



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

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

Module 8

June 2013

PREP's Online Training of the FIFRA Section 18 Emergency Exemption Program: Transcript for Module 8: Interactive Review of Training Concepts

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Welcome to Module 8, an interactive review of concepts from this training course.

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In this final module you will examine five different scenarios to help reinforce your understanding of some major concepts presented in Modules one through seven. These concepts are: choosing the appropriate path for registration or exemption; determining if the problem is "urgent and non-routine"; identifying the elements to consider in an analysis of "significant economic loss"; and identifying whether the request is eligible for recertification.

So let's take a look at a handful of situations to see how well you can apply what you've learned.

As you answer the questions for each scenario, click your best answer first and consider the feedback. But we encourage you to go back and select the other responses to learn more. We've added some navigation boxes to help you.

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Teff is a small grain that has been cultivated on relatively few acres for many years. Recently, demand for teff has increased because it is gluten-free. Typically, teff is cultivated as part of a rotation and depends on relatively clean fields that are mechanically tilled. Production is limited by weed infestations and some weed species have developed resistance to herbicides commonly used in rotational crops. There are no herbicides registered on teff.

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Could this problem qualify for a Section 18 exemption?

- Yes.** If a case is to be made, more information will be needed. On the face of it, there is not a non-routine situation. It may be problematic if there are no registered herbicides, especially if growers want to increase production, but it is not a new situation for teff growers. Herbicide resistance isn't relevant if there were never any registered herbicides. And Section 18s are not to be used to expand acreage.
- No.** No, this would probably not qualify for a Section 18 exemption because there doesn't seem to be a non-routine situation. If there aren't registered herbicides, resistance wouldn't change the production system. And Section 18s are not to be used to expand acreage.

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While there isn't anything registered for use on teff, the local research/extension program identifies an effective unregistered product that has a tolerance for teff.

What is the best available path to address this problem?

Section 18. Probably not. For this situation to qualify for a Section 18, something about it must meet the criterion of "non-routine."

Section 3. This would be a viable (but not best) option, if the registrant is willing to submit an application and provide any required data. It's not a short-term solution, however.

Section 24(c)/SLN. This may be the best option. Depending on the state, either the stakeholders (teff producers) or the registrant could petition the SLA. Some additional data may be required – which could necessitate an Experimental Use Permit (EUP). After review by the SLA, a 24(c) registration could be issued.

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Spring came early for basil producers and resulted in wet and warm conditions, which are perfect for downy mildew. There are two registered fungicides for use on basil to control downy mildew. One is limited to only one application per year and the other can be applied up to four times per year, but no more than twice in a row. Typically, growers make four applications each year, at about two-week intervals. This year, high fungal pressure and a longer growing season will mean most growers will need six or seven fungicide applications. Lack of season-long control will result in yield loss of more than 30%.

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Could this problem qualify for a Section 18 exemption?

Yes. Yes, this problem could more than likely qualify for a Section 18 exemption. The unusual weather conditions, which lead to higher-than-normal pest pressure, make this a non-routine situation. Of course, you will also have to document the extent of losses to show "Significant Economic Loss." That means providing evidence of yield loss to support the SEL claim.

No. Don't rule this out just yet as it could qualify for a Section 18 exemption. You have to make sure you have a complete application which documents that the emergency conditions exist.

Let's say there's another fungicide registered for use on basil but it does not list downy mildew on the label. However, the research/extension program knows that the product provides reasonable control.

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What action can the SLA take to address this problem?

Section 18. This may seem like an option because the situation is clearly “non-routine”. However, since the fungicide is already registered under FIFRA on basil, an emergency exemption would not be appropriate. Use under Section 2(ee) would be a more likely option. If the SLA doesn’t recognize 2(ee), then a 24(c) may be the appropriate avenue.

Section 24(c)/SLN. This is probably not the best use of resources, at least not immediately. The product is already registered on basil. However, if the registrant doesn’t want to put downy mildew on the Section 3 label, and the SLA does not recognize 2(ee), then a 24(c) registration might be the way to go.

