



***A GUIDE
FOR REQUESTING
SECTION 18 EMERGENCY
EXEMPTIONS FROM
REGISTRATION IN
WASHINGTON
STATE***

***REGISTRATION SERVICES PROGRAM
PESTICIDE MANAGEMENT DIVISION
WASHINGTON STATE DEPARTMENT OF AGRICULTURE***

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I. THE APPLICATION PROCESS

Emergency Pest Problems and the Section 18 Process

What happens when a new pest attacks your crop and there are no effective pesticides registered to control it? Or an unusual period of weather has promoted a pest problem that is out of the ordinary? Maybe the manufacturer of the only effective pesticide left for your crop has decided to no longer register the product? Or that devastating pest has finally developed resistance to the last effective product registered to control it?

These and other emergency situations occur every year in Washington State, and they do adversely affect growers. However, the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), has a provision (Section 18) that allows the EPA to temporarily exempt a pesticide from the full requirements of registration to deal with emergency situations. Because the state of Washington is one of the leading minor crop states in the nation and grows over 300 different commercial crops, it is not surprising that we have our fair share of emergencies. The Washington State Department of Agriculture (WSDA) has a strong program for obtaining Section 18 emergency exemptions.

If you are dealing with an urgent, non-routine pest problem and have no viable options for control, you may have a valid reason for requesting a Section 18 emergency exemption. This guide has been published to assist you in applying to WSDA for an emergency exemption. For a quick overview of the requirements, refer to the WSDA Section 18 application checklist (Part V).

When to Consider Requesting an Emergency Exemption

An emergency exemption from registration may be considered for situations in which an emergency condition exists. An emergency condition exists only when the situation is urgent and non-routine and all three of the following conditions are met: (1) No effective registered pesticides are available, (2) no economically or environmentally feasible alternative practices are available, and (3) the situation involves the introduction of a new pest or will present significant risks to human health or the environment or will cause significant economic loss (SEL).

Requests for Section 18 emergency exemption use are normally compiled and submitted to WSDA by agricultural consultants, Washington State University (WSU) research and extension specialists, and/or commodity organizations. Registrants of pesticide products often provide key information for the request, but the emergency must be the result of and driven by actual field conditions. Requests for emergency exemptions cannot be submitted by a registrant.

The EPA has established a 50-day period to review Section 18 requests. WSDA also needs time to review and compose a petition to EPA. As a rule of thumb, the following time lines should be observed when submitting a Section 18 request:

- Request for a repeat Section 18: submit to WSDA at least 80 days prior to the earliest use.
- Request for a new Section 18: submit to WSDA at least 120 days prior to the earliest use.

These are minimum time lines; the more time for Agency review, the better chance of obtaining emergency use by the time it is needed.

Submit requests for new Section 18 emergency exemptions to:

Erik W. Johansen / Special Pesticide Registration Program Coordinator
Washington State Department of Agriculture
Pesticide Management Division
1111 Washington Street SE, 2nd Floor
PO Box 42560
Olympia, WA 98504-2560

Submit requests for repeat Section 18 emergency exemptions to the WSDA Pesticide Registration Specialist assigned to the request:

Steve Foss, 360-902-2049, sfoss@agr.wa.gov

Erik Johansen, 360-902-2078, ejohansen@agr.wa.gov

Mike Norman, 360-902-1851, mnorman@agr.wa.gov

Wendy Sue Wheeler, 360-902-1972, wswheeler@agr.wa.gov

If you have administrative questions regarding the submission of a Section 18 emergency exemption request, please contact Joy Harkness (WSDA Help Desk) at (360) 902-2030 or e-mail jharkness@agr.wa.gov.

Regional Requests vs. Washington Only Requests

Under certain circumstances it may be expedient for state lead agencies in multiple states to submit a Section 18 request to the EPA as a regional request, such as two or more states in the Pacific Northwest (PNW). There are a number of factors that are taken into consideration when WSDA makes a decision to join other states in submitting a regional request. It is important that commodity groups seeking to submit a regional request contact the WSDA before they begin working with the other state lead agencies. All states participating in a regional Section 18 request need to receive a copy of the request and the supporting documentation.

What is a Crisis Exemption and When is it Appropriate to Ask WSDA to Declare a Crisis?

The word “crisis” and the word “emergency” may mean about the same thing, but in FIFRA terminology, a crisis is only one of several types of emergency exemptions that can be requested under the provisions of Section 18. A Crisis Exemption is an exemption that is reserved for dire situations - those unpredictable emergency situations that seemingly occur overnight; situations where EPA does not have time to complete a full review of a Section 18 request. The very nature of a Crisis Exemption excludes them from becoming commonplace. Prior to issuing a Crisis Exemption, WSDA must receive verbal approval from EPA.

Some commodity groups have been habitually late in submitting Section 18 requests to WSDA. It is one thing to go crisis after EPA has exceeded their allotted review time, it is quite another to seek a Crisis Exemption on a repeat Section 18 simply because the request was not submitted to EPA in a timely fashion.

