

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

1. IDENTIFICATION OF THE INFORMATION COLLECTION

1(a) Title of the Information Collection

Application and Summary Report for an Emergency Exemption for Pesticides

OMB No.: 2070-0032

EPA No.:

0596.09

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 February 28, 2008. Section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizes the Environmental Protection Agency (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. A Section 18 action arises when growers and others encounter a 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 public health and quarantine reasons.

Most requests for emergency exemptions are made by state lead agricultural agencies, although agencies such as the United States Departments of Agriculture (USDA), Defense (DOD) and Interior (USDI) also request exemptions. This process is generally initiated when growers in particular regions identify an urgent, non-routine situation which registered pesticides will not alleviate. The growers contact their state lead agency (usually a state's department of agriculture) and request that the state agency apply to EPA for a Section 18 emergency exemption for a particular use. The state agency evaluates the requests and submits 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.

2. NEED FOR AND USE OF THE COLLECTION

2(a) Need/Authority for the Collection

This information collection allows the Agency to access needed 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 give rise to a section 18 emergency exemption request. In these situations there is an immediate need for a pesticide for a use for which it is not registered and for which there is insufficient time to obtain registration.

Requests for Section 18 emergency exemptions, i.e., the submission of applications, are

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 require an exemption and the risks are acceptable, EPA typically approves the emergency exemption request. EPA will deny an 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 unpredictable emergency situations when insufficient time for a formal section 18 application and review process is available to address the problem, a state agency may issue a crisis exemption which allows for the immediate use of an unregistered pesticide for no longer than 15 days, unless an application for the specific exemption request has been submitted to EPA.

The state issuing the crisis exemption must coordinate the declaration with EPA prior to releasing it to the users. 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.

Over the past three years 2004, 2005, 2006, EPA has received an average of approximately 494 section 18 requests. Producers of minor crops are especially reliant on the emergency exemption program. Less frequently, emergency exemption applications are submitted in order to combat pests which pose a threat to public health. The section 18 emergency exemption program is also supporting certain agricultural homeland security initiatives.

New Streamlined Regulations:

On January 27, 2006, EPA published a final rule (71 FR 4495) revising the regulations governing emergency exemptions. EPA received considerable stakeholder involvement and identified several opportunities to streamline and improve the pesticide emergency exemption process without compromising protection for human health and the environment. The new section 18 rule 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. Second, major revision was to clarify the definition of significant economic loss and revision of data requirements for documenting loss. Specifically, the revised regulations allow states to submit an abbreviated recertification request in certain instances. This recertification request cites previously submitted and reviewed data to support their response to an on-going emergency pest problem. The Agency anticipates that the new streamlined recertification process will reduce the burden on states and expedite the processing of emergency exemption requests. The new economic approach is a tiered method which allows

an applicant to easily classify the emergency situation while minimizing data requirements. The thresholds in the tiered approach provide clear, uniform standards to determine the significance of anticipated economic losses, rather than the previous approach of comparing revenues under the emergency to historical variations in revenues for the particular crop and region. Since the new process has only been in place for just over a year, it is too early to tabulate the anticipated reduction in burden for this renewal request.
(see http://www.epa.gov/opprd001/section18/section18rule_fs.htm).

Section 18 of FIFRA (see **Attachment A**) 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 contained in 40 CFR Part 166 (see **Attachment B**).

Section 408 of the Federal Food, Drug, and Cosmetic Act (see **Attachment C**) requires that EPA establish tolerances, or 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 actions. 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 decisions must be conducted in a timely manner, and 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 D**.

2(b) Practical Utility/Users of the Data

EPA uses the information collected to carry out its statutory responsibilities under FIFRA section 18. This data collected allows EPA to evaluate an application for a permit for the temporary use of a pesticide product for an unregistered use and 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 environments; and 3) the requested product's effectiveness in allaying the emergency. The application and follow-up reporting is essential to weighing the emergency nature of the situation as well as the effectiveness, risks of the treatment program, and comparing the cost impacts based on the new tiered thresholds for significant economic loss determination.

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. The possibility of duplication does not exist by any other federal agency.

3(b) Public Notice and Opportunity to Comment

In preparing the renewal for this ICR, EPA published a notice in the Federal Register (72 FR 30794) on June 4, 2007 which provided a 60-day public notice and comment period on the draft ICR. The Agency did not receive any public comments on the draft renewal ICR.

3(c) Consultations

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, Agency staff participates in stakeholder training workshops with state pesticide regulatory representatives. These communications permit an exchange of 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.

