

**EMERGENCY EXEMPTIONS UNDER SECTION 18 OF
THE FEDERAL INSECTICIDE FUNGICIDE AND RODENTICIDE ACT**

I. GUIDANCE FOR STATE AND FEDERAL AGENCIES



**REGISTRATION DIVISION
OFFICE OF PESTICIDE PROGRAMS**

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This guidance does not establish or affect legal rights or obligations. It does not establish a binding norm and it is not finally determinative of the issues addressed. Agency decisions in any particular case will be made applying the applicable law and regulations to the specific facts of that case. In any proceeding in which the guidance may be applied, the Agency will thoroughly consider the guidance's applicability to the facts, the underlying validity of the guidance, and whether changes should be made in the guidance based on submissions made by any person.

EXECUTIVE SUMMARY

In 1989, EPA formed an internal work group to discuss issues which had arisen from the Agency's experience with the revised section 18 emergency exemption regulations. The work group selected for discussion those issues which had proven to be problematic in administering the emergency exemption program. The goal of the work group was to clarify the Agency's position on these issues and communicate the Agency's position to the appropriate Federal and State lead agencies.

This document summarizes the Agency's positions and policies regarding those issues reviewed by the section 18 work group. It does not address every issue associated with emergency exemptions and is not intended to supplant the section 18 regulations at 40 CFR part 166. It is meant to clarify certain parts of the existing regulations and to serve as additional guidance to Federal and State agencies submitting section 18 emergency exemption requests.

The document is organized into several general discussion areas. The major points from each area are summarized below.

I. EVALUATION OF THE EMERGENCY SITUATION

A. Definition of "Emergency Condition"

- An "emergency condition" is defined in 40 CFR §166.3(d) as an urgent, non-routine situation that requires the use of a pesticide(s) and shall be deemed to exist when three conditions are met. EPA believes that an "emergency condition" exists **only** when the situation is urgent and non-routine **and** all three conditions are met; (1) no effective registered pesticides are available, (2) no feasible alternative control practices are available, and (3) the situation involves the introduction of a new pest or will present significant risks to human health or the environment or will cause significant economic loss.

B. Demonstration of an "Urgent, Non-routine situation"

- To be "urgent" and "non-routine" the situation must require immediate attention and be other than an ordinary one.
- 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. Other situations, such as those involving the loss of a registered pesticide, would likely continue until a new pesticide is registered. Emergency exemptions will not be disallowed just because the emergency situation has occurred in two or more consecutive years. The Agency will control the number of years a use is authorized under section 18 through careful monitoring of the progress that is being made toward registration.

- A situation need not be unpredictable to be “urgent and non-routine”. The Agency will entertain emergency exemption requests based on the expectation that, under certain specific conditions, an emergency will exist in the future.
 - Chronic or continually occurring pest problems are specifically excluded from the definition of an emergency condition.
- C. Demonstration that no registered pesticides or alternative practices which provide adequate control of the pest are available**
- For each pesticide registered to control the pest problem, the applicant must demonstrate that it is either not effective in the given situation or not available in adequate supplies. Claims regarding the efficacy of registered alternatives must be supported by data or testimony of qualified experts. Claims regarding the unavailability of a registered pesticide must be accompanied by a discussion of the attempts made to obtain adequate supplies.
 - The applicant must also identify the alternative practices (nonpesticidal means of control) available to control the pest problem and explain why they are not adequate or feasible to use.
- D. Demonstration of a Significant Economic Loss**
- A "significant economic loss" means 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 fixed assets. In defining an emergency condition as one that is expected to result in "significant economic losses, the Agency has in mind consequences 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 expected economic loss. 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 loss estimate. Exemptions may not be granted for the purpose of increasing yield or income to offset losses resulting from some other cause (foreign competition, for example).
 - The "normal range in profitability" refers to the range of profits for a productive activity over the past several years. Typically, the Agency requires 5 years of yield, price, and cost of production data to conduct an economic analysis of an emergency situation. In evaluating the significance of an anticipated economic loss, the Agency compares expected profits under the conditions of the emergency to the historical, "normal" range. If estimated profits are substantially below the normal range, the expected loss is considered significant.

- An emergency exemption may be granted in situations where a significant economic loss is not expected, but **only** in those situations where the expected loss would affect the long-term financial viability expected for the activity.

II. EMERGENCY EXEMPTION APPLICATIONS

A. Documentation of the Emergency

- 40 CFR §166.20 outlines the information required in an application for a specific, quarantine, or public health exemption. The Agency may discontinue the processing of any application which does not contain all of the required information until the missing information is submitted by the applicant.

Each application will be reviewed on its own merit. EPA will not use information from one state's application to evaluate another state's exemption request.

- Efficacy claims for the proposed pesticide, registered alternative pesticides, and alternative practices should be supported by data or other scientific information.
- In cases where significant economic loss is the basis of the request, the application should contain at least 5 years of historical economic information. The information should reflect the situation in the area of the state where the emergency pest problem exists. Statewide data should only be submitted if the problem exists on a statewide basis.

Estimated gross and net revenues for the site without the proposed pesticide should be based on the mean expected yield loss if growers use the next best practical means of control, rather than on worst case maximum yield reductions if no alternative control measure is used.

If the Agency's standard economic analysis is not appropriate to the applicant's situation, the applicant must explain why and provide an alternative analysis demonstrating that an emergency condition exists.

- The Agency's review of exemption applications is facilitated when the following information, not specifically required in the regulations, is submitted: 1) Dates application of the pesticide would begin and end, 2) specific location of sites to be treated within the state, and 3) a discussion of the current "registered" usage of the proposed pesticide within the state.

B. Expedited Review of Applications for Repeat Section 18s

- Repeat emergency exemption applications, to a certain extent, already receive an expedited review. The Agency is opposed to further expediting the review of repeat requests. EPA believes it would be more appropriate to investigate ways to improve or expedite the overall section 18 process.

C. Applications for Regional Section 18s

- The Agency has no previous experience with regional section 18 applications, but is willing to accept regional applications on a trial basis to evaluate their practicality.

III. EMERGENCY EXEMPTIONS FOR PEST RESISTANCE MANAGEMENT

- Emergency exemptions may only be authorized for resistance management in cases where documented pest resistance to the registered alternative(s) has already developed and is expected to result in significant economic losses.

IV. EMERGENCY EXEMPTIONS FOR TWO ACTIVE INGREDIENTS TO CONTROL THE SAME PEST ON THE SAME CROP

- The current section 18 regulations do not preclude the granting of exemptions for the use of more than one pesticide for the same emergency condition; however, such use under section 18 will be authorized only when necessary to provide adequate control of a pest or situation. Authorization of more than one chemical will not be made for competitive or marketing purposes.

V. EMERGENCY EXEMPTIONS FOR NEW CROPS

- It is the Agency's position that the section 18 process is not the appropriate mechanism for EPA to make pesticides available to control routine pest problems on new crops. Emergency exemptions for new crops may only be granted when the situation is urgent and non-routine, there are no effective alternative pesticides or practices available, and the situation will result in significant economic losses.
- Only those situations involving
 - 1) a pest not previously known to affect the crop, or
 - 2) an abnormal variation in the severity of a known pest problem would be considered non-routine by the Agency.
- Historical yield and economic data are not usually available for new crops. In lieu of these data, the Agency will examine research data to determine expected yield under normal growing conditions.

