



Oregon
Department
of Agriculture

Guidelines for Pesticide Emergency Exemptions (Section 18 of FIFRA)

February 2001

CONTACT:

**David L. Priebe
Section 18 Coordinator
Pesticides Division
Oregon Department of Agriculture
635 Capitol Street NE
Salem, OR 97301-2532**

Phone: (503) 986-4656 or (503) 986-4635

FAX: (503) 986-4735

E-Mail: dpriebe@oda.state.or.us

Oregon Department of Agriculture
Pesticides Division

Guidelines for Preparing Applications
for
EMERGENCY EXEMPTIONS (SECTION 18 of FIFRA)

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EMERGENCY EXEMPTIONS (FIFRA SECTION 18) - ODA GUIDELINES

February 2001

“The Administrator [of EPA] may, at the Administrator’s discretion, exempt any Federal or State agency from any provision of this Act if the Administrator determines that emergency conditions exist which require such exemption. The Administrator, in determining whether or not such emergency conditions exist, shall consult with the Secretary of Agriculture and Governor of any State concerned if they request such determination.” Section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, August 3, 1996.

INTRODUCTION

Section 18 of FIFRA authorizes the U. S. Environmental Protection Agency (EPA) to allow States to use a pesticide for an unregistered use for a limited time if EPA determines that emergency conditions exist. Emergency pesticide uses authorized by EPA under Section 18 are commonly referred to as “Section 18s” or “emergency exemptions.”

The Oregon Department of Agriculture (ODA), as the lead pesticide regulatory agency for the State of Oregon, is the state agency authorized by EPA to request Section 18 exemptions for emergency pesticide uses in Oregon. However, ODA relies on entities who are familiar with the emergency pest situations at the local level to compile and provide to ODA the information necessary for the formal application that is submitted to EPA.

Specific Exemptions. There are four types of emergency exemptions that may be authorized by EPA under FIFRA Section 18: Specific exemptions, quarantine exemptions, public health exemptions, and crisis exemptions. Historically, the vast majority of Section 18s granted by EPA have been specific exemptions that authorize use of pesticides to control emergency pest situations in agricultural crops. Specific exemptions are the focus of this document.

These guidelines have been developed to assist persons who intend to submit Section 18 specific exemption requests on behalf of growers, processors, commodity organizations, or their representatives, in providing complete and accurate information to ODA.

PART I. THE EMERGENCY CONDITION REQUIREMENT

The first step in determining whether to apply for a Section 18 exemption involves an assessment of the pest situation to determine whether it qualifies as an emergency condition, as defined by EPA. The application for a Section 18 emergency exemption must provide information, data, and discussion to adequately demonstrate to EPA the existence of an emergency condition.

For the purpose of emergency exemptions under FIFRA Section 18, EPA defines the term “emergency condition” as:

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

- (1) No effective pesticides are available that are registered for use to control the pest under the conditions of the emergency; and
- (2) No economically or environmentally feasible practices which provide adequate control are available; and
- (3) The situation (a) involves a new pest, (b) will cause significant economic loss to the affected crop, or (c) presents significant risks to human health, endangered or threatened species, beneficial organisms, or the environment.

Key elements of the emergency condition definition are as follows.

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

In EPA’s review of a Section 18 request to evaluate the expectation that significant economic losses will occur, only those losses caused by the emergency condition are relevant. Losses due to obvious mismanagement or losses due to an agent other than the target pest problem are not considered in EPA’s assessment of significant economic loss. Exemptions are not granted for the purpose of increasing yield, maximizing profits, or offsetting losses resulting from some other cause (foreign competition, for example).

EPA requires that a Section 18 application include five (5) years of yield, price, production cost, and revenue data, in order to conduct an economic analysis of the emergency situation. These five-year data provide a baseline, or “normal range of profitability,” against which the expected profits under the conditions of the emergency are compared. If estimated profits are substantially below the normal range, the expected loss is considered significant. More information about significant economic loss and EPA’s economic analysis for emergency

exemptions is provided in Part IV, in the Section on “Discussion of Economic Loss” (see pages 17-20).

PART II. ADDITIONAL REQUIREMENTS FOR EXEMPTIONS

This section provides information on factors other than the emergency condition requirement that should be considered in determining whether to apply for a Section 18 exemption.