For this renewal, EPA consulted by telephone and e-mail with representatives of three state agencies that are active in this regulatory process in order to seek 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 program. The solicitation for consultation included state representatives from the Department of Environmental Conservation, Bureau of Pesticides Management from New York, the Colorado Department of Agriculture, and the Pesticide and Plant Pest Management Division in the State of Michigan.

While only briefly summarized here, generally, each of the states consulted agreed that the new streamlined process for re-certified section 18 applications has produced savings in both the amount of time and money. Two of the three states, MI and NY stated that the Agency's burdens and cost estimates were accurate, while CO disagreed. 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 burden hours and costs have been made for this ICR renewal request to OMB. Two states, CO and MI expressed some degree of concern about web based submissions and/or electronically submitted data to the Agency because of security concerns. However, NY noted that it submitted re-certifications only electronically in the past year. The details of consultant contacts and the comments received in the consultation process are part of this document in **Attachment E**.

3(d) Effects of Less Frequent Collection

As discussed above, there is no collection schedule for this information collection activity, per se. State and federal agencies initiate the information collection activity when they prepare an emergency exemption application for submission to EPA. State and federal agencies determine the frequency in which to pursue an emergency exemption request with EPA. EPA

does not solicit or request the exemption application.

3(e) General Guidelines

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. Therefore, 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 and will not be exceeded in this program.

3(f) Confidentiality

Although the EPA urges the submitter to minimize the amount of claimed Confidential Business Information (CBI), certain limited all data and/or information brought 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 the EPA under FIFRA section 10 and the associated regulation as contained in 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.

When trade secret information or Confidential Business Information is provided to the Agency, such information is protected from disclosure under FIFRA Section 10, as amended and EPA's confidentiality regulation, Title 40 CFR, 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 Prevention, Pesticides and Toxic Substances paper shredder.

3(g) Sensitive Questions

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

Respondents affected by the collection activities under this ICR are federal and state agencies which regulate pesticides or pesticide products. The North American Industrial Classification System (NAICS) code assigned to the states and federal government agencies responding to this information is 9241, The Administration of Environmental Quality Programs subsector groups of government establishments primarily engaged in the administration of environmental quality.

4(b) Information Requested

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 the EPA.

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

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.
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	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.
Discussion of residues for food uses	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.
Discussion of risk information	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.
Coordination with other affected state or federal agencies.	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.
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:

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.
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<p>For a quarantine exemption</p>	<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.
<p>For a public health exemption</p>	<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.
<p>For a crisis exemption, only the following information must be provided:</p>	<p>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:</p> <ul style="list-style-type: none"> ▪ name of active ingredient authorized for the crisis use, including the common name and the Chemical Abstracts Service (CAS) number; ▪ crop or site on which the pesticide is to be used; ▪ use pattern (method, number, and rate of applications); ▪ dates that applications started or will begin and end; ▪ an estimate of the level or residues of the pesticide expected to result from use under the crisis exemption (for food crops); and ▪ 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.

4(c) Data Items, Including Record keeping requirements

EPA Form No. 8570-4, *Confidential Statement of Formula*, (**Attachment F**) is the single form associated with either the application for, or summary reports on, an emergency exemption. 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:

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 ▪ any other information requested by the Administrator.
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.

4(d) Applicant Activities

To obtain a permit to use an unregistered pesticide product under emergency conditions, an applicant must petition EPA in writing and provide information addressing the data items listed above and commit to the submission of the summary report on the action taken to meet the emergency 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:

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

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

5(a) Agency Activities

On October 25, 2000, EPA published a Final Rule in the Federal Register (65 FR 64125) entitled "Time-Limited Tolerances for Pesticide Emergency Exemptions." This rule, which became effective on November 24, 2000, set into place 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. Under this rule, 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 the Office of Pesticide Programs (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. 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.

5(b) Collection Methodology and Management

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.

5(c) Small Entity Flexibility

No flexibility for small entities exists under this information collection activity. Section 18 of FIFRA applies 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.

5(d) Collection Schedule

There is no collection schedule associated with this information collection activity, per se. This information collection activity is initiated by the States or by certain federal agencies when they 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

6(a) Estimating Respondent Burden

The total annual response burden associated with submitting an application for Emergency Exemption (Section 18s) is estimated to be 49,500 burden hours per year at a cost of \$2,472,770 indexed to 2006 dollars for the next three years. The number of applications received by EPA has decreased from an average of 500 per year for the years 2001 - 2003 to an average of about 494 per year for the years ranging from 2004 - 2006. The important trends seen in the applications received in the past three years are:

- the successful transition of a high number of minor crop section 18 programs to full registrations and tolerances under section 3 labels;
- in spite of the focus on eliminating long-running section 18 applications there are continuing pest management challenges that are national in scope that trigger emergency exemption requests (e.g. the use of coumaphos and thymol in bee hives to control varroa mite; expanding reliance on section 18 programs to plan for and respond to public health and agricultural homeland security threats - such as anthrax decontamination, foot and mouth disease, and soybean rust;
- States have started requesting Section 18 emergency exemptions for more than one chemical to deal with some pest problems;

The Agency expects that some of these factors will persist and subsequently expects to receive an average of 500 applications annually for the next three years.

