

application, the Administrator will review the schedule and the supporting information and data and respond with approval or denial of the treatment schedule. If the Administrator determines the treatment schedule to be of potential general use, the Administrator may add the new treatment schedule to the PPQ Treatment Manual or revise an existing schedule, as appropriate, in accordance with §305.3.

(d) APHIS is not responsible for losses or damages incurred during treatment and recommends that a sample be treated first before deciding whether to treat the entire shipment.

[75 FR 4241, Jan. 26, 2010, as amended at 76 FR 60360, Sept. 29, 2011]

**§305.3 Processes for adding, revising, or removing treatment schedules in the PPQ Treatment Manual.**

(a) *Normal process for adding, revising, or removing treatment schedules.* Unless there is a need to immediately add, revise, or remove a treatment schedule, as provided in paragraph (b)(1) of this section, a treatment schedule may be added to the PPQ Treatment Manual, revised, or removed from the PPQ Treatment Manual as follows:

(1) *Notice of change to treatment schedule.* APHIS will publish in the FEDERAL REGISTER a notice describing the reasons we have determined that it is necessary to add, revise, or remove a treatment schedule and, if necessary, making available the new or revised treatment schedule as it would be added to the PPQ Treatment Manual. In our notice, we will provide for a public comment period on the new or revised treatment schedule or on the removal of the treatment schedule from the PPQ Treatment Manual.

(2) *Response to comments.* (i) APHIS will issue a notice after the close of the public comment period indicating that the treatment schedule specified in the initial notice will be added to the PPQ Treatment Manual, revised as described in the notice, or removed from the PPQ Treatment Manual if:

(A) No comments were received on the notice;

(B) The comments on the notice supported our action; or

(C) The comments on the notice were evaluated but did not change our deter-

mination that it is necessary to add, revise, or remove the treatment schedule, as described in the notice.

(ii) If the notice issued after the close of the public comment period indicates that a change will be made to the PPQ Treatment Manual, APHIS will make available a new version of the PPQ Treatment Manual that reflects the addition, revision, or removal of the particular treatment schedule.

(iii) If comments present information that causes us to determine that the change described in the notice is not appropriate, APHIS will issue a notice informing the public of this determination after the close of the comment period.

(b) *Process for immediately adding, revising, or removing treatment schedules.* Treatment schedules may be immediately added to the PPQ Treatment Manual, revised, or removed from the PPQ Treatment Manual under the circumstances described in paragraph (b)(1) of this section and in accordance with the process described in paragraphs (b)(2) and (b)(3) of this section.

(1) *Circumstances in which the immediate process may be used.* Treatment schedules may be immediately added to the PPQ Treatment Manual, revised, or removed from the PPQ Treatment Manual if any of the following circumstances apply:

(i) PPQ has determined that an approved treatment schedule is ineffective at neutralizing the targeted plant pest(s);

(ii) PPQ has determined that, in order to neutralize the targeted plant pest(s), the treatment schedule must be administered using a different process than was previously used;

(iii) PPQ has determined that a new treatment schedule is effective, based on efficacy data, and that ongoing trade in an article or articles may be adversely impacted unless the new treatment schedule is approved for use; or

(iv) The use of a treatment schedule is no longer authorized by the U.S. Environmental Protection Agency or by any other Federal entity.

(2) *Process for immediate change to treatment schedules.* If PPQ determines that one or more of the circumstances

in paragraph (b)(1) of this section applies and that it is necessary to take immediate action, APHIS will publish in the FEDERAL REGISTER a notice describing the reasons we have determined that it is necessary to immediately add, revise, or remove a treatment schedule and, if necessary, making available the new or revised treatment schedule as it has been added to the PPQ Treatment Manual. Treatment schedules that have been added to the PPQ Treatment Manual or revised under this process will be identified in the PPQ Treatment Manual as having been added or revised through the immediate process described in this paragraph (b). The PPQ Treatment Manual will indicate that these treatment schedules are subject to change or removal based on public comment. In our notice, we will provide for a public comment period on the new or revised treatment schedule or on the removal of the treatment schedule from the PPQ Treatment Manual.

(3) *Response to comments.* (i) APHIS will issue a notice after the close of the public comment period affirming the action described in the initial notice if:

(A) No comments were received on the notice;

(B) The comments on the notice supported our action; or

(C) The comments on the notice were evaluated but did not change our determination that it was necessary to add, revise, or remove the treatment schedule, as described in the notice.

(ii) If the notice issued after the close of the public comment period indicates that the initial change to the PPQ Treatment Manual is affirmed, APHIS will make available a new version of the PPQ Treatment Manual that will reflect the addition, revision, or removal of the particular treatment schedule in the main body of the PPQ Treatment Manual.

(iii) If comments present information that causes us to determine that it is necessary to change a treatment schedule added to the PPQ Treatment Manual under this process or to further revise a treatment schedule that was revised under this process, APHIS will publish a notice in the FEDERAL REGISTER informing the public of this determination after the close of the com-

ment period and will revise the treatment schedule accordingly.

(iv) If comments present information that causes us to determine that the change described in the initial notice was not appropriate, APHIS will publish a notice in the FEDERAL REGISTER informing the public of this determination after the close of the comment period and will, if necessary, remove the new or revised treatment schedule from the separate section of the PPQ Treatment Manual.

#### **§ 305.4 Monitoring and certification of treatments.**

(a) All treatments approved under part 305 are subject to monitoring and verification by APHIS.

(b) Any treatment performed outside the United States must be monitored and certified by an inspector or an official authorized by APHIS. During the entire interval between treatment and export, the consignment must be stored and handled in a manner that prevents any infestation by pests and noxious weeds.

#### **§ 305.5 Chemical treatment requirements.**

(a) *Certified facility.* The fumigation treatment facility must be certified by APHIS. Facilities are required to be inspected and recertified annually, or as often as APHIS directs, depending upon treatments performed, commodities handled, and operations conducted at the facility. In order to be certified, a fumigation facility must:

(1) Be capable of administering the required dosage range for the required duration and at the appropriate temperature, as specified in the treatment schedules in the PPQ Treatment Manual or in another treatment schedule approved in accordance with § 305.2.

(2) Be adequate to contain the fumigant and be constructed from material that is not reactive to the fumigant.

(3) For vacuum fumigation facilities, be constructed to withstand required negative pressure.

(b) *Monitoring.* Treatment must be monitored by an official authorized by APHIS to ensure proper administration of the treatment, including that the correct amount of gas reaches the target organism and that an adequate