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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 abnormals in the affected lot(s) as well as any product disposition actions either taken or proposed by the establishment.

(Approved by the Office of Management and Budget under control number 0583–0015)

[51 FR 45619, Dec. 19, 1986, as amended at 57 FR 37872, Aug. 21, 1992; 57 FR 55443, Nov. 25, 1992; 62 FR 45025, Aug. 25, 1997; 65 FR 34389, May 30, 2000; 65 FR 53532, Sept. 5, 2000]

### § 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.

[51 FR 45619, Dec. 19, 1986]

### § 318.311 Recall procedure.

Establishments shall prepare and maintain a current procedure for the recall of all canned product covered by this subpart. Upon request, the recall procedure shall be made available to Program employees for review.

(Approved by the Office of Management and Budget under control number 0583–0015)

# PART 319—DEFINITIONS AND STANDARDS OF IDENTITY OR COMPOSITION

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AUTHORITY: 7 U.S.C. 450, 1901–1906; 21 U.S.C. 601–695; 7 CFR 2.18, 2.53.

SOURCE: 35 FR 15597, Oct. 3, 1970, unless otherwise noted.

## Subpart A—General

### § 319.1 Labeling and preparation of standardized products.

(a) Labels for products for which standards of identity or composition are prescribed in this part shall show the appropriate product name, an ingredient statement, and other label information in accordance with the special provisions, if any, in this part, and otherwise in accordance with the general labeling provisions in part 317 of this subchapter, and such products shall be prepared in accordance with the special provisions, if any, in this part and otherwise in accordance with the general provisions in this subchapter. Any product for which there is a common or usual name must consist of ingredients and be prepared by the use of procedures common or usual to such products insofar as specific ingredients or procedures are not prescribed or prohibited by the provisions of this subchapter.

(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 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 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,

except that safe and suitable ingredients permitted for use in meat food products as provided in a regulation permitting that use in this subchapter or in 9 CFR Chapter III, Subchapter E, or in 21 CFR Chapter I, Subchapter A or Subchapter B, may be used at the minimum level necessary to improve texture and prevent syneresis, so that the substitute product is not inferior in performance characteristics from the standardized product defined in this part for which it is a substitute.

(2) An ingredient that is specifically required by the standard prescribed in this part shall not be replaced or exchanged with a similar ingredient from another source, for example, turnip chunks shall not replace potatoes in corned beef hash.

(3) An ingredient that is specifically prohibited from use in any meat food product by this part shall not be added to the substitute meat food product under this section.

(4) Unless otherwise specified in this part, a substitute meat food product must meet all other requirements of the applicable standards of identity or composition.

(5) Water and fat-replacers (*e.g.*, binders), in combination, may be added to replace fat in accordance with paragraph (c) of this section.

(6) Textured vegetable protein may be used by itself or in combination with other binders and water as a fat replacer in accordance with paragraph (c) of this section.

(d) *Nomenclature*. The name of a substitute meat food product that complies with all parts of this section is the appropriate expressed nutrient content claim and the applicable standardized term.

(e) *Label declaration*. (1) Each of the ingredients used in the substitute meat food product shall be declared on the label as required by this section and part 317 of this subchapter.

(2) Ingredients not provided for, and ingredients used in excess of those levels provided for, by the standard as defined in this part, shall be identified as such with an asterisk in the ingredients statement. The statement "*Ingredients not in regular _____" (the blank shall be filled in with the name of the traditional standardized product) or "**Ingredients in excess of amounts permitted in regular _____" (the blank shall be filled in with the name of the traditional standardized product), or both, as appropriate, shall immediately follow the ingredients statement in the same type and size.

[70 FR 33818, June 10, 2005]

## Subpart B—Raw Meat Products

### § 319.15 Miscellaneous beef products.

(a) *Chopped beef, ground beef*. "Chopped Beef" or "Ground Beef" shall consist of chopped fresh and/or frozen beef with or without seasoning and without the addition of beef fat as such, shall not contain more than 30 percent fat, and shall not contain added water, phosphates, binders, or extenders. When beef cheek meat (trimmed beef cheeks) is used in the preparation of chopped or ground beef, the amount of such cheek meat shall be limited to 25 percent; and if in excess of natural proportions, its presence shall be declared on the label, in the ingredient statement required by § 317.2 of this subchapter, if any, and otherwise contiguous to the name of the product.

(b) *Hamburger*. "Hamburger" shall consist of chopped fresh and/or frozen beef with or without the addition of beef fat as such and/or seasoning, shall not contain more than 30 percent fat, and shall not contain added water, phosphates, binders, or extenders. Beef cheek meat (trimmed beef cheeks) may be used in the preparation of hamburger only in accordance with the conditions prescribed in paragraph (a) of this section.

(c) *Beef patties*. "Beef Patties" shall consist of chopped fresh and/or frozen beef with or without the addition of beef fat as such and/or seasonings. Binders or extenders, Mechanically Separated (Species) used in accordance with § 319.6, and/or partially defatted beef fatty tissue may be used without added water or with added water only in amounts such that the product characteristics are essentially that of a meat pattie.

(d) *Fabricated steak*. Fabricated beef steaks, veal steaks, beef and veal steaks, or veal and beef steaks, and

similar products, such as those labeled "Beef Steak, Chopped, Shaped, Frozen," "Minute Steak, Formed, Wafer Sliced, Frozen," "Veal Steaks, Beef Added, Chopped—Molded—Cubed—Frozen, Hydrolyzed Plant Protein, and Flavoring" shall be prepared by comminuting and forming the product from fresh and/or frozen meat, with or without added fat, of the species indicated on the label. Such products shall not contain more than 30 percent fat and shall not contain added water or extenders. Transglutaminase enzyme at levels of up to 65 ppm may be used as a binder. Beef cheek meat (trimmed beef cheeks) may be used in the preparation of fabricated beef steaks only in accordance with the conditions prescribed in paragraph (a) of this section.

(e) *Partially defatted beef fatty tissue.* "Partially Defatted Beef Fatty Tissue" is a beef byproduct derived from the low temperature rendering (not exceeding 120 °F.) of fresh beef fatty tissue. Such product shall have a pinkish color and a fresh odor and appearance.

[35 FR 15597, Oct. 3, 1970, as amended at 38 FR 29215, Oct. 23, 1973; 43 FR 26424, June 20, 1978; 47 FR 10784, Mar. 12, 1982; 47 FR 28257, June 29, 1982; 66 FR 54916, Oct. 31, 2001]

### § 319.29 Miscellaneous pork products.

(a) *Partially defatted pork fatty tissue.* "Partially Defatted Pork Fatty Tissue" is a pork byproduct derived from the low temperature rendering (not exceeding 120 °F.) of fresh pork fatty tissue, exclusive of skin. Such product shall have a pinkish color and a fresh odor and appearance.

## Subpart C—Cooked Meats

### § 319.80 Barbecued meats.

Barbecued meats, such as product labeled "Beef Barbecue" or "Barbecued Pork," shall be cooked by the direct action of dry heat resulting from the burning of hard wood or the hot coals therefrom for a sufficient period to assume the usual characteristics of a barbecued article, which include the formation of a brown crust on the surface and the rendering of surface fat. The product may be basted with a sauce during the cooking process. The weight of barbecued meat shall not exceed 70 percent of the weight of the fresh uncooked meat.

### § 319.81 Roast beef parboiled and steam roasted.

"Roast Beef Parboiled and Steam Roasted" shall be prepared so that the weight of the finished product, excluding salt and flavoring material, shall not exceed 70 percent of the fresh beef weight. Transglutaminase enzyme at levels of up to 65 ppm may be used as a binder in such product. Beef cheek meat and beef head meat from which the overlying glandular and connective tissues have been removed, and beef heart meat, exclusive of the heart cap may be used individually or collectively to the extent of 5 percent of the meat ingredients in the preparation of canned product labeled "Roast Beef Parboiled and Steam Roasted." When beef cheek meat, beef head meat, or beef heart meat is used in the preparation of this product, its presence shall be reflected in the statement of ingredients required by part 317 of this subchapter.

