



US Environmental Protection Agency Office of Pesticide Programs

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

Module 1: A Critical Pest Situation Develops

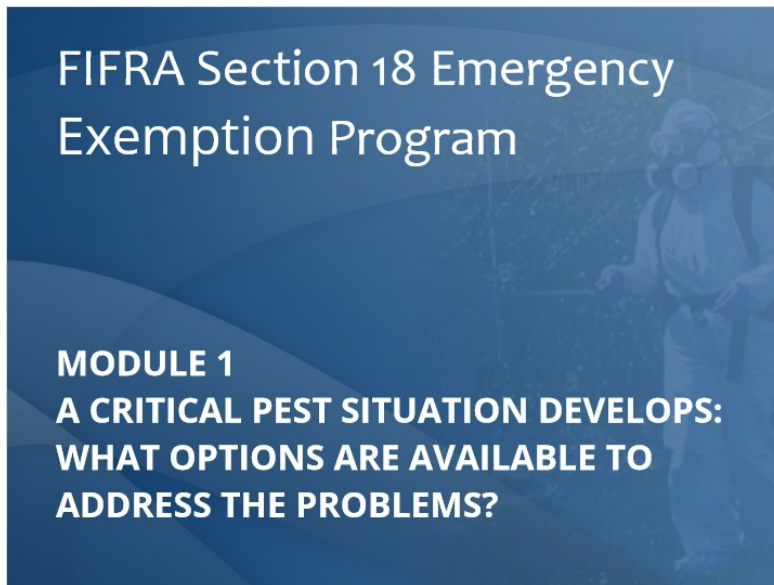
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Module 1: Critical Pest Situation Develops

1. Module 1

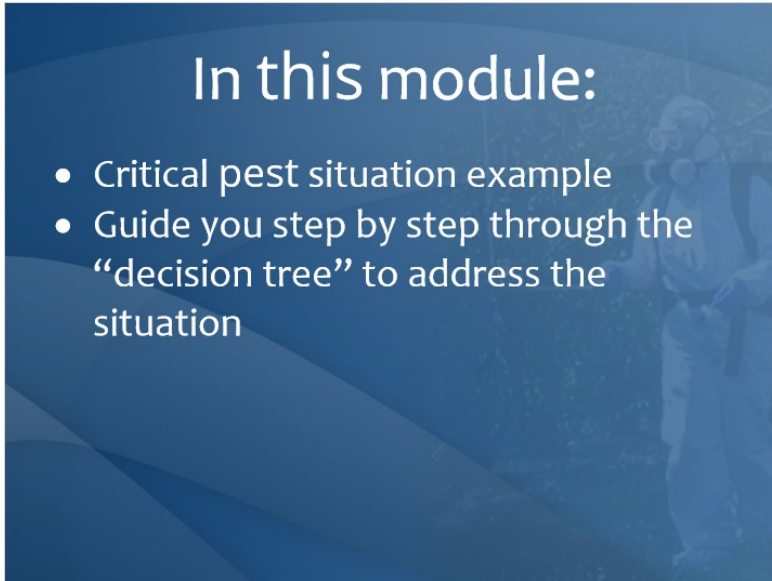
1.1 Welcome



Notes:

Welcome to Module 1, A Critical Pest Situation Develops: What Options Are Available to Address the Problem?

1.2 In this module:



In this module:

- Critical pest situation example
- Guide you step by step through the “decision tree” to address the situation

Notes:

This module will assume a critical pest situation and take you step by step through a “decision tree” that asks various questions you need to consider in order to determine how best to address the situation under FIFRA. Keep in mind that individual states will also be working within the bounds of varying state laws and procedures.

1.3 We will cover:



We will cover:

- Section 3 registration process
- Section 2(ee) recommendation
- Section 24(c) special local needs registration
- Section 18 emergency exemption

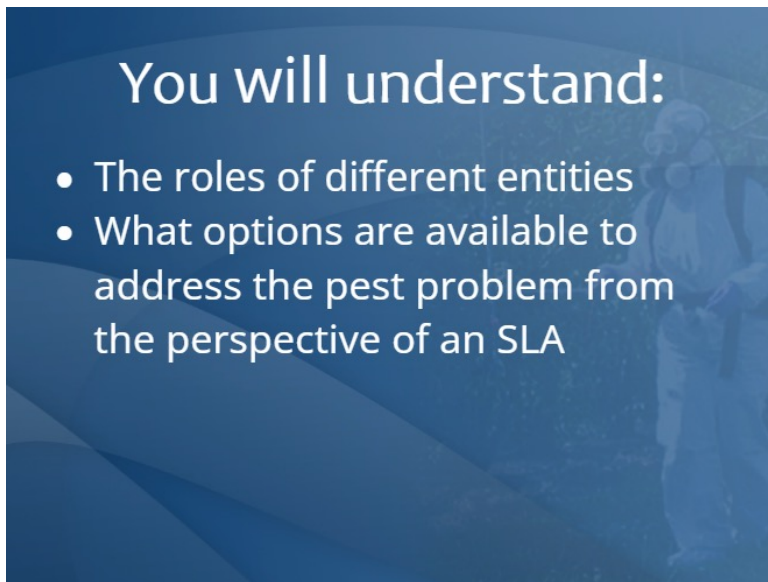
Notes:

The possible resolutions, or “tools”, we will cover are the Section 3 registration process, a Section 2(ee) recommendation, a Section 24(c) special local needs registration and the Section 18 emergency exemption process. The decision tree was created to capture common scenarios. Unique or rare situations might not fit squarely in the decision tree and would need to be looked at on a case-by-case basis, probably in consultation with EPA’s Section 18 Team.

1.4 You will understand

You will understand:

- The roles of different entities
- What options are available to address the pest problem from the perspective of an SLA



You will understand:
Let’s get started!

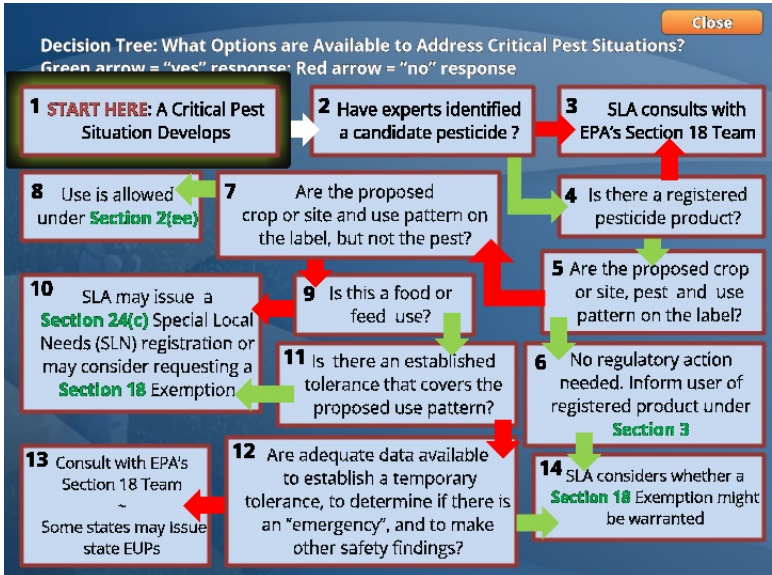
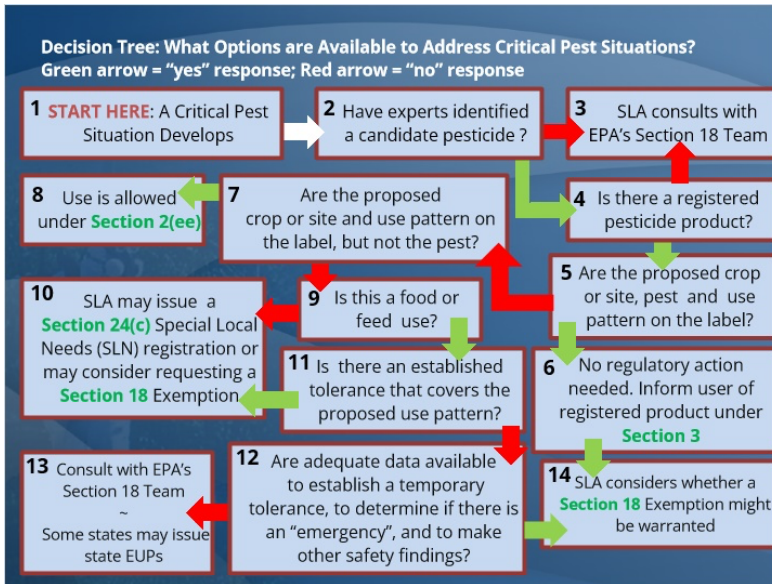