Requesting a Crisis Exemption for a repeat Section 18 request because of tardiness in submitting the request is an unacceptable use of the Crisis provision.

II. JUSTIFYING THE EMERGENCY

Urgent and Non-Routine

In order to obtain Section 18 use, any emergency must be both urgent and non-routine. To be urgent and non-routine the situation must require immediate attention and be other than an ordinary one. Chronic or continually occurring pest problems are specifically excluded from the definition of an emergency condition.

The nature of the urgent, non-routine situation determines, in part, how long it would be expected to endure. Emergency situations brought about by unusual environmental conditions would not ordinarily be expected to occur in subsequent years (and therefore EPA would not normally expect repeat requests). Other situations, such as those involving the loss of a registered pesticide, would likely continue until a new pesticide is registered.

It is important that a thorough explanation be given to explain all of the factors (other than mismanagement) that have caused the urgent and non-routine situation. Unusual weather patterns may be enough alone to justify an emergency; however, if there are other reasons for the emergency those reasons must also be included. For example, if pest resistance to available pesticides is building up, and the situation is exasperated by extreme weather conditions, both factors should be explained. If pest resistance is not discussed on the original request, the following year may experience normal weather patterns and there would be no justification for the emergency (even though pest resistance is occurring). It is difficult to convince EPA that there is an urgent and non-routine situation when the reasons change each year (how did pest resistance come about overnight?). However, if all of the reasons are stated the first year, including any abnormal weather, the emergency may remain justified the second year or thereafter even if the weather is no longer a factor.

Occasionally there have been requests for multiple chemicals to address a specific emergency pest problem. Though resistance management is an important concern, the EPA does not allow this as justification for requesting multiple chemicals. Therefore, when requesting multiple chemicals it is necessary to thoroughly explain the justification. Essentially the justification must be that one chemical alone is not sufficient to control the pest problem, but the reasons for this must be documented.

Availability of Effective Registered Pesticides

For each pesticide registered to control the pest problem, the applicant must demonstrate that it is either not effective or not available in adequate supplies. In most situations, efficacy claims must be supported by data; however, in rare cases testimony of qualified experts can be used as a sole support of efficacy claims. Claims of unavailability of registered pesticides must be accompanied by a discussion of the attempts made to obtain adequate supplies.

WSU maintains a database of all pesticide products currently registered in the state of Washington (and Oregon). The Pesticide Information Center On-Line (PICOL) at WSU Tri-Cities can provide a list of currently registered insecticides, herbicides, fungicides, rodenticides, etc., on almost any pest for any given crop in the Pacific Northwest. Applicants for Section 18's are strongly encouraged to utilize PICOL to account for all possible registered alternatives to the Section 18 use requested. Failure to utilize PICOL information may cause unnecessary delays

when WSDA reviews the Section 18 request. For further information contact CharLee Parker (WSU) at (509) 372-7489 or refer to the WSU web site (<http://wspr.s.wsu.edu/>).

Alternative Practices

Alternative practices available to control the pest problem must be identified and an explanation of their limitations must be presented. Alternative practices may include such things as mechanical, biological, cultural and other means of control.

Significant Economic Loss

A significant economic loss (SEL) means that, compared to the situation without the pest emergency and despite the best efforts of the affected persons, the emergency conditions at the specific use site identified in the application are reasonably expected to cause losses meeting any of the following criteria:

(1) For pest activity that primarily affects the current crop or other output, one or more of the following:

Tier 1 - Yield loss greater than or equal to 20%;

Tier 2 - Economic loss, including revenue losses and cost increases, greater than or equal to 20% of gross revenues;

Tier 3 - Economic loss, including revenue losses and cost increases, greater than or equal to 50% of net revenues.

(2) For any pest activity where EPA determines that the above criteria (Tiers 1-3) would not adequately describe the expected loss: substantial loss or impairment of capital assets, or a loss that would affect the long-term financial viability expected from the productive activity.

In defining an emergency condition as one that is expected to result in a SEL, the consequences must be more serious than a failure to maximize profits in a particular growing season. Only those losses caused by the emergency condition are relevant in determining the SEL. Losses due to obvious mismanagement are excluded from the loss estimate. Losses due to an agent other than the target pest problem are also excluded from the SEL.

Another important consideration in presenting economic information is to present data on the specific portion of a crop that is actually affected with the pest problem (and will actually be treated with Section 18 materials if approved). For example, if comparative efficacy studies demonstrate that a 20% yield loss will occur on 25% of the crop acreage that is affected by the pest problem when using the best available alternative, then the Tier 1 criteria for a SEL is met for the affected acreage. In contrast, a 10% yield loss from a pest problem would not meet the Tier 1 criteria for a SEL for the affected acreage and an emergency exemption could not be requested, unless there were revenue losses and/or cost increases that met the Tier 2 or Tier 3 criteria for a SEL. Therefore, it is very important that the economic data be representative of the area that is affected by the pest problem.

