

PART 166—EXEMPTION OF FEDERAL AND STATE AGENCIES FOR USE OF PESTICIDES UNDER EMERGENCY CONDITIONS

Subpart A—General Provisions

Sec.

- 166.1 Purpose and organization.
- 166.2 Types of exemptions.
- 166.3 Definitions.
- 166.7 User notification; advertising.

Subpart B—Specific, Quarantine, and Public Health Exemptions

- 166.20 Application for a specific, quarantine, or public health exemption.
- 166.22 Consultation with the Secretary of Agriculture and Governors of the States.
- 166.24 Public notice of receipt of application and opportunity for public comment.
- 166.25 Agency review.
- 166.28 Duration of exemption.
- 166.30 Notice of Agency decision.
- 166.32 Reporting and recordkeeping requirements for specific, quarantine, and public health exemptions.
- 166.34 EPA review of information obtained in connection with emergency exemptions.
- 166.35 Revocation or modification of exemptions.

Subpart C—Crisis Exemptions

- 166.40 Authorization.
- 166.41 Limitations.
- 166.43 Notice to EPA and registrants or basic manufacturers.
- 166.45 Duration of crisis exemption.
- 166.47 Notification of FDA, USDA, and State health officials.
- 166.49 Public notice of crisis exemptions.
- 166.50 Reporting and recordkeeping requirements for crisis exemption.
- 166.53 EPA review of crisis exemption and revocation of authority.

AUTHORITY: 7 U.S.C. 136–136y.

SOURCE: 51 FR 1902, Jan. 15, 1986, unless otherwise noted.

Subpart A—General Provisions

§ 166.1 Purpose and organization.

(a) *Purpose and scope.* Section 18 of the Act authorizes the Administrator to exempt State and Federal agencies from any provision of the Act, if he determines that emergency conditions exist which require an exemption. The regulations in this part establish procedures whereby the Administrator

may exempt a Federal or State agency from the provisions of the Act which regulate the manner in which a pesticide is made available for use or is used.

(b) *Organization.* (1) The provisions in subpart A of this part describe the four types of emergency exemptions authorized by the Agency and define terms used in this part.

(2) Subpart B of this part establishes procedures and criteria for specific, quarantine, and public health exemptions.

(3) Subpart C of this part establishes procedures and criteria for crisis exemptions.

§ 166.2 Types of exemptions.

There are four types of emergency exemptions which may be authorized: specific, quarantine, public health, and crisis exemptions.

(a) *Specific exemption.* A specific exemption may be authorized in an emergency condition to avert:

- (1) A significant economic loss; or
- (2) A significant risk to:
 - (i) Endangered species,
 - (ii) Threatened species,
 - (iii) Beneficial organisms, or
 - (iv) The environment.

(b) *Quarantine exemption.* A quarantine exemption may be authorized in an emergency condition to control the introduction or spread of any pest new to or not theretofore known to be widely prevalent or distributed within and throughout the United States and its territories.

(c) *Public health exemption.* A public health exemption may be authorized in an emergency condition to control a pest that will cause a significant risk to human health.

(d) *Crisis exemption.* A crisis exemption may be utilized in an emergency condition 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.

§ 166.3 Definitions.

Terms used in this part shall have the meanings established by the Federal Insecticide, Fungicide, and Rodenticide Act. In addition, as used in

§ 166.3

40 CFR Ch. I (7-1-04 Edition)

this part, the following terms shall also apply:

(a) The term *the Act* means the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, 7 U.S.C. 136 *et seq.*

(b) The terms *the Agency* and *EPA* mean the U.S. Environmental Protection Agency.

(c) The term *beneficial organism* means any pollinating insect, or any pest predator, parasite, pathogen or other biological control agent which functions naturally or as part of an integrated pest management program to control another pest.

(d) The term *emergency condition* means an urgent, non-routine situation that requires the use of a pesticide(s) and shall be deemed to exist when:

(1) No effective pesticides are available under the Act that have labeled uses registered for control of the pest under the conditions of the emergency; and

(2) No economically or environmentally feasible alternative practices which provide adequate control are available; and

(3) The situation:

(i) Involves the introduction or dissemination of a pest new to or not theretofore known to be widely prevalent or distributed within or throughout the United States and its territories; or

(ii) Will present significant risks to human health; or

(iii) Will present significant risks to threatened or endangered species, beneficial organisms, or the environment; or

(iv) Will cause significant economic loss due to:

(A) An outbreak or an expected outbreak of a pest; or

(B) A change in plant growth or development caused by unusual environmental conditions where such change can be rectified by the use of a pesticide(s).

(e) The term *first food use* refers to the use of a pesticide on a food or in a manner which otherwise would be expected to result in residues in a food, if no permanent tolerance, exemption from the requirement of a tolerance, or food additive regulation for residues of the pesticide on any food has been es-

tablished for the pesticide under section 408 (d) or (e) or 409 of the Federal Food, Drug, and Cosmetic Act.

(f) The term *food* means any article used for food or drink for man or animals.

(g) The term *new chemical* means an active ingredient not contained in any currently registered pesticide.

(h) The term *significant economic loss* means that, under the emergency conditions: for a productive activity, the profitability would be substantially below the expected profitability for that activity; or, for other types of activities, where profits cannot be calculated, the value of public or private fixed assets would be substantially below the expected value for those assets. Only losses caused by the emergency conditions, specific to the impacted site, and specific to the geographic area affected by the emergency conditions are included. The contribution of obvious mismanagement to the loss will not be considered in determining loss. In evaluating the significant of an economic loss for productive activities, the Agency will consider whether the expected reduction in profitability exceeds what would be expected as a result of normal fluctuations over a number of years, and whether the loss would affect the long-term financial viability expected from the productive activity. In evaluating the significance of an economic loss for situations other than productive activities, the Agency will consider reasonable measures of expected loss.

(i) The term *Special Review* refers to any interim administrative review of the risks and benefits of the use of a pesticide conducted pursuant to the provisions of EPA's Rebuttable Presumption Against Registration rules, 40 CFR 162.11(a), or any subsequent version of those rules.

(j) The term *unreasonable adverse effects on the environment* means any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide.