



State of Wisconsin
Governor Tony Evers

Department of Agriculture, Trade and Consumer Protection
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Guide to Requesting Section 18 Emergency Exemptions in the State of Wisconsin

**Special Pesticide Registration Program
Agricultural Resource Management Division**

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INTRODUCTION

Section 18 of FIFRA authorizes the U. S. Environmental Protection Agency (EPA) to allow States to use a pesticide for an unregistered use for a limited time if the EPA determines that emergency conditions exist. Emergency pesticide uses authorized by EPA under Section 18 are commonly referred to as “Section 18’s” or “emergency exemptions.” As the lead pesticide regulatory agency for the state, the Wisconsin Department of Agriculture, Trade and Consumer Protection (WDATCP), is the primary agency that is authorized by the EPA to request Section 18 exemptions for emergency pesticide uses in Wisconsin. WDATCP relies on entities who are familiar with the emergency pest situations at the local

level to compile and provide to WDATCP the information necessary for the formal application that is submitted to EPA.

There are four types of emergency exemptions defined under 40 CFR 166.2 that may be authorized by EPA under FIFRA Section 18: 1) Specific exemptions, 2) Quarantine exemptions, 3) Public health exemptions, and 4) Crisis exemptions.

1. Specific Exemptions:

A specific exemption may be authorized in an emergency condition to avert significant economic loss, or significant risk to endangered or threatened species, beneficial organisms, or the environment.

2. Quarantine Exemptions:

A quarantine exemption may be authorized in an emergency condition to control the introduction or spread of any pest that is an invasive species, or is otherwise new to or not known to be widely prevalent or distributed.

3. Public Health Exemptions:

A public health exemption may be authorized in an emergency condition to control a pest that will cause a significant risk to human health.

4. Crisis Exemptions:

A crisis exemption may be authorized in an emergency condition only in situations where the time from the discovery of the emergency to when the pesticide use is needed is insufficient to allow for the authorization of a specific, quarantine, or public health exemption.

These guidelines have been developed to assist persons who intend to submit Section 18 exemption requests in providing complete and accurate information to WDATCP.

Historically, the majority of Section 18s granted by EPA have been specific exemptions that authorize use of pesticides to control emergency pest situations in agricultural crops. For more information on specific, quarantine, public health or crisis exemptions, or if you have any questions about submitting a Section 18 emergency exemption, please contact the Wisconsin Pesticide Registration Specialist at 608-224-4547 or at alyssa.foss@wisconsin.gov.

PART I. THE EMERGENCY CONDITION REQUIREMENT

Prior to applying for a Section 18 exemption, first determine if the pest situation qualifies as an emergency condition as defined by the EPA. The application for a Section 18 emergency exemption must provide information, data, and discussion to adequately demonstrate to the EPA the existence of an emergency condition. For the purpose of emergency exemptions under FIFRA Section 18, EPA defines the term “emergency condition” as:

An **urgent, non-routine situation** that requires the use of a pesticide(s) where:

- (1) No effective pesticides are available that are registered for use to control the pest under the conditions of the emergency; and
- (2) No economically or environmentally feasible practices which provide adequate control are available; and

- (3) The situation (a) involves a new pest, (b) will cause significant economic loss to the affected crop, or (c) presents significant risks to human health, endangered or threatened species, beneficial organisms, or the environment.

Key elements of the emergency condition definition are as follows:

- **Urgent and Non-Routine:** The pest situation requires immediate attention and is other than ordinary. That is, chronic or continually occurring pest problems would be considered a routine problem and, therefore, would not be considered an emergency. Examples of urgent and nonroutine pest situations include unusual environmental conditions (e.g., weather) that cause severe pest pressure or problems in using normal control practices; development of resistance to registered alternative pesticides; cancellation of registered pesticides, etc. The situations may exist for one season only, or may continue for several years (e.g., until a new pesticide becomes registered).
- **Lack of Adequate Control with Registered Pesticides:** All of the pesticides currently registered to control the pest are either not effective or not available in adequate supplies.
- **Lack of Adequate Control with Alternate Practices:** Mechanical, biological, cultural, or other nonpesticidal control practices are not available, not effective, not environmentally sound, or not economically viable.
- **Significant Economic Loss:** The EPA is very specific in their definition of “Significant Economic Loss”. This is defined as “a substantial reduction in normally expected profitability; or, for types of activities where profits cannot be calculated, a substantial reduction in the value of public or private assets.” Such reductions are caused by an outbreak, or an expected outbreak, of a pest; or by a change in plant growth or development caused by unusual environmental conditions, where such change can be rectified by the use of a pesticide(s).

As the EPA evaluates the expectation that significant economic loss will occur, only those losses caused by the emergency condition are relevant. Losses due to obvious mismanagement or losses due to an agent other than the target pest problem are not considered within the EPA’s assessment of significant economic loss. Exemptions are not granted for the purpose of increasing yield, maximizing profits, or offsetting losses resulting from some other cause (e.g., foreign competition).

In order to conduct an economic analysis of the emergency situation, the EPA requires that a Section 18 application include five years of yield, price, production cost(s), and revenue data. This data will provide a baseline, or “normal range of profitability,” against which the expected profits under the conditions of the emergency are compared. If estimated profits are substantially below the normal range, the expected loss is considered significant. More information about significant economic loss and the EPA’s economic analysis for an emergency exemption is provided in Part IV, “Discussion of Economic Loss” (see pages 17-19).

PART II. ADDITIONAL REQUIREMENTS FOR EXEMPTIONS

This section provides information on other factors that should be considered in determining whether or not to apply for a Section 18 exemption.

