

Chapter 5

Supplemental Labeling

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Section 5.1

FIFRA Section 24(c) Special Local Needs

Interprets FAC section 12973; 3 CCR section 6000; and 40 CFR part 162.152

Background

To address a pest situation that a FIFRA section 3 (normally registered) product cannot mitigate, DPR, under the authority of FIFRA section 24(c) and 40 CFR part 162.152, may register a new end-use product or an additional use of a federally-registered pesticide product, provided there is a special local need within the state and the following conditions exist:

- The use is covered by the necessary tolerances or exemption from tolerance if the pesticide is used on a food or feed commodity.
- Registration for the same use has not been previously denied, disapproved, suspended, or cancelled by U.S. EPA, or voluntarily cancelled by the registrant.
- The pesticide does not contain a new active ingredient not registered by U.S. EPA.
- There is no other federally-registered pesticide for the specific use or no federally-registered product available to address the special local need.

A special local need may address a new pest, method or timing of application, different use rate, new crop/use site, and Integrated Pest Management in certain crops.

Two types of registrations under section 24(c)

There are two types of special local need (SLN) registrations:

1. A first-party SLN in which the applicant is the manufacturer of the pesticide (most commonly issued by the manufacturer as product bulletins).
2. A third-party SLN in which the applicant is someone other than the manufacturer, such as a grower, grower association, or UC extension (issued by DPR in an SLN format). Both are subject to the same limitations regarding residue tolerance, cancellation, etc.

SLN registrations are product-specific and must be in possession of the user at the time of application.

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FIFRA Section 24(c) Special Local Needs, Continued

Information regarding special local need registrations

The following items must be submitted by the applicant in order for the SLN application to be processed:

- The California *Request for a Special Local Need Registration (SLN)*, section 24(c) form
- Efficacy and phytotoxicity data to support the SLN use pattern
- For a first-party SLN, six copies of the proposed labeling that addresses the SLN use pattern. Third-party SLN labeling is developed from the State application form.
- A letter of authorization from the manufacturer of the pesticide supporting the use of their product as an SLN
- A U.S. EPA SLN form (Form 8570-25, rev. 1/94), *Application for/Notification of State Registration of a Pesticide to Meet a Special Local Need*, filled out and signed

Detailed letters or documentation from experts, such as UC Farm Advisors or UC Extension Specialists, demonstrating the SLN pesticide/use pattern has been shown to address an existing or imminent pest problem and no federally-registered pesticide product is sufficiently available.

Dealer responsibility for current SLN labeling

Pest control dealers act as quasi-agents of the registrant in the distribution of pesticide products. As such, they are expected to distribute current labeling. 3 CCR section 6301 provides a two-year “window” for the dealer to continue distribution of unregistered products. However, dealers are expected to distribute only current supplemental labeling regardless of when they placed the product into their inventory. When SLNs are amended, the dealer is responsible for obtaining and distributing the most current version of the labeling.

Continued use after inactivation of SLN

Material purchased by the end user under a valid SLN may continue to be applied pursuant to that use, after the SLN is inactivated or the product has been deleted from an active SLN, only until that specific amount of stock has been exhausted. Any material purchased after the inactivation date cannot be used pursuant to the SLN. If uses are not in compliance with the parameters of the SLN, then a use in conflict with the registered labeling has occurred. However, any state or U.S. EPA suspension action would supersede this approval.

Section 5.2

FIFRA Section 18 Emergency Exemption

Interprets FAC sections 12973 and 12833; 3 CCR sections 6000 and 6206; and 40 CFR part 166

Background

FIFRA section 18 grants U.S. EPA the authority to authorize any federal or State agency to allow the use of a pesticide without registration for a limited time, if U.S. EPA determines that emergency conditions exist. The regulations governing FIFRA section 18 (found at 40 CFR part 166) define *Emergency Condition* as an urgent, non-routine situation that requires the use of a pesticide(s). Such uses are often referred to as "emergency exemptions," "section 18s," or simply "exemptions."

The issuance of a section 18 is not the same as the issuance of a product license (registration). A section 18 exemption allows for the time-limited use of a pesticide product (registered or unregistered) to control an urgent, non-routine pest problem.

An applicant for a section 18 must be someone other than the product registrant. Examples include farm advisors, county agricultural commissioners, grower groups, etc. Once the application has been reviewed by DPR, the request is forwarded to U.S. EPA for final approval or denial.

