

EPA's Prospective On Insecticide Registration and Exemptions for Spotted Wing Drosophila

SWD Working Group

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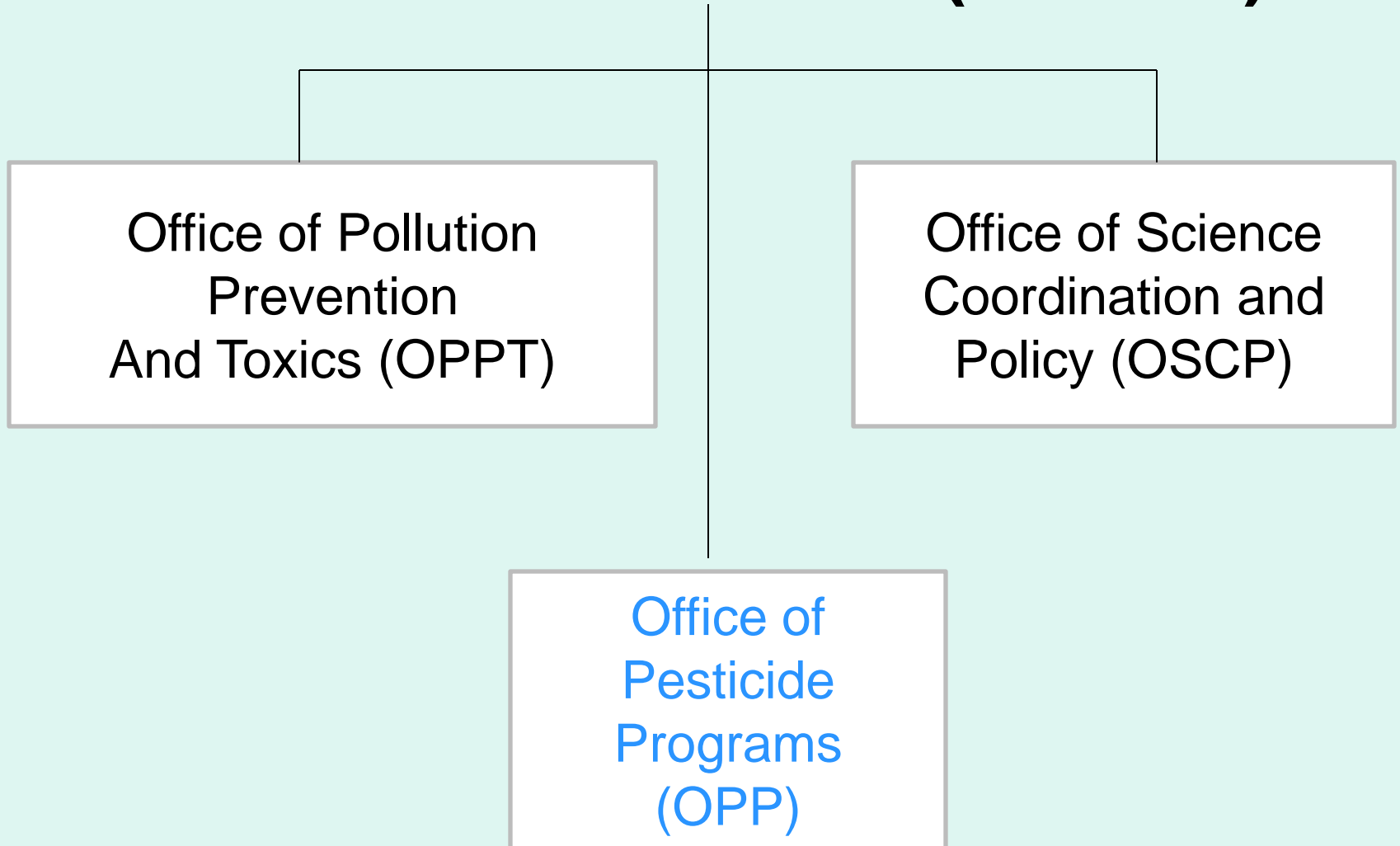


Outline

- ❑ USEPA Organization
- ❑ FIFRA Section 24(c) Registrations
- ❑ FIFRA Section 18 Overview
- ❑ Types of Emergency Exemptions Under Section 18
- ❑ Revised Section 18 Under the January 2006 Final Rule
- ❑ Resources and Contact Information