6(b) Estimating Respondent Costs

Agency economists revised the estimated wages, benefits and overhead for all labor categories for affected industries, state government, and EPA employees based on publicly available data from the US Bureau of Labor Statistics. The formulas used to estimate the labor rates and formulas used to derive the fully loaded rates and overhead costs for this ICR renewal are listed in **Attachment G**.

Methodology: The methodology uses data on each sector and labor type for an *Unloaded wage rate* (hourly wage rate), and calculates the *Loaded wage rate* (unloaded wage rate + benefits), and the *Fully loaded wage rate* (loaded wage rate + overhead). Fully loaded wage rates are used to calculate respondent costs. This renewal uses 2003 base data.

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

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

Loaded Wage Rate: Unless stated otherwise, all benefits represent 43% of unloaded wage rates, based on benefits for all civilian non-farm workers, from <http://www.bls.gov/news.release/ecec.t01.htm>. However, if other sectors are listed for which 43% is not applicable; the applicable percentage will be stated.

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

The total respondent burden in terms of hours is estimated to be 49,500 hours annually. The total respondent cost for this ICR renewal is estimated to be \$2,472,770 annually. To derive the labor rates for all respondents associated with submitting an application for Section 18 Emergency Exemptions, Agency economists estimated the wages for the management, technical, and clerical labor categories using the methodology cited above. The state respondent costs for this renewal for managerial, technical and clerical rates are estimated at \$74.41, \$49.38, \$33.78 hour, respectively and \$93.07, \$66.34, and \$47.17 for management, technical, and clerical labor, respectively for federal agencies. These labor rates are fully loaded and include benefits and overhead costs. Using the Agency's burden estimate and the fully-loaded labor rates, the Agency estimates the applicant labor costs to be approximately \$4945.54 per response.

State Government “Applicant” Burden/Cost Estimates

COLLECTION ACTIVITY	Burden Hours (per application)			Total	
	Mgmt. \$71.41/hr	Tech. \$49.38/hr	Cler. \$33.78/hr	Hours	Costs (\$)
Read FIFRA and FQPA requirements and CFR regulations.	4	4	0	8	483.16
Process, compile, and review the requested data for accuracy and appropriateness.	0	74	0	74	3,654.12
Generate application correspondence and follow-up summary report.	0	15	0	15	740.70
Store/maintain/submit information	0	0	2	2	67.56
Totals	4	93	2	99	4945.54

ANNUAL BURDEN: 99 Total Hours x 500 applications = 49,500 Hours

ANNUAL COSTS: (a) Management: 4 hours x \$ 71.41 500 applicants = \$ 142,820
 (b) Technical: 93 hours x \$49.38x 500 applicants = \$2,296,170
 (c) Clerical: 2 hours x \$33.78x 500 applicants = \$ 33,780
 Total= **\$2,472,770**

6(c) Estimating Agency Burden and Cost

The estimated cost to the Federal government of the Emergency Exemption program consists of two components. The first is the number of hours and costs incurred by the Agency to complete a standard application. The second component is the costs for other elements that do not fall under the category of collection activities, but are required as part of the program.

The total Agency burden in terms of hours is estimated to be 54,000 hours annually. The total annual Agency cost for processing Emergency Exemption Requests is estimated to be **\$3,637,575**

Annual Agency Burden/Cost Estimates

COLLECTION ACTIVITY	Burden Hours (per application)			Total	
	Mgmt. \$93.07/hr	Tech. \$66.34/hr	Cler. \$47.17/hr	Hours	Costs
Read and review the applications or reports for completeness.	0	8	1	9	577.89
Route the application/report to appropriate scientists and economists for review.	0	4	0	4	265.36
Review information submitted for scientific accuracy.	0	16	0	16	1,061.44
Perform: - a biological, ecological, and economic analysis - a multi-disciplinary risk assessment - make FFDCA section 408(b)(2)(A) (ii) safety findings - forward a regulatory recommendation on the proposed exemption along with a draft notification to the requestor.	2	40	1	43	2,886.91
Reach final decision, prepare Final Rule Notice and notify applicant.	5	28	1	34	2,370.04
Record electronic data in Agency's Pesticide Regulatory Action Tracking System (PRATS), record receipt in branch tracking system and file hard copy in Branch files.	0	1	1	2	113.51
Totals	7	97	4	108	7,275.15

