



Washington
State Department of
Agriculture

HOW TO APPLY FOR A SECTION 18 EMERGENCY EXEMPTION FROM REGISTRATION IN WASHINGTON STATE

**REGISTRATION AND LICENSING SERVICES PROGRAM
PESTICIDE MANAGEMENT DIVISION**

AGR PUB 631-226 (R/04/17)

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Contact Information:

Submit applications for new Section 18 emergency exemptions to:

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Submit applications for repeat Section 18 emergency exemptions to the WSDA Pesticide Registration Specialist assigned to the request
(<http://agr.wa.gov/PestFert/Pesticides/ProductRegistration.aspx#RegContacts>).

Submission of documents by email (pdf format) is strongly encouraged.

If you have administrative questions regarding the submission of an application for a Section 18 emergency exemption, please contact the WSDA Pesticide Registration Help Desk at (360) 902-2025 or e-mail pestreg@agr.wa.gov.

I. WSDA SECTION 18 APPLICATION CHECKLIST

DOES THE SECTION 18 APPLICATION CONTAIN THE REQUIRED INFORMATION?

Applicants for new Section 18 emergency exemptions, and repeat Section 18 applications not eligible for re-certification, must submit the following information to WSDA:

General Information:

1. TYPE OF APPLICATION: Specific Public Health Quarantine
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 applications 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 applications 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 applications cannot be submitted as regional applications.

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

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

1. Letter of support from the registrant – all Section 18 applications.
2. Draft Section 18 label – all Section 18 applications.
3. Current federal label – all Section 18 applications.
4. Letter of support from a WSU researcher, extension specialist and/or other unaffiliated expert verifying the emergency condition – new Section 18 applications only.
5. Residue data (food or feed uses) – new Section 18 applications only, unless additional studies were conducted.
6. Efficacy data – new Section 18 applications only, unless additional studies were conducted.
7. Data on risks to human health and the environment – new Section 18 applications only, unless additional studies were conducted.
8. Aquatic risk assessment form for all uses reviewed by WSDA - NRAS – new Section 18 applications only.
9. Use report - repeat Section 18 applications 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 application (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.

II. INFORMATION TO SUBMIT TO WSDA

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

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:

A. GENERAL INFORMATION

1. TYPE OF EXEMPTION: Specific, Public Health, Quarantine.
2. CONTACT PERSONS: Identify one or more knowledgeable experts who can be contacted for comment on technical and economic aspects of the application. Include name, affiliation, address, telephone number, and e-mail address (if available).
3. DESCRIPTION OF PESTICIDE: Identify the active ingredient using the accepted 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 proposed 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 use period cannot be longer than one year for a specific or public health exemption, or three years for a quarantine exemption.
 - i. Earliest possible 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 application 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 application must include 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 proposed 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 application must 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 non-detectable, the application 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:** The Food Quality Protection Act (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 applications:

- **Groundwater:** 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:** Include information on residential uses of the chemical.
- **Mode of Action:** Include a discussion of whether there are other pesticides with the same mode of action as the active ingredient 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 can attempt to establish a time limited tolerance prior to harvest.
- **Worker Protection Standard (WPS):** Any applicable WPS requirements need to be addressed in the application and on proposed labeling.

b. **Environmental Issues:** Environmental hazards will be identified in Part 8 of the Section 18 application, and will be mitigated by statements as outlined in Part 4 of the application. 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 application.

- (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.
- (ii) Aquatic Organisms: The application 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 application that requires review by the WSDA Natural Resource Assessment Section (such as aquatic uses). We frequently use mathematical simulation models, such as GENEEC (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 proposed and adverse effects are predicted by GENEEC, 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.

- (iii) Plants: If T/E plants occur in a county where herbicide use is proposed, 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.

- (iv) Chemigation: A chemigation statement will be required for pesticides that will be applied through irrigation water. The chemigation 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 application does not require a chemigation statement (except a reference to the Section 3 label and WSDA chemigation rules). The chemigation statement must list the allowed types of irrigation systems, and it cannot allow chemigation through the following types of irrigation systems (unless specifically authorized in writing by a WSDA Chemigation Specialist): big gun, border, flood (basin), furrow, or traveler.

- (v) 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.
- (vi) Beneficial Insects: A pollinator protection statement (PPS) is required for insecticides, miticides and fungicides that are toxic to bees, when applied to a crop or site that is attractive to bees.
- For crops pollinated by honey bees, WSDA will generally require PPS based on the federal label unless additional restrictions are deemed necessary. Either repeat the PPS from the federal label (if the PPS is fairly brief), or include a statement referring the user to the PPS on the federal label (if the PPS is lengthy). In addition, please include any use limitations to protect bees that are relevant to the crop or site (e.g., the federal label prohibits use during bloom).
 - For crops (e.g., alfalfa grown for seed) pollinated by other species of bees (e.g., alkali bees and alfalfa leafcutting bees), WSDA may require alternative PPS to address any specific risk to other species of bees that is not adequately addressed by the federal label. Please contact an entomologist (e.g., WSU, OSU, Univ. of Idaho, and USDA-Logan, Utah) that conducts research on the toxicity of pesticides to other species of bees to determine if the federal PPS is adequate to protect other species of bees. At present, the WSU entomologist that conducts research on alfalfa grown for seed is Dr. Doug Walsh.
 - Refer to Appendix A for information regarding bee pollination of crops grown in Washington State. The appendix has links to several university publications or databases that might be useful in determining whether alternative PPS is needed, an EPA web site on protecting pollinators, and a USDA publication regarding the attractiveness of agricultural crops to bees.

