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40 CFR Ch. I (7-1-06 Edition)

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 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 emergency 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

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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.

(3) *Description of the proposed use.* The application shall identify all of the following:

(i) Sites to be treated, including their locations within the State;

(ii) The method of application;

(iii) The rate of application in terms of active ingredient and product;

(iv) The maximum number of applications;

(v) The total acreage or other appropriate unit proposed to be treated;

(vi) The total amount of pesticide proposed to be used in terms of both active ingredient and product;

(vii) All applicable restrictions and requirements concerning the proposed use which may not appear on labeling;

(viii) The duration of the proposed use; and

(ix) Earliest possible harvest dates.

(4) *Alternative methods of control.* The application shall contain:

(i) A detailed explanation of why the pesticide(s) currently registered for the particular use proposed in the application is not available in adequate supplies and/or effective to the degree needed to control the emergency. If the

applicant states that an available registered pesticide is ineffective for the given situation, the statement must be supported by field data which demonstrate ineffectiveness of registered pesticides, or, if such data are unavailable, statements by qualified agricultural experts, extension personnel, university personnel or other persons similarly qualified in the field of pest control; and

(ii) A detailed explanation of why alternative practices, if available, either would not provide adequate control or would not be economically or environmentally feasible.

(5) *Effectiveness of proposed use.* The application shall contain data, a discussion of field trials, or other evidence which provide the basis for the conclusion that the proposed pesticide treatment will be effective in dealing with the emergency.

(6) *Discussion of residues for food uses.* If the proposed use is expected to result in residues of the pesticide in or on food, the application shall list the food likely to contain such residues and shall contain an estimate of the maximum amount of the residue likely to result from the proposed use, together with the information on which such estimates are based.

(7) *Discussion of risk information.* The application shall address the potential risks to human health, endangered or threatened species, beneficial organisms, and the environment expected to result from the proposed use, together with references to data and other supporting information.

(8) *Coordination with other affected State or Federal agencies.* If the proposed use of the pesticide is likely to be of concern to other Federal or State agencies, the application shall indicate that such agencies have been contacted prior to submission of the application, and any comments received from such agencies shall be submitted to EPA.

(9) *Acknowledgment by registrant.* The application shall contain a statement by the registrants of all pesticide products proposed for use acknowledging that a request has been made to the Agency for use of the pesticide under this section. This acknowledgment shall include a statement of support for

the requested use, including the expected availability of adequate quantities of the requested product under the use scenario proposed by the applicant(s); and the status of the registration in regard to the requested use including appropriate petition numbers, or of the registrant's intentions regarding the registration of the use.

(10) *Description of proposed enforcement program.* Prior to approval, the applicant shall provide an explanation of the authority of the applicant or related State or Federal agencies for ensuring that use of the pesticide under the proposed exemption would comply with any special requirements imposed by the Agency and a description of the program and procedures for assuring such compliance.

(11) *Repeated uses.* Applications for the use of a pesticide at a site for which the applicant has previously been exempted under section 18 shall contain an interim report summarizing the results of the specific, quarantine, or public health exemption previously issued, if the application is submitted prior to the time the final report for the previous exemption is due. The interim report shall contain that information specified in §166.32 to the extent available at the time the application is made.

(b) *Information required for a specific exemption.* An application for a specific exemption shall provide all of the following information, as appropriate, concerning the nature of the emergency:

(1) The scientific and common name of the pest or pest complex;

(2) A discussion of the events which brought about the emergency condition;

(3) A discussion of the anticipated risks to endangered or threatened species, beneficial organisms, or the environment that would be remedied by the proposed use of the pesticide; and

(4) A discussion of the anticipated significant economic loss, together with data and other information supporting the discussion, that addresses one or more of the following, as appropriate:

(i) Yield or utilized yield reasonably anticipated in the absence of the emer-

gency and expected losses in quantity due to the emergency;

(ii) The information in paragraph (b)(4)(i) of this section plus prices reasonably anticipated in the absence of the emergency and changes in prices and/or production costs due to the emergency;

(iii) The information in paragraph (b)(4)(ii) of this section plus operating costs reasonably anticipated in the absence of the emergency;

(iv) Any other information explaining the economic consequences of the emergency.