[35 FR 15597, Oct. 3, 1970, as amended at 38 FR 29215, Oct. 23, 1973; 66 FR 54916, Oct. 31, 2001]

## Subpart D—Cured Meats, Unsmoked and Smoked

### § 319.100 Corned beef.

"Corned Beef" shall be prepared from beef briskets, navels, clods, middle ribs, rounds, rumps, or similar cuts using one or a combination of the curing ingredients specified in a regulation permitting that use in this subchapter or 9 CFR Chapter III, Subchapter E, or in 21 CFR Chapter I, Subchapter A or Subchapter B. Canned product labeled "Corned Beef" shall be prepared so that the weight of the finished product, excluding cure, salt, and flavoring material, shall not exceed 70 percent of the fresh beef weight. Corned beef other than canned shall be cured in pieces weighing not less than 1 pound, and if cooked, its weight shall not exceed the weight of the fresh uncured beef. Beef cheek meat, beef head meat and beef heart meat may be used to the extent of 5 percent of the meat ingredient in preparation of this product when trimmed as specified in

§ 319.81. When beef cheek meat, beef head meat, or beef heart meat is used in preparation of this product, its presence shall be reflected in the statement of ingredients required by part 317 of this subchapter. The application of curing solution to beef cuts, other than briskets, which are intended for bulk corned beef shall not result in an increase in the weight of the finished cured product of more than 10 percent over the weight of the fresh uncured meat.

[35 FR 15597, Oct. 3, 1970; 36 FR 11903, June 23, 1971, as amended at 38 FR 29215, Oct. 23, 1973; 64 FR 72174, Dec. 23, 1999]

### § 319.101 Corned beef brisket.

In preparing "Corned Beef Brisket," the application of curing solution to the beef brisket shall not result in an increase in the weight of the finished cured product of more than 20 percent over the weight of the fresh uncured brisket. If the product is cooked, the weight of the finished product shall not exceed the weight of the fresh uncured brisket.

### § 319.102 Corned beef round and other corned beef cuts.

In preparing "Corned Beef Round" and other corned beef cuts, except "Corned Beef Briskets," the curing solution shall be applied to pieces of beef weighing not less than one pound and such application shall not result in an increased weight of the cured beef product of more than 10 percent over the weight of the fresh uncured beef cut. If the product is cooked, the weight of the finished product shall not exceed the weight of the fresh uncured beef cut.

### § 319.103 Cured beef tongue.

In preparing "Cured Beef Tongue," the application of curing solution to the fresh beef tongue shall not result in an increase in the weight of the cured beef tongue of more than 10 percent over the weight of the fresh uncured beef tongue.

### § 319.104 Cured pork products.

(a) Cured pork products, including hams, shoulders, picnics, butts and loins, shall comply with the minimum meat Protein Fat Free (PFF) percentage requirements set forth in the following chart:

| Type of cured pork product | Minimum meat PFF percentage [1] | Product name and qualifying statements |
|---|---|---|
| Cooked ham, loin [2]. | 20.5 | (Common and usual). |
| | 18.5 | (Common and usual) with natural juices. |
| | 17.0 | (Common and usual) water added. |
| | <17.0 | (Common and usual) and water product—X% of weight is added ingredients. [3] |
| Cooked shoulder, butt, picnic [2]. | 20.0 | (Common and usual). |
| | 18.0 | (Common and usual) with natural juices. |
| | 16.5 | (Common and usual) water added. |
| | <16.5 | (Common and usual) and water product—X% of weight is added ingredients. [3] |
| Uncooked cured ham, loin. | 18.0 | Uncooked (common and usual). |
| | <18.0 | Uncooked (common and usual) and water product—X% of weight is added ingredients. [3] |
| Uncooked cured shoulder, butt, picnic. | 17.5 | Uncooked (common and usual). |
| | <17.5 | Uncooked (common and usual) and water product—X% of weight is added ingredients. [3] |

[1] The minimum meat PFF percentage shall be the minimum meat protein which is indigenous to the raw unprocessed pork expressed as a percent of the non-fat portion of the finished product; and compliance shall be determined under § 318.19 of this subchapter for domestic cured pork product and § 327.23 of this subchapter for imported cured pork product.

[2] The term "cooked" is not appropriate for use on labels of cured pork products heated only for the purpose of destruction of possible live trichinae.

[3] Processors may immediately follow this qualifying statement with a list of the ingredients in descending order of predominance rather than having the traditional ingredients statement. In any case, the maximum percent of added substances in the finished product on a total weight percentage basis would be inserted as the X value; e.g., Ham and Water Product—20% of Weight is Added Ingredients.

(b) Cured pork products for which there is a qualifying statement required in paragraph (a) of this section shall bear that statement as part of the product name in lettering not less than ⅜ inch in height, or in lettering not less than one-third the size of the largest letter in the product name if it is in the same color and style of print and on the same color background as the product name. However, the Administrator may approve smaller lettering for labeling of packages of 1 pound or less, provided such lettering is at least

one-third the size and of the same color and style as the product name.

(c) Cured pork product prepared pursuant to this section shall be subject to the compliance procedures in § 318.19 of this subchapter.

(d) The binders provided for use in cured pork products in a regulation in this subchapter, in 9 CFR Chapter III, Subchapter E, or in 21 CFR Chapter I, Subchapter A or Subchapter B, may be used singly in those cured pork products labeled as "Ham Water Added," "Ham and Water Product-X% of Weight is Added Ingredients," and "Ham with Natural Juices." In addition to the binders referred to in the preceding sentence, the following substances are permitted for use as binders and may be used singly in those cured pork products labeled as "Ham Water Added," "Ham and Water Product-X% of Weight is Added Ingredients," and "Ham with Natural Juices": pork collagen at up to 3.5% of the product formulation. Unless their use is provided for in a regulation in this subchapter, in 9 CFR Chapter III, Subchapter E, or in 21 CFR Chapter I, Subchapter A or Subchapter B, or in this paragraph, these binders are not permitted to be used in combination with another such binder listed for use in cured pork products. When any such substance is added to these products, the substance shall be declared in the ingredients statement by its common or usual name in order of predominance.

[49 FR 14879, Apr. 13, 1984, as amended at 50 FR 9792, Mar. 12, 1985; 53 FR 5151, Feb. 22, 1988; 57 FR 42888, Sept. 17, 1992; 62 FR 45026, Aug. 25, 1997; 63 FR 148, Jan. 5, 1998; 64 FR 27904, May 24, 1999; 65 FR 34389, May 30, 2000; 66 FR 54916, Oct. 31, 2001]

### § 319.105 "Ham patties," "Chopped ham," "Pressed ham," "Spiced ham," and similar products.

(a) Finely divided (chopped, ground, flaked, chipped) cured ham products such as "Ham patties," "Chopped ham," "Pressed ham," and "Spiced ham" shall comply with minimum meat Protein Fat Free (PFF) percentage requirements set forth in the following chart:

| Type of cured pork product | Minimum meat PFF percentage [1] | Product name and qualifying statements |
|---|---|---|
| "Ham Patties," "Chopped Ham," "Pressed Ham," and "Spiced Ham" | 19.5 | (Common and usual). |
| "Ham Patties," "Chopped Ham," "Pressed Ham," and "Spiced Ham" | 17.5 | (Common and usual) with natural juices. |
| "Ham Patties," "Chopped Ham," "Pressed Ham," and "Spiced Ham" | 16.0 | (Common and usual) water added. |
| "Ham Patties," "Chopped Ham," "Pressed Ham," and "Spiced Ham" | <16.0 | (Common and usual) and water product—(x)% of weight is added ingredients. [2] |

[1] The minimum meat PFF percentage shall be the minimum meat protein which is indigenous to the raw, unprocessed pork expressed as a percent of the nonfat portion of the finished product; and compliance shall be determined under section 318.19 of this subchapter.

[2] Processors may immediately follow this qualifying statement with a list of the ingredients in descending order of predominance rather than having the traditional ingredients statement. In any case, the maximum percent of added substances in the finished product on a total weight percentage basis would be inserted as the X value; e.g., Ham and Water Product—20% of Weight is Added Ingredients.

