

Requirements for Section 18 & 24(C) Registrations for Herbicides in Vegetable Crops

Anne Downs, Senior Registration Specialist, Wilbur Ellis Company
841 W. Elkhorn Blvd., Rio Linda, CA 95673 adowns@wilburellis.com

Access to pesticides for use on minor crops may be accomplished using two different sections of law within FIFRA (Federal Insecticide, Fungicide, and Rodenticide Act). They include Section 24(c), (aka Special Local Need) registrations and Section 18 “permits to use”.

Minor use of pesticides.....

- Are those for which the total US production for a crop is fewer than 300,000 acres
- Also applies to pesticide uses which do not provide sufficient economic incentive for a registrant to support initial or continuing registrations

States have authority under Section 24(c) of FIFRA to register additional uses of a federally registered pesticide based on special local needs. A Special Local Need, or SLN, means an existing or imminent pest problem, within a state, for which the State Lead Agency (DPR), has determined that an appropriate federally registered pesticide product is not sufficiently available.

Section 24(C) SLNs

- ☛ Are for distribution and use only within a particular state.
- ☛ States may consider uses such as the following as candidates for SLNs:
 1. Adding a new method or timing of application.
 2. Adding a new crop (new site).
 3. Changing the rate of application.
 4. Application in a particular soil type.
 5. New product/different formulation.
 6. The new product will enhance resistance management.
- ☛ SLNs involving use on a food crop must have an established tolerance or be exempted from the requirement for a tolerance for that crop.
- ☛ Some crops are considered non-food/non-feed sites e.g. ornamentals and most seed crops.
- ☛ Generally SLNs are prepared and submitted by grower groups.
- ☛ SLN submission requirements vary by state.

CA DPR’s SLN form may be found, on line, at the following web address:

<http://www.cdpr.ca.gov/docs/registration/regforms/sec24/24app02.pdf>

The SLN applicant must provide the following information:

1. A complete description of the problem and submit evidence such as field data, copies of published articles, or written statements from qualified experts that a special local need exists.
 2. Must list other products that are registered in California for this use and give reasons why the alternatives are not available or are not controlling the pest(s).
 3. Must also report similar uses for which the product is registered.
 4. Must advise whether the crop will be marketed fresh or processed and what, if any, are the anticipated hazards to bees, fish, wildlife or any non-target organisms?
 5. Must estimate the total amount of acreage to be treated and whether or not a residue tolerance has been established for the food or feed crop?
 6. Must submit efficacy and phytotoxicity data, as well as, a letter of authorization from the manufacturer.
 7. And, finally, the applicant, in cooperation with the registrant, must develop label language.
- A state must notify EPA within 10 days of when they issue a SLN registration.
 - EPA has 90 days from the date the state issued the SLN to make a final decision whether to disapprove the SLN.
 - If EPA makes no objections, the SLN becomes a federal registration.
 - SLN registrations remain in effect unless EPA, the State, the Registrant, or the Applicant, takes action to cancel the registration.
 - Ideally, a registrant will move towards adding the SLN use to their Section 3 label as the nature of a SLN makes it vulnerable.

Common Questions

1. **Are there circumstances under which a §24(c), aka SLN, should not be issued?** Yes, if expanding the use triggers further data requirements, raises human or environmental risk concerns, etc.
2. **Can states issue SLNs which negate restrictions on §3 labels?** It depends. §24(c)s often allow new uses or new use directions which may differ from those on the §3 label. However, if the SLN provisions raise risk concerns, the use of the SLN would be inappropriate.
3. **Is offering growers a choice of products or a less hazardous formulation (to humans, NTOs, or other environmental component) an acceptable justification for a SLN registration?** Yes. This would enable pollution prevention and risk reduction as determined by the state. A clear explanation of the benefits and the data to support such a contention would be required.

4. **Can a state issue a SLN registration for the purpose of avoiding buildup of pest resistance?** Yes, however, the SLN pesticide must have a different mode of action from that already available.
5. **May a state issue a SLN registration for a use which has been voluntarily deleted?** Yes, but only if the registrant or SLN applicant submits any missing data required to register that use.
6. **Can more than one SLN registration be issued for the same use in the same state?** Yes, however, the state must ensure that the additional §24(c) registrations are necessary and adequate data have been submitted.
7. **Can a product be used up according to the SLN product label as long as it is in the possession of the user?** Yes, unless either the state or EPA has prohibited the use of the product as part of a cancellation order.

