

## § 166.25

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 pro-

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posed 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

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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