Section 2(ee). This could be the best option. The SLA could contact the registrant and, if appropriate efficacy data are available, request that a 2(ee) bulletin be issued that provides recommended rates and instructions. However, a bulletin is not a requirement for use under 2(ee).

If the SLA does not recognize 2(ee) then a 24(c) may be the best option.

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Suppose there aren’t any fungicides registered for use on basil. There’s a fungicide registered for use on other crops, however, and research indicates excellent control against downy mildew. There’s no existing tolerance for this fungicide on basil.

Is the SLA ready to submit a Section 18 request?

Yes. Well, you are certainly close, but you should confirm a couple of things before starting work. First, you need to confirm that the registrant will support the use. Second, you need to confirm that residue data have been developed and can be submitted to EPA to establish a temporary tolerance.

No. Good answer! You are almost there, but you should confirm a couple of things before starting work. First, you need to confirm that the registrant will support the use. Second, you need to confirm that residue data have been developed and can be submitted to EPA to establish a temporary tolerance.

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Would this Section 18 be eligible for recertification next year?

Yes. Not so much. Remember, to be eligible, the emergency must be the kind that is likely to continue into the future. This emergency is based on unusual weather conditions and those conditions aren’t likely to happen again. They might, of course. If that happens, the SLA could certainly make a repeat request, but a complete application would need to be submitted.

- No.** Right! To be eligible, the emergency must be the kind that is likely to continue into the future. This emergency is based on unusual weather conditions and those conditions aren't likely to happen again. They might, of course. If that happens, the SLA could certainly make a repeat request, but a complete application would need to be submitted.

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Growers of sweet corn for seed have typically relied upon Insecticide X to control several species of mites, especially the two-spotted spider mite. However, EPA recently increased the Restricted Entry Interval (REI) on the insecticide from seven days to 13 days. The longer REI interferes with some crucial worker activities, especially scouting for and removing tassels to control hybridization, so many growers can no longer use the insecticide. Other registered insecticides include Insecticide Y, and Insecticide Z. Insecticide Y is limited to a single application, which typically targets caterpillar pests, and Insecticide Z is associated with higher mite populations later in the season, probably because it kills insects that prey on mites. Uncontrolled mites result in shorter ears, undeveloped ears, and even barren plants. Among the seeds that are produced, there is a higher proportion of poor quality, lower weight seeds that must be removed.

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Is this an urgent and non-routine problem?

- Yes.** It sure is! The regulatory change is something new to the system. Uncontrolled mites cause immediate damage and other registered pesticides are not available that will address the issue, at least not without causing other problems (caterpillars or more mites). You will have to demonstrate that losses expected from this situation will meet the 'significant economic loss' requirement.
- No.** You don't think so? Remember, "urgent" means problems occur more or less immediately and uncontrolled mites result in lower yields (smaller, undeveloped, or non-existent ears) this cropping season. And "non-routine" means something has happened to change the system. The longer REI on the typically used pesticide is definitely a change to the system. There are other registered products available, but they have problems as well. It is true that you would need to determine how severe the problems are before concluding that there is an Emergency Condition.

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When growers approached the extension service, the extension agent quickly determined that the registered insecticides could not be used to address the mite problems. The extension agent knew that the registrant of Insecticide D was pursuing a Section 3 registration for mite control so much of the data needed for safety findings would be available. Before submitting a Section 18 request, however, the SLA needs to do an analysis to see if the situation meets the threshold for 'significant economic loss.'

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What is the appropriate comparison to determine if there is a 'significant economic loss'?

Yields with and without Insecticide D, the requested chemical. Nope! This is a common mistake. Comparisons with the requested chemical show how much the problem can be mitigated, but it doesn't tell you how bad the problem is. And it can appear that the request is seeking to improve yields and revenues, which is not the purpose of Section 18.

Yields with and without Insecticide X, the typically used chemical. Yes! You might be surprised at how many applications get that wrong! Comparing yields with and without Insecticide X, which was the standard before the regulatory change, demonstrates how bad the problem is. That is what you want to show if you are going to justify using an emergency exemption.

