



US Environmental Protection Agency Office of Pesticide Programs

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

Module 4

June 2013

PREP's Online Training of the FIFRA Section 18 Emergency Exemption Program: Transcript for Module 4: What's in a Section 18 Application?

Slide 1

Welcome to Module 4, What's in a Section 18 Application?

Slide 2

You now know whether your critical pest situation qualifies as an emergency condition and you're ready to put your Section 18 application together. In this module, we will look at what information and data EPA needs to efficiently consider your application for a Specific, Quarantine or Public Health emergency exemption request, and the steps you should follow when the need arises for a Crisis exemption.

Slide 3

As outlined in the regulations governing Emergency Exemptions (40 CFR 166.20), there are certain required elements for a Section 18 application. We'll first look at all the required information for Specific, Quarantine and Public Health exemptions, as well as discuss additional requirements unique to each of these three. Finally, we'll go through the process for Crisis exemptions. We'll discuss repeat emergency exemption requests in Module 7.

Before we get started, we should mention that there is no application fee associated with submitting an exemption request to EPA. In addition, an application must be submitted in writing by the head of the requesting Federal or State agency, the Governor of the State involved, or their official designee. And finally a word about data quality.

Ideally, the data submitted are publically available and are quantitative. But EPA recognizes that comprehensive and quantitative data are not always available. EPA may also use qualitative information in its decision-making. The bottom line is that when submitting data to EPA, you should submit the best available data to ensure that EPA can make a determination about the emergency conditions and the safety findings. OK, let's get started.

Slide 4

A Specific, Quarantine or Public Health exemption request must contain the following pieces of information before you submit it to EPA: identity of contact persons; description of the pesticide; description of the proposed use; discussion of events leading to the emergency situation, addressing any unique requirements for Specific, Quarantine and Public Health requests; scientific and common name of the pest; alternative methods of control; effectiveness of the proposed use; information needed to support risk assessments (including a discussion of residues for food/feed uses and a discussion of risk information); coordination with other affected state or federal agencies; acknowledgment by the registrant; and finally, a description of any proposed enforcement program.

Let's take a closer look at each of these elements to see what information you will need to provide.

Slide 5

Identify the contact person(s) (one of which is usually you, the state contact), with a phone number, address, and e-mail address. Also provide this same contact information for any subject matter experts whom EPA reviewers can call if technical questions arise during their evaluation of your application. This person(s) is often the extension agent who is working with your growers, but may also be an expert from another organization, such as the registrant company or a commodity group.

Slide 6

Describe the pesticide proposed for use. Include the trade name, active ingredient, formulation and manufacturer. For a federally registered product, submit a draft of proposed Section 18 use directions to be used in conjunction with the full product labeling, outlining the conditions and terms of the use being requested. Frequently, the registrant will provide this as supplemental use directions to be distributed with the product under the exemption, if authorized. However, this is not a requirement, and some states distribute EPA's authorizing correspondence to users as Section 18 use directions. We will discuss Section 18 use directions more at the end of this module.

If you are requesting an emergency exemption based on a new formulation of a registered active ingredient (we'll refer to that as an unregistered product), or a new active ingredient that is not contained in any currently registered product (we'll refer to that as a new chemical), you will add time to EPA's processing of your request. EPA will need to clear the inert ingredients, develop appropriate safety statements for use, and evaluate the proposed container labeling to determine whether it meets EPA's pesticide label requirements. More extensive review is also likely if the request is for a food use of a chemical that does not yet have any registered food uses.

For an unregistered product or a new chemical, your application should include a copy of the Confidential Statement of Formula, and a complete proposed label to be used in conjunction with the exemption use, if authorized. You should also outline provisions for the users to return unused/unopened product to the distributor or manufacturer so that unregistered product is not circulating after the Section 18 authorization expires. Check with the registrant to see if they can provide details for this, or at the very least, ensure they are in agreement with this requirement.

Slide 7

You must also provide a detailed description of the proposed use. It is extremely important that the SLA ensure that key elements of the use pattern requested are clearly stated so that EPA can prepare accurate risk assessments on the requested use.

- Sites to be treated, including the location within the state if available. More detailed information regarding location is helpful for EPA to determine if there are any environmental concerns, such as ground or surface water contamination, or impact to sensitive areas, or endangered or threatened species or their designated critical habitats.
- Method of application. Include any requirements that may be needed for mitigating potential risks from the pesticide, such as for spray drift control, or specialized application equipment to minimize exposure to workers.
- Rate of application to be used. Provide in terms of active ingredient (a.i.) and product. This is typically on a per acre basis, but be sure to specify if other units are used such as square feet or pounds of commodity.