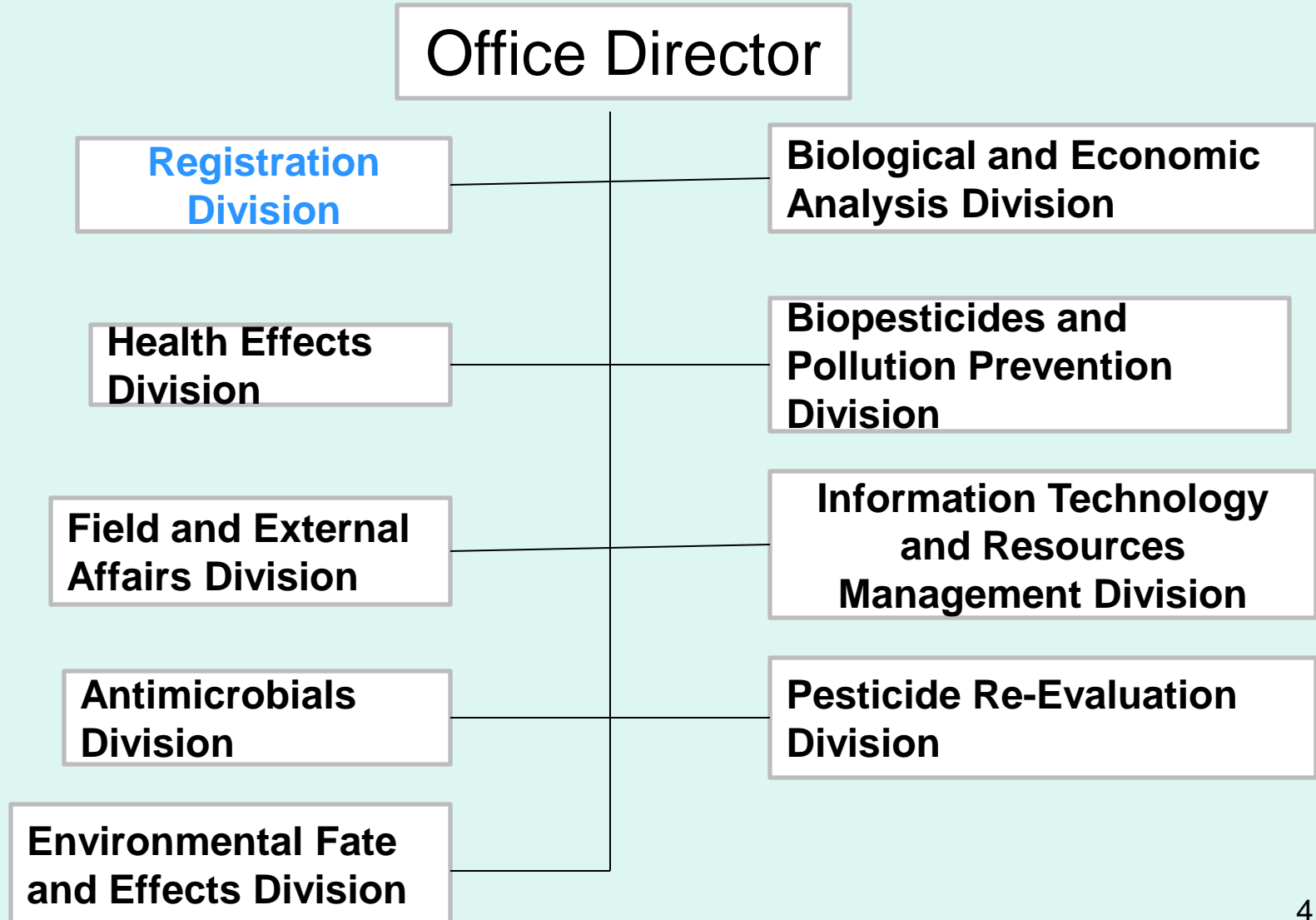


Office of Chemical Safety and Pollution Prevention (OCSPP)