VI. EMERGENCY EXEMPTIONS FOR VOLUNTARILY CANCELED PESTICIDES

- The Agency is not inclined to grant exemptions for voluntarily canceled pesticides unless the applicant can demonstrate that reasonable progress toward registration has been made or is expected, or that an alternative to the canceled pesticide is expected to be available in the near future, or that a program will be carried out to find an alternative pesticide for use.
- The Agency does not endorse use of the section 18 process as a means to retain minor uses lost through the reregistration process. If, however, a pesticide registration for a minor crop is canceled due to reregistration and the criteria for an emergency condition as outlined in the section 18 regulations have been satisfied, the Agency may grant an emergency exemption.
- The Agency is not inclined to grant a section 18 exemption for a use that was voluntarily canceled under circumstances which suggest the likelihood of unreasonable adverse effects on the environment.

VII. EMERGENCY EXEMPTIONS FOR NEW CHEMICALS AND THE FIRST FOOD USE OF REGISTERED PESTICIDES

- The issuance of emergency exemption requests for new chemicals or the first food use of a registered pesticide depends heavily on the available scientific data base for the chemical being requested and the gravity of the emergency situation. The Agency weighs very heavily the progress that has been made toward registration in evaluating repeated emergency exemption requests for a new chemical or the first food use of a registered pesticide. The section 18 regulations prohibit utilization of the crisis provision for pesticides which contain a new chemical or the first food use of a registered pesticide.

VIII. EMERGENCY EXEMPTIONS FOR SAFER PESTICIDES

- EPA believes its regulations do not allow for the authorization of a section 18 exemption based solely upon 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. If the effective registered alternative is sufficiently dangerous that the Office of Pesticide Programs would prefer that growers use an unregistered pesticide, the statutory scheme normally contemplates cancellation or suspension of the registered alternative, rather than ignoring the registered alternative and granting a section 18 for an unregistered chemical.

IX. EMERGENCY EXEMPTIONS FOR EXPANDED ACREAGE

- The Agency will only grant repeat exemptions for use on expanded acreage when the pest emergency has spread to areas outside the original range. In particular, the Agency will not look favorably on repeat exemption requests 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 emergency exemption to control an anticipated pest problem.

X. REASONABLE PROGRESS TOWARD REGISTRATION

- The Agency is not inclined to grant repeated exemptions unless reasonable progress toward registration of the use has been made.
- If a complete application for registration of a use, which has been under a specific or public health exemption for any 3 previous years, has not been submitted, it shall be presumed that reasonable progress toward registration has not been made. The Agency will exercise its discretion in determining whether or not reasonable progress has been made on an IR-4 minor food use. Generally, IR-4 minor food uses will be judged against a 5-year standard, as opposed to the 3-year standard for all other uses.
- Once a complete application for registration has been submitted, the Agency evaluates progress toward registration on a case-by-case basis, taking into account a number of different factors, including:
 - 1) Compliance with the Agency's registration data requirements and guidelines
 - 2) The registrant's responsiveness to application deficiencies identified during Agency review
 - 3) New registration data requirements
 - 4) The registrant's compliance with reregistration requirements
- If registration has not occurred within 3 years of receipt of an application, the Agency will presume that reasonable progress toward registration has not occurred and will not be inclined to grant further emergency exemptions for the use, except when an "emergency condition" exists and Agency inaction (supporting data has not been reviewed or a final decision has not been made) is the cause of the delay.
- The section 18 application should contain a discussion of progress toward registration, including a summary of deficiencies and data gaps and the registrant's timetable for rectifying registration deficiencies.
- Letters notifying emergency exemption applicants of the Agency's decision will also discuss the registration status of the proposed use. When applicable, notification letters will also include a discussion of the reregistration status of the pesticide.

XI. INNOVATIVE APPROACHES TO REPEAT SECTION 18 PROBLEMS

- The Agency would like to identify pest problems that consistently result in emergency exemption requests and work with the states and affected growers to develop ways to address these problems using new and/or little known technologies. Authorization of repeat section 18 requests may be conditioned upon evidence that the State applicant is attempting to find an innovative alternative solution.

XII. CRISIS EXEMPTIONS

- The crisis provisions of FIFRA should be invoked only in dire situations where the emergency condition is unpredictable and there is no other way to mitigate the emergency.

It is the Agency's belief that situations in which there is insufficient time to file a request for a specific exemption far enough in advance to allow the Agency the normal 50-days of processing time should be rare. In most situations, by determining the magnitude of the outbreak that would constitute an emergency and submitting a request to the Agency incorporating this threshold level, the specific exemption can be requested far enough in advance to allow EPA an adequate opportunity to review the application without resorting to the crisis provisions.

- The State or Federal Agency issuing a crisis exemption must notify the Agency, when feasible, at least 36 hours in advance of utilization of the crisis provisions. In no case shall notice be given to the Agency later than 24 hours after the State or Federal agency's decision to avail itself of a crisis exemption.
- The Agency may revoke crisis exemptions or a State or Federal agency's authority to issue crisis exemptions when the agency is not complying the requirements of the crisis provisions.

INTRODUCTION

Section 18 of the Federal Insecticide Fungicide and Rodenticide Act (FIFRA) gives the Administrator of EPA the authority, at his discretion, to exempt any Federal or State agency from any provision of FIFRA if he determines that emergency conditions exist which require such exemption. Regulations to implement the exemption provision were promulgated in 1973. A 1982 Office of Pesticide Programs (OPP) review of the regulations and audit of the exemption program concluded that the regulations could be improved with some revisions. The House Subcommittee on Department Operations, Research, and Foreign Agriculture released a report on December 17, 1982, entitled "Regulatory Procedures and Public Health Issues in the EPA's Office of Pesticide Programs". This report expressed concern that States or industry may have been using section 18 authority to circumvent more stringent data and risk control requirements which apply to registration actions.

In response to the OPP audit and Congressional report, EPA decided to revise the section 18 regulations through a negotiated rulemaking process. Representatives from environmental and public interest groups, agricultural trade associations, State pesticide regulatory agencies, and other Federal agencies participated in the negotiations. The proposed rule revising the regulations was published in the **Federal Register** on April 8, 1985 (Vol. 50, No. 67, **FR**, April 8, 1985). The final rule was published January 15, 1986 (Vol 51, No. 10, **FR**, January 15, 1986).

In 1989, EPA formed an internal work group to discuss issues which had arisen from the Agency's experience with the revised regulations. The work group selected for discussion those issues which had proven to be problematic in administering the section 18 program. The goal of the work group was to clarify the Agency's position on these issues and communicate the Agency's position to the appropriate Federal and State lead agencies.

This document summarizes the Agency's positions and policies regarding those issues reviewed by the section 18 work group. It does not address every issue associated with emergency exemptions, and it is not intended to supplant the section 18 regulations at 40 CFR part 166. It is meant to clarify certain parts of the existing regulations and to serve as additional guidance to Federal and State agencies submitting section 18 emergency exemption requests.