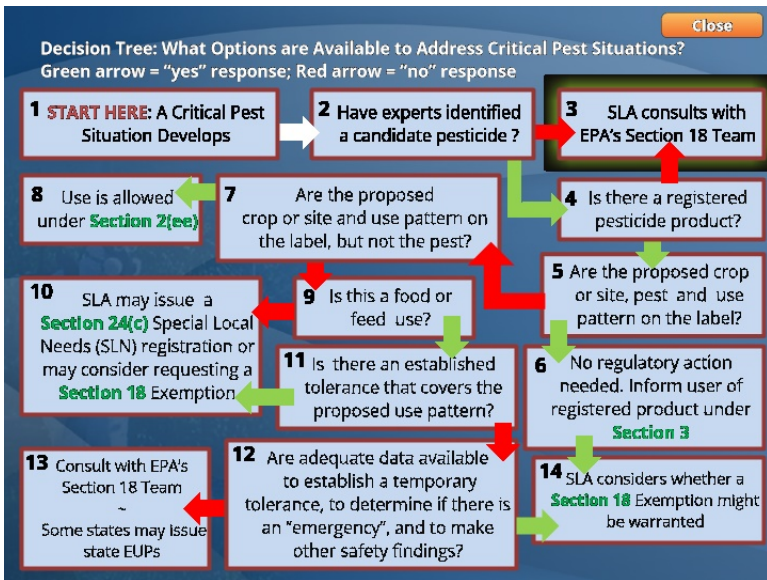
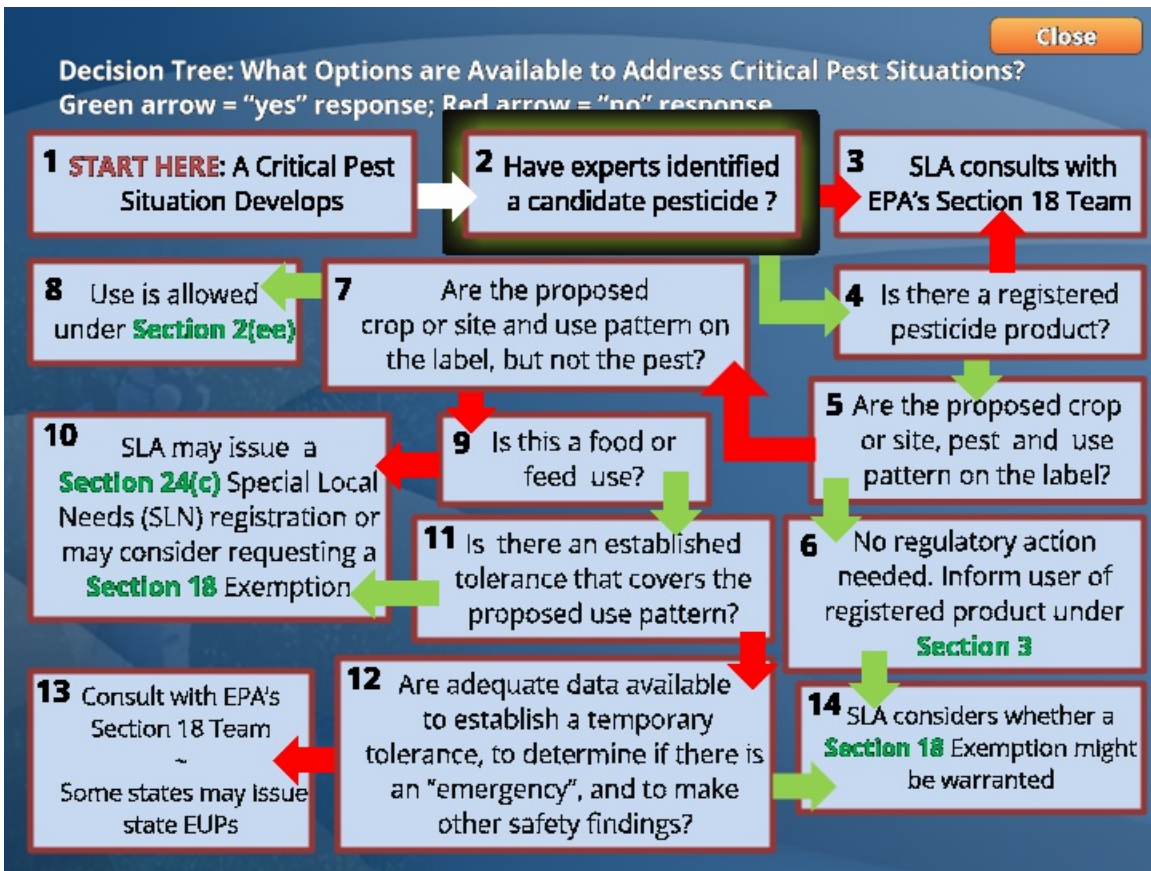
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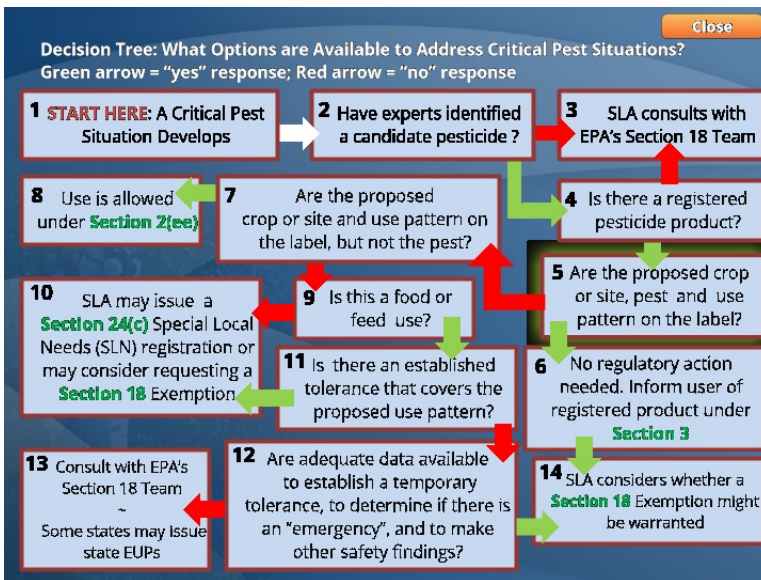
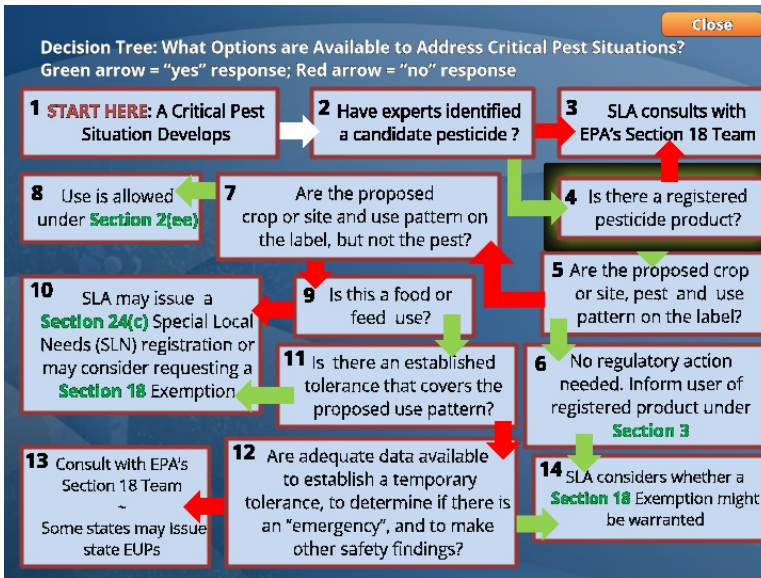
After you complete this module, you will have a better understanding of the roles of different people/organizations who respond to critical pest situations and what options are available to address the pest problem from the perspective of an SLA.

