

### § 166.3

### 40 CFR Ch. I (7-1-07 Edition)

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.

[51 FR 1902, Jan. 15, 1986, as amended at 71 FR 4510, Jan. 27, 2006]

#### § 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 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 an invasive species or 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, ben-

eficial 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 tolerance or exemption from the requirement of a tolerance for residues of the pesticide on any food has been established for the pesticide under section 408(b)(2) and (c)(2) 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, compared to the situation without the pest emergency and despite the best efforts of the affected persons, the emergency conditions at the specific use site identified in the application are reasonably expected to cause losses meeting any of the following criteria:

(1) For pest activity that primarily affects the current crop or other output, one or more of the following:

(i) Yield loss greater than or equal to 20%;

(ii) Economic loss, including revenue losses and cost increases, greater than or equal to 20% of gross revenues;

(iii) Economic loss, including revenue losses and cost increases, greater than or equal to 50% of net revenues;

(2) For any pest activity where EPA determines that the criteria in paragraph (h)(1) would not adequately describe the expected loss, substantial loss or impairment of capital assets, or a loss that would affect the long-term financial viability expected from the productive activity.

(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

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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.

(k) The term *invasive species* means, with respect to a particular ecosystem, any species that is not native to that ecosystem, and whose introduction does or is likely to cause economic or environmental harm or harm to human health.

(l) The term *IR-4 program* means the Interregional Research Project No. 4, a cooperative effort of the state land grant universities, the U.S. Department of Agriculture and EPA, to address the chronic shortage of pest control options for minor crops, which are generally of too small an acreage to provide economic incentive for registration by the crop protection industry.

[51 FR 1902, Jan. 15, 1986, as amended at 71 FR 4510, Jan. 27, 2006]

### § 166.7 User notification; advertising.

(a) A State or Federal agency that obtains an exemption may notify eligible users of the availability of the exempted pesticide(s) through user groups, retail dealers, and other means. Notification may include distributing copies of the section 18 approval letter, labeling, or other information to eligible persons.

(b) As set forth more fully in § 168.22 of this chapter, EPA interprets FIFRA sections 12(a)(1) (A) and (B) as making it unlawful for any person who distributes, sells, offers for sale, holds for sale, ships, delivers for shipment, or receives and (having so received) delivers or offers to deliver any pesticide, to advertise the pesticide for any use authorized by an emergency exemption, except for advertisements that are placed in media that address only persons in the geographical area to which the exemption applies, state the name and address of one or more retail dealers where users may buy the pesticide, and contain a prominent notice of the limitations on use under the emer-

gency exemption. EPA may withdraw an exemption if the use of the pesticide covered by the exemption is advertised unlawfully.

[54 FR 1125, Jan. 11, 1989]

### Subpart B—Specific, Quarantine, and Public Health Exemptions

#### § 166.20 Application for a specific, quarantine, or public health exemption.

(a) *General information required in an application for a specific, quarantine or public health exemption.* An application must be submitted in writing by the head of the Federal or State agency, the Governor of the State involved, or their official designee. If a designee has been delegated authority to request exemptions, written authorization of such delegation must accompany the request or be on file with the Agency. In addition, the application must contain all applicable information specified in paragraphs (a) (1) through (11) of this section.

(1) *Identity of contact persons.* (i) Unless otherwise specified, the person who submits the application will be considered the contact person for all matters relating to administration of the emergency exemption.

(ii) Requests should identify by name and telephone number one or more qualified experts who may be contacted in case any questions arise concerning the application.

(2) *Description of the pesticide.* The application shall contain a description of the pesticide(s) proposed for use under the exemption. Such information shall include:

(i) For a federally registered pesticide product:

(A) A copy of the label(s) if a specific product(s) is/are requested; or the formulation(s) requested if a specific product is not requested; and

(B) A copy of any additional labeling proposed for the emergency exemption; or

(ii) For any other pesticide products:  
(A) A confidential statement of formula or reference to one already submitted to the Agency; and

(B) Complete labeling to be used in connection with the proposed exemption use.