The document is organized into the following general discussion areas:

- I. EVALUATION OF THE EMERGENCY SITUATION**
- II. EMERGENCY EXEMPTION APPLICATIONS**
- III. EMERGENCY EXEMPTIONS FOR PEST RESISTANCE MANAGEMENT**
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- V. EMERGENCY EXEMPTIONS FOR NEW CROPS**
- VI. EMERGENCY EXEMPTIONS FOR VOLUNTARILY CANCELED PESTICIDES**
- VII. EMERGENCY EXEMPTIONS FOR NEW CHEMICALS AND THE FIRST FOOD USE OF REGISTERED PESTICIDES**
- VIII. EMERGENCY EXEMPTIONS FOR SAFER PESTICIDES**
- IX. EMERGENCY EXEMPTIONS FOR EXPANDED ACREAGE**
- X. REASONABLE PROGRESS TOWARD REGISTRATION**
- XI. INNOVATIVE APPROACHES TO REPEAT SECTION 18 PROBLEMS**
- XII. CRISIS EXEMPTIONS**

I. EVALUATION OF THE EMERGENCY SITUATION

A. Definition of "Emergency Condition"

The first issue a State or Federal Agency should consider before requesting a section 18 emergency exemption is whether an "emergency condition" exists. The term "emergency condition", as defined in 40 CFR §166.3(d), means an urgent, non-routine situation that requires the use of a pesticide. It shall be deemed to exist when:

1. No effective pesticides are available under FIFRA that have labeled uses registered for control of the pest under the conditions of the emergency; **and**
2. No economically or environmentally feasible alternative practices which provide adequate control are available; **and**
3. The situation:
 - i. Involves the introduction or dissemination of a pest new to or not theretofore known to be widely prevalent or distributed within or throughout the United States and its territories; **or**
 - ii. Will present significant risks to human health; **or**
 - iii. Will present significant risks to threatened or endangered species, beneficial organisms, or the environment; **or**
 - iv. Will cause significant economic loss due to:
 - A. An outbreak or an expected outbreak of a pest; **or**
 - B. 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).

B. Demonstration of an "Urgent, Non-routine situation"

EPA interprets the regulations in 40 CFR 166.3(d) to require a finding that an urgent, non-routine situation exists distinct from the findings in 40 CFR 166.3(d)(1)(2) and (3).

To be "urgent" the situation must require immediate attention.

To be "non-routine" the situation must be one other than an ordinary one.

An urgent, non-routine situation is brought about by some change in the overall pest management environment for a particular pest problem, such as an abnormal fluctuation in pest population, an abnormal fluctuation in environmental conditions, loss of a registered pesticide(s), or documented loss of efficacy of a registered pesticide(s).

The nature of the urgent, non-routine situation determines, in part, how long it would be expected to endure. Certain situations would not be expected to occur year after year. Unusual weather, such as droughts and heavy rains, can result in pest outbreaks that become urgent, non-routine situations, when the registered pesticides no longer control the pest at economic levels generally obtained for the crop, or there are insufficient quantities of registered pesticides to deal with the pest outbreak. However, the return to normal weather patterns in the subsequent growing season would eliminate the urgent, non-routine situation.

Others situations could be expected to occur for two or more consecutive years. There are instances where a registered pesticide(s) loses its effectiveness due to resistance build-up or the registered pesticide(s) is lost, resulting in an urgent, non-routine situation. Once such a situation occurs, an emergency situation will likely continue to exist unless a new pesticide is registered prior to the next growing season. Although the emergency situation has occurred in two consecutive years and could continue until a new pesticide is registered, the emergency situation has not changed and may not be disallowed just because it has occurred in two or more consecutive years.

In fact, in promulgating the section 18 regulations, the Agency realized that there would be cases where an emergency condition could continue for two or more consecutive years. Thus, in order to provide relief for true emergencies and yet prevent the section 18 process from being used to circumvent the section 3 registration process, a provision was added to the regulations concerning the need for progress toward registration of a use under section 18. The Agency will control the number of years a use is authorized under section 18 through careful monitoring of the progress that is being made toward registration. Section X discusses in full the criteria the Agency will use in determining whether reasonable progress toward registration of a section 18 use has been made.

Since a critical issue in determining whether or not an emergency exists is determining whether or not the situation is non-routine, the applicant needs to provide the Agency with adequate scientific information to support the claim that a situation is non-routine, in that it is being caused by a new pest problem having recently developed, or a pest problem which occurs rarely or infrequently in the state, unusual weather conditions, or the current situation is abnormal for some other reason. The Agency will make a decision on whether or not a situation is urgent and non-routine on a case-by-case basis based on the information provided in the application.

For a situation to be "urgent and non-routine" does not mean that it must be unpredictable. In some circumstances an emergency can be predicted. An emergency exemption application can be submitted to the Agency for consideration prior to the actual

existence of an emergency condition based on the expectation that an emergency condition will exist in the future. The application must identify what conditions would have to be experienced in order for the emergency condition to develop. Authorization of the exemption would include a "threshold" or other level which would have to be met before applications of the pesticide could occur. Examples of threshold levels include a specified number of plant 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. It is appropriate for a State or Federal agency to submit an application for an emergency exemption in advance to authorize use of pesticide to deal with the predicted emergency when reasonable evidence indicates that a pest outbreak will occur.

The particular wording of the definition of "emergency condition" was developed following extensive discussions by the negotiating committee, comprised of representatives from states, industry, and environmental groups. As discussed in the preamble to the final rule (51 FR 1896), the negotiating committee decided to exclude chronic or continually occurring pest problems from the definition of an emergency. In promulgating the section 18 regulations, EPA supported the negotiating committee's decision to exclude chronic pest problems from the definition of an emergency. A chronic problem is one that is caused by an ongoing pest problem within the state or region, with pest intensity or environmental conditions within the levels of normal fluctuation. Although such problems may be significant to the growers, in that they occur every year and registered efficacious chemicals are not available to address the problem, they do not fit the Agency's criteria for an emergency condition. Similarly, the mere availability of a new pesticide to control an ongoing pest problem does not constitute an emergency unless it can be demonstrated that the pest problem has intensified in recent years.

C. Demonstration That No Registered Pesticides or Alternative Practices Which Provide Adequate Control of the Pest Are Available

When requesting an emergency exemption, the applicant is expected to identify the registered pesticides and alternative cultural practices available to control the pest problem and to provide a detailed explanation of why the available control strategies will not provide adequate control under the conditions of the emergency.

For each pesticide registered to control the pest problem, the applicant must demonstrate that it is either not effective in the given situation or not available in adequate supplies. If a registered pesticide is available but not recommended by the appropriate State officials, an explanation of why it is not recommended must be provided. If the applicant claims that an available registered pesticide is ineffective for the given situation, the claim must be supported by field data demonstrating its ineffectiveness. If such data are unavailable, testimony of qualified agricultural experts, extension personnel, university personnel or other persons similarly qualified in the field of pest control must be provided.

If a registered pesticide is not available, the applicant must explain the attempts that were made to obtain adequate supplies and the results of those attempts. If application equipment

required to use a registered pesticide is unavailable, the applicant must explain why and discuss the attempts that were made to acquire the necessary equipment.

The applicant must also identify the alternative practices available to control the pest problem and provide a detailed explanation of why the alternative practices, if any, are not adequate or not economically or environmentally feasible to use. The term "alternative practices" is meant to encompass any nonpesticidal means of control including, but not limited to, crop rotation, tillage, use of tolerant/resistant crop varieties, burning, hoeing, hand weeding and employment of good farm management practices.

The Agency acknowledges that unforeseen circumstances may preclude the use of a registered pesticide or alternative practice to avert an emergency condition. For example, an unexpected pest outbreak might occur after the application "window" for a registered pesticide has passed. However, the Agency expects registered pesticides and/or alternative practices, when feasible, to be employed in subsequent years and will not allow continued use of a pesticide under emergency exemptions in these situations.

D. Demonstration of a Significant Economic Loss

Most emergency exemptions are requested to avert a significant economic loss. The term "significant economic loss" means a substantial reduction in normally expected profitability in the area affected by the emergency, or; for types of activities where profits cannot be calculated, a substantial reduction in the value of public or private fixed assets.

