

(4) *Sanitary handling and storage practices.* Fully-cooked patties shall be handled in accordance with the following provisions so as to assure that the patties are not recontaminated.

(i) To prevent direct contamination of fully-cooked patties, official establishments shall:

(A) Physically separate areas where unpackaged, fully-cooked patties are handled from areas where less-than-fully-cooked products are handled using a solid impervious floor to ceiling wall; or

(B) Handle unpackaged, fully-cooked patties and less-than-fully-cooked product at different times, and cleaning the entire area after handling other products before handling unpackaged, fully-cooked patties; or

(C) Submit a written procedure through the inspector-in-charge to the Regional Director detailing the steps to be taken which would avoid recontamination of fully-cooked patties by less-than-fully-cooked cooked product during processing.

(ii) To prevent indirect contamination of fully-cooked patties:

(A) Any work surface, machine, or tool which contacts other product shall be cleaned and sanitized before it contacts unpackaged fully-cooked patties. The sanitizer shall be germicidally equivalent to 50 ppm chlorine.

(B) Employees shall wash their hands with soap and water and sanitize their hands whenever they enter the fully-cooked patty area or before handling unpackaged, fully-cooked patties. They must also wash and sanitize their hands whenever they become contaminated during operations to avoid contamination of fully-cooked patties. The sanitizer shall be germicidally equivalent to 50 ppm chlorine.

(C) All employee outer garments, including aprons, smocks, and gloves shall be identified as restricted for use in the fully-cooked area only. The employee shall change garments at least daily. The garments shall be hung in a designated location before the employee leaves the area.

(iii) Fully-cooked patties stored in the same room with other product, shall first be packaged or covered to prevent microbial contamination.

(iv) Fully-cooked, partially-cooked, and char-marked patties shall be stored at a chamber temperature of 40 °F or below.

(c) *Requirements for handling heating or cooling deviations.* (1) If for any reason a heating or cooling deviation has occurred, the official establishment shall investigate and identify the cause; take steps to assure that the deviation will not recur; and place on file in the official establishment, available to any duly authorized representative of the Secretary, a report of the investigation, the cause of the deviation, and the steps taken to prevent recurrence; and

(2) In addition, in the case of a heating deviation, the official establishment may (i) reprocess the affected product, by a method in paragraph (b)(1)(i) in this section, or (ii) use the affected product as an ingredient in another product processed to one of the temperature and time combinations in paragraph (b)(1)(i) in this section, provided this does not violate the final product's standard of composition, upset the order of predominance of ingredients, or perceptibly affect the normal product characteristics, or (iii) relabel the affected product as a partially-cooked patty product, if it meets the partially-cooked requirements in paragraph (b)(1)(ii) of this section.

(3) In addition, in the case of a cooling deviation, contact the Regional Director to determine the disposition of the product.

[58 FR 41151, Aug. 2, 1993]

**§318.24 Compliance procedures for meat derived from advanced meat/bone separation machinery and recovery systems.**

(a) The product resulting from the separating process shall not have a calcium content exceeding 0.15 percent or 150 mg/100 gm of product within a tolerance of 0.03 percent or 30 mg, as prescribed in §301.2(rr)(2) of this subchapter.

(b) To verify the calcium content in meat derived from advanced meat/bone separation machinery and recovery systems, a compliance program consisting of the following parameters shall be followed by manufacturers of

meat defined in §301.2(rr)(2) of this subchapter.

(1) An analysis of a sample of at least 1 pound from each lot shall be performed by the operator of the establishment or his or her agent. For purposes of this paragraph, a lot shall consist of the meat derived from advanced meat/bone separation machinery and recovery systems, designated as such by the operator of the establishment or his or her agent, from the product produced from a single species of livestock in no more than one continuous shift of up to 12 hours. Individual results from the chemical analyses shall be compared to the calcium limit, prescribed in paragraph (a) of this section, in order to demonstrate compliance. If compliance is not demonstrated, that is, if any single analytical result is more than 0.18 percent,<sup>1 2</sup> before product from a production lot that is still at the establishment or one that is subsequently produced can be considered to be in compliance, at least three samples from that production lot shall be taken and analyzed for calcium, either separately, or, at the option of the establishment, as a composite (i.e., combining the three samples for analysis). The average of the results or the composite result must be less than or equal to 0.15 percent. Taking three samples from each subsequently produced lot and analyzing them in order to demonstrate compliance shall continue until five consecutive lots have mean or composite results less than or equal to 0.15 percent. If the statistical evidence indicates that a production lot is not in compliance with the calcium limit, as prescribed in §301.2(rr)(2) of this subchapter, the lot must be labeled as MS(S) and meet all of the re-

<sup>1</sup>The value 0.18 percent was derived by multiplying by 3 the expected analytical standard deviation obtained by FSIS laboratories on the approved chemical procedure for measuring calcium which uses Ethylenediaminetetraacetic acid (EDTA) as provided in the "Official Methods of Analysis of the AOAC International" (formerly the Association of Official Analytical Chemists), 15th Ed. (1990).

<sup>2</sup>Individual or an average of results shall be rounded to the nearest 0.01 percent calcium.

quirements for MS(S) in §319.5 of this subchapter.

(2) The management of the establishment must maintain records to support the validity of the calcium content (as a measure of bone solids) to assure the process is in control. Such records shall be made available to the inspector or any other duly authorized representative of the Agency upon request. (Recordkeeping requirements were approved by the Office of Management and Budget under control number 0583-0095.)

[59 FR 62561, Dec. 6, 1994]

### Subparts B—F [Reserved]

### Subpart G—Canning and Canned Products

SOURCE: 51 FR 45619, Dec. 19, 1986, unless otherwise noted.

#### § 318.300 Definitions.

(a) *Abnormal container.* A container with any sign of swelling or product leakage or any evidence that the contents of the unopened container may be spoiled.

(b) *Acidified low acid product.* A canned product which has been formulated or treated so that every component of the finished product has a pH of 4.6 or lower within 24 hours after the completion of the thermal process unless data are available from the establishment's processing authority demonstrating that a longer time period is safe.

(c) *Bleeders.* Small orifices on a retort through which steam, other gasses, and condensate are emitted from the retort throughout the entire thermal process.

(d) *Canned product.* A meat food product with a water activity above 0.85 which receives a thermal process either before or after being packed in a hermetically sealed container. Unless otherwise specified, the term "product" as used in this Subpart G shall mean "canned product."

(e) *Closure technician.* The individual(s) identified by the establishment as being trained to perform specific container integrity examinations as required by this subpart and designated