A. General Requirements for the Requested Pesticide

EPA conducts thorough reviews of the requested pesticide to confirm that it will be effective in controlling the emergency pest situation, without presenting unreasonable risks to human health or the environment. If a pesticide is being requested for the first time, ODA should be contacted well in advance in order to verify with EPA that the pesticide to be requested does not have special problems that would make it ineligible for the emergency use. The following general rules may be helpful.

- ◇ Registered Pesticides: Pesticides that have new registrations since 1997 have undergone risk assessments under strict criteria imposed by the Food Quality Protection Act of 1996 (FQPA); usually, but not always, these will be good candidates. Pesticides that were initially registered before August 1996 but with no new registrations under FQPA criteria will require additional time for review, and data must be available to meet FQPA requirements.
- ◇ Canceled Pesticides: EPA is very reluctant to grant exemptions for canceled pesticides, especially if voluntarily canceled due to potential for adverse effects on the environment. However, they may be considered: If reasonable progress toward full registration of the proposed use has been made or is expected; or if an alternative to the canceled pesticide is expected to be available in the near future; or if the application includes assurances that a program will be carried out to find an acceptable alternative.
- ◇ New, Unregistered Pesticides: EPA closely scrutinizes requests for emergency use of new, unregistered pesticides, because of concerns that the Section 18 process may be used to circumvent the full (FIFRA Section 3) registration process. **Section 18s will not be granted to for the sole purpose of bringing a new product on the market** (i.e., in the absence of a qualifying emergency condition). A review of data required for an FQPA risk assessment usually must be completed before a new pesticide will be authorized for use under Section 18. Generally, this means that a full registration petition for this new chemical must already be submitted and under review at EPA.

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

It is essential that the manufacturer/registrant of the requested pesticide is supportive of proposed use. In the near term, especially for an unanticipated emergency for which an immediate solution is being sought, the manufacturer must be willing and able to provide adequate supplies of the requested pesticide, product stewardship, and appropriate labeling. In the longer term, the manufacturer must demonstrate a commitment to obtaining full registration of the use being requested under Section 18. “Reasonable progress toward

registration” is a specific EPA requirement for gaining approval for repeat emergency exemptions. The Section 18 application must include a letter of support from the product manufacturer and evidence that progress is being made toward full registration.

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

The FQPA amended the Federal Food, Drug, and Cosmetic Act (FFDCA) by adding the requirement that, when EPA grants an emergency exemption for use of a pesticide on a food or feed crop, it must establish a tolerance or exemption from the requirement for a tolerance for the pesticide chemical residue. Such tolerances must have an expiration date (i.e., be “time-limited”), which is related to the length of time required for the treated crop to clear channels of trade.

In order to establish the necessary time-limited tolerance, EPA must review specific data under FQPA safety criteria and make a finding that “there is a reasonable certainty that no harm will result from aggregate exposure to pesticide chemical residue.” These data must be provided to EPA in the Section 18 request, if they have not already been provided in connection with a pending registration petition.

D. **Special Situations Where Emergency Exemptions may NOT be Justified**

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

demonstrate the occurrence of an unanticipated spread of the pest situation to acreage outside of the original emergency area.

PART III. THE SECTION 18 APPLICATION PROCESS

A. Time Line

The Section 18 emergency exemption process requires TIME!!!! The various steps in the process, and their approximate time requirements, are described below.

1. Application submitted to ODA: Requests for Section 18 emergency exemptions are compiled and submitted to ODA by grower groups, processors, or their representatives, such as agricultural researchers, consultants, Cooperative Extension staff, commodity organizations, etc. The registrant or manufacturer of the product to be requested should be contacted early in the process to confirm their support of the request; they must provide some essential information and documentation for the application, but should not otherwise be actively involved in preparation or advocacy of the request.
 - ◇ *Ideally, ODA should receive a first-time request 100 to 120 days before the earliest anticipated use. Repeat requests should be submitted 80 to 90 days before the earliest use.*
2. Formal Request Submitted to EPA: ODA performs a preliminary review of the application for completeness and for a general confirmation that an emergency condition exists. If ODA does not receive all of the data and information required for a complete application, the request will not be submitted to EPA until deficiencies are addressed. A final use report for the previous exemption for the same use must be received by ODA before a repeat request is submitted to EPA.
 - ◇ *A formal request usually can be prepared by ODA and submitted to EPA within 5 to 10 working days after ODA receives a complete application package from industry.*
3. EPA Review and Approval/Denial: The ODA request is initially checked by EPA for completeness, then sent to various offices within EPA for biological and economic, environmental fate, and human health effects reviews. Finally, a decision letter is drafted, signed, and transmitted electronically to ODA. EPA considers its “normal” processing time for emergency exemption requests to require 50 days.
 - ◇ *As a general rule, ODA expects to receive a final decision from EPA within about 60 days for a repeat request and within about 90 days for a first-time request.*
4. Notifications/Labeling: Immediately after receiving the EPA decision letter, ODA transmits a copy to both the product registrant and the person who submitted the original application to ODA. If the exemption has been approved, other agencies are notified as appropriate, to coordinate compliance with any special conditions or restrictions imposed by EPA on the emergency use. The registrant is expected to prepare a Section 18 supplemental label in a timely manner and according to ODA specifications based on the request and the EPA approval.