EPA interprets the definition of an emergency condition in 40 CFR 166.3 to mean those situations which could not reasonably have been anticipated and addressed through the section 3 registration process and which will have dire consequences if the exemption is not granted. In defining an "emergency condition" as one which will result in a significant economic loss, the Agency has in mind consequences more serious than a failure to realize maximum profits in a particular growing season. It is the Agency's position that section 18 of FIFRA was not intended to help growers maximize yields or profits.

1. Cause of an Expected Loss

According to the regulations at 40 CFR §166.3(h), only losses caused by the emergency conditions are relevant in determining the expected economic loss. This issue of causation is a troublesome one in administering section 18.

The regulations clearly state that losses resulting from obvious mismanagement must be excluded from the loss estimate. However, the regulations do not address those situations in which business decisions falling short of mismanagement are, in part, responsible for the loss. In some instances, management decisions may be the principle cause of an anticipated loss and the unexpected pest problem a relatively insignificant contributing factor. The negotiated rule making committee was concerned that section 18

could become a means for growers to recover losses resulting from unsuccessful business decisions. The Agency, however, does not consider this a legitimate use of the section 18 provisions and will not be inclined to grant exemptions in these situations.

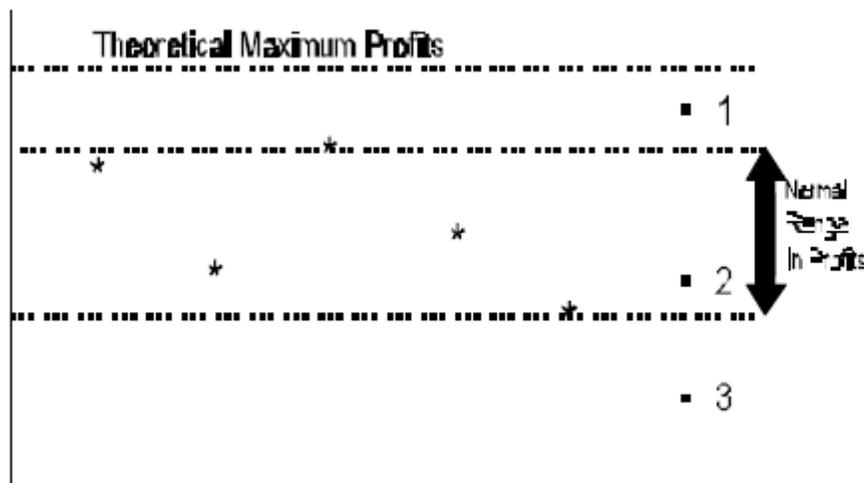
EPA interprets its regulations to provide for section 18 emergency exemptions only when use of the pesticide authorized by the exemption will address the cause(s) of the emergency. The Agency deems it inappropriate to grant an exemption for the use of a pesticide against a pest which is not the cause of the emergency in order to increase yields or income to offset losses caused by another agent. EPA believes this construction is implicit in its definition of "emergency condition" at 40 CFR 166.3(d) as "...an urgent, non-routine situation that requires the use of a pesticide(s)..." The most natural reading of this phrase is that the pesticide is required for use against the cause of the urgent, non-routine situation.

Public policy also dictates that the granted exemption be limited to situations in which the emergency is due to the target organism(s) of the pesticide whose use is being authorized. As noted in the preamble to EPA's final rule at 40 CFR Part 166, concern was expressed that the granting of emergency exemptions on the basis of "significant economic loss" would be similar to providing crop insurance through FIFRA (51 FED. REG. 1897, January 15, 1986). The Agency clearly did not intend for such exemptions to be the vehicle by which growers could recover losses due to causes other than the target organism(s) of the pesticide requested. Otherwise, the section 18 program has the potential for becoming a crop insurance program in situations which are due to causes (e.g. foreign competition) totally outside the scope of FIFRA.

2. Evaluating the Significance of an Economic Loss for Productive Activities

i) The Normal Range in Profitability

This graph depicts hypothetical grower profits over the past five years and three different profit scenarios for the current growing season:



The "normal range in profitability" refers to the range of profits for a productive activity over the past several years. Typically, the Agency looks at profitability over the past five years to determine the normal range. In the above hypothetical example, grower profits were highest three years ago and lowest last year. These two points on the graph would define the upper and lower bounds of the normal range in profitability for this hypothetical enterprise.

In evaluating the significance of an anticipated economic loss for a productive activity, the Agency estimates profits for the current year to determine whether they fall within the normal range in profitability. If they do (scenario 2 on the above graph), the expected loss is not considered by the Agency to be significant, since it would not exceed what would be expected as a result of normal fluctuation over a number of years. If expected profits fall below the normal range (scenario 3 on the above graph), the expected loss is considered significant, since it exceeds what would be expected as a result of normal fluctuation.

The Agency frequently receives applications requesting exemptions for the use of a "new" pesticide which is more effective or less expensive than the registered pesticides or alternative practices available to control a particular pest problem. In such cases, growers are attempting to increase their profits above the historical or "normal" range (scenario 1 on the above graph). Since profits without the requested exemption are expected to fall within the normal range, an emergency condition would not exist. As noted above, in defining an emergency situation as one that is expected to result in "significant economic losses", the Agency has in mind consequences more serious than a failure to maximize profits in a particular

growing season. When a new pesticide is developed which offers better or more economical control of a pest problem, growers may understandably want the use of the product to maximize their profits. However, this situation does not meet the criteria for emergency exemption under section 18.

ii) The Economic Analysis

To conduct an economic analysis of an emergency situation, Agency scientists examine yield, price, and cost of production (or crop budget) data for a number of years. In most cases, the Agency requires at least five years of data to complete its analysis. Using these data, Agency economists first calculate the mean profit over the past five years and the range of profits over this same period. Next, the economists calculate expected profits for the upcoming year, based on the yield losses expected as a result of the emergency condition. If the expected profits are below the historical range of profits, then a "significant" economic loss is expected to occur. A hypothetical example of a typical analysis is shown below:

Year	Yield per Acre (Flats)	Price per Flat	Gross Revenue per Acre	Cost per Acre	Net Revenue per Acre
Year 1	1,325	\$10.00	\$13,250	\$3,250	\$10,000
Year 2	997	\$13.86	\$13,818	\$3,318	\$10,500
Year 3	1,479	\$10.00	\$14,790	\$3,790	\$11,000
Year 4	1,357	\$10.42	\$14,140	\$4,390	\$9,750
Year 5	1,285	\$10.86	\$13,955	\$4,455	\$9,500
Average	1,289	\$11.03	\$13,991	\$3,840	\$10,150
Range of Profits:		\$9,500	To	\$11,000	
Current Year ¹	1,031	\$11.03 ²	\$11,371	\$3,840 ³	\$7,531⁴

¹ Yield loss of 20% expected by technical expert.

² Average price is used unless a target price or other known price is available.

³ Average production cost used unless better estimate is available.

⁴ In this case a significant economic loss is anticipated, since the emergency situation is expected to reduce net revenue (profit) below the historical, five-year range (\$9,500 to \$11,000 per acre).

The Agency recognizes that in certain situations where an emergency condition exists, significant economic losses may not always be demonstrated using this analytical scheme. For instance, if the historical data include data from one or

more atypical years (either unusually profitable or unprofitable), the average profits and the historical range of profits calculated by this analysis might not reflect the "normal" profitability for the productive activity. It is the applicant's responsibility in these situations to explain the abnormal data and provide an alternative estimate of the normal range in profitability. The application should fully explain how the alternative estimate was derived.

