Authority: 7 U.S.C. 138f, 450, 1901–1906; 21 U.S.C. 601–695; 7 CFR 2.18, 2.53.

§ 318.6 [Amended]

■ 9. Section 318.6 is amended as follows:
■ a. Paragraph (b)(1) is amended by removing the word ''cattle'' and adding the following new sentence at the end of the paragraph: ''Casings from cattle may be used as containers of products provided the casings are not derived from the small intestine.''
■ b. Paragraph (b)(4) is amended by adding the following new sentence at the end of the paragraph: ''Detached spinal cords from cattle 30 months of age and older shall not be used as raw materials for edible rendering.''
■ c. Paragraph (b)(8) is amended by adding the following new sentence at the end of the paragraph: ''The small intestine of cattle shall not be used in any meat food products or for edible rendering.''

PART 319—DEFINITIONS AND STANDARDS OF IDENTITY OR COMPOSITION

■ 10. The authority citation for part 319 continues to read as follows:

Authority: 7 U.S.C. 450, 1901–1906; 21 U.S.C. 601–695; 7 CFR 2.17, 2.55.

■ 11. Section 319.5 is amended as follows:
■ a. A new paragraph (b) is added to read as follows:

§ 319.5 Mechanically Separated Species.

* * * * *

(b) Mechanically Separated (Beef) is inedible and prohibited for use as human food.

* * * * *

Done at Washington, DC, on January 7, 2004.

Garry L. McKee,

Administrator.

[FR Doc. 04–625 Filed 1–8–04; 1:43 pm]

BILLING CODE 3410–DM–P

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Parts 301, 318, and 320

[Docket No. 03–038IF]

RIN 0583–AC51

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

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Interim final rule and request for comment.

SUMMARY: The Food Safety and Inspection Service (FSIS) is issuing this interim final rule on meat produced by advanced meat recovery (AMR) systems. This new regulation is a prophylactic measure designed, in part, to prevent human exposure to the Bovine Spongiform Encephalopathy (BSE) agent by ensuring that AMR systems are not a means of introducing central nervous system tissue into product labeled as ''meat.'' In addition to the measures related to BSE, FSIS is finalizing restrictions related to bone solids and bone marrow for livestock products. This rule articulates the criteria that FSIS will use to ensure that AMR products can be represented as ''meat'' and thus are not adulterated or misbranded. Finally, the Agency is requiring that Federally-inspected establishments that process the carcasses or parts of cattle develop, implement, and maintain written procedures for the removal, segregation, and disposition of specified risk materials (SRMs), including non-complying product from beef AMR systems. Establishments must incorporate these procedures into their HACCP plans or in their Sanitation SOPs or other prerequisite program. FSIS is issuing this document as an interim final rule because of the discovery of a BSE-positive cow in this country.

DATES: This interim final rule is effective January 12, 2004. Comments on this interim final rule must be received by April 12, 2004.

ADDRESSES: Submit written comments to: FSIS Docket Clerk, Docket #03–038IF, Room 102, Cotton Annex, 300 12th Street, SW., Washington, DC 20250–3700. Reference materials cited in this document and any comments received will be available for public inspection in the FSIS Docket Room from 8:30 a.m. to 4:30 p.m., Monday through Friday. Reference materials that are not copyrighted will also be available on the FSIS Web site at *http://www.fsis.usda.gov.* All comments will be available for inspection in the FSIS Docket Room or on the FSIS Web site at *http://www.fsis.usda.gov.*

FOR FURTHER INFORMATION CONTACT: Daniel L. Engeljohn, Ph.D., Executive Associate, Policy Analysis and Formulation, Office of Policy and Program Development, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250–3700; (202) 205–0495.

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Background

The mission of the Food Safety and Inspection Service (FSIS) is to ensure that meat and meat food products are wholesome, not adulterated, and properly marked, labeled and packaged. Under the Federal Meat Inspection Act (FMIA) (21 U.S.C. 601 *et seq.*), FSIS has the authority to determine that product is unfit for human food, *i.e.*, adulterated, within the meaning of section 1(m)(3) of the FMIA (21 U.S.C. 601(m)(3)). Furthermore, a meat or meat food product is misbranded under any of a number of circumstances, including if its labeling is false or misleading in any particular; if it is offered for sale under the name of another food; if it is an imitation of another food, unless its label bears (in type of uniform size and prominence) the word ''imitation'' and, immediately thereafter, the name of the food imitated; or if it purports to be or is represented as a food for which a definition and standard of identity or composition is prescribed by regulations, unless it conforms to the regulations and its label bears the name of the food specified in the definition and standard (21 U.S.C. 601(n)(1), (n)(2), (n)(3), and (n)(7)). This interim final rule addresses both the adulteration and misbranding provisions of the FMIA.

BSE

Bovine Spongiform Encephalopathy (BSE) is a slowly progressive degenerative disease that affects the central nervous system (CNS) of adult cattle and is a member of the family of diseases known as transmissible spongiform encephalopathies (TSEs). TSEs also include scrapie in sheep and goats, chronic wasting disease in elk and deer, and variant Creutzfeldt-Jakob Disease (vCJD) in humans.

The typical incubation period (the time from when an animal becomes infected until it first shows signs of disease) is believed to be from two to eight years. BSE was first documented in the United Kingdom in 1986, and has since been identified and confirmed in a number of other European and non-European nations.

The agent that causes BSE and other TSEs has yet to be fully characterized. The theory that is most accepted in the scientific community is that the agent is a prion, which is an abnormal form of a normal protein known as cellular prion protein, although other types of agents have been implicated. FSIS has determined that this interim final rule is necessary to ensure that AMR systems are not a means of introducing CNS-type tissues (including brain, trigeminal ganglia, spinal cord, and dorsal root ganglia (DRG)), which have been identified as a potential source for the BSE infective agent into the food supply.

Animal Age and BSE Infectivity

Age-of-onset was known and recorded for approximately 135,000 cattle with confirmed clinical BSE in the United Kingdom between 1988 and August 2003. The age distribution data show that, of the cattle that developed clinical BSE in the field, only 0.01 percent were less than 30 months of age. Therefore, cattle younger than 30 months of age are less likely to be in the later stages of BSE incubation than older BSE-infected cattle and are less likely to contain high levels of BSE infectivity. For additional information about the onset of clinical BSE, see the interim final rule ''Prohibition of the Use of Specified Risk Materials for Human Food and Requirements for the Disposition of Non-Ambulatory Disable Cattle,'' Docket No. 03–025IF, also in this issue of the **Federal Register**.

FSIS is providing a method for its inspection program personnel in slaughter establishments to use to determine the age of cattle when supporting documentation is not provided by the establishment. This is relevant to this rulemaking on advanced meat/bone separation machinery and meat recovery (AMR) systems because AMR systems generally are operated separate from slaughter operations. Thus, establishments will need to process skulls and vertebral columns under control programs (*i.e.*, Hazard Analysis Critical Control Point (HACCP) plans, Sanitation Standard Operation Procedures (Sanitation SOPs), or prerequisite programs) separate from their slaughter operation controls. To ensure that the skulls and vertebral columns are appropriately handled, the slaughter establishment will need to provide documentation associated with the age of the skulls and vertebral columns to the receiving processing operation. Establishments using AMR systems will need to ensure that the skulls and vertebral columns are not from cattle 30 months of age and older.

