondence and follow-up summary report	0	15	0	15	\$865
Store/maintain/submit information	0	0	2	2	\$78
Totals	4	93	2	99	\$ 5,774

¹ Hourly wages rates are fully loaded wage rates based on NAICS 999200 – State Government, from U.S. Dept. of Labor, Bureau of Labor Statistics, May 2010. See Attachment H for wage calculations.

² Totals may not sum due to rounding.

Table 2 shows the total annual costs for management, technical, and clerical time, as well as the estimated total annual respondent costs of \$739,013 for filing Section 18 applications and summary reports.

Table 2. FIFRA §18 – Total Annual Applicant (State Government) Burden Hours and Cost Estimates

Labor Category	Total Burden Hours per Request	Number of applications	Total Annual Hours	Labor Rate (\$/hr)	Total Annual Costs (\$)
Managerial	4	128	512	\$82.63	\$42,305
Technical	93	128	11,904	\$57.68	\$686,672
Clerical	2	128	256	\$39.20	\$10,036
Totals	99	128	12,672	---	\$739,013

Notice of Pesticide Registration by States to Meet a Special Local Need (FIFRA §24(c))

For Section 24(c) applications for SLN registrations, respondents include both pesticide product registrants and state governments, as each bears a burden for an application. Costs for the two respondent groups are presented separately, and then summed together, in the tables below.

Table 3 displays estimates of the cost per SLN registration application for registrants, both by collection activity and the total. Total costs per application to registrants are estimated to be \$3,063. Table 4 shows the total costs for all applications per year for each labor category and in total. The total estimated annual costs to registrants for Section 24(c) applications is approximately \$995,000.

Table 3. FIFRA §24(c) - Applicant (Registrant) Burden Hours and Cost Estimates per Application

COLLECTION ACTIVITY	Burden per application (hours) ¹			Total ²	
	Managerial \$120.28/hr	Technical \$60.85/hr	Clerical \$37.11/hr	Hours	Costs (\$)
Gather data	5.0	12.5	0.0	17.5	\$1,362
Submit materials to state	9.0	5.5	1.0	15.5	\$1,454
Store/file/maintain the data	0.0	1.0	5.0	6.0	\$ 246
Totals	14.0	19.0	6.0	39.0	\$3,063

¹ Hourly wages rates are fully loaded wage rates based on NAICS 325300 - Pesticide, Fertilizer, and Other Agricultural Chemical Manufacturing from U.S. Dept. of Labor, Bureau of Labor Statistics, May 2010. See Attachment H for wage calculations.

² Totals may not sum due to rounding.

Table 4. FIFRA §24(c) - Total Annual Applicant (Registrant) Burden Hours and Cost Estimates

Labor Category	Total Burden Hours per Request	Number of applications	Total Annual Hours	Labor Rate (\$/hr)	Total Annual Costs (\$)
Managerial	14	325	4,550	\$120.28	\$547,271
Technical	19	325	6,175	\$60.85	\$375,752
Clerical	6	325	1,950	\$37.11	\$72,371
Totals	39	325	12,675		\$995,394

Table 5 presents estimates of costs per application for state governments, by collection activity and total for Section 24(c) applications. Table 6 displays the total cost to states for all applications per year. Total annual costs to states for SLN applications are estimated at about \$240,000.

Table 5. FIFRA §24(c) – Applicant (State Government) Burden Hours and Cost Estimates per Application

COLLECTION ACTIVITY	Burden per application (hours) ¹			Total ³	
	Mgmt. \$82.63/hr	Tech. \$57.68/hr	Clerical \$39.20/hr	Hours	Costs (\$)
Compile information	0.0	1.0	0.0	1.0	\$58
Review submission information	0.0	5.5	0.0	5.5	\$317
Complete and transmit paperwork to EPA ²	0.0	5.4	0.4	5.8	\$327
Store/file/maintain the data	0.0	0.0	0.1	0.1	\$4
Respond to registrant (if necessary)	0.0	0.4	0.2	0.6	\$31
Totals	0.0	12.3	0.7	13.0	\$737

¹ Hourly wages rates are fully loaded wage rates based on NAICS 999200 - State Government, U.S. Dept. of Labor, Bureau of Labor Statistics, May 2010. See Attachment H for wage calculations.

² Includes label revisions, SLN registration cancellations, and other follow-up actions data.

³ Totals may not sum due to rounding.

Table 6. FIFRA §24(c) - Total Annual Applicant (State Government) Burden Hours and Cost Estimates

Labor Category	Total Burden Hours per Request	Number of applications	Total Annual Hours	Labor Rate (\$/hr)	Total Annual Costs (\$)
Managerial	0	325	0	\$82.63	\$0
Technical	12.3	325	3,998	\$57.68	\$230,592
Clerical	0.7	325	228	\$39.20	\$8,919
Totals	13.0	325	4,225		\$239,511

Table 7 shows the total annual combined costs for registrants and states for Section 24(c) applications. Total annual costs of the Section 24(c) program for respondents is approximately \$1.23 million.