9. COORDINATION WITH OTHER AGENCIES (Note - WSDA will include this language in the application to EPA): *The US Fish & Wildlife Service, the Yakama Nation, and the Washington State Departments of Ecology, Health and Fish & Wildlife have received copies of this application. Any comments received will be forwarded to the US EPA.*

10. ACKNOWLEDGEMENT OF REGISTRANT: The application 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 application to EPA): *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 include the applications that were submitted to WSDA when the exemption was not approved.

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 application. 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 applications 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 applied for during any three previous years, regardless of whether the applications 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 REMEDIATED 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** (refer to Appendix B for examples of the Tiered Approach): 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 (https://www.nass.usda.gov/Statistics_by_State/Washington/) 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 and 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 applications.

Other Types of Expected Losses. 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.

Applications for Public Health or Quarantine Exemptions Require Different Information Concerning the Nature of the Emergency (refer to 40 CFR 166.20).

III. 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 review your application 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 application 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 (<https://www.epa.gov/sites/production/files/2016-09/documents/warranty.pdf>).

EXAMPLE OF SECTION 18 LABEL FORMAT:

Federal / State Restricted Use Pesticide Statement (If 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 applying for 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 applies for the use.

IV. BACKGROUND INFORMATION

Emergency Pest Problems and the Section 18 Application 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 well-established program for processing applications for 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 to apply for a Section 18 emergency exemption. This guidance has been published to assist you in applying to WSDA for an emergency exemption.

When to Consider Applying for an Emergency Exemption

An emergency exemption from registration may be considered for situations in which an emergency condition exists. For a Specific Exemption, 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 will cause significant economic loss (SEL); or a significant risk to endangered species, threatened species, beneficial organisms, or the environment. The other types of emergency exemptions are Public Health, Quarantine, and Crisis.

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

- Application for a repeat Section 18: Submit to WSDA at least 80 days prior to the earliest use.
- Application 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 EPA review, the better chance of obtaining emergency use by the time it is needed.

Regional Applications vs. Washington Only Applications

Under certain circumstances it may be expedient for state lead agencies in multiple states to submit a Section 18 application to the EPA as a regional application, 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 application. It is important that commodity groups seeking to submit a regional application contact WSDA before they begin working with the other state lead agencies. All states participating in a regional Section 18 application need to receive a copy of the application and the supporting documentation.

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

The word “crisis” and the word “emergency” may seem quite similar, but in FIFRA terminology, a Crisis Exemption is one of the four types of emergency exemptions that can be applied for 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 application. 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 applications to WSDA. It is one thing to ask for a Crisis Exemption if EPA has exceeded their allotted review time, it is quite another to ask for a Crisis Exemption because the application was not submitted to WSDA in a timely fashion. Asking WSDA for a Crisis Exemption because of tardiness in submitting the Section 18 application is an unacceptable use of the Crisis provision.

V. JUSTIFYING THE EMERGENCY

Urgent and Non-Routine

In order to apply for a Section 18, the 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 applications). 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 provided for 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 exacerbated by extreme weather conditions, both factors should be documented. If pest resistance is not discussed on the original application, 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 applications for multiple pesticides 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 pesticides. Therefore, when submitting an application that includes multiple pesticides it is necessary to thoroughly explain the justification.

Essentially, the justification must be that one pesticide alone is not sufficient to control the pest problem, but the reasons for this must be clearly 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 Puyallup can provide a list of currently registered insecticides, herbicides, fungicides, rodenticides, etc., for most crops and pests in the Pacific Northwest. Applicants for Section 18's are strongly encouraged to utilize PICOL to account for all possible registered alternatives to the proposed use. Failure to utilize PICOL information may cause unnecessary delays when WSDA reviews the Section 18 application. For further information contact Lenora Jones (WSU) at (253) 445-4517 or refer to the WSU web site (<http://cru66.cahe.wsu.edu/LabelTolerance.html>).

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 products 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.

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

Re-certification of Repeat Specific Exemptions

EPA allows submission of an abbreviated application for repeat specific exemptions, when EPA determines that a repeat Section 18 application 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 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 application 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 Section 18 applications cannot be submitted as regional applications.