(b) Cured pork products prepared under this section except "Ham patties" may contain finely chopped ham shank meat to the extent of 25 percent over that normally present in boneless ham. Mechanically Separated (Species) Product may be used in accordance with § 319.6.

(c) Cured pork product prepared pursuant to this section shall be subject to the compliance procedures in § 318.19 of this subchapter, and those cured pork products prepared under this section for which there is a qualifying statement required shall comply with the requirements of § 319.104(b) of this subchapter.

(d) In addition to the other requirements of this section, "Ham Patties" may not contain more than 35 percent fat, by analysis.

[49 FR 14880, Apr. 13, 1984, as amended at 53 FR 5151, Feb. 22, 1988; 62 FR 45026, Aug. 25, 1997; 65 FR 34389, May 30, 2000]

**§ 319.106 "Country Ham," "Country Style Ham," "Dry Cured Ham," "Country Pork Shoulder," "Country Style Pork Shoulder," and "Dry Cured Pork Shoulder."**

(a) "Country Ham," "Country Style Ham," or "Dry Cured Ham," and "Country Pork Shoulder," "Country Style Pork Shoulder," or "Dry Cured Pork Shoulder." are the uncooked, cured, dried, smoked or unsmoked meat food products made respectively from a single piece of meat conforming to the definition of "ham," as specified in § 317.8(b)(13) of this subchapter, or from a single piece of meat from a pork shoulder. They are prepared in accordance with paragraph (c) of this section by the dry application of salt (NaCl), or by the dry application of salt (NaCl) and one or more of the optional ingredients as specified in paragraph (d) of this section. They may not be injected with curing solutions nor placed in curing solutions.

(b) The product must be treated for the destruction of possible live trichinae in accordance with such methods as may be approved by the Administrator upon request in specific instances and none of the provisions of this standard can be interpreted as discharging trichinae treatment requirements.

(c)(1) The entire exterior of the ham or pork shoulder shall be coated by the dry application of salt or by the dry application of salt combined with other ingredients as permitted in paragraph (d) of this section.

(2) Additional salt, or salt mixed with other permitted ingredients, may be reapplied to the product as necessary to insure complete penetration.

(3) When sodium or potassium nitrate, or sodium or potassium nitrite, or a combination thereof, is used, the application of salt shall be in sufficient quantity to insure that the finished product has an internal salt content of at least 4 percent.

(4) When no sodium nitrate, potassium nitrate, sodium nitrite, potassium nitrite or a combination thereof is used, the application of salt shall be in sufficient quantity to insure that the finished product has a brine concentration of not less than 10 percent or a water activity of not more than 0.92.

(5) For hams or pork shoulders labeled "country" or "country style," the combined period for curing and salt equalization shall not be less than 45 days for hams, and shall not be less than 25 days for pork shoulders; the total time for curing salt equalization, and drying shall not be less than 70 days for hams, and shall not be less than 50 days for pork shoulders. During the drying and smoking period, the internal temperature of the product must not exceed 95 °F., provided that such temperature requirement shall not apply to product dried or smoked under natural climatic conditions.

(6) For hams or pork shoulders labeled "dry cured," the combined period for curing and salt equalization shall not be less than 45 days for hams, and shall not be less than 25 days for pork shoulders; and the total time for curing, salt equalization, and drying shall not be less than 55 days for hams and shall not be less than 40 days for pork shoulders.

(7) The weight of the finished hams and pork shoulders covered in this section shall be at least 18 percent less than the fresh uncured weight of the article.

(d) The optional ingredients for products covered in this section are:

(1) Nutritive sweeteners, spices, seasonings and flavorings.

(2) Sodium or potassium nitrate and sodium or potassium nitrite if used as prescribed in this section and in accordance with a regulation permitting that use in this subchapter or 9 CFR Chapter III, Subchapter E, or in 21 CFR Chapter I, Subchapter A or Subchapter B.

[42 FR 3299, Jan. 18, 1977, as amended at 64 FR 72174, Dec. 23, 1999]

EFFECTIVE DATE NOTE: At 46 FR 1257, Jan. 6, 1981, the Safety and Quality Service, Department of Agriculture, announced that "the temperature and time period provisions of 9 CFR 319.106, paragraphs (c)(5) and (c)(6), have not been in effect since November 17, 1980, and will not be enforced pending future Agency action in the matter. However, ham and pork shoulders must continue to be prepared in compliance with all other provisions of 9 CFR 319.106 in order to be labeled 'country ham,' 'country style ham,' or 'dry cured ham,' and 'country pork shoulder,'

'country style pork shoulder,' or 'dry cured pork shoulder.'"

### § 319.107 Bacon.

The weight of cured pork bellies ready for slicing and labeling as "Bacon" shall not exceed the weight of the fresh uncured pork bellies.

[49 FR 14880, Apr. 13, 1984]

## Subpart E—Sausage Generally: Fresh Sausage

### § 319.140 Sausage.

Except as otherwise provided in this section, or under the Poultry Products Inspection Act with respect to products consisting partly of poultry, sausage is the coarse or finely comminuted meat food product prepared from one or more kinds of meat or meat and meat byproducts, containing various amounts of water as provided for elsewhere in this part, and usually seasoned with condimented proportions of condimental substances, and frequently cured. Certain sausage as provided for elsewhere in this part may contain binders and extenders as provided in a regulation permitting that use in this subchapter or in 9 CFR Chapter III, Subchapter E, or in 21 CFR Chapter I, Subchapter A or Subchapter B. In addition to the binders and extenders referred to in the preceding sentence, the following two substances may also be used as binders in those sausages in which the use of such class of substances is permitted: pork collagen at up to 3.5% of the product formulation and transglutaminase enzyme at up to 65 ppm of the product formulation. Sausage may not contain phosphates except that phosphates listed in a regulation permitting that use in this subchapter or in 9 CFR Chapter III, Subchapter E, or in 21 CFR Chapter I, Subchapter A or Subchapter B may be used in cooked sausage. To facilitate chopping or mixing or to dissolve the usual curing ingredients, water or ice may be used in the preparation of sausage which is not cooked in an amount not to exceed 3 percent of the total ingredients in the formula. Cooked sausages such as Polish sausage, cotto salami, braunschweiger, liver sausage, and similar cooked sausage products may contain no more than 10 percent of added water in the finished product. Sausage may contain Mechanically Separated (Species) used in accordance with § 319.6.

[55 FR 34683, Aug. 24, 1990, as amended at 64 FR 72175, Dec. 23, 1999; 66 FR 54916, Oct. 31, 2001]

### § 319.141 Fresh pork sausage.

"Fresh Pork Sausage" is sausage prepared with fresh pork or frozen pork or both, but not including pork byproducts, and may contain Mechanically Separated (Species) in accordance with § 319.6, and may be seasoned with condimental substances as permitted under part 318 of this subchapter. The finished product shall not contain more than 50 percent fat. To facilitate chopping or mixing, water or ice may be used in an amount not to exceed 3 percent of the total ingredients used.

[35 FR 15597, Oct. 3, 1970, as amended at 43 FR 26424, June 20, 1978; 47 FR 28257, 28258, June 29, 1982]

### § 319.142 Fresh beef sausage.

"Fresh Beef Sausage" is sausage prepared with fresh beef or frozen beef, or both, but not including beef byproducts, and may contain Mechanically Separated (Species) used in accordance with § 319.6, and may be seasoned with condimental substances as permitted under part 318 of this subchapter. The finished product shall not contain more than 30 percent fat. To facilitate chopping or mixing, water or ice may be used in an amount not to exceed 3 percent of the total ingredients used.

[35 FR 15597, Oct. 3, 1970, as amended at 43 FR 26424, June 20, 1978; 47 FR 28257, June 29, 1982]

### § 319.143 Breakfast sausage.

"Breakfast sausage" is sausage prepared with fresh and/or frozen meat; or fresh and/or frozen meat and meat byproducts, and may contain Mechanically Separated (Species) in accordance with § 319.6, and may be seasoned with condimental substances as permitted in part 318 of this subchapter. The finished product shall not contain more than 50 percent fat. To facilitate chopping or mixing, water or ice may be used in an amount not to exceed 3 percent of the total ingredients used.