It is DPR's position that all materials used under an emergency exemption program should be applied using the best available pest control methods and technology. These may include pest population monitoring, treatment thresholds, methods of application designed to reduce environmental contamination, and limitations to mitigate effects on nontarget organisms. When feasible methods and technologies are available, their use will be required for application under the exemption.

Any pesticide used under an emergency exemption is automatically a restricted material [3 CCR section 6400(b)] and requires a restricted material permit.

Product uses issued under section 18 cannot be advertised unless criteria outlined in 40 CFR part 168.22 are met.

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FIFRA Section 18 Emergency Exemption, Continued

Deviations from labeling not allowed

U.S. EPA considers section 18s exemptions from labeling rather than supplemental labeling, and therefore, users are not allowed the deviations from labeling requirements granted in *3 CCR section 6000 (Conflict with Labeling)*. Any deviation from a section 18 would be considered a violation of permit conditions under *FAC section 12973*. A pesticide must be used in compliance with all section 18 requirements, including rate, concentration, method, timing, and target pest.

U.S. EPA has given DPR permission to add the following standard language, allowing tank mixing of section 18 materials:

- Tank mixing with other compatible pesticides, spray adjuvants and fertilizers is allowed as long as all labeling and regulation requirements are met and tank mixing is not otherwise prohibited.
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Tolerances - time limited

Emergency exemptions are often requested for food uses for which no tolerance or exemption from tolerance has already been established. Food uses with existing residue tolerances or exemption from the requirement of a tolerance would be processed under FIFRA section 24(c) as an SLN. If the emergency use involves the treatment of a food crop, U.S. EPA will establish a temporary tolerance (maximum allowable residue levels) to cover any pesticide residues that may result. These are usually granted for two to three years.

Tolerances - regional

U.S. EPA has informed us that from an enforcement standpoint, regional tolerances are no different from national tolerances and the FDA and DPR would not consider any commodity with residues below a regional tolerance in violation, no matter where the commodity was grown.¹

The regional tolerance is a guide for government agencies to use for placing area use limitations on product labeling, including SLNs.

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¹ April 9, 1990 letter quoting Hoyt Jamerson, U.S. EPA, Office of Pesticide Programs.

FIFRA Section 18 Emergency Exemption, Continued

Section 18 - four types of emergency exemptions

The federal regulations adopted for section 18 provide for **four** types of emergency exemptions:

1. Specific exemption
 2. Public health exemption
 3. Quarantine exemption
 4. Crisis exemption
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1. Specific exemption

- Majority of requests are for specific exemptions
 - Requested when an emergency condition exists, in order to avert a significant economic loss or a significant risk to endangered or threatened species, beneficial organisms, or the environment
 - Growers or agricultural research scientists identify a pest situation which registered pesticides cannot control
 - Growers request their State lead agency (DPR) to request an emergency exemption from U.S. EPA
 - U.S. EPA evaluates request and decides whether or not to authorize use
 - Specific exemptions may be authorized for up to one year
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2. Public health exemption

- Requested to control a pest that will cause significant risk to human health
 - "Emergency" based upon the potential for a pest to be a vector for disease that possess risk to human health
 - Public health exemptions may be authorized for up to one year
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3. Quarantine exemption

- Requested to prevent the introduction or spread of an invasive pest species not previously known to occur in the United States
 - "Emergency" rests on the potential of an invasive species to cause a significant economic loss
 - U.S. EPA may issue the quarantine exemption directly to a federal agency, such as U.S.D.A.
 - Quarantine exemptions may be authorized for up to three years
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FIFRA Section 18 Emergency Exemption, Continued

4. Crisis exemption

- Immediate need for a specific, quarantine, or public health exemption. Applicant may request the crisis exemption with an already-submitted specific, quarantine, or public health emergency exemption request. This procedure allows the use to begin while U.S. EPA makes a decision on the corresponding exemption request. **This is usually done simultaneously in California.**
 - Applicant confers with U.S. EPA prior to use. U.S. EPA performs a cursory review to ensure there are no concerns, and whether the appropriate safety findings required by the Food Quality Protection Act of 1966 can be made.
 - If U.S. EPA identifies concerns, they will confer with the applicant; if concerns are not resolved, U.S. EPA may disallow a crisis exemption to be issued. Following communication with, and clearance by, U.S. EPA (oral approval 36 hours before issuance), DPR or federal agency may issue a crisis exemption, allowing the unregistered use to proceed for up to 15 days.
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Application requirements