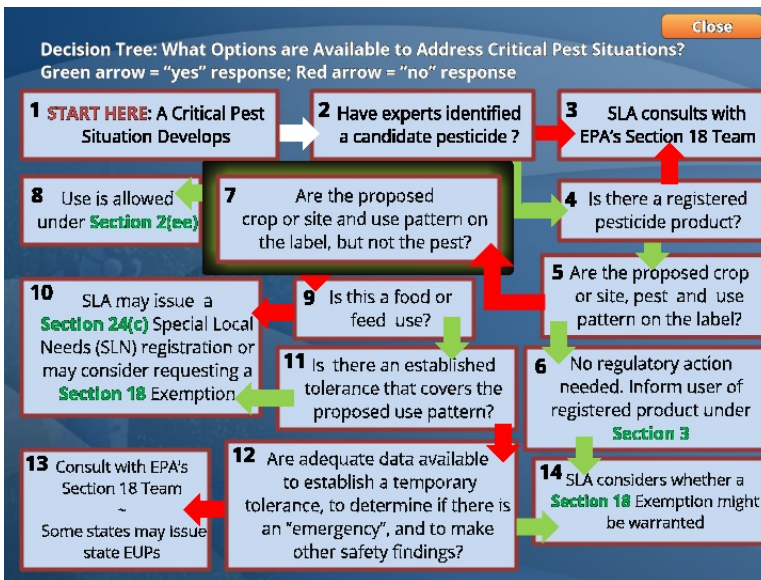
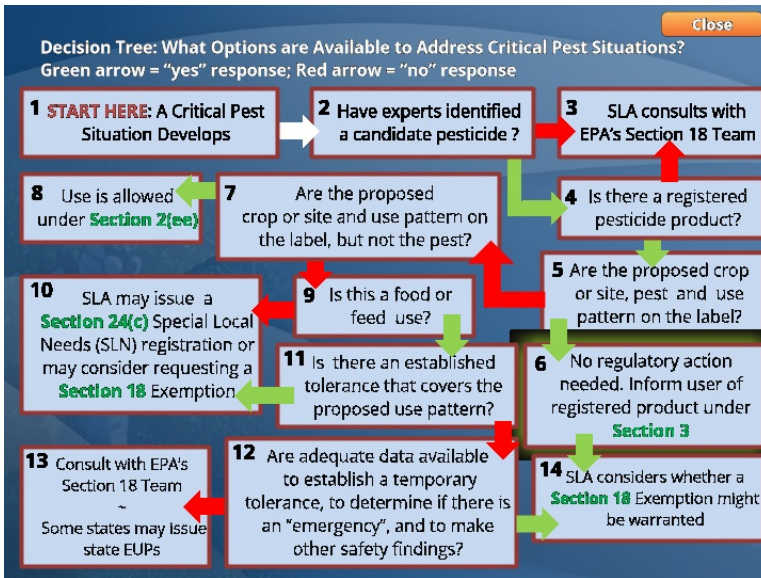
So let's get started.