Table 7. FIFRA §24(c) - Total Annual Applicant (Registrant and State Government) Burden Hours and Cost Estimates

Applicant	Total Burden Hours per Application	Number of Applications	Total Annual Hours	Cost per Application (\$)	Total Annual Costs (\$)
Registrant	39	325	12,675	\$3,063	\$995,394
State	13	325	4,225	\$737	\$239,511
Totals	52	325	16,900	\$3,800	\$1,234,905

6(c). Estimating Agency (EPA) Burden and Cost

Methodology for Estimating Agency Burden and Cost

For this ICR, the EPA estimates Agency burden hours using employee time accounting data on OPP Divisions that provide significant support and analysis for the FIFRA Section 18 emergency exemption and Section 24(c) special local need programs. The 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. In the past, the Agency burden calculations for this ICR reflected only activities for the emergency exemption and special local need lead divisions (the Registration Division (RD), the Biopesticides and Pollution Prevention Division (BPPD), and the Antimicrobial Division (AD)). In 2009, the appropriate FTE activity data from the Health Effects Division (HED), the Biological and Economic Analysis Division (BEAD), the Pesticide Re-evaluation Division (PRD) (formerly the Special Review and Registration Division (SRRD)), Field and External Affairs Division (FEAD), and the Environmental Fate and Effects Division (EFED) were added.¹ The Agency believes that using data from the TAIS more accurately

¹ The Agency burden related to OPP's Information Technology and Resource Management Division (ITRMD) processing activities are not included in the burden estimate because ITRMD provides the preliminary data processing and tracking for many OPP ICR activities including tolerance petitions. These

reflects the time spent on implementing and administering emergency exemption and SLN activities than former estimates.

Total annual FTEs are presented below, in separate tables for sections 18 and 24(c), by labor category and OPP Division, and summed for Division and OPP totals. Other tables show estimated annual burden hours for each program, by multiplying 2,080 hours in a work year by the FTEs.

The costs per burden hour are the fully loaded wage rates, which are estimated in the same manner as they are for respondents. The fully loaded wage rate for the Agency is based on NAICS 999100, Federal government - calculated for federal employees based on 2010 wage data as detailed in Attachment H. The wage rates for federal agencies are \$119.85, \$71.58, and \$43.21 per hour for management, technical, and clerical labor, respectively. The total annual burden hours for each labor category are estimated by the applicable wage rate to get the total cost per category. Then labor category estimates are summed to get total estimated annual agency costs for each program.

Applications and Summary Report for Emergency Exemption (FIFRA §18)

The TAIS data displayed in Table 8, by OPP Division and total, indicate that the estimated number of Agency FTE's dedicated to Section 18 emergency exemption activities is approximately 1 managerial FTE, 7 technical FTEs, and 1 clerical FTE, for total of 9 FTEs allocated to emergency exemption activities.

Table 8. Distribution of Agency FTEs Supporting Section 18 Activities ²

FTE Type	AD	BEAD	BPPD	EFED	HED	RD	PRD	OPP Total ¹
Managerial	0.0	0.2	0.0	0.0	0.0	0.5	0.0	1
Technical	0.1	1.4	0.1	0.3	0.1	4.3	0.0	7
Clerical	0.0	0.1	0.0	0.0	0.0	0.3	0.0	1
Totals	0.1	1.7	0.1	0.4	0.1	5.1	0.0	9

¹ OPP Total is rounded up to the next FTE.

Using total burden hours of 2,080 per FTE, the total annual Agency burden hours for Section 18 activities are approximately 18,270 per year, averaged over the years 2008-2010. Table 9 shows the burden hours and the calculations for deriving the total annual Agency cost of the Section 18 program of approximately \$1.38 million.

systems are integrated for efficient processing, tracking, and maintaining data but they do not readily lend themselves to a clear burden breakdown by ICR activity.

² The FTE burden in AD, BPPD, EFED, FEAD, HED, and PRD across labor categories (managerial, technical and clerical) amounted to significantly less than 1 FTE. The estimate for the Agency FTE for each labor category was rounded up to account for the contribution OPP's Information Technology and Resource Management Division (ITRMD) processing activities that are not included in the burden estimate.

Table 9. Agency Hours, Hourly Wage Rates, and Total Costs by Employment Class Supporting Section 18 Activities

FTE Type	FTEs (rounded)	Hours / FTE ¹	Total burden hours	Fully loaded wage rates (\$/hr) ²	Annual per FTE cost	Total Cost
Managerial	1	2,080	2,080	\$119.85	\$249,285	\$ 249,285
Technical	7	2,080	14,560	\$71.58	\$148,881	\$1,042,167
Clerical	1	2,080	2,080	\$43.21	\$89,875	\$89,875
OPP totals	9	2,080	18,720			\$1,381,327

¹ Hours per FTE = 40 hours/week × 52 weeks/year

² See Attachment H for data sources and calculations of fully loaded wage rates.