- ◇ *Registrants are expected to make available at appropriate retail outlets supplies of properly labeled product within 5 to 10 working days of their being notified by ODA of an approved Section 18. If the product is registered for other uses in Oregon, supplies may be available almost immediately, but additional time may be required for new, unregistered products.*

B. Regional Requests

In situations where an emergency pest problem exists in several states in the same region of the country, it may be possible for those states to join together in a regional request for a Section 18 exemption. The State Departments of Agriculture in Idaho, Oregon, and Washington have submitted numerous regional Section 18 requests in recent years for pest problems that are common in our Pacific Northwest growing areas. EPA feedback has been positive concerning our regional requests, because it reduces the amount of paperwork they receive, and they are better able to conduct reviews for several states simultaneously.

If a person intending to submit a Section 18 application in Oregon has knowledge of the same emergency situation occurring in our neighboring state(s), ODA should be contacted to discuss the possibility of submitting a regional application. The decision to submit a regional request to EPA can only be made by the pesticide regulatory agencies in the states involved. If the decision is made at the state level to pursue a regional request, it is imperative that complete information for all participating states be submitted to each of the state pesticide agencies at the same time, so that our agencies can coordinate review and submittal to EPA in a timely manner.

A regional request contains all relevant information for all of the states involved, and is submitted to EPA by one of the states (i.e., the lead state) on behalf of itself and the other participating states. The other participating states, having reviewed all of the jointly submitted materials to ensure completeness and accuracy of their state-specific information, must formally “join” the regional request by sending a short letter to EPA. It is important to note that, although the submittal and reviews of the request are conducted on a regional basis, EPA issues its final decision on the exemption to each state individually.

C. Crisis Exemptions

The federal regulations for implementing FIFRA Section 18 include a provision for a state (or federal agency) to issue crisis exemptions in situations involving “unpredictable” emergency situations when there is insufficient time to request a specific (or quarantine or public health) exemption, or for EPA to review such a request. The state must consult with and obtain consent from EPA several days before a crisis exemption can be issued.

Crisis exemptions are an absolute last resort, to be invoked only in dire situations where the emergency condition is unpredictable, there is not enough time for EPA to conduct a full review of a specific exemption request, and there is no other way to mitigate the emergency. In rare cases, a crisis exemption can be authorized when the emergency was predicted and the specific exemption was requested far in advance, but the EPA has exceeded the time for which a completed review and approval would reasonably be expected.

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

D. Section 18 Supplemental Labeling

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

When an exemption is granted by EPA, ODA will immediately provide a copy of the EPA decision letter to the registrant, along with specific instructions for preparing a final label. Such labeling must specify: (1) the use directions, restrictions, and precautions presented in the ODA request letter to EPA, as approved or modified by EPA; (2) the time period during which the exemption is in effect; and (3) any additional instructions identified by EPA in its approval document. **The Section 18 labeling must be approved by ODA prior to use of the product under the emergency exemption, and the label must be in possession of the user at the time of application.**

E. Use Reports

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

Generally, the final use report must be submitted no later than six months after the expiration of the exemption. As with the exemption request itself, the use report is submitted to EPA by the Oregon Department of Agriculture. Also like the exemption request, however, assembly of the required information and timely delivery to ODA is the responsibility of the person, organization, commodity group, etc., that submitted the Section 18 application to ODA.

Preparation of the use report requires a coordinated effort among growers, fieldmen, extension agents, chemical company representatives, and others involved with the use to accurately report the following information:

- Total acreage (or other unit) treated under the exemption;
- Range of application rates used and total quantity of the pesticide used, in terms of both formulated product and active ingredient;

- Discussion of the effectiveness of the pesticide used in dealing with the emergency condition, and estimated economic and crop yield benefits realized from the use as compared to untreated sites or sites treated with alternative methods/pesticides;
- Description of any unexpected adverse effects resulting from the emergency use; and
- Any other information requested by EPA in connection with or required as a condition of the granting of the Section 18.