In evaluating the significance of an economic loss for productive activities, the Agency will also consider whether the loss would affect the long-term financial viability expected for the activity. 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.

3. Evaluating the Significance of an Economic Loss for Activities Where Profits Cannot Be Calculated

Most emergency exemptions involve a request to use a pesticide on an agricultural commodity in a productive enterprise. However, exemptions are, or could be, requested for the protection of structures, museum pieces, park land, or for other purposes unrelated to agricultural production. The significance of an expected economic loss associated with these applications will be considered on a case by case basis using measures of loss appropriate to the particular situation.

II. EMERGENCY EXEMPTION APPLICATIONS

A. Documentation of the Emergency

Applications for emergency exemptions are often inadequate, lacking essential information needed by the Agency to evaluate emergency situations. Inadequate applications can result in unnecessary processing delays and may force the Agency to deny requests when information in the application is not adequate to demonstrate that an emergency condition exists. 40 CFR §166.20 outlines the information required in an application for a specific, quarantine, or public health exemption. It is the responsibility of the State or Federal agency submitting emergency exemption requests to ensure that each request contains the required information.

The Agency may discontinue the processing of any application which does not contain all of the information required by §166.20 until the additional information is submitted by the applicant. Incoming emergency exemption requests are reviewed for completeness when they

are received in the Emergency Response and Minor Use Section. If the application is incomplete, the applicant will be notified of the deficiencies and asked to submit additional information. If the deficiencies are minor, the missing information will be requested by phone and processing of the application will proceed. If major information is missing, the application will be rejected and the applicant will be notified in writing that no further processing will take place until the missing information is received.

Each application will be reviewed on its own merit. The Agency will not use information from one state's application to evaluate another state's exemption request for the same or similar use. Although emergencies in neighboring states might be similar, it cannot be assumed that information from one state would be applicable in other states. Similarly, the finding that an emergency exists in one state does not necessarily dictate the finding by EPA that an emergency exists in other states. The Agency may grant exemption requests for a particular use in certain states but not in others, based on a separate evaluation of each state's request. Therefore, it is particularly important that each state's application contain the information required in 40 CFR §166.20.

1. Efficacy Data

Efficacy claims for the proposed pesticide, registered alternative pesticides, and alternative practices should be supported by data, if available. Applicants tend to submit efficacy data for the pesticide being requested under the exemption but do not provide the Agency with data comparing the efficacy of the proposed pesticide with the efficacy of the currently registered pesticides or alternative practices in controlling the pest problem.

If valid efficacy testing data are not available for any of the alternative control measures, other scientific information should be provided to support claims that a particular control measure is inadequate or impractical.

If available, yield data from studies comparing the proposed pesticide to the next best alternative(s) should be provided by the applicant. Efficacy studies often measure a pesticide(s) effect on the pest using variables other than yield, such as percent defoliation, number of insects per plant, number of leaf lesions, weed density, etc. Although valuable, this information may not be useful in substantiating yield loss claims, unless the relationship between these variables and yield loss is known.

2. Economic Data

In a majority of cases of inadequately documented emergencies, the applicant has failed to provide sufficient economic data to demonstrate that a significant economic loss is expected to occur. The previous section in this document, "Demonstration of a Significant Economic Loss", explains the Agency's process for evaluating the significance of an anticipated loss. The sub-section entitled "The Economic Analysis" contains a table showing five years of yield, price, production cost, and gross and net

revenue data for a hypothetical emergency situation. This same information should be submitted with every exemption application where significant economic loss is the basis of the request. If some of this information is unavailable, the application should explain why it cannot be obtained.

The economic information in an application should reflect the situation in the area of the state where the emergency pest problem exists. Applications often contain statewide data when the emergency condition exists only in certain geographical areas. Use of statewide data in these situations may mask the true impact of the pest problem in the affected areas. In general, statewide economics data are inappropriate for demonstrating that an emergency condition exists, unless the problem exists on most of the crop acreage within the state.

Section 166.20(b)(4)(ii) requires the applicant to provide estimated net and gross revenues for the site without the use of the proposed pesticide. In developing these estimates, the applicant should assume that the next best alternative pesticide or cultural practice, if available, will be used to control the pest. The revenue estimates should also be based on average expected yield reductions, not the maximum potential yield loss. Many applications provide revenue estimates for the site based on worst-case maximum yield reductions for the entire affected acreage if no alternative pesticides or cultural practices are used to control the pest problem. This approach results in an inflated, unrealistic estimate of expected losses which is unusable by the Agency in evaluating the applicant's request. The estimated gross and net revenues for the site without the use of the proposed pesticide should reflect the mean expected yield loss if growers use the next best practical means of control.

The Agency may entertain emergency exemption applications based on an expectation that an emergency condition will exist in the future when a pest problem reaches some threshold level (e.g. number of pests per plant, amount of rainfall within a specified time period, weed density, or percent defoliation). In this case, the applicant should estimate net and gross revenues without the proposed pesticide, based on average yield losses expected at the threshold level.

The Agency acknowledges that its economic analysis may not be appropriate in every emergency situation. If it is not relevant to the applicant's situation, the applicant must explain why and provide an alternate analysis demonstrating that an emergency condition, as defined in the section 18 regulations, exists.

3. Other Useful Information

Although not specifically required in the regulations, the following information should be included in emergency exemption applications, when appropriate, to alleviate some problems that have delayed Agency review of requests in the past.

i. Use Season

The application should give the date applications of the pesticide under the exemption should begin and the date applications of the pesticide should end.

ii. Location of Sites to Be Treated

Applications for emergency exemptions should identify the location of the sites to be treated under the exemption as specifically as possible, especially when the proposed use may pose a risk to Federally listed endangered or threatened species. Unless the proposed pesticide will be applied statewide, the application should identify the counties and, if known, the specific areas within those counties where the pesticide will be applied. To facilitate review of requests where Federally listed endangered or threatened species may be at risk from the proposed use, the applicant should contact the appropriate office of the U.S. Fish and Wildlife Service and obtain a list of endangered or threatened species which may be exposed to the pesticide from the proposed use. The USFWS's species list should be included in the application or submitted to the Agency as soon as it becomes available.

iii. Registered Uses of the Requested Chemical

In evaluating the risks to human health and the environment from a proposed pesticide, the Agency may consider the current, "registered" usage of the pesticide on other sites in the area of the pest emergency. To facilitate the Agency's risk assessment, the emergency exemption applicant should identify the sites within the region already being treated with the pesticide and recommended application rates for each site. The applicant should also provide an estimate, if available, of the total acreage already being treated with the pesticide in the area of the pest emergency.

B. Expedited Review of Applications for Repeat Section 18s.

One of the major concerns of State agencies is the length of time it takes EPA to review section 18 requests. To address this concern, the State FIFRA Issues Research and Evaluation Group (SFIREG) proposed that the Agency consider an abbreviated section 18 application and expedited review process for repeat exemption requests, provided the initial request had met the requirements for a section 18 exemption. Review of requests in subsequent years would be limited to consideration of unreasonable adverse effects on the environment identified during the first year's use, the efficacy of the product in the first year, and progress toward registration of the proposed use.

The section 18 decision making process requires several policy judgements. Although EPA may have granted an emergency exemption in a particular year, the Agency might want to

reconsider and make a different policy judgement in subsequent years. The proposed expedited review process for repeat section 18 requests would preclude such reconsideration by the Agency. In addition, further expediting the review of repeat requests would necessarily result in longer review times for new requests, given the limited resources available to the section 18 program.