Although EPA expects to accept a valid re-certification application as sufficient basis for the applicant 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 includes a change in any of the use parameters (e.g., rate, method or number of applications, number of acres, 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 complete (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 criteria for an emergency exemption. Usually 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. 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 criteria for an 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, but these situations do not meet the urgent and non-routine criteria of a Section 18 emergency exemption.

Appendix A - Bee Pollination of Crops Grown in Washington State

In 2013, the value of bee pollinated crops in Washington State was approx. \$3 billion.

Bees are commercially managed for the pollination of a variety of crops in the state of Washington, including tree fruits (e.g. apple, apricot, cherry, nectarine, peach, pear, plum, prune), berries (e.g. blackberry, blueberry, cranberry, currant, raspberry, strawberry), cucurbits (e.g. cucumber, squash, watermelon), and seed crops (e.g. alfalfa, cabbage, carrot, clover, mustard, onion, radish). Bees also pollinate a variety of fruit and vegetable plants in home gardens, as well as native plants.

The honey bee is the most widely used pollinator, although several other species of bees also pollinate crops. These include the alfalfa leafcutting bee, alkali bee, bumble bee (several species) and orchard mason bee.

Berry:

- **Blackberry:** Blooming crop is pollinated by honey bees. Blooming broadleaf weeds may also be a concern.
- **Blueberry:** Blooming crop is pollinated by honey bees. Blooming broadleaf weeds may also be a concern.
- **Cranberry:** Blooming crop is pollinated by bumble bees and honey bees. Blooming broadleaf weeds may also be a concern.
- **Currant:** Blooming crop is pollinated by honey bees. Blooming broadleaf weeds may also be a concern.
- **Raspberry:** Blooming crop is pollinated by honey bees. Blooming broadleaf weeds may also be a concern.
- **Strawberry:** Blooming crop is attractive to bees, some varieties may benefit from pollination by honey bees.

Cereal grain:

- **Barley:** Wind pollinated crop, not attractive to bees.
- **Buckwheat:** Blooming crop is attractive to honey bees.
- **Corn, field:** Wind pollinated crop, pollen-shedding corn can be attractive to honey bees, based on bee kill incidents investigated by WSDA.
- **Oat:** Wind pollinated crop, not attractive to bees.
- **Triticale:** Wind pollinated crop, not attractive to bees.
- **Wheat:** Wind pollinated crop, not attractive to bees.

Hay/silage:

- **Alfalfa hay:** Blooming alfalfa is highly attractive to bees.
- **Clover hay:** Blooming clover is highly attractive to bees.
- **Grass hay (includes Timothy hay):** Wind pollinated crop, not attractive to bees.
- **Mixed timothy/alfalfa hay or timothy/clover hay:** Blooming crop is attractive to bumble bees (clover) and honey bees (alfalfa and clover).

Herb:

- **Dill grown for oil:** Blooming crop can be attractive to honey bees.
- **Hops:** Crop not attractive to bees. Native bees (esp. Halictidae) have been observed visiting drip puddled water in hop yards surveyed by WSU.

- ***Marijuana (Cannabis spp. as defined in RCW 69.50.101)***: Crop not attractive to bees.
- ***Mint (Peppermint, Spearmint)***: Blooming crop is highly attractive to honey bees, based on bee kill incidents investigated by WSDA.

Nursery and Ornamental:

- ***Flower bulb (Daffodil, Tulip)***: Crop not attractive to bees.
- ***Holly***: Blooming crop is attractive to honey bees, based on bee kill incidents investigated by WSDA.
- ***Lavender***: Blooming crop is attractive to bees.
- ***Rhododendron***: Blooming crop is highly attractive to bumble bees.
- ***Turfgrass***: Crop not attractive to bees.

Oilseed:

- ***Canola***: Blooming crop is highly attractive to bees, based on bee kill incidents investigated by WSDA. Some varieties require pollination by bees (primarily honey bees).
- ***Industrial hemp (Cannabis spp. as defined in RCW 15.120.005)***: Wind pollinated crop, can be attractive to honey bees and bumble bees, based on research in Canada.
- ***Sunflower***: Blooming crop is pollinated by honey bees.

Orchard and Vineyard:

- ***Apple***: Blooming crop is pollinated by honey bees, some growers may also use orchard mason bees. Blooming broadleaf weeds may also be a concern.
- ***Apricot***: Blooming crop is pollinated by honey bees, some growers may also use orchard mason bees. Blooming broadleaf weeds may also be a concern.
- ***Cherry (sweet or tart)***: Blooming crop is pollinated by honey bees, some growers may also use orchard mason bees. Blooming broadleaf weeds may also be a concern.
- ***Filbert (Hazelnut)***: Wind pollinated crop, can be attractive to honey bees.
- ***Grape (wine or juice)***: Self-pollinated crop, not attractive to bees. Blooming broadleaf weeds may be a concern.
- ***Nectarine***: Blooming crop is pollinated by honey bees, some growers may also use orchard mason bees. Blooming broadleaf weeds may also be a concern.
- ***Peach***: Blooming crop is pollinated by honey bees, some growers may also use orchard mason bees. Blooming broadleaf weeds may also be a concern.
- ***Pear***: Blooming crop is pollinated by honey bees, some growers may also use orchard mason bees. Blooming broadleaf weeds may also be a concern.
- ***Plum***: Blooming crop is pollinated by honey bees, some growers may also use orchard mason bees. Blooming broadleaf weeds may also be a concern.

