by the applicant, the Administrator determines, in accordance with paragraph (a) of this section, that reconsideration of his prior order is warranted, he will then publish notice in the FEDERAL REGISTER setting forth his determination and briefly describing the basis for the determination. Such notice shall announce that a formal public hearing will be held in accordance with 5 U.S.C. section 554. The notice shall specify: (1) The date on which the hearing will begin and end, (2) the issues of fact and law to be adjudicated at the hearing, (3) the date on which the presiding officer shall submit his recommendations, including findings of fact and conclusions, to the Administrator, and (4) the date on which a decision by the Administrator is anticipated.

§ 164.132 Procedures governing hearing.

(a) The burden of proof in the hearing convened pursuant to § 164.131 shall be on the applicant and he shall proceed first. The issues in the hearing shall be whether: (1) Substantial new evidence exists and (2) such substantial new evidence requires reversal or modification of the existing cancellation or suspension order. The determination of these issues shall be made taking into account the human and environmental risks found by the Administrator in his cancellation or suspension determination and the cumulative effect of all past and present uses, including the requested use, and uses which may reasonably be anticipated to occur in the future as a result of granting the requested reversal or modification. The granting of a particular petition for use may not in itself pose a significant risk to man or the environment, but the cumulative impact of each additional use of the cancelled or suspended pesticide may re-establish, or serve to maintain, the significant risks previously found by the Administrator.

(b) The presiding officer shall make recommendations, including findings of fact and conclusions and to the extent feasible, as determined by the presiding officer, the procedures at the hearing shall follow the Rules of Practice, set forth in subparts A and B of this part 164.

§ 164.133 Emergency waiver of hearing.

(a) In the case of an application subject to this subpart D which is filed under section 18 of FIFRA, and regulations thereunder, and for which a hearing is required pursuant to § 164.131, the Administrator may dispense with the requirement of convening such a hearing in any case in which he determines:

(1) That the application presents a situation involving need to use the pesticide to prevent an unacceptable risk: (i) To human health, or (ii) to fish or wildlife populations when such use would not pose a human health hazard; and

(2) That there is no other feasible solution to such risk; and

(3) That the time available to avert the risk to human health or fish and wildlife is insufficient to permit convening a hearing as required by § 164.131; and

(4) That the public interest requires the granting of the requested use as soon as possible.

(b) Notice of any determination made by the Administrator pursuant to paragraph (a) of this section shall be published in the FEDERAL REGISTER as soon as practicable after granting the requested use and shall set forth the basis for the Administrator's determination.

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

Subpart A—General Provisions

Sec.

Subpart B—Specific, Quarantine, and Public Health Exemptions

Subpart C—Crisis Exemptions

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 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 established 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.

§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 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) The registration number and the name of the pesticide product if a specific product is requested; or the formulation(s) requested if a specific product is not desired; 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 total acreage or other appropriate unit proposed to be treated;

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

(vi) All applicable restrictions and requirements concerning the proposed use and the qualifications of applicators using the pesticide.

(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) *Notification of registrant or basic manufacturer.* The application shall contain a statement that the registrants of all pesticide products proposed for use or, if appropriate, the basic manufacturer have been notified that a request has been made to the Agency for use of the pesticide under a specific, quarantine, or public health exemption.

(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, which addresses all of the following:

(i) Historical net and gross revenues for the site;

(ii) The estimated net and gross revenues for the site without the use of the proposed pesticide; and

(iii) The estimated net and gross revenues for the site with use of the proposed pesticide.

(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]

§ 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 for a specific or public health exemption, if:

(i) An emergency exemption has been requested or granted for that use in any 3 previous years, 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

(7) 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 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.

§ 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 level of residues in or on all food resulting from the proposed use;

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

(4) The potential risks to the 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, has not been submitted, reasonable progress towards registration has not been made.

§ 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 which does not contain all of the information required by § 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) *Notification of FDA, USDA, and State health officials.* If a use authorized under a specific, quarantine, or public health exemption will result in residues of the pesticide chemical in or on food, the Agency shall notify the Food and Drug Administration, U.S. Department of Health and Human Services, and the Food Safety and Inspection Service, U.S. Department of Agriculture, as appropriate, of the level of residues expected to result. Additionally, the Agency shall ensure that State health and food officials, as appropriate, are also provided with the information specified in this paragraph.

(c) FEDERAL REGISTER *publication.* (1) At least quarterly, the Administrator 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.

§ 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) *Final reports.* A report summarizing the results of pesticide use under a specific, quarantine, and public health exemption must be submitted to the Agency within 6 months from the expiration of the exemption unless otherwise specified by the Agency. The information in this report 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]

§ 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.

(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 emergency condition exists; and

(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.

§ 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) When feasible, the State or Federal Agency issuing the crisis exemption must notify the Administrator at least 36 hours in advance of utilization of the crisis provisions. In no case shall notice be given to the Agency later than 24 hours after the decision to avail itself of a crisis exemption.

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

(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 or the date on which use of the pesticide began;

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

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

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

§ 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.

§ 166.47 Notification of FDA, USDA, and State health officials.

If a use authorized under a crisis exemption will result in residues of the pesticide chemical in or on food, the Agency will notify the authorizing agency, the Food and Drug Administration, U.S. Department of Health and Human Services and the Food Safety and Inspection Service, U.S. Department of Agriculture, as appropriate, of the level of residues expected to result and whether such residues pose an unacceptable risk to public health. This notice shall be provided as soon as the Agency makes its determination. Additionally, the Agency will ensure that State health and food officials, as appropriate, are also provided with this information.

§ 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 State or Federal agency using a crisis exemption;

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

(3) The site to be treated;

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

(5) Whether a specific, quarantine, or public health exemption has been requested.

(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.

§ 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;

(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.

Subpart B—Registration Requirements

Subparts C and D—[Reserved]

Subpart E—Recordkeeping and Reporting Requirements

AUTHORITY: 7 U.S.C. 136 (e) and (w).

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