



**US Environmental Protection Agency
Office of Pesticide Programs**

**Pesticide Regulatory Education Program's (PREP)
FIFRA Section 18 Emergency Exemption Program
Training Resource**

Module 2

June 2013

PREP's Online Training of the FIFRA Section 18 Emergency Exemption Program: Transcript for Module 2: Section 18 Emergency Exemptions in Detail

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Welcome to Module 2, Section 18 Emergency Exemptions in Detail.

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In this module, we'll go over the four different types of emergency exemptions available under Section 18 of FIFRA: Specific, Quarantine, Public Health and Crisis.

The main goals for this module are to help you identify the circumstances which are considered to be emergency pest problems under FIFRA and to help you understand the types of emergency requests that SLAs (or federal agencies) can pursue. We'll talk a lot about emergency conditions because all exemption requests must document that an emergency exists in order to be authorized.

The Specific, Quarantine and Public Health exemptions all call for the SLA to develop an application package and submit that to EPA. The idea is that EPA will carefully review the application and then respond. EPA's review process will proceed more quickly if SLAs develop complete applications and present the information in a clear fashion. Module 4 will give you more details on exactly what information you must provide in a Section 18 emergency exemption request.

By the end of this module, you will have a better understanding of what constitutes an emergency and what types of exemptions are available as a remedy, according to the consequences of the critical pest problem you may be facing. Let's get started.

If you want to refer to the Section 18 regulations, they are in Title 40 of the Code of Federal Regulations, Part 166.

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So what exactly is a Section 18 emergency exemption?

Section 18 of FIFRA says that EPA can exempt a state or federal agency from the requirements of FIFRA when an emergency exists. The practical meaning of this provision is that the SLA can request EPA to authorize an emergency exemption to temporarily use a pesticide that is not registered for the proposed use when growers or research scientists identify an urgent and non-routine situation where there are no registered pesticides or alternative practices that will effectively address the problem. While either a state or federal agency can request a Section 18 exemption, for the purposes of this training, we'll assume it's the SLA who is applying for one.

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Most exemption requests involve a chemical for which some EPA risk assessments are already available. In other words, it's a chemical that is contained in a pesticide which has some registered uses, but a new and unlabeled crop or site is being requested under the emergency exemption.

The SLA should ensure that the application describes the particular emergency condition fully. Describe to EPA, "here's what's new and problematic" with respect to

the pest circumstances you're facing. Then do a comparison of the routine situation versus the emergency condition. This will facilitate EPA's considerations for making a supportive finding on the application and agreeing that the growers are indeed faced with an urgent and non-routine problem.

Additionally, exemptions are limited to the specific geographic area where the emergency conditions exist and are requested for a specific pest/use site combination. If it's appropriate a state-wide request can be made. If approved, the emergency exemption is valid for a limited time, usually a year at the longest. EPA expects that you will work with registrants and the extension community to transition out of long-running emergency situations. Often a requested use will become available under a Section 3 registration once the field trial data are available.

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Let's look at the emergency conditions in a little more detail, because emergency conditions are what lead SLAs to submit Section 18 requests. Specifically, we'll talk about situations: that are urgent and non-routine, that have no effective registered pesticides, that have no alternative practices that provide effective control, and how the consequences of the emergency will determine the exemption type. So let's look at the first condition, what we really mean by "urgent" and "non-routine".

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The Merriam-Webster dictionary defines urgent as "calling for immediate attention" and that definition is relevant to an emergency condition as well. That is, the consequences of the pest problem or situation must be significant and fairly immediate. If there is not an immediate risk of injury, the Section 3 process should be used to obtain a registration to meet the pest control needs.

The definition of non-routine is equally straightforward. For a problem to be non-routine it must be "unusual" or "out of the ordinary." There should be a noticeable difference between a routine or typical situation and one where unexpected developments occur outside the grower's control that is non-routine. Problems that ARE routine can and should be addressed through other avenues such as the Section 3 or 24(c) registration processes.

So how can we boil this down to a single sentence? An "urgent and non-routine" situation is one in which the status quo has changed in an unusual way that was unforeseen by the grower and immediate action requiring the use of a pesticide is needed.

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Another criterion that you must demonstrate is that there are no effective control options either through existing registered pesticides or through alternative practices. The discussion of alternatives must include biological materials as well as non-pesticide management techniques.

This is where the application package for an emergency exemption would detail, for example, whether the alternative pesticides are not effective in controlling a new pest or are unsuitable for assisting in the response to the emergency situation for other reasons. Often, emergency exemption requests involve specialty crop needs where

there may be very limited alternatives. In describing the routine or “no emergency” situation, the SLA should identify the best available pest control option, whether that involves crop varietal selection or an alternative registered pesticide. Sometimes, applications describe the pest emergency as a situation where fields go un-treated or no management has taken place. The regulations assume that growers will utilize the best available pest management option.