Binders or extenders may be added as provided in §319.140 of this part.

[55 FR 34683, Aug. 24, 1990, as amended at 66 FR 54916, Oct. 31, 2001]

### §319.144 Whole hog sausage.

"Whole Hog Sausage" is sausage prepared with fresh and/or frozen meat from swine in such proportions as are normal to a single animal, and may include any Mechanically Separated (Species) produced from the animal and used in accordance with §319.6, and may be seasoned with condimental substances as permitted under part 318 of this subchapter. The finished product shall not contain more than 50 percent fat. To facilitate chopping or mixing, water or ice may be used in an amount not to exceed 3 percent of the total ingredients used.

[35 FR 15597, Oct. 3, 1970, as amended at 43 FR 26424, June 20, 1978; 47 FR 28257, 28258, June 29, 1982]

### §319.145 Italian sausage products.

(a) Italian sausage products are cured or uncured sausages containing at least 85 percent meat, or combination of meat and fat, with the total fat content constituting not more than 35 percent of the finished product. Such products shall be prepared in accordance with the provisions of paragraph (a) (1), (2) or (3) of this section, and shall contain salt, pepper, and either fennel or anise, or a combination of fennel and anise. Such products may contain any or all of the optional ingredients listed in paragraph (b) of this section.

(1) "Italian Sausage" shall be prepared with fresh or frozen pork, or pork and pork fat, and may contain Mechanically Separated (Species) in accordance with §319.6.

(2) "Italian Sausage with Beef," "Italian Sausage with Veal," or "Italian Sausage with Beef and Veal," shall be prepared so that fresh or frozen pork constitutes the major portion of the meat content requirement of this paragraph. Mechanically Separated (Species) may be used in accordance with §319.6. When pork muscle tissue is combined with beef or veal, or both, in the preparation of bulk-packed products, or patties, it shall be treated for the destruction of possible live trichinae in accordance with §318.10 of this subchapter.

(3) "Italian Beef Sausage" or "Kosher Italian Beef Sausage" shall be prepared with fresh or frozen beef or beef and beef fat. "Italian Veal Sausage" or "Kosher Italian Veal Sausage" shall be prepared with fresh or frozen veal or veal and veal fat. Mechanically Separated (Species) may be used in accordance with §319.6.

(4) Italian sausage products made in conformance with the provisions of paragraphs (a) (1), (2), and (3) of this section, and with paragraphs (b) and (c) of this section, may contain sodium nitrite or potassium nitrite in amounts not to exceed those allowed in a regulation permitting that use in this subchapter or in 9 CFR Chapter III, Subchapter E, or in 21 CFR Chapter I, Subchapter A or Subchapter B, provided that such products are labeled with the word "cured" in the product name, such as "Cured Italian Sausage." The word "cured" shall be displayed on the product label in the same size and style of lettering as other words in the product name.

(b) Optional ingredients permitted in Italian sausage products include:

(1) Spices (including paprika) and flavorings.

(2) Water or ice to facilitate chopping or mixing, but not to exceed 3 percent of the total weight of all ingredients including the water.

(3) Red or green peppers, or both.

(4) Dehydrated or fresh onions, garlic, and parsley.

(5) Sugar, dextrose, corn syrup, corn syrup solids, and glucose syrup.

(6) Monosodium glutamate and antioxidants in accordance with the chart of substances a regulation permitting that use in this subchapter or in 9 CFR Chapter III, Subchapter E, or in 21 CFR Chapter I, Subchapter A or Subchapter B.

(c) If Italian sausage products are cooked or smoked, determination of compliance with the provisions of paragraphs (a) and (b) of this section shall be based on the uncooked or unsmoked product. The product before cooking or smoking shall contain no more than 3 percent water as specified in paragraph (b)(2) of this section. Product which is cooked shall be labeled with the word

"cooked" in the product name, such as "Cooked Italian Sausage" or "Cooked Cured Italian Sausage." Product which is smoked shall be labeled with the word "smoked" in the product name, such as "Smoked Italian Sausage" or "Smoked Cured Italian Sausage." The words "cooked" and "smoked" shall be displayed on the product label in the same size and style of lettering as other words in the product name.

[41 FR 2630, Jan. 19, 1976, as amended at 43 FR 26424, June 20, 1978; 47 FR 28257, 28258, June 29, 1982; 49 FR 46533, Nov. 27, 1984; 64 FR 72175, Dec. 23, 1999]

## Subpart F—Uncooked, Smoked Sausage

### § 319.160 Smoked pork sausage.

"Smoked Pork Sausage" is pork sausage that is smoked with hardwood or other approved nonresinous materials. It may be seasoned with condimental substances as permitted in part 318 of this subchapter. The finished product shall not contain more than 50 percent fat. To facilitate chopping or mixing, water, or ice may be used in an amount not to exceed 3 percent of the total ingredients used.

[35 FR 15597, Oct. 3, 1970, as amended at 47 FR 28258, June 29, 1982]

## Subpart G—Cooked Sausage

### § 319.180 Frankfurter, frank, furter, hotdog, weiner, vienna, bologna, garlic bologna, knockwurst, and similar products.

(a) Frankfurter, frank, furter, hotdog, wiener, vienna, bologna, garlic bologna, knockwurst and similar cooked sausages are comminuted, semisolid sausages prepared from one or more kinds of raw skeletal muscle meat or raw skeletal muscle meat and raw or cooked poultry meat, and seasoned and cured, using one or more of the curing agents in accordance with a regulation permitting that use in this subchapter or in 9 CFR Chapter III, Subchapter E, or in 21 CFR Chapter I, Subchapter A or Subchapter B. They may or may not be smoked. The finished products shall not contain more than 30 percent fat. Water or ice, or both, may be used to facilitate chopping or mixing or to dissolve the curing ingredients but the sausage shall contain no more than 40 percent of a combination of fat and added water. These sausage products may contain only phosphates approved under part 318 of this chapter. Such products may contain raw or cooked poultry meat and/or Mechanically Separated (Kind of Poultry) without skin and without kidneys and sex glands used in accordance with § 381.174, not in excess of 15 percent of the total ingredients, excluding water, in the sausage, and Mechanically Separated (Species) used in accordance with § 319.6. Such poultry meat ingredients shall be designated in the ingredient statement on the label of such sausage in accordance with the provisions of § 381.118 of this chapter.

(b) Frankfurter, frank, furter, hotdog, wiener, vienna, bologna, garlic bologna, knockwurst and similar cooked sausages that are labeled with the phrase "with byproducts" or "with variety meats" in the product name are comminuted, semisolid sausages consisting of not less than 15 percent of one or more kinds of raw skeletal muscle meat with raw meat byproducts, or not less than 15 percent of one or more kinds of raw skeletal muscle meat with raw meat byproducts and raw or cooked poultry products; and seasoned and cured, using one or more of the curing ingredients in accordance with a regulation permitting that use in this subchapter or in 9 CFR Chapter III, Subchapter E, or in 21 CFR Chapter I, Subchapter A or Subchapter B. They may or may not be smoked. Partially defatted pork fatty tissue or partially defatted beef fatty tissue, or a combination of both, may be used in an amount not exceeding 15 percent of the meat and meat byproducts or meat, meat byproducts, and poultry products ingredients. The finished products shall not contain more than 30 percent fat. Water or ice, or both, may be used to facilitate chopping or mixing to dissolve the curing and seasoning ingredients, the sausage shall contain no more than 40 percent of a combination of fat and added water. These sausage products may contain only phosphates approved under part 318 of this chapter. These sausage products may contain poultry products and/or Mechanically

Separated (Kind of Poultry) used in accordance with §381.174, individually or in combination, not in excess of 15 percent of the total ingredients, excluding water, in the sausage, and may contain Mechanically Separated (Species) used in accordance with §319.6. Such poultry products shall not contain kidneys or sex glands. The amount of poultry skin present in the sausage must not exceed the natural proportion of skin present on the whole carcass of the kind of poultry used in the sausage, as specified in §381.117(d) of this chapter. The poultry products used in the sausage shall be designated in the ingredient statement on the label of such sausage in accordance with the provisions of §381.118 of this chapter. Meat byproducts used in the sausage shall be designated individually in the ingredient statement on the label for such sausage in accordance with §317.2 of this chapter.