ANNUAL BURDEN: 108 Total Hours x 500 applications = 54,000 Hours

ANNUAL COSTS: (a) Management: 7 hours x \$93.07 x 500 applicants = \$ 325,745

(b) Technical: 97 hours x \$66.34 x 500 applicants = \$ 3,217,490

(c) Clerical: 4 hours x \$47.17 x 500 applicants = \$ 94,340

Total= \$3,637,575

OTHER ANNUAL AGENCY COSTS:

Average annual frequency of related Federal Register publications (avg. cost = \$2000):

Type of Federal Register Document	Number per Year	Cost
Notice: Receipt of Application for Emergency Exemption; Solicitation of Public Comment	5	\$10,000
Final Rule: Pesticide Tolerance for Emergency Exemptions	25	\$50,000
Final Rule: Extension of Tolerance(s) for Emergency Exemptions	3	\$6,000
Notice: Pesticide Emergency Exemptions; Agency Decisions and State and Federal Agency Crisis Declarations	2	\$4,000
Total	35	\$70,000

OVERALL TOTAL ANNUAL AGENCY COST BURDEN:

\$3,635,500 + \$70,000 = \$3,705,500

6(d) Bottom Line Burden Hours and Cost Tables**Total Burden and Cost Estimates**

	TOTAL ESTIMATES	
	Hours	Costs
State Government Applicants - Annual	49,500	\$2,472,770
Agency - Annual	54,000	\$3,637,575

6(e) Reasons for Change in Burden

There is no change in the estimated annual respondent burden for this renewal ICR over the previous ICR. The Agency expects to receive 500 section 18 applications annually over the next three years. The Agency believes that respondents will experience some measure of 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 2006 use season, EPA identified 188 exemptions eligible for the less data-intensive application process through the recertification program. Further, in 2006 the Agency made registration decisions for 146 use determinations which negated the need for additional applications to be submitted with regard to those same uses. During the consultation period for this renewal, all three states, CO, MI, and NY noted that there was a cost savings as a result of the stream lining 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.

6(f) Burden Statement

The annual respondent burden for collection of information associated with the rule is estimated to average 99 hours per application. According to the Paperwork Reduction Act, "burden" means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. For this

collection, it is the time reading the regulations, planning the necessary data collection activities, conducting tests, analyzing data, generating reports and completing other required paperwork, and storing, filing, and maintaining the data. The agency 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 appears at the beginning and the end of this document. 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-2007-0320, which is available for online viewing at www.regulations.gov, or in person viewing at the OPP Regulatory Public Docket in Rm. S-4400, One Potomac Yard (South Building), 2777 S. Crystal Drive, Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305-5805. You may submit comments regarding the Agency's need for this information, the accuracy of the provided burden estimates and any suggested methods for minimizing respondent burden, including the use of automated collection techniques.

Submit your comments, referencing Docket ID No. EPA-HQ-OPP-2007-0320 and OMB Control No. 2070-0032, to (1) EPA online using www.regulations.gov (our preferred method), or by mail to: Public Information and Records Integrity Branch (PIRIB), Mail Code: 7502P, Office of Pesticide Programs (OPP), Environmental Protection Agency, 1200 Pennsylvania Ave., NW, Washington, DC 20460, and (2) OMB by mail to: Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), Attention: Desk Officer for EPA, 725 17th Street, NW, Washington, DC 20503.

ATTACHMENTS TO THE SUPPORTING STATEMENT

Attachments to the supporting statement are available in the public docket established for this ICR under docket identification number **EPA-HQ-OPP-2007-0320**. These attachments are available for online viewing at www.regulations.gov or otherwise accessed as described in section 6(f) of the supporting statement.

- Attachment A:** 7 U.S.C. 136p - Section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act. Also available at online at the US House of Representatives' [US Code website](#)
- Attachment B:** 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 C:** 21 U.S.C 346a - Tolerances and exemptions for pesticide chemical residues, FFDC section 408. Also available at online at the US House of Representatives' [US Code website](#)
- Attachment D:** 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 E:** Consultant Contacts for Application and Summary Report for an Emergency Exemption for Pesticides & Questions Asked EPA During Consultations
- 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:** State Government and EPA Labor Wage Formulas
- Attachment H:** Display Related to OMB Control #2070-0032 -Listings of Related Regulations in 40 CFR 9.1