- Maximum number of applications that may be allowed.
- Total proposed acreage or other unit of treatment.
- Total amount of pesticide proposed to be used in terms of a.i. and product.
- Any other application restrictions or requirements that may not be included on the federal label, but are specific to the proposed use. This includes things like worker PPE, a re-entry period, a pre-harvest interval, or feeding restrictions.
- Duration of the proposed use. Provide the desired beginning date and date the program will end. This is very important for EPA to prioritize Section 18 work, particularly if the use season is imminent.
- Earliest possible harvest dates. This information is necessary for EPA to determine the deadline for publishing the tolerance or tolerances in the Federal Register, if needed to support the authorized use.

Slide 8

It is extremely important that you provide a detailed discussion describing the emergency situation. You should include a complete description of the emergency and the potential consequences, along with supporting data. This should include both the common and scientific name of the pest(s), and a discussion of the damage the pest(s) causes.

There should be a clear explanation of the non-routine element or elements that led to the problem. A good way to explain the unusual elements is to provide a clear description of the routine situation as a comparison. Clearly distinguishing between the routine and non-routine situations will also help you determine the best data to demonstrate the severity of the problem. You should clearly state how the situation has changed from previous years and explain why the present situation meets criteria to be deemed an emergency.

One of the biggest problems EPA sees in applications is the lack of explanation as to why the current situation is non-routine. If EPA cannot determine a clear emergency situation based on your application, the review may be delayed. EPA will likely ask you to provide more information to help substantiate your claim of an emergency, and if this can't be done, EPA may simply ask if you would like to withdraw the request.

Slide 9

The type of information to include in this portion of your application depends upon whether the application is for a Specific, a Quarantine, or a Public Health exemption, and the nature of the problem. Examples might include evidence of pest resistance such as documented failure in the field or lab studies showing decreased susceptibility. Scouting reports can validate the presence of new pests or unusually high populations of common pests. Weather data might provide supporting evidence of conditions conducive to pest development. EPA encourages states to be proactive and anticipate where and when problems will emerge. We all know that such predictions can't always be precise, but the more concrete evidence provided, the easier it is for EPA to verify the problem and complete its review.

The following slides will provide more detail on what should be included in this portion of your application for each of the three types of exemptions.

Slide 10

The most common basis for requesting a Specific exemption is expectation of significant economic losses due to the emergency condition. The tiered method EPA uses to determine a significant economic loss is explored in depth in Module 3 of this training. The request must include a discussion of the anticipated significant economic loss, together with data and other information supporting the discussion. When discussing the losses expected, the key point to keep in mind is that you should compare the situation without the presence of the emergency, that is under “routine” circumstances, to the situation expected from the non-routine emergency situation using best available controls.

Slide 11

Your discussion should include information on one or more of the following aspects, as appropriate:

Yield that could reasonably be expected without the emergency condition, contrasted to yield under the emergency.

Losses incurred as a result of the emergency should reflect only the losses that would be expected if growers use the best available means of control, whether registered pesticides or cultural practices. Therefore, you will need to address the available alternatives. We’ll talk about this a bit more in a few slides. Considering any drawbacks to their use, identify the best alternative control pesticide or practice. Loss is estimated by comparing yields or revenue using that alternative in the emergency situation to yields or revenue under routine conditions.

Slide 12

Data comparing the ultimate impacts on yield or revenue are most useful for calculating loss. Keep in mind that efficacy studies measure a pesticide’s effect on the pest using variables other than yield, such as number of insects per plant, number of leaf lesions, percent defoliation, weed density, etc. While this information may be used to support the need for the requested use, it does not usually substantiate potential losses necessary to support the emergency claim, unless the relationship between these variables and yield loss is known.

Prices reasonably anticipated in the absence of the emergency and changes in prices due to the emergency, such as downgrading due to quality losses.

Operating costs reasonably anticipated in the absence of the emergency and additional costs that result from the emergency (for instance, additional pesticide applications or hand weeding).

Any other information explaining the economic consequences of the emergency. Qualitative information can be helpful, but you should strive to quantify the losses as much as possible.

Slide 13

Less commonly, a Specific exemption may be requested on the basis of anticipated risks to endangered or threatened species, or their designated critical habitats, beneficial organisms, or the environment that would be caused by the unusual pest problem. An example of this may include new risks from a disease or predator to the endangered or threatened species.