(c) A cooked sausage as defined in paragraph (a) of this section shall be labeled by its generic name, e.g., frankfurter, frank, furter, hotdog, wiener, vienna, bologna, garlic bologna, or knockwurst. When such sausage products are prepared with meat from a single species of cattle, sheep, swine, or goats they shall be labeled with the term designating the particular species in conjunction with the generic name, e.g., "Beef Frankfurter," and when such sausage products are prepared in part with Mechanically Separated (Species) in accordance with §319.6, they shall be labeled in accordance with §317.2(j)(13) of this subchapter.

(d) A cooked sausage as defined in paragraph (b) of this section shall be labeled by its generic name, e.g., frankfurter, frank, furter, hotdog, wiener, vienna, bologna, garlic bologna, or knockwurst, in conjunction with the phrase "with byproducts" or "with variety meats" with such supplemental phrase shown in a prominent manner directly contiguous to the generic name and in the same color on an identical background.

(e) Binders and extenders as provided in §319.140 of this part may be used in cooked sausage that otherwise comply with paragraph (a) or (b) of this section. When any such substance is added to these products, the substance shall be declared in the ingredients statement by its common or usual name in order of predominance.

(f) Cooked sausages shall not be labeled with terms such as "All Meat" or "All (Species)," or otherwise to indicate they do not contain nonmeat ingredients or are prepared only from meat.

(g) For the purposes of this section: Poultry meat means deboned chicken meat or turkey meat, or both, without skin or added fat; poultry products mean chicken or turkey, or chicken meat or turkey meat as defined in §381.118 of this chapter, or poultry byproducts as defined in §381.1 of this chapter; and meat byproducts (or variety meats), mean pork stomachs or snouts; beef, veal, lamb, or goat tripe; beef, veal, lamb, goat, or pork hearts, tongues, fat, lips, weasands, and spleens; and partially defatted pork fatty tissue, or partially defatted beef fatty tissue.

[38 FR 14742, June 5, 1973]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting §319.180, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at www.fdsys.gov.

### §319.181 Cheesefurters and similar products.

"Cheesefurters" and similar products are products in casings which resemble frankfurters except that they contain sufficient cheese to give definite characteristics to the finished article. They may contain binders and extenders as provided in §318.7(c)(4) of this subchapter. Limits on use as provided in §318.7 are intended to be exclusive of the cheese constituent. When any such substance is added to these products, the substance shall be designated in the ingredients statement by its common or usual name in order of predominance. These products shall contain no more than 40 percent of a combination of fat and added water, and no more than 30 percent fat and shall comply with the other provisions for cooked sausages that are in this subchapter.

[55 FR 34683, Aug. 24, 1990, as amended at 56 FR 41448, Aug. 21, 1991]

**§ 319.182 Braunschweiger and liver sausage or liverwurst.**

(a) "Braunschweiger" is a cooked sausage made from fresh, cured, and/or frozen pork, beef, and/or veal and at least 30 percent pork, beef, and/or veal livers computed on the weight of the fresh livers. It may also contain pork and/or beef fat. Mechanically Separated (Species) may be used in accordance with § 319.6. Binders and extenders may be used as permitted in § 319.140. The product may have a smoked taste characteristic, which may be imparted by use of smoked meats, smoke flavoring or smoking. If prepared from components of a single species, the product name may reflect the species, e.g., "Beef Braunschweiger." Braunschweiger may also be labeled as any of the following: "Braunschweiger—A Liver Sausage," "Braunschweiger—A Liverwurst," or "Braunschweiger (Liver Sausage)" or "Braunschweiger (Liverwurst)."

(b) "Liver Sausage" or "Liverwurst" is a cooked sausage made from fresh, cured, and/or frozen pork, beef, and/or veal and at least 30 percent pork, beef, veal, sheep, and/or goat livers computed on the weight of the fresh livers. It may also contain pork and/or beef byproducts. Mechanically Separated (Species) may be used in accordance with § 319.6. Binders and extenders maybe used as permitted in § 319.140. If prepared from components of a single species, the product name may reflect that species, e.g., "Pork Liver Sausage."

[47 FR 36108, Aug. 19, 1982]

## Subpart H [Reserved]

## Subpart I—Semi-Dry Fermented Sausage [Reserved]

## Subpart J—Dry Fermented Sausage [Reserved]

## Subpart K—Luncheon Meat, Loaves and Jellied Products

**§ 319.260 Luncheon meat.**

"Luncheon Meat" is a cured, cooked meat food product made from comminuted meat. Mechanically Separated (Species) may be used in accordance with § 319.6. To facilitate chopping or mixing or to dissolve the usual curing ingredients, water or ice may be used in the preparation of luncheon meat in an amount not to exceed 3 percent of the total ingredients.

[35 FR 15597, Oct. 3, 1970, as amended at 43 FR 26425, June 20, 1978; 47 FR 28257, June 29, 1982]

**§ 319.261 Meat loaf.**

"Meat Loaf" is a cooked meat food product in loaf form made from comminuted meat. Mechanically Separated (Species) may be used in accordance with § 319.6. To facilitate chopping or mixing, water or ice may be used in an amount not to exceed 3 percent of the total ingredients used.

[35 FR 15597, Oct. 3, 1970, as amended at 43 FR 26425, June 20, 1978; 47 FR 28257, June 29, 1982]

## Subpart L—Meat Specialties, Puddings and Nonspecific Loaves

**§ 319.280 Scrapple.**

"Scrapple" shall contain not less than 40 percent meat and/or meat byproducts computed on the basis of the fresh weight, exclusive of bone. Mechanically Separated (Species) may be used in accordance with § 319.6. The meal or flour used may be derived from grain and/or soybeans.

[35 FR 15597, Oct. 3, 1970, as amended at 43 FR 26425, June 20, 1978; 47 FR 28257, June 29, 1982]

**§ 319.281 Bockwurst.**

(a) Bockwurst is an uncured, comminuted meat food product which may or may not be cooked. It contains meat, milk or water or a combination thereof, eggs, vegetables, and any of the optional ingredients listed in paragraph (b) of this section; and is prepared in accordance with the provisions of paragraphs (a)(1), (2), (3), and (4) of this section.

(1) Meat shall constitute not less than 70 percent of the total weight of the product and shall consist of pork or a mixture of pork and veal, pork and beef, or pork, veal, and beef. Such meat shall be fresh or fresh frozen meat. Pork may be omitted when the specie or species of meat used in the product is identified in the product name (e.g., Veal Bockwurst, Beef Bockwurst, or

Beef and Veal Bockwurst). Mechanically Separated (Species) may be used in accordance with §319.6.

(2) The "milk" may be fresh whole milk, dried milk, nonfat dry milk, calcium reduced dried skim milk, enzyme (rennet) treated calcium reduced dried skim milk and calcium lactate, or any combination thereof.

(3) "Eggs" refer to whole eggs that are fresh, frozen, or dried.

(4) "Vegetables" refer to onions, chives, parsley, and leeks, alone or in any combination.

(b) Bockwurst may contain one or more of the following optional ingredients:

(1) Pork fat.

(2) Celery, fresh or dehydrated.

(3) Spices, flavorings.

(4) Salt.

(5) Egg whites, fresh, frozen, or dried.

(6) Corn syrup solids, corn syrup, or glucose syrup with a maximum limit of 2 percent individually or collectively, calculated on a dry basis. The maximum quantities of such ingredients shall be computed on the basis of the total weight of the ingredients.

(7) Autolyzed yeast extract, hydrolyzed plant protein, milk protein hydrolysate, and monosodium glutamate.

(8) Sugars (sucrose and dextrose).

(9) Binders and extenders may be added as provided in §318.7(c)(4) of this subchapter. When any such substance is added to bockwurst, the substance shall be designated in the ingredients statement by its common or usual name in order of predominance.