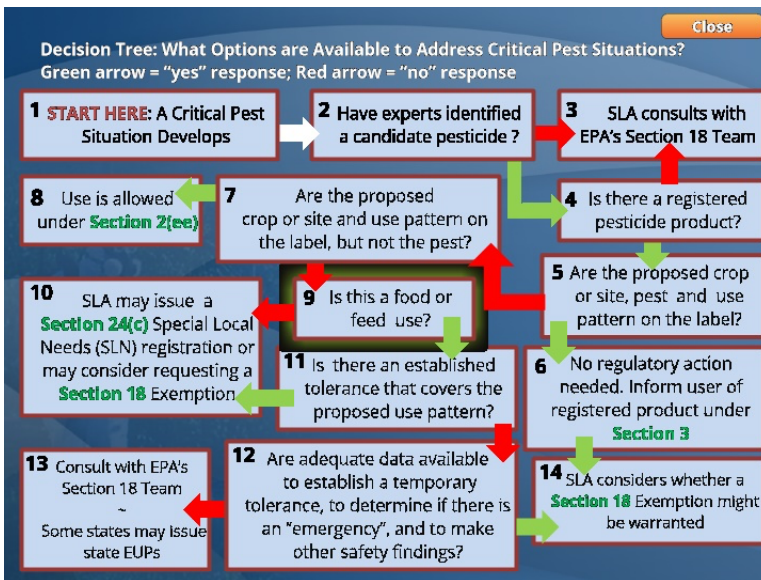
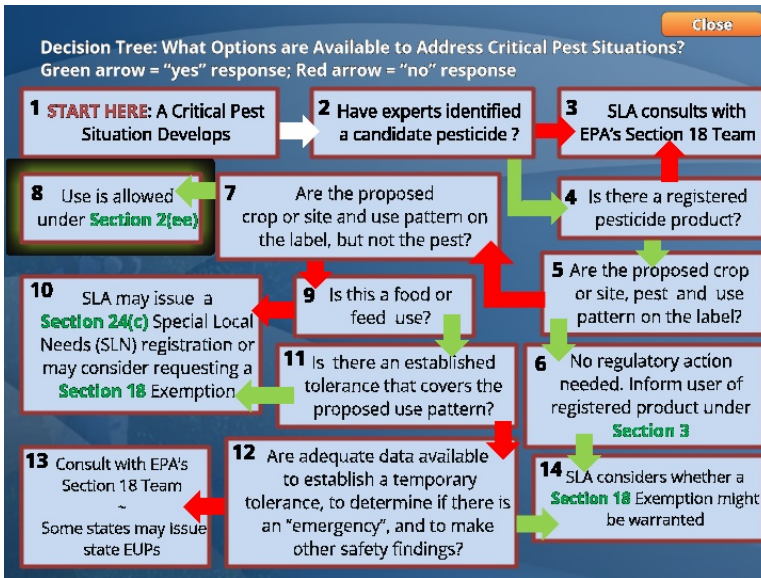
1.5 Decision Tree