In the past, the department has received emergency exemption requests in which the cost of production per acre exceeded the gross revenue per acre. When this occurs, a detailed explanation is required.

Also, if there are any intangible losses that will be incurred but cannot be quantified, it is helpful to describe these in the narrative. These types of losses may not prove that use of a pesticide under emergency exemption is economically justified, but they can help to bolster the justification.

Re-certification of Repeat Specific Exemption Requests

EPA allows submission of an abbreviated application for repeat specific exemption requests, when EPA determines that a repeat Section 18 request is eligible for re-certification by WSDA. The applicant must certify to WSDA that the emergency continues to exist and that the use parameters and previously submitted information remains unchanged from the previous year. Eligibility requirements for re-certification are as follows:

- EPA granted the same specific emergency exemption (to the same applicant) the previous year.
- The emergency situation can reasonably be expected to continue for longer than one year, such as emergency conditions resulting from loss of a previously relied-upon pesticide or documented pest resistance development. Situations which would not be expected to continue include more temporary pest emergencies such as a temporary supply problem of a registered product, an isolated weather event, or, a sporadic pest outbreak.
- The request is not for a new chemical, a first food use, a chemical under Special Review, or for cancelled or suspended chemicals, including those voluntarily cancelled by the registrant. These requests warrant heightened review and also enhanced public involvement and transparency.

Additionally, EPA may declare any repeat exemption ineligible to use a streamlined re-certification application at any time, and will do so when the EPA concludes that an updated application would be appropriate.

If EPA determines that a repeat Section 18 request is eligible for re-certification, then WSDA will need a letter or email from the applicant certifying the following: (1) the emergency condition still exists, (2) the information is still accurate, (3) the conditions of use are identical, (4) any conditions or limitations from previous exemptions are satisfied, and (5) there are no new alternative control measures that are effective. Re-certification requests cannot be submitted as regional requests.

Although EPA expects to accept a valid re-certification application as sufficient basis for the requestor to rely on previously submitted data to characterize the pest problem, the EPA will continue to evaluate and consider whether the criteria necessary for granting an exemption have been met. In particular, EPA will independently evaluate whether any alternative control materials or measures have become available, whether the health and environmental risk assessments remain valid, and whether adequate progress toward registration of the use is being made. WSDA expects that applicants will provide complete documentation of any changes from previously submitted data, especially any new control materials or methods. If a re-certification application requests a change in any of the use parameters (rate, method or number of applications, number of acres, and geographic area), EPA may need to conduct a revised risk assessment. Changes in any of these criteria may impact EPA review time and the regulatory outcome.

If an exemption is not classified as a candidate for re-certification by EPA, applicants must submit a conventional (i.e. non-re-certification) emergency exemption application to WSDA that contains all of the information outlined in 40 CFR 166.20. Eligibility to use a re-certification application will be communicated to applicants for all specific emergency exemptions granted by EPA. If a previously issued emergency exemption has not been identified as eligible for re-certification, and an applicant believes that subsequent information would make it eligible, WSDA may contact EPA to request re-evaluation of the eligibility determination.

Situations that are Not Justified as an Emergency

WSDA receives inquiries every year regarding pest problems that do not meet the requirements for an emergency exemption. Most often there is a clear need for a product to address a pest problem, but the pest problem does not meet the urgent and non-routine criteria established in federal regulation. Applicants often focus their attention on convincing WSDA that the product/use is needed, when in reality the request cannot be submitted to EPA because it does not meet the urgent and non-routine nature of a Section 18 emergency exemption. Often these requests are made for new products that are undergoing the registration process, but have not received full registration by the EPA. Requesting Section 18 use for such products attempts to short-cut the registration process. WSDA sympathizes with the need, but must adhere to federal requirements. This is not to say that none of these requests are legitimate. There are times when the urgent and non-routine nature of a pest emergency can be documented and a new product that is undergoing registration may be a good fit.

There are other situations when a new product that is undergoing registration is a more efficacious and/or a less expensive alternative than what is currently registered. WSDA recognizes the value in obtaining the legal use of these products, but these situations do not meet the urgent and non-routine criteria of a Section 18 emergency exemption.

III. INFORMATION TO SUBMIT TO WSDA

The following sections coincide with the requirements of federal regulation (40 CFR 166.20) as well as related WSDA requirements. Each section contains a detailed description of the information that must be provided. Please submit the information in the following format (also see example request attached):

A. GENERAL INFORMATION

1. TYPE OF EXEMPTION: Specific, Quarantine, Public Health or Crisis.
2. CONTACT PERSONS: Identify one or more knowledgeable experts who can be contacted for comment on technical and economic aspects of the request. Include name, affiliation, address, telephone number, fax number, and e-mail address (if available).
3. DESCRIPTION OF PESTICIDE: Identify the active ingredient using the accepted American National Standards Institute (ANSI) name or the most accurate common chemical name.
 - a. Federally registered pesticides: Specify the EPA Registration Number, registrant, and the name of the product. Provide a copy of the federally

registered label, and any additional labeling proposed for the emergency exemption use. In an effort to minimize processing time, products approved by the EPA should be used whenever possible. If a specific product is not requested, specify the formulation(s) requested and the percent active ingredient.