Seed crop:

- ***Alfalfa grown for seed***: Blooming crop is pollinated by alkali bees and alfalfa leafcutting bees.
- ***Asparagus grown for seed***: Crop can be attractive to honey bees during fern stage.
- ***Beet grown for seed***: Wind pollinated crop, not attractive to bees.
- ***Cabbage grown for seed***: Blooming crop is pollinated by honey bees.
- ***Carrot grown for seed***: Blooming crop is pollinated by honey bees.
- ***Clover grown for seed***: Blooming crop is pollinated by bumble bees and honey bees.

- **Grass grown for seed:** Wind pollinated crop, not attractive to bees.
- **Mustard grown for seed:** Blooming crop is pollinated by honey bees.
- **Onion grown for seed:** Blooming crop is pollinated by honey bees.
- **Potato grown for seed:** Crop not attractive to bees.
- **Radish grown for seed:** Blooming crop is pollinated by honey bees.
- **Spinach grown for seed:** Wind pollinated crop, not attractive to bees.

Tree (commercial):

- **Christmas tree:** Conifers not attractive to bees, unless conifer aphids are producing honeydew. Blooming broadleaf weeds may be a concern.
- **Cottonwood / Poplar plantation:** Trees may be visited by honey bees as a source of propolis. Blooming broadleaf weeds may also be a concern.
- **Forest site:** Conifers not attractive to bees, unless conifer aphids are producing honeydew. Blooming broadleaf plants may be a concern, esp. in clearcuts.

Vegetable:

- **Asparagus:** Crop can be attractive to honey bees during fern stage.
- **Bean (green or dry):** Blooming *Lima beans* are attractive to honey bees. Other species of beans are self-pollinated and are not attractive to bees.
- **Beet:** Crop not attractive to bees.
- **Cabbage:** Crop not attractive to bees.
- **Carrot:** Crop not attractive to bees.
- **Chickpea (Garbanzo bean):** Self-pollinated crop, not attractive to bees.
- **Cucumber:** Blooming crop is pollinated by honey bees.
- **Corn, sweet:** Wind pollinated crop, pollen-shedding corn can be attractive to honey bees, based on bee kill incidents investigated by WSDA.
- **Garlic:** Crop not attractive to bees.
- **Lentils:** Self-pollinated crop, not attractive to bees.
- **Onion:** Crop not attractive to bees.
- **Pea (green or dry):** Blooming *Austrian winter peas* are attractive to honey bees. Other species of peas are self-pollinated and are not attractive to bees.
- **Pepper:** Generally self-pollinated, bumble bees and honey bees are used to pollinate some varieties.
- **Potato:** Crop not attractive to bees. Drift onto adjacent alfalfa grown for seed can be a concern, based on bee kill incidents investigated by WSDA.
- **Radish:** Crop not attractive to bees.
- **Rhubarb:** Crop not attractive to bees.
- **Spinach:** Crop not attractive to bees.
- **Squash:** Blooming crop is pollinated by honey bees.
- **Tomato:** Pollination by bees not generally required (self-pollinated), unless grown in a greenhouse. Greenhouse tomatoes are pollinated by bumble bees.

Other crops/sites:

- **Aquatic site:** Site not attractive to bees, unless site is infested with purple loosestrife or other bee attractive emergent plant / weed species.
- **Mushroom:** Crop not attractive to bees.

- **Potato breeding:** Some male-fertile potato varieties have been shown to benefit from pollination by *Bombus terricola* (a species of bumble bee), presumably when potatoes are being grown for breeding in a greenhouse. (Note - *B. terricola* is native to the northeastern US and eastern Canada.)
- **Shellfish bed (e.g. clam, oyster):** Crop not attractive to bees.
- **Watermelon:** Blooming crop is pollinated by honey bees.

Selected References

Crop Protection Guide for Tree Fruits in Washington, EB0419. Washington State University Extension. (www.tfrec.wsu.edu/pages/cpg/Home)

How to Reduce Bee Poisoning from Pesticides, PNW 591. L. Hooven, R. Sagili and E. Johansen. 2013. Oregon State University. (catalog.extension.oregonstate.edu/pnw591)

UC IPM / Bee Precaution Pesticide Ratings. University of California. (www2.ipm.ucanr.edu/bee precaution/)

USEPA - Protecting Bees and Other Pollinators from Pesticides. (www.epa.gov/pollinator-protection)

USDA - Attractiveness of Agricultural Crops to Pollinating Bees for Collection of Nectar and/or Pollen. (http://www.ree.usda.gov/ree/news/Attractiveness_of_Agriculture_crops_to_pollinating_bees_Report-FINAL.pdf)

Appendix B -

Examples of Tiered Approach to Significant Economic Loss

Example 1. Crop with Yield Loss (Wheat in the Pacific Northwest)

Scenario. The emergency situation is that resistance has developed to an herbicide. Competition from weeds for water and nutrients may reduce crop yields. There is a registered herbicide, but it has limited efficacy.

