

or revocation decision. An oral hearing shall be granted if there is any dispute of material fact joined in such responsive statement. The proceeding shall thereafter be conducted in accordance with the applicable rules of practice which shall be adopted for the proceeding. Any such refusal, suspension, or revocation shall be effective upon the receipt by the laboratory of the notification and shall continue in effect until final determination of the matter by the Administrator.

(Reporting and recordkeeping requirements approved by the Office of Management and Budget under control number 0583-0015)

[52 FR 2185, Jan. 20, 1987, as amended at 58 FR 65260, 65262-65264, Dec. 13, 1993; 59 FR 33642, June 30, 1994; 59 FR 66448, Dec. 27, 1994; 60 FR 10305, Feb. 24, 1995; 69 FR 254, Jan. 5, 2004]

§ 318.22 Determination of added water in cooked sausages.

(a) For purposes of this section, the following definitions apply.

(1) *Cooked sausage.* Cooked sausage is any product described in § 319.140 and §§ 319.180-319.182 of this chapter.

(2) *Group 1 Protein-Contributing Ingredients.* Ingredients of livestock or poultry origin from muscle tissue which is skeletal or which is found in the edible organs, with or without the accompanying and overlying fat, and the portions of bone, skin, sinew, nerve, and blood vessels which normally accompany the muscle tissue and which are not separated from it in the process of dressing; meat byproducts; mechanically separated (species); and poultry products; except those ingredients processed by hydrolysis, extraction, concentrating or drying.

(3) *Group 2 Protein-Contributing Ingredients.* Ingredients from Group 1 protein-contributing ingredients processed by hydrolysis, extraction, concentrating, or drying, or any other ingredient which contributes protein.

(b) The amount of added water in cooked sausage is calculated by:

(1) Determining by laboratory analysis the total percentage of water contained in the cooked sausage; and

(2) Determining by laboratory analysis the total percentage of protein contained in the cooked sausage; and

(3) Calculating the percentage of protein in the cooked sausage contributed by the Group 2 protein-contributing ingredients; and

(4) Subtracting one percent from the total percentage of protein calculated in (b)(3); and

(5) Subtracting the remaining percentage of protein calculated in (b)(3) from the total protein content determined in (b)(2); and

(6) Calculating the percentage of indigenous water in the cooked sausage by multiplying the percentage of protein determined in (b)(5) by 4, (This amount is the percentage of water attributable to Group 1 protein-contributing ingredients and one percent of Group 2 protein-contributing ingredients in a cooked sausage.); and

(7) Subtracting the percentage of water calculated in (b)(6) from the total percentage of water determined in (b)(1). (This amount is the percentage of added water in a cooked sausage.)¹

[55 FR 7299, Mar. 1, 1990]

§ 318.23 Heat-processing and stabilization requirements for uncured meat patties.

(a) *Definitions.* For purposes of this section, the following definitions shall apply:

(1) *Patty.* A shaped and formed, comminuted, flattened cake of meat food product.

(2) *Comminuted.* A processing term describing the reduction in size of pieces of meat, including chopping, flaking, grinding, or mincing, but not including chunking or sectioning.

(3) *Partially-cooked patties.* Meat patties that have been heat processed for less time or using lower internal temperatures than are prescribed by paragraph (b)(1) of this section.

¹The equation for the narrative description of the calculation for added water is as follows: $AW = TW - (TP - (P - 1.0))4$. Where AW=Added Water, TW=Total Water Determined by Laboratory Analysis, TP=Total Protein Determined by Laboratory Analysis, P=Protein Contributed by Group 2 Protein-Contributing Ingredients, 1.0=Percent Allowance for Group 2 Protein-Contributing Ingredients, 4=Moisture-Protein Ratio for Cooked Sausage.

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(4) *Char-marked patties.* Meat patties that have been marked by a heat source and that have been heat processed for less time or using lower internal temperatures than are prescribed by paragraph (b)(1) of this section.

(b) *Heat-processing procedures for fully-cooked patties.* (1) Official establishments which manufacture fully-cooked patties shall use one of the following heat-processing procedures:

PERMITTED HEAT-PROCESSING TEMPERATURE/TIME COMBINATIONS FOR FULLY-COOKED PATTIES

Minimum internal temperature at the center of each patty (Degrees)		Minimum holding time after required internal temperature is reached (Time)	
Fahrenheit	Or centigrade	Minutes	Or seconds
151	66.168	41
152	66.754	32
153	67.243	26
154	67.834	20
155	68.327	16
156	68.922	13
157 (and up)	69.4 (and up)17	10

(2) The official establishment shall measure the holding time and temperature of at least one fully-cooked patty from each production line each hour of production to assure control of the heat process. The temperature measuring device shall be accurate within 1 degree F.

(3) Requirements for handling heating deviations. (i) If for any reason a heating deviation has occurred, the official establishment shall investigate and identify the cause; take steps to assure that the deviation will not recur; and place on file in the official establishment, available to any duly authorized FSIS program employee, a report of the investigation, the cause of the deviation, and the steps taken to prevent recurrence.

(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 log₁₀ 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.¹

¹The 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 (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

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