Infective Tissue

In 2001, the European Commission's Scientific Steering Committee (SSC), an advisory committee for the European Union, considered the amount and distribution of BSE infectivity in a typical case of BSE and estimated that, in an animal with clinical disease, the brain contains 64.1 percent of the total infectivity in the animal, and the spinal cord contains 25.6 percent. According to the SSC, the highest remaining proportion of infectivity in a typical animal with clinical BSE is found in the DRG (3.8 percent). In experimentally infected cattle with clinical BSE, infectivity has been demonstrated in the brain, spinal cord, DRG, trigeminal ganglia, and the distal ileum of the small intestine. For additional information about BSE infectivity, see Docket No. 03–025IF.

The Harvard BSE Risk Assessment

In 1998, USDA commissioned the Harvard Center for Risk Analysis to conduct an analysis and evaluation of the current measures implemented by the government to prevent the introduction and spread of BSE in the United States and to reduce the potential exposure of consumers to the BSE agent.

Using a probabilistic simulation model to characterize the consequences of introducing BSE into the country through a variety of pathways, the Harvard study concluded that the risk to consumers in the United States was low, and that the country is highly resistant to the spread of the disease, if introduced.[1]

In evaluating the potential risk mitigation actions that could be taken to further reduce the likelihood that BSE could spread to cattle or humans, the risk assessment recommended three courses of action. The first is to prevent infected or potentially infected animals or contaminated feed from entering the country. The second is to ensure compliance with Food and Drug Administration's (FDA's) ruminant feed ban. The third is to prohibit the infective materials of BSE-infected animals from entering both the human food and animal feed chains.

The Harvard study divided potential sources of human exposure to BSE infectivity into two categories: Specific high-risk tissues and contamination of low-risk tissues. The former include, in order of infectivity, brain, spinal cord, DRG, distal ileum, trigeminal ganglia, and other tissues found in the head (*e.g.*, eyes and tonsils). As for the latter, the Harvard study indicated that the most important means by which low-risk tissue can become contaminated is through the use of AMR systems that can leave spinal cord and DRG in the recovered meat product.

The AMR Process

AMR systems are newer models of systems that have been used since the 1960s. The new systems emulate the physical action of hand-held high-speed knives for the removal of skeletal muscle tissue from bone through the use of hydraulic pressure. AMR systems apply pressure to detach the meat (skeletal muscle) tissue from the bones in a ''hard separation'' process. Desinewers that typically use belt pressure against a rotating perforated steel drum then separate meat from connective tissue, sinews, and other non-meat components in a ''soft separation'' process. In addition to vertebrae, typical bones processed by piston-driven AMR systems are brisket bones (breast or lower chest), rib bones, flat bones (scapulas), and hip bones (pelvis).

AMR product is an intermediate product that is typically blended at about 5 to 12 percent of the formulation of ground products derived from manufacturing trimmings. Descriptive labeling for the product of AMR includes ''(species) trimmings, finely textured,'' ''finely ground (species),'' or any other term that accurately reflects its form.

AMR technology enables processors to remove attached skeletal muscle tissue from livestock bones without incorporating significant amounts of bone and bone products into the final meat product. When produced properly, product from AMR systems is comparable to meat derived by hand deboning and can be labeled as ''meat'' (9 CFR 301.2). Under the FSIS regulations, spinal cord is not a component of meat, and therefore, product from AMR systems identified as ''meat'' that contains spinal cord is misbranded. Until today, FSIS has not taken regulatory action against ''meat'' containing DRG and other CNS-type tissues.

From January through August 2002, FSIS conducted a survey of AMR products derived from the vertebral column of cattle to establish a baseline for the prevalence of spinal cord and DRG in beef AMR products (referred to as the 2002 Beef AMR Survey). In the 2002 Beef AMR Survey, the Agency found that while some establishments were able to consistently produce beef AMR product that was free of spinal cord and DRG, a majority of the establishments had difficulty keeping spinal cord and DRG out of their AMR products. Overall, FSIS found that that approximately 76% (25 of 34) of the establishments whose AMR product was tested had positive laboratory results for spinal cord, DRG, or both in their final beef AMR products. The survey also found that approximately 35% (89 of 256) of all final AMR product samples that were tested had positive laboratory results for spinal cord, DRG, or both.

In March 2003, after completion of the 2002 Beef AMR Survey, FSIS implemented a routine regulatory sampling program of beef products from AMR systems as an additional measure to prevent misbranding of beef AMR products. Prior to the implementation of this regulatory sampling program, FSIS inspection program personnel collected AMR product samples for analysis for the presence of spinal cord tissue only if they believed that the establishment was not completely removing spinal cord from the vertebral column before the vertebral bones entered the AMR system (FSIS Directive 7160.2, April 14, 1997). Under the revised regulatory sampling program, FSIS inspection program personnel take samples of beef AMR product on a routine basis to verify that spinal cord tissue is not present in such product (FSIS Directive 7160.03, Revision 1, August 25, 2003). If spinal cord tissue is detected in beef AMR product, FSIS inspection program personnel take regulatory control action against the AMR product and equipment to prevent misbranded product from entering commerce. If the establishment has distributed misbranded beef AMR product, FSIS requests a voluntary recall.

Removal of the spinal cord before the vertebral columns enter the AMR system does not always ensure that spinal cord or DRG will not be incorporated into the final product. The Harvard study (discussed below) found that, if a beef carcass is mis-split when the spinal cord is removed, a portion of the spinal cord may remain encapsulated in the spinal canal of the vertebral column, and, if it is not removed before the vertebral bones enter the AMR system, the spinal cord could contaminate the final AMR product. Even when the spinal cord is completely removed from the vertebral column, the DRG of cattle are firmly attached to the bones of the vertebral column and are not removed along with the spinal cord. Thus, removing the spinal cord from the vertebral column does not prevent the DRG from entering an AMR system and becoming incorporated into the final AMR product.

Although FSIS and the regulated industry have recently taken actions to prevent the incorporation of spinal cord and, in some instances, DRG, in beef AMR products, FSIS continues to detect spinal cord and DRG in its routine regulatory sampling of beef AMR products, although to a lesser extent than it did in the 2002 Beef AMR Survey. In its routine regulatory sampling conducted from March to December in 2003, FSIS found spinal cord in 23 of 340 randomly scheduled samples, an estimated prevalence of 6.8 percent. In addition, the prevalence in follow-up samples was 13.6 percent, indicating that establishments with an initial positive continued to have some problems controlling for spinal cord in beef AMR systems. While FSIS was testing samples for spinal cord, FSIS also recorded the results for DRG. The prevalence for DRG was found in 10.9 percent of the samples in which DRG was recorded.[2]

Under the current regulations, AMR product that contains DRG, or any other CNS tissue except spinal cord, is not misbranded and can be identified as meat. However, given the nature of DRG and other CNS tissue except spinal cord, and the fact that BSE has been confirmed in a cow in the United States, FSIS has reconsidered its approach to the presence of all CNS tissues, particularly from cattle, as further discussed below. In addition, for a more complete explanation as to why skulls and vertebral columns of cattle 30 months of age and older are designated as specified risk materials (SRMs) and cannot be used in AMR systems, *see* Docket No. 03–025IF in this issue of the **Federal Register**.

In addition to the measures identified to address BSE through restrictions associated with SRMs, FSIS also is identifying additional measures to restrict the use of beef product and spent bone materials associated with CNS-type tissues from cattle younger than 30 months of age, as described below. Finally, FSIS is finalizing new bone solids and bone marrow restrictions that are slightly modified from those previously proposed for livestock product labeled as ''meat.''

Previous Rulemaking

In 1994, the Agency published a final rule (59 FR 62551) to amend the definition of ''meat'' to include product resulting from AMR systems. The 1994 rule reflected the Agency's position that calcium limits and the physical conformation of the bones exiting the system were sufficient to ensure that the production process was in control, and that the characteristics and composition of the resulting product were those of meat.

