

Environmental Protection Agency

§ 166.2

(d) *How must a State inform EPA of revisions to its containment regulations?* Any state that has received authorization to continue implementing its state containment regulations must inform EPA by letter signed by the designated State Lead Agency within 6 months of any revision to the State's containment regulations. EPA will inform the state by letter if it determines that the State's containment regulations are no longer adequate based on the revisions. The State's containment regulations will remain in effect, unless and until EPA sends the state a letter making this determination.

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.
166.49 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 that is an invasive species, or is otherwise 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

§ 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

Environmental Protection Agency**§ 166.20**

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.

§ 166.20

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

(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

Environmental Protection Agency**§ 166.20**

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 emergency 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 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

§ 166.22

(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

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

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;

(5) The proposed number of acres or other appropriate units proposed to be treated;

(6) A summary of the applicant's description of the emergency conditions including the pest and the site or crop to be treated;

(7) A description of the major conditions of use of the pesticide as proposed by the applicant;

(8) If the pesticide proposed for use meets the criteria of paragraph (a) (3), (4), or (5) of this section, an identification of the types of risks that were the basis for EPA's regulatory action; and

(9) The name, telephone number, and address of a person in the Agency who can provide further information.

(c) *Length of comment period.* Normally, a notice of receipt shall give the public 15 days in which to file comments on the application. The Administrator may shorten or eliminate the comment period if he determines that the time available for a decision on the application requires it and shall state reasons for such action in a notice in

Environmental Protection Agency**§ 166.30**

the FEDERAL REGISTER. The Administrator may extend the comment period if additional time for comment is requested and such an extension would not interfere with a timely decision on the application.

[51 FR 1902, Jan. 15, 1986, as amended at 71 FR 4511, Jan. 27, 2006]

§ 166.25 Agency review.

(a) *General.* The Agency will review all requests as expeditiously as possible, making every attempt to respond to requests prior to the time when the proposed use is needed. The Agency will review the application and other available data necessary to make a determination with respect to all of the following:

(1) Whether an emergency condition exists or will exist;

(2) The Agency's ability and intention to establish a time-limited tolerance(s) or exemption(s) from the requirement of a tolerance for any pesticide residues resulting from the authorized use, identifying the level of permissible residues in or on food or feed resulting from the proposed use;

(3) The anticipated benefits to be derived from the proposed use; and

(4) The potential risks to human health, endangered or threatened species, beneficial organisms, and the environment from the proposed use.

(b) *Criteria for approval.* The Administrator may authorize a specific, public health, or quarantine exemption, based on the information available to the Agency, after:

(1) He determines that:

(i) An emergency condition exists;

(ii) The use of the pesticide under the exemption will not cause unreasonable adverse effects on the environment;

(iii) Registration of the pesticide use for which the exemption is requested has not been suspended under section 6(c) of the Act or cancelled following a notice under section 6(b) of the Act, unless the use is authorized in accordance with the provisions of §§164.130 through 164.133 of this chapter;

(2) Giving due consideration to:

(i) Whether the pesticide is reasonably likely to be used in compliance with the requirements imposed by the Agency under the exemption; and

(ii) The progress which has been made toward registration of the proposed use, if a repeated specific or public health exemption is sought. It shall be presumed that if a complete application for registration of a use, which has been under a specific or public health exemption for any 3 previous years, or any 5 previous years if the use is supported for registration by the IR-4 program, has not been submitted, reasonable progress towards registration has not been made.

[51 FR 1902, Jan. 15, 1986, as amended at 71 FR 4511, Jan. 27, 2006]

§ 166.28 Duration of exemption.

(a) *Specific or public health exemptions.* EPA shall allow use of a pesticide under a specific or public health exemption for as long a period as is reasonably expected to be necessary but in no case for longer than 1 year.

(b) *Quarantine exemption.* EPA shall allow use of a pesticide under a quarantine exemption for as long a period as is deemed necessary but in no case for longer than 3 years. Quarantine exemptions may be renewed. Interim reports containing the information specified in §166.32(b) to the extent available shall be filed annually.

§ 166.30 Notice of Agency decision.

(a) *Notification of applicants.* The Agency shall notify an applicant of its decision to approve or deny an application request for an emergency exemption in a timely manner.

(1) *Incomplete applications.* The Agency may discontinue the processing of any application that does not address all of the requirements of §166.20 until such time the additional information is submitted by the applicant.

(2) *Complete applications—(i) Denials.* The Agency shall provide the specific reasons and rationale for denying the exemption request. If the denial is based on a specific information gap, the decision shall be reconsidered in a timely manner when the information gap is filled.

(ii) *Approvals.* The Agency shall provide the specific terms and conditions under which the exempted pesticide may be used.