- b. Any other pesticide products: A confidential statement of formula (CSF) or reference to one already submitted to the EPA as part of a previous or pending action for the active ingredient (EPA File Symbol, EUP number, or SLN number), and complete labeling which will be used in connection with the proposed exemption use. Include a description of how unused material will be disposed of upon expiration of the emergency exemption.

4. DESCRIPTION OF THE PROPOSED USE: Specify all of the following:

- a. Crop(s)/site(s) to be treated and location: Provide the name of the crop(s)/site(s) to be treated. Specify the geographical location (e.g. counties) where the emergency exists and applications will occur (if not statewide), giving as much detail as possible (e.g. proximity to water bodies, residences, etc.). In order to reduce the potential need for an endangered species risk assessment (and mitigation measures), it is important to provide detailed information regarding the location of the application sites, and to only include counties where the use is actually needed.

- b. Method of application: Be as specific as possible, particularly if an innovative method which may reduce exposure will be used.

- c. Rate of application: Active ingredient and formulated product.

- d. Number of applications: Typical and maximum number of applications.

- e. Total acreage (or other appropriate units) expected to be treated under the exemption. This should be the maximum acreage anticipated, but should not be excessive, since risk assessments will be based on maximum acreage.

- f. Total amount of pesticide to be used in terms of both active ingredient and formulated product.

- g. All applicable restrictions, user precautions, qualifications of applicators and other requirements concerning the proposed use.

- h. Use period (or season): State the time period for which use of the pesticide is requested. Be sure to explain if there are anticipated product production or distribution concerns that may delay getting product to the end user. The request cannot be for a time period greater than one year. Include the earliest anticipated harvest date (food or feed uses).

5. ALTERNATIVE METHODS OF CONTROL: List **all** pesticides that are registered for the proposed use, along with a detailed explanation of why each of these pesticides are not sufficient to control the emergency.

If lack of efficacy is the reason given, field data demonstrating the ineffectiveness of the registered alternatives must be included. Under extenuating circumstances or in the absence of such field data, written statements from extension or

university personnel, or other similarly qualified experts verifying the lack of efficacy may be acceptable.

If an effective pesticide is available but not recommended by researchers, extension staff or other experts, an explanation of why it is not recommended must be provided.

If a pesticide is recommended in a WSU or PNW extension publication, but is determined to be ineffective for this particular emergency situation, this discrepancy must also be explained.

If necessary application equipment is not available, an explanation of the attempt to obtain the equipment and the results of the attempt must be provided.

When a registered alternative is not available in sufficient quantity, provide an explanation of the attempts to obtain sufficient quantities.

The request must also contain a detailed explanation of why alternative practices (if available) either would not provide adequate control or would not be economically and/or environmentally feasible. Alternative practices may include such things as mechanical, biological, cultural and other means of control.

6. **EFFICACY DATA:** The request must contain data, a discussion of field trials, or other evidence (e.g. experimental testing, small plot trials, laboratory trials, or corroborating evidence from similar uses) which provided the basis for the conclusion that the proposed use will be effective.
7. **RESIDUE DATA:** If the requested use is for a food or feed crop or potable water, residue levels must be estimated. Residue levels must be estimated for all the food commodities even if residues in a processed food are expected to be lower than those in the treated commodity. The request shall address whether residues are expected in or on food, a list of the food item(s) likely to contain residues, and an estimate of the maximum amount of residues likely to result from the proposed use. If residue levels are expected to be nondetectable, the request should so state and specify the limit of detection.

The residue data from which the above residue estimate is derived must be provided if not already on file with the EPA. If data are on file with the EPA, please provide the appropriate reference number, such as the tolerance petition number or Master Record Identification (MRID) number.

If certain potential food/feed items will not be allowed into the marketplace, cite the method(s) for controlling distribution in the marketplace.

8. **RISK INFORMATION:** Include a detailed discussion of the potential risks from the proposed use. The discussion must address the potential risk to human health, threatened or endangered species, beneficial organisms, and the environment. A description of the application sites including proximity to aquatic systems, endangered species habitats, residences, etc., as well as soil type should be provided, along with references to data or other supporting information. Proposals to mitigate risk (protective clothing, setback restrictions, soil type restrictions, etc.) should be listed.

a. Human health: FQPA requires the EPA to consider aggregate exposure from multiple routes (food, water and the environment) when reviewing section 18 applications. The following information (most of which can be obtained from registrants) must be submitted with all food/feed use Section 18 requests:

- **Groundwater:** The request should include 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. It should also provide information on any drinking water monitoring program (monitoring, detections and limits of detection) in the state.
- **Residential Use:** Information on residential uses of the chemical.
- **Mode of Action:** Data on other pesticides with the same mode of action as the active ingredient being requested in the section 18.
- **Timing of Crop Harvest:** A time-limited tolerance must be established for all Section 18 food/feed uses. EPA needs to know the earliest anticipated harvest date so that they will be able to establish the time limited tolerance prior to harvest.
- **Worker Protection Standard (WPS):** Any applicable WPS requirements need to be addressed in the request and on proposed labeling.

b. Environmental Issues: Environmental hazards will be identified in Part 8 of the Section 18 request, and will be mitigated by statements as outlined in Part 4 of the request. Environmental hazard mitigation statements will be required for pesticides that are toxic to fish or wildlife, or have the potential for contaminating groundwater or surface water. These statements should be consistent with standard EPA language, unless WSDA determines that more specific restrictions are necessary. Environmental hazards that are adequately mitigated by the Section 3 label do not need to be mitigated on the Section 18 request.

- (i) Ecological Risk & Threatened or Endangered (T/E) Species: The application must include a list of endangered or threatened species present in the areas to be treated (except for indoor or seed treatment uses), and must include measures to insure that T/E species will not be adversely affected from the emergency use of a pesticide.

Aquatic Organisms: The request must discuss any potential adverse effects to T/E aquatic organisms. When EPA and WSDA assess the risk of pesticides to aquatic organisms, we consider the toxicity and amount of pesticide to which the aquatic organisms may be exposed. The WSDA Aquatic Risk Assessment form

(<http://agr.wa.gov/PestFert/Pesticides/docs/AquatRiskAssess4129.pdf>)

must be submitted with every request (except for indoor or seed treatment uses). We frequently use mathematical simulation models, such as GENECC (GENeric Estimated Environmental Concentration), to predict pesticide concentrations in water for use in aquatic risk assessments. If T/E aquatic organisms occur in a county where pesticide

use is requested and adverse effects are predicted by GENECC, then use restrictions to protect T/E aquatic organisms may be required. The following is an example of use restrictions (aerial application):

“To protect endangered aquatic species, use one of the following options: (1) Apply only when there is sustained wind away from fish-bearing waters, or (2) Leave a 150 foot untreated buffer between treatment area and fish-bearing waters.”

In addition, the following statement is required for 54 active ingredients impacted by a U.S. District Court final order, unless EPA has made a “no effect” determination or a “not likely to adversely affect” determination:

“Certain uses of (active ingredient) may be restricted by a U.S. District Court final order. You may refer to the WSDA Endangered Species Program web site at <http://agr.wa.gov/PestFert/natresources/Buffers.aspx> for information regarding pesticides that are impacted by the final order.”

Plants: If T/E plants occur in a county where herbicide use is requested, then use restrictions to protect T/E plants may be required. The following is an example of use restrictions to protect T/E plants (ground application):

“To protect endangered plant species, use one of the following options: (1) Apply only when there is sustained wind away from native plant communities, (2) Leave a 25 foot untreated buffer between treatment area and native plant communities, or (3) Use low pressure nozzles according to manufacturer’s specifications that produce only coarse or very coarse droplets.”

For other T/E species (e.g. mammals, reptiles, amphibians, birds or insects), WSDA will develop risk mitigation statements in cooperation with the appropriate agency.

- (ii) Chemigation: A chemigation statement will be required for pesticides that will be applied through irrigation water. This statement should be consistent with standard EPA language, and should also refer to WSDA chemigation rules. If the Section 3 label already has a chemigation statement, then the Section 18 request does not require a chemigation statement (except a reference to the Section 3 label and WSDA chemigation rules).
- (iii) Herbicides: A statement referring to WSDA herbicide rules is required for herbicides used in areas that are subject to those rules (e.g. phenoxy, desiccant, and sulfonyleurea herbicides in portions of Eastern Washington). A form to request WSDA laws and rules is available on the internet (<http://agr.wa.gov/PestFert/docs/Form4311.pdf>). Consult with WSDA for specific wording referring to WSDA herbicide rules.

(iv) Beneficial Insects: A pollinator protection statement (PPS) is required for insecticides and fungicides that are toxic to bees, when applied to a crop or site that is attractive to bees. The PPS must include a description of the hazard, followed by a statement consistent with WSDA requirements for the active ingredient and the crop or site. Refer to “Pollinator Protection Requirements for Section 18 Emergency Exemptions and Section 24(c) Special Local Need Registrations in Washington State” for guidance on PPS (<http://agr.wa.gov/PestFert/Pesticides/docs/PollinatorSLNSect18.pdf>).