A. General Requirements for the Requested Pesticide

The EPA conducts a thorough review of the requested pesticide to confirm that it will be effective in controlling the emergency pest situation, without presenting unreasonable risks to human health or the environment. If this is the first request for a specific pesticide product, contact the WDATCP in advance to verify if there are any unforeseen issues or concerns with the requested pesticide product/active ingredient that could make the request ineligible for the emergency use. The following guidelines may be helpful.

- **Canceled Pesticides:** The EPA is reluctant to grant exemptions for canceled pesticides, especially if products are voluntarily canceled due to potential adverse effects on the environment. However, they may be considered: If reasonable progress toward full registration of the proposed use has been made or is expected; or if an alternative to the canceled pesticide is expected to be available in the near future; or if the application includes assurances that a program will be carried out to find an acceptable alternative.
- **New, Unregistered Pesticides:** EPA closely scrutinizes requests for emergency use of new, unregistered pesticides, because of concerns that the Section 18 process may be used to circumvent the full (FIFRA Section 3) registration process. **EPA will not grant Section 18s for the sole purpose of bringing a new product on the market** (i.e., in the absence of a qualifying emergency condition). A review of data required for a Food Quality Protection Act (FQPA) risk assessment usually must be completed before a new pesticide will be authorized for use under Section 18. Generally, this means that a full registration petition for this new chemical must already be submitted and under review at EPA.

B. Registrant Support for the Exemption; Progress Toward Full Registration

It is essential that the manufacturer/registrant of the requested pesticide is supportive of the proposed use. In the near term, particularly for an unanticipated emergency for which an immediate solution is being sought, the manufacturer must be willing and able to provide adequate supplies of the requested pesticide product, appropriate labeling, and product stewardship.

In the longer term, the manufacturer must demonstrate a commitment to obtaining full registration of the pesticide product being requested under the Section 18 allowances. “Reasonable progress toward registration” is a specific EPA requirement in gaining approval for repeat emergency exemptions.

C. Time-Limited Tolerances Required for Emergency Uses on Food or Feed Crops

The FQPA amended the Federal Food, Drug, and Cosmetic Act (FFDCA) by requiring the EPA to establish a minimum tolerance or exemption for pesticide chemical residue(s), for each emergency exemption of a pesticide for use on a food or feed crop. Such tolerances must have an expiration date (i.e., be “time-limited”). This date must correlate to the length of time required for the treated crop to clear the channels of trade.

To establish the necessary time-limited tolerance, the EPA must review specific data under the FQPA safety criteria, and make a finding that “there is a reasonable certainty that no harm will result from aggregate exposure to pesticide chemical residue.”

D. Special Situations That Do Not Qualify for Emergency Exemptions

1. Pest Resistance Management: Emergency exemptions may only be granted for resistance management in cases where **documented** pest resistance to the registered alternative pesticide(s) has already developed and is expected to result in significant economic losses. Cases where pest resistance is only suspected do not qualify for an emergency exemption.
2. Exemptions for More than One Chemical for the Same Emergency: In rare cases, the EPA may grant exemptions for more than one pesticide to control the same pest on the same crop during the same year. The Section 18 application must provide a justification for the need for more than one product; for example, when supplies of one chemical are inadequate to control the pest situation, or when there is a need to manage pest resistance or control different life stages of the pest. However, **authorization for more than one chemical will not be made for competitive or marketing purposes.** Requests for multiple pesticides may be made in a single Section 18 application.
3. Exemptions for New Crops: The EPA will not authorize a Section 18 emergency pesticide use(s) for control of a routine (i.e., expected) pest problem on a new crop or new variety, based solely on a lack of available registered pesticides. As for all emergency exemptions, the pest situation must be urgent and non-routine.
4. Exemptions for Safer Pesticides: The EPA will not authorize a Section 18 exemption based solely on a determination that a pesticide which is unregistered for a particular use is safer than, or environmentally preferable to, a pesticide which is registered for that use.
5. Exemptions for Expanded Acreage: The EPA will not approve a repeat Section 18 exemption request for expanded acreage in situations where growers have planted additional acreage of a crop, based on the expectation that a pesticide will be available under an exemption to control an anticipated problem. The Section 18 application must demonstrate the occurrence of an unanticipated spread of the pest situation to acreage outside of the original emergency area.

PART III. THE SECTION 18 APPLICATION PROCESS

A. Time Line

Due to the uniqueness of each Section 18 emergency exemption application, a definitive timeline cannot be calculated. The various steps within the process, and their approximate time requirements, are described below.

1. Application submitted to WDATCP: Requests for Section 18 emergency exemptions are compiled and submitted to WDATCP by grower groups, processors, or their representatives, such as agricultural researchers, consultants, Cooperative Extension staff, commodity organizations, etc. Contacting the registrant or manufacturer of the product requested should be done early in the process to confirm their support of the request. In addition, the registrant/manufacturer must provide essential information and documentation for the application. However, the registrant/manufacturer should not be actively involved in the preparation or advocacy of the request.
 - ***Ideally, WDATCP should receive a first-time request 100 to 120 calendar days before the earliest anticipated use. Repeat requests should be submitted 80 to 90 calendar days before the earliest use.***