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

PART IV. SPECIFIC INFORMATION REQUIRED FOR THE SECTION 18 APPLICATION

This section provides detailed descriptions of the information, data, and discussions that must be presented in the Section 18 application. These guidelines reflect information provided in EPA guidance documents published in June 1992, as well as the requirements in the Code of Federal Regulations, Title 40, Part 166 (i.e., 40 CFR 166), which contains the federal regulations for implementing provisions of FIFRA Section 18; and the more recent requirements imposed by the Food Quality Protection Act of 1996. The information contained in the Section 18 application submitted to ODA should be arranged in the same format as the outline presented below.

A. Summary of the General Information Required in 40 CFR 166.20(a).

1. Type of Exemption. Specific.

2. Contact Persons. Identify knowledgeable persons who are familiar with the following aspects of emergency situation:

- Technical/Scientific Aspects:** (persons familiar with the biology of the pest [e.g., insect, pathogen, weed] and its extent and effects in/on the crop; persons familiar with efficacy of the requested pesticide and/or the alternative cultural and chemical control methods that are no longer efficacious).
- Economic Aspects:** (persons familiar with economics of production of the affected crop and the crop yield/quality/revenue impacts of not controlling the emergency pest).
- Pesticide Aspects:** (knowledgeable representative(s) of the registrant/manufacturer of the requested pesticide, e.g., the product registration manager, state/federal registration specialist, and/or development scientist).

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

Name
Job title or Business Unit
Company name
Mailing address

City, State ZIP
Phone number
FAX number
E-mail address

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

- a. Active Ingredient: Identify the active ingredient (a.i.) using the official name accepted by the American National Standards Institute (ANSI) or International Organization for Standardization (ISO), or the most accurate common name.
- b. Trade Name and EPA Registration Number of the Product: (see **NOTE** below if the requested product is not EPA registered).
- c. Formulation: Identify both type (e.g., emulsifiable concentrate, wettable powder, etc.) and concentration (e.g., xx% a.i., equivalent to xx lb. a.i. per gallon).
- d. Registrant/Manufacturer: Identify the name of the registrant (manufacturer, if the product is not EPA registered). If this is not a domestic company, please also include the name of the company through which the product is distributed in the U.S.

Attach a copy of the federally registered label or specimen label (most recent revision).

NOTE: If the requested product is not EPA registered, the application should include a confidential statement of formula or reference to one already submitted to the EPA as part of previous or pending action for the active ingredient (give EPA File Symbol, EUP number, or SLN number), and complete labeling which will be used in connection with the proposed emergency use.

If the requested product is not EPA registered (or is EPA registered, but has no labeled use sites in Oregon and, thus, is not registered by the State of Oregon), then include a description of how unused product will be managed upon expiration of the exemption. For example, "Unused and unopened containers of the product must be returned to the retailer after the use season is completed."

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

- a. Sites to be Treated: Identify the crop to be treated and the specific locations within the state where that crop is affected by the emergency pest (thus, where the requested pesticide will be applied). List all of the counties where the emergency use is anticipated. Note any additional geographic (sub-county level) limitations to the proposed treatment area, e.g., proximity to water bodies, ecologically sensitive areas, residences, etc.
- b. Method of Application: Identify whether the product will be applied by ground, air, and/or chemigation (i.e., through irrigation equipment). If chemigation, specify the types of irrigation systems that can be used. Specify any other specialized or innovative equipment that will be used.

- c. Rate of Application: Identify the rate (or rate range) at which applications will be made, in terms of both formulated product and active ingredient per acre (or other unit). Include registrant specifications for dilution volumes.
- d. Maximum Number of Applications: Identify the maximum number of applications that may be made per acre (or other unit) under the emergency exemption.
- e. Total Acreage to be Treated: Identify the maximum number of acres, or other appropriate unit (e.g., tons of a stored commodity), that may be treated.
- f. Total Amount of Pesticide to be Used: Identify the total amount of the pesticide to be used under the exemption, in terms of both formulated product and active ingredient (i.e., maximum rate X maximum number of applications X maximum acreage).
- g. Use Season: Identify the time period for which the emergency use is requested. Both beginning and ending dates of the proposed use are required. Calendar dates are required, but if the treatment period is associated with specific growth stages of the crop, this should be described here. The time period may not exceed one year. If there are distinct, shorter time periods (within the overall use season) when applications are to be made, identify and describe.

