

Pesticide Registration Manual:

Chapter 17 - State Regulatory Authority

State Regulatory Authority

FIFRA authorizes states to issue [Experimental Use Permits \(EUPs\)](#), [Special Local Needs \(SLNs\)](#) registrations, and to apply for Emergency Exemptions under specific conditions. This chapter provides detailed information relevant to state actions under FIFRA. State contact information can be found at the

- [Association of American Pesticide Control Officials](#),
- [National Association of State Departments of Agriculture](#), and
- [EPA Regional Office contact information](#).

In general, authorized states can issue experimental use permits only for the purpose of gathering data necessary to support the state registration of a pesticide to meet special local needs under [FIFRA section 24\(c\)](#) and for the purpose of experimentation.

Important Note: Most states require state registration in addition to federal registration. This chapter covers state actions under the federal registration regulatory framework but does not cover state registrations. Registrants should contact the appropriate state for information on obtaining a state registration.

State Issuance of Experimental Use Permit (EUP)

[FIFRA section 5](#) authorizes any state to issue an Experimental Use Permit in accordance with an EPA-approved state plan (40 CFR Part 172 provides detailed information on state experimental use permits).

Contact for More Information: For additional information concerning state EUPs, you should contact the pesticide regulatory authority in the state in which you wish to obtain a state EUP.

State Registration of Special Local Needs

[FIFRA section 24\(c\)](#) authorizes state lead agencies to register additional uses of federally registered pesticides (also called Special Local Needs (SLN) registrations or SLNs). The

SLN permits distribution and use only in the registering state. The SLN is otherwise deemed a federal registration for all other purposes under FIFRA. All SLNs must be submitted to EPA for review subsequent to registration by the state.

See:

- [40 CFR Part 162, Regulations Pertaining to State Registration of Pesticides to Meet Special Local Needs](#); and
- [Guidance on FIFRA 24\(c\) Registrations](#).

24(c) Registration Regulations

In general, section 24(c) registration regulations specify:

- types of registrations a state may grant under [40 CFR Part 162](#) (FIFRA section 24(c));
- circumstances under which a special local needs registration may be granted by a state; and
- circumstances under which the EPA Administrator may disapprove or invalidate a special local needs registration.

Important Notes:

- A state may not register an amendment to a federally registered manufacturing-use product (40 CFR 162.152(b)(1)(iv)).
- A state may only grant 24(c) registrations for voluntarily canceled uses of products after consulting with appropriate EPA personnel (40 CFR 162.152(b)(1)(iii)).
- A state may not register a new manufacturing-use product (40 CFR 162.152(b)(2)(iv)).

Conditions for a Section 24(c) Registration

Under FIFRA section 24(c) and its implementing regulations at 40 CFR Part 162, states are authorized to register new end use products or additional uses of federally registered pesticides if the following conditions exist:

- There is a **special local need** for that product use.
- The use, if a food or feed use, is covered by an appropriate tolerance or has been exempted from the requirement of a tolerance.
- The registration for the same use has not previously been denied, disapproved, suspended, or canceled by EPA, or voluntarily canceled by the registrant subsequent to EPA's issuance of a notice of intent to cancel because of health or environmental

concerns about an ingredient contained in the product, unless EPA has reversed the original action.

- The registration is in accord with the purposes of FIFRA.
- If the proposed use or product falls into one of the following categories, the state must first determine that it will not cause unreasonable adverse effects on man or the environment:
 - its composition is not similar to any federally registered product;
 - its use pattern is not similar to any federally registered use of the same product or a product of similar composition; and
 - other uses of the same product, or uses of a product of similar composition, have had their registration denied, disapproved, suspended, or canceled by the Administrator.

Under the special local needs registration regulations, a state may register a new end-use product (not previously federally registered) meeting one of the following conditions (as well as the basic requirements for all special local needs registrations) (40 CFR 162.152(b)(2)(A) and (B)):

- a product that is identical in composition to a federally registered product but has differences in packaging, or in the identity of the formulator; or
- a product that contains the same active and inert ingredients as a federally registered product, but in different percentages.

In addition, 40 CFR 162.152(b)(2)(ii) sets forth the criteria for a state to register a new end-use product that contains a new combination of active, or active and inert, ingredients. A state may register such a product:

- only if each of the active ingredients in the new product is present because of the use of one or more federally registered products and if each of the inert ingredients in the new product is contained in a federally registered product

A state can issue a 24(c) registration for any use of a new end-use product containing an ingredient described in 40 CFR 162.152(a)(3) (i.e., registration for the same use has not previously been denied, disapproved, suspended, or canceled by the Agency, or voluntarily canceled subsequent to the issuance of a notice of intent to cancel that registration, unless the action is superseded by subsequent action of the Agency). A state may register any use of a federally registered product for which registration of other uses was denied, disapproved, suspended, or canceled if the new product is for a formulation or a use not included in the denial, disapproval, suspension, or cancellation, or if the federally registered use was voluntarily canceled without a prior notice of intent to cancel. However, a formulation or use not considered by the Agency during the aforementioned proceedings, or which was not the

subject to a notice of intent to cancel, may be registered by a state only after the state consults with the appropriate Agency personnel regarding the application.