It should be noted, however, that the Section 18 emergency exemption program is not intended to address risks to the environment or wildlife from currently available pesticide products. If the use of a currently registered pesticide exceeds levels of concern, other processes or sections of FIFRA would be used to address those concerns.

Slide 14

The basis of an emergency to request a Quarantine exemption is the need to prevent the introduction or control the spread of a harmful pest that is an invasive species, or is otherwise new or not widely distributed or established in the U.S. Your application should include the scientific and common name of the pest, the origin of the pest, the means of its introduction or spread, if known, and a thorough explanation of the anticipated impacts of not controlling the pest, including the damage caused.

Not all introduced plants/animals become invasive pests so EPA needs some evidence to support that the introduced organism is actually a pest, whether to agriculture, the environment, or the public.

Slide 15

A Public Health emergency exemption request must explain the “significant risks” to human health. You should describe the pest, including the scientific name and any common names for the pest, and any diseases it may vector.

Explaining the magnitude of the health problems expected without controlling the pest is key to demonstrating the “significance” of the pest problem. The number of people at risk and the range of health symptoms that could occur should be discussed.

The application should also discuss any available medical treatment that might mitigate the health consequences of the pest problem. You might also discuss the costs of such treatment and the capacity of health services to deal with the expected magnitude of the problem.

Slide 16

Now we’re back to considering information needed for all three types of emergency exemption requests. You may have touched upon some of the following information in your discussion of the events leading up the emergency situation, and that’s ok if there is overlap. You just have to be sure you detail the information in your application.

All available alternative registered pesticides or cultural practices must be discussed. A detailed explanation must be given of why alternative methods of control are not adequate to address the situation. This would include, for example, whether the alternative registered pesticides are not effective in controlling the pest or are unsuitable for the emergency situation for other reasons, such as phytotoxicity to the crop or the need for specialized equipment that is not available. Claims of ineffectiveness of the

alternatives must be supported by field data when possible. You should support the emergency claim with the best available scientific data. If such data are not available, statements from qualified experts may be included.

Another reason registered alternative products are not adequate may involve the availability or supply of product. Claims of insufficient availability of the product must be supported by communication with the registrant/supplier of the alternative product(s).

At this point, don't eliminate an alternative on the basis that the growers may view it as "too expensive." This type of information should be included in the explanation of why significant economic losses may occur.

Slide 17

In addition to chemical controls, alternative methods of control also refer to non-chemical means or cultural practices such as mechanical weeding or good field sanitation and equipment practices to prevent spread of a disease. Include a detailed explanation of any alternative practices, if available, and why the practices would be insufficient to address the pest situation, such as inadequate control (especially given unusual pest outbreaks), insufficient resources (particularly labor), or inappropriate for environmental reasons (for example, mechanical weed control may lead to erosion).

Slide 18

The effectiveness of the proposed use also needs to be addressed in the application. Your application should include data, a discussion of efficacy trials, or other evidence supporting the assertion that the proposed pesticide will be effective in dealing with the emergency. Your application must provide a clear discussion supporting the claim that the requested use is one that is well-suited to the situation. Such information should show that it is reasonable to expect that the requested use will avert the negative consequences anticipated if the emergency is not addressed.

Slide 19

If the proposed use is likely to result in residues in food or feed items, you must give estimated maximum residues for all items affected, and provide supporting field trial data or reference data already submitted to the Agency. If you are going to rely on surrogate data from another crop, then you should explain that as well. If any portion of the treated crop will be fed to livestock, you should explain and provide as much information as possible as to secondary residues that might result in meat, milk, eggs, or other animal commodities. EPA does not require residue data for a proposed use on non-food crops (for example, ornamental trees, Christmas trees, etc.).

Slide 20

EPA will conduct the needed human health risk assessments according to Agency guidelines and typically uses human health data on file if it is a registered pesticide. However, your application should address potential risks to human health through dietary and other exposures (such as residential uses), that are anticipated from this use. Additionally, you should address worker risk with any mitigating measures proposed to reduce risks to workers. Provide references to relevant data and any other supporting information.

Slide 21

You should address any known general ecological risks associated with the requested pesticide, such as aquatic toxicity, tendency to leach to groundwater or impacts to non-target plants, animals and pollinators. However, in considering information to address ecological risk, the most critical information to provide is the potential impact to threatened and endangered species, or their designated critical habitats, which must be protected under Federal law. Be certain to discuss any measures to mitigate these risks as well.