The rule required that product resulting from the bone separation process not exceed a calcium content of 0.15 percent or 150 milligrams/100

grams of product (150 mg/100 g) within a tolerance of 0.03 percent or 30 mg/100 g of product for each sample analyzed. The rule also required that the bones emerging from the AMR machinery be comparable to those resulting from hand deboning; that is, they must be essentially intact and in their natural physical conformation, such that they are recognizable as, for example, loin bones and rib bones, when they emerge from the machinery.

Shortly after FSIS issued the 1994 rule, consumer groups expressed concern that the regulatory requirements for meat produced by AMR systems were not being met consistently. Consumer groups alleged that, in certain AMR operations, the starting materials and machinery were being manipulated to produce a product that conformed to the requirements for Mechanically Separated (Species) (MS(Species)), a finely comminuted meat food product that may include spinal cord and dorsal root ganglia (DRG), but not to the requirements for meat. (At the time, FSIS considered spinal cord to be central nervous system (CNS) tissue. However, FSIS did not include DRG within the meaning of CNS tissue. Rather, it considered DRG to be more a part of the peripheral nervous system instead of a CNS-type tissue because it was contained within the nexus between the spinal cord and the muscle tissue.)

In 1995, FSIS conducted a survey of federally inspected meat establishments using AMR systems. Inspection program personnel in 13 of the 48 surveyed establishments reported results that were not in compliance with the requirements for AMR established in the 1994 rule.[3]

To determine whether the product that was being produced by AMR systems was compositionally consistent with hand-deboned meat, in 1996, FSIS began conducting a survey to profile the chemical and histological composition of meat derived from beef neck bones. Beef neck bones from the upper vertebral column are split during the slaughter dressing process, as opposed to long bones which generally are not split, and thus are inherently likely to contribute bone content (*e.g.*, marrow) to the product resulting from the AMR system. Samples were found to contain spinal cord and fragments of other CNS-type tissue. FSIS concluded that the AMR product produced was likely not comparable to corresponding hand-deboned product, even when the calcium criterion of the 1994 rule was for the most part met.

The results of the 1996 survey demonstrated that the provisions of the 1994 rule, if met, were not sufficient to ensure that AMR product would be comparable to hand-deboned meat in composition. A final report on the 1996 survey results is available in the Docket Room and on the FSIS web site.[4]

After considering information from consumer groups about compliance concerns, reviewing the 1995 field survey and the response to a 1996 notice soliciting public comment on that survey, and studying the results of the 1996 neck bone survey, FSIS concluded that it was necessary to propose amending its regulations and to issue a directive to inspection personnel to ensure that manufacturers were not incorporating spinal cord into AMR product labeled as meat. In 1997, FSIS published Directive 7160.2 to instruct inspection program personnel that establishments must completely remove spinal cord from any neck or back bones before the bones enter the AMR system. The directive emphasized that the definition of ''meat'' in 9 CFR 301.2 does not apply when the use of AMR systems results in product that contains spinal cord. FSIS did not address DRG in the directive because, at that time, FSIS did not have validated methodology to identify DRG, and DRG was not yet identified as a potential risk material.

On April 13, 1998, FSIS issued a proposed rule (63 FR 17959), in which it stated that provisions in the 1994 final rule needed revision to prevent misbranding and economic adulteration of AMR product labeled as ''meat.'' Specifically the Agency proposed to: (1) Adopt performance standards for bone solids and bone marrow; (2) adopt a zero tolerance for the presence of spinal cord; and (3) delete the provision that focused upon the condition of the bones emerging from the AMR systems to determine whether or not the production process was in control. The Agency's objective was to ensure that the regulations provided clear standards for industry to meet.

Prior to December 23, 2003, FSIS had not addressed AMR systems in the context of BSE, although FSIS had taken numerous steps to limit the presence of spinal cord in product derived from AMR systems. In particular, in March 2003, FSIS announced the results of the 2002 Beef AMR Survey and stated that FSIS soon would clarify its intent by rulemaking on AMR to ensure that DRG was excluded from the definition of product labeled as ''meat.''

By 2002, FSIS had a validated methodology to detect and discern DRG, there was widespread agreement within the scientific community that DRG was included within the meaning of CNS-type tissue, and there was scientific evidence that DRG carried the BSE infective agent. FSIS did not contemplate addressing tissues of brain and trigeminal ganglia in product from AMR systems because FSIS was not aware of any establishments using bone material, such as skulls, that would contain these tissues in the production of meat. Brain and trigeminal ganglia, along with spinal cord and DRG, all fit within the meaning of CNS-type tissues for purposes of further discussion in this document. Currently, FSIS does not analyze meat for tissues of brain and trigeminal ganglia. However, since skulls may in the future be used in AMR systems, FSIS is reassessing whether it should validate its testing methodology to detect and discern brain and trigeminal ganglia in product recovered from AMR systems.

FSIS has concluded that the 1994 rule, the 1998 proposed rule, and the FSIS Directives will not keep spinal cord and other CNS-type tissue out of product derived from livestock, particularly cattle, that is labeled as ''meat.'' FSIS concludes that restrictions for CNS-type tissues need to be explicitly stated in the regulations, along with a requirement to have written process control procedures and testing by the establishment, to ensure that the process control procedures are effective in producing product labeled as ''meat.''

Furthermore, FSIS has initiated a survey on pork AMR products and believes that the lack of process control regarding the presence of CNS-type tissues in pork product recovered from AMR systems also may be a concern. The new requirements in this interim final rule are applicable, for the most part, to products derived from pork bones.

FSIS has decided to publish this new AMR regulation as an interim final rule and to address both CNS-type tissues and the restrictions related to bone solids and bone marrow. The presence of spinal cord or other CNS-type tissue in AMR product, that is, in meat, particularly from cattle, represents a potential threat to the public health of the United States. The Administrator thus finds that there is good cause to make this new AMR regulation effective immediately. It is especially designed to prevent the occurrence of spinal cord and other CNS-type tissues in ''meat'' and meat food products derived from cattle, and to prevent the occurrence of spinal cord and other CNS-type tissues in ''meat'' derived from livestock other than cattle.

Before explaining in more detail the provisions of this interim final rule, a

brief discussion of the comments received on the proposal and FSIS' responses follows.

Discussion of Public Comments on Docket 96–027P

The 60-day comment period on the 1998 proposed AMR rule ended on June 12, 1998. Forty-five comments were received from food and equipment manufacturers, professional and industrial trade associations, consumers and consumer advocacy organizations, academia, and consultants.

On December 16, 1999, FSIS issued a notice (64 FR 70200) reopening the comment period for an additional 30 days to give the public an opportunity to review and comment on the methods and results used by Agricultural Research Service (ARS) scientists to derive new iron-to-protein values. The Agency also sought comment on a report submitted by a meat industry group regarding economic and worker safety issues relevant to the proposed rule. The reopened comment period closed on January 18, 2000. Twenty-six additional comments were received in response to the notice. The two sets of comments and FSIS' responses are merged in this ''Comment'' section.

Bone Solids

Comment: Many commenters disagreed with the proposed calcium requirement that was established as a measure of the bone solids content of AMR product, to ensure that AMR product is meat. One commenter stated that the limit was too high, and another suggested that the limit should be lowered to approximate the calcium level in hand-deboned meat, with a reasonable allowance for variation. Another commenter pointed out that FSIS asserted in the 1994 final rule that its purpose was to ensure that the characteristics and composition of AMR are consistent with those of meat. Another commenter claimed that the proposed reduction in the calcium level was arbitrary and determined on the basis of a limited data set and not based on actual process data. Another commenter requested that the calcium performance standard account for differences among meat species.

