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).

* * * * *

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 × Protein × 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.

[FR Doc. 04–626 Filed 1–8–04; 1:43 pm]

BILLING CODE 3410–DM–P

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.

DATES: Effective January 12, 2004; comments received on or before April 12, 2004 will be considered prior to issuance of a final rule.

ADDRESSES: Send an original and two copies of comments to: FSIS Docket Clerk, Docket #01–033IF, Room 102, Cotton Annex, 300 C 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.

FOR FURTHER INFORMATION CONTACT: Daniel 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.

SUPPLEMENTARY INFORMATION:

Background

BSE is a slowly progressing, fatal degenerative disease that affects the central nervous system (CNS) of cattle. BSE belongs to the family of diseases known as the transmissible spongiform encephalopathies (TSEs), which include scrapie in sheep and goats, chronic wasting disease (CWD) in deer and elk, and Creutzfeldt-Jakob Disease (CJD) in humans. In 1996, following outbreaks of BSE in cattle in the United Kingdom, scientists found a possible link between