Tier 1 Analysis. What is the yield loss?

The most appropriate comparison would be to compare yields before and after the development of resistance. However, this may be difficult because resistance develops over time and there may be other changes in production that would make comparison across many years difficult or inaccurate. In this case, the requested chemical may be used as a proxy for the non-emergency situation. Therefore, the applicant submits data from product performance studies, comparing the requested chemical to the registered alternative. Two studies are submitted. The most important elements are shown in Tables 1A and 1B.

Table 1A shows the results of a trial that compares the requested herbicide to the registered alternative, which is applied at different times. The trial is a randomized block design that allows statistical comparisons. Note that the measure of weed control is not necessarily aligned with measures of crop injury or yield. (There appears to be an error in the reporting of crop injury associated with the check, or no treatment, block.)

Table 1A. Comparative efficacy study, Trial 1.

Treatment	Rate (lb a.i./acre)	% Crop Injury	% Control	Yield (bu/acre)
Requested Chemical	0.42	11.3 c	100.0 a	130.6 a
Registered Alternative	0.011	15.0 bc	52.5 c	102.5 b
Registered Alternative	0.011	20.0 ab	85.3 b	118.2 a
Registered Alternative	0.011	25.0 a	52.5 c	83.4 c
Check	0.0	0.0 d	0.0 d	35.2 d

Notes: Registered alternative applied at different times.

Different letters within a column indicate statistically different means.

The second trial, shown in Table 1B, compares results for different rates of application. No statistically significant differences are noted in this trial.

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Table 1B. Comparative efficacy study, Trial 2.

Treatment	Rate (lb a.i./acre)	% Control 25 May	% Control 21 April	% Control 21 May	Yield (bu/acre)
Requested Chemical	0.3333	80.0	71.3	62.5	33.7
Requested Chemical	0.4175	82.5	73.8	40.0	33.5
Registered Alternative	0.0110	57.5	57.5	22.5	24.8
Registered Alternative	0.0132	55.0	56.3	40.0	26.0
Check	0.0	0.0	0.0	0.0	9.4

To calculate a percentage yield loss, we would take the difference between the treatment representing the non-emergency situation (Y_0), which in this case is the requested chemical, and compare that to the emergency situation (Y_E), which is the registered alternative. The percentage loss in yield is $(Y_0 - Y_E)/Y_0$. In Trial 1, we see yield losses of 9.5%, 21.5%, and 36.1%. In Trial 2, we see yield losses of 22.4% and 26.0%, when we compare the registered alternative to the lower of the two treatments with the requested chemical.

These results indicate that the typical yield loss will be over 20%, probably around 22-25%. This exceeds the yield-loss threshold for Tier 1 and imply that a significant economic loss would occur due to the emergency. No further information, on baseline yield, price or variable operating cost, needs to be submitted.

Note that in small test plots, the measured yield in bu/acre is quite different from a baseline yield you would obtain on-farm and see in agricultural statistics. For comparative efficacy or economic injury studies, we are interested in the relative impact of the emergency.

Example 2. Crop with Yield Loss (Cauliflower in California)

Scenario. The emergency situation is that an insecticide has been withdrawn from the market. There is no registered alternative for use against the main target pest. Feeding damage will result in yield losses, but there is no other source of loss.

Tier 1 Analysis. Product performance studies, like those shown in Example 1, are submitted. They compare infested plots to plots treated with the old pesticide, and show that the pest inflicts, on average, a 15% yield loss (%YL). A 15% yield loss does not meet the Tier 1 criterion for SEL. Therefore, no determination can be made at this tier.

Tier 2 Analysis. Typically, at this stage, the applicant would submit baseline yield and price information, which may come from agricultural statistics. Baseline yield (Y_0) and price (P_0) for California cauliflower is 16,200 lb/acre and \$3.10/cwt, based on a 5-year (2000-2004) average from USDA NASS agricultural statistics (Vegetables, Annual Summary, various years). Given average yield and price, gross revenue without the emergency would be about \$5,022/acre (GR_0).

Note that this is the data that had been required under the old method. However, it is not the only way the baseline could be established. If the problem were more localized, county-level statistics might be more appropriate. If the crop is mainly grown under contract, a market survey might be used to establish the price growers would receive this year, instead of an average over past years.

