

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.

§ 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 per-

cent, 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)-(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) A prerequisite for label approval for products consisting of or containing "Mechanically Separated (Species)" is that such "Mechanically Separated (Species)" shall have been produced by an establishment under an establishment quality control system. Such a plant quality control system shall provide the controls and information necessary to assure that the product will meet the requirements described in § 319.5(a) and to enable establishment personnel and program employees to monitor the system for effectiveness. The system shall include a written description of the methods used by the establishment to maintain uniformity of the raw ingredients used in manufacturing product, to control the handling and processing of the raw ingredients and the finished product, and shall contain provisions for chemical analyses of the product and other procedures to determine and assure compliance with standards for the product. For purposes of this paragraph, a lot shall consist of the "Mechanically Separated (Species)" designated as such by the operator of the establishment or his or her