Repeat requests, to a certain extent, already receive an expedited review. The Agency is concerned about further expediting the review of repeat requests for the reasons cited above. EPA believes it would be more appropriate to investigate ways to improve or expedite the overall section 18 process and is currently exploring a number of alternatives.

C. Applications for Regional Section 18s

The Agency has been asked to consider allowing regional section 18 exemption requests in situations where the emergency pest problem exists on a regional basis. The Agency has no previous experience with regional section 18 applications. However, the Agency is willing to accept regional applications on a trial basis to evaluate their practicality. Applications for regional emergency exemptions must be accompanied by an application letter signed by the head of each Federal or State agency, the Governor of each State, or their official designee. Every participating State should review the application carefully to ensure that the information in the application is relevant to the emergency situation in their state. Regional exemption applicants should be aware that unresolved issues in one part of the region, such as unresolved endangered species concerns, could delay authorization of the use throughout the region.

If two or more states share a common emergency situation but do not wish to submit a regional application, the Agency encourages the states, if possible, to coordinate their requests so that they arrive at the Agency within a few days of each other. The Agency can often review similar requests more efficiently and in less time if all of the requests are submitted during the same time period.

III. EMERGENCY EXEMPTIONS FOR PEST RESISTANCE MANAGEMENT

The development of pest resistance to registered pesticides as the condition causing an emergency is a troublesome issue under section 18. Since resistance occurs over a period of years, it is difficult to make a case that an emergency exists in any one year, even though the longer term effect may be significant. In addition, the localized nature of resistance makes it difficult to document its economic effects. Nevertheless, EPA's current position is that exemptions may only be authorized for resistance management in cases where documented pest resistance to the registered alternative(s) has already developed and is expected to result in significant economic losses.

IV. EMERGENCY EXEMPTIONS FOR TWO ACTIVE INGREDIENTS TO CONTROL THE SAME PEST ON THE SAME CROP

The Agency has occasionally received specific exemption requests for the use of two different pesticide products, containing different active ingredients, to control the same pest on the same crop. Prior to the 1986 it was the Agency's policy not to grant such requests. This policy was announced in the December 5, 1979, memorandum from Ed Johnson, OPP Director, to State Lead Personnel and Federal Agencies.

The negotiating committee that revised the section 18 regulations in 1985/86 revisited this issue of multiple pesticides for a single pest emergency. As discussed in the preamble to the proposed rule (50 FR, April 8, 1985), concerns were raised that the use of several pesticides on the same field would lead to complex risk analyses or enforcement problems. However, the Committee agreed that there may be instances when the use of more than one pesticide is necessary and justifiable; such as 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. The current section 18 regulations do not preclude the granting of exemptions for the use of more than one pesticide for the same emergency condition; however, such use under section 18 will be authorized only when necessary to provide adequate control of a pest or situation. Authorization of more than one chemical will not be made for competitive or marketing purposes.

Essentiality is a key factor in section 18 decisions. When EPA grants an exemption for one active ingredient to control a pest emergency, an emergency condition requiring the use of another pesticide would ordinarily no longer exist, since an effective alternative would be available to control the pest problem. Only under certain circumstances, such as those discussed above, would an emergency condition requiring the use of another pesticide still exist. It is the responsibility of the emergency exemption applicant to demonstrate that a special circumstance exists which would warrant approval of an exemption for multiple pesticides. Requests for multiple pesticides should be made in a single application so these issues may be properly considered by EPA.

V. EMERGENCY EXEMPTIONS FOR NEW CROPS

The U.S. Federal Government/USDA encourages the diversification of U.S. agriculture through the introduction of new crops. However, there are often few or no pesticides registered to control pests on these crops, because of their recent introduction. State agencies frequently request authorization under section 18 to use a pesticide to control a routine (i.e. expected) pest problem on a new crop or crop variety, based solely on the lack of available registered alternatives. It is the Agency's position that the section 18 process is not the appropriate mechanism for EPA to make pesticides available to control routine pest problems on new crops. This position may be seen as undermining USDA's policy of encouraging the diversification of U.S. agriculture. However, the Agency does not believe its section 18 regulations may be interpreted otherwise.

In evaluating emergency exemption requests involving new crops or crop varieties, the Agency will use the same criteria used to evaluate all exemption requests. Applicants seeking

emergency exemptions for new crops must demonstrate that the situation is urgent and non-routine, that no effective alternative pesticides or practices are available, and that the situation will result in significant economic losses without the exemption. These criteria should provide growers of new crops with adequate means to protect against unexpected, non-routine pest emergencies.

A. Non-routine Pest Problems for New Crops/Crop Varieties

The issue of what constitutes a non-routine pest problem for a new crop is a difficult one. Generally, potential pest problems would be identified during the research conducted on a crop in the development process, prior to its release for general use. A person undertaking to grow a new crop is assumed to have accepted the economic risks associated with the crop, including the risk of loss due to normal variation in known pest problems for which there are no effective controls. Only those situations involving 1) a pest not previously known to affect the crop, or 2) an abnormal variation in the severity of a known pest problem would be considered non-routine by the Agency.

If an exemption is requested for a new crop, based on the claim that the severity of the pest problem exceeds what would reasonably be expected, the applicant should provide historical information on the pest problem sufficient to demonstrate that the current situation is non-routine. The applicant should also address the factors (e.g. unusual weather) responsible for the abnormally severe pest problem.

B. Alternative Pesticides and Practices

The Agency will evaluate alternative control measures for new crops no differently than for established crops. Therefore, when requesting an emergency exemption involving a new crop or crop variety, the applicant is expected to identify the registered pesticides and alternative cultural practices available to control the pest problem and to provide a detailed explanation of why the available control strategies will not provide adequate control under the conditions of the emergency.

C. Significant Economic Loss for New Crops/Crop Varieties

Historical yield, price, and production cost data are usually not available for recently introduced crops or crop varieties. In lieu of these data, the Agency will examine data from field trials or similar research to determine the expected yield under normal growing conditions with normal pest pressures. The Agency will compare the normal yield to the yield expected under the conditions of the emergency to determine the anticipated yield reduction. The applicant should also provide price information and a crop budget or best estimate of production costs. The Agency will use this information in determining whether the expected yield reduction will result in a significant economic loss.

VI. EMERGENCY EXEMPTIONS FOR VOLUNTARILY CANCELED PESTICIDES

With the implementation of the 1988 revisions to FIFRA, the Agency expects to receive an increased number of emergency exemption requests based on the loss of a pesticide due to voluntary cancellation. Requests are expected to be of two types; requests for an alternative pesticide to replace the canceled pesticide and requests for the pesticide that has been canceled. Requests for the use of an alternative pesticide should not present any unique problems and will, therefore, be evaluated under the same criteria as other emergency exemption requests.

Section 18 requests for the use of a pesticide or a pesticide use which has been voluntarily canceled present a potential problem to the Agency if progress toward registration cannot be demonstrated. When a pesticide or pesticide use has been voluntarily canceled the Agency must assume that the registrant is not interested in pursuing its registration in the future. Therefore, progress toward registration for any voluntarily canceled pesticide or pesticide use is very questionable. Prior to acting on a section 18 request for a voluntarily canceled pesticide or pesticide use the Agency will require evidence demonstrating that; (1) there is progress toward registering the pesticide or use once again, or (2) an alternative pesticide will be registered in the near future, or (3) a program will be carried out to find an alternative pesticide for use. Prior to authorizing a section 18 an emergency situation must still be demonstrated.