(b) *Federal Register publication.* (1) At least quarterly, the Administrator

§ 166.32**40 CFR Ch. I (7-1-07 Edition)**

shall issue a notice in the FEDERAL REGISTER announcing all approvals of specific, quarantine, and public health exemptions. The notice shall contain all of the following:

- (i) The name of the applicant;
- (ii) The pesticide authorized for use;
- (iii) The crop or site to be treated; and
- (iv) The name, address, and telephone number of a person in the Agency who can provide further information.

(2) In addition, if EPA has issued a Notice of Receipt of an application for an exemption, it will issue a notice of its final decision and the reasons for that decision.

[51 FR 1902, Jan. 15, 1986, as amended at 71 FR 4512, Jan. 27, 2006]

§ 166.32 Reporting and recordkeeping requirements for specific, quarantine, and public health exemptions.

(a) *Unexpected adverse effects information.* Any unexpected adverse effects resulting from the use of a pesticide under a specific, quarantine, or public health exemption must be immediately reported to the Agency.

(b) *Interim and final reports.* A final report summarizing the results of pesticide use under any specific, quarantine, or public health exemption must be submitted to the Agency within 6 months from the expiration of the exemption unless otherwise specified by the Agency. For quarantine exemptions granted for longer than 1 year, interim reports must be submitted annually. When an application for renewal of the exemption is submitted before the expiration of the exemption or before submission of the final report, an interim report must be submitted with the application. The information in interim and final reports shall include all of the following:

- (1) Total acreage, amount of commodity or other unit treated and the total quantity of the pesticide used;
- (2) A discussion of the effectiveness of the pesticide in dealing with the emergency condition;
- (3) A description of any unexpected adverse effects which resulted from use of the pesticide under the exemption;

(4) The results of any monitoring required and/or carried out under the exemption;

(5) A discussion of any enforcement actions taken in connection with the exemption;

(6) Method(s) of disposition of a food crop, if required to be destroyed under an exemption; and

(7) Any other information requested by the Administrator.

(c) *Records.* Records for all treatments involving the first food use of a pesticide will be maintained by the agency to which the emergency exemption was granted for a minimum of 2 years following the date of expiration of the exemption. On request by the Agency these records shall be made available to the Administrator. Records will include all of the following:

- (1) Locations where the pesticide was applied;
- (2) Dates of application (range); and
- (3) Total quantity of the pesticide used.

[51 FR 1902, Jan. 15, 1986, as amended at 58 FR 34203, June 23, 1993; 71 FR 4512, Jan. 27, 2006]

§ 166.34 EPA review of information obtained in connection with emergency exemptions.

EPA shall review information submitted in connection with emergency exemptions and, when applicable, use it in connection with other regulatory decisions under the Act.

§ 166.35 Revocation or modification of exemptions.

(a) *Grounds.* The Administrator may revoke or modify the terms or conditions of a specific, quarantine, or public health exemption if he determines one of the following:

- (1) An emergency no longer exists;
- (2) Use of the pesticide under the exemption may cause unreasonable adverse effects on the environment;
- (3) The pesticide authorized under the exemption is not effective at controlling the pest or conditions causing the emergency; or
- (4) The terms and conditions established by the exemption and these regulations are not being complied with.

Environmental Protection Agency**§ 166.45**

(b) *Implementation.* The revocation or modification becomes effective as soon as the Administrator notifies the State or Federal agency which submitted the application. Upon notification, the applicant is required immediately to take all necessary steps to assure that further use complies with the terms and conditions of any modification or, if the exemption has been revoked, to stop further use.

Subpart C—Crisis Exemptions**§ 166.40 Authorization.**

The head of a Federal or State agency, the Governor of a State, or their official designee, may issue a crisis exemption in situations involving an unpredictable emergency situation when:

(a) An unpredictable emergency condition exists;

(b) The time element with respect to the application of the pesticide is critical, and there is not sufficient time either to request a specific, quarantine, or public health exemption or, if such a request has been submitted, for EPA to complete review of the request; and

(c) EPA has provided verbal confirmation that, for food uses, a tolerance or exemption from the requirement of a tolerance can be established in a timely manner, responsive to the projected timeframe of use of the chemical and harvest of the commodity, and that, for any use, the Agency has no other objection.

[51 FR 1902, Jan. 15, 1986, as amended at 71 FR 4512, Jan. 27, 2006]

§ 166.41 Limitations.

The crisis provisions may not be utilized to authorize a pesticide use if any of the following has occurred:

(a) EPA has informed the head of the Federal or State agency, the Governor, or their official designee, not to issue such an exemption;

(b) The pesticide use has been suspended under section 6(c) of the Act;

(c) The pesticide use has been cancelled following a notice issued under section 6(b) of the Act;

(d) The pesticide contains a new chemical; or

(e) The application proposes the first food use of a pesticide.

§ 166.43 Notice to EPA and registrants or basic manufacturers.