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At this point, economics shouldn't be a factor. That is, don't eliminate an alternative on the basis that it is too expensive. That is really part of explaining why the losses associated with the pest problem are 'significant.' Module 3 provides a detailed explanation for how to document “significant economic loss.”

Claims of ineffectiveness of the alternatives must be supported by field data demonstrating lack of efficacy, or, if such data are not available, statements from qualified experts may be included. This might be applicable when the emergency problem involves pests that develop resistance. Other claims of problematic circumstances should be documented with the best scientifically relevant data.

Finally, the application should include a detailed explanation of why alternative cultural or other practices, if available, would be insufficient to address the pest situation.

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Let's look at examples of situations that would be urgent and non-routine and contrast that with situations that would not qualify for a Section 18 emergency exemption.

The loss of a pesticide, where there are no other effective control methods available for an important pest, represents a non-routine situation. A pesticide might be “lost” because of regulatory action or because the pest develops resistance to it.

Another example of a qualifying situation is the introduction of a new pest. This might mean a pest that has expanded beyond its typical range or invaded from some other location. You could certainly say that would be unusual.

Unusual weather or environmental conditions could cause a problem that a pesticide could alleviate. Examples include severe drought conditions that lead to pest population explosions, unusually warm winters that allow pests to overwinter, and cool, wet conditions that lead to fungal outbreaks.

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In contrast, situations that would not be good candidates for an emergency request involve a rationale that is based on changing market factors that cause returns to shrink for a crop, or one where foreign competition has reduced the profitability for a certain sector.

Also, in consideration of novel modes of action and the topic of resistance management, EPA does not consider the availability of a new chemical class to be the basis for an emergency finding. The decision-making platform for an emergency request is very immediate. So if there are effective registered alternatives for a pest at the time of submission, it's not likely that EPA can make an emergency finding for a new mode of

action. Resistance management is a challenging area. If SLAs have questions about it, it's best to contact the Section 18 Team Leader to discuss the issue.

Finally, management decisions made with knowledge of the risks of agriculture do not qualify. For example, if growers plant in marginal lands, knowing that weed problems are likely, then seeking an emergency exemption is not an appropriate solution.

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This flow diagram focuses on the three main types of emergency exemptions, highlighting the commonalities of the emergency condition criteria and showing some of their key differences. The SLA should develop the Section 18 application based on the pathway that's most appropriate to the emergency scenario.

We are now going to look at all the types of emergency exemptions in detail, focusing on the consequences of the situation associated with each type of exemption.

We'll start with Specific exemptions as these are the most common type.

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Assuming the situation has been identified as urgent and non-routine, a Specific exemption may be appropriate when the situation is associated with either a significant economic loss, or a significant risk to the environment, including risks to endangered or threatened species, and their designated critical habitats, or beneficial organisms. EPA may authorize Specific exemptions for a growing season but no longer than a one year period.

Let's expand on these consequences that may pertain to a Specific exemption request.

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The concept of an emergency condition includes the notion that the novel pest problem is very significant or high impact, and results in "significant economic loss" to justify an emergency exemption.

The best way to show the consequences of an unusual pest problem is to compare the routine or normal situation against that posed by the non-routine or emergency situation.

The loss is not determined by comparing the emergency or non-routine situation with and without the requested chemical. First, a Section 18 may not be granted for the purpose of revenue enhancement and comparing the situation with and without the requested chemical can make it appear to be exactly that: revenue enhancement. The truth is you should be able to make the case for a significant economic loss without even mentioning the requested chemical!

Because of the importance of the SEL requirement, Module 3 is devoted in its entirety to how to demonstrate significant economic loss.

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Additional consequences from an emergency pest problem that may lead to a Specific exemption request are significant risks to the environment, such as risks to threatened and endangered species, and their designated critical habitats, beneficial organisms, such as pollinators, or other non-target organisms.

Control of a pest or disease may be necessary to protect a native species or the environment. For example, EPA has approved programs under Section 18 for ecological restoration activities. But historically speaking, this type of request is infrequent.

In submitting a Specific exemption request based upon risks to the environment, including endangered, threatened, or beneficial species, the application must fully discuss the anticipated risks that would be remedied by the proposed use of the pesticide, and provide the best available supporting scientific data.

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The second type of emergency exemption is the Quarantine exemption. This type of exemption may be appropriate for programs necessary to control the introduction or spread of invasive species.

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State or federal agencies make Section 18 Quarantine exemption requests when growers or research scientists identify the introduction or spread of an invasive pest species not previously known to occur in the United States and its Territories. The emergency is based on the need to prevent the introduction or spread of an invasive species. The consequence of not controlling the species is the damage an invasive species would cause, including agricultural or personal property losses.