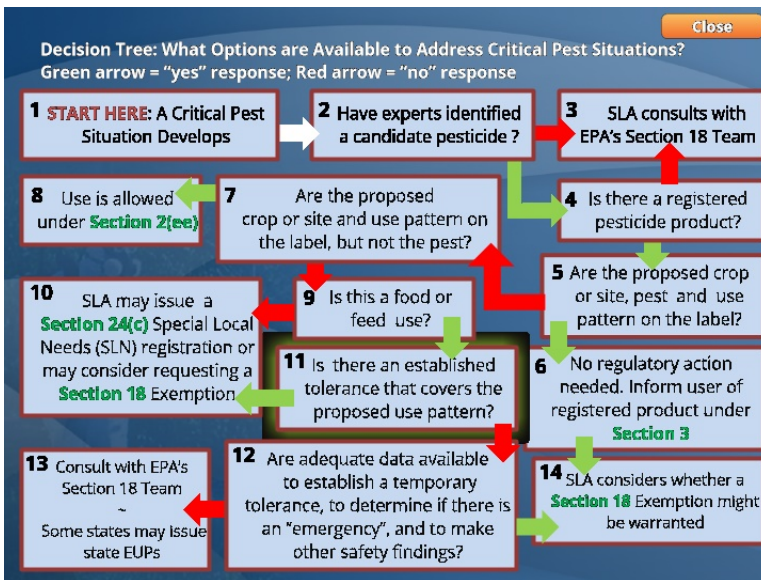
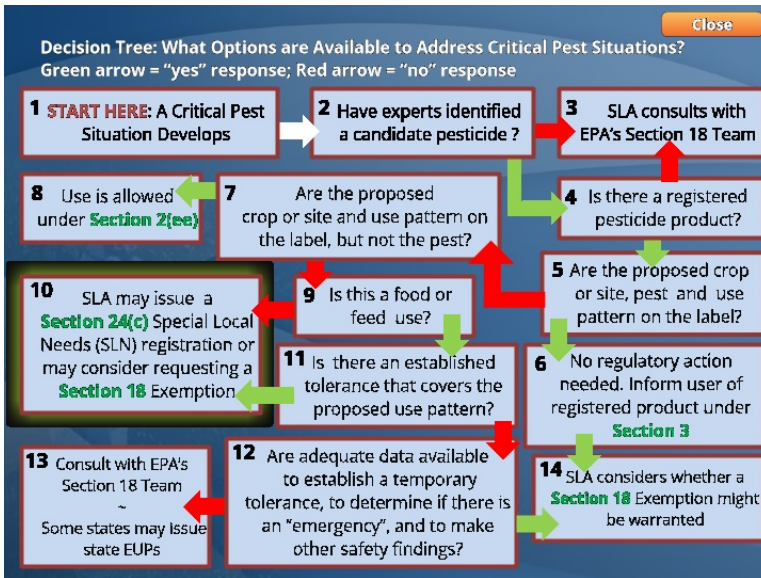


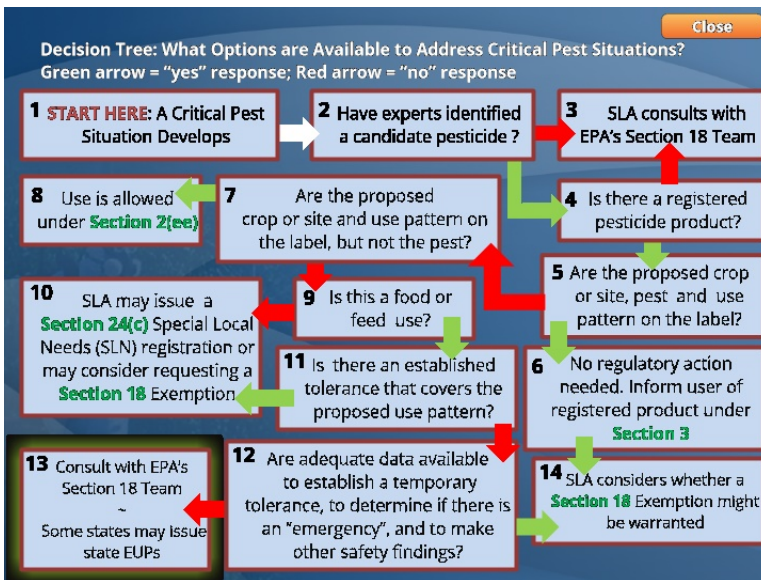
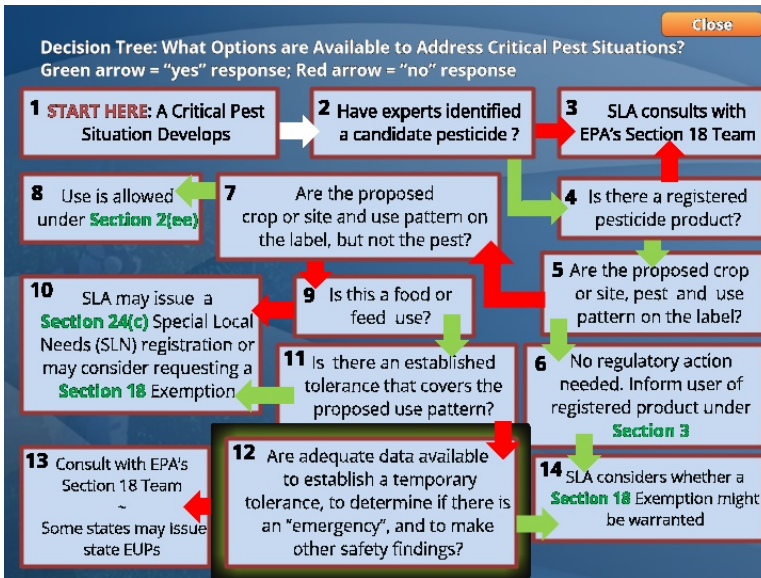


