



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

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

**Module 5**

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## **PREP's Online Training of the FIFRA Section 18 Emergency Exemption Program: Transcript for Module 5: The Review and Decision Process: A Look Inside EPA**

### **Slide 1**

Welcome to Module 5, The Review and Decision Process: A Look Inside EPA.

### **Slide 2**

Up until this point, we've talked about emergency conditions that must be met, and information and data that must be submitted to support a robust Section 18 exemption application to EPA. Well, let's suppose an application package has been completed and submitted by a state - what happens next?

Join us as we follow an exemption application from its arrival at EPA, through the review process, and finally to the decision made by EPA. After you complete this module, you will understand how EPA processes a Section 18 application, the types of reviews conducted by different EPA divisions, how EPA comes to a decision and how EPA notifies the SLA of the decision.

### **Slide 3**

Let's briefly review the overall process from the beginning, using the SLA as the one who is submitting the Section 18 application. SLAs should send applications in as early as possible, and for most requests, EPA tries to process the request in approximately 50 calendar days.

Once the SLA has put together a robust application with all the necessary documentation, the SLA has a choice of either mailing a hard copy and/or emailing the file(s) to the EPA Section 18 Team Leader. This may change to electronic-only submissions in the future.

For electronic submissions, the SLA must submit the complete package and all attachments in PDF or MS Word format since other formats may delay processing (EPA prefers the PDF format). Once you have submitted the application, it's a good idea to follow up with a phone call to the Section 18 Team Leader to ensure that the Team Leader received the submission and all applicable files.

### **Slide 4**

The first thing to happen with your application is that the Section 18 Team Leader assigns it to a lead staff reviewer on the Section 18 Team, who coordinates the entire review and decision process.

We'll talk intermittently about the role of the lead staff reviewer, but the first job of the lead reviewer is to decide if EPA must publish a Notice of Receipt in the Federal Register for the Section 18 request. Notice is required for certain types of requests, such as for new chemicals, first food uses, repeat uses that are not adequately moving toward registrations, or uses that are of higher concern, to allow a 15-day public

comment period. The complete criteria requiring publication are found at 40 CFR 166.24.

The reviewer also ensures that the SLA has included all required information and will contact the SLA to address any missing information. The lead staff reviewer then determines the science reviews necessary to process your package and sends the application information onto the appropriate divisions in EPA. From there, the lead staff reviewer coordinates closely with the science divisions and facilitates communications between the reviewers and the SLA to address questions raised, additional information requests, or deficiencies. Open dialog between EPA and the SLA early in the process is particularly important to determine whether there is additional information the SLA can submit to support deficiencies in the Section 18 application.

### **Slide 5**

So your application is now making its way through EPA for review. EPA evaluates the application as a team, with different divisions taking on different roles. The lead staff reviewer sends all Section 18 requests that involve conventional pesticides to the Biological and Economic Analysis Division (BEAD), the Health Effects Division (HED) and the Environmental Fate and Effects Division (EFED) for specific types of concurrent reviews that we'll look at more closely in a minute. If the request is for an antimicrobial or biological pesticide, the lead staff reviewer will work with the Antimicrobial Division (AD) or the Biopesticides and Pollution Prevention Division (BPPD), as appropriate, to obtain the needed reviews.

If the application is not complete, the reviewers in each division may contact the SLA for additional information, or work with the lead staff reviewer to obtain the necessary information.

Let's take a closer look at each division's review process, beginning first with BEAD's role.

### **Slide 6**

Upon arrival in BEAD, BEAD assigns the application to a biologist and an economist. These reviewers work together to review the description of the emergency, the crop, pest, and other descriptive information, and for Specific exemptions, any yield or quality loss data submitted with the package. Sometimes efficacy data are available and considered. The BEAD review determines if the situation meets the criteria for urgent and non-routine; and if the request is for a Specific exemption, whether claims of yield and quality losses are reasonable, and whether the situation will result in significant economic loss. (There is detailed information concerning these criteria in Modules 2 and 3).

