(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;

(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.

[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