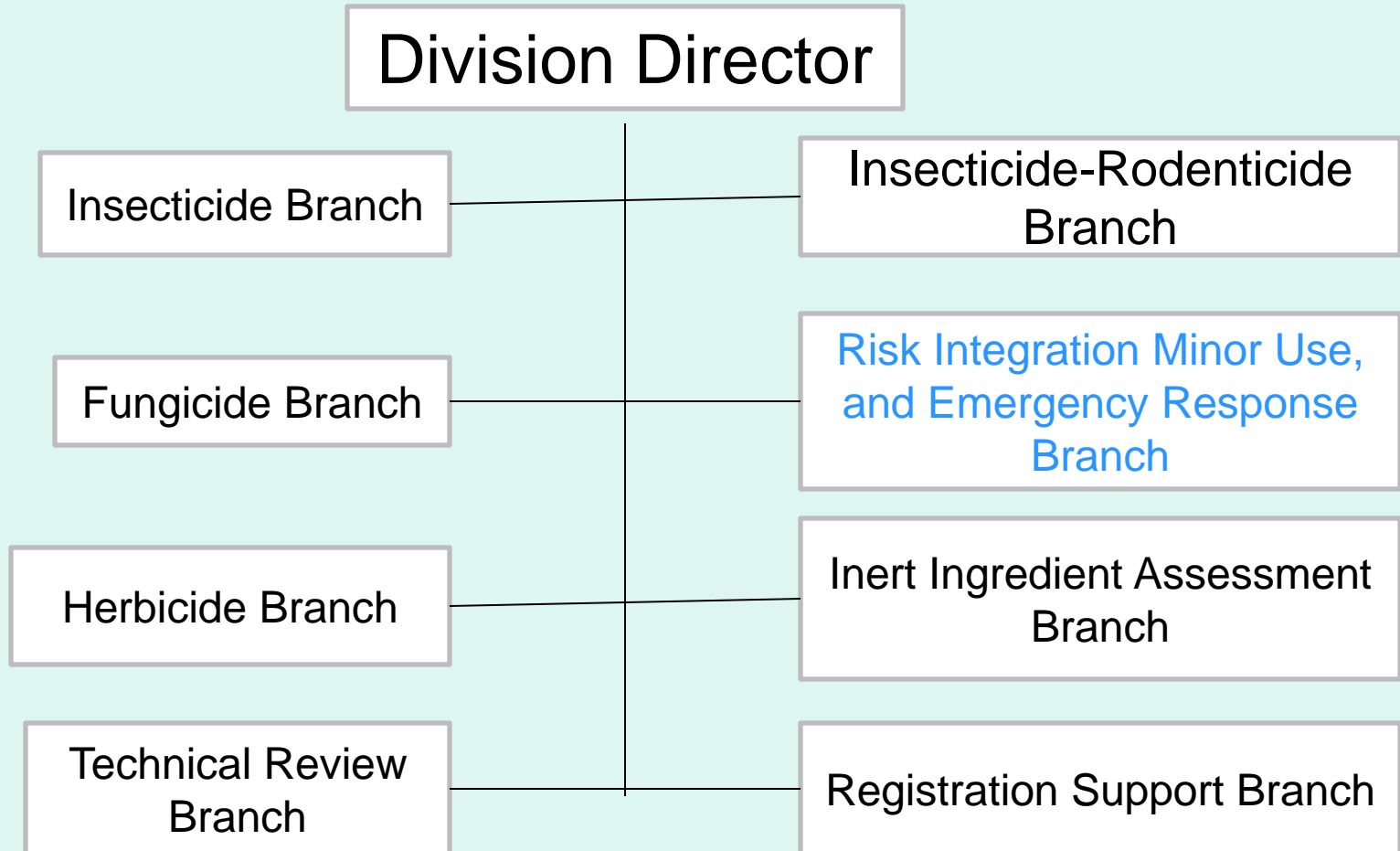


Office of Pesticide Programs



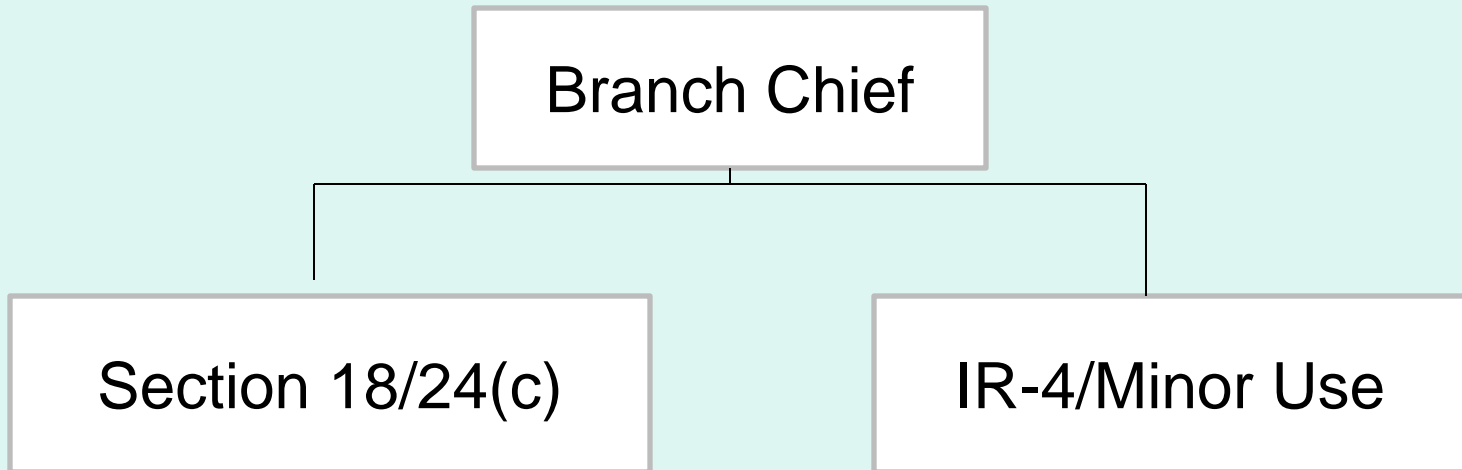


Registration Division





Risk Integration, Minor Use & Emergency Response Branch



FIFRA Section 24(c) Registrations Overview

- Under the authority of Section 24(c) of FIFRA, States may register an additional use of a federally registered pesticide product, or a new end use product to meet [special local needs](#).

24(c) Definition of "Special Local Need"

- Special local need means an existing or imminent pest problem within a State; and
- State can document that a federally registered product a) is not available in the state for the desired site(s) to adequately control the target pest(s), or b) cannot be applied without causing unacceptable risks to human health or the environment, or c) is necessary to maintain an IPM, resistance management, or minor use pest control program, or d) could be replaced by a formulation that poses less risk to man or the environment.

FIFRA Section 24(c) Registrations Overview (Cont.)

- States must follow the specific procedures set forth in the regulations to assure that their 24(c) registrations are properly issued and reported to EPA, which can be found at:

<http://www.epa.gov/opprd001/24c/>

- This includes a completed Notification of State Registration (EPA Form [8570-25](#)).

FIFRA Section 24(c) Registrations (Cont.)

- EPA's role is to assure that each 24(c) registration meets the requirements of FIFRA since these registrations become federal registrations within 90 days unless EPA objects to them.
- EPA will limit its review of individual 24(c) registrations to a minimal level which empowers states to meet the requirements of FIFRA and which avoids any duplication of effort by EPA.

FIFRA Sect 18 Overview

- Authorizes EPA to allow an unregistered use of a pesticide for a limited time if EPA determines that an emergency condition exists
- Requests usually involve pesticides that have other approved uses
- “Emergency Condition” defined as an urgent, non-routine situation that requires the use of a pesticide(s).