State Registration Procedures

Pesticide companies generally make requests for Special Local Need registrations to the specific state.

States require all applicants for registration to submit the following information:

- Name and address of the applicant and any other person whose name will appear on the labeling or in the directions for use.
- The name of the pesticide product, and if the application is for an amendment to a federally registered product, the EPA registration number of that product.
- A copy of proposed labeling, including all claims made for the product as well as directions
- for its use to meet the special local need, consisting of:
 - for a new product, a copy of the complete proposed labeling; or
 - for an additional use of a federally registered product, a copy of proposed supplemental labeling and a copy of the labeling for the federally registered product.
- The complete formula of the product, if the application is for a new product registration.
- Any other information that is required to be reviewed prior to registration under this section.
- Electronic reporting under state registration of pesticide products for special local needs. States that choose to receive electronic documents under the regulations pertaining to state registration of pesticides to meet special local needs must ensure that the requirements of [40 CFR Part 3](#) (Cross-Media Electronic Reporting) are satisfied by their state procedures for such registrations.

The state then reviews the application according to 40 CFR 162.153(b) – (g). Within 10 working days from the date the state issues, amends, or revokes a registration, the state notifies EPA, in writing, of the action.

EPA's Responsibilities with the Section 24(c) Registration Program

EPA's role is to ensure that each FIFRA section 24(c) registration meets the requirements of FIFRA, because these registrations become federal registrations unless the Agency

disapproves them. EPA reviews the individual section 24(c) registrations and broadly oversees the states section 24(c) registration programs.

With section 24(c) registrations, states have the initial obligation to ensure that the SLNs they issue meet the requirements of FIFRA. Given the statutory time period for EPA review under section 24(c), EPA's review of SLN was not intended to be – and is not – the equivalent of its review of new registration actions under section 3. For example, EPA will generally not request data for amendments to federal products or new products that are substantially similar to currently registered products in composition and use.

For products registered under section 24(c) that are not substantially similar to a registered product, EPA generally will ask for only a brief summary of the data, the state's conclusions, and a certification that the product will not cause unreasonable adverse effects as defined in FIFRA for registration of pesticides (40 CFR 162.153). Refer to

- [Guidance on FIFRA 24\(c\) Registrations, dated February 9, 1996.](#)

Quality Control and Conflict Resolution

EPA will also conduct general oversight by periodically reviewing all records of section 24(c) registrations to ensure that states and EPA have properly followed procedures and policies. If EPA finds problems, it will discuss and resolve them with the appropriate state(s).

EPA will make every effort to work out problems with states, but EPA retains the authority under 40 CFR 162.155 to suspend a state's authority to issue section 24(c) registrations, if necessary.

Grounds for Disapproving a State Registration

General Disapprovals

40 CFR 162.154(a) sets forth the process and requirements for disapproving a state registration that involves products with composition or use patterns that are not similar to a currently registered product. Reasons for disapproving these types of special local need registrations include, but are not limited to:

- probable creation of unreasonable adverse effects on man or the environment by the registered use;
- refusal of the registering state to submit information supporting the registration, i.e., application form (within 10 working days), labeling for the section 24(c) registration, Confidential Statement of Formula (new product only), final printed label (within 60 days), state revocation notice with date of revocation and reason(s) for revocation,

and scientific studies supporting a no unreasonable adverse effects finding by the state (within 15 working days);

- failure of the information submitted by the state to support the decision to issue the section 24(c) registration under the standards set forth in 40 CFR 162.153.

Special Disapprovals

Under 40 CFR 162.154(b), EPA may disapprove any special local needs registration at any time (even beyond the 90-day period) if it is determined that the registration:

- would constitute an imminent hazard; or
- may result in a residue on food or feed exceeding, or not covered by, a tolerance, exemption, or other clearance under the FFDCa.

Once the special local needs use is registered under FIFRA, it is subject to any additional data requirements that may be required by EPA either as the result of a Reregistration Eligibility Decision Document, [registration review](#), or other FIFRA section 3(c)(2)(B) data call-in. FIFRA section 24(c)(1).