(c) If bockwurst is cooked or partially cooked, the composition of the raw mix from which it is prepared shall be used in determining whether it meets the requirements of this section.

[40 FR 18542, Apr. 29, 1975, as amended at 41 FR 18089, Apr. 30, 1976; 43 FR 26425, June 20, 1978; 45 FR 10318, Feb. 15, 1980; 47 FR 26374, June 18, 1982; 47 FR 28257, 28258, June 29, 1982; 55 FR 34683, Aug. 24, 1990; 56 FR 41448, Aug. 21, 1991]

## Subpart M—Canned, Frozen, or Dehydrated Meat Food Products

### §319.300 Chili con carne.

"Chili con carne" shall contain not less than 40 percent of meat computed on the weight of the fresh meat. Mechanically Separated (Species) may be used in accordance with §319.6. Head meat, cheek meat, and heart meat exclusive of the heart cap may be used to the extent of 25 percent of the meat ingredients under specific declaration on the label. The mixture may contain binders and extenders as provided in §318.7(c)(4) of this subchapter.

[55 FR 34684, Aug. 24, 1990]

### §319.301 Chili con carne with beans.

*Chili con carne with beans* shall contain not less than 25 percent of meat computed on the weight of the fresh meat. Mechanically Separated (Species) may be used in accordance with §319.6. Head meat, cheek meat, or heart meat exclusive of the heart cap may be used to the extent of 25 percent of the meat ingredients, and its presence shall be reflected in the statement of ingredients required by part 317 of this subchapter. The mixture may contain binders and extenders as provided in §318.7(c)(4) of this subchapter.

[55 FR 34684, Aug. 24, 1990]

### §319.302 Hash.

"Hash" shall contain not less than 35 percent of meat computed on the weight of the cooked and trimmed meat. The weight of the cooked meat used in this calculation shall not exceed 70 percent of the weight of the uncooked fresh meat. Mechanically Separated (Species) may be used in accordance with §319.6.

[35 FR 15597, Oct. 3, 1970, as amended at 43 FR 26425, June 20, 1978; 47 FR 28257, June 29, 1982]

### §319.303 Corned beef hash.

(a) "Corned Beef Hash" is the semisolid food product in the form of a compact mass which is prepared with beef, potatoes, curing agents, seasonings, and any of the optional ingredients listed in paragraph (b) of this section, in accordance with the provisions of paragraphs (a) (1), (2), (3) and (4) of this section and the provisions of paragraph (c) of this section.

(1) Either fresh beef, cured beef, or canned corned beef or a mixture of two or more of these ingredients, may be used, and the finished product shall contain not less than 35 percent of beef

computed on the weight of the cooked and trimmed beef. The weight of the cooked meat used in this calculation shall not exceed 70 percent of the weight of the uncooked fresh meat.

(2) "Potatoes" refers to fresh potatoes, dehydrated potatoes, cooked dehydrated potatoes, or a mixture of two or more of these ingredients.

(3) The curing agents that may be used are salt, sodium nitrate, sodium nitrite, potassium nitrate, or potassium nitrite, or a combination of two or more of these ingredients. When sodium nitrate, or sodium nitrite, potassium nitrate, or potassium nitrite is used it shall be used in amounts not exceeding those specified in a regulation permitting that use in this subchapter or in 9 CFR Chapter III, Subchapter E, or in 21 CFR Chapter I, Subchapter A or Subchapter B.

(4) The seasonings that may be used, singly or in combination, are salt, sugar (sucrose or dextrose), spice, and flavoring, including essential oils, oleoresins, and other spice extractives.

(b) Corned beef hash may contain one or more of the following optional ingredients:

(1) Beef cheek meat and beef head meat from which the overlying glandular and connective tissues have been removed, and beef heart meat, exclusive of the heart cap, may be used individually or collectively to the extent of 5 percent of the meat ingredients;

(2) Onions, including fresh onions, dehydrated onions, or onion powder;

(3) Garlic, including fresh garlic, dehydrated garlic, or garlic powder;

(4) Water;

(5) Beef broth or beef stock;

(6) Monosodium glutamate;

(7) Hydrolyzed plant protein;

(8) Beef fat;

(9) Mechanically Separated (Species) when derived from carcasses of cattle may be used in accordance with § 319.6.

(c) The finished product shall not contain more than 15 percent fat nor more than 72 percent moisture.

(d)(1) When any ingredient specified in paragraph (b)(1) of this section is used, the label shall bear the following applicable statement: "Beef cheek meat constitutes 5 percent of the meat ingredient," or "Beef head meat constitutes 5 percent of the meat ingredient," or "Beef heart meat constitutes 5 percent of the meat ingredient." When two or more of the ingredients are used, the words "Constitutes 5 percent of meat ingredient" need only appear once.

(2) Whenever the words "corned beef hash" are featured on the label so conspicuously as to identify the contents, the statements prescribed in paragraph (d)(1) of this section shall immediately and conspicuously precede or follow such name without intervening written, printed, or other graphic matter.

[35 FR 15597, Oct. 3, 1970, as amended at 43 FR 26425, June 20, 1978; 47 FR 28257, June 29, 1982; 64 FR 72175, Dec. 23, 1999]

### § 319.304 Meat stews.

Meat stews such as "Beef Stew" or "Lamb Stew" shall contain not less than 25 percent of meat of the species named on the label, computed on the weight of the fresh meat. Mechanically Separated (Species) may be used in accordance with § 319.6.

[35 FR 15597, Oct. 3, 1970, as amended at 43 FR 26425, June 20, 1978; 47 FR 28257, June 29, 1982]

### § 319.305 Tamales.

"Tamales" shall be prepared with at least 25 percent meat computed on the weight of the uncooked fresh meat in relation to all ingredients of the tamales. When tamales are packed in sauce or gravy, the name of the product shall include a prominent reference to the sauce or gravy; for example, "Tamales With Sauce" or "Tamales With Gravy." Product labeled "Tamales With Sauce" or "Tamales With Gravy" shall contain not less than 20 percent meat, computed on the weight of the uncooked fresh meat in relation to the total ingredients making up the tamales and sauce or the tamales and gravy. Mechanically Separated (Species) may be used in accordance with § 319.6.

[35 FR 15597, Oct. 3, 1970, as amended at 43 FR 26425, June 20, 1978; 47 FR 28257, 28258, June 29, 1982]

### § 319.306 Spaghetti with meatballs and sauce, spaghetti with meat and sauce, and similar products.

"Spaghetti with Meatballs and Sauce" and "Spaghetti with Meat and Sauce," and similar products shall contain not

less than 12 percent of meat computed on the weight of the fresh meat. Mechanically Separated (Species) may be used in accordance with § 319.6. The presence of the sauce or gravy constituent shall be declared prominently on the label as part of the name of the product. Meatballs may be prepared with farinaceous material and with other binders and extenders as provided in § 318.7(c)(4) of this subchapter.

[55 FR 34684, Aug. 24, 1990]

### § 319.307 Spaghetti sauce with meat.

"Spaghetti Sauce with Meat" shall contain not less than 6 percent of meat computed on the weight of the fresh meat. Mechanically Separated (Species) may be used in accordance with § 319.6.

[35 FR 15597, Oct. 3, 1970, as amended at 43 FR 26425, June 20, 1978; 47 FR 28257, June 29, 1982]

### § 319.308 Tripe with milk.

"Tripe with Milk" shall be prepared so that the finished canned article, exclusive of the cooked-out juices and milk, will contain at least 65 percent tripe. The product shall be prepared with not less than 10 percent milk.

### § 319.309 Beans with frankfurters in sauce, sauerkraut with wieners and juice, and similar products.

"Beans with Frankfurters in Sauce," "Sauerkraut with Wieners and Juice," and similar products shall contain not less than 20 percent frankfurters or wieners computed on the weight of the smoked and cooked sausage prior to its inclusion with the beans or sauerkraut.

### § 319.310 Lima beans with ham in sauce, beans with ham in sauce, beans with bacon in sauce, and similar products.

"Lima Beans with Ham in Sauce," "Beans with Ham in Sauce," "Beans with Bacon in Sauce," and similar products shall contain not less than 12 percent ham or bacon computed on the weight of the smoked ham or bacon prior to its inclusion with the beans and sauce.