You should first check to see whether EPA has completed an ecological assessment for the use you are requesting in another state, or for a generally similar use pattern. Any existing ecological reviews for the requested chemical may help target your own discussion of potential ecological risks to specific habitats and species.

You may search all published regulatory and scientific information on pesticide active ingredients on EPA's website at the chemical search portal. The address is <http://www.epa.gov/pesticides/chemicalsearch>. If you do not find any such information, you should check with EPA's Section 18 Team to see whether such an assessment has recently been conducted.

Slide 22

The most important specific information you should share with EPA, however, is a detailed understanding of the proposed use sites within your state and the potential co-location of endangered or threatened species, or their designated critical habitats. This information is available through State agencies and your local or regional office of the U.S. Fish and Wildlife Service.

In some cases, detailed data may demonstrate that co-location is not an issue, which further expedites EPA's consideration of the request. More detailed information generally means a more realistic and successful EPA review of potential endangered species exposure and impacts, furthering your chances for a successful and faster Section 18 application review. Also, detailed information may enable EPA to better propose measures that will significantly reduce potential impacts.

Slide 23

Detailed information would include:

- Maps of the agricultural treatment area within the state. Make sure the county is given as well as any other available geographic description. Be sure to explain if only a limited treatment area within the larger agricultural area is to be targeted. Focusing on the realistic maximum number of acres is also useful.
- Description of treatment blocks; for example is the block a large contiguous area or is it several widely scattered smaller blocks?
- Identification of listed species in proposed treatment area. Describe habitat in the vicinity of the treatment area. Is it likely to support any identified species? Discuss why or why not. What is the likelihood of co-existence with respect to application timing? Will the chemical affect a food resource of a listed species? If so, what percentage of the diet for the listed species may be affected? Will the chemical affect habitat of a listed species? If so, what is the likely effect?

- Are there any mitigation measures possible that could provide protection, such as buffers, application restrictions, or other precautions? If the species is likely to be present during application, are mitigation measures proposed? Such measures should be in place on the proposed Directions for Use.

It is also valuable to include any endangered species assessments you have received from other qualified agencies. A statement in the application simply stating that there will not be an impact to endangered species is not sufficient. The application should provide the basis for such a conclusion. Failure to include this information will likely lead to a delay in EPA's evaluation of your Section 18 request.

In general, EPA does not need you to provide ecological study information from registrants. This information is usually available to EPA through its registration, reregistration or registration review programs. The most useful information you can provide to EPA is state and county specific information.

Slide 24

If the use is likely to be of interest to other agencies (such as state environmental or U.S. Fish and Wildlife), indicate that you have contacted the appropriate agencies. Include any comments received from other agencies, and indicate that any additional comments received will be forwarded to EPA.

Include acknowledgement by the registrant indicating support of the use, availability of the product, and status of registration of the use or intent to pursue registration.

State the authority you have to enforce the exemption program and include a description of the program for ensuring that use under the exemption will comply with any special requirements imposed.

Slide 25

A Crisis exemption can be considered where a use is urgently sought but there is not adequate time for submission and review of a Specific, Quarantine, or Public Health exemption. This provision could be appropriate if an extension agent or crop advisor discovers a significant pest issue which could not have been planned for or anticipated. A Crisis exemption provides a means by which urgent priority uses can occur after a quick review by EPA. It's a true last ditch safe guard for necessary priority uses under a Section 18. As a reminder, a Crisis exemption cannot be issued for a pesticide that has been suspended or cancelled, that contains a new active ingredient, or that is for the first food use of a pesticide.

If an urgent situation develops, and you are considering a Crisis exemption, it's important to immediately contact EPA to determine whether there are any problems or objections with the proposed use. The best person to start with is the Section 18 Team Leader, but if that person is not immediately available, please phone and email other members of the Section 18 Team or the Registration Division.

The Agency will give these situations priority and will work quickly to give you feedback on the requested use. Further, it's critical and necessary for the SLA to coordinate with and gain prior clearance from EPA for any uses sought as a Crisis exemption.

Once you have communicated to EPA and EPA has no objections to the requested use, you will also have to submit written notification that contains: the identity of contact persons, a description of the proposed use, effective dates for the program (15 day maximum), earliest anticipated harvest date and estimated residues for feed or food uses, a short description of the emergency situation, and a discussion of how the pest issue will be addressed after the 15 day crisis period. It's particularly important to clearly identify the requested use pattern, along with information on the emergency pest situation.