A. Minor Uses

EPA, USDA and agricultural chemical companies are concerned about the loss of pesticide minor uses due to reregistration. These groups have worked cooperatively to develop an early notification network to notify user groups of the potential loss of pesticides while there is still time for affected groups to take action to alter the outcome of reregistration. In association with the notification network, EPA and USDA have jointly issued a Minor Use Fact Sheet intended to help user groups plan for future reregistration decisions. In addition, EPA is cooperating with IR-4 in the implementation of a strategy for the reregistration of as many as 1,000 high priority minor uses.

Because of all the efforts underway to save minor use pesticides, the Agency does not endorse use of the section 18 process as a means to retain minor uses lost through the reregistration process. If, however, a pesticide registration for a minor crop is canceled due to reregistration and the criteria for an emergency condition as outlined in the section 18 regulations have been satisfied, the Agency may grant an emergency exemption. The Agency expects growers in this situation to actively pursue registration of the use requested under section 18. The progress that is being made toward registration should be addressed in the exemption application. In lieu of evidence of progress toward registration, the Agency may allow the use of a voluntarily canceled pesticide or pesticide use upon evidence that an alternative pesticide will be registered in the near future or upon evidence that a program will be carried out to find an alternative pesticide for use.

Under sections 6(b) and 6(c) of FIFRA, EPA may cancel or suspend the registration of a pesticide if the Agency determines that the pesticide causes unreasonable adverse effects on the

environment. 40 CFR §166.25(b)(iii) of the section 18 regulations prohibits the Agency from granting exemptions for pesticide uses that have been suspended under section 6(c) of FIFRA or canceled following a notice under section 6(b) of FIFRA, unless the use is authorized in accordance with the regulations at 40 CFR §§164.130 through 164.133. Similarly, the Agency will not be inclined to grant a section 18 exemption for a use that was voluntarily canceled under circumstances which suggest the likelihood of unreasonable adverse effects on the environment. In such situations, EPA would not likely be able to make the determination required by 166.25(b)(ii) that the use will not cause unreasonable adverse effects on the environment.

VII. EMERGENCY EXEMPTIONS FOR NEW CHEMICALS AND THE FIRST FOOD USE OF REGISTERED PESTICIDES

A new chemical is defined as any pesticide containing an active ingredient not contained in any currently registered pesticide. The Agency gives particularly close scrutiny to emergency exemption requests for the use of new chemicals and for the first food use of registered pesticides. The Agency is concerned that the section 18 process may be used to circumvent the more rigorous requirements of the section 3 registration process, and thus permit early market entry of a new chemical or food use pesticide.

The issuance of such emergency exemption requests depends heavily on the available scientific data base for the pesticide and the gravity of the emergency situation. The Agency usually has a substantial data base on the pesticide before it will allow such use. The Agency needs to have, at a minimum, the same studies required to support an experimental use permit for the use in question. For example, the data base needed to evaluate risks to human health would include, at least, acute toxicity, subchronic feeding, teratology, and mutagenicity studies. (Special studies, such as neurotoxicity, cholinesterase inhibition, or inhalation toxicity, would be required if the chemical structure indicates that such studies are needed.) Only after the Agency is reasonably satisfied that there would be no significant adverse effect and there is an emergency condition is an emergency exemption granted for a new chemical or the first food use of a registered pesticide.

In evaluating a repeated emergency exemption request for a new chemical or the first food use of a registered pesticide the Agency will weigh very heavily the progress that has been made toward registration of that use. The regulations state that if a complete application for registration of a use "which has been under a specific or public health exemption for any 3 previous years", has not been submitted, it shall be presumed that reasonable progress toward registration has not been made. As further discussed in Section X of this document, the Agency will not be inclined to grant repeated exemptions unless reasonable progress toward registration has been made.

It should be noted that the regulations at 40 CFR 166.41 **prohibit** utilization of the **crisis provisions** for pesticides which contain a new chemical and for the first food use of a registered pesticide.

VIII. EMERGENCY EXEMPTIONS FOR SAFER PESTICIDES

Section 166.3(d) defines "emergency condition" as an urgent, non-routine situation that requires the use of a pesticide(s) and shall be deemed to exist when three conditions are met. EPA believes that an "emergency condition" exists **only** when the situation is urgent and non-routine **and** all three conditions are met; (1) no effective registered pesticides are available, (2) no feasible alternative control practices are available, and (3) the situation involves the introduction of a new pest or will present significant risks to human health or the environment or will cause significant economic loss.

EPA believes its regulations do not allow for the authorization of a section 18 exemption based solely upon 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. The primary mechanism for weighing risks and benefits under FIFRA is the registration process. If the effective registered alternative is sufficiently dangerous that the Office of Pesticide Programs would prefer that growers use an unregistered pesticide, the statutory scheme normally contemplates cancellation or suspension of the registered alternative, rather than ignoring the registered alternative and granting a section 18 for an unregistered chemical.

IX. EMERGENCY EXEMPTIONS FOR EXPANDED ACREAGE

State or Federal agencies seeking repeat emergency exemptions should be aware of the Agency's policy regarding expansion of acreage. In general, the Agency will only grant repeat exemptions for use on expanded acreage when the pest emergency has spread to areas outside the original range. The Agency will not be inclined to grant exemptions for expanded acreage within the original range of the emergency unless the applicant can demonstrate that the pest problem on the additional acreage could not have been anticipated.

In particular, the Agency will not look favorably on repeat exemption requests 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 emergency exemption to control an anticipated pest problem. The purpose of section 18 is to provide relief from unexpected pest emergencies. Growers choosing to plant new acreage of a crop in an area where a pest is expected to occur are assumed by the Agency to have accepted the risk of loss from the pest problem. If an expected pest outbreak occurs, the Agency will consider the losses as having resulted from "obvious mismanagement" and will not grant an emergency exemption for use on the expanded acreage.

X. REASONABLE PROGRESS TOWARD REGISTRATION

In accordance with 40 CFR §166.25(b)(2)(ii), one of the factors the Agency must consider in deciding whether to grant an emergency exemption is the progress toward registration of the proposed use if a repeated specific or public health exemption is sought. Except in unusual circumstances, the Agency is not inclined to grant repeated exemptions unless

reasonable progress toward registration has been made. In evaluating progress toward registration, the Agency will take into consideration delays which were beyond the control of the registrant or the emergency exemption applicant.

The regulations state that if a complete application for registration of a use, "which has been under a specific or public health exemption for any 3 previous years", has not been submitted, it shall be presumed that reasonable progress toward registration has not been made. The Agency interprets this standard to apply to uses which have been requested under section 18 for any 3 previous years, regardless of whether the requests were granted or denied. This interpretation is consistent with the intent of the negotiating committee. The Agency interprets "complete application" to mean an application which contains all of the scientific studies and other information required for registration and which passes the Agency's front end screening process. If the application for registration is rejected by the Agency because it is incomplete and the application deficiencies cannot be rectified within 75 days, the Agency will presume that reasonable progress toward registration has not been made.

EPA has reconsidered the 3-year standard set forth in the regulations and concluded that, although it is reasonable in most cases, it may be unrealistic for many IR-4 minor food uses due to the program's limited resources and consequent backlog. Therefore, in evaluating progress toward registration, the Agency will exercise its discretion in determining whether or not reasonable progress has been made on an IR-4 minor food use. Generally, IR-4 minor food uses will be judged against a 5-year standard, as opposed to the 3-year standard for all other uses.