(a) *Timing of notice.* (1) The State or Federal Agency issuing the crisis exemption must notify the Administrator in advance of utilization of the crisis provisions.

(2) The State or Federal agency issuing the crisis exemption shall notify the registrant(s) or, if appropriate, the basic manufacturer(s) of the pesticide(s) being used under the crisis exemption at the same time notice is given to EPA or as soon thereafter as possible.

(b) *Contents of notice.* Information required to be provided in notices shall include all of the following:

(1) The name of the product and active ingredient authorized for use, along with the common name and CAS number if available, including a copy of the EPA registered label and use directions appropriate to the authorized use;

(2) The site on which the pesticide is to be used or is being used;

(3) The use pattern;

(4) The date on which the pesticide use is to begin and the date when the use will end;

(5) An estimate of the level of residues of the pesticide expected to result from use under the crisis exemption;

(6) Earliest anticipated harvest date of the treated commodity;

(7) Description of the emergency situation; and

(8) Any other pertinent information available at the time.

[51 FR 1902, Jan. 15, 1986, as amended at 58 FR 34203, June 23, 1993; 71 FR 4512, Jan. 27, 2006]

§ 166.45 Duration of crisis exemption.

A crisis exemption may be authorized for:

(a) Only as long as is necessary to control the pest or conditions causing the emergency; and

(b) No longer than 15 days, unless an application requesting a specific, quarantine, or public health exemption for this use has been submitted to the Agency.

§ 166.49

§ 166.49 Public notice of crisis exemptions.

(a) *Periodic notices.* At least quarterly, the Administrator shall issue a notice in the FEDERAL REGISTER announcing issuance of crisis exemptions. The notice shall contain all of the following:

- (1) The name of the applicant;
- (2) The pesticide authorized for use;
- (3) The crop or site to be treated; and
- (4) The name, address, and telephone number of a person in the Agency who can provide further information.

(b) *Annual reports.* Annually, the Agency shall issue a notice in the FEDERAL REGISTER that shall summarize:

- (1) The number of crisis exemptions declared; and
- (2) The number of crisis exemptions revoked.

[51 FR 1902, Jan. 15, 1986, as amended at 71 FR 4512, Jan. 27, 2006]

§ 166.50 Reporting and recordkeeping requirements for crisis exemption.

(a) *Adverse effects information.* Any adverse effects resulting from the use of a pesticide under a crisis exemption must be immediately reported to the Agency.

(b) *Final reports.* (1) A report summarizing the results of treatment under a crisis exemption will be required to be submitted to the Agency within 3 months following the last date of treatment. If a specific, quarantine, or public health exemption has been approved while the crisis exemption is in effect, however, the crisis exemption report may be incorporated into the specific, quarantine, or public health exemption final report required under §166.32(b) and submitted at the time it is due.

(2) Information to be included in the crisis exemption report includes the same information as required in §166.32(b) and an explanation as to why there was a need to utilize the crisis provisions.

(c) *Records.* Records will be maintained for a minimum of 2 years following the date of expiration of the exemption. On request by the Agency, these records shall be made available to the Administrator. Records will include all of the following:

- (1) Location where the pesticide was applied;

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

- (2) Dates of application (range); and
- (3) Total quantity of the pesticide used.

[51 FR 1902, Jan. 15, 1986, as amended at 58 FR 34203, June 23, 1993]

§ 166.53 EPA review of crisis exemption and revocation of authority.

(a) *Review.* When a crisis exemption is about to be or has already been declared by a State or Federal agency, EPA will undertake an expedited review of the pesticide to determine if use of the pesticide may result in such unreasonable health or environmental risks that the crisis authority should not be exercised or the crisis exemption should be revoked.

(b) *Revocation*—(1) *Individual crisis exemptions.* A crisis exemption for the use of a specific pesticide may be revoked if the Administrator determines that:

- (i) There are insufficient data to determine the risks posed from the use;
- (ii) Such action is necessary to protect man or the environment; or
- (iii) The State or Federal agency is not complying with the requirements of this subpart C.

(2) *State or Federal agency authority.* The Administrator may revoke the authority of a State or Federal agency to issue crisis exemptions for any pesticide if he determines that:

- (i) Such action is necessary to protect man or the environment; or
- (ii) The State or Federal agency is not complying with the requirements of this subpart C.

(c) *Reason for revocation.* The Agency shall provide the specific reasons for revoking an agency's authority to issue a crisis exemption and for revoking an issued crisis exemption.

PART 167—REGISTRATION OF PESTICIDE AND ACTIVE INGREDIENT PRODUCING ESTABLISHMENTS, SUBMISSION OF PESTICIDE REPORTS

Subpart A—General Provisions

Sec.
167.3 Definitions.

Subpart B—Registration Requirements

167.20 Establishments requiring registration.