Section 18 EMERGENCY EXEMPTIONS

A GUIDE TO UNDERSTANDING PESTICIDE REGISTRATION

THIS FACT SHEET WILL ANSWER THESE QUESTIONS:

- What is a Section 18 emergency exemption from registration?
- Who can apply?
- How do I apply?
- How do Section 18 emergency exemptions and Section 24(c) special local need (SLN) registrations differ?

What is a Section 18 emergency exemption from registration?

Section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizes the U.S. Environmental Protection Agency (U.S. EPA) to allow an unregistered use of a pesticide for a limited time if U.S. EPA determines that an emergency condition exists. The regulations governing FIFRA Section 18 (found in Title 40, Code of Federal Regulations (40 CFR), part 166), define "emergency condition" as an urgent, nonroutine situation that requires the use of a pesticide. It allows for the time-limited use of a pesticide product (not registered or not registered for that use) to control the emergency. Such uses are often referred to as "emergency exemptions," "Section 18s," or simply "exemptions."

FIFRA Section 18 also authorizes U.S. EPA to allow a federal or state agency the ability to grant the use of a pesticide product without registration, if an emergency condition exists. The issuance of a Section 18 is not the same as the issuance of a product license.



Section 18 EMERGENCY EXEMPTIONS

There are four types of Section 18 emergency exemptions from registration:

SPECIFIC EXEMPTION

- These form the majority of requests.
- Requested 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 that registered pesticides cannot control.
- May be authorized for up to one year.

QUARANTINE EXEMPTION

- Requested to control the introduction or spread of an invasive pest not previously found in the U.S.
- "Emergency" rests on the potential of an invasive species to cause a significant economic loss.
- May be authorized for up to three years.

PUBLIC HEALTH EXEMPTION

- Requested to control a pest that will cause a significant risk to human health.
- "Emergency" based upon the risk to human health from the pest to be controlled.
- May be authorized for up to one year.

CRISIS EXEMPTION

- May only be issued when there is an immediate need for a specific, quarantine, or public health exemption in situations involving an unpredictable 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 an exemption through normal means.
- DPR must confer with, and receive verbal authorization from, U.S. EPA before issuance. U.S. EPA performs a preliminary review to ensure there are no concerns, and whether the appropriate safety findings required by the Food Quality Protection Act (FQPA) can be made. If authorized by U.S. EPA, a state or federal agency may issue a crisis exemption allowing the use for up to 15 days.
- An applicant may follow up the crisis exemption with a specific, quarantine, or public health emergency exemption request. This allows the use to continue until U.S. EPA makes a decision on the corresponding exemption requested. This follow up request is usually done simultaneously in California.

Important To Note

- All uses under a Section 18 emergency exemption require a restricted materials permit from the appropriate county agricultural commissioner's office before purchase and use.
- Product uses under a
 Section 18 cannot be
 advertised unless criteria
 outlined in 40 CFR §168.22
 are met.
- If the emergency use involves treatment of a food crop, U.S. EPA will establish a time-limited tolerance (maximum allowable residue levels) to cover any pesticide residues that may result. These are usually granted for two to three years.

Section 18 EMERGENCY EXEMPTIONS

Who can apply?

Applicants must be someone other than the product registrant. University of California (UC) Extension personnel, county agricultural commissioners, grower groups and others may apply. DPR recommends that applicants contact the designated Section 18 staff person at DPR before submitting an application to ensure all requirements are clearly understood.

How do I apply?

The applicant must submit the following information to DPR. If DPR approves the submission, it is then forwarded to U.S. EPA for review and approval.

- DPR's application form <u>DPR-REG-003</u>, Application for Section 18 Emergency Exemption (or go to the A-Z index on DPR's home page at http://www.cdpr.ca.gov and scroll to "Section 18"). No application fee is required. The application form must include:
 - A complete description of the emergency pest problem.
 - Contact information for knowledgeable experts who can confirm the emergency.
 - A detailed explanation of why currently registered pesticides or cultural practices are not adequate to address the situation.
 - Product label instructions describing how to apply the product in order to control the pest problem.
 - Documentation that a significant economic loss has occurred, or is about to occur, due to a pest problem.
 - The economic history (typically three to five 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.
- Scientific data to support the Section 18
 - Efficacy, residue chemistry, and phytotoxicity data.
 - If pest resistance is the basis for the exemption, field data to demonstrate resistance to currently registered products is required. It is important that data be collected in the region where the pest problem is occurring.
 - If the product is not registered in California, acute toxicology and product chemistry data are also required.
- A letter of authorization from the product registrant.
- A draft product label and product formulation sheet if the product is not federally registered, or a copy of the U.S. EPA-accepted label and confidential statement of formula if the product is federally registered.

Section 18 EMERGENCY EXEMPTIONS

How do Section 18 emergency exemptions and Section 24(c) special local need registrations differ?

SECTION 18	SECTION 24(C) SPECIAL LOCAL NEED
No tolerance yet established. U.S. EPA will establish a time-limited tolerance.	Tolerance or exemption already established.
For limited use to treat sudden and limited emergency pest infestations.	To meet a special local need (which may be a region of the state or the whole state).
Emergency situation must be well documented and not a historical pest problem. Economics and lack of alternatives must be verified.	Justification and lack of alternatives must be documented.
Can be used during the 30-day public comment period.	Must be posted for a 30-day public comment period before use is allowed.
Request made through DPR and issued after U.S. EPA approval, which includes the use, limitations on acreage and location, and the time-limited tolerance. DPR may issue a "crisis" Section 18 after consultation with U.S. EPA.	DPR issues without U.S. EPA review, although U.S. EPA has 90 days to comment.
Expiration date not to exceed one year, except quarantine exemptions (up to three years). Renewable if the emergency recurs or persists, although renewal difficult after the third year.	Usually issued without expiration date. May be inactivated by applicant, DPR, or U.S. EPA.
Applicant must be third-party (someone other than the registrant).	Applicant may be first-party (the registrant) or third-party (someone other than the registrant).
Not subject to U.S. EPA maintenance fee. No DPR fee.	Subject to U.S. EPA maintenance fee. No DPR fee.
Use requires a restricted materials permit even if the product is not a restricted material.	Use requires a restricted materials permit only if the product is a restricted material.

Both Section 18s and Section 24(c) SLNs require scientific evaluation (efficacy, phytotoxicity, residue chemistry, and other data as required) and a letter of authorization from the registrant. For more information about Section 24(c) SLNs, see DPR's guide Section 24(c) Special Local Need Registrations.

For more information, please contact:

Morgan Thai

California Department of Pesticide Regulation

Pesticide Registration Branch 1001 | Street P.O. Box 4015

Sacramento, CA 95812-4015

Telephone: (916) 445-3054

E-mail: Morgan.Thai@cdpr.ca.gov