

## §319.2

(b) Any binder or antimicrobial agent that has been found to be safe and suitable by the Food and Drug Administration and the Food Safety and Inspection Service may be used in the production of meat products with standards of identity in this part, where the product standards and applicable Federal regulations already permit the use of these types of ingredients.

[35 FR 15597, Oct. 3, 1970, as amended at 68 FR 22578, Apr. 29, 2003]

### §319.2 Products and nitrates and nitrites.

Any product, such as frankfurters and corned beef, for which there is a standard in this part and to which nitrate or nitrite is permitted or required to be added, may be prepared without nitrate or nitrite and labeled with such standard name when immediately preceded with the term "Uncured" in the same size and style of lettering as the rest of such standard name: *Provided*, That the product is found by the Administrator to be similar in size, flavor, consistency, and general appearance to such product as commonly prepared with nitrate and nitrite: *And provided further*, That labeling for such product complies with the provisions of §317.17(c) of this subchapter.

[44 FR 48961, Aug. 21, 1979]

### §319.5 Mechanically Separated (Species).

(a) Mechanically Separated (Species) is any finely comminuted product resulting from the mechanical separation and removal of most of the bone from attached skeletal muscle of livestock carcasses and parts of carcasses and meeting the other provisions of this paragraph. Examples of such product are "Mechanically Separated Beef", "Mechanically Separated Veal", "Mechanically Separated Pork", and "Mechanically Separated Lamb". At least 98 percent of the bone particles present in such product shall have a maximum size no greater than 0.5 millimeter in their greatest dimension and there shall be no bone particles larger than 0.85 millimeter in their greatest dimension. The product resulting from the separating process shall not have a calcium content exceeding 0.75 percent, as

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a measure of a bone solids content of not more than 3 percent, and shall have a minimum PER of 2.5 (except as modified in paragraph (e)(1) of this section). Such product also shall have a protein content of not less than 14 percent and a fat content of not more than 30 percent, or it shall be deemed to be product for processing. Such product failing to meet the bone particle size, calcium, or PER requirements of this paragraph shall only be used in producing animal fats. Where such product meets the bone particle size, calcium, and PER requirements of this paragraph, it may also be used in the formulation of meat food products in accordance with §319.6.

(b) Mechanically Separated (Beef) is inedible and prohibited for use as human food.

(c)-(d) [Reserved]

(e)(1) An essential amino acid content of at least 33 percent of the total amino acids presents in "Mechanically Separated (Species)" shall be accepted as evidence of compliance with the protein quality requirement set forth in paragraph (a) of this section. For purposes of this paragraph, essential amino acid content includes isoleucine, leucine, lysine, methionine, phenylalanine, threonine, and valine content, and the total amino acids present include isoleucine, leucine, lysine, methionine, phenylalanine, threonine, valine, tyrosine, arginine, histidine, alanine, aspartic acid, glutamic acid, glycine, proline, serine, and hydroxyproline content.

(2) Analytical methods used by establishments in verifying the fat, protein, and calcium content of product consisting of or containing Mechanically Separated (Species) shall be among those listed in "Official Methods of Analysis of the Association of Official Analytical Chemists (AOAC)," 16th edition, 1995, §§960.39, 976.21, 928.08 (Chapter 39), and 940.33 (Chapter 45), which is incorporated by reference, or, if no AOAC method is available, in the "Chemistry Laboratory Guidebook," U.S. Department of Agriculture, Washington, D.C., March 1986 edition, sections 6.011-6.013, Revised June 1987 (pages 6-35 through 6-65), or by appropriate methods validated by scientific

bodies in collaborative trials. The “Official Methods of Analysis of the Association of Official Analytical Chemists,” Chapter 39 and Chapter 45, subsection 45.2.06 (AOAC Official Method 940.33), 16th edition, 1995, are incorporated by reference with the approval of the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR Part 51.

[47 FR 28256, June 29, 1982, as amended at 54 FR 40631, Oct. 3, 1989; 59 FR 33642, June 30, 1994; 62 FR 45026, Aug. 25, 1997; 65 FR 34389, May 30, 2000; 69 FR 1874, Jan. 12, 2004]

**§ 319.6 Limitations with respect to use of Mechanically Separated (Species).**

(a) Meat food products required to be prepared from one species shall not contain Mechanically Separated (Species) of any other species.

(b) Mechanically Separated (Species) described in § 319.5 that has a protein content of not less than 14 percent and a fat content of not more than 30 percent may constitute up to 20 percent of the livestock and poultry product portion of any meat food product except those listed in paragraph (d) of this section.

(c) Mechanically Separated (Species) for processing described in § 319.5 may constitute up to 20 percent of the livestock and poultry product portion of any meat food product that is subject to a definition and standard of identity or composition in part 319 which establishes a maximum limit on the fat content of such meat food product except those listed in paragraph (d) of this section.

(d) Mechanically Separated (Species) and Mechanically Separated (Species) for processing described in § 319.5 shall not be used in baby, junior, or toddler foods, ground beef, hamburger, fabricated steaks (§ 319.15 (a), (b), and (d)), barbecued meats (§ 319.80), roast beef-parboiled and steam roasted (§ 319.81), corned (cured) beef cuts (§§ 319.100–319.103), certain cured pork products (§§ 319.104 (a)–(e) and 319.106), tripe with milk (§ 319.308), lima beans with ham and similar products (§ 319.310), beef with gravy and gravy with beef (§ 319.313), and meat pies (§ 319.500).

[47 FR 28257, June 29, 1982]

**§ 319.10 Requirements for substitute standardized meat food products named by use of an expressed nutrient content claim and a standardized term.**

(a) *Description.* The meat food products prescribed by this general definition and standard of identity are those products that substitute, in accordance with § 317.313(d), for a standardized product defined in this part and use the name of that standardized product in their statements of identity, but that do not comply with the established standard because of a compositional deviation that results from a reduction of a constituent that is described by an expressed nutrient content claim that has been defined by regulation in part 317, subpart B, of this subchapter. The expressed nutrient content claim shall comply with the requirements of § 317.313 of this subchapter and with the requirements of part 317, subpart B, of this subchapter which define the particular nutrient content claim that is used. The meat food product shall comply with the relevant standard in this part in all other respects, except as provided in paragraphs (b) and (c) of this section.

(b) *Performance characteristics.* The performance characteristics, such as physical properties, functional properties, and shelf-life, of the meat food product shall be similar to those of the standardized meat food product produced under this part. If there is a significant difference in a performance characteristic that materially limits the use of the product compared to the use of the standardized product defined in this part, the label shall include a statement in accordance with § 317.313(d)(1) and (2) of this subchapter that informs the consumer of such differences (*e.g.*, if appropriate, “not recommended for frozen storage” or “not suitable for roller grilling”). Deviations from the ingredient provisions of the standard must be the minimum necessary to qualify for the nutrient content claim, while maintaining similar performance characteristics.

(c) *Ingredients used in substitute products.* (1) Ingredients used in the product shall be those ingredients provided for in the standard as defined in this part,