

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

(c) *Stabilization.* (1) Fully cooked, partially cooked, and char-marked meat patties must be produced using processes ensuring no multiplication of toxigenic microorganisms such as *Clostridium botulinum*, and no more than a 1 log<sub>10</sub> multiplication of *Clostridium perfringens*, within the product.

(2) For each meat patty product produced using a stabilization 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, 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 an establishment in order to evaluate and approve the safety and efficacy of each process schedule.

(3) 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.

(4) Partially cooked patties must bear the labeling statement "Partially cooked: For Safety Cook Until Well Done (Internal Meat Temperature 160 degrees F.)." The labeling statement must be adjacent to the product name, and prominently placed with such conspicuousness (as compared with other

words, statements, designs or devices in the labeling) as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(5) Char-marked patties must bear the labeling statement "Uncooked, Char-marked: For Safety, Cook Until Well Done (Internal Meat Temperature 160 degrees F.)." The labeling statement shall be adjacent to the product name, at least one-half the size of the largest letter in the product name, and prominently placed with such conspicuousness (as compared with other words, statements, designs or devices in the labeling) as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

[64 FR 744, Jan. 6, 1999]

**§318.24 Product prepared using advanced meat/bone separation machinery; process control.**

(a) *General.* Meat, as defined in §301.2 of this subchapter, may be derived by mechanically separating skeletal muscle tissue from the bones of livestock, other than skulls or vertebral column bones of cattle 30 months of age and older as provided in §310.22 of this subchapter, using advances in mechanical meat/bone separation machinery (*i.e.*, AMR systems) that, in accordance with this section, recover meat—

(1) Without significant incorporation of bone solids or bone marrow as measured by the presence of calcium and iron in excess of the requirements in this section, and

(2) Without the presence of any brain, trigeminal ganglia, spinal cord, or dorsal root ganglia (DRG).

(b) *Process control.* As a prerequisite to labeling or using product as meat derived by the mechanical separation of skeletal muscle tissue from livestock bones, the operator of an establishment must develop, implement, and maintain procedures that ensure that the establishment's production process is in control.

(1) The production process is not in control if the skulls entering the AMR system contain any brain or trigeminal ganglia tissue, if the vertebral column bones entering the AMR system contain any spinal cord, if the recovered

product fails otherwise under any provision of paragraph (c)(1), if the product is not properly labeled under the provisions of paragraph (c)(2), or if the spent bone materials are not properly handled under the provisions of paragraph (c)(3) of this section.

(2) The establishment must document its production process controls in writing. The program must be designed to ensure the on-going effectiveness of the process controls. If the establishment processes cattle, the program must be in its HACCP plan, its Sanitation SOP, or other prerequisite program. The program shall describe the on-going verification activities that will be performed, including the observation of the bones entering the AMR system for brain, trigeminal ganglia, and spinal cord; the testing of the product exiting the AMR system for bone solids, bone marrow, spinal cord, and DRG as prescribed in paragraph (c)(1) of this section; the use of the product and spent bone materials exiting the AMR system; and the frequency with which these activities will be performed.

(3) The establishment shall maintain records on a daily basis sufficient to document the implementation and verification of its production process.

(4) The establishment shall make available to inspection program personnel the documentation described in paragraphs (b)(2) and (b)(3) of this section and any other data generated using these procedures.

(c) *Noncomplying product.* (1) Notwithstanding any other provision of this section, product that is recovered using advanced meat/bone separation machinery is not meat under any one or more of the following circumstances:

(i) *Bone solids.* The product's calcium content, measured by individual samples and rounded to the nearest 10th, is more than 130.0 mg per 100 g.

(ii) *Bone marrow.* The product's added iron content, measured by duplicate analyses on individual samples and rounded to the nearest 10th, is more than 3.5 mg per 100 g.<sup>1</sup>

<sup>1</sup>The excessive iron (ExcFe) measurement for an analyzed sample is equal to the obtained iron (Fe) result expressed in mg/100 g measured and rounded to the nearest 100th or more for that sample, minus the product of three factors: (1) The iron to protein ratio

(iii) *Brain or trigeminal ganglia.* Skulls that enter the AMR system have tissues of brain or trigeminal ganglia.

(iv) *Spinal cord.* Vertebral column bones that enter the AMR system have tissues of spinal cord, or the product that exits the AMR system contains spinal cord.

(v) *DRG.* The product that exits the AMR system contains DRG.

(2) If product that may not be labeled or used as "meat" under this section meets the requirements of § 319.5 of this subchapter, it may bear the name "Mechanically Separated (Species)" except as follows:

(i) If skulls or vertebral column bones of cattle younger than 30 months of age that enter the AMR system have tissues of brain, trigeminal ganglia, or spinal cord, the product that exits the AMR system shall not be used as an ingredient of a meat food product.