2. Formal Request Submitted to the EPA: WDATCP performs a preliminary review of the application for completeness and for a general confirmation that an emergency condition exists. If WDATCP does not receive all of the data and information required for a complete application, the request will not be submitted to the EPA until those deficiencies are addressed. For a repeat request, a final use report for the previous exemption must be submitted prior to reapplying.
 - ***A formal request usually can be prepared by the department and submitted to the EPA within 10 to 15 business days after WDATCP receives a complete application package from the applicant.***
3. EPA Review and Approval/Denial: The WDATCP request is initially checked by the EPA for completeness. The application is then routed through the various offices within the EPA for biological, economic and environmental fate; and review of human health effects. Afterwards, a decision letter is drafted, signed, and transmitted electronically to WDATCP. The EPA considers its “normal” processing time for emergency exemption requests to require 50 business days, however this number is only a guideline.
 - ***As a general rule, WDATCP expects to receive a final decision from EPA within about 60 calendar days for a repeat request and within about 90 calendar days for a first-time request.***
4. Notifications/Labeling: Immediately after receiving the EPA decision letter, WDATCP transmits a copy to both the product registrant and the person who submitted the original application to WDATCP. The registrant is expected to prepare a Section 18 supplemental label in a timely manner and according to WDATCP specifications based on the request and the EPA approval.

B. Crisis Exemptions

When a dire, unpredictable, and sudden pest problem arises and there is not adequate time to apply for a specific, quarantine, or public health exemption, then a crisis exemption may be appropriate.

FIFRA Section 18 includes a provision for a state or federal agency to issue a crisis exemption in those rare instances where an unpredictable emergency situation would occur, and there is insufficient time to request the EPA to review a specific, quarantine or public health exemption. The state must consult with and obtain consent from EPA before a crisis exemption can be issued.

A crisis exemption can only be authorized for up to 15 calendar days, unless an application requesting a specific, quarantine, or public health exemption for this use has been submitted to the EPA.

The crisis provisions may not be utilized to authorize a pesticide use if any of the following has occurred:

- (a) EPA has informed the head of the Federal or State agency, the Governor, or their official designee, not to issue such an exemption;
- (b) The pesticide use has been suspended under section 6(c) of FIFRA;
- (c) The pesticide use has been cancelled following a notice issued under section 6(b) of FIFRA;
- (d) The pesticide contains a new chemical; or
- (e) The application proposes the first food use of a pesticide.

Crisis exemptions are an absolute last resort, to be invoked only in dire situations where the emergency condition is unpredictable, there is not enough time for EPA to conduct a full review of a specific exemption request, and there is no other way to mitigate the emergency.

In rare cases, a crisis exemption can be authorized when the emergency was predicted and the specific exemption was requested far in advance, but the EPA has failed to review the request and make a determination in a reasonable timeframe.

- **Tardiness in submitting a specific exemption request is not viewed as an acceptable reason for seeking a crisis exemption. Also, crisis exemptions are not allowed for emergency uses of new, unregistered pesticides; and they are not allowed for emergency uses of a registered pesticide on food or feed crops, if the pesticide has no previously registered food or feed uses.**

C. Regional Requests

In situations where an emergency pest problem exists in several states in the same region of the country, it may be possible for those states to join together and submit a regional request for a Section 18 exemption. Feedback from the EPA concerning regional requests has been positive because it minimizes the number of requests they may receive, and provides them with the opportunity to conduct simultaneous reviews in lieu of individual state requests.

If a person intending to submit a Section 18 application in Wisconsin has knowledge of the same emergency situation occurring in our neighboring state(s), they should contact WDATCP to discuss the possibility of submitting a regional application. The decision to submit a regional request to the EPA can be made only by the pesticide regulatory agencies of the states that are involved. If the decision is made at the state level to pursue a regional request, it is imperative that complete information for all participating states be submitted to each of the state pesticide agencies at the same time, so that our agencies can coordinate a review, and submittal, of the information to the EPA in a timely manner. A regional request contains all relevant information for all of the states involved, and is submitted to EPA by one of the states (i.e., the lead state) on behalf of itself and the other participating states. The other participating states, having reviewed all of the jointly submitted materials to ensure completeness and accuracy of their state-specific information, must formally “join” the regional request by submitting a letter to the EPA. It is important to note, although the submittal and reviews of the request are conducted on a regional basis, the EPA issues its final decision on the exemption to each state individually.

D. Section 18 Supplemental Labeling

WDATCP requires the registrant/manufacture of a pesticide to prepare, and make available at the point of sale, supplemental labeling that contains adequate and necessary directions for an emergency use authorized under Section 18. The original Section 18 application submitted to WDATCP must include a draft label, prepared by the registrant/manufacture. The label must contain the basic information to identify the pesticide (trade name, active ingredient, EPA Reg. No., etc.) and directions for the proposed use [e.g., counties where use is proposed; rate, dilution, method, timing of application(s)], including beginning and ending dates of the proposed use period. Additional directions and restrictions applicable to the emergency use must also be included on the label. After the application is received, WDATCP will work with the registrant to refine the draft label, if necessary.

When an exemption is granted by the EPA, WDATCP will immediately provide a copy of the EPA decision letter to the registrant, along with specific instructions for preparing a final label. Such labeling must specify: (1) the use directions, restrictions, and precautions presented in the WDATCP request letter to EPA, as approved or modified by EPA; (2) the time period during which the exemption is in effect; and (3) any additional instructions identified by the EPA in its approval document.

- **The Section 18 labeling must be approved by WDATCP prior to use of the product under the emergency exemption, and the label must be in possession of the user at the time of application.**

E. Waiver of Liability Statements

Wisconsin does not allow labeling that requires written agreements or contracts. WDATCP is tasked with enforcing all label requirements, however WDATCP does not have authority to enforce contractual agreements between parties. Therefore the department's policy will not allow for requirements of written agreements or contracts to be mandated on labels used in Wisconsin.