9. COORDINATION WITH OTHER AGENCIES (Note - WSDA will include this language in the final request): The US Fish & Wildlife Service, the Yakama Nation, and the Washington State Departments of Ecology, Health and Fish & Wildlife have received copies of this request. Any comments received will be forwarded to the US EPA.
10. ACKNOWLEDGEMENT OF REGISTRANT: The request must include a letter from the registrant or manufacturer of the pesticide indicating that they support the request. This letter should also include information regarding product availability and progress towards registration of the proposed use (refer to Part 13).
11. ENFORCEMENT PROGRAM (Note – WSDA will include this language in the final request): WSDA has adequate authority for enforcing provisions of Section 18 Emergency Exemptions and has been doing so for many years. We would be glad to answer any specific questions regarding our enforcement program.
12. PREVIOUS USE UNDER SECTION 18: If an emergency exemption has previously been granted an interim report summarizing the results of previously issued exemption(s) must be included. List the year(s) in which previous exemption(s) were granted. Also list the requests that have been submitted to the department where the exemption was never granted.

Use Reporting Requirement: Federal regulations (40 CFR 166.32) require that a final report be submitted that summarizes the results of the pesticide use under an emergency exemption. WSDA requests submission of a use report by the applicant within 30 days of the report due date in the EPA granting document and/or at least 80 days before the first use date of the next request. The timely delivery of this report to WSDA is the responsibility of the person, organization, or commodity group that submitted the Section 18 application. Future requests will not be submitted to the EPA until a use report from Washington is received. The report must include (1) total quantity of pesticide used (2) the rate per acre or other measure, and (3) Total number of acres treated. The final report should discuss the effectiveness of the pesticide in dealing with the emergency condition, any adverse effects resulting from the section 18 use, and any other information requested by EPA.
13. PROGRESS TOWARD REGISTRATION: Include a discussion of the progress being made toward registration of the proposed use. A summary of deficiencies and data gaps and the registrant’s timetable for rectifying the deficiencies must also be included in the discussion.

If a complete application for federal registration of the proposed use, which has been under an emergency exemption for any three previous years, has not been submitted, the EPA will assume reasonable progress toward registration has not been made. This standard applies to uses which have been requested for any three previous years, regardless of whether the requests were granted or denied. Uses supported by IR-4 are judged against a 5-year standard.

B. INFORMATION REQUIRED FOR A SPECIFIC EXEMPTION

1. **PEST(S) TO BE CONTROLLED:** Include the scientific and common name of the pest or pest complex for which use of the pesticide is sought.
2. **EVENTS WHICH BROUGHT ABOUT THE EMERGENCY CONDITIONS:** Include a **DETAILED** discussion of all the events which brought about the emergency (weather conditions, severe pest pressure, resistance development, pesticide cancellations, etc.). Claims of severe pest or disease pressure must be documented with data or written testimony of qualified experts. If the request is being made prior to the existence of an emergency condition, a detailed explanation of why such emergency condition is expected must be submitted. In addition a threshold level should be specified, above which an emergency condition would be deemed to exist. Examples of threshold levels include a specified number of pests per plant, some level of rainfall occurring within a specific timeframe, the presence of weeds at a given crop stage, or some percentage of crop defoliation due to a pest. Once a pest population or a situation progressed to this threshold level, use under the exemption would be allowed.

If resistance development, phytotoxicity, or similar claims are the basis for the emergency exemption, the applicant 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 loss is being claimed, studies comparing the proposed pesticide with existing registered alternatives must be provided.

3. **DISCUSSION OF THE ANTICIPATED RISKS TO THREATENED OR ENDANGERED (T/E) SPECIES, BENEFICIAL ORGANISMS, OR THE ENVIRONMENT THAT WOULD BE REMEDIED BY THE PROPOSED USE OF THE PESTICIDE:** If the emergency exemption is needed to address risks to a T/E species, beneficial organism or the environment, then provide information which demonstrates those risks and how using the pesticide will mitigate the risks.
4. **DISCUSSION OF ANTICIPATED SIGNIFICANT ECONOMIC LOSS:** If the emergency exemption is needed to address a significant economic loss, then discuss the anticipated SEL associated with the emergency condition and provide data and other information supporting the discussion. EPA considers that a significant economic loss (SEL) would result from the non-routine condition if the threshold for any of the following tiers is met (per 40 CFR 166.20):

Tier 1 - Yield Loss of at least 20%. Yield loss due to the non-routine condition must be estimated assuming the use of the best available alternative controls.

Supporting Data: Comparative efficacy or economic injury studies documenting percentage yield loss (or absolute loss and baseline yield) comparing yields without an emergency with those involving the best available control means (i.e., the registered alternative).

Tier 2 - Total Economic Loss of at least 20% of gross revenue. In addition to losses in gross revenues due to yield losses, total economic loss includes other impacts resulting from the non-routine condition, such as quality losses that cause reductions in price and losses owing to increased production costs. Total economic losses will be compared to baseline gross revenues, that is, gross revenues (price times yield) expected in the absence of the non-routine condition.