In certain situations, it may be necessary for the BEAD reviewers to meet with the Section 18 Team and/or the SLA (via phone conference) to discuss the emergency exemption situation. In these cases, BEAD considers any new information provided and may revise their review if appropriate.

The BEAD reviewers write up their findings and submit the document to the Product Review Panel (PRP). The PRP is an internal group of biologists and economists in BEAD which reviews the document for scientific accuracy and clarity. The lead staff reviewer often participates in the PRP meeting. The BEAD reviewers may revise the document at this point to reflect any comments. Once the document is final, BEAD returns it to the lead staff reviewer on the Section 18 Team.

### **Slide 7**

Meanwhile, HED has assigned your application to a review team, usually a chemist and a toxicologist, to determine if EPA can make the necessary safety findings with respect to human exposure. If a pesticide is used on food commodities (which means there is dietary exposure), HED must make a safety finding that there is a “reasonable certainty of no harm” to human health as required by the Food Quality Protection Act. If there is only non-dietary and occupational exposures (that is, the pesticide is not used on food commodities), the FIFRA standard of “no unreasonable adverse effects” to human health or the environment must be met.

In order to make these determinations, HED looks at all potential routes of exposure by doing a dietary, non-dietary (residential, for example), as well as an occupational risk assessment. HED calculates the potential dietary exposure using potential maximum residue levels in food and drinking water. EFED provides drinking water residue estimates to HED for use in the dietary assessment, if data are not already available. HED calculates non-dietary risk of exposure to non-food uses, such as residential, ornamental, pet or public use areas. And HED calculates occupational risk based on inhalation and dermal exposure to workers.

### **Slide 8**

All of these risk estimates are also based upon available toxicology data, usually from animal studies, with appropriate conversion and uncertainty factors to extrapolate to estimated human toxicity.

If the requested use is on a food commodity, HED determines a maximum allowable limit for residues of the pesticide on the commodity, and uses this to establish a “tolerance”. The tolerance is a legal limit set for enforcement purposes that clears use of the registered pesticide on the crop site faced with an emergency pest issue. If residue levels higher than the tolerance are discovered, it may indicate the pesticide was not used lawfully according to the labeled use directions. An investigation may be conducted to determine if misuse occurred, and the crop may be subject to seizure.

For emergency exemptions under Section 18, the tolerance will be time-limited and published with an expiration date because Section 18 uses are also time-limited. The expiration date can be extended as needed, if exemptions are authorized in subsequent years.

When completed, HED sends its assessment back to the lead staff reviewer in the Section 18 Team.

### **Slide 9**

Now let's take a look at what's going on EFED. EFED considers what happens to the pesticide in the environment, including things like how long it persists, how it breaks down and the toxicity of its degradates, and the potential for surface and groundwater contamination. As we said earlier, EFED provides HED with potential pesticide residue levels in drinking water, if the data are not already available, for use in HED's assessment of dietary exposure and risk.

EFED also evaluates toxicity data for a broad range of representative animal and plant species, both terrestrial and aquatic. Combining the fate of the chemical in the environment, which determines the potential for exposure, with the toxicity of the pesticide, is how EFED derives the risk estimates to non-target terrestrial and aquatic animals and plants. This includes risks to beneficial organisms such as honey bees and other pollinators, and federally-listed endangered and threatened species, and their habitats.

Remember there was some suggested information in Module 4 regarding threatened and endangered species that you should include in your application. It is important to note that the Endangered Species Act requires all federal agencies, including EPA, to ensure that their regulatory actions, in this case allowing a pesticide use, do not jeopardize federally-listed endangered and threatened species or their habitat. EPA must take this into consideration as they evaluate the scope of potential use and whether additional restrictions or mitigations will be needed.

After the Section 18 Team receives EFED's completed review, the Section 18 Team may talk with the SLA and the registrant about measures to reduce adverse impacts to non-target species. These may include: narrowing the number of counties where the pesticide is used in order to avoid impacting endangered species habitat; prohibiting certain application methods and adding buffer zones to reduce exposure to sensitive species; and limiting the number of applications or reducing the rate of application to reduce adverse impacts.