Please note that per the EPA requirements, waivers of liability must be preceded by the statement "TO THE EXTENT CONSISTENT WITH APPLICABLE LAW," and then followed by the product specific liability statement.

F. Use Reports

EPA regulations require that a final report be submitted summarizing the results of the pesticide use under an emergency exemption. The EPA will not grant repeat exemptions unless a final use report has been submitted for previous exemptions for the same emergency use.

Generally, the final use report must be submitted no later than six months after the expiration of the exemption. As with the exemption request itself, the use report is submitted to the EPA by WDATCP. Like the exemption request, assembly of the required information and timely delivery to WDATCP is the responsibility of the person, organization, commodity group, etc., that submitted the Section 18 application to WDATCP. Preparation of the use report requires a coordinated effort among growers, extension agents, chemical company representatives, and others involved with the use to accurately report the following information:

- Total acreage (or other unit) treated under the exemption or if unknown, total quantity sold;
- Range of application rates used and total quantity of the pesticide used, in terms of both formulated product and active ingredient;
- Discussion of the effectiveness of the pesticide used in dealing with the emergency condition, and estimated economic and crop yield benefits realized from the use as compared to untreated sites or sites treated with alternative methods/pesticides;
- Description of any unexpected adverse effects resulting from the emergency use;
- Any other information requested by the EPA in connection with or required as a condition of the granting of the Section 18.

WDATCP will be responsible for adding information related to state regulatory/enforcement activities and for transmitting the report to the EPA.

PART IV. REQUIRED APPLICATION INFORMATION

This section provides detailed descriptions of the information, data, and discussions that must be presented in the Section 18 application. These guidelines reflect information provided in EPA guidance documents published in June 1992, as well as the requirements in the Code of Federal Regulations, Title 40, Part 166 (i.e., 40 CFR 166), which contains the federal regulations for implementing provisions of FIFRA Section 18. The information contained in the Section 18 application submitted to WDATCP may be arranged in the same format as the outline presented below.

An applicant may utilize the *Checklist for Requesting a Section 18 Emergency Exemption from Registration in Wisconsin* to ensure that all required information is submitted and that it is presented in organized manner. Submit all required information to Alyssa Foss at alyssa.foss@wisconsin.gov. If your application materials will exceed 10 MB, submit clearly identified separate e-mails with smaller attachments. Any questions about a Section 18 request can be submitted to Alyssa Foss at 608-224-4547 or at alyssa.foss@wisconsin.gov.

A. General Information Required for All Section 18 Request - 40 CFR 166.20(a).

- 1. Type of Exemption.** Specific, Quarantine, Public Health or Crisis.
- 2. Contact Persons.** Identify knowledgeable persons who are familiar with the following aspects of emergency situation:
 - a. Technical/Scientific Aspects: (persons familiar with the biology of the pest [e.g., insect, pathogen, weed] and its extent and effects in/on the crop; persons familiar with efficacy of the requested pesticide and/or the alternative cultural and chemical control methods that are no longer efficacious).
 - b. Economic Aspects: (persons familiar with economics of production of the affected crop and the crop yield/quality/revenue impacts of not controlling the emergency pest).
 - c. Pesticide Registrant: (knowledgeable representative(s) of the registrant/manufacture of the requested pesticide, e.g., the product registration manager, state/federal registration specialist, and/or development scientist).

These persons may be contacted by WDATCP or the EPA during review of the Section 18 application. For each listed person, provide the following:

- Name
- Job title or Business Unit
- Company name
- Mailing address
- City, State ZIP
- Phone number
- E-mail address

3. Description of the Pesticide. Provide the following information:

- a. For federally registered pesticide products, include a copy of the federal label (most recent revision) and a copy of the proposed labeling for the emergency exemption. Active Ingredient: Identify the active ingredient (a.i.) using the official name accepted by the American National Standards Institute (ANSI) or International Organization for Standardization (ISO), or the most accurate common name.
- b. For any other pesticide product (those not federally registered): provide a confidential statement of formula or a reference to one previously submitted and a copy of the proposed labeling for the emergency exemption.

4. Description of the Proposed Use. Provide the following information:

- a. Sites to be Treated: Identify the crop to be treated and the specific locations within the state where that crop is affected by the emergency pest (thus, where the requested pesticide will be applied). List all of the counties where the emergency use is anticipated (if not statewide). Note any additional geographic (sub-county level) limitations to the proposed treatment area, e.g., proximity to water bodies, ecologically sensitive areas, residences, etc.
- b. Method of Application: Identify whether the product will be applied by ground, air, and/or chemigation (i.e., through irrigation equipment). If chemigation, specify the types of irrigation systems that can be used. Specify any other specialized or innovative equipment that will be used.
- c. Rate of Application: Identify the rate (or rate range) at which applications will be made, in terms of both formulated product and active ingredient per acre (or other unit). Include registrant specifications for dilution volumes.
- d. Maximum Number of Applications: Identify the maximum number of applications that may be made per acre (or other unit) under the emergency exemption.
- e. Total Acreage to be Treated: Identify the expected number of acres, or other appropriate unit (e.g., beehives), that may be treated. This should be the maximum unit anticipated and will be used for risk assessments.
- f. Total Amount of Pesticide to be Used: Identify the total amount of the pesticide to be used under the exemption, in terms of both formulated product and active ingredient (i.e., maximum rate X maximum number of applications X maximum acreage).
- g. Use Season: Identify the time period for which the emergency use is requested. Both beginning and ending dates of the proposed use are required. Calendar dates are required, but if the treatment period is associated with specific growth stages of the crop, this should be described here. The time period may not exceed one year. If there are distinct, shorter time periods (within the overall use season) when applications are to be made, identify and describe.