Supporting Data: Data for Tier 1, plus: Data involving baseline yield and price information from the USDA National Agricultural Statistics Service (http://www.nass.usda.gov/Statistics_by_State/Washington/index.asp) or other appropriate sources. Quality loss data documenting shift in grade or uses from marketing studies or surveys (e.g., shift in grade or price reduction) from economic injury studies; added production costs (e.g., sorting or repacking costs, additional pest control costs) from marketing studies and surveys, labor demand studies or crop budgets. Similar to Tier 1, the critical comparison involves revenue without an emergency situation versus projections for losses expected when using the best alternative control.

Tier 3 - Total Economic Loss of at least 50% of net operating revenues. Total economic losses, as defined in Tier 2, will be compared to baseline net operating revenues. Net operating revenues are defined as gross revenues less variable operating costs.

Supporting Data: Data for Tier 2, plus: Baseline variable production costs from enterprise budgets: purchased inputs such as pesticides and hired labor; fuel costs should be included. Other items that are relevant to short-term operating costs such as costs for seed, fertilizer, irrigation, labor, and typical pest management costs. However, longer term obligations such as machinery depreciation and costs or other overhead costs should not be included.

Emergency exemption decisions must be based on reliable data. Applicants should prepare packages that contain the best available information. 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;
- Quality (grades, etc): marketing studies and surveys

- Cost increases: market surveys, labor demand studies, crop budgets (e.g., from university extension programs)
- Operating costs: crop budgets.

It may be difficult to submit comprehensive data for certain fast-moving and emerging pest problems, or for very minor or new crops. If such data are not available, EPA may consider using qualitative information in making its decision. However, if an exemption is granted on the basis of qualitative data, EPA will require that substantiating data be generated during the first year of use, and submitted to support any repeat requests.

For any pest activity where EPA determines that the above criteria (Tiers 1-3) would not adequately describe the expected loss: substantial loss or impairment of capital assets, or a loss that would affect the long-term financial viability expected from the productive activity.

For example, an emergency exemption may be justified for a pest problem that adversely affects a perennial crop, but does not meet the SEL criteria for yield and/or revenue losses for a single year of production. An emergency exemption may also be justified for pest problems unrelated to agricultural production, such as for protection of structures, museum pieces, or park land.

Any non-economic or qualitative information which describes the benefits from using the pesticide will be taken into consideration by EPA.

IV. SECTION 18 LABEL GUIDANCE

1. WSDA REQUIREMENTS

The General Pesticide Rules (WAC 16-228-1400(2)) require that Section 18 labels for pesticides distributed under an emergency exemption must be approved by WSDA:

Any pesticide exempted from registration under the provisions of section 18 of FIFRA must be labeled as follows:

(a) Pesticides distributed under section 18 of FIFRA must be accompanied by a label approved by the department prior to distribution. All conditions set forth in the document granting the emergency exemption and all other requirements determined to be necessary by the department must be included on the label.

(b) In situations where a label cannot be developed and approved prior to the intended use period, the department may allow the use of the document granting the emergency exemption in lieu of labeling. Conditions set forth as part of the granting document, and any attached or associated documentation from the department shall be considered labeling for purposes of enforcement.

The Registration Specialist assigned to your request can give you specific guidance on what WSDA will require on the Section 18 label. In general, you will need to include the directions for use and all other restrictions and precautions specified under Section 4 of the request that WSDA submits to EPA. In addition, other restrictions and precautions may be required by either WSDA or EPA. Please be aware that the granting document issued by the EPA may not include all necessary label requirements.

2. WAIVER OF LIABILITY STATEMENT

Waiver of liability statements are used to limit product liability and are only applicable for crops grown on very limited acreage (e.g. some seed crops). EPA is opposed to enforcing limitations of user's rights, and will only allow certain waiver of liability language on Section 18 labels. Additional information on this issue is available on the EPA web site (<http://www.epa.gov/pesticides/regulating/labels/pdf/warranty.pdf>). The following is an example of waiver of liability language that is acceptable to EPA:

“(Registrant’s) Special Conditions and Disclaimer for use of (Product) on (Crop)”

“(Registrant) intends that this Section 18 label be distributed only by the (Grower Association) only to end users and/or growers who agree in writing to the terms and conditions required by the (Grower Association) including a waiver and release from all liability and indemnification by the user and/or grower of (Registrant), (Grower Association), and others for failure to perform and crop damage from the use of (Product) on (Crop). If such terms and conditions are unacceptable, return (Product) at once unopened.”

“This product when used on (Crop) may lead to crop injury, loss, or damage. (Registrant) recommends that the user and/or grower test this product in order to determine its suitability for such intended use. The (Grower Association) and (Registrant) make this product available to the user and/or grower solely to the extent the benefit and utility, in the sole opinion of the user and/or grower, outweigh the extent of potential injury associated with the use of this product. The decision to use or not to use this (Pesticide) must be made by each individual (Product) user and/or grower on the basis of possible crop injury from (Product), the severity of (Pest) infestation, the cost of alternative (Pest) controls, and other factors. (Registrant) intends that because of the risk of failure to perform or crop damage that all such use is at the user’s and/or grower’s risk, to the extent consistent with applicable law.”