The following items must be submitted by the applicant in order for the emergency exemption request to be processed:

- California *Application for Section 18* Emergency Exemption that includes:
 - A complete description of the emergency pest problem
 - The contact information for knowledgeable experts
 - The emergency use instructions needed to apply the product in order to control the pest problem
 - Information to support the argument that a significant economic loss (SEL) has occurred, or is about to occur, due to a pest problem
 - The economic history (typically three years worth of information) of the crop, including information on annual production, price of commodity, and cost of production before the pest problem occurred or became significant
 - Data to support section 18
 - A letter of authorization from the product registrant
 - Draft product labeling and product formulation sheet if the product has not been federally registered, or a copy of the U.S. EPA stamped--accepted label and confidential statement of formula (CSF) if the product is not currently registered in California
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Section 5.3

SLN Restrictions for Food/Feed Use -- Alfalfa

Interprets FAC sections 12972 and 12973

Background

Assembly Bill 697 (Chapter 287, Statutes of 1995) added section 12832 to the FAC. The bill was adopted to allow alfalfa and certain vegetable crops grown for seed to be considered non-food/non-feed sites under FIFRA section 24(c). This means that a section 24(c) registration could be issued for the use of a pesticide on these crops when grown for seed, in the absence of a tolerance or an exemption from tolerance, if used in accordance with the conditions of FAC section 12832.

Governing authorities

Authorities that regulate alfalfa seed crops treated under an SLN registration:

- The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)
 - Food and Agricultural Code (FAC)
 - SLN labeling
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FAC restrictions

FAC section 12832 establishes that alfalfa, when grown for seed production, is classified as a non-food/non-feed site when the following conditions are met:

- All seed screenings shall be disposed of in such a way that they cannot be distributed or used for food/feed. The seed conditioner shall keep records of screenings disposal for three years from the date of disposal.
- No portion of the seed plant may be used or distributed for food/feed.
- All seed crops grown on a non-food/non-feed site or conditioned in California must bear a tag or container label that forbids the use of the seed for human consumption or animal feed.
- Seed grown on a non-food/non-feed site or conditioned in California may not be distributed for human consumption or animal feed.

This provision allows the use of section 24(c) labeling rather than a section 18 exemption to authorize use even in the absence of a tolerance.

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SLN Restrictions for Food/Feed Use -- Alfalfa, Continued

SLN labeling

Labeling requirements found on SLNs for alfalfa grown for seed incorporate by reference requirements found in FAC section 12832. In addition, the SLN labeling prohibits seed from treated plants to be used for growing sprouts for human or animal consumption.

The later establishment of a tolerance does not eliminate a violation of FAC section 12972 if the crop or by-products are used for food/feed in conflict with labeling statements.

No harvest from subsequent growing seasons

Alfalfa seed is a perennial crop and creates a unique situation regarding harvesting subsequent crop production.

FAC section 12832 restrictions and SLN labeling do not provide an exemption for perennial crops, therefore, requirements carry over from one growing season to the next until the plant is removed from the ground. Alfalfa seed crops treated under section 24(c) labeling cannot be harvested for food/feed, in conflict with labeling prohibitions, in subsequent growing seasons.

Pre-harvest interval requests

Interested parties may request to establish a tolerance and appropriate pre-harvest interval (PHI) through the following steps:

1. Provide required data to U.S. EPA
 2. Submit a section 24(c) amendment request to the DPR
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Section 5.4

SLN Always Controlling Document

Interprets FAC section 12973; 3 CCR section 6000

Interpretation When confronted with both the container label and supplemental labeling, supplemental labeling is always the controlling document in the field whether or not it is in conflict with an express prohibition on the container label. If supplemental labeling is sought and obtained either by the registrant, user or DPR, it is by definition approval of some aspect of use inconsistent with the container label, expressed or implied.

DPR will attempt to avoid, insofar as possible, using 24(c) labeling to add restrictions to current labeled uses due to the enforcement challenges presented. It is sometimes difficult to prove that the labeling was actually delivered with the pesticide and that the labeling is required at the use site.

This is not interpreted as allowing new amended FIFRA section 3 container labels to be distributed as supplemental labeling to allow new uses of old product. To upgrade the old product to allow new section 3 approved uses, the product must be relabeled with the new label in compliance with U.S. EPA registered establishment requirements or an SLN issued to add the new uses to the old label.