NOTE: If the requested pesticide is not registered with the EPA, additional lead time may be required for manufacture, labeling, and distribution to ensure availability by the identified use season. Such anticipated delays should be explained here.

- h. Earliest Possible Harvest Dates: Identify the earliest anticipated date at which harvest of the crop treated under the exemption will occur.
- i. Other Restrictions, User Precautions, and Requirements: Any additional information, precautions, restrictions, etc., pertaining to the proposed use must be provided in this section. In general, the restrictions on the registered label will also be applicable to the emergency use. Federal label restrictions, as well as additional restrictions applicable to the proposed emergency use, should be listed in the Section 18 application. Types of information to include here are identified below (all, or only some, may apply, depending on the situation), with example statements provided in quotes:

Restricted Use Classification: If a pesticide has any uses that are classified as Restricted Use, then use under an exemption also will follow the requirements of the Restricted Use classification.

Worker Protection Requirements: “Worker protection requirements on the federal label, including the restricted entry interval (REI) of xx hours, shall apply to this use.”

Application Method Restrictions: Specify prohibitions such as aerial or chemigation applications. “Application by air or through any type of irrigation equipment (i.e., chemigation) is not permitted.”

Application Timing Restrictions: For example, if use of the proposed pesticide during a specific part of the proposed use season will be harmful to the target crop, neighboring crops, or beneficial organisms, list the necessary restrictions.

Preharvest Interval: “A xx-day preharvest interval must be observed.” *Grazing/Feeding Restrictions:* In general, grazing of treated fields, or feeding of residues or by-products from fields treated under an emergency exemption will not be allowed. There are exceptions if the appropriate residue tolerances have been established.

Application Site Restrictions: If there are restrictions against applying near other crops, residential areas, or ecologically sensitive areas, describe them here.

- j. Attach a proposed Section 18 supplemental label for this use.

5. Alternate Methods of Control. The Section 18 application must identify all alternative methods that are available to control the emergency pest situation, and must provide an explanation of why each is not effective or cannot feasibly be used. Both cultural practices and currently registered pesticides should be addressed.

- a. **Registered Alternative Pesticides.** Identify all pesticides currently registered for use on this crop to control the pest. For each pesticide, provide an explanation of why it is not effective in controlling the emergency. This explanation must be supported by field data that demonstrate

the ineffectiveness of the registered pesticides. If such data are not available, provide written statements by qualified agricultural experts, university/extension personnel, or other persons qualified to verify the lack of efficacy. If there are specific restrictions or recommendations against using a registered pesticide, explain such recommendations. If the product is not available in sufficient quantities to adequately address the emergency, or if specialized equipment required for applying a registered alternative pesticide is not available, explain such limitations.

- b. **Alternative Cultural Control Practices.** Identify all alternative control practices for the emergency pest situation, other than registered pesticides. Such practices may include rotating crops, using tolerant/resistant crop varieties, adjusting planting densities, using hand labor operations, etc. Provide a detailed explanation of why alternative practices, if available, either would not provide adequate control or would not be economically or environmentally feasible. For each available control measure not considered to be cost effective, supply appropriate economic cost/benefit information to support the claim.

- **Attach copies of research reports showing lack of efficacy or resistance development for registered alternative pesticides, and documentation of ineffectiveness of alternative (nonpesticide) control practices, if available.**

6. Efficacy of the Proposed Use. The application must contain data, a discussion of field trials, or other evidence (e.g., experimental testing, small plot trials, laboratory trials, etc.) to demonstrate that the proposed pesticide will be effective in alleviating the emergency pest situation. The data and supporting information must demonstrate efficacy under conditions (e.g., climate, soil resources) found in

Wisconsin, or equivalent. Especially helpful are data from trials that include both the proposed pesticide and the registered alternatives. If there are any phytotoxicity concerns associated with the proposed use, explain those here.

- **Attach copies of efficacy data and phytotoxicity data (if applicable).**

7. Residue Information. Unless the pesticide already has a tolerance for the use site, the Federal Food, Drug, and Cosmetic Act (FFDCA) requires EPA to establish time-limited tolerances or tolerance exemptions for each approved Section 18 pesticide use that may result in residues of the pesticide in or on food or feed. Therefore, if the requested use is for a food or feed crop, the application must include residue data, generated under EPA guidelines, which will support establishment of the time-limited tolerance or tolerance exemption for the requested pesticide on the harvested commodity, or on processed foods and/or byproducts from the harvested commodity. If such data are already on file with EPA, provide the appropriate reference number (for example, tolerance petition number or MRID number) to assist EPA reviewers in locating the file.

- **Attach copies of residue data, if not already on file with EPA. Provide documentation from IR4 or the registrant that references data already on file with EPA.**

8. Risk Information. The application must include a detailed discussion of the potential risks posed by the proposed emergency use. The discussion must address the potential risks to human health, endangered and threatened species, beneficial organisms, fish and aquatic species (details outlined below). Also include a general description of typical application sites for the proposed emergency use in relation or proximity to aquatic systems, endangered or threatened species habitats, residences, sensitive crops, etc., along with supporting data or information, if available.