EPA may authorize a Quarantine exemption for up to three years.

An example of a quarantine pest problem involves activities to manage and eradicate exotic fruit flies in citrus-producing states. Another historic example relates to zebra mussel control, requested in order to protect drinking water systems.

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The third type of emergency exemption we'll look at is the Public Health exemption.

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State or federal agencies make Section 18 Public Health exemption requests when growers or research scientists identify a pest that will cause a significant risk to human health. The emergency is based upon the risk to human health presented by the pest to be controlled.

If approved, EPA may authorize a Public Health exemption for up to one year.

Past examples of Public Health exemptions involve control activities against ticks which vector Lyme Disease.

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Finally, the last type of emergency exemption, and the one that is the most time-critical, is the Crisis exemption.

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According to the intent of the Section 18 exemption process, Crisis exemptions are meant to be a last resort in addressing an emergency situation and are expected to be rare. It's possible, however, that a Crisis exemption may be an essential means of responding to a critical pest development. It's also possible to work through difficult situations with EPA after hours or over a weekend when the situation calls for this type of response.

A state or federal agency may issue a Crisis exemption for unpredictable and immediate, emergency pest situations, when the time from discovery of the emergency to the time when the pesticide use is needed is insufficient to allow for the authorization of a Specific, Quarantine, or Public Health exemption by EPA.

As a first step, the SLA must contact the EPA Section 18 Team Leader about the situation and its intent to utilize the Crisis exemption. The SLA can work with EPA to quickly explore the situation and troubleshoot any potential safety concerns. EPA must concur on a Crisis exemption prior to the SLA's issuance of one. At the same time, or as soon thereafter as possible, the SLA must contact and ensure the support of the registrant or basic manufacturer of the pesticide to be used under the Crisis exemption.

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Unless EPA makes an initial determination that the Crisis exemption criteria cannot be satisfied, the SLA then develops and submits a draft Crisis exemption letter to EPA for review. Module 4 contains the details of what must be included in the Crisis letter. Briefly, the letter must describe the emergency situation, what the pest is and what adverse effects it causes. It must also describe the pesticide use pattern, any residue concerns with food or feed, the pesticide use period, and harvest dates for food or feed crop use sites. The SLA must also affirm that they have notified the registrant of the crisis.

Based on the draft Crisis letter and other information provided, EPA conducts an expedited review and must provide confirmation to the SLA that, for food uses, a tolerance or an exemption from the requirement of a tolerance can be established quickly, if needed, and EPA has no other concerns or objections. EPA's goal for this review and concurrence, usually by email, is 2-3 days.

After receiving concurrence from EPA, the SLA then issues the Crisis exemption authorizing immediate pesticide applications for control of the pest situation.

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A Crisis exemption may be authorized for only as long as is necessary to control the pest or conditions causing the emergency, and no longer than 15 days, unless an application requesting a Specific, Quarantine, or Public Health exemption for the same situation and same use is submitted to EPA.

So Crisis exemptions can either be “stand-alone” exemptions, or they can be followed up with a full exemption request. Let’s look at the difference between the two options.

Stand-alone crisis exemptions authorize pesticide applications for no longer than 15 days. The Crisis letter identifies the exemption as stand-alone, and must explain why a full Specific, Quarantine, or Public Health exemption request will not be submitted to EPA. This option obviously is limited to emergency pest situations where control can be achieved in a very short time period, for example when the proposed pesticide is effective only when applied during a specific life stage of an insect.

The alternative to a stand-alone Crisis exemption is when the SLA submits a request for a full Specific, Quarantine, or Public Health exemption for the same emergency situation to EPA. The full exemption request may have been submitted prior to issuance of the Crisis exemption, but if not, then it must be submitted within 15 days after the Crisis is issued. In this case, the Crisis exemption remains in effect until EPA reaches a decision on the full application.

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Let’s go over some conditions and limitations concerning Crisis exemptions.

EPA strongly discourages repeat use of a Crisis exemption for the same situation. If the emergency is expected to recur in subsequent years, EPA expects the SLA to submit a full exemption request.

Crisis exemptions cannot be issued if EPA has informed the SLA that the Crisis exemption may not be issued, if the pesticide proposed for use is suspended or canceled, if the pesticide contains a new active ingredient, or if the request is for the first food use of a pesticide.

EPA may also revoke a Crisis exemption if it identifies risk concerns or noncompliance with the Section 18 regulations.

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In this module, we talked about the conditions that emergency situations must meet to qualify for a Section 18 emergency exemption, and which exemption is appropriate based on the consequences of the situation. In the next module, we’ll look in more detail at how to demonstrate “significant economic loss” to support a Specific exemption request.