### **Slide 10**

We just finished going over what happens in the review process with BEAD, HED, and EFED, which have a role in the review of all Section 18 requests for conventional agricultural pesticides. The lead staff reviewer may involve AD if the requested pesticide is an antimicrobial, or BPPD if the requested pesticide is a biological. These divisions may provide the needed reviews, or they may work with BEAD, HED and EFED to evaluate the requested use.

### **Slide 11**

After receiving the necessary internal science reviews for the requested use, the ball is back in the court of the lead staff reviewer and the Section 18 Team. At this point, the lead staff reviewer evaluates the science reviews from BEAD, HED, EFED and possibly AD or BPPD, depending upon the material involved in the request.

In addition, if the science divisions recommend restrictions or use conditions to mitigate risks, the lead reviewer coordinates with the SLA to ensure these conditions can be smoothly implemented and enforced.

The lead staff reviewer compiles the relevant information into an internal decision memorandum to inform management and make a recommendation for a decision on the request. Let's take a look at the potential outcomes for an application.

### **Slide 12**

If the SLA clearly demonstrated that an emergency condition exists, and EPA can make the human health and environmental safety findings, then the lead staff reviewer will transmit an approval letter to the SLA once it is signed. We'll talk more on this outcome in a minute.

If EPA cannot make such a clear determination, and requires additional information to clarify, the lead staff reviewer will contact the SLA to discuss these findings. At this point and depending upon what's deficient about the request, the lead staff reviewer may also discuss whether the SLA and its cooperators are able to respond to the questions or possible deficiency. If so, the revised application could be reconsidered by EPA. But if the SLA cannot respond to the deficiencies, other options could be considered such as an agreement to withdraw the request on the basis that a fully responsive application was not developed.

If the situation does not meet the emergency criteria of a Section 18, or if there are risk issues identified, and the SLA does not wish to withdraw the request, the reviewer will draft correspondence to the SLA informing them of EPA's decision to deny the request, and outline the basis for this decision. All denials must be signed by the OPP Office Director.

### **Slide 13**

If a Section 18 request is on track for approval, and if it is for a repeat use, there are a couple of more questions the Section 18 Team needs to answer. First off, in the case of a Specific exemption or Public Health exemption, is the requested use making "adequate progress toward registration"? The term adequate progress is defined in 40 CFR 166.25(b)(2)(ii). Generally, an application for registration must be submitted after 3 years for registrant-supported uses and after 5 years for IR-4 supported uses. However, there may be, and often are, special circumstances beyond anyone's control that delay submission, so this isn't always a hard and fast rule.

EPA will also confirm that the original safety findings for the repeat use are still valid. Another consideration for a repeat application is whether EPA has requested, and the SLA has provided, follow-up data to address questions or uncertainties regarding the emergency, such as data on yield and economic losses, pest pressures, or the feasibility of alternative registered pesticides. Finally, EPA must receive an interim or final report for the previously authorized Section 18 before reissuing an emergency use for another growing season.

If all these considerations point toward EPA approval of the SLA's request, the Section 18 Team will prepare an internal decision memorandum and an authorization letter to the SLA for management concurrence and signature. EPA's current process for both first-time Section 18s and for long-running 18s, where progress toward registration has become an issue, is to request signature by the OPP Director. Applications for repeat uses with no such issues are usually signed by the Director for the Registration Division.

#### **Slide 14**

EPA sends the signed letter by email to the SLA authorizing use under Section 18 of FIFRA. EPA trivia warning: some Section 18 "old timers" refer to these letters as "telegrams", since at one point in EPA's long Section 18 history the EPA actually sent these letters via Western Union Telegram!

Often EPA's authorization allows use of a stand-alone document with use directions prepared by the registrant, or in some cases SLAs, which is sometimes referred to as a Section 18 "label". That document must be consistent with the signed EPA letter authorizing the emergency use. EPA guidance for drafting these stand-alone documents is available by clicking on the box marked "Section 18 Label Guidance". Unless the Section 18 is a rare case involving an unregistered product, both the authorization letter and any stand-alone use directions direct readers to the approved label for the federally registered product. Users must follow those directions as well unless they are superseded by EPA's Section 18 authorization.