STATE OF CALIFORNIA
REQUEST FOR A SPECIAL LOCAL NEED
REGISTRATION (SLN), SECTION 24(c)
PR REG-004 (Est. 7/91)/Rev. 05/02

THE PROPOSED LABEL

Product Name: _____ U.S. EPA Reg. No. _____

Manufacturer: _____ Location: _____

Crop/Commodity/Site: _____ Pest(s): _____

Proposed Dosage: _____ Proposed Dilution Rate: _____

Method of Application: _____ Frequency/Timing of Application: _____

Proposed Restricted Entry Interval (REI): _____ Proposed Preharvest Interval (PHI): _____

Other Special Requirements:

Name and Address of the SLN Registrant:

Contact Person: _____ Telephone Number: _____

Signature _____ Date _____

Signature of County Agricultural Commissioner (Approval for Permit if Necessary)

Return This Form to: Department of Pesticide Regulation
Pesticide Registration Branch
1001 I Street
Sacramento, California 95812-4015
(916) 445-4400; fax: (916) 324-5872

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Section 18 (Permit to Use)

States may also request that EPA allow use of an unregistered active ingredient, or an additional use for a registered pesticide, to respond to emergency conditions, under Section 18 of FIFRA.

- Section 18 of FIFRA, authorizes EPA to allow an unregistered use of a pesticide for a limited time if EPA determines that an emergency conditions exists.
- An “emergency condition” is an urgent, non-routine situation that requires the use of a pesticide.

Four Types of Section 18s

1. Specific
2. Quarantine
3. Public Health
4. Crisis

Requests are made for pesticides needed for pest problems that impact production of agricultural goods when there are no alternatives for controlling the pest.

- Specific or Public Health Exemptions may only be issued for a year.
- Quarantine exemptions may be issued for no more than three years.

EPA generally takes approximately 60 days, from date of receipt, to make a decision regarding a Section 18 request. If the emergency is determined to be valid and the risks are acceptable, EPA approves the request.

- The majority of requests that EPA receives are for Specific Exemptions. Most Specific Exemptions involve the treatment of agricultural goods and EPA will, therefore, establish a formal tolerance (or maximum allowable residue level) for that active ingredient on that crop.
- Current Section 18's may be found at the following link on the EPA website:
<http://cfpub1.epa.gov/oppref/section18/search.cfm>

In 2006, EPA published a final rule that revised the regulations governing emergency exemptions. They included:

1. A streamlining of the recertification application.
2. A redefinition of what constitutes significant economic loss and revision of data requirements for documenting the loss.

Components of a Section 18

Description of the Proposed Use including:

- Method and rate of application
- Maximum number of applications
- Total acreage to be planted and treated
- Use season
- Date first and last application needed
- PHI
- REI
- Earliest harvest date
- Any additional precautions, requirements, etc.
- Address registered alternative pesticides and alternative control practices.
- Include efficacy data which should include statistical data on comparative California registered products. The data should also compare the California registered products to the proposed product. Effects on crop yield and quality should be documented.
- A letter of authorization from the registrant must also be included.
- Address registered alternative pesticides and alternative control practices.
- Include efficacy data which should include statistical data on comparative California registered products. The data should also compare the California registered products to the proposed product. Effects on crop yield and quality should be documented.
- A letter of authorization from the registrant must also be included.

COMPARISON between SECTION 24(C) and SECTION 18

Section 24(c) aka SLN	Section 18
Applicant: Any person or group	Applicant: Must be a third party such as grower group, county, university, etc. (cannot be the registrant)
2 Types: First Party (the manufacturer) or Third Party (other than manufacturer)	4 Types: Specific Crisis Quarantine Public Health
Tolerance or Exemption from tolerance already established	No tolerance established.
Justification and lack of alternatives must be documented	Emergency, non-routine situation must be well- documented. Economics and lack of suitable alternatives must be verified
Data Needed Includes..... Residue Efficacy Phytotoxicity	Data Needed Includes..... Residue Efficacy Phytotoxicity Economic
Letter of Authorization from Registrant	Letter of Authorization from Registrant
Post for Public Comment is Required	Post for Public Comment is not Required
Issued generally without an expiration date	When issued, <u>always</u> includes an expiration date. Use period cannot exceed a 12 month period
Fees: ■ Must pay USEPA maintenance fees on an annual basis. ■ No DPR fees	Fees: None to either USEPA nor DPR