



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

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

**Module 7**

June 2013

# **PREP's Online Training of the FIFRA Section 18 Emergency Exemption Program: Transcript for Module 7: Repeat Emergency Exemption Requests & Recertifications**

## **Slide 1**

Welcome to Module 7, Repeat Emergency Exemption Requests & Recertifications.

## **Slide 2**

In the last module, we looked at the requirements for recordkeeping during the emergency exemption use, as well as the reporting requirements after the use concludes.

In this part of the training, we'll discuss what to do if the urgent and non-routine situation leading to an emergency condition continues past a single year. Some emergencies that repeat are eligible for a streamlined recertification application process and some are not. By the end of this module, you will understand the criteria to determine which repeat emergency exemptions are eligible for the recertification process and why.

Additionally, you will know what information you will need to submit in your Section 18 recertification application. Recertification means you are confirming that the emergency situation continues to exist, as outlined in a prior exemption request. Recertification does not mean that EPA is automatically reauthorizing the use requested.

The idea, of course, is to reduce the work load for both EPA and the requesting agency and to speed the process when some, if not all aspects of the situation, have been previously agreed upon by everyone.

## **Slide 3**

Let's look at what criteria EPA considers in determining whether an emergency condition may be recertified.

First, the recertification option is available for Specific exemptions only.

Second, EPA must have authorized the same request to the same applicant in the previous year. As a side note, and similar to our discussion of "regional requests" in Module 4, eligibility for, and submittal of, recertification requests is ultimately on a state-by-state basis. Each state must submit a separate request.

Third, the emergency situation must be one that can be expected to continue for more than one year. What does this mean? Examples of continuing emergencies that would be eligible are essentially irreversible events, such as pest resistance, the cancellation of a pesticide, or restrictions on a pesticide's use. These events usually continue into subsequent years and represent a permanent change to the system. If an emergency situation results from such an event, it is likely that the emergency will continue until a permanent solution, such as registration of an effective pesticide, is found.

#### **Slide 4**

Other situations might lie in a gray area. Say a new pest appears. Maybe it moves from a different region or from a different crop. It may not be immediately clear whether this situation represents a permanent expansion of the pest's territory or a permanent change in behavior. If you have any questions about this type of situation, you should discuss it with the Section 18 Team Leader.

An example of an emergency situation that could repeat but is not eligible for the recertification process is one that is more temporary or reversible, such as an urgent and non-routine weather event. A 100-year flood that occurs two years in a row may cause an emergency situation to repeat, but requires a full Section 18 application.

#### **Slide 5**

A fourth eligibility criterion is that EPA has not declared the requested use ineligible for recertification. We'll talk in a few slides about how EPA communicates whether authorized Section 18 requests are eligible or not.

Lastly, the use for which you are requesting recertification cannot be one that requires public notice in the Federal Register. Let's look at what this means.

Even if your situation meets the other eligibility criteria, your situation will not be eligible for recertification if the requested chemical:

- Is a new active ingredient, that is, it is not registered on any other site;
- Is the first time the chemical is used on a food or feed item; or
- Is under Special Review, or is a cancelled or suspended chemical, including those voluntarily cancelled by the registrant.

Because the risks of these chemicals may not be fully understood or could be cause for concern, EPA needs to fully evaluate these cases each year. Additionally, these requests are subject to enhanced public involvement and transparency and, therefore, are subject to public notice and comment. Because these situations require public comment, they are not eligible for recertification.

#### **Slide 6**

We've discussed the criteria for recertification eligibility. Now let's look at the different ways EPA communicates whether a particular situation meets the criteria for recertification.

First, EPA makes a preliminary determination on recertification eligibility for the following year at the time an exemption is authorized. You will get that notice in the authorization for the exemption. If the authorization letter specifies a situation is not eligible or is silent on eligibility for recertification, you may submit additional information to EPA and request them to reconsider their previous decision.

Second, before the usual start of the growing season the Section 18 Team Leader will send out a list of all the exemptions authorized in the previous year, identifying each exemption's eligibility for submission as a recertification request in the upcoming year.

The list is sent by email to every state and federal agency to which a specific exemption was authorized the previous year.

Third, the list is also posted on the EPA's Section 18 web site at the following address: <http://www.epa.gov/opprd001/section18/eligible.htm>. The list also includes a brief description of any conditions that were placed on the exemption's recertification eligibility and it will provide internet links to the authorization letters that provide details on any conditions for submitting a recertification request.

Coming up, we'll describe five basic points you need to certify in a recertification request. Then we'll discuss some additional information that may be needed according to any conditions EPA may have place on the eligibility.

### **Slide 7**

Under the recertification process, you will need to submit a new letter of support from the registrant. You also need to submit the proposed use directions for the coming year. In addition, you must 'certify' five basic points, which basically cite back to the previous, full Section 18 application. We will first talk about the five basic certifications and later we will talk about how to report changes.

First, you will certify that the emergency conditions still exist. In particular, you certify that the nature of the emergency, the urgent and non-routine aspects that we discussed in Module 2, hasn't changed. Remember, the emergency conditions also include the consequences, the significant economic loss or significant risk to the environment, discussed in Modules 2 and 3.