(ii) If product that exits the AMR system contains spinal cord or DRG from bones of cattle younger than 30 months of age, it shall not be used as an ingredient of a meat food product.

(iii) If product derived from any bones of cattle of any age does not

(IPR) factor associated with corresponding hand-deboned product; (2) the obtained protein (P) result (%) for that sample; and (3) a constant factor of 1.10. In formula, this can be written as:  $\text{ExcFe} = \text{mFe} - \text{IPR} \times \text{Protein} \times 1.10$ , where ExcFe represents the excess iron, expressed in units of mg/100 g; mFe represents the measured level of iron (Fe, mg/100 g), IPR is the iron to protein ratio for the appropriate hand-deboned product, and "Protein" is the measured level of protein rounded to the nearest 100th and expressed as a percentage of the total weight of the sample. In lieu of data demonstrating otherwise, the values of IPR to be used in the above formula are as follows: For beef products the value of IPR is equal to 0.104, except for any combination of bones that include any beef neckbone product, for which the value of 0.138 is to be used; for pork product, the IPR value is 0.052. Other IPR values can be used provided that the operator of an establishment has verified and documented the ratio of iron content to protein content in the skeletal muscle tissue attached to bones prior to their entering the AMR system, based on analyses of hand-deboned samples, and the documented value is to be substituted for the IPR value (as applicable) in the above formula with respect to product that the establishment mechanically separates from those bones.

comply with (c)(1)(i) or (ii), it may bear a common or usual name that is not false or misleading, except that the product may not bear the name “Mechanically Separated (Beef).”

(3) Spent skulls or vertebral column bone materials from cattle younger than 30 months of age that exit the AMR system shall not be used as an ingredient of a meat food product.

[69 FR 1884, Jan. 12, 2004]

### Subparts B–G [Reserved]

## PART 319—DEFINITIONS AND STANDARDS OF IDENTITY OR COMPOSITION

### Subpart A—General

Sec.

- 319.1 Labeling and preparation of standardized products.
- 319.2 Products and nitrates and nitrites.
- 319.5 Mechanically Separated (Species).
- 319.6 Limitations with respect to use of Mechanically Separated (Species).
- 319.10 Requirements for substitute standardized meat food products named by use of an expressed nutrient content claim and a standardized term.

### Subpart B—Raw Meat Products

- 319.15 Miscellaneous beef products.
- 319.29 Miscellaneous pork products.

### Subpart C—Cooked Meats

- 319.80 Barbecued meats.
- 319.81 Roast beef parboiled and steam roasted.

### Subpart D—Cured Meats, Unsmoked and Smoked

- 319.100 Corned beef.
- 319.101 Corned beef brisket.
- 319.102 Corned beef round and other corned beef cuts.
- 319.103 Cured beef tongue.
- 319.104 Cured pork products.
- 319.105 “Ham patties,” “Chopped ham,” “Pressed ham,” “Spiced ham,” and similar products.
- 319.106 “Country Ham,” “Country Style Ham,” “Dry Cured Ham,” “Country Pork Shoulder,” “Country Style Pork Shoulder,” and “Dry Cured Pork Shoulder.”
- 319.107 Bacon.

### Subpart E—Sausage Generally: Fresh Sausage

- 319.140 Sausage.
- 319.141 Fresh pork sausage.
- 319.142 Fresh beef sausage.
- 319.143 Breakfast sausage.
- 319.144 Whole hog sausage.
- 319.145 Italian sausage products.

### Subpart F—Uncooked, Smoked Sausage

- 319.160 Smoked pork sausage.

### Subpart G—Cooked Sausage

- 319.180 Frankfurter, frank, furter, hotdog, weiner, vienna, bologna, garlic bologna, knockwurst, and similar products.
- 319.181 Cheesefurters and similar products.
- 319.182 Braunschweiger and liver sausage or liverwurst.

### 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.
- 319.261 Meat loaf.

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

- 319.280 Scrapple.
- 319.281 Bockwurst.

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

- 319.300 Chili con carne.
- 319.301 Chili con carne with beans.
- 319.302 Hash.
- 319.303 Corned beef hash.
- 319.304 Meat stews.
- 319.305 Tamales.
- 319.306 Spaghetti with meatballs and sauce, spaghetti with meat and sauce, and similar products.
- 319.307 Spaghetti sauce with meat.
- 319.308 Tripe with milk.
- 319.309 Beans with frankfurters in sauce, sauerkraut with wieners and juice, and similar products.
- 319.310 Lima beans with ham in sauce, beans with ham in sauce, beans with bacon in sauce, and similar products.
- 319.311 Chow mein vegetables with meat, and chop suey vegetables with meat.
- 319.312 Pork with barbecue sauce and beef with barbecue sauce.