### § 319.311 Chow mein vegetables with meat, and chop suey vegetables with meat.

"Chow Mein Vegetables with Meat" and "Chop Suey Vegetables with Meat" shall contain not less than 12 percent meat computed on the weight of the uncooked fresh meat prior to its inclusion with the other ingredients. Mechanically Separated (Species) may be used in accordance with § 319.6.

[35 FR 15597, Oct. 3, 1970; 36 FR 11903, June 23, 1971, as amended at 43 FR 26425, June 20, 1978; 47 FR 28257, June 29, 1982]

### § 319.312 Pork with barbecue sauce and beef with barbecue sauce.

"Pork with Barbecue Sauce" and "Beef with Barbecue Sauce" shall consist of not less than 50 percent cooked meat of the species specified on the label. Mechanically Separated (Pork) may be used in accordance with § 319.6.

[69 FR 34916, June 23, 2004]

### § 319.313 Beef with gravy and gravy with beef.

"Beef with Gravy" and "Gravy with Beef" shall not be made with beef which, in the aggregate for each lot contains more than 30 percent trimmable fat, that is, fat which can be removed by thorough, practicable trimming and sorting.

## Subpart N—Meat Food Entree Products, Pies, and Turnovers

### § 319.500 Meat pies.

Meat pies such as "Beef Pie," "Veal Pie," and "Pork Pie" shall contain meat of the species specified on the label, in an amount not less than 25 percent of all ingredients including crust and shall be computed on the basis of the fresh uncooked meat.

## Subpart O—Meat Snacks, Hors d'Oeuvres, Pizza, and Specialty Items

### § 319.600 [Reserved]

## Subpart P—Fats, Oils, Shortenings

### § 319.700 Margarine or oleomargarine.[1]

(a) Margarine or oleomargarine is the food in plastic form or liquid emulsion, containing not less than 80 percent fat determined by the method prescribed under § 938.06 (Chapter 33) of the "Indirect Methods" in "Official Methods of Analysis of the Association of Official Analytical Chemists", 15th edition, 1990.[2] The "Official Methods of Analysis of the Association of Official Analytical Chemists," 15th edition, 1990, is 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. It is produced from one or more of the ingredients designated in paragraph (a)(1) of this section, and one or more of the ingredients designated in paragraph (a)(2) of this section, to which may be added one or more of the optional ingredients designated in paragraph (b) of this section. Margarine or oleomargarine contains Vitamin A as provided for in paragraph (a)(3) of this section.

(1) Edible fats and oils or mixtures of these, whose origin is vegetable or rendered animal fats from cattle, sheep, swine or goats.

(2)(i) Water; milk; milk products including, but not limited to, the liquid, condensed, or dry form of whey, reduced lactose whey, reduced minerals whey, or whey protein concentrate, non-lactose-containing whey components, casein, or caseinate; or other suitable edible protein, including albumin, vegetable proteins, or soy protein isolate; or any mixture of two or more of the articles designated in this subparagraph, in amounts not greater than reasonably required to accomplish the desired effect.

(ii) The articles designated in this subparagraph shall be pasteurized and then may be subjected to the action of harmless bacterial starters. One or more of the articles designated in this subparagraph is intimately mixed with the edible fat or oil ingredients, or both, to form a solidified or liquid emulsion.

(3) Vitamin A in such quantity that the finished margarine or oleomargarine contains not less than 15,000 International Units (IU) of ViTamin A per pound or 33,000 IU per kilogram.

(b)(1) Vitamin D in such quantity that the finished margarine or oleomargarine contains not less than 1,500 IU of Vitamin D per pound or 3,300 IU per kilogram.

(2) Salt (sodium chloride); or potassium chloride for dietary margarine or oleomargarine.

(3) Nutritive carbohydrate sweeteners.

(4) Emulsifiers identified in a regulation permitting that use in this subchapter or a regulation permitting that use in this subchapter or in 9 CFR Chapter III, Subchapter E, or in 21 CFR Chapter I, Subchapter A or Subchapter B, within these maximum amounts in percent by weight of the finished food: Mono- and diglycerides of fatty acids esterified with any or all of the following acids: acetic, acetyltartaric, citric, lactic, tartaric, and their sodium and calcium salts, 0.5 percent; such mono- and diglycerides in combination with the sodium sulfoacetate derivatives thereof, 0.5 percent; polyglycerol esters of fatty acids, 0.5 percent; 1,2-propylene glycol esters of fatty acids, 2 percent; lecithin, 0.5 percent.

(5) Preservatives identified in a regulation permitting that use in this subchapter or in 9 CFR Chapter III, Subchapter E, or in 21 CFR Chapter I, Subchapter A or Subchapter B, within these maximum amounts in percent by weight of the finished food: Sorbic

[1] Insofar as the standard contains provisions relating to margarine or oleomargarine which does not contain any meat food products, such provisions merely reflect the applicable standard under the Federal Food, Drug, and Cosmetic Act.

[2] A copy of the "Official Methods of Analysis of the Association of Official Analytical Chemists," 15th edition, 1990, is on file with the Director, Office of the Federal Register, and may be purchased from the Association of Official Analytical Chemists, Inc., 2200 Wilson Boulevard, Suite 400, Arlington, Virginia 22201.

acid, benzoic acid and their sodium, potassium, and calcium salts, individually, 0.1 percent, or in combination, 0.2 percent, expressed as the acids; calcium disodium EDTA, 0.0075 percent; stearyl citrate, 0.15 percent; isopropyl citrate mixture, 0.02 percent.

(6) Antioxidants identified in a regulation permitting that use in this subchapter or in 9 CFR Chapter III, Subchapter E, or in 21 CFR Chapter I, Subchapter A or Subchapter B, within these maximum amounts in percent by weight of the finished food: propyl, octyl and dodecyl gallates, BHT (butylated hydroxytoluene), BHA (butylated hydroxyanisole), ascorbyl palmitate, ascorbyl stearate, all individually or in combination, 0.02 percent. Instead of these antioxidants, TBHQ (tertiary butylhydroquinone), alone or in combination only with BHT and/or BHA, with a maximum 0.02 percent by weight of the fat and oil content.

(7) Coloring agents identified in a regulation permitting that use in this subchapter or in 9 CFR Chapter III, Subchapter E, or in 21 CFR Parts 73, 74, 81, or 82, in amounts sufficient for purpose.[3] For the purpose of this subparagraph, provitamine A (beta-carotene) shall also be deemed to be a coloring agent.

(8) Flavoring substances in amounts sufficient for purpose.

(9) Acidulants identified in a regulation permitting that use in this subchapter or in 9 CFR Chapter III, Subchapter E, or in 21 CFR Chapter I, Subchapter A or Subchapter B, in amounts sufficient for purpose: adipic acid; citric and lactic acids and their potassium and sodium salts; phosphoric acid; L-tartaric acid and its sodium and sodium-potassium salts; and hydrochloric acid.

(10) Alkalizers identified in a regulation permitting that use in this subchapter or in 9 CFR Chapter III, Subchapter E, or in 21 CFR Chapter I, Subchapter A or Subchapter B, in amounts sufficient for purpose: potassium bicarbonate, potassium carbonate, sodium bicarbonate, sodium carbonate, and sodium hydroxide.

(11) For the purposes of this section, the term "milk" unqualified means milk from cows. If any milk other than cow's milk is used in whole or in part, the animal source shall be identified in conjunction with the word "milk" in the ingredient statement.

[48 FR 52697, Nov. 22, 1983, as amended at 50 FR 3739, Jan. 28, 1985; 54 FR 40632, Oct. 3, 1989; 59 FR 33642, June 30, 1994; 64 FR 72175, Dec. 23, 1999]

### § 319.701 Mixed fat shortening.

Shortening prepared with a mixture of meat fats and vegetable oils may be identified either as "Shortening Prepared with Meat Fats and Vegetable Oils" or "Shortening Prepared with Vegetable Oils and Meat Fats" depending on the predominance of the fat and oils used, or the product may be labeled "Shortening" when accompanied by an ingredient statement with ingredients listed in descending order of predominance.