- a. **Human health:** The FQPA requires that EPA evaluate aggregate exposure to the pesticide chemical residue from multiple routes (food, water, environment) when reviewing Section 18 exemption requests. The aggregate exposure assessment is used to determine whether there is a “reasonable certainty that no harm will result” if the proposed use is allowed. This safety determination is necessary in order to establish the time-limited tolerance required for emergency exemptions under FQPA. To evaluate potential exposures, submit the following information (most of which can be obtained from registrants) with all food/feed use Section 18 requests:
 - I. **SDS Sheet:** Attach a current safety data sheet for the pesticide product. Safety data sheets provide a portion of the required human health and environmental risk information.
 - II. **Groundwater:** Information and available modeling data on the persistence, mobility and chemistry for the product when there is a potential for transfer of residues to drinking water.
 - III. **Residential Use:** Information on residential uses of the pesticide.
 - IV. **Mode of Action:** Data on other pesticides with the same mode of action as the active ingredient being requested in the section 18.
 - V. **Worker Protection Standard (WPS):** Risks to pesticide handlers and agricultural workers (addressed by Worker Protection Standard provisions) are usually addressed on the federally registered label. For new, unregistered pesticides, worker and handler risks and protective measures should be addressed in the Section 18 application, and will be required on the Section 18 labeling. Specific proposals to mitigate any identified risks (e.g., protective clothing, setback or buffer zone requirements, application timing restrictions, soil type restrictions) should be listed.
 - VI. **Unreasonable Harm:** A discussion of how this proposed use will not cause unreasonable harm to human health.
- b. **Environmental Risks:** In order to evaluate potential risks to the environment, the application should include the following information:

- I. **Endangered and Threatened Species:** Discussion of how endangered and threatened species will not be adversely affected by this emergency use.
 - II. **List of Endangered and Threatened Species:** Include a list of endangered and threatened species present in the areas to be treated (more information can be found at <http://www.fws.gov/midwest/Endangered/lists/wisc-cty.html>).
 - III. **Beneficial Organisms:** Information on the pesticide's toxicity to bees if the crop or use site is attractive to pollinators. Include a description of any label language used to mitigate risk to pollinators or other beneficial organisms.
 - IV. **Fish and Aquatic Species:** Information on the pesticide's toxicity to fish and aquatic species. Include a discussion on how fish and aquatic species will not be adversely affected by this emergency use. Include a description of any label language used to mitigate risk to pollinators or other beneficial organisms.
 - V. **Other Environmental Risks:** A discussion of any other environmental risks that may be applicable to this proposed use.
- **Attach copies of documents that provide information to assess risks associated with the proposed use; examples include SDS, technical data bulletins, toxicological and environmental fate data, FQPA Supplemental Information Documents, *Federal Register* notices of residue tolerance establishment, draft pesticide petitions.**

9. Coordination with Other Agencies. WDATCP may need to coordinate with other state or federal agencies on issues of human health and/or environmental concern posed by the requested use. For this item, use the following standard statement: "The Wisconsin DNR and the Wisconsin Fish and Wildlife Office of the U.S. Fish and Wildlife Service may be given a copy of this request. Any comments received will be forwarded to the U.S. EPA." (If WDATCP deems it appropriate, additional agencies will be notified and cited in the final Section 18 request submitted to EPA.)

10. Notification/Support of Registrant. The Section 18 application must include a letter from the registrant or manufacturer of the requested pesticide, indicating that the company has been notified of this request and will support the emergency use of its product, by providing an adequate product supply, product stewardship, and supplemental labeling. Also include information on the progress toward full registration of the proposed use (see Item 13, below) within the letter.

- **Attach a copy of the registrant/manufacturer letter of support.**

11. Enforcement Program. The emergency exemption request in its final form, as submitted to EPA from WDATCP, will include an explanation of the department's legal authorities for ensuring that the emergency use of the pesticide will comply with WDATCP requirements, and any specific requirements imposed by EPA in its approval of the Section 18 exemption.

The application submitted to WDATCP from the industry representative(s) should contain a standard set of statements equivalent to the following:

“The Wisconsin Department of Agriculture, Trade and Consumer Protection (WDATCP) has adequate authorities for enforcing provisions of Section 18 emergency exemptions. WDATCP will require the registrant (or manufacturer, if unregistered) of [the requested pesticide], XYZ Corporation, to prepare and make available to end users supplemental labeling that complies with WDATCP and EPA requirements for the emergency use, if approved.”

12. Repeat Uses. The application must indicate whether the same emergency use (same crop/pesticide) being requested has previously been granted by EPA. If this is a repeat request, then the requesting entity must ensure that a final use report for the previous exemption has been provided to the department; indicate who submitted the report and the date it was submitted. If the proposed use was requested previously but denied by EPA, that should be noted here. If this is a first-time request, so indicate.

13. Progress Toward Registration. The application must include a discussion of progress toward full registration of the proposed use. Include in the discussion specific reference to registration petitions already submitted to EPA, or a brief summary of any studies that are still in progress to address deficiencies or data gaps that are impeding the registration.

EPA regulations contain a requirement that a complete registration application must be submitted within the first three years that the proposed use is requested under Section 18. Minor food uses being pursued through the IR-4 Program may be judged against a five-year standard. The entity preparing the Section 18 application should contact the registrant (or IR-4, if the use being proposed is a minor food use registration project of IR-4) to obtain progress toward registration information.

B. Additional Information Required for a Specific Exemption - 40 CFR 166.20(b).

1. Pest to be Controlled. Provide both the common name and scientific name of the pest to be controlled by the proposed emergency pesticide use.