Contacts for More Information

Additional information concerning applications for a state special local need registration should be addressed to the state in which you wish to make an application for a SLN registration. A listing of the various state pesticide agencies can be found in [Chapter 21](#) of this manual.

Emergency Exemptions under FIFRA Section 18

FIFRA section 18 authorizes the Administrator to exempt state and federal agencies from any provision of FIFRA when emergency conditions exist that require an exemption. 40 CFR Part 166 sets forth the four types of emergency exemptions that may be authorized:

1. specific,
2. quarantine,
3. public health, and
4. crisis.

Notably, the section 18 exemption process can be relied upon as a time-limited authorization from EPA to use a pesticide for a use that is not registered if a determination is made that

emergency conditions exist and that use of the pesticide will not cause unreasonable harm to human health or the environment.

Regulations in [40 CFR Part 166](#) establish procedures by which the Administrator may exempt a federal or state agency from the registration requirements of FIFRA.

Types of Emergency Exemptions that May Be Authorized

Specific Exemption (40 CFR 166.2(a) and 40 CFR Part 166, Subpart B)

A specific exemption may be authorized in an emergency condition to avert a significant economic loss or a significant risk to endangered species, threatened species, beneficial organisms, or the environment. EPA shall allow the use of a pesticide under a specific exemption for as long a period as is reasonably expected to be necessary, up to one year.

Quarantine Exemption (40 CFR 166.2(b) and 40 CFR 166, Subpart B)

A quarantine exemption may be authorized in an emergency condition to control the introduction or spread of any pest new to or not previously known to be widely prevalent or distributed within and throughout the United States and its territories. EPA shall allow use of a pesticide under a quarantine exemption for as long a period as is deemed necessary but in no case for longer than three years.

Public Health Exemption (40 CFR 166.2(c) and 40 CFR Part 166, Subpart B)

A public health exemption may be authorized in an emergency condition to control a pest that will cause a significant risk to human health. EPA shall allow the use of a pesticide under a public health exemption for as long a period as is reasonably expected to be necessary but in no case for longer than one year.

Note: Specific, quarantine, and public health exemptions may be renewed. Interim reports containing the information specified in [40 CFR 166.32\(b\)](#) to the extent available shall be filed annually.

Crisis Exemption (40 CFR 166.2(d) and 40 CFR Part 166, Subpart C)

A crisis exemption may be utilized in an emergency situation when the time from discovery of the emergency to the time when the pesticide use is needed is insufficient to allow for the authorization of a specific, quarantine, or public health exemption. A state or federal agency may issue a crisis exemption. The state or federal agency must notify EPA in advance of issuing a crisis exemption. EPA will review the proposed use to determine whether the crisis authority should not be exercised or the crisis exemption should be revoked.

Important Note: The crisis exemption may not be used to authorize a pesticide use if any of the following have occurred:

- EPA has informed the head of the federal or state agency, the Governor, or his/her official designee, not to issue such an exemption;
- the pesticide use has been suspended under section 6(c) of FIFRA;
- the pesticide use has been canceled following a notice issued under section 6(b) of FIFRA;
- the pesticide contains a new chemical; or
- the application proposes the first food use of a pesticide.

Duration of a Crisis Exemption (40 CFR 166.45)

A crisis exemption may be authorized for:

- only as long as is necessary to control the pest or conditions causing the emergency; and
- no longer than 15 days, unless an application requesting a specific, quarantine, or public health exemption for this use has been submitted to the Agency.

Tolerances for Pesticide Chemical Residues in Food or Feed Owing to an Emergency Exemption

[Section 408\(l\)\(6\) of the Federal Food, Drug, and Cosmetic Act \(FFDCA\)](#) requires the establishment of time-limited tolerances or exemptions from tolerance requirements for residues of those pesticides exempted from regulation under FIFRA section 18.

The tolerances or exemptions must be consistent with the FFDCA safety standard, namely that there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.

More information on safety findings and information required for tolerance setting can be found in [Chapter 11](#), Tolerance Petitions

References Cited in Chapter 17

Refer to [Chapter 19](#) for information on the source of these documents.

[Code of Federal Regulation, Title 40](#)

- Part 162 - State registration of pesticide products
- Part 166 - Exemption of federal and state agencies for use of pesticides under emergency conditions
- Part 172 - Experimental use permits

[Federal Insecticide, Fungicide, and Rodenticide Act](#), as amended by the [Food Quality Protection Act](#) of August 3, 1996

- Section 3 - Registration of pesticides
- Section 5 - Experimental use permits
- Section 6 - Administrative review, suspension
- Section 18 - Exemption of federal and state agencies
- Section 24 - Authority of States

[Standard Operating Procedure 4001.7: 24\(c\) Review Process](#), Office of Pesticide Programs, EPA, February 9, 1996