NOTE: If the requested pesticide is not EPA registered, or is registered but not labeled for any use sites in Oregon (thus not registered in the state), additional lead time may be required for manufacture, labeling, and distribution to ensure availability by the identified use season. Such anticipated delays should be explained here.

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

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

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

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

Application Timing Restrictions: For example, if use of the proposed pesticide during a specific part of the proposed use season will be harmful to the target crop, neighboring crops, or beneficial organisms, the necessary restriction(s) should be listed.

Preharvest Interval: “A xx-day preharvest interval must be observed.”

Grazing/Feeding Restrictions: In general, grazing of treated fields, or feeding of residues or by-products from fields treated under an emergency exemption will not be allowed. There are exceptions if the appropriate residue tolerances have been established.

Application Site Restrictions: If there are restrictions against applying near other crops, residential areas, or ecologically sensitive areas, these should be described here.

Generally, ODA or EPA will prescribe such restrictions, or they are available on the federally registered label.

Attach a proposed Section 18 supplemental label for this use.

- 5. Alternate Methods of Control.** The Section 18 application must identify all alternative methods that are available to control the emergency pest situation, and must provide an explanation of why each is not effective or cannot feasibly be used. Both cultural practices and currently registered pesticides should be addressed.
- a. Registered Alternative Pesticides. Identify all pesticides currently registered for use on this crop to control the pest. For each pesticide, provide an explanation of why it is not effective in controlling the emergency. This explanation must be supported by field data that demonstrate the ineffectiveness of the registered pesticides. If such data are not available, provide written statements by qualified agricultural experts, university/extension personnel, or other persons qualified to verify the lack of efficacy.

If there are specific restrictions or recommendations against using a registered pesticide, such recommendations must be explained. If the product is not available in sufficient quantities to adequately address the emergency, or if specialized equipment required for applying a registered alternative pesticide is not available, such limitations must be explained.
 - b. Alternative Cultural Control Practices. Identify all alternative control practices for the emergency pest situation, other than registered pesticides. Such practices may include rotating crops, using tolerant/resistant crop varieties, adjusting planting densities, using hand labor operations, etc. Provide a detailed explanation of why alternative practices, if available, either would not provide adequate control or would not be economically or environmentally feasible. For each available control measure not considered to be cost effective, appropriate economic cost/benefit information should be supplied to support the claim.

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

6. **Efficacy of the Proposed Use.** The application must contain data, a discussion of field trials, or other evidence (e.g., experimental testing, small plot trials, laboratory trials, etc.) to demonstrate that the proposed pesticide will be effective in alleviating the emergency pest situation. The data and supporting information must demonstrate efficacy under conditions (e.g., climate, soil resources) found in Oregon, or equivalent. Especially helpful are data from trials that include both the proposed pesticide and the registered alternatives. If there are any phytotoxicity concerns associated with the proposed use, those should be explained here.

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

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

Attach copies of residue data, if not already on file with EPA. Provide documentation from IR-4 or the registrant that references data already on file with EPA.

8. **Risk Information.** The application must include a detailed discussion of the potential risks posed by the proposed emergency use.
- ◇ A general description of typical application sites for the proposed emergency use in relation or proximity to aquatic systems, endangered or threatened species habitats, residences, sensitive crops, etc., should be provided, along with supporting data or information, if available.
 - ◇ Potential risks to human health and various elements of the environment surrounding typical application sites for the proposed pesticide (e.g., beneficial organisms, fish and aquatic species, endangered and threatened species and their habitats) should be described. Examples of good sources for information on which to base this discussion include (these types of materials are good supporting documentation to include with the Section 18 application):
 - Material Safety Data Sheets (MSDS) and technical data bulletins for the pesticide, available from the manufacturer, or try the internet site at <http://www.ilpi.com/msds/index.html#Pesticides> which provides links to manufacturer web sites, or broader sites such as the Crop Data Management Systems internet site for label and MSDS information: <http://www.cdms.net/manuf/manuf.asp>
 - EPA Pesticide Fact Sheets, some of which may be found at the internet site: <http://www.epa.gov/opprd001/factsheets/>

- Pesticide Information Profiles from the Extension Toxicology Network (EXTOXNET): <http://ace.orst.edu/info/extoxnet/>

Risks to pesticide handlers and agricultural workers (addressed by Worker Protection Standard provisions) are usually addressed on the federally registered label. For new, unregistered pesticides, worker and handler risks and protective measures should be addressed in the Section 18 application, and will be required on the Section 18 labeling.