- Most requests are made by state lead agricultural agencies.

Sect 18 Overview (cont.)

Four types of emergency exemptions governing Section 18's of FIFRA:

- 1) Specific
- 2) Quarantine
- 3) Public Health
- 4) Crisis

Sect 18 Overview (cont.)

- Uses are requested for a limited period of time to address the emergency situation only:
 1. Specific or public health exemptions: no longer than 1 year
 2. Quarantine exemptions: no longer than 3 years.

Sect 18 Overview (cont.)

- EPA attempts to make decisions on the requests within a 50 day time frame from date of receipt
- EPA performs a multi-disciplinary evaluation of the request, including the following:
 - 1) Assessment of the validity of the emergency claim and economic loss.
 - 2) Human dietary risk assessment.
 - 3) Occupational risk assessment.
 - 4) Ecological and environmental risk assessment.
 - 5) Assessment of the progress toward registration for the use for specific or public health exemption requests.

Types of Section 18 Emergency Exemptions

1) Specific Emergency Exemptions

- 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 will not alleviate.

Specific Emergency Exemptions (Cont.)

- Growers request their state lead agency to request an emergency exemption from EPA.
- EPA evaluates request and decides whether or not to authorize use.
- Specific exemptions may be authorized for up to one year.

Types of Section 18 Emergency Exemptions (Cont.)

2) Quarantine Emergency Exemptions

- Requested to control the introduction or spread of an invasive pest species not previously known to occur in the United States and its Territories.
- “Emergency” rests on the need to prevent the introduction or spread of an invasive species.
- Quarantine exemptions may be authorized for up to 3 years.

Types of Section 18 Emergency Exemptions (Cont.)

3) Public Health Emergency Exemptions

- Requested to control a pest that will cause a significant risk to human health.
- “Emergency” based upon the risk to human health presented by the pest to be controlled.
- Public health exemptions may be authorized for up to one year.