Response: FSIS does not agree that the calcium standard should be based only on actual process data and does not agree that the calcium level for AMR products needs to approximate that of hand-deboned products. The calcium level in hand-deboned products is nearly negligible. The increased amount in the AMR product that the Agency proposed to allow represented a small amount of calcium that would not in any appreciable way affect the safety or quality of the product. When the vertebrae are split, increased bone dust (*i.e.*, material high in calcium) is created and may accumulate in the AMR product. In hand-deboning, such material is less likely to be incorporated into the product. The calcium limit that FSIS proposed was based on the results of its 1996 survey and the data that were submitted to FSIS by industry. FSIS believes that this calcium limit can be consistently achieved by industry and represents a more appropriate level than that in the 1994 rule.

Regarding the comment about different calcium levels for beef and pork, FSIS considered data for different species that were submitted by industry groups as well as the data gathered by FSIS in the 1996 survey. A summary of the data is presented in the technical addendum, which is available in the Docket Room and on the FSIS web page. The data show that average calcium levels for AMR pork and beef products are approximately 100 mg/100 g. FSIS believes that these data suggest that with regard to bone solids, there would not be any significant difference between pork and beef. Therefore, the required calcium targets for pork and beef AMR products are the same in this interim final rule.

As mentioned above, in 1994, FSIS believed that the performance standards it established regarding calcium as a measure of bone solids content, and the physical conformation of the bones exiting the system were sufficient to ensure that the AMR production process was in control, and that the characteristics and composition of the resulting AMR product would be comparable to those of meat. However, based on the results of the 1996 AMR survey, FSIS concluded that the established performance standards, even if met, were not sufficient to ensure that AMR product would be comparable to meat and as a consequence proposed different standards in 1998. In particular, regarding compositional parameters, the 1996 results showed that the AMR products produced at the time were not comparable to hand-deboned product with respect to a number of measures, even when the calcium limit designed to measure bone solids content was met.

The 1998 proposed rule identified a calcium limit of 130 mg/100 g product. This level was premised on a target average level of approximately 100 mg/100 g product but did not specify whether the 130 mg/100 g was an average or an absolute level. Data collected by the Agency and submitted by industry indicated that the average calcium level obtained for AMR pork and beef products is approximately 100 mg/100 g, but that there was wide variation in individual establishment results. Furthermore, the average of the calcium results in the 2002 Beef AMR Survey was below 100 mg/100 g, but again, there was wide variation in individual results.

FSIS is clarifying in this interim final rule that no analysis can exceed the regulatory maximum of 130 mg/100 g sample. This level of calcium in the product does not affect the appearance, texture, or other quality aspects of the product and is a small amount of calcium when compared to the calcium content generally contained in MS(Species).

In deciding on a calcium level, FSIS understands that it is virtually impossible for calcium levels in AMR product to be equal to those of hand-deboned product, which is essentially 0 mg/100 g. The presence of small amounts of calcium does not affect the qualitative characteristics of the product and only trivially affect its compositional aspects. Thus the standard will ensure that AMR product is ''meat.'' In addition, this standard creates a clear distinction between AMR product and MS(Species) product, which generally has more than triple the calcium of AMR. At the same time, FSIS has tried not to set such a low level for calcium that it would not be economically feasible to produce AMR product.

Comment: A commenter thought that calcium samples should be taken at the intermediate stage of the AMR process, because at this stage the calcium samples would indicate whether bones are being broken or crushed.

Response: FSIS is only concerned about the levels of calcium in the final AMR product as a means of ensuring that an excess amount of bone solids is not introduced into the product. It is not using a calcium measurement level to determine if bones are broken or crushed. Thus, FSIS is not including a standard to measure calcium at an intermediate stage in the AMR process in this interim final rule.

Bone Marrow

Comment: Commenters stated that the methodology and data used to derive the iron criterion that was proposed as a measure for noncomplying product were incorrect, and that, therefore, the proposed values were not appropriate. Specifically, it was pointed out that the analytical procedures used in the FSIS 1996 survey were based on procedures that understated iron values. Further, a commenter disagreed with the Agency's

approach of correlating histological data and the bone marrow cell assessment, with iron content. The commenter claimed that the correlation was not high, and thus was not accurate.

A commenter agreed that a measurement of total iron is a good indicator of the presence of marrow in meat and further claimed that the amount of iron in beef is well established. However, there were many comments that questioned both using excess iron as a measure of bone marrow and the methodology used to establish the limit in the standard. A commenter suggested not using protein at all in adjusting the iron requirement but, rather, using a straight iron value level. A commenter suggested that FSIS needs to account for the fact that AMR procedures remove connective tissue that contains little or no iron, and that muscle adjacent to the bone is higher in iron than is hand-deboned muscle. Therefore, even if marrow components were absent, iron-to-protein ratios (IPRs) would be higher in AMR products than those in hand-deboned meat.

Another commenter claimed that the use of iron as proposed by the Agency would be biased against low fat, high protein products and suggested a simple IPR. Some commenters said that the iron levels established were too high and urged FSIS to make the target levels more consistent with hand-deboned product. These commenters suggested a 5 to 10 percent variation in the IPR between AMR and hand-deboned meat. Commenters also suggested that establishments should not be permitted to determine their own IPR values, as was proposed.

Response: FSIS will first address the measurement and methodology issue and then provide a justification for the excess iron measure it proposed. In the course of doing so, it will provide an explanation for the procedures that it used for deriving the iron performance standard contained in this interim final rule.

Excess iron is the iron in excess of that which would be expected given the protein value if the product was meat. The measure for excess iron for the 2002 survey was: excFe=Fe-kP, where P is the protein (%), Fe is the iron (mg per 100 g), and k is a constant equal to 1.1 times 0.138. The 0.138 is the assumed IPR for the corresponding hand-deboned meat product, and the 1.1 is an adjustment factor.

Measurement and methodology. While the measurement used by FSIS was accurate, the Agency agrees that the methodology and measurement procedures used in developing the standards for iron in the 1998 proposed rule were not consistent with common laboratory analyses for iron measurement. FSIS used a hydrochloric acid wet-ash digestion procedure to measure the iron levels of samples collected in the 1996 survey because this methodology was considered faster and less labor intensive than traditional dry-ash procedures (*i.e.*, dry-ash procedure for digestion). The wet-ash procedure predictably underestimates the true level of iron. In contrast, the method used by ARS scientists, which is based on a dry-ash procedure for digestion, dries the samples and obtains iron results approximately double those obtained by the FSIS procedure. Further, the results obtained by the ARS dry-ash procedure are more consistent with levels previously reported for hand-deboned product in Agricultural Handbook 8 (now called USDA Nutrient Database for Standard Reference, Release 12).

ARS analyzed split samples from the 1996 survey for FSIS, and FSIS used the ARS results along with more current FSIS data for deriving the standards for iron in this interim final rule. For samples in which there were no dry-ash procedure results, the FSIS wet-ash procedure results were multiplied by 2.11, which is the average ratio of the results from the dry-ash procedure to those that FSIS found using the hydrochloric acid wet-ash procedure (*See* the technical addendum for additional information in the FSIS docket room and on the web site).[5]

FSIS agrees with the commenter's concern about FSIS'' approach of correlating histological data and bone marrow cells with iron content and thus is not including a standard for bone marrow cells in this interim final rule. Although bone marrow cells are unique to bone marrow, they have been found in hand-deboned product probably as a consequence of contamination of the muscle tissue during the carcass splitting process during slaughter.

