

available to Program employees upon request.

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[51 FR 45619, Dec. 19, 1986, as amended at 53 FR 49848, Dec. 12, 1988; 62 FR 45025, Aug. 25, 1997; 65 FR 34389, May 30, 2000; 65 FR 53532, Sept. 5, 2000]

§ 318.309 Finished product inspection.

(a) Finished product inspections must be handled according to:

(1) A HACCP plan for canned product that addresses hazards associated with microbiological contamination;

(2) An FSIS-approved total quality control system;

(3) Alternative documented procedures that will ensure that only safe and stable product is shipped in commerce; or

(4) Paragraph (d) of this section.

(b)–(c) [Reserved]

(d) Procedures for handling finished product inspections where the HACCP plan for thermally processed/commercially sterile product does not address food safety hazards associated with microbial contamination, where there is no approved total quality control system, or where the establishment has no alternative documented procedures for handling process deviations.

(1) *Incubation of shelf stable canned product*—(i) *Incubator*. The establishment shall provide incubation facilities which include an accurate temperature/time recording device, an indicating temperature device, a means for the circulation of the air inside the incubator to prevent temperature variations, and a means to prevent unauthorized entry into the facility. The Program is responsible for the security of the incubator.

(ii) *Incubation temperature*. The incubation temperature shall be maintained at 95±5 °F (35±2.8 °C). If the incubation temperature falls below 90 °F (or 32 °C) or exceeds 100 °F (or 38 °C) but does not reach 103 °F (or 39.5 °C), the incubation temperature shall be adjusted within the required range and the incubation time extended for the time the sample containers were held at the deviant temperature. If the incubation temperature is at or above 103 °F (or 39.5 °C) for more than 2 hours, the incubation test(s) shall be termi-

nated, the temperature lowered to within the required range, and new sample containers incubated for the required time.

(iii) *Product requiring incubation*. Shelf stable product requiring incubation includes:

(a) Low acid products as defined in § 318.300(m); and

(b) Acidified low acid products as defined in § 318.300(b).

(iv) *Incubation samples*. (a) From each load of product processed in a batch-type thermal processing system (still or agitation), the establishment shall select at least one container for incubation.

(b) For continuous rotary retorts, hydrostatic retorts, or other continuous-type thermal processing systems, the establishment shall select at least one container per 1,000 for incubation.

(c) Only normal-appearing containers shall be selected for incubation.

(v) *Incubation time*. Canned product requiring incubation shall be incubated for not less than 10 days (240 hours) under the conditions specified in paragraph (d)(1)(ii) of this section.

(vi) *Incubation checks and record maintenance*. Designated establishment employees shall visually check all containers under incubation each working day and the inspector shall be notified when abnormal containers are detected. All abnormal containers should be allowed to cool before a final decision on their condition is made. For each incubation test the establishment shall record at least the product name, container size, container code, number of containers incubated, in and out dates, and incubation results. The establishment shall retain such records, along with copies of the temperature/time recording charts, in accordance with § 318.307(e).

(vii) *Abnormal containers*. The finding of abnormal containers (as defined in § 318.300(a)) among incubation samples is cause to officially retain at least the code lot involved.

(viii) *Shipping*. No product shall be shipped from the establishment before the end of the required incubation period except as provided in this paragraph or paragraph (b) or (c) of this section. An establishment wishing to ship product prior to the completion of

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the required incubation period shall submit a written proposal to the area supervisor. Such a proposal shall include provisions that will assure that shipped product will not reach the retail level of distribution before sample incubation is completed and that product can be returned promptly to the establishment should such action be deemed necessary by the incubation test results. Upon receipt of written approval from the area supervisor, product may be routinely shipped provided the establishment continues to comply with all requirements of this subpart.

(2) *Container condition*—(i) *Normal containers*. Only normal-appearing containers shall be shipped from an establishment as determined by an appropriate sampling plan or other means acceptable to Program employees.

(ii) *Abnormal containers*. When abnormal containers are detected by any means other than incubation, the establishment shall inform the inspector, and the affected code lot(s) shall not be shipped until the Program has determined that the product is safe and stable. Such a determination will take into account the cause and level of abnormality in the affected lot(s) as well as any product disposition actions either taken or proposed by the establishment.

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§318.310 Personnel and training.

All operators of thermal processing systems specified in §318.305 and container closure technicians shall be under the direct supervision of a person who has successfully completed a school of instruction that is generally recognized as adequate for properly training supervisors of canning operations.

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§318.311 Recall procedure.

Establishments shall prepare and maintain a current procedure for the recall of all canned product covered by

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this subpart. Upon request, the recall procedure shall be made available to Program employees for review.

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PART 319—DEFINITIONS AND STANDARDS OF IDENTITY OR COMPOSITION

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- 319.106 “Country Ham,” “Country Style Ham,” “Dry Cured Ham,” “Country Pork Shoulder,” “Country Style Pork Shoulder,” and “Dry Cured Pork Shoulder.”
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