“This Special Conditions and Disclaimer statement is required by (Registrant) and is not required or enforced by the USEPA or the WSDA.”

When a waiver of liability statement is included on the Section 18 label it must be placed on the last page. A sentence referring the user to the waiver of liability statement may be placed on the first page of the Section 18 label.

“Read and understand the (Registrant’s) Special Conditions and Disclaimer for use before using (Product) on (Crop).”

Waiver of liability certificates are not part of the Section 18 label. These certificates are agreements made between the Registrant and/or Grower Association and the users.

SAMPLE FORMAT FOR A SECTION 18 LABEL

~Federal / State Restricted Use Pesticide Statement~ (When Applicable)

EMERGENCY EXEMPTION USE DIRECTIONS
EPA FILE SYMBOL NUMBER xx-WA-xx

STATE: Washington

CHEMICAL: Active ingredient (Brand Name)

CROP / SITE: Crop / Site authorized

PEST: Pest authorized

EFFECTIVE: Effective Dates of exemption

USE RATE: Authorized Rate

RESTRICTIONS: (Some examples follow)

- Do not make more than x applications or apply more than x ounces of product (x lb. a.i.) per acre per year.
- The Pre-harvest Interval (PHI) is xx days.
- **Brand Name** may be applied by ground equipment only.
- Applications must be made in at least xx gallons of water per acre.
- Applications through any type of irrigation system (chemigation) are prohibited.

These directions for use must be in the possession of the user at the time of application.

All applicable directions, restrictions and precautions on the registered product label for Brand Name (EPA Registration Number xxx-xx) are to be followed.

Any adverse effects resulting from the use of Brand Name under this emergency exemption must be immediately reported to the Washington State Department of Agriculture.

Company Name (Registrant)
Address

Note: Section 18 labels for unregistered pesticides must contain all label elements required by EPA (such as precautionary statements, first aid, environmental hazards, worker protection, and storage and disposal). If multiple states are requesting the use, then the registrant should prepare a generic container label, and a separate state specific Section 18 label (including complete use directions) for each state that requests the use.

V. WSDA SECTION 18 APPLICATION CHECKLIST

DOES THE SECTION 18 REQUEST CONTAIN THE REQUIRED INFORMATION?

Applicants for new Section 18 requests, and repeat Section 18 requests not eligible for recertification, must submit the following information to WSDA:

General Information:

1. TYPE OF REQUEST: Specific Quarantine Public Health Crisis
2. Contact persons (technical and economic.)
3. Description of pesticide.
4. Description of proposed use.
5. Alternative methods of control.
6. Efficacy data – summarize data.
7. Residue data – summarize data, must support the proposed time-limited tolerance.
8. Risk information – summarize risks to human health and the environment, list proposed mitigation measures.
9. Acknowledgement of registrant.
10. Previous use under Section 18 (repeat requests only.)
11. Progress towards registration.

Information required for specific exemption, as appropriate:

1. Pest(s) to be controlled.
2. Events which brought about the emergency conditions.
3. Risks to T/E species, beneficial organisms, or environment that are mitigated.
4. Discussion of economic loss – Tier 1, 2, or 3 as appropriate.

Applicants for repeat Section 18 requests eligible for re-certification must submit a letter or email to WSDA certifying the following:

1. The emergency condition still exists.
2. The information is still accurate.
3. The conditions of use are identical.
4. Any conditions or limitations from previous exemptions are satisfied.

5. There are no new alternative control measures that are effective.

Re-certification requests cannot be submitted as regional requests.

IS THE SUPPORTING DOCUMENTATION COMPLETE (ALL SECTION 18 REQUESTS)?

The following items must be included with Section 18 requests (when applicable):

1. Letter of support from the registrant – all Section 18 requests.
2. Draft Section 18 label (1 copy) – all Section 18 requests.
3. Current federal label (1 copy) – all Section 18 requests.
4. Letter of support from a WSU researcher, extension specialist and/or other unaffiliated expert verifying the emergency condition – new Section 18 requests only.
5. Residue data (food or feed uses) – new Section 18 requests only, unless additional studies were conducted.
6. Efficacy data – new Section 18 requests only, unless additional studies were conducted.
7. Data on risks to human health and the environment – new Section 18 requests only, unless additional studies were conducted.
8. Aquatic risk assessment form (except for indoor and seed treatment uses) – new Section 18 requests only.
9. Use report - repeat Section 18 requests only. Also, be sure to include any data required by the EPA granting document (if applicable).

IS THE SECTION 18 LABEL FORMAT CONSISTENT WITH EPA AND WSDA REQUIREMENTS?

Refer to the Section 18 guidance document and WAC 16-228-1400(2):

1. All applicable requirements and conditions from the request (crop/site, use rate, restrictions, etc.) submitted by WSDA.
2. Any additional requirements and conditions from the EPA granting document (including the EPA file symbol number, first use date and expiration date.)
3. If the Section 18 label has a waiver of liability statement, it must be consistent with EPA and WSDA requirements.