FSIS justification for using excess iron as a measure of bone marrow. FSIS has determined that there is no practical methodology to measure bone marrow using commercial practices. Bone marrow contains many of the same components as muscle tissue and blood. Therefore, FSIS sought to establish in the 1998 proposal a practical methodology that would predict whether the known composition of hand-deboned meat was sufficiently different from AMR as a consequence of the incorporation of bone content (other than calcium) in AMR. FSIS deemed this additional bone content to be an indication of the presence of bone marrow. Consequently, iron, which is contained in marrow and in blood tissue, was chosen as a practical surrogate for bone marrow.

To determine whether there were excess iron levels in AMR, and thus bone marrow in this product, the Agency proposed using an adjustment based on the protein value because an analysis of the data from a prior survey demonstrated that there was a correlation between iron and protein results. Protein levels will change with iron levels, everything else being equal. If bone marrow, which has a higher IPR value than meat, is added to product, the measured IPR value would be greater than the IPR for corresponding hand-deboned product without bone marrow. Accounting for measurement error, if this difference is large enough, it can then be concluded that bone marrow at more than a negligible amount is in the product.

One of the commenters pointed out that a problem with the above model is that the AMR process removes connective tissue that contains little or no iron. The Agency believes that the effect of this removal is not large and would not change the basic premise of the model presented above. From the 1996 FSIS survey, the Agency determined that the average difference in protein between pre- and post-desinewed AMR product was about 0.5 percent, based on a post-desinewed product average protein of about 16.5 percent. Therefore, as a percentage of protein, the amount of protein associated with connective tissue removed during the desinewing step averaged only about 3 percent and does not represent a large proportion of the protein that is in the final product.

In addition, it is possible that, during AMR processing, some unbound water is removed which would result in the removal of some water-soluble protein and dissolved solids.[6]

FSIS recognizes that these two factors, removal of connective tissue with low iron and protein and removal of unbound water, may result in an increase in the IPRs of AMR product. However, FSIS does not believe that such a possible increase renders the use of an excess iron measurement inaccurate for assessing AMR process control. Although FSIS does not believe that the effects of these factors would be substantial, it has taken them into consideration in this interim final rule and is using a 10 percent factor for adjusting the protein levels used for calculating levels of excess iron in AMR product.

Another issue raised by the commenters regarding the appropriateness of the excess iron

measurement was that meat close to the bone has higher IPRs than meat farther from the bone. FSIS agrees with the commenter. However, the IPRs would be expected to be higher in AMR product than in hand-deboned product, even though no bone marrow would be introduced.

FSIS has decided to allow alternative IPRs to be used in this interim final rule to reflect the inherent differences that exist among starting products.

Regarding the comment made that the use of the excessive iron measure as proposed would be biased against high protein and low fat products, FSIS believes that for practical purposes, the difference between the excessive iron and the IPR calculations is not great.

In this interim final rule, however, FSIS is adopting a different excess iron limit measurement than the one proposed in 1998. This new limit is based on a more current examination of excess iron measurements for hand-deboned product from the 2002 survey of AMR product. *See* footnote 1 in new § 318.24(c)(1)(ii) for a detailed explanation of the formula derived for the excess iron value measurement.

An assumption used by FSIS in the derivation of the excess iron value measurement for this interim final rule was that there would be duplicate measurements of iron and protein taken by establishments on an individual sample. Performing duplicate measurements on an individual sample is recommended because, on a few occasions in the 2002 survey, large differences for samples were found when duplicate measurements were made. Thus, to ensure that AMR product is consistent with meat, FSIS is adopting a measured 3.5 mg/100 g excess iron limit based on duplicate analyses of samples of AMR product.

Related Comments

Comment: Several commenters alleged that FSIS has singled out AMR technology for scrutiny while products derived from a low temperature rendering process (LTRP) were approved by FSIS for the school lunch program without any scientific basis or public input. The suggestion was made that FSIS withdraw the proposed rule on AMR products until comparable rules to regulate LTRP products have been developed and implemented.

Response: The Agency has focused on meat produced by AMR systems because it is the main product not produced by hand-deboning, and is a product in which constituents not expected in boneless meat can be incorporated as a result of the process used for its production. Other technologies, such as LTRP, generally involve the removal of components such as fat and muscle. The Agency intends to further evaluate how it regulates other types of operations that are used to manufacture meat and poultry trimmings from various starting materials. The Agency seeks more specific comment and data on the compositional characteristics of LTRP and similar products derived from non-AMR systems.

Comment: A commenter said the proposal was based on an antiquated regulatory foundation because the definition of meat is obsolete and is, in effect, an anatomical description. In addition, the commenter maintained that the proposal was an attempt to relate a chemical constituent of AMR-derived product to the former USDA Handbook 8 references for regulatory purposes and conflicted with Agency policies regarding constituents of other meat products.

Response: Meat is defined in anatomical terms, and not chemically, because it is directly obtained from livestock and not chemically derived from other elements. Therefore, the regulatory definition of meat refers to the parts of livestock that are edible (as opposed to inedible parts/organs). The former Handbook 8 details the composition of foods but does not represent a formula for making ''meat.'' FSIS is not relating a constituent of AMR product to former Handbook 8 data on the composition of meat. AMR product is meat unless it includes constituents such as spinal cord and DRG that are not expected constituents of boneless meat. In addition, FSIS has determined that AMR product is meat unless the process by which it is produced incorporates expected constituents, such as calcium and iron, at excessive levels.

Comment: A commenter asked about FSIS' response to the report on AMR technology and on worker safety issues related to AMR systems.[7]

Response: Regarding the report, which was produced by the Georgetown University Center for Food and Nutritional Policy, FSIS generally agrees with the historical and technical aspects of the report on AMR systems. The report addressed the disagreements that have characterized the regulated introduction of mechanical deboning in this country, and how these initiatives have attracted the attention of consumer advocacy groups. The 1999 report states that the presence of CNS tissue in meats of any kind should be avoided and cited FSIS' prohibition against spinal cord in AMR meat since 1997.

The report discussed the reduction in worker-related injuries as perhaps the greatest societal advantage of AMR systems. FSIS agrees that manual deboning and the use of motorized knives are dangerous because they are associated with direct injuries and cumulative trauma disorders (CTDs). The report noted that some studies have demonstrated a 38 percent increase in CTDs as a consequence of working in deboning operations.

FSIS agrees with the statements in the report about the efficiency of AMR systems that makes meat processing operations more safe and profitable. However, for the reasons presented in this interim final rule, the Agency disagrees with the Sparks report's assertion that further rulemaking to refine the 1994 final rule is unwarranted.

Comment: A commenter asked whether FSIS agreed with the cost estimates in the Sparks Companies, Inc., report, which provided an economic analysis of the 1998 proposed AMR rule.[8]

Response: FSIS does not agree with some of the conclusions in the Sparks report. For example, FSIS believes that it is unlikely that all AMR systems will be removed and replaced with tertiary hand-deboning procedures, as the report suggests. Not all of the AMR systems are used to process split vertebral columns with exposed and extruding bone marrow tissue. Some systems are used to process only brisket or sternum and rib bones. The expected continued use of non-vertebral bones in AMR systems would considerably reduce the capital cost loss of $40 million estimated in the report.

The report's discussion of capital costs also fails to take into account depreciation of the AMR systems since 1994, which would considerably reduce the capital cost loss. In addition, the cost of auto-knives may be somewhat over-estimated because the report assumes that the knives depreciate within a year. FSIS would suggest that the authors of the report should have used only the flow of services of the knives, not the depreciation of the entire capital stock of the knives within a year.

However, the report was helpful and provided the Agency with important data to gauge volume and yield data, for example, and to gain a greater understanding of the extent of the AMR beef and pork industry in this country.

These comments and all of the other public comments submitted in response to the 1998 proposal are available for review in the FSIS Docket Room and at the FSIS Web site.