It's possible to convey the nuts and bolts of a Crisis request in just a few pages or even a page. And as a practical suggestion, SLAs are encouraged to e-mail draft and unsigned Crisis proposals to the Section 18 Team Leader for input before formally submitting the action.

Slide 26

Now that we've considered the information that is required in a Section 18 application, let's talk a little more about Section 18 use directions. You can click here to see the EPA's General Guidance for Preparation of Use Directions/Labeling in Connection with Emergency Exemptions.

In most cases, the pesticide product authorized for use under an emergency exemption is already EPA-registered for other uses. It is imperative that the special directions for use and any restrictions or precautions relating to the emergency exemption be available to the user at the time of pesticide application.

You have two options to make sure this happens. First, you can prepare Section 18 use directions for distribution to end users. In some states the registrant may have input into the drafting or may actually draft the Section 18 use directions, and in other cases the state drafts the use directions. You must submit these use directions to EPA as part of the Section 18 application package. It is very important that the Section 18 use directions are consistent with the accepted Section 3 label, EPA's authorization letter for the Section 18 and any additional state requirements. Upon authorization of an exemption, these use directions, combined with the federal product label, provide conditions and restrictions of the use.

The second option is for you to distribute the Section 18 authorization letter you received from EPA that contains the use directions. (This second option may not be applicable in all states.) Either method is acceptable to EPA, though using the stand-alone use directions has become more common. And in either option, the Section 18 pesticide must be shipped bearing the EPA accepted label for that pesticide.

Slide 27

In those unusual cases where it may be possible for EPA to grant an exemption for an unregistered pesticide product, you must submit the proposed label to EPA with the Section 18 application for evaluation. Typically the registrant will assist in this, and may actually provide you with the proposed label. You can refer to EPA's Label Review Manual for a sample label format. While the Section 18 label must follow the format and contain the same elements as labels that are accepted by EPA under Section 3 of FIFRA, the Section 18 labels are evaluated during EPA's review of the Section 18

exemption request but are not considered “stamped and accepted” labels.

The Section 18 use directions for an unregistered product should include a statement instructing the user on how to return unused product to the distributor or manufacturer when the program ends. As mentioned previously in this module, it is a good idea to get input on this from the registrant, or at the very least, ensure they are in agreement with this requirement.

Once authorized, the SLA and the supporting registrant are responsible for ensuring that a full and complete label is attached to the product for shipping purposes, and to make sure the pesticide is used according to the emergency exemption.

Slide 28

It is not unusual for emergency situations to arise that involve the same pest infesting the same crop or other use site at the same time in several different states. Even for such common emergency situations, it is important to remember that emergency exemptions are granted only to individual states, territories, or federal agencies, and each entity must submit a qualifying request to EPA.

Now that electronic communication and data sharing capabilities are universally available, it is easier for states with common emergencies to cooperate in the development of their Section 18 requests. Whereas in the past, each state always prepared and submitted its own full Section 18 requests, it is becoming more common for multi-state emergency situations to be addressed on a coordinated, regional basis. EPA has encouraged states to cooperate in developing “regional” requests where feasible, in order to reduce the duplication of effort in both preparation and review phases of the exemption process.

Slide 29

If an emergency situation involves a large number of states, EPA can assist by identifying one or two states that are in the best position to develop a full Section 18 request. EPA will then recommend to other states with the same emergency that they prepare more streamlined requests that cite the general information in another state’s request, but that provide certain state-specific information (for example, acreage to be treated, threatened/endangered species, analysis of significant economic loss). Recent examples of this type of situation include the exemptions for control of soybean rust in soybeans grown in about 25 different states, and for control of Varroa mites in honeybee colonies located in nearly all 50 states.

In situations involving a small number of adjoining states that often work together to address common emergencies, the SLAs, in consultation with EPA, may agree among themselves to have one state submit a complete request containing information, data, and analyses for all states in the region. The other states participating in regional requests of this type only need to submit a simple letter to “join” the regional request submitted by their neighbor state. Emergencies involving crops grown only in small regions of the country would lend themselves to this type of regional exemption. Examples might include hops, which are commercially grown only in the Pacific Northwest states of Idaho, Oregon, and Washington, and sugarcane grown only in limited areas of the Southeast.

Slide 30

In this module, we reviewed the required elements of a Section 18 application package for submittal to EPA. In the next module, we will take a look at how EPA processes a Section 18 application, the types of reviews conducted by different EPA divisions, how EPA comes to a decision, and what happens once EPA makes that decision.