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Suppose yield losses are determined to be around 10% due to the mite problems.

What can we conclude from this information?

There is no 'significant economic loss' (SEL). Not quite. It's true that the Tier 1 threshold for SEL is a 20% yield loss, which this case does not reach. However, Tier 1 is only a screening level analysis. At a screening level, we can't find that there is SEL in this case, but neither can we say that there is not SEL. We'll need to conduct further analysis. If you remember, there are also quality problems with mite infestations (for example, lower weight seeds). There may also be higher costs associated with removing poor quality seeds. We can consider those problems, and compare the consequences to gross revenue at Tier 2 and, if necessary, to net operating revenue at Tier 3.

No conclusion is possible. Yes! It's true that the Tier 1 threshold for SEL is a 20% yield loss, which this case does not reach. However, Tier 1 is only a screening level analysis. At a screening level, we can't find that there is SEL in this case, but neither can we say that there is not SEL. We'll need to conduct further analysis. If you remember, there are also quality problems with mite infestations (for example, lower weight seeds). There may also be higher costs associated with removing poor quality seeds. We can consider those problems, and compare the consequences to gross revenue at Tier 2 and, if necessary, to net operating revenue at Tier 3.

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The SLA is able to document SEL, given yield and quality loss, and EPA approves the request. Growers rejoice.

What's left for the SLA and other stakeholders to do?

Nothing! The ordeal is over. If only! At a minimum, you'll need to collect information for the final report on how much of Insecticide D, the requested chemical, was used and how many acres were treated.

Start preparing next year's application package. Probably. But it may not be so bad. This situation is likely to be eligible for 'recertification' because the change in regulations for Insecticide X, the chemical previously used, represents a permanent change to the system. And because it's permanent, growers will have the same problem next year unless a Section 3 is obtained before the next season. And don't forget that your application or recertification request will need to include your report on use of Insecticide D, the chemical used under Section 18.

Collect the information needed for final report. Definitely! This information, including the amount of Insecticide D that was used and how many acres were treated, is important for a number of reasons. One reason is to properly track the performance of the Section 18 program to show its value at budget time! It's necessary whether or not you will make the same request next year.

Confirm that the request is eligible for recertification and identify any conditions or requirements. Probably. This situation is likely to be eligible for 'recertification' because the change in regulations for Insecticide X, the chemical previously used, represents a permanent change to the system. And because it's permanent, growers will have the same problem next year unless a Section 3 is obtained before the next season. However, EPA may have some conditions or questions that you will need to address and that might require you to generate some data during this use season. For example, EPA may want data to confirm the level of low quality seed in mite-infested fields and that might require some trials. And don't forget that your application or recertification request will need to include your report on use of Insecticide D, the chemical used in the Section 18.

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Hydrilla is a non-native aquatic plant. It is extremely hardy and can grow quickly in favorable conditions. This year, your state is facing unusually high densities of hydrilla in several water bodies within state parks. The rapidly growing hydrilla have overwhelmed the usual control methods, a combination of physical removal and the Herbicide A. Researchers are testing for resistance to Herbicide A, but it has not been confirmed. The hydrilla forms thick mats that block sunlight from reaching native aquatic plant species and interfere with recreational activities including boating and swimming, which are the primary uses for the affected water bodies.

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Is this situation urgent and non-routine?

- Yes.** Correct! Something out of the ordinary seems to be going on, even if resistance has not been confirmed. It's nice to know what is underlying the problem, but that's not always possible in unexpected situations and shouldn't be a block to obtaining a Section 18. Further, the consequences of the problem are immediate, so the situation is urgent.
- No.** You don't think so? Something out of the ordinary seems to be going on, even if resistance has not been confirmed. It's nice to know what is underlying the problem, but that's not always possible in unexpected situations and shouldn't be a block to obtaining a Section 18. Further, the consequences of the problem are immediate, so the situation is urgent. So this situation would meet the first criterion for a Section 18 emergency exemption.

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In addition to Herbicide A, the research/extension service identifies several other registered herbicides that list hydrilla on the label. Data show that these other herbicides are efficacious against hydrilla.