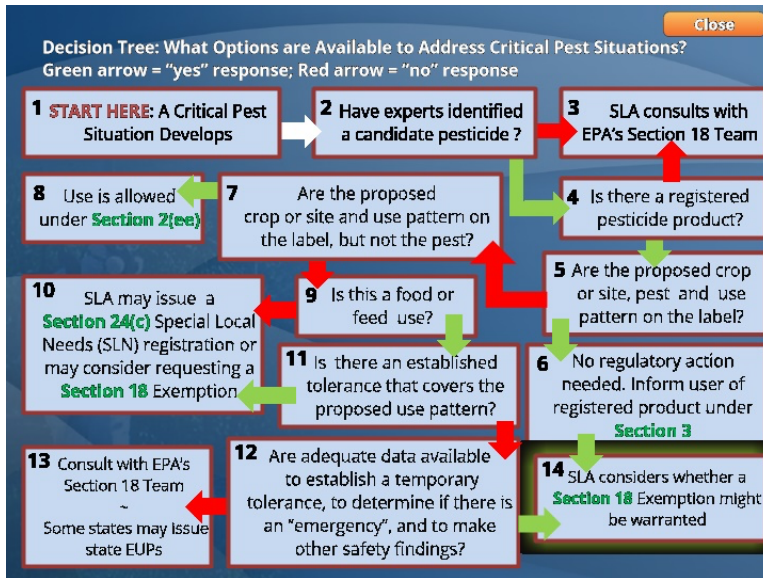












Notes:

Click a box on the decision tree to see more information about that action. We recommend you go in numerical order.

Box 1

Since their everyday activities, and their livelihoods, revolve around the control of pests, growers will frequently be the first to notice when a problem develops. Some of the more common types of critical pest situations affecting growers include:

- A pest that has developed resistance to pesticides that have previously controlled it;
- Introduction of a new pest where available pesticides are insufficient to manage it, either due to lack of products labeled for the needed application site or due to lack of efficacy;
- Loss of registered products, or uses of products, due to regulatory changes such as the cancellation of registered uses of older pesticides; or
- Those caused by unusual weather conditions.

Growers may not be the only source of information on emerging pest concerns. For example, what if people were becoming ill because a new pest was causing disease and that pest was not listed on existing pesticide labels? It is likely that SLAs, state health agencies, and university researchers would be flooded with calls from citizens, pest control operators and others looking for ways to control the pest.

So what are growers, producers, grower organizations or others likely to do if they are faced with what they believe is a critical pest situation? They seek help, many times by contacting university cooperative extension agents. They may also reach out to their state government, and if they are familiar with the system may directly contact the SLA.

Box 2

University extension agents and researchers usually have the expertise and knowledge needed to review effective choices and make recommendations for the control of pests. Registrants are also a source of information concerning product use, labeling, environmental properties and potential hazards. On occasion, the expertise may reside in a government agency or other non-university organization. Wherever the knowledge exists, if stakeholders contact SLAs directly, the SLA will typically identify and contact appropriate experts who can determine if there is a pesticide available to address the critical pest situation.

The identified pesticide may be a registered pesticide, or extension agents and researchers may be aware of potential tools still under development and not registered for that use. We'll come back to how university extension

agents/researchers can assist the SLA later in this decision tree if the path leads you to a Section 24(c) registration or a Section 18 emergency exemption.

Box 3

If the experts cannot identify a candidate pesticide to address the problem, or have identified an unregistered pesticide, it would be wise at this point to call EPA, more specifically the Section 18 Team, to determine possible solutions to the pest problem. EPA personnel may be aware of existing products, or new products or uses in the registration process that the state may not know about. EPA will also be a valuable source to determine the suitability of a product for a proposed use and may be aware of Agency actions or assessments that may affect the success of a Section 18 application.

In certain situations contacting EPA is required. One of the options available to SLAs under the Section 18 program is the issuance of a Crisis exemption. We will cover the different types of Section 18s, including Crisis exemptions, in much greater detail in Module 2. It is worth noting at this point that before SLAs can issue a Crisis, the regulations at 40 CFR 166.40 require them to contact EPA and obtain verbal confirmation that, for food uses, the Agency will be able to establish a tolerance or tolerance exemption in a timely manner, and that the Agency has no other objections.

Box 4

If the extension agents or researchers identify a federally registered pesticide that can effectively address the pest problem, there are more questions that need to be answered to determine if and how that product can be used. Again, if the product identified is not federally registered, the SLA should consult with EPA's Section 18 Team.

Box 5

The first question you want to answer regarding the registered pesticide that has been recommended to address your critical pest situation is, "Are the proposed crop/site, pest and use pattern on the label?" And in your search to answer this question, remember to check Section 3 and supplemental labels, as well as Section 24(c) labels. If the answer to all three parts of the question is yes, then it appears you have a federally registered product under FIFRA Section 3 or 24(c) that fits your needs, the ideal outcome.