Consumer Group Petition

Because of its concerns about the presence of spinal cord and DRG in AMR product, in 2001, a consumer group, the Center for Science in the Public Interest (CSPI) on behalf of other consumer and public health associations, petitioned USDA to institute regulatory actions to prohibit spinal cord and DRG in AMR beef products.[9] In addition, a consortium of 14 animal welfare, farmer, environmental, and public health groups voiced similar concerns and urged USDA and the FDA to take immediate regulatory action.[10]

2002 Survey of AMR Products

In order to assess the current industry practices associated with AMR systems, the petition submitted by CSPI, and the need for further Agency action with regard to AMR, the Agency determined that it needed to conduct a survey of AMR systems (*i.e.*, the 2002 Survey of AMR Products). Another purpose of this survey was to characterize the recovered product of AMR systems regarding texture and appearance, look at current production practices (*e.g.*, pressure settings and type of source materials) and yield data, and determine how those practices influence the calcium and iron levels of the final product.

In January 2002, FSIS began collecting random samples from the 42 piston-driven AMR systems in production at 34 establishments harvesting AMR product derived from beef vertebrae or beef vertebrae mixed with other types of beef bones. Several establishments had more than one operating AMR system processing beef vertebrae.

Over a 7-month period, samples from each AMR system that uses beef vertebrae as source material were randomly collected. An FSIS laboratory tested the products for the presence of spinal cord and DRG. At random times over the 7-month period, FSIS collected final (after the desinewer) product samples and intermediate (before the desinewer) samples from each of the active machines. In addition, the AMR system model and identification number, type of starter (input) product, and the maximum pressure applied and pressure hold or dwell time (at the maximum pressure) of the systems were noted. Most of the samples also were tested for the food chemistry constituents calcium, iron, and protein.

Although some of the establishments (4 of 34 or 12 percent) were able to produce final AMR product with no spinal cord or DRG on a consistent basis (based on all (six or more) samples being negative), other establishments consistently produced samples that tested positive for spinal cord and DRG. For the survey, approximately 35 percent of the final AMR product samples tested positive for spinal cord or DRG: 29 percent for spinal cord and 10 percent for DRG.

The occurrence of spinal cord and DRG was not considered to be significantly correlated; that is, the presence of one of these tissues in a sample did not significantly affect the likelihood of the presence of the other. This lack of significant correlation suggests that there may be different factors that determine the presence of these tissues in AMR product. On the other hand, estimated values of excess iron and calcium were positively correlated, suggesting that there is a common set of factors that influence their levels. See the final report on the 2002 survey results in the FSIS Docket Room or at the FSIS web site for additional details.[11]

FSIS Directive 7160.3

In August 2003, FSIS issued Directive 7160.3, Revision 1, to provide instructions to inspection program personnel for sampling boneless comminuted beef products from AMR systems in which vertebral columns are used and on actions to take if the product contains spinal cord.[12] The directive did not address the presence of DRG tissue in AMR product because the Agency had not included DRG in the 1998 proposed rule.

After doing follow-up verification sampling, the Agency was especially concerned that some establishments were not adequately addressing the problem of spinal cord in AMR product. The directive defined the range of follow-up actions available to the Agency when product from an AMR system is found to contain spinal cord tissue. FSIS withheld label approval for those establishments whose AMR system repeatedly failed to produce product that was free of spinal cord. Thus, these establishments effectively were not allowed to produce AMR meat from beef vertebrae.

Overview of This Interim Final Rule and Request for Comments

FSIS is amending the meat inspection regulations in Parts 301, 318, and 320 of the Code of Federal Regulations by modifying the definition of ''meat;'' adding or modifying non-compliance criteria for bone solids, bone marrow, brain, trigeminal ganglia, spinal cord, and DRG; requiring the development, implementation, and maintenance of a written program, including documentation and recordkeeping requirements, for ensuring process control; and declaring inedible the skulls and vertebral column bones from cattle that are 30 months of age and older. As indicated in a new Section 310.22, which is adopted in another interim final rule issued today (*see* Docket #03–025IF in this issue of the **Federal Register**), skulls and vertebral column bones from cattle 30 months of age and older are inedible and cannot be used for human food. Therefore, if skulls or vertebral column bones from cattle 30 months of age and older are used in AMR systems, the product exiting the AMR system is adulterated, and the product and the spent bone materials are inedible and cannot be use used for human food. For AMR product derived from the bones of cattle younger than 30 months, the presence of CNS-type tissues will render the product misbranded. Similarly, for AMR product derived from the bones of livestock other than cattle, the presence of CNS-type tissues will result in misbranding. For AMR product derived from the bones of all livestock, the restrictions associated with bone solids and bone marrow also relate to misbranding.

FSIS is amending § 301.2(b), the definition of ''meat'' to make it clear that boneless meat may not include significant portions of bone or related components, such as bone marrow, or any amount of CNS-type tissues. Therefore, product produced using an AMR system must not include significant amounts of bone or related components. It also must not include any brain, trigeminal ganglia, spinal cord, or DRG.

Section 318.24(a) provides that skulls and vertebral column bones of cattle 30 months of age and older, as provided for in a new section 310.22 which is adopted in another interim final rule issued today (*See* Docket #03–025IF in this issue of the **Federal Register**), cannot be used in AMR systems. In addition, the recovered meat product exiting the AMR system must not significantly incorporate bone solids or bone marrow, as measured by the presence of calcium and excess iron, and cannot contain any brain, trigeminal ganglia, spinal cord, or DRG.

Section 318.24(b) provides that establishments operating AMR systems are required to develop, implement, and maintain procedures that ensure that their production process is in control. The establishment must incorporate its production process procedures in a written program that is designed to ensure the ongoing effectiveness of the process control program. Because of the food safety concerns presented by SRMs, for establishments that process

cattle, the written program must be in the establishment's Hazard Analysis and Critical Control Point (HACCP) plan, or in its Sanitation Standard Operating Procedure (Sanitation SOP) or other prerequisite program.

By declaring SRMs inedible and prohibiting their use for human food, FSIS will ensure that materials that could present a significant risk to human health, but whose infectivity status cannot be readily ascertained, are excluded from the human food supply.

Because BSE was recently confirmed in a cow in the United States, FSIS has determined that the SRMs, adopted in another interim final rule issued today (*see* Docket #03–025IF in this issue of the **Federal Register**), are unfit for human food. Thus, the status of these materials has changed from edible to inedible. Such a change is likely to affect the underlying hazard analysis that must be conducted as prescribed by 9 CFR 417.4(a)(3). Therefore, in response to this change, FSIS expects that establishments that slaughter cattle or process carcasses or parts of cattle will reassess their HACCP plans in accordance with 9 CFR 417.4(a)(3) to address SRMs.

Under § 318.24(b), the written program must include the observation of bones entering the AMR system and the testing of the product exiting the AMR system. The establishment shall maintain records on a daily basis sufficient to document the implementation and verification of its production process. The establishment shall make the documentation available to inspection program personnel.

Section 318.24(b) makes clear that establishments will be expected to determine how and when they will test product for calcium, iron, spinal cord, and DRG. Based on the supporting documentation provided by the establishment, and FSIS's own verification, FSIS will make a determination whether the product is misbranded or adulterated. FSIS expects that the establishment will ensure that each production lot is in compliance with the provisions of this regulation.

Regarding the testing methodology for spinal cord and DRG, FSIS will continue to use its validated histological procedures. However, FSIS is aware that establishments have access to methodology that is not as specific or sensitive as the FSIS methodology and that is considerably less expensive to perform. FSIS encourages establishments to use any methodology that is effective. FSIS cautions establishments, however, that if the establishment's methodology is not adequate to discern complying product from non-complying product, FSIS will ensure that non-complying product is not allowed to enter commerce.