Specific proposals to mitigate any identified risks (e.g., protective clothing, setback or buffer zone requirements, application timing restrictions, soil type restrictions) should be listed. Statements in the Environmental Hazards section of a federal label also should be listed. ODA will require specific risk mitigation measures and Environmental Hazards statements to be included on the Section 18 supplemental label.

- ◇ During its reviews of the Section 18 request, EPA may consult with other federal agencies concerning possible risks to federally listed endangered and threatened species that may occur in areas near proposed use sites. ODA periodically receives updated lists of such species from the U.S. Fish and Wildlife Service, and will enclose lists of these species for all counties in which the emergency use is proposed with the Section 18 request when it is submitted to EPA.
- ◇ FQPA Aggregate Exposure Assessment for Emergency Exemption Pesticide Uses on Food and Feed Crops: The Food Quality Protection Act of 1996 (FQPA) requires that EPA evaluate aggregate exposure to the pesticide chemical residue from multiple routes (food, water, environment) when reviewing Section 18 exemption requests. The aggregate exposure assessment is used to determine whether there is a “reasonable certainty that no harm will result” if the proposed use is allowed. This safety determination is necessary in order to establish the time-limited tolerance required for emergency exemptions under FQPA.

EPA requires that specific data and other information be included in the Section 18 request to evaluate potential exposures:

- from residential uses of the pesticide,
- from residues that may be transferred to drinking water supplies, and
- from other pesticides with the same mode of action as the active ingredient in the proposed pesticide.

It may be necessary to contact the registrant/manufacture of the pesticide to obtain these specific data (or sometimes IR-4, if the proposed use is being pursued as a minor use registration through IR-4). However, if a pesticide petition already has been submitted to EPA for registration of the proposed chemical/use site, the data and other information necessary for the aggregate exposure assessment are already on file at EPA, and the petition should be cited. If the registration petition is still under development, the registrant should be contacted to prepare an “FQPA Supplemental Information Document” for inclusion in the Section 18 application. For repeat Section 18 requests for food/feed uses, the necessary aggregate exposure assessment will have already been conducted and the results published in the *Federal Register* in the final

rule in which the time-limited tolerance was established; in this case, the Federal Register notice should be cited and a copy provided in the Section 18 application.

Attach copies of documents that provide information to assess risks associated with the proposed use; examples include MSDS, technical data bulletins, toxicological and environmental fate data, FQPA Supplemental Information Documents, *Federal Register* notices of residue tolerance establishment, draft pesticide petitions....

9. **Coordination with Other Agencies.** ODA may need to coordinate with other state or federal agencies on issues of human health and/or environmental concern posed by the requested use. For this item, use the following standard statement: “The Oregon Fish and Wildlife Office of the U.S. Fish and Wildlife Service will receive a copy of this request. Any comments received will be forwarded to the U.S. EPA.” (If ODA deems it appropriate, additional agencies will be notified and cited in the final Section 18 request submitted to EPA.)
10. **Notification/Support of Registrant.** The Section 18 application must include a letter from the registrant or manufacturer of the requested pesticide, indicating that the company has been notified of this request and will support the emergency use of its product, by providing an adequate product supply, product stewardship, and supplemental labeling. The letter should also include information on the progress toward full registration of the proposed use (see Item 13, below).

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

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

The application submitted to ODA from the industry representative(s) should contain a standard set of statements equivalent to the following: “The Oregon Department of Agriculture (ODA) has adequate authorities for enforcing provisions of Section 18 emergency exemptions. ODA will require the registrant (or manufacturer, if unregistered) of [the requested pesticide], XYZ Corporation, to prepare and make available to end users supplemental labeling that complies with ODA and EPA requirements for the emergency use, if approved. Applicators will be required to keep adequate records of application use and acreage. The [commodity group or processor], in cooperation with XYZ Corporation, will be required to provide to ODA a report summarizing results of the emergency use after the end of the use period.”

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

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

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

Attach documentation from the registrant or IR-4 that provides current information on the progress toward registration status.

