

Section 18 Emergency Exemption Program

What? When? Who? How?



Tulio B. Macedo

Senior Environmental Scientist

Tulio.Macedo@cdpr.ca.gov

916-324-3527

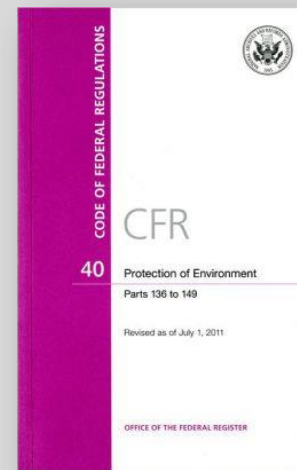
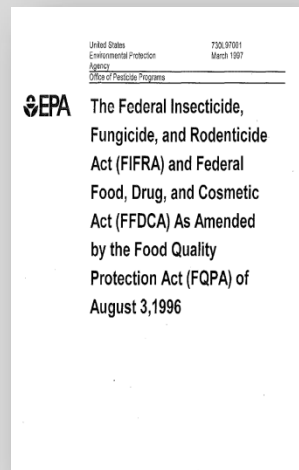
Outline:

- ❖ **What** is a Section 18 emergency exemption?
- ❖ **When** is it an emergency situation?
- ❖ **Who** can apply?
- ❖ **How** to apply?



What?

- ❖ **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**
- ✓ **Allows the use of an unregistered pesticide, OR permits the treatment of a crop site currently not approved by the U.S. EPA**



❖ **Example: Use of Intrepid®2F* (Methoxyfenozide) on dates to control carob moth**



***Note: Products mentioned in this presentation are not in anyway indorsed by DPR**

When?

- ❖ **Emergency condition is defined as an urgent, non-routine situation that requires the use of a pesticide**
- ❖ **The following conditions must be met:**
 - 1. No effective registered pesticides are available**
 - 2. No feasible alternative control practices available (e.g., cultural practices)**
 - 3. Situation involves the introduction of a new pest, or will present significant risks to human health, environment, or will cause “significant” economic loss**

Four “types” of Section 18s

1. Specific Exemption (up to one year)

- ✓ Majority of requests
- ✓ To avert a significant economic loss or a significant risk to endangered or threatened species, beneficial organisms, or the environment
- ✓ Growers or scientists identify a pest situation that registered pesticides cannot control
- ✓ **Example: Movento[®] (spirotetramat) on dry bulb onions to control thrips**

2. Quarantine Exemption (up to three years)

- ✓ To control the introduction or spread of an invasive pest not previously found in U.S.
- ✓ Justified based on the potential of an invasive species to cause significant economic loss
- ✓ **Example: Environ LpH on laboratory surfaces to control prions**

3. Public Health Exemption (up to one year)

- ✓ To control a pest that will cause significant risk to human health
- ✓ Justified based on the risk to human health from the pest to be controlled
- ✓ **Example: Anvil 10+10 ULV (piperonyl butoxide + phenothrin) on crop lands to control mosquitoes**

4. Crisis Exemption (up to 15 days)

- ✓ Issued when time from discovery of the emergency to the time when the pesticide use is needed is insufficient to allow authorization through normal means (e.g., critical imminent pest losses)
- ✓ DPR must receive verbal authorization from U.S. EPA prior to issuance
- ✓ Applicant must follow up with a specific, quarantine, or public health emergency exemption request
- ✓ **Example: Pristine Fungicide on Belgian Endive to control *sclerotinia***

Who?

- ❖ **Someone other than the product registrant, such as:**
 - ✓ **University of California Extension personnel**
 - ✓ **County Agricultural Commissioners**
 - ✓ **Grower or commodity group**
 - ✓ **Private consultant**



How?

- ❖ Applicant submit a request to DPR. If DPR approves the request, it is forwarded to U.S. EPA for further review and authorization
- ❖ No fees required
- ❖ Application form available on DPR's Web site

www.cdpr.ca.gov/docs/registration/regforms/sec18/18app3.pdf

State of California
Department of Pesticide Regulation
Pesticide Registration Branch
PR-REG-005 (Est. 7/91) (Rev. 3/10)

APPLICATION FOR SECTION 18 EMERGENCY EXEMPTION

The following information is required for an emergency exemption request based on the revised United States Environmental Protection Agency (USEPA) Code of Federal Regulations, Title 40, Part 166 concerning Section 18 requests. Requests which are incomplete will be denied by the USEPA without review. In order to comply with these requirements, the information listed below must be provided. Use additional pages if necessary. Please note that the more complete the questionnaire, the better your chances are of obtaining the exemption.