2. Discussion of the Emergency Condition. The application must include a detailed discussion what makes this situation urgent and non-routine including all the events which brought about the emergency (e.g., unusual weather conditions, severe pest pressure, development of resistance to registered alternative pesticides, cancellation of registered pesticides, etc.). Claims of severe pest or disease pressure must be documented with data or written testimony of qualified experts. A “threshold level for treatment” should be specified, above which the emergency condition would be deemed to exist and use under an exemption allowed.

Examples of threshold levels include a specified number of insect pests per plant; weed densities (e.g., number of weeds per square yard) or presence of weeds at a given stage of the crop; some level of rainfall occurring within a specific time frame; or some percentage of crop defoliation due to a pest.

If resistance development, phytotoxicity, or other claims concerning ineffectiveness of registered alternative pesticides are the basis for the emergency condition, the application must include evidence (in the form of field or laboratory data) to support the claim. Written testimony from qualified experts may be considered when data are not available.

If yield losses and/or decreases in quality of the crop are being claimed, the application must include reports from studies comparing yields or crop quality achieved with use of the proposed pesticide against those resulting from use of the registered alternative(s).

NOTE: A chronic or continually occurring problem is not considered by EPA to represent an urgent, nonroutine situation. Also, a proposal based solely on using a pesticide (not registered for use on the subject crop) to improve yields and/or income because the proposed pesticide is significantly more effective or less expensive than any of the existing control measures is not an acceptable basis for a Section 18 request for an ongoing pest problem which has not intensified in recent years.

□ Attach copies of research reports, extension publications, written testimony of qualified experts, weather data, photographs, etc. documenting the extent and severity of the emergency pest situation.

3. Environmental Benefits Information. Where applicable, include a discussion of the anticipated risks to endangered or threatened species, beneficial organisms, or the environment that would be remedied by the proposed use of the pesticide.

In those instances where EPA determines that a significant risk is posed by a proposed use, that Agency will conduct an in-depth benefits analysis. Certain economic impacts of not addressing the emergency condition with the proposed use will be considered in EPA's analysis, if a thorough discussion of those impacts is included in the application. EPA specifies the following types of economic impacts that it will consider:

- a. Impacts at the pesticide user level.
- b. Measurable change in price and availability of the commodity to consumers.
- c. Measurable reduction in sales and/or employment of organizations supplying the affected producers.
- d. Measurable reduction in business volume and/or employment of organizations marketing the output of affected producers.
- e. Measurable reduction in the economic base, including employment of communities affected by the supplier and marketing organizations.

- **Attach supporting documentation as appropriate and available.**

4. Discussion of Economic Loss. If the emergency exemption is being requested to avoid a significant economic loss (SEL), then the application must include a discussion and analysis of anticipated economic losses associated with the emergency condition.

The EPA uses a three tiered system for determining if an economic loss is significant or not.

The EPA defines an economic loss as "significant" if it meets any one of these three tiers:

- I. Tier 1 – Yield loss of at least 20%
- II. Tier 2 – Loss of at least 20% of gross revenue
- III. Tier 3 - Total Economic Loss of at least 50% of net operating revenues

The application must demonstrate that the emergency meets one of these three tiers. If the emergency situation does not meet any of the thresholds for the three tiers, then the situation is not predicted to have a significant economic loss. In certain situations where the criteria in the three tiers does not adequately describe the expected loss, the EPA will also consider a discussion of expected losses related to the emergency situation that affect the long-term financial viability from the activity.

WDATCP suggests compiling five years of average yield, price and cost of production data from years prior to the emergency situation to establish a baseline of information. These 5 year averages can then be compared to expected yield, price, and cost of production data under the emergency condition. Emergency exemption decisions must be based on reliable data. Applicants should prepare packages that contain the best available information. Be sure to cite what sources were used to find the numbers used in the analysis. Typical sources of appropriate data are:

- Yield loss: economic injury studies or comparative efficacy studies taken to yield, industry field trial experiments
- Baseline yield and prices: agricultural statistics (e.g., USDA/NASS data), crop reports, market surveys, futures market;
- Crop Quality: marketing studies and surveys
- Cost increases: market surveys, labor demand studies, crop budgets (e.g., from university extension programs)
- Operating costs: crop budgets

For Tier 1, the threshold is a yield loss of at least 20%. Begin by calculating yield or utilized yield reasonably anticipated in the absence of the emergency and expected losses in yield due to the emergency. The analysis should address not only the expected yield loss resulting from no treatment, but also what the yield loss would be using the best currently registered treatment for the emergency.

Consider using the format of the example table below for a Tier 1 analysis of yield loss.

Example Table for Documenting Tier 1 Yield Loss

Treatment	Percent Control of Pest (efficacy)	Percent Crop Injury	Yield per Acre	Percent Change Compared to five-year average yield
Requested chemical	-----	-----	-----	-----
Registered alternative	-----	-----	-----	-----
Registered alternative	-----	-----	-----	-----
Untreated	-----	-----	-----	-----

If the criteria for Tier 1 are not met, include all information requested for tier one plus the information for Tier 2, loss of at least 20% of gross revenue. Tier 2 data consists of prices reasonably anticipated in the absence of the emergency and changes in prices and/or production costs due to the emergency. Often times this tier is used to demonstrate losses in quality of the crop and therefore losses in price. This tier can also demonstrate added production costs caused by the emergency the lower gross revenue.

Consider using the format of the example table below for a Tier 2 analysis of gross revenue loss.

Example Table for Documenting Tier 2 Gross Revenue Loss

Crop	Baseline- average yield without pest emergency	Emergency- average yield with best alternative control measure	Difference Between Baseline & Emergency	Percent Change
yield/acre	----	----	----	----
Price per unit	----	----	----	----
Gross revenue	----	----	----	----

If the threshold for Tier 1 and Tier 2 are not met, include both Tier 1 and Tier 2 analysis plus the analysis for Tier 3, total economic loss of at least 50% of net operating revenues. For Tier 3 analysis, compare the net operating revenue per acre under the pest emergency with the average net operating revenue per acre before the emergency condition began.