Second, you certify that all the information submitted in the previous year's request is still accurate.

Third, the requested chemical will be used in an identical manner as was previously approved, including the rate, method of application, and any other conditions previously imposed.

Fourth, and a bit redundantly, certify that no new effective control methods have been identified or registered. I say, "Redundantly" because continued significant economic loss or significant risk to the environment (certified in Point 1) is a function of available control measures. However, EPA has noticed that many SLAs don't address recently registered products in repeat requests, so we list this as a separate point.

Fifth, you must certify that you have satisfied any conditions or limitations that EPA placed on the previous year's request regarding eligibility for recertification. We'll talk more about this in a bit.

Now let's expand a little on these recertification points and what you do if you have new information to report.

## **Slide 8**

EPA recognizes that new information concerning repeat emergencies can arise from year to year. So the basic points can be certified, subject to some minor changes. That is, you certify that everything is the same “except for . . . (fill in the blank here).”

Information that may need updating includes the state contact person, any progress or setbacks to registration, new data from residue studies, and any corrections of errors identified in the original request.

Recertification requests are still allowed if there are only minor changes in the proposed use pattern. Examples might include a change in ownership and/or EPA Registration Number of the product to be used, a change in the time period during which use is being proposed, changes in number of applications or application rate, and changes in the acreage to be treated. Let’s say, for example, that the basis of the emergency is resistance to an herbicide and that resistant weeds had been found in a couple of counties. In the following year, resistant weeds are identified in other areas. As a result, you may need to request a larger amount of the herbicide to treat more acres affected by the problem. Of course, you would also submit data or information justifying the need to change the use pattern or expand acreage. Please keep in mind, however, that certain changes to the use may require additional EPA review and may increase the turnaround time for your request.

Another reason to include additional information is that some alternative cultural control method has been identified, or alternative chemicals have become newly registered, for the use site and pest. Because the request is recertifying the existence of the emergency situation, you must describe why the identified alternatives do not provide adequate control of the situation. Note that you may need to conduct and report a new SEL analysis, using the newly registered product as the best response to the emergency. That is, the comparison would be between the non-emergency or usual situation and the emergency situation using the new product. Refer to Module 3 for details of the SEL analysis.

## **Slide 9**

Now to the conditions identified by EPA. Examples of requests for more data may include: more economic data to help with SEL analysis, efficacy data to support the proposed use pattern, or more research data for alternative lower risk chemicals. In such cases, additional data would have to be submitted and explained in the recertification request.

If there are significant changes in the proposed use pattern, you may want to talk to EPA to determine if those changes will necessitate new biological, economic or risk reviews, prior to submitting your recertification request. If you make a significant change, like requesting a different chemical, this will definitely require a full Section 18 application.

There is no established limit on the number of years an exemption is eligible for recertification. However, EPA has the authority to declare that an exemption is no longer eligible at any time. This may occur if the emergency runs for many years and EPA decides it is time to take a new look at the situation. There is a flip side to this, which is an exemption can be declared eligible for recertification after one or more

repeat exemptions with full applications. Remember those gray areas we talked about when discussing what emergencies are eligible? Like a new pest that may or may not become established? EPA may withhold judgment on eligibility at first, but with subsequent applications, and data, be able to determine that the emergency is likely to continue in subsequent years.

### **Slide 10**

Because recertification requests are generally very short letters with a minimum of supporting documentation, EPA may accept these submissions electronically via email, without requiring a hard-copy submission. As discussed previously in this training, first-time and repeat requests that are not recertifications may be submitted by mail or e-mail if all information is available in electronic format, preferably PDF. Electronic submissions are to be sent to the Section 18 Team Leader (and copied to the lead staff reviewer on the Section 18 Team, if known), and should include a request that receipt be acknowledged.

### **Slide 11**

You should be aware that EPA does not automatically approve recertification requests, and that goes for repeat requests submitted as a full application. EPA has an ongoing commitment to evaluate ALL requests to ensure that they meet the criteria for an emergency and that public health and environmental safety are not adversely affected. As with all Section 18 requests, EPA will authorize the recertification request only if no reasonable and effective alternatives have become available and adequate progress toward registration of the proposed use is still being made. Reviews of recertification requests also involve ensuring that the previous health and environmental risk assessments remain valid. In other words, recertification streamlines the SLA's work, but EPA's job remains the same.

However, given that recertification generally only requires EPA to review past assessments, not conduct new assessments, the review can frequently be expedited. While the Agency has a standard expectation that reviews of first-time requests will require at least 50 days, reviews of recertification requests do not usually require as much time.

Soon after EPA adopted the regulations for the recertification process, a work group within SFIREG (State FIFRA Issues Research and Evaluation Group) developed a template for a recertification request. This template may be downloaded from the AAPCO (Association of American Pesticide Control Officials) web site or just click on the link on your screen.

### **Slide 12**

In this module, we looked at the criteria EPA uses to determine which repeat emergencies are eligible for the recertification process and why. And we examined what you will need to submit for an emergency exemption request that qualifies for recertification.

In the next (and final) module, you will have an opportunity to review the major concepts from this training course through a series of interactive exercises.