(5) *Re-certification of an emergency condition.* Applicants for specific exemptions may submit re-certification applications relying on previously submitted information to satisfy the information requirements of paragraphs (a)(1) through (a)(10) of this section, and of paragraphs (b)(1) through (b)(4) of this section, where all of the following conditions are met:

(i) An exemption was granted for the same pesticide at the same site to the same applicant the previous year;

(ii) The emergency condition could reasonably be expected to continue for longer than 1 year;

(iii) EPA has not declared the use ineligible for re-certification;

(iv) The use is not subject to public notice pursuant to §166.24(a)(1) through (a)(6);

(v) The applicant certifies that all of the following are true:

(A) The emergency condition described in the preceding year's application continues to exist;

(B) Except as expressly identified, all information submitted in the preceding year's application is still accurate;

(C) Except as expressly identified, the proposed conditions of use are identical to the conditions of use EPA approved for the preceding year;

(D) Any conditions or limitations on the eligibility for re-certification identified in the preceding year's notice of approval of the emergency exemption have been satisfied;

(E) The applicant is not aware of any alternative chemical or non-chemical practice that may offer a meaningful level of pest control, or has provided documentation that each such known

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practice does not provide adequate control or is not economically or environmentally feasible.

(c) *Information required for a quarantine exemption.* An application for a quarantine exemption shall provide all of the following information concerning the nature of the emergency:

(1) The scientific and common name of pest;

(2) The origin of pest and the means of its introduction or spread if known; and

(3) The anticipated impact of not controlling the pest.

(d) *Information required for a public health exemption.* An application for a public health exemption shall provide all the following information concerning the nature of the emergency:

(1) The scientific and common name of the pest to be controlled and, if the pest is a vector, a description of the disease it is expected to transmit;

(2) A discussion of the magnitude of the health problems which are expected to occur without the pesticide use; and

(3) Discussion of the availability of medical treatment for the health problem.

[51 FR 1902, Jan. 15, 1986, as amended at 58 FR 34203, June 23, 1993; 71 FR 4511, Jan. 27, 2006]

§ 166.22 Consultation with the Secretary of Agriculture and Governors of the States.

The Agency, in determining whether or not such emergency conditions exist, shall consult with the Secretary of Agriculture and the Governor of any State concerned if they request such determination.

§ 166.24 Public notice of receipt of application and opportunity for public comment.

(a) *Publication requirement.* The Administrator shall issue a notice of receipt in the FEDERAL REGISTER for a specific, quarantine, or public health exemption and request public comment when any one of the following criteria is met:

(1) The application proposes use of a new chemical;

(2) The application proposes the first food use of an active ingredient;

(3) The application proposes any use of a pesticide if the pesticide has been subject to a suspension notice under section 6(c) of the Act;

(4) The application proposes use of a pesticide which:

(i) Was the subject of a notice under section 6(b) of the Act and was subsequently cancelled, and

(ii) Is intended for a use that poses a risk similar to the risk posed by any use of the pesticide which was the subject of the notice under section 6(b);

(5) The application proposes use of a pesticide which:

(i) Contains an active ingredient which is or has been the subject of a Special Review, and

(ii) Is intended for a use that could pose a risk similar to the risk posed by any use of the pesticide which is or has been the subject of the Special Review;

(6) The application proposes use of a pesticide which:

(i) Was voluntarily canceled under section 6(f) of the Act, and

(ii) Is intended for a use that poses a risk similar to the risk posed by any use of the pesticide which was voluntarily canceled under section 6(f);

(7) The application proposes use of a pesticide for a specific or public health exemption, if:

(i) An emergency exemption has been requested or approved for that use in any 3 previous years, or any 5 previous years if the use is supported by the IR-4 program, and

(ii) A complete application for registration of that use and/or a petition for tolerance for residues in or on the commodity has not been submitted to the Agency; or

(8) The Administrator determines that publication of notice is appropriate.

(b) *Contents.* The notice of receipt of an application for an emergency exemption shall contain the following information:

(1) The name of the applicant;

(2) The name of the active ingredient requested for use, including, if available, the common name and the Chemical Abstracts Service (CAS) number;

(3) The total amount of product or active ingredient proposed for use;

(4) The geographical location where treatment is proposed;