B. Summary of the Economic Loss Information Required in 40 CFR 166.20(b).

- 1. Pest(s) to be Controlled.** Provide both the common name(s) and scientific name(s) of the pest(s) to be controlled by the proposed emergency pesticide use.
- 2. Discussion of the Emergency Condition.** The application must include a detailed discussion of all the events which brought about the emergency (e.g., unusual weather conditions, severe pest pressure, development of resistance to registered alternative pesticides, cancellation of registered pesticides, etc.).

Claims of severe pest or disease pressure must be documented with data or written testimony of qualified experts. A “threshold level for treatment” should be specified, above which the emergency condition would be deemed to exist and use under an exemption allowed. Examples of threshold levels include a specified number of insect pests per plant; weed densities (e.g., number of weeds per square yard) or presence of weeds at a given stage of the crop; some level of rainfall occurring within a specific time frame; or some percentage of crop defoliation due to a pest.

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

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

NOTE: A chronic or continually occurring problem is not considered by EPA to represent an urgent, non-routine situation. Also, a proposal based solely on using a pesticide (not registered for use on the subject crop) to improve yields and/or income because the proposed pesticide is significantly more effective or less expensive than any of the existing control

measures is not an acceptable basis for a Section 18 request for an ongoing pest problem which has not intensified in recent years.

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

- 3. Additional Benefits Information.** In those instances where EPA determines that a significant risk is posed by a proposed use, that Agency will conduct an in-depth benefits analysis. Certain economic impacts of not addressing the emergency condition with the proposed use will be considered in EPA's analysis, if a thorough discussion of those impacts is included in the application. EPA specifies the following types of economic impacts that it will consider:
- a. Impacts at the pesticide user level.
 - b. Measurable change in price and availability of the commodity to consumers.
 - c. Measurable reduction in sales and/or employment of organizations supplying the affected producers.
 - d. Measurable reduction in business volume and/or employment of organizations marketing the output of affected producers.
 - e. Measurable reduction in the economic base, including employment of communities affected by the supplier and marketing organizations.

Attach supporting documentation as appropriate and available.

- 4. Discussion of Economic Loss.** The application must include a discussion of anticipated economic losses associated with the emergency condition.

◇ Five-Year History

EPA requires five (5) years of yield and price data, cost of production data (either five years of production cost data, or a crop budget), and gross and net revenues calculated from those data, to conduct the economic analysis. Cost of production data for each year should include the costs of all pest control practices used on the affected crop, including both product and application costs for the pesticides that were used. These economic data must be for the most recent five years prior to the year for which the emergency use is requested.

EPA's economic analysis uses the five-year historical data to calculate the mean profit over that period, and to establish a "normal range in profitability" for the crop during that period. Then, expected profits for the upcoming year are calculated and compared to the normal range to determine whether significant economic loss is expected to occur. Therefore, if the five-year history includes data from abnormal years, either extremely favorable (ideal growing conditions) or unfavorable (drought, flooding/too wet), these data need to be clearly identified and explained. The application also should provide data and detailed discussion to support an alternate estimate of the normal range in profitability.

The data submitted should pertain specifically to the area within the state impacted by the emergency. Be cautious about submitting statewide data. Statewide data are generally

inadequate for demonstrating the nature and extent of a problem, unless the problem exists on the vast majority of the crop acreage within the state.

The following table is a recommended format for presenting the five-year history of economic data pertaining to production of the crop affected by the emergency. The table should be adequately footnoted to provide information on the source(s) of the data, explanations for data from abnormal years, etc.

Five-Year History

Year (most recent five years)	Average Yield (ton, lb.,bu. per acre)	Average Price (\$ per ton, lb., bu.)	Gross Revenue (\$/acre)	Cost of Production (\$/acre)	Net Revenue (\$/acre)
1996					
1997					
1998					
1999					
2000					
Average					

◇ Estimates for the Upcoming Year

In addition to the above data, estimates of the net and gross revenues with and without the proposed use must be submitted. The estimated revenues without the proposed use must be calculated based on the next best registered alternative pesticide or cultural practice being utilized. The revenue estimates should also be based on average expected yield reductions, not the maximum potential yield loss. If a reduction in quality is the nature of the emergency, provide information on the proportion of yield falling into each grade over the past five years and the effect of the emergency on quality of production (provide prices for each grade over the last five years).