The section 18 regulations do not set forth criteria for evaluating progress toward registration once a complete application for registration has been submitted. After this point in the registration process, the Agency evaluates progress toward registration on a case-by-case basis, taking into account a number of different factors, including:

A. Compliance with the Agency's Registration Data Requirements and Guidelines

The pesticide registration data requirements are clearly presented in 40 CFR §158. The Pesticide Assessment Guidelines contain the standards for conducting acceptable tests, guidance on evaluation and reporting of data, definition of terms, further guidance on when data are required, and examples of acceptable protocols. Registrants are expected to read and apply the Guidelines when conducting and submitting studies in support of registration. If studies are determined by the Agency to be deficient and not in compliance with the Pesticide Assessment Guidelines, the Agency may determine that reasonable progress toward registration has not been made.

Many of the registration data requirements in 40 CFR §158 are tiered. The results of lower tier studies may trigger the need for additional, higher tier studies. The Agency expects the registrant to evaluate results of its lower tier studies and conduct higher tier studies when warranted. If the results of lower tier studies clearly indicate the need for additional studies which the registrant has not conducted, the Agency may determine that reasonable progress toward registration has not been made.

B. The Registrant's Responsiveness to Application Deficiencies Identified During Agency Review

Under the Agency's current policy, registrants are given 75 days to respond when notified of deficiencies associated with registration or amended registration applications and tolerance petitions. The response must indicate how the registrant plans to address the deficiencies. Therefore, if the registrant fails to respond to notification of deficiencies within 75 days or has not provided the Agency with an acceptable plan and timetable for rectifying the deficiencies, the Agency may determine that reasonable progress toward registration has not been made.

C. New Registration Data Requirements

The Agency may occasionally require additional data to support registration of a use which the registrant could not have anticipated at the time the original application for registration was submitted. The Agency will take this into consideration in evaluating progress toward registration. However, the Agency expects the registrant to commit to generate the required data and to provide the Agency with an acceptable timetable for submission of the additional data. If the registrant fails to do this, the Agency will presume that reasonable progress toward registration has not been made.

D. The Registrant's Compliance with Reregistration Requirements

The reregistration provisions of FIFRA '88 establish mandatory timeframes and duties for reregistration of pesticides. In evaluating progress toward registration of repeated section 18 uses, the Agency will also consider the registrant's reregistration record. The Agency will not be inclined to grant repeated emergency exemptions for a pesticide unless the registrant is meeting its reregistration obligations.

The amount of time required to obtain section 3 registration once an application has been submitted varies, depending on the pesticide and the particular use pattern. However, 2 to 3 years should be adequate in most cases, if the registrant submits a complete registration package in accordance with Agency guidelines and the Agency meets its obligations in reviewing the application. Therefore, if registration has not occurred within 3 years of receipt of an application, the Agency will presume that reasonable progress toward registration has not occurred. The Agency will conduct a thorough evaluation of the factors responsible for the delay but will not be inclined to grant further emergency exemptions for the use, except when an "emergency condition" exists and Agency inaction (supporting data has not been reviewed or a final decision has not been made) is the cause of the delay.

The Agency expects the applicant to keep abreast of the progress that is being made toward registration of uses requested under section 18. Prior to making an application for

a repeated specific or public health exemption, the State or Federal agency should contact the registrant regarding the progress being made toward registration of the proposed use.

The section 18 application should contain a discussion of progress toward registration, including a summary of deficiencies and data gaps and the registrant's timetable for rectifying registration deficiencies.

In the past, the Agency has provided little information to emergency exemption applicants concerning the registration status of uses requested under section 18. To better enable State and Federal agencies to plan and develop strategies to manage pest emergencies, the Agency has adopted a new policy of providing this information to section 18 applicants in its decision notification letters. The letters will discuss the registration status of the proposed use, summarizing the outstanding deficiencies and issues which may affect registration. When applicable, notification letters will also include a discussion of the reregistration status of the pesticide and the potential for reregistration issues to affect registration of the proposed use.

XI. INNOVATIVE APPROACHES TO REPEAT SECTION 18 PROBLEMS

The Office of Pesticide Programs (OPP) is embarking on a new initiative to develop innovative and non-traditional approaches to achieve the Agency's environmental objectives. The primary goals of this initiative are to identify issues and environmental problems that elude traditional regulatory methods and determine innovative ways to address them. As part of this strategy, OPP is considering new opportunities under the section 18 process that will allow the Agency to effectively deal with pest emergencies and reduce risk. In general, the Agency would like to identify pest problems that consistently result in emergency exemption requests, and work with the states and affected growers to develop ways to address these problems using new and/or little known technologies.

Currently, OPP is considering a broad range of potential alternative pest control strategies. The availability of alternate control measures tend to be site specific. In the future, authorization of repeat section 18 requests may be conditioned upon evidence that the State applicant is attempting to find an innovative alternative solution.

XII. CRISIS EXEMPTIONS

It was the Agency's intention in promulgating the section 18 regulations that resort to the crisis provisions would be relatively rare. When proposing the current section 18 rules at 40 CFR Part 166, EPA noted that the regulatory negotiating committee gave some thought to abolishing crisis exemptions. The Committee retained the crisis exemption provisions of the pre-existing regulations, agreeing that, "the crisis provisions should be invoked only in dire situations where the emergency condition is unpredictable and there is no other way to mitigate the emergency" (Fed. Reg. 13953; April 8, 1985).

Section 166.40 allows the head of a Federal or State agency, the Governor of a State, or their official designee, to issue crisis exemptions in situations involving "unpredictable" emergency situations when there is insufficient time to request a specific, quarantine, or public health exemption, or for EPA to review such a request. It is the Agency's belief that situations in which there is insufficient time to file a request for a specific exemption far enough in advance to allow the Agency the normal 50-days of processing time should be rare. In almost any emergency situation, an applicant would have adequate time to submit a request to the Agency for a specific exemption prior to declaring a crisis. Indeed, in most situations, by determining the magnitude of the outbreak that would constitute an emergency and submitting a request to the Agency incorporating this threshold level, the specific exemption can be requested far enough in advance to allow EPA an adequate opportunity to review the application. Crisis exemptions should not be issued to mitigate emergencies for which crisis exemptions have been issued or specific exemptions requested in previous years. It is difficult to imagine how these pest emergencies could be considered unpredictable and why a specific exemption request could not have been submitted in time to address the emergency. Tardiness in preparing emergency exemption requests for predictable emergencies will not be viewed by the Agency as a valid reason for resorting to the section 18 crisis provisions.

Section 166.42(a)(1) of the regulations requires the State or Federal Agency issuing a crisis exemption to notify the Agency, when feasible, at least 36 hours in advance of utilization of the crisis provisions. In no case shall notice be given to the Agency later than 24 hours after the State or Federal agency's decision to avail itself of a crisis exemption. EPA does not consider an indication from a State or Federal Agency that they are considering a crisis exemption adequate notification.

Section 166.53(b) gives the Agency the authority to revoke crisis exemptions or a State or Federal agency's authority to issue crisis exemptions when the agency is not complying the requirements of the crisis provisions in 40 CFR §166, subpart C. Improper notification to the Agency of crisis exemptions or resort to the crisis provisions to mitigate predictable pest emergencies will be considered noncompliance with the crisis provisions and may result in revocation of the State or Federal agency's crisis exemption or crisis authority.