Notice of Pesticide Registration by States to Meet a Special Local Need (FIFRA §24(c))

The TAIS data indicate that the estimated number of Agency FTE’s dedicated to Section 24(c) special local need (SLN) activities is approximately 0.1 managerial FTE, 1.2 technical FTEs, and less than 0.1 clerical FTE (see Table 10). The aggregated Agency estimated FTEs dedicated to SLN activities are 1.4.

Table 10. Distribution of Agency FTEs Supporting Section 24(c) Activities

FTE Type	AD	BEAD	BPPD	EFED	FEAD	HED	RD	PRD	OPP Total
Managerial	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1	0.1	<0.1	0.1
Technical	<0.1	<0.1	<0.1	0.1	<0.1	0.1	1.0	<0.1	1.2
Clerical	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1
Totals	<0.1	<0.1	<0.1	0.2	<0.1	0.1	1.1	<0.1	1.4

Table 11 presents the total annual Agency burden hours and costs for Section 24(c) activities of approximately 2,900 hours and \$220,000 per year, averaged over the years 2008-2010.

Table 11. Agency Hours, Hourly Wage Rate, and Total Costs by Employment Class Supporting Section 24(c) Activities

FTE Type	FTEs	Hours / FTE ¹	Total burden hours	Fully loaded wage rates (\$/hr) ²	Annual per FTE cost	Total Cost
Managerial	0.1	2,080	306	\$119.85	\$249,287	\$36,673
Technical	1.2	2,080	2,505	\$71.58	\$148,882	\$179,311
Clerical	<0.1	2,080	84	\$43.21	\$89,876	\$3,627
Totals	1.4	2,080	2,895	---	---	\$219,612

¹ Hours per FTE = 40 hours/week × 52 weeks/year

² See Attachment H for data sources and calculations of fully loaded wage rates.

6(d). Bottom Line Burden Hours and Cost Tables

Table 12. FIFRA §18 - Total Annual Burden and Cost Estimates for Applications and Summary Reports for Emergency Exemptions

	Previous Estimates		Current Estimates	
	Hours	Costs	Hours	Costs
Respondents (state governments)	49,500	\$2,472,770	12,672	\$739,013
Agency	54,000	\$3,637,575	18,720	\$1,381,327

Table 13. FIFRA §24(c) - Total Annual Burden and Cost Summary for Notice of Pesticide Registration by States to Meet a Special Local Need

	Previous Estimates		Current Estimates	
	Hours	Costs	Hours	Costs
Respondents (registrants & states)	36,036	\$2,401,245	16,900	\$1,234,905
Agency	8,320	\$594,880	2,895	\$219,612

Table 14. Combined Respondent Burden for this ICR

Programs	Previous Estimates		Current Estimates ¹	
	Hours	Costs	Hours	Costs
Section 18	49,500	\$2,472,770	12,672	\$739,013
Section 24(c)	36,036	\$2,401,245	16,900	\$1,234,905
Total	85,536	\$4,874,015	48,760	\$3,376,010

¹ Total annual burden hours revised based on 3-year average number of applications from 2009 - 2011; costs based on wage rates indexed to 2010 dollars

6(e). Reasons for Change in Burden

This is a request for a new ICR. As explained in section 1(b) of this supporting statement, the existing collection activities that are approved under OMB Control No. 2070-0032 and OMB Control No. 2070-0055 are being consolidated into this ICR. Relative to the existing collections, there are some significant changes to the estimated burden. These changes stem primarily from activities in EPA's registration program; i.e., many uses commonly sought for limited-time approvals under sections 18 & 24(c) have been since registered under section 3. Under section 18 these were largely uses for which there were repeat requests from numerous states. Minor uses now have more permanent pest management tools available. Relative to the existing approved collections, these changes are adjustments. However, since this is a new ICR, the entire burden associated with this consolidation will be noted as a program change. Likewise, when EPA ultimately discontinues the existing approved ICRs that are being consolidated herein, EPA will log those change as program changes.

Applications and Summary Report for Emergency Exemption (FIFRA §18)

Although the estimated unit burden for a given Section 18 application is unchanged, EPA estimates a decline in the number of section 18 application submissions and estimated annual burden relative to the existing, approved collection. EPA estimates that the total *annual* respondent burden has decreased from 49,500 hours to about 12,700 hours. The decrease corresponds with a large decrease in the average number of Section 18s requested per year, from 494 to 128. Although EPA does not require Section 18s and cannot estimate precisely how many submissions will be received in the future, the Agency expects to receive approximately 128 Section 18 applications each year over the next three years.