In this case, there are no sources of loss beyond yield. Therefore, loss as a percent of gross revenue is also 15%.

$$\frac{\text{Revenue Loss}}{\text{Gross Revenue}} \equiv \frac{P_0 \times (\%YL \times Y_0)}{P_0 \times Y_0} \equiv \%YL$$

This does not meet the Tier 2 criterion for SEL. No determination can be made at this tier.

Tier 3 Analysis. In addition to the yield loss data, baseline yield, and baseline price, the applicant will need to provide operating costs. Table 1 presents this data and the results of the analysis.

Operating costs are from the University of California Cooperative Extension service and represent Imperial County for 2004 (see <http://www.agecon.ucdavis.edu/>). Table 2 presents a summary of important categories. Baseline operating costs are around \$4,719/acre, which means net operating revenue is about \$303/acre.

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Table 2. Emergency Exemption, Tier 3 Analysis, California Cauliflower.

	Baseline	Emergency	Change	% Change
Yield (lb/acre)	16,200	13,770	-2,400	-15.0%
Price (\$/lb)	0.310	0.310	0	0.0%
Gross Revenue (\$/acre)	5,022	4,269	-753	-15.0%
Costs (\$/acre)				
Insecticides	140	120	-20	-14.3%
Other Operating Costs	1,057	1,057	0	0.0%
Harvest	3,522	2,993	-528	-15.0%
Total Operating Costs (\$/acre)	4,719	4,170	-548	-11.6%
Net Operating Revenue (\$/acre)	303	98	-205	-67.6%

Shaded cells indicate critical information on the emergency for this analysis.

With the emergency, an average of 15% decrease in yield is expected. This allows us to calculate yields and gross revenue under the emergency: 13,770 lb/acre worth \$4,269. This analysis considers changes in production cost, which in this scenario are favorable to the grower. The loss of an insecticide results in a savings of \$20/acre, as there is no alternative to control the pest. Further, the crop budget indicates that harvest costs depend on yield. Costs are reported to be \$5.00 per 23-lb carton. (More realistically, harvest costs may include a fixed charge, plus costs dependent on yield.) Therefore, a 15% reduction in yields also reduces harvest costs by 15%. Total operating costs with the emergency are \$4,170/acre, meaning net operating revenue is only \$98/acre.

Net operating revenue would decline about \$205/acre, or 67.6%, under the emergency. This exceeds the threshold (*i.e.*, meets the criterion) for SEL at Tier 3.

Example 3. Crop with Quality Loss (Cherry in Washington)

Scenario. The emergency situation is that resistance is developing to a fungicide within an area of Washington. There is no effective alternative. The pathogen does not result in yield losses, but many cherries cannot be sold in the fresh market and must be sold for processing, which brings a lower price.

Tier 1 Analysis. There is no yield loss, therefore the situation does not meet the Tier 1 criterion for SEL.

Tier 2 Analysis. The emergency has resulted in a shift in the amount of production from fresh to processed market. Because the situation has been developing over time, the applicant presents baseline information from 1998-2001, from USDA NASS statistics (Noncitrus Fruits and Nuts, various years), to calculate a 4-year average for yields and distribution between the fresh and processed market. At that time, yield was about 4.2 tons/acre and approximately 75% of Washington cherries went to the fresh market (*i.e.*, 3.15 tons/acre sold as fresh and 1.05 tons/acre sold for processing). Fresh cherry prices are currently (average over 2001-2003) about \$1,715/ton while the price for processed cherries is about \$535/ton (USDA NASS, Noncitrus Fruits and Nuts, various years). This implies gross revenue of about \$5,964/acre ($\$1,715 \times 3.15 + \535×1.05).

To inform the emergency situation, the state surveys packing houses in the affected counties. The results show that the fresh cherries make up only 50% of production. The rest is now sold for processing. Due to the emergency, only 2.1 tons make fresh grade, a decrease of 33.3%. Prices for the grades are unchanged. Under the emergency, gross revenue is about \$4,725/acre ($\$1,715 \times 2.1 + \535×2.1).

Table 3 compares the baseline and emergency scenarios. Gross revenue declines by over \$1,200/acre or 20.8% due to the emergency. This meets the criterion for SEL at Tier 2.

No data on operating costs would have to be submitted.

Table 3. Emergency Exemption, Tier 2 Analysis, Washington Cherry.

	Baseline	Emergency	Change	% Change
Yield (ton/acre)	4.20	4.20	0.00	0.0%
Fresh (% of yield)	75%	50%		
(ton/acre)	3.15	2.10	-1.05	-33.3%
Processed (% of yield)	25%	50%		
(ton/acre)	1.05	2.10	1.05	100.0%
Price, Fresh (\$/ton)	1,715	1,715	0	0.0%
Price, Processed (\$/ton)	535	535	0	0.0%
Gross Revenue (\$/acre)	5,964	4,725	-1,239	-20.8%

Shaded cells indicate critical information on the emergency for this analysis.

