

§ 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