

promptly by the official establishment under supervision of an inspector and rehandled as follows:

(1) Separate and condemn all product in damaged or extensively rusted containers.

(2) Remove paper labels and wash the remaining containers in warm soapy water, using a brush where necessary to remove rust or other foreign material. Disinfect these containers by either of the following methods:

(i) Immerse in a solution of sodium hypochlorite containing not less than 100 p/m of available chlorine or other equivalent disinfectant approved by the Administrator,<sup>1</sup> rinse in potable water, and dry thoroughly; or

(ii) Immerse in 212 °F. water, bring temperature of the water back to 212 °F. and maintain the temperature at 212 °F. for 5 minutes, then remove containers from water and cool them to 95 °F. and dry thoroughly.

(3) After handling as described in paragraph (c)(2) of this section, the containers may be relacquered, if necessary, and then relabeled with approved labels applicable to the product therein.

(4) The identity of the canned product shall be maintained throughout all stages of the rehandling operations to insure correct labeling of the containers.

[35 FR 15586, Oct. 3, 1970, as amended at 38 FR 34455, Dec. 14, 1973]

**§ 318.15 Tagging chemicals, preservatives, cereals, spices, etc., "U.S. retained."**

When any chemical, preservative, cereal, spice, or other substance is intended for use in an official establishment, it shall be examined by a Program employee and if found to be unfit or otherwise unacceptable for the use intended, or if final decision regarding acceptance is deferred pending laboratory or other examination, the employee shall attach a "U.S. retained" tag to the substance or container thereof. The substance so tagged shall

<sup>1</sup>A list of approved disinfectants is available upon request to Scientific Services, Meat and Poultry Inspection Program, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250.

be kept separate from other substances as the circuit supervisor may require and shall not be used until the tag is removed, and such removal shall be made only by a Program employee after a finding that the substance can be accepted, or, in the case of an unacceptable substance, when it is removed from the establishment.

**§ 318.16 Pesticide chemicals and other residues in products.**

(a) *Nonmeat ingredients.* Residues of pesticide chemicals, food additives and color additives or other substances in or on ingredients (other than meat, meat byproducts, and meat food products) used in the formulation of products shall not exceed the levels permitted under the Federal Food, Drug, and Cosmetic Act, and such nonmeat ingredients must otherwise be in compliance with the requirements under that Act.

(b) *Products, and meat, meat byproduct, or other meat food product ingredients.* Products, and products used as ingredients of products, shall not bear or contain any pesticide chemical, food additives, or color additive residue in excess of the level permitted under the Federal Food, Drug, and Cosmetic Act and the regulations in this subchapter, or any other substance that is prohibited by such regulations or that otherwise makes the products adulterated.

(c) *Standards and procedures.* Instructions specifying the standards and procedures for determining when ingredients of finished products are in compliance with this section shall be issued to the inspectors by the Administrator. Copies of such instructions will be made available to interested persons upon request made to the Administrator.

**§ 318.17 Requirements for the production of cooked beef, roast beef, and cooked corned beef products.**

(a) Cooked beef, roast beef, and cooked corned beef products must be produced using processes ensuring that the products meet the following performance standards:

(1) *Lethality.* A 6.5-log<sub>10</sub> reduction of *Salmonella* or an alternative lethality that achieves an equivalent probability

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that no viable *Salmonella* organisms remain in the finished product, as well as the reduction of other pathogens and their toxins or toxic metabolites necessary to prevent adulteration, must be demonstrated to be achieved throughout the product. The lethality process must include a cooking step. Controlled intermediate step(s) applied to raw product may form part of the basis for the equivalency.

(2) *Stabilization*. There can be no multiplication of toxigenic microorganisms such as *Clostridium botulinum*, and no more than 1-log<sub>10</sub> multiplication of *Clostridium perfringens* within the product.

(b) For each product produced using a process other than one conducted in accordance with the Hazard Analysis and Critical Control Point (HACCP) system requirements in part 417 of this chapter, an establishment must develop and have on file and available to FSIS, a process schedule, as defined in §301.2 of this chapter. Each process schedule must be approved in writing by a process authority for safety and efficacy in meeting the performance standards established for the product in question. A process authority must have access to the establishment in order to evaluate and approve the safety and efficacy of each process schedule.

(c) Under the auspices of a processing authority, an establishment must validate new or altered process schedules by scientifically supportable means, such as information gleaned from the literature or by challenge studies conducted outside the plant.

[64 FR 744, Jan. 6, 1999]

### §318.18 Handling of certain material for mechanical processing.

Material to be processed into "Mechanically Separated (Species)" shall be so processed within 1 hour from the time it is cut or separated from carcasses or parts of carcasses, except that such product may be held for no more than 72 hours at 40 °F. (4 °C.) or less, or held indefinitely at 0 °F. (-18 °C.) or less. "Mechanically Separated (Species)" shall, directly after being processed, be used as an ingredient in a meat food product except that it may be held prior to such use for no more

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than 72 hours at 40 °F. (4 °C.) or less or indefinitely at 0 °F. (-18 °C.) or less.

[43 FR 26423, June 20, 1978, as amended at 47 FR 28256, June 29, 1982]

### §318.19 Compliance procedure for cured pork products.

(a) *Definitions*. For the purposes of this section:

(1) A *product* is that cured pork article which is contained within one *Group* as defined in paragraph (a)(2) of this section and which purports to meet the criteria for a single product designated under the heading "Product Name and Qualifying Statements" in the chart in §319.104 or the chart in §319.105.

(2) A *Product Group* or a *Group* means one of the following:

Group I, consisting of cured pork products which have been cooked while imperviously encased. Any product which fits into the Group will be placed in this Group regardless of any other considerations.

Group II, consisting of cured pork products which have been water cooked. Any product which does not fit into Group I but does fit into Group II will be placed into Group II regardless of any other considerations.

Group III, consisting of boneless smokehouse heated cured pork products. Any boneless product that does not fit into Group I or Group II shall be placed in Group III.

Group IV, consisting of bone-in or semi-boneless smokehouse heated cured pork products. Any product that is not completely boneless or still contains all the bone which is traditional for bone-in product, and does not fit into Group I, Group II, or Group III shall be placed in this Group.

(3) A *lot* is that product from one production shift.

(4) A *production rate* is frequency of production, expressed in days per week.

(5) *Protein fat free percentage, protein fat free content, PFF percentage, PFF content or PFF* of a product means the meat protein (indigenous to the raw, unprocessed pork cut) content expressed as a percent of the non-fat portion of the finished product.

(b) *Normal Compliance Procedures*. The Department shall collect samples of cured pork products and analyze them for their PFF content. Analyses shall be conducted in accordance with the "Official Methods of Analysis of the Association of Official Analytical Chemists §§950.46, and 928.08 (Chapter