Net Operating Revenue = Gross Revenue -Variable Operating Costs.

The variable operating costs should only change as a result of the emergency condition. This information can be gather from university crop production cost analysis or from grower group surveys.

Consider using the format of the example table below for a Tier 3 analysis of total economic loss.

Example Table for Documenting Tier 3 Percent Loss of Net Operating Revenue

Crop	Baseline – 5 Year Average yield without pest emergency	Emergency- average yield with best control alternative	Difference Between Baseline & Emergency	Percent Change
Yield/Acre	----	----	----	----
Price per unit	----	----	----	----
Gross Revenue	----	----	----	----
Costs (\$/acre)	----	----	----	----
Total Operating Costs (\$/acre)	----	----	----	----
Net Operating Revenue (\$/acre)	----	----	----	----

C. Information for Repeat Requests for a Specific Exemption - 40 CFR 166.20(b) (5).

For repeat specific exemption requests that are substantially similar from year to year, it will not always be necessary to submit all of the supporting documentation every year. The proposed Section 18 label, registrant support letter, and documentation of progress toward registration are required for every Section 18 request; regardless of how many times the request has been submitted previously. Any new data or information that has become available since the previous request should, of course, be submitted.

Requests for a repeat specific exemption must include the following:

1. **Emergency Condition Still Exists?** Verify the emergency condition described in the previously submitted emergency exemption application continues to exist.
2. **Previous Information Still Accurate?** Verify all information submitted in the previously submitted emergency exemption application is still accurate; or if new information is available or needs to be updated, expressly identify any new or updated information
3. **Proposed Use Conditions Identical?** Verify that the proposed conditions of use are identical to the conditions of use EPA approved previously. If there are any updates to the condition, explain and expressly identify the changes.
4. **Re-certification Conditions and Limitations Satisfied?** Verify that there were no additional conditions or limitations on the eligibility for re-certification identified in the previous notice of approval. If there were additional conditions or limitations on the eligibility for re-certification, verify that they have been satisfied.
5. **Continued Lack of Alternatives?** Verify that there has not been any new alternative chemical or nonchemical practice that may offer a meaningful level of pest control since the previous application. If any such new alternative controls are available, document that each such known chemical or practice does not provide adequate control or is not economically or environmentally feasible.
6. **Interim Report to EPA Submitted?** Verify that a final or interim report to was submitted, or is attached.

D. Additional Information Required for a Quarantine Exemption - 40 CFR 166.20(c).

1. **Pest to be Controlled.** Provide both the common name and scientific name of the pest to be controlled by the proposed emergency pesticide use.
2. **Origin of Pest and the Means of its Introduction or Spread if Known.** Provide a background on the pest including information on the origin of the pest. A discussion of the introduction or spread of the pest to the area. Be sure to include a timeline of events. Possible events to discuss may include; discovery of the pest in the area, estimated timeline between pest introduction and discovery, rate of spread of the pest, and estimated area affected or to be affected by the pest.
3. **Anticipated Impact of Not Controlling the Pest.** Include a detailed discussion on the estimated impact of not controlling the pest. Data may include economic or environmental consequences of not controlling the pest. Include a discussion on the potential for the pest to spread beyond the current area if left uncontrolled and the consequences of further spread of the pest.

The “emergency” status of the pest situation will be determined by the potential of the invasive species to cause a significant economic loss or significant harm to the environment.

Quarantine exemptions may be approved for up to three years.

E. Additional Information Required for a Public Health Exemption - 40 CFR 166.20(d).

- 1. Pest to be Controlled.** Provide both the common name and scientific name of the pest to be controlled by the proposed emergency pesticide use.
- 2. Vectored Disease Transmission.** If the pest is a vector, a description of the disease it is expected to transmit. Description should include a full description of the disease.
- 3. Magnitude of Health Problems.** A discussion of the magnitude of the health problems which are expected to occur without the pesticide use. The discussion should address those who are most at risk to the health problem, predicted potential spread of the health problem without the pesticide use and expected control with the requested pesticide use.
- 4. Treatment for the Health Problem.** A discussion of the availability of medical treatment for the health problem. Identify what treatments if any are available for dealing with the health problem.

Public Health exemptions may be authorized for up to one year.

F. Additional Information Required for a Crisis Exemption - 40 CFR 166.43(b).

- 1. Discussion of the Dire, Unpredictable and Sudden Situation.** Provide a complete description of the emergency situation which explains what makes this situation a dire, and sudden pest problem which was not predictable. Also explain why there is not adequate time to apply for a specific, quarantine, or public health exemption.

Tardiness in submitting a specific exemption request is not viewed as an acceptable reason for seeking a crisis exemption. Also, crisis exemptions are not allowed for emergency uses of new, unregistered pesticides; and they are not allowed for emergency uses of a registered pesticide on food or feed crops, if the pesticide has no previously registered food or feed uses.

- 2. Pesticide Use Timing.** Outline the proposed dates when pesticide use is to begin and end.

Note: A crisis exemption can only be authorized for up to 15 calendar days unless an application requesting a specific, quarantine, or public health exemption for this use has been submitted to the EPA.

Explain if the pest emergency will exist beyond the 15 calendar days and if an application requesting a specific, quarantine, or public health exemption for this use will be submitted to the EPA.