Box 6

After the SLA has identified a federally registered product that can be used, the SLA will need to ensure this product is registered for use in their state. The SLA can inform the user of the good news and no further regulatory action is needed. For more information on the requirements of Section 3 or 24(c), click on the resources button at the top of the page.

Box 7

If both the proposed crop/site and the proposed use pattern are on the label of a federally registered pesticide, but the pest that is the subject of your situation is not on the label, this scenario most likely can be addressed under FIFRA Section 2(ee).

Box 8

Section 2(ee) of FIFRA describes special circumstances for the use of a pesticide in a manner for which it is not specifically labeled, and this scenario is one of them. Though not required by FIFRA, the registrant of the product may produce a FIFRA Section 2(ee) recommendation bulletin and may also request EPA to add the pest to the Section 3 label. It's important to note that some states may have additional data requirements prior to the use of Section 2(ee), or may not allow the use of 2(ee) in their state. In this instance, Section 2(ee) would not be available to growers/applicators in that state and the remaining options include the Section 24(c) registration or the Section 18 program. For more information on the requirements of Section 2(ee), click on the resources button at the top of the page.

Box 9

If the proposed crop/site and/or use pattern are not on the label ask yourself if the crop/site can be used for human or animal food. If the answer is yes, you will want to check to see if the required tolerance or tolerance exemption

exists for that crop/site and use pattern by checking 40 CFR 180. As an aside, EPA establishes tolerances or can exempt the pesticide from needing a tolerance. A tolerance is the maximum residue level allowed on a food or feed commodity. If residues above this level are found, the commodity is considered adulterated by the Food and Drug Administration and may have to be destroyed to make sure it doesn't enter the food supply.

Box 10

If the site is not a food or feed crop, and the product proposed has other federally registered uses, OR if the site is a food or feed crop, AND a residue tolerance has been established that covers the proposed use pattern, the SLA may consider issuing a Section 24(c) registration. Section 24(c) registrations, also known as Special Local Need (SLN) registrations, are state-specific registrations that address existing or imminent pest problems.

The EPA encourages SLAs to consult with EPA on whether to issue a 24(c), especially in circumstances where the product is not federally registered, or whether to pursue a Section 18 exemption. Section 18 exemptions are only for situations that can demonstrate that an emergency condition exists.

For more information on the requirements of Section 24(c)s and a comparison for how they differ from Section 18s, click on the resources button at the top of the page.

Boxes 11 and 12

So what if the candidate pesticide you identified isn't registered for the needed food or feed use, and doesn't have a tolerance or tolerance exemption for the food/feed crop where the pest problem exists? You will definitely want to confer with EPA's Section 18 Team to determine whether there are adequate data available for EPA to set a time-limited tolerance, to determine if an "emergency" exists and to make the other necessary safety findings (like occupational and environmental safety) that would be needed for a Section 18.

Box 13

If data critical for EPA to make any of the necessary safety findings are missing, the candidate pesticide isn't going to be available in the short term and you will need to look for other options. It is worth mentioning here that some states in the country have the ability to issue state experimental use permits (either under FIFRA - see 40 CFR 172, Subpart B, or state law) or other research type permits/registrations to generate missing data to support a 24(c) registration. The permits could be used, for example, to measure residue on foliage or evaluate efficacious rates and usage patterns. In contrast, a federal experimental use permit is not an option for generating data in the short term to address a critical pest situation, but rather is used to support the Section 3 registration process.

Box 14

If EPA indicates that data are available to set a temporary tolerance, there are other factors to consider. You will need to consider the circumstances of the pest problem you are facing, and whether there are sufficient data to demonstrate that emergency conditions exist and the other necessary safety findings can be made. If so, a Section 18 emergency exemption may be the most appropriate route for you to pursue.


You will find that your friends in extension and research will be critical for documenting the history, nature, and extent of the pest emergency, the lack of available effective alternatives, and uncovering any evidence of resistance development. The extension service and researchers will also prove helpful in collecting data that demonstrate the economic consequences of the critical pest situation, demonstrate the effectiveness of a proposed pesticide, and/or demonstrate residue levels in support of a tolerance. These experts can be crucial in helping make the case that there is a critical need for the proposed product/use.

1.6 Up Next

Up Next:
Section 18 Emergency Exemption Program

Objectives:

- Understand how the emergency exemption program works
- Information needed to submit to EPA for justifying Section 18



Notes:

It's now time to delve into the Section 18 emergency exemption program. We hope that after taking this training, you'll understand how the emergency exemption program works and what information you will need to submit to EPA in order to justify an emergency exemption.