Should the SLA pursue a Section 18 request?

- No. There are registered herbicides to address the problem.** You could be correct. However, just because a pesticide is effective doesn't necessarily mean it's appropriate for this situation. There may be reasons that these chemicals can't be used or they may be so expensive that you would still incur "significant economic loss" with their use.
- Yes. Let EPA be the bad guy and turn down the request.** That may be the correct answer, but it isn't a good reason! You may still want to pursue the Section 18 if the registered alternatives are not appropriate for this particular situation. There may be reasons that these chemicals can't be used or they may be so expensive that you would still incur "significant economic loss" with their use.
- Maybe. The registered herbicides might not address this problem.** Correct! Just because a pesticide is effective doesn't necessarily mean it's appropriate for any situation. There may be reasons that these chemicals can't be used or they may be so expensive that you would still incur "significant economic loss" with their use.

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Let's suppose that the registered alternatives are inappropriate for use in this situation. Maybe they are broad spectrum herbicides and you don't want to kill all the plants in the lakes. In fact, one of the native aquatic plants that can be crowded out by the hydrilla is an endangered species. Meanwhile, complaints from boaters and recreational fishermen about the water quality are three times higher this year than last.

What type of Section 18 request should the SLA pursue?

Specific. The SLA will need to show that the hydrilla is causing significant economic loss – and the increase in complaints show that there's a significant loss of value to users of the park. Good answer! The other Specific answer is a good response as well. SEL does not have to be measured via the tiered approach where you show yield loss or price impacts or cost increases. The regulations allow you the flexibility to demonstrate other ways that a pest problem results in loss, including losses in capital assets or in non-market goods and services like recreational activities.

Specific. The hydrilla poses a significant risk to an endangered species. Good answer! The other Specific answer is a good response as well. Yes, a Specific exemption is appropriate when a pesticide is needed to address a significant risk to endangered or threatened species, or their designated critical habitats, beneficial organisms, or the environment.

Quarantine. The hydrilla is an invasive species. Possibly! Just because a pest is “invasive” doesn't necessarily mean it's harmful. Typically, a Quarantine exemption is used to keep harmful invasive pests from establishing themselves or spreading further, not to control them once they are present.

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OK, here's one final scenario to consider before you can graduate...

Onion growers have typically relied upon three insecticides for the control of onion maggots, which can be very damaging to emerging seedlings. Two of the insecticides are applied to the soil just prior to seedling emergence. The third is a seed treatment. Onion maggots are notorious for developing resistance and extension personnel recommend that growers alternate among the available insecticides, even though the seed treatment is somewhat more effective. Nonetheless, onion maggots have developed resistance to one of the pre-emergent pesticides and resistance to the other pre-emergent pesticide is feared. If growers rely solely on the seed treatment, selection pressure will likely encourage resistance to it as well. Researchers identify a new seed treatment that belongs to a different chemical class and has a different mode of action. There is no tolerance established for onion for this new insecticide, but there are residue data.

Is this situation urgent and non-routine?

Yes. No, not really. This is a hard one, in a number of ways. True, the development of resistance is not routine (even if the pest has a propensity to develop resistance). However, an effective alternative remains. Thus, it is hard to see that there will be any immediate damages. The possibility, however strong, that resistance will develop in the future is not a basis for a Section 18. EPA has thought about this carefully on a number of occasions and decided that it did not fit with the purpose of FIFRA. There

are other options, like a Section 3 or a 24(c) that should be pursued and hopefully issued before the problem becomes urgent.

No. Correct! This is a really difficult one, but given that an effective alternative can be used, there aren't immediate damages. EPA has thought about this carefully on a number of occasions and decided that it did not fit with the purpose of FIFRA. There are other options, like a Section 3 or a 24(c) that can be pursued and hopefully issued before the problem becomes urgent.

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That's it, you're done! This concludes Module 8, an interactive review of concepts from this training course on the requirements and use of the Section 18 Emergency Exemption program.

If you have further questions or comments about this training, please submit your questions/comments to this email address: section18training@epa.gov.