Because of the expense and time associated with highly sensitive and specific tests, such as the methodology used by FSIS, researchers have been working on quicker and less costly tests. One such research effort has employed ELISA technology. For the 2002 AMR beef survey, an ELISA procedure was examined by FSIS, but FSIS concluded that the test was not sufficiently specific or sensitive. Not only were there many false positive and negative results (when compared to the FSIS histological results), the rates of false positive and negative results were establishment dependent. This latter finding could imply that there was some other component in the product interfering with the test.

FSIS is aware that there are a number of research efforts underway to improve the sensitivity and specificity of the rapid tests that can be used in lieu of the normative histological tests for evaluating the presence of spinal cord and DRG. FSIS does not want to preclude the use of such tests by establishments. Therefore, FSIS is soliciting information during the comment period on alternative test methods and performance specificity and sensitivity. FSIS is interested in identifying a test for use by establishments that is as sensitive to the presence of spinal cord and DRG in product as the histological test employed by FSIS, but that is less expensive and less time consuming.

The production process is not in control if the skulls of livestock entering the AMR system contain any brain or trigeminal ganglia tissue, or the vertebral column entering the AMR system has any spinal cord. In addition, the process is not in control if the recovered product contains unacceptable levels of bone solids or bone marrow, or any level of spinal cord or DRG, as provided for in §318.24(c). In addition, the production process is not in control if the product is not properly labeled or spent bone materials are not properly handled.

Section 318.24(c)(1) describes the five criteria that define when recovered AMR product may not be used and labeled as ''meat.'' They include a measure for excess bone solids (calcium content above the stated level); a measure for excess bone marrow (iron in relation to protein above the stated level); the presence of brain or trigeminal ganglia; the presence of spinal cord; and the presence of DRG.

In §318.24(c)(2), if the recovered product derived from any livestock fails under any of these criteria, it cannot be labeled as ''meat.'' In addition, product derived from beef skulls or vertebral column bones from cattle younger than 30 months containing CNS-type tissues cannot be used as an ingredient of a meat food product. For example, this product, if it contained spinal cord, cannot be labeled as ''Beef with Spinal Cord'' or ''Beef with Spinal Cord Meat Food Product'' because detached spinal cord is prohibited from use in the preparation of edible product other than for edible rendering (9 CFR 318.6(b)(4)). It also cannot be labeled as MS(Beef) because FSIS has determined MS(Beef) to be inedible and prohibited its use as human food (*see* Docket #03–025IF in this issue of the **Federal Register**. Such product can be rendered to produce products identified as beef stock, beef extract, and beef flavoring without any identification of the source materials other than ''beef'' because the source materials are edible, not inedible. FSIS has determined that it is appropriate to now prohibit product that contains CNS-type tissues derived from cattle younger than 30 months of age for use in a meat food product, except for the sale of brain or the use of brain in which its presence is required to be reflected prominently and conspicuously in labeling. FSIS has established precedent for not allowing detached spinal cord for use in meat food products, but does allow its use for edible rendering. FSIS requests comment on whether product derived from the bones of cattle younger than 30 months (as well as product from livestock other than cattle) that may contain CNS-type tissues should continue to be allowed in edible rendering, or whether such product should be inedible and not allowed in edible rendering or allowed in descriptively labeled meat food product. FSIS requests comment on whether edible rendered products derived from bones of livestock in which the bones may contain CNS-type tissues should be required to bear a common or usual name that reflects the potential presence of CNS-tissue (*e.g.*, ''beef stock derived from materials that may contain spinal cord''). FSIS will be working with FDA on this issue.

As discussed above, skulls or vertebral column bones from cattle 30 months of age and older may not be used at all in AMR systems. Product derived from bones of cattle other than skulls or vertebral column bones may bear a name that is not false or misleading but cannot bear the name ''Mechanically Separated (Beef).'' In another interim final rule issued today (*see* Docket #03–025IF in this issue of

the **Federal Register**), FSIS has determined that MS(Beef) is inedible and prohibited its use as human food. Such product would not contain CNS-type tissues because only the skulls and vertebral column bones contain CNS-type tissues.

For purposes of this rule, bone marrow from cattle is not identified as an SRM. The scientific evidence to establish that cattle bone marrow is a tissue that demonstrates infectivity is inconclusive at this time (see Docket No. 03–025IF, also published in this issue of the **Federal Register** for additional information about bone marrow). Therefore, product from cattle of any age (*e.g.*, through the use of AMR systems using long bones rather than vertebral column bones) that fails to meet the bone marrow standard is misbranded. FSIS seeks comment on this issue.

Section 318.24(c)(3) provides that spent skulls and vertebral column bone materials from cattle eligible to enter an AMR system (*i.e.*, from cattle younger than 30 months of age) are eligible for edible rendering, as is the product derived from these bones that contains CNS-type tissues (*see* §318.24 (c)(2)(i) or (ii).

Although some non-complying AMR product derived from the vertebral column of pork and livestock other than cattle may be diverted to use as MS(Species), such a practice has not been customary in the past because MS(Species) rarely, if ever, is produced in the United States. FSIS is considering rulemaking on MS(Species) from species other than cattle regarding the presence of CNS-type tissue in this product and is seeking comment on this issue.

Section 320.1 is amended to extend the recordkeeping requirements to the entire AMR process control system. The current regulation applies only to the calcium criteria. This change is necessary to ensure that establishments maintain appropriate records documenting that they are controlling the entire process, including the appropriate identification and segregation of cattle and their derived products. The establishment may determine to incorporate the control procedures and recordkeeping into their HACCP plan or into their Sanitation SOP or other prerequisite program. Such control procedures may be based on the guidance prepared by the Canadian government for their industry.

Request for Comments

FSIS requests comments on the measures contained in this interim final rule, and specifically on whether the Agency has chosen measures that are most appropriate for preventing human exposure to the BSE agent in the United States.

Emergency Action

Given the fact that a cow in Washington State tested positive for BSE on December 23, 2003, it is necessary to issue this rule on an emergency basis. BSE infectivity has been confirmed in the brain, eyes, trigeminal ganglia, tonsils, spinal cord, DRG, and distal ileum. Furthermore, most of these tissues have demonstrated infectivity before experimentally infected animals developed clinical signs of disease. Thus, BSE infectivity in these tissues is not readily ascertainable. Therefore, FSIS has determined that it must take immediate action to ensure that materials that could present a significant risk to human health in beef derived from AMR systems and the spent bone materials derived from AMR systems are excluded from the human food supply.

Under these circumstances, the FSIS Administrator has determined that prior notice and opportunity for public comment are contrary to the public interest, and that there is good cause under 5 U.S.C. 553 for making this rule effective less than 30 days after publication in the **Federal Register**. FSIS will consider comments received during the comment period for this interim rule (*see* **DATES** above). After the comment period closes, the Agency will publish another document in the **Federal Register**. The document will include a discussion of any comments received in response to this interim rule and any amendments made as a result of those comments.

In an effort to ensure that establishments comply with this interim final rule upon publication in the **Federal Register**, FSIS will provide guidance to inspection program personnel regarding the implementation strategy. At a minimum, FSIS inspection program personnel will be directed to meet with management of each affected establishment to discuss how and when the establishment expects to complete its reassessment of its HAACP plan to ensure that SRMs and MS(Beef) do not adulterate product.

Executive Order 12866 and the Regulatory Flexibility Act

This rule has been reviewed under Executive Order 12866. It has been determined to be economically significant for purposes of E.O. 12866.

The emergency situation surrounding this rulemaking makes timely compliance with Executive Order 12866 and the Regulatory Flexibility Act (5. U.S.C. 601 *et seq.*) impracticable.