This concludes the EPA's review process. Now that EPA has approved your Section 18 exemption, it's time for you to take whatever procedures are in place at the SLA to notify all affected parties of the approval, and to ensure the approved chemical is available and used properly. Procedures will vary from state to state, but generally the SLA will: review the authorization letter, make sure directions for use comply with the authorization letter and are available, notify technical experts who will do outreach, work with registrants and dealers to ensure the pesticide is available, and finally ensure the pesticide is being used properly.

#### **Slide 15**

Before we leave this module, let's look at some examples that illustrate some potential problem areas that may cause EPA to deny, or SLAs to withdraw, Section 18 applications.

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The first example is that EPA cannot make a human health safety finding for the requested use. You've heard it before, "the risk cup is full". This means that the requested pesticide has existing uses where the estimated risks are already high enough that no further risk can be added without exceeding EPA's level of concern. If

the pesticide results in dietary exposures, EPA must add together or aggregate the risks from all possible routes of exposure, including dietary (food and drinking water) and any dermal, oral or inhalation that results from non-occupational (that is, usually residential) exposures. In these cases, it's usually young children that are of greatest concern.

### **Slide 17**

Another common problem in making a safety finding is for a pesticide that is a member of a chemical class that shares a common mode of toxicity, such as cholinesterase inhibition (which causes over firing of the nervous system). These chemicals must be assessed as a group. That is, in addition to assessing all routes of exposure for an individual pesticide (the aggregate assessment), EPA must also add together the exposures from all the single pesticide assessments for the chemicals in that class. This is called a cumulative assessment. The allowable estimated risks for some of these chemical classes may not allow room for additional risks from new uses. So, even if the addition of a use for a single pesticide in that class doesn't result in risks of concern for that individual pesticide, it could result in additional risk that exceeds the allowable risk level when exposures to all the chemicals of that class are added together cumulatively. The risk cup is full again.

### **Slide 18**

A second example of why EPA may not approve a Section 18 is that the requested pesticide use presents ecological risks of concern, particularly those that, in addition to their toxicity, are persistent or bioaccumulative. The combination of these chemical characteristics means that pesticide exposure and effects to non-target species will continue long after the requested use, and may magnify with subsequent use of the pesticide, both in the directly contacted species, and in the food chain.

### **Slide 19**

A third example of why a Section 18 cannot be authorized is that EPA cannot determine whether the emergency claim is supported, based upon available information. This means that the SLA has not adequately substantiated the claim of an emergency situation. Even though the requested use meets the human health and ecological safety criteria, it must still meet the emergency conditions as defined by the Section 18 regulations to qualify. The common biological and economic reasons that applications fail to meet the "urgent and non-routine" criteria for an emergency condition were discussed earlier in the course. Briefly, Section 18 requests for agricultural uses that are denied are frequently unable to identify a non-routine event that relates to increased pest pressure. An example of a non-routine event is a confirmed surge in the pest due to biological or weather related conditions. Other factors, such as market conditions that are unrelated to pest pressures do not constitute an urgent and non-routine situation under FIFRA.

### **Slide 20**

Finally, another common problem is using the incorrect comparison to demonstrate significant economic loss for Specific exemption requests. Growers are naturally

tempted to look at their current situation without the requested pesticide compared to how much better their yields would be (maybe up to 20%) if they had a Section 18 for that pesticide. The correct comparison, however, is the yield before the emergency event and the yield after that event assuming the grower has used the best available registered product to control the pest problem. A metaphor for the correct Section 18 mindset is “holding the fort” against pillaging as opposed to trying to build up the supplies to expand the fort. EPA may not grant exemptions for the purpose of increasing yield above normal, or income to offset losses resulting from other causes, such as foreign competition.

### **Slide 21**

In this module, we examined what happens to a state’s application once it is completed and submitted to EPA, the types of reviews conducted by different EPA divisions, and what happens once EPA makes a decision. Finally, we looked at common reasons for denying some Section 18 emergency requests.

In the next module, we will look at the reporting and record keeping requirements under a Section 18 emergency exemption.