

801(b) of the act. The provisions found in this proposed paragraph are consistent with section 303 of the Bioterrorism Act, and are designed to keep foods that present a threat of serious adverse health consequences or death from moving in commerce.

Proposed § 1.381(b) prohibits, except as provided in proposed § 1.381(c), the transfer of a detained article of food within or from the place where it has been detained, or from the place to which it was moved, until an authorized FDA representative releases the article of food under proposed § 1.384 or the detention period expires under proposed § 1.379, whichever occurs first. This provision is necessary to ensure that the article of food subject to a detention order is not released into commerce.

Proposed § 1.381(c) provides that an authorized FDA representative may approve, in writing, a request for a limited conditional release of the detained article of food for any of the following purposes:

1. To destroy the article of food,
2. To move the detained article of food to a secure facility as described in the detention order,
3. To maintain or preserve the integrity or quality of the article of food, or
4. For any other purpose that the authorized FDA representative believes is appropriate in that case.

A limited conditional release of a detained article of food will be considered only in rare circumstances and only for the purposes described. We do not envision authorizing a limited conditional release under many circumstances because any movement increases the risk of inappropriate or unauthorized movement of detained articles of food into commerce. In order to decrease the chance of detained articles of food moving into commerce, the food should not be moved unless absolutely necessary. However, we recognize there may be cases where some movement is necessary. For example, it may be necessary to take steps to preserve the article of food until the detention is resolved, e.g., movement of a detained article of food from refrigerated storage to a freezer. This proposed section would allow such action in those limited circumstances that the agency finds appropriate.

As noted below, an article of food subject to a limited conditional release is still subject to detention and the requirements of this proposed rule.

Proposed § 1.381(d) requires you to submit a request for a limited conditional release in writing to the authorized FDA representative who

approved the detention order. Your request must state the following:

- Reasons for movement;
- Exact address of and location in the new facility (or the new location within the same facility) where the detained article of food will be transferred;
- Explanation of how the new address and location will be secure, if FDA has directed that the article of food be detained in a secure facility; and
- Explanation of how the article of food will be held under any applicable conditions described in the detention order.

If your request is for the purpose of destroying the detained article of food, you also must submit a verified statement identifying the ownership or proprietary interest you have in the detained article of food. Under “Federal Rules of Civil Procedure,” Supplemental Rule C(6)(a), a person who asserts an interest in or right against property that is the subject of a seizure action in federal court must file a verified statement identifying the interest or right. The purpose of this requirement is to minimize the possibility that the detained article of food would be released for destruction to a person without the proper ownership or proprietary interest in the food.

Proposed § 1.381(e) states that a detained article of food remains under detention before, during, and after the transfer under a limited conditional release. Accordingly, we will prescribe applicable transportation conditions to an article transferred under a limited conditional release. This section also provides another security measure to prevent the detained article of food from moving into commerce. That is, we also require FDA supervision of all transfers of detained articles of food made under a limited conditional release, unless FDA declines such supervision in writing. If FDA declines such supervision, you will be required to immediately notify in writing the authorized FDA representative who approved the limited conditional release, that the article of food has reached its new location, and the specific location of the detained article of food within the new location. Such notification may be in the form of a fax, e-mail, or other form agreed to by the authorized FDA representative.

Proposed § 1.381(f) requires you to ensure that any tags or labels required under proposed § 1.382 accompany the detained article of food during and after movement. If FDA labels or marks the detained article of food under proposed § 1.382, this proposed provision would require that the tags or labels remain

with the article of food until FDA terminates the detention order or the detention period expires, whichever occurs first, unless otherwise permitted by the approving official.

Proposed § 1.381(g) provides that the transfer of an article of food in violation of a detention order issued under proposed § 1.393 is a prohibited act under section 301 of the act. This proposed provision is consistent with the statutory language in section 303 of the Bioterrorism Act.

6. What Labeling or Marking Requirements Apply to a Detained Article of Food? (Proposed § 1.382)

Proposed § 1.382 describes the labeling or marking requirements that apply to a detained article of food. This proposed section states that the officer or qualified employee of FDA who issues the detention order may label or mark the detained article of food with official FDA tags or labels that include the following information:

- A statement that the article of food is detained by FDA in accordance with section 304(h) of the act;
- A statement that the article of food must not be consumed, moved, altered, or tampered with in any manner for the period shown, without the written permission of an authorized FDA representative;
- A statement, consistent with the statutory language in section 303 of the Bioterrorism Act, that the violation of a detention order or the removal or alteration of the tag or label is a prohibited act under section 301 of the act, punishable by fine or imprisonment or both; and
- The detention order number, the date and hour of the detention order, the detention period, and the name of the officer or qualified employee of FDA who issued the detention order.

Any label or mark of detention will be attached as appropriate given the circumstances. In some instances, the mark or label may be attached to the food container, while in other instances, the mark may be fastened to a packing container. Where the agency cannot mark or label a container or packing container, a mark or label may be attached to accompanying documents. FDA may use other means of marking or labeling as appropriate or necessary. Once the detained article is released, or the detention period expires, FDA would remove, or authorize the removal of, the required labels or tags, as described in proposed § 1.384. Accordingly, we would not expect the proposed labeling and marking provision to impair the future ability to