Example 4. Crop with Cost Increase (Alfalfa in Idaho)

Scenario. The emergency situation is an unusually large outbreak of a pest that typically does not cause economic injury. A registered alternative is available, but it provides only fair control and would have to be applied twice. With two applications, however, no damage is anticipated.

Tier 1 Analysis. Comparative product efficacy studies show that two applications of the registered pesticide provide sufficient control to avoid injury. Since there is no yield loss, the situation does not meet the Tier 1 criterion for SEL.

Tier 2 Analysis. The emergency has resulted in an increase in the cost of production. Baseline yield and price may be obtained from agricultural statistics. According to USDA NASS statistics (Crop Production 2004 Summary), the three-year average for alfalfa-hay mixtures is 3.9 tons dry matter/acre. The three-year average is appropriate because of moderate drought conditions over this period are expected to continue this year. Currently, USDA market news (<http://www.ams.usda.gov/LSMNPubs/HayW.htm>) reports alfalfa hay prices in Idaho of about \$115/ton for premium quality. The summer price is more appropriate, however, and was around \$95/ton last year. Baseline gross revenue is therefore about \$370/acre.

Increased production costs arise because growers must pay for two applications of a chemical they typically would not use. According to a survey of pesticide applicators, the chemical costs about \$10.50/acre, including labor for the application, so the total increase in production costs is about \$21/acre.

A \$21/acre increase in costs represents 5.7% of gross revenue (Table 4A). This does not meet the Tier 2 criterion for SEL.

Table 4A. Emergency Exemption, Tier 2 Analysis, Idaho Alfalfa.

	Baseline	Emergency	Change	% Change
Yield (ton/acre)	3.9	3.9	0	0.0%
Price (\$/ton)	95.00	95.00	0	0.0%
Gross Revenue (\$/acre)	371	371	0	0.0%
Additional Costs (\$/acre)				
Insecticide	0	21	-21	
% change (compared to gross revenue)				-5.7%

Shaded cells indicate critical information on the emergency for this analysis.

Tier 3 Analysis. In addition to baseline information for Tier 2, the applicant supplies cost of production data, in this case from the University of Idaho Cooperative Extension program. The cost of production, summarized in Table 4B, is based on the 2003 estimates for southwestern Idaho (<http://www.ag.uidaho.edu/aers/PDF/Crops/EBB2-AH-03.pdf>). Total operating costs are just over \$200/acre, implying net operating revenues of about \$167/acre.

The increase in cost is as estimated in the Tier 2 analysis, \$21/acre. While this represents a near doubling of insecticide costs, the \$21/acre loss is only 12.6% of net operating revenue. This does not meet the Tier 3 threshold for SEL. This would not be considered an emergency.

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Table 4B. Emergency Exemption, Tier 3 Analysis, Idaho Alfalfa.

	Baseline	Emergency	Change	% Change
Yield (ton/acre)	3.9	3.9	0	0.0%
Price (\$/ton)	95.00	95.00	0	0.0%
Gross Revenue (\$/acre)	371	371	0	0.0%
Costs (\$/acre)				
Insecticides	22	43	21	95.5%
Other Operating Costs	122	122	0	0.0%
Harvest	60	60	0	0.0%
Total Operating Costs (\$/acre)	204	225	21	10.3%
Net Operating Revenue (\$/acre)	167	146	-21	-12.6%

Shaded cells indicate critical information on the emergency for this analysis.

Example 5. Post-Harvest Losses (Pear in Oregon)

Scenario. The emergency situation is a fungal pathogen that attacks stored fruit. The registered control is failing as resistance develops and there is not another registered pesticide to control it. Cultural controls are likewise ineffective.

Stored fruit is sold in the fresh market, which receives a higher price than the processed market. To reduce storage losses, more fruit could be sold immediately, but it would probably have to be sold in the processing market. Prices would probably fall regardless of which end market the fruit was sold and there would still be some loss in the stored fruit. In addition to the direct loss, disease-damaged fruit may result in severe price penalties or rejection of shipments. However, packing houses can examine the fruit, discard those damaged, and repack for shipment.

The most likely result is that the amount of marketable fresh fruit is reduced and the grower incurs additional marketing (labor) costs, but price effects can be avoided.

Tier 1 Analysis. There is no yield loss in terms of harvested quantities. However, there are losses in storage. For this analysis, baseline information is needed on yield, distribution between end markets and typical storage losses. Agricultural statistics (NASS, Noncitrus Fruits and Nuts, various years) are used to establish baseline yield of 12.9 tons/acre. About one-third, 4.4 tons/acre, are processed and the rest, 8.5 tons/acre are sold in the fresh market. The fresh market includes fruit kept in cold storage and a survey of packing houses, conducted by the applicant, indicates that almost 95% of the fresh market produce is actually kept in cold storage for as much as 10 months. Typical storage losses are about 2% of the stored commodity (according to the survey), which implies post harvest losses of around 0.2 ton/acre. Utilized production is therefore about 12.7 tons/acre (USDA NASS often reports utilized production as well).