### § 319.702 Lard, leaf lard.

(a) Lard is the fat rendered from clean and sound edible tissues from swine. The tissues may be fresh, frozen, cooked, or prepared by other processes approved by the Administrator in specific cases, upon his determination that the use of such processes will not result in the adulteration or misbranding of the lard. The tissues shall be reasonably free from blood, and shall not include stomachs, livers, spleens, kidneys, and brains, or settlings and skimmings. "Leaf Lard" is lard prepared from fresh leaf (abdominal) fat.

(b) Lard (when properly labeled) may be hardened by the use of lard stearin or hydrogenated lard or both and may contain refined lard and deodorized lard, but the labels of such lard shall state such facts, as applicable.

(c) Products labeled "Lard" or "Leaf Lard" must have the following identity and quality characteristics to insure good color, odor, and taste of finished product:

| | |
|---|---|
| (1) Color | White when solid, Maximum 3.0 red units in a 5¼ inch cell on the Lovibond scale. |
| (2) Odor and taste | Characteristic and free from foreign odors and flavors. |

[3] Colored margarine or oleomargarine is also subject to the provisions of section 407 of the Federal Food, Drug, and Cosmetic Act, as amended (21 U.S.C. 347), as reflected in § 317.8(h)(24) of this subchapter.

| | |
|---|---|
| (3) Free fatty acid ..... | Maximum 0.5 percent (as oleic) or 1.0 acid value, as milligrams KOH per gram of sample. |
| (4) Peroxide value ..... | Maximum 5.0 (as milliequivalents of peroxide per kilogram fat). |
| (5) Moisture and volatile matter. | Maximum 0.2 percent. |
| (6) Insoluble impurities .... | By appearance of liquid, fat or maximum 0.05 percent. |

(d) Product found upon inspection not to have the characteristics specified in paragraph (c) of this section but found to be otherwise sound and in compliance with paragraph (a) of this section may be further processed for the purpose of achieving such characteristics.

[43 FR 25420, June 13, 1978]

### § 319.703 Rendered animal fat or mixture thereof.

"Rendered Animal Fat," or any mixture of fats containing edible rendered animal fat, shall contain no added water, except that "Puff Pastry Shortening" may contain not more than 10 percent of water.

[35 FR 15597, Oct. 3, 1970, as amended at 43 FR 25420, June 13, 1978]

## Subpart Q—Meat Soups, Soup Mixes, Broths, Stocks, Extracts

### § 319.720 Meat extract.

Meat extract (e.g., "Beef Extract") shall contain not more than 25 percent of moisture.

### § 319.721 Fluid extract of meat.

Fluid extract of meat (e.g., "Fluid Extract of Beef") shall contain not more than 50 percent of moisture.

## Subpart R—Meat Salads and Meat Spreads

### § 319.760 Deviled ham, deviled tongue, and similar products.

(a) "Deviled Ham" is a semiplastic cured meat food product made from finely comminuted ham and containing condiments. Mechanically Separated (Species) may be used in accordance with § 319.6. Deviled ham may contain added ham fat: *Provided*, That the total fat content shall not exceed 35 percent of the finished product. The moisture content of deviled ham shall not exceed that of the fresh unprocessed meat.

(b) The moisture content of "Deviled Tongue" and similar products shall not exceed that of the fresh, unprocessed meat.

[35 FR 15597, Oct. 3, 1970, as amended at 43 FR 26425, June 20, 1978; 47 FR 28257, June 29, 1982]

### § 319.761 Potted meat food product and deviled meat food product.

"Potted Meat Food Product" and "Deviled Meat Food Product" shall not contain cereal, vegetable flour, nonfat dry milk, or similar substances. The amount of water added to potted meat food product and deviled meat food product shall be limited to that necessary to replace moisture lost during processing.

### § 319.762 Ham spread, tongue spread, and similar products.

"Ham Spread," "Tongue Spread," and similar products shall contain not less than 50 percent of the meat ingredient named, computed on the weight of the fresh meat. Other meat and fat may be used to give the desired spreading consistency provided it does not detract from the character of the spreads named. Mechanically Separated (Species) may be used in accordance with § 319.6.

[35 FR 15597, Oct. 3, 1970, as amended at 43 FR 26425, June 20, 1978; 47 FR 28257, June 29, 1982]

## Subpart S—Meat Baby Foods [Reserved]

## Subpart T—Dietetic Meat Foods [Reserved]

## Subpart U—Miscellaneous

### § 319.880 Breaded products.

The amount of batter and breading used as a coating for breaded product shall not exceed 30 percent of the weight of the finished breaded product.

### § 319.881 Liver meat food products.

Meat food products characterized and labeled as liver products such as liver loaf, liver cheese, liver spread, liver mush, liver paste, and liver pudding shall contain not less than 30 percent

of pork, beef, sheep, or goat livers computed on the fresh weight of the livers.

[36 FR 12004, June 24, 1971]

# PART 320—RECORDS, REGISTRATION, AND REPORTS

Sec.
320.1 Records required to be kept.
320.2 Place of maintenance of records.
320.3 Record retention period.
320.4 Access to and inspection of records, facilities and inventory; copying and sampling.
320.5 Registration.
320.6 Information and reports required from official establishment operators.
320.7 Reports by consignees of allegedly adulterated or misbranded products; sale or transportation as violations.

AUTHORITY: 21 U.S.C. 601–695; 7 CFR 2.7, 2.18, 2.53.

SOURCE: 35 FR 15603, Oct. 3, 1970, unless otherwise noted.

## § 320.1 Records required to be kept.

(a) Every person (including every firm or corporation) within any of the classes specified in paragraph (a) (1), (2), or (3) of this section is required by the Act to keep records which will fully and correctly disclose all transactions involved in his or its business subject to the Act:

(1) Any person that engages, for commerce, in the business of slaughtering any cattle, sheep, swine, goats, horses, mules, or other equines, or preparing, freezing, packaging, or labeling any carcasses, or parts or products of carcasses, of any such animals, for use as human food or animal food;

(2) Any person that engages in the business of buying or selling (as a meat broker, wholesaler, or otherwise), or transporting in commerce, or storing in or for commerce, or importing, any carcasses, or parts or products of carcasses, of any such animals;

(3) Any person that engages in business, in or for commerce, as a renderer, or engages in the business of buying, selling, or transporting in commerce, or importing, any dead, dying, disabled, or diseased cattle, sheep, swine, goats, horses, mules, or other equines, or parts of the carcasses of any such animals that died otherwise than by slaughter.

(b) The required records are:

(1) Records, such as bills of sale, invoices, bills of lading, and receiving and shipping papers, giving the following information with respect to each transaction in which any livestock or carcass, part thereof, meat or meat food product is purchased, sold, shipped, received, transported, or otherwise handled by said person in connection with any business subject to the Act:

(i) The name or description of the livestock or article;

(ii) The net weight of the livestock or article;

(iii) The number of outside containers (if any);

(iv) The name and address of the buyer of livestock or article sold by such person, and the name and address of the seller of livestock or articles purchased by such person;

(v) The name and address of the consignee or receiver (if other than the buyer);

(vi) The method of shipment;

(vii) The date of shipment; and

(viii) The name and address of the carrier.

(ix) In the case of a person belonging to the class specified in paragraph (a)(1), and engaged, for commerce, in the business of slaughtering any swine for use as human or animal food, the name and address (including the city and state, or the township, county, and state) of each person from whom the person belonging to the class so specified purchased or otherwise obtained each swine, and the telephone number, if available, of the person from whom the swine were purchased or otherwise obtained, and all serial numbers and other approved means of identification appearing on all test swine selected at antemortem inspection by FSIS representatives for residue testing.

(2) Shipper's certificates and permits required to be kept by shippers and carriers of articles under part 325 of this subchapter.

(3) A record of seal numbers required to be kept by consignees of inedible products shipped under unofficial seals under § 325.11(b) or (e) of this subchapter, and a record of new consignees of inedible products diverted under § 325.11(e) of this subchapter.