Types of Section 18 Emergency Exemptions (Cont.)

4) Crisis Emergency Exemptions

- Immediate need for a specific, quarantine, or public health exemption.
- Following communication with and clearance by EPA, State lead agency or federal agency may issue a crisis exemption allowing the unregistered use to proceed for up to 15 days.

Crisis Emergency Exemptions (Cont.)

- Applicant confers with EPA prior to use. EPA performs a cursory review to ensure there are no concerns, and whether the appropriate safety findings required by FQPA may be made. If EPA identifies concerns, confers with applicant and if concerns are not resolved, may disallow a crisis exemption to be issued.
- Applicant may follow up the crisis with, or may have already submitted, a specific, quarantine, or public health emergency exemption request, which allows the use to continue until EPA makes a decision on the corresponding exemption request.

Sect. 18 Crisis Exemptions for SWD

Chemical	Site	Pest	Applicant	Received Date	Response Date	Status
Malathion	Blueberry	Spotted wing drosophila	New Jersey	7/13/12	7/16/12	Crisis approved
Malathion	Blueberries	Spotted wing drosophila	Maine	7/31/12	8/2/12	Crisis approved
Spinetoram	Blueberries	Spotted wing drosophila	Michigan	7/8/13	7/8/13	Crisis approved



Section 18 Revised Rule

- On January 27, 2006, EPA published a final rule that revised the regulations governing emergency exemptions.
- Update regulations to be consistent with FQPA.
- Reflect improvements to process that have been identified since regulations were last revised.

2006 Rule change for Crisis Exemptions

- Prior to using chemical under crisis exemption, applicant must:
 - Notify EPA of intent to declare crisis
 - Receive verbal notice of no objections from EPA
 - ❖ **Goal is response within 36 hours**
- New required elements of notice to EPA:
 - Appropriate label
 - Use period (start and end dates)
 - Earliest harvest date
 - Description of emergency

Crisis Exemptions

What's Not Changed

- Crisis exemptions for unpredictable emergencies
- States should use crisis provisions rarely
- Assurance needed that
 - Tolerance can be established
 - No other immediate concerns/objections seen

New Required Elements for (Non-Crisis) Applications

- Label for requested product
- Site/Use information
 - Maximum number of applications
 - Use period (start and end dates)
 - Earliest harvest date
- Registrant statement
- Interim use report for repeat request if prior to due date of final report
- Incomplete applications cannot be processed

Other Regulatory Changes

- Presumption of reasonable progress toward registration extended to 5 years for uses supported by IR-4 (previously 3 years)
- Revised definition of first food use
- Clarified control of “invasive species” is acceptable use of quarantine exemption
 - ❑ Opportunity for necessary pest management of new high-impact pests, *e.g. soybean rust*)

General Recommendations for Section 18s

- Submit requests prior to use season
- EPA can help scope/advise states about applications
- EPA's goal is to ensure decision happens BEFORE use season
- For repeats, follow up on conditions, i.e. data requirement from previous year
- File post-exemption use reports



Resources and Contact Information

❖ Information about EPA's pesticide emergency exemption program may be found at

<http://www.epa.gov/opprd001/section18/> ; including a searchable database of past exemption requests

[http://www.epa.gov/opprd001/section18/#
crisis](http://www.epa.gov/opprd001/section18/#crisis)

Resources

- **EPA Launches New FIFRA Section 18 Emergency Exemption Online Training Resource - June 18, 2013**
- a new online training resource for the Section 18 Emergency Exemption Program is found at the following website:
http://www.epa.gov/pesticides/regulating/section18_training/

Section 18 Emergency Exemption Online Training (Cont.)

- The primary goal of this online resource is to assist state and federal agencies in determining situations where it is appropriate to request a section 18 emergency exemption and, when doing so, how to submit a complete and accurate application to facilitate a timely and effective review by the EPA.

Section 18 Emergency Exemption Online Training (Cont.)

- The multimedia resource focuses on the following four types of exemptions available under section 18 of FIFRA.
- Highlights of the resource include:
 - ❑ section 18 application requirements,
 - ❑ overview of the EPA review process,
 - ❑ other options available to address significant pest problems, and
 - ❑ interactive exercises to review the important concepts covered.

Section 18 Emergency Exemption Online Training (Cont.)

- The training was developed through the Pesticide Regulatory Education Program (PREP) cooperative agreement with the University of California-Davis Extension, with funding provided by the U.S. Environmental Protection Agency.
- For more information on the new online tool, please contact Dea Zimmerman at zimmerman.dea@epa.gov.

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