The survey of packing houses also indicates that the new pathogen is causing storage losses to increase to about 10% of the stored commodity. While this is a four-fold increase in storage losses, it represents only about 5% of utilized yield. This does not meet the Tier 1 criterion for SEL. Table 5A displays this information.

Table 5A. Emergency Exemption, Tier 1 Analysis, Oregon Pears.

	Baseline	Emergency	Change	% Change
Yield (ton/acre)	12.9	12.9	0.0	0.0%
Processed	4.4	4.4		
Fresh	8.5	8.5		
Stored	8.0	8.0		
Storage loss	0.2	0.8	0.6	400.0%
Utilized Yield (ton/acre)	12.7	12.1	-0.6	5.0%

Shaded cells indicate critical information on the emergency for this analysis.

Tier 2 Analysis. The emergency has two consequences to consider in calculating expected losses. One, the loss of production (yield) is in the higher-valued fresh produce, which implies an additional revenue impact. Two, additional marketing costs are incurred when boxes must be sorted and repacked.

Therefore, the baseline calculation of gross revenue should distinguish between the fresh and processed market. Again, USDA NASS statistics can be used to determine the appropriate prices: about \$170/ton for processed and \$470/ton for fresh, which is a weighted average of prices for the

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whole year. Baseline gross revenue, given utilized production, is calculated to be about \$4,670/acre ($\$170 \times 4.4 + \470×8.3).

Under the emergency, less produce is sold in the fresh market. Therefore, gross revenue with the emergency is calculated to be about \$4,370/acre ($\$170 \times 4.4 + \470×7.9), or about \$300 less than baseline.

To determine additional marketing costs, the survey of packing houses is again used to support the application. The survey finds that initial packing costs about \$4.00/44-lb box for labor, material, and storage fees. Repacking prior to shipping costs \$2.75/box for labor and material. The fungus progresses during the year but is somewhat controlled by the cold storage. Packing houses expect to have to repack about 15% of the utilizable stored commodity, about 2,400 lb or 55 boxes ($8.0 \text{ ton} \times 15\% \div 44 \text{ lb}$). At \$2.75/box, the additional cost is about \$150/acre.

Total losses are around \$450/acre, which is about 9.7% of baseline gross revenue. This does not meet the Tier 2 criterion for SEL. Table 5B displays this information.

Table 5B. Emergency Exemption, Tier 2 Analysis, Oregon Pear.

	Baseline	Emergency	Change	% Change
Utilized Yield (ton/acre)	12.7	12.1	-0.6	-5.0%
Processed	4.4	4.4		
Fresh	8.3	7.2	-0.6	-7.5%
Price, Processed (\$/ton)	170.00	170.00		
Price, Fresh (\$/ton)	470.00	470.00		
Gross Revenue (\$/acre)	4,670.00	4,370.00	-300	-6.4%
Repacking Costs (\$/acre)			150	
Total Losses (% change compared to gross revenue)			-450	-9.7%

Shaded cells indicate critical information on the emergency for this analysis.

Tier 3 Analysis. In addition to information for Tier 2, the applicant supplies cost of production data in the form of an enterprise budget from the Oregon State University Extension Service (http://oregonstate.edu/Dept/EconInfo/ent_budget/PDF/EM8679.pdf). This information is summarized in Table 5C. The enterprise budget does not include marketing costs, which appears to be an oversight. The applicant should explain this sort of discrepancy. The budget does include harvest costs of \$12.80/bin, where a bin weighs 1,050 lb. Total baseline operating costs are about \$3,855/acre, leaving the grower net operating revenues of \$817/acre, assuming both harvest and marketing costs are incurred.

Total losses in gross revenue and increased marketing costs are as calculated in Tier 2, \$450/acre. This represents 55.2% of net operating revenue. This meets the Tier 3 criterion for SEL.

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Table 5C. Emergency Exemption, Tier 3 Analysis, Oregon Pear.

	Baseline	Emergency	Change	% Change
Utilized Yield (ton/acre)	12.7	12.1	-0.6	-5.0%
Processed	4.4	4.4		
Fresh	8.3	7.2	0	-7.5%
Price, Processed (\$/ton)	170.00	170.00		
Price, Fresh (\$/ton)	470.00	470.00		
Gross Revenue (\$/acre)	4,670.00	4,370.00	-300	-6.4%
Production Costs (\$/acre)	1,990.00	1,990.00		
Harvest Costs (\$/acre)	315.00	315.00		
Marketing Costs (\$/acre)	1,550.00	1,700.00	150	9.7%
Total Operating Costs (\$/acre)	3,855.00	4,005.00	150	3.9%
Net Operating Revenue (\$/acre)	815.00	365.00	-450	-55.2%

Shaded cells indicate critical information on the emergency for this analysis.