Meat Produced by Advanced Meat/Bone Separation Machinery and Meat Recovery (AMR) Systems

New Regulatory Language	What it means

PART 301-TERMINOLOGY
 	
    1.   The authority citation for part 301 continues to read as follows:
 	
Authority: 7 U.S.C. 450, 1901-1906; 21 U.S.C. 601-695; 7 CFR 2.18, 2.53.
 	
    2.   In § 301.2, the definition of "Meat" is revised to read as follows:
 	
§301.2 Definitions.
 	
*   *   *   *   *
 	
Meat. (1) The part of the muscle of any cattle, sheep, swine, or goats which is skeletal or which is found in the tongue, diaphragm, heart, or esophagus, with or without the accompanying and overlying fat, and the portions of bone (in bone-in product such as T-bone or porterhouse steak), skin, sinew, nerve, and blood vessels which normally accompany the muscle tissue and that are not separated from it in the process of dressing. As applied to products of equines, this term has a comparable meaning.
(a) Meat does not include the muscle found in the lips, snout, or ears.
(b) Meat may not include significant portions of bone, including hard bone and related components, such as bone marrow, or any amount of brain, trigeminal ganglia, spinal cord, or dorsal root ganglia (DRG).
	"Meat" derived from Advanced Meat Recovery (AMS) systems can be labeled as "meat" if it does not violate criteria for CNS-type tissue, bone solids, or bone marrow.

New Regulatory Language	What it means

PART 318-ENTRY INTO OFFICIAL ESTABLISHMENTS; REINSPECTION AND PREPARATION OF PRODUCTS
 	
    3.   The authority citation for part 318 continues to read as follows:
 	
Authority: 7 U.S.C. 138f, 450, 1901-1906; 21 U.S.C. 601-695; 7 CFR 2.7, 2.18, and 2.53.
 	
    4. Section 318.24 is revised to read as	

follows: 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 sub-chapter, 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	You can no longer use the skull or certain portions of the vertebral column from cattle 30 months of age and older in AMR systems.

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[1] The excessive iron (ExcFe) measurement for an analyzed sample is equal to the obtained iron (Fe) result expressed in mg/100g 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: $ExcFe = mFe - IPR \times Protein \times 1.10$, where ExcFe represents the excess iron, expressed in units of mg/100g; mFe represents the measured level of iron (Fe, mg/100g), 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.

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.	A written program is required. If you process bones from cattle, the program must be a part of the HACCP plan, Sanitation SOP, or prerequisite program.
(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	If you use the skull or bone from the vertebral column, you must document when and how often you will observe the bones to ensure that they do not have brain, trigeminal ganglia, or spinal cord. If you use the skull or bone from the vertebral column, you must document when and how often you will test the recovered product for spinal cord and DRG.

	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.	You must test the recovered product for bone solid content (excess calcium), bone marrow content (excess iron), spinal cord, and DRG.
	(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]. *(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	You cannot label recovered product from beef that contain brain, trigeminal ganglia, spinal cord, or DRG as "meat," "meat food product," or "Mechanically Separated (Beef))," and such product must be designated for edible use (e.g., rendering)

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 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.	

New Regulatory Language	What it means
PART 320-RECORDS, REGISTRATION AND REPORTING 5. The authority citation for part 320 continues to read as follows: Authority: 21 U.S.C. 601-695; 7 CFR 2.7, 2.18, and 2.53. 6. Section 320.1, paragraph (b)(10), is amended by removing "of calcium content in meat derived from" and adding, in its place, "documenting the development, implementation,	

and maintenance of procedures for the control of the production process using."	