FSIS is currently assessing the potential economic effects of this action. When this work is complete, the Agency will publish a notice of availability in the **Federal Register** and will provide an opportunity for public comment.

Executive Order 12988

This interim final rule has been reviewed under Executive Order 12988, Civil Justice Reform. This rule: (1) Preempts State and local laws and regulations that are inconsistent with this rule; (2) has no retroactive effect; and (3) does not require administrative proceedings before parties may file suit in court challenging this rule. However, the administrative procedures specified in 9 CFR 306.5. must be exhausted before any judicial challenge of the application of the provisions of this interim final rule, if the challenge involves any decision of an FSIS employee relating to inspection services provided under the FMIA or PPIA.

Paperwork Reduction Act

In accordance with section 3507(j) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the information collection and recordkeeping requirements included in this interim final rule have been submitted for emergency approval to the Office of Management and Budget (OMB). OMB has assigned control number 0583–XXXX to the information and recordkeeping requirements.

Title: Advanced Meat Recovery Systems.

Type of collection: New.

Abstract: FSIS has reviewed the paperwork and recordkeeping requirements in this interim final rule in accordance with the Paperwork Reduction Act. Under this interim final rule, FSIS is requiring a new information collection activity. FSIS is requiring establishments that produce meat from AMR systems to ensure that bones used for AMR systems do not contain brain, trigeminal ganglia, or spinal cord, to test for calcium (at a different level than previously required), iron, protein, spinal cord, and DRG, to document their testing protocols, to assess the age of cattle product used in the AMR system, and to document their procedures for handling product from cattle of any age in a manner that does not cause product to be misbranded or adulterated, and to maintain records of their documentation and test results.

Estimate of burden: FSIS estimates that it will take establishments on a daily basis 30 minutes to collect the

information such as for calcium and iron and 30 minutes to sample for spinal cord and DRG. The Agency estimates that it will take 2 minutes to do recordkeeping of test results. FSIS also estimates that it will take establishments 2 hours to develop their testing protocols.

Respondents: Establishments that produce livestock product (*e.g.*, beef and pork) from AMR systems.

Estimated Number of Respondents: 56.

Estimated Number of Responses per Respondent: 1,201.

Estimated Total Annual Burden on Respondents: 18,088 hours.

Copies of this information collection assessment can be obtained from John O'Connell, Paperwork Reduction Act Coordinator, FSIS, USDA, 112 Annex, 300 12th Street, SW., Washington, DC 20250–3700.

Additional Public Notification

Public involvement in all segments of rulemaking and policy development is important. Consequently, in an effort to better ensure that minorities, women, and persons with disabilities are aware of this interim final rule and informed about the mechanism for providing their comments, FSIS will announce it and make copies of this **Federal Register** publication through the FSIS Constituent Update, which is communicated via Listserv, a free e-mail subscription service. In addition, the update is available online through the FSIS web page located at *http://www.fsis.usda.gov.* The update is used to provide information regarding FSIS policies, procedures, regulations, **Federal Register** notices, FSIS public meetings, recalls, and any other types of information that could affect or would be of interest to our constituents and stakeholders. The constituent Listserv consists of industry, trade, and farm groups, consumer interest groups, allied health professionals, scientific professionals, and other persons who have requested to be included. Through the Listserv and web page, FSIS is able to provide information to a much broader, more diverse audience.

For more information, contact the Congressional and Public Affairs Office, at (202) 720–9113. To be added to the free e-mail subscription service (Listserv) go to the ''Constituent Update'' page on the FSIS Web site at *http://www.fsis.usda.gov/oa/update.htm.* Click on the ''Subscribe to the Constituent Update Listserv'' link, then fill out and submit the form.

Footnotes

The following sources are referred to in this document and are available for review in the FSIS Docket Room (*See* **ADDRESSES** above) between 8:30 a.m. and 4 p.m., Monday through Friday.

1. Harvard Center for Risk Analysis, Harvard School of Public Health, and Center for Computations Epidemiology, College of Veterinary Medicine, Tuskegee University, November 2001. Evaluation of the Potential for Bovine Spongiform Encephalopathy in the United States.
2. Summary of Calendar Year 2003 AMR Testing, FSIS.
3. Hasiak, R.J. and H. Marks, The ''Advanced Meat Recovery System'' Survey Project Final Report, February 21, 1997.
4. FSIS Directive 7160.2, ''Meat'' Prepared Using Advanced Mechanical Meat/Bone Separation Machinery and Meat Recovery Systems, April 14, 1997.
5. FSIS technical paper, Derivation of excess iron limits for meat products produced by Advanced Recovery Systems, July 21, 1999.
6. Wyndom, W.R. and R.A. Field, Effect of method of analysis on iron content of beef from advanced meat recovery systems, May 2000.
7. Georgetown University Center for Food & Nutritional Policy, Advanced Meat Recovery Systems, 1999.
8. Sparks Companies, Inc., Advanced Meat Recovery Systems—An Economic Analysis of Proposed USDA Regulations, July 1999.
9. Letter to FDA and USDA, submitted by Public Citizen, and signed by the Animal Welfare Institute. Cancer Prevention Coalition, Center for Food Safety, Community Nutrition Institute, Family Farm Defenders, Farm Sanctuary, Global Resource Action Center for the Environment, Government Accountability Project, Project Humane Farming Association, Institute for Agriculture and Trade Policy, National Family Farm Coalition, Organic Consumers Association, Public Citizen, and the U.S. Public Interest Research Group, April 13, 2001.
10. Petition for Regulatory Action to Bar the Use of Spinal Cord and Columns and Other Potentially Infectious Tissue from Beef in the Human Food Supply, submitted by the Center for Science in the Public Interest, on behalf of the American Public Health Association, Consumer Federation of America, Government Accountability Project, National Consumers League, and Safe Tables Our Priority, August 9, 2001.
11. Analysis of 2002 FSIS Bovine AMR Survey Results, prepared by the USDA, FSIS, February 2003.
12. FSIS Directive 7160.3, Revision 1, Advanced Meat Recovery Using Beef Vertebral Raw Materials, August 25, 2003.

List of Subjects

9 CFR Part 301

Meat and meat products.

9 CFR Part 318

Meat inspection, Records.

9 CFR Part 320

Meat inspection, Records.

■ For the reasons set forth above, FSIS is amending 9 CFR, chapter III, as follows:

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.

(i) Meat does not include the muscle found in the lips, snout, or ears.

(ii) 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).

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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:

§ 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]

(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 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.

[1] 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 (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/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.

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.

§ 320.1 [Amended]

■ 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.''

Done in Washington, DC, on: January 7, 2004.

Garry L. McKee,

Administrator.

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DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Parts 310 and 313

[Docket No. 01–033IF]

Prohibition of the Use of Certain Stunning Devices Used to Immobilize Cattle During Slaughter

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Interim final rule with request for comments.

SUMMARY: The Food Safety and Inspection Service (FSIS) is amending the Federal meat inspection regulations to prohibit the use of penetrative captive bolt stunning devices that deliberately inject air into the cranial cavity of cattle. This rulemaking responds to the findings of a risk assessment on bovine spongiform encephalopathy (BSE) conducted by the Harvard Center for Risk Analysis (referred to as the Harvard study) and is part of a series of actions that the USDA is taking to strengthen its BSE prevention programs.

The Harvard study found that, owing to already ongoing Federal programs, the U.S. is highly resistant to the introduction and spread of the disease. Even so, the USDA response to BSE has always been proactive and preventive.

Therefore, FSIS is taking this action to address the potential risk posed by stunning devices that may force visible pieces of brain, known as macro-emboli, into the circulatory system of stunned cattle.