Check box if this is a reissuance request. (Year)

TYPE OF EXEMPTION BEING REQUESTED (check one)

- SPECIFIC
 QUARANTINE
 PUBLIC HEALTH

DESCRIPTION OF PESTICIDE REQUESTED

Common Chemical Name

(Active Ingredient): _____

Trade Name/Brand Name: _____

U.S. EPA Reg. No.: _____

Formulation: _____ % Active Ingredient: _____ %

Manufacturer: _____



Applications must include the following information:

- ❖ Complete description of the emergency pest problem**
- ❖ Knowledgeable expert contact information - to confirm the emergency situation**
- ❖ Explanation of available alternatives - Detailed why currently registered pesticides or cultural practices are not adequate to address pest situation**
- ❖ Emergency Exemption Use Instructions (label) - 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 the pest problem**
- ❖ **Economic history of the crop, including annual production, price of commodity, and cost of production**
 - ✓ **Average crop loss, not worse case scenario**
 - ✓ **Losses can be changes in yield, reduction in quality of product, increase of production costs**



❖ **Scientific data to support request, must include:**

- ✓ **Efficacy**
- ✓ **Residue chemistry**
- ✓ **Phytotoxicity**
- ✓ **If claiming pest resistance - field data is required**
- ✓ **If product is not registered in California:**
 - **Acute toxicology**
 - **Product chemistry data**

Scientific data review (14 to 30 days)*:

❖ Registration:

- ✓ Chemistry
- ✓ Efficacy / Phytotoxicity
- ✓ Fish and Wildlife
- ✓ Significant Economic Loss (SEL)

❖ Pest Management and Licensing:

- ✓ Endangered species

❖ Human Health Assessment:

- ✓ Acute toxicology

❖ Worker Health and Safety:

- ✓ Worker safety issues



Other documents required:

- ❖ **A Letter of Authorization from the product registrant**
- ❖ **If product is not federally registered:**
 - ✓ **Draft product label and product formulation sheet from registrant**
- ❖ **If product is federally registered, but not registered in California:**
 - ✓ **Copy of U.S. EPA-accepted label, and**
 - ✓ **Confidential Statement of Formula (CSF)**



We are not done yet!

- ❖ **Once DPR concludes its review, application package is forwarded to U.S. EPA**
- ❖ **U.S. EPA's review time frame ranges from 50 to 60 days**
- ❖ **Risk Integration Minor Use, and Emergency Response Branch**
 - ✓ **Section 18 team**
 - ✓ **HED – Health Effects Division**
 - ✓ **BEAD – Biological and Economic Analysis Division**
 - ✓ **EFED – Environmental Fate and Effects D**
- ❖ **U.S. EPA establishes a time-limited tolerance**



Post-authorization activities

- ❖ If U.S. EPA approves, DPR then:
 - ✓ Issues: Emergency Exemption Use Instructions, cover letter, and/or the registrant product label (if unregistered product) to appropriate County Agricultural Commissioner's
 - ✓ Notifies applicant (requestor), registrant, IR-4 Project, other interested parties
- ❖ User must obtain a **restricted materials permit** and follow directions provided by the emergency use instructions and registrant product label
- ❖ CACs must file a **final use report** to DPR upon expiration of the Section 18 emergency exemption

Impediments to Consider

❖ U.S. EPA approvals may be impacted by:

✓ Product chemical concerns

- Safety finding cannot be made (e.g., bystander exposure concerns, chemical risk cup full)

✓ Review time frames to establish a time-limited tolerance (50 days – 4 months)

- Tolerance establishment ≠ Emergency time frame



Thank you

Tulio Macedo – tulio.macedo@cdpr.ca.gov

Margaret Reiff – margaret.reiff@cdpr.ca.gov

Additional Web Resources

<http://www.cdpr.ca.gov/docs/registration/sec18/sect18s.htm>

<http://apps.cdpr.ca.gov/section18/>

http://www.epa.gov/pesticides/regulating/section18_training/