The Agency believes that respondents will experience some burden reduction over the next three years due to the streamlined recertification process for Section 18 applications discussed in Section 2 of this document. For example, during the 2010 use season, EPA identified 97 exemptions that were eligible for the less data-intensive application process through the recertification program. Further, in 2010, the Agency made registration decisions for 36 use determinations which negated the need for additional applications to be submitted for those same uses. During the consultation period for this ICR, all three states, WI, NE, and CA, noted that there was a cost savings as a result of the streamlined process. Although EPA expects that this process change will result in some burden reduction, there is insufficient information available to the Agency at this time to fully assess the impact of these changes.

Notice of Pesticide Registration by States to Meet a Special Local Need (FIFRA §24(c))

There is no change in the estimated respondent burden hours per SLN application for this ICR from the currently-approved ICR for Section 24(c) applications, for either registrants or states. However, the total annual respondent burden estimate has decreased from 36,036 to 16,900. This is an adjustment, as the decrease is due to a large decrease in the average number of petitions received annually, from about 693 to 325. As a result of the decrease in the number of applications and updating the wage rates, the estimated respondent cost changed from \$2.40 million to \$1.23 million.

6(f). Burden Statement

The respondent burden for collection of information associated with the Applications and Summary Report for Emergency Exemption rule is estimated to average 99 hours per application. The respondent burden for the Notice of Pesticide Registration by States to Meet a Special Local Need rule is estimated to average 52 hours per response (39 hours per registrant and 13 hours per State), including time for compiling the information/data submitted by the registrant, reviewing the information for special local needs determination, completing paperwork to notify the federal government, storing/filing/maintaining the data, and responding back to the registrant if the registration is disapproved by EPA. The burden estimate includes hours spent by the registrant in preparing the application for submission to EPA.

According to the Paperwork Reduction Act, “burden” is defined at 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. The OMB control number for this information collection will appear on all forms associated with this ICR. In addition OMB control numbers for EPA’s regulations, after initial display in the final rule, are listed in 40 CFR Part 9.

The Agency has established a public docket for this ICR under Docket ID No. EPA-HQ-OPP-2008-0473, which is available for online viewing at <http://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 Director, Collection Strategies Division, U.S. Environmental Protection Agency (2822T), 1200 Pennsylvania Ave., NW, Washington, D.C. 20460. 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-2008-0473 in any correspondence.

ATTACHMENTS TO THE SUPPORTING STATEMENT

Attachments to the supporting statement are available in the public docket established for this ICR under docket identification number **EPA-HQ-OPP-2008-0473**. These attachments are available for online viewing at <http://www.regulations.gov> or otherwise accessed as described in Section 6(f) of the supporting statement.

- Attachment A-1** 7 U.S.C. 136p - **Section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)**. Also available at online at the US House of Representatives' [US Code website](#).
- Attachment A-2** 7 U.S.C. 136v - **Section 24(c) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)**. Also available online at: <http://www.epa.gov/opp00001/regulating/fifra.pdf>.
- Attachment A-3** 21 U.S.C 346a - **Tolerances and exemptions for pesticide chemical residues, Section 408 of the Federal Food, Drug and Cosmetic Act (FFDCA)**. Also available at online at the US House of Representatives' [US Code website](#).
- Attachment B-1** 40 CFR part 166 - **Exemption of Federal and State Agencies for Use of Pesticides under Emergency Conditions**. Also available online at the National Archives and Records Administration's [Electronic CFR Website](#).
- Attachment B-2** 40 CFR part 162 - **State Registration of Pesticide Products**. Also available online at the National Archives and Records Administration's [Electronic CFR Website](#).
- Attachment C** 40 CFR Part 176 - **Time-Limited Tolerances for Pesticide Emergency Exemptions**. Also available online at the National Archives and Records Administration's [Electronic CFR Website](#).
- Attachment D** FIFRA §18 – **Consultation Contacts & Questions for Application and Summary Report for an Emergency Exemption for Pesticides**.
- Attachment E** FIFRA §24(c) – **Consultation Contacts & Questions for State Registration of Pesticide Products**.
- Attachment F** EPA Form No. 8570-4 - **Confidential Statement of Formula**. Also available online at <http://www.epa.gov/opprd001/forms/8570-4.pdf>.
- Attachment G** EPA Form 8570-25 - **Application for/Notification of State Registration of a Pesticide to Meet a Special Local Need**. This attachment can be also accessed via the internet at: <http://www.epa.gov/opprd001/forms/8570-25.pdf>.
- Attachment H** **Labor Wage Formulas**.
- Attachment I** **Listings of Related Regulations in 40 CFR 9.1** - Display Related to the Existing OMB Control Numbers.