Estimates for 2001

Current or upcoming year of production	Average Yield (ton, lb.,bu. per acre)	Average Price (\$ per ton, lb., bu.)	Gross Revenue (\$/acre)	Cost of Production (\$/acre)	Net Revenue (\$/acre)
With proposed pesticide					
Without proposed pesticide					

The table above is a recommended format for presenting the estimated economics of producing the crop affected by the emergency, with and without the requested pesticide.

The estimated economic data should be adequately defended in the Section 18 application narrative. For example, field or trial plot data should be available which provide the basis for the decrease in crop yield or quality reflected in the data. Based on such information, provide a discussion of the level (e.g., percentage) of control of the emergency pest that is expected to be achieved with use of the proposed pesticide compared to the control expected without the proposed pesticide, but use of the next best alternative registered pesticide or practice. If not footnoted in the table, the estimated percentage yield decline (without the proposed pesticide) should be clearly stated in the discussion. Also, information on costs of the proposed pesticide compared to the next best registered alternative(s) should be clearly explained, including application costs which may be different because of different method or number of applications. These cost differences should be reflected in the cost of production data in the table. Further, identify and explain the “source” of the base economic data (usually, the 5-year average data for yield, price, costs, revenues) upon which the loss estimates are made.

The per acre losses that are estimated in the table should be extrapolated to the entire acreage affected by the emergency, to provide an estimate of total losses that might occur for that commodity as a whole, if the emergency pesticide use is not available. In some cases, such total estimated losses can be put into perspective for EPA reviewers by including a five-year history of total acreage, production volume, and farm-gate value of the commodity.

For some emergency situations, denial of the requested exemption could result in growers significantly reducing their crop acreage to avoid economic loss. Such acreage reductions may not “fit” conveniently within a calculated estimate for revenues per acre with/without the proposed pesticide and, therefore, should be described in the narrative. Likewise, there may be rotational benefits to growing the crop that would not be realized with acreage reductions under an uncontrolled emergency situation; such benefits also should be described.

In evaluating the significance of an economic loss for productive activities, EPA will also consider whether the loss would affect the long-term financial viability expected for the activity. Such circumstances should be discussed in detail, where applicable. For example, an enterprise may face a situation where, due to circumstances beyond its control (e.g., bad weather), it must have a remarkably good upcoming crop year to remain financially viable. Even though profits, without an exemption, are expected to be within the historical range, this will not be sufficient to make up for the previous crop failures. The enterprise will only realize the above-average profits needed to assure its long-term financial viability if an emergency exemption is granted to control an emergency pest problem. In such a situation, an emergency exemption could be granted, even though profits without the exemption are expected to be within the historical range.

Data and other Supporting Documentation to be Submitted with the Section 18 Application

The following items should be enclosed in support of the Section 18 emergency exemption application submitted to ODA. These items should be cited in the appropriate sections of the body of the application as described in the foregoing sections of *PART IV* of this document.

- A copy of the most recent version of the federally registered label (specimen label), or the proposed container label if the pesticide is not EPA registered.
- Proposed Section 18 supplemental label.
- Copies of research reports showing lack of efficacy or resistance development for registered alternative pesticides. Documentation of ineffectiveness of alternative (non-pesticide) control practices, if available.
- Copies of data showing efficacy of the proposed pesticide compared to efficacy of registered alternative pesticides. Include phytotoxicity data if applicable.
- Copies of residue data/reports for the proposed pesticide/use site, including information on the use pattern under which data were generated, and proposed residue tolerances based upon the residue data, if the proposed use site is a food or feed crop (if not already on file at EPA).
- A copy of the most recent version of the Material Safety Data Sheet (MSDS) for the pesticide.
- Copies of other risk information for the pesticide (toxicity studies, Pesticide Fact Sheets, technical data bulletins, Pesticide Information Profiles, etc.).
- Copies of county lists of endangered and threatened species (will be added by ODA).
- Copies of information and data required for the FQPA aggregate exposure assessment/safety determination (e.g., the FQPA Supplemental Information Document, *Federal Register* notices of tolerance establishment for the pesticide, excerpts from draft pesticide petition, etc.)
- Copies of research reports, extension publications, written testimony of qualified experts, weather data, photographs, etc. documenting the extent and severity of the emergency pest situation.
- Copies of extension publications, enterprise budgets, or other data in support of the five-year history economic data.
- Copies of supporting documentation for the economic loss estimates.

NOTE: Please include with the Section 18 application package a separate page on which a complete listing of the enclosures/attachments is provided. This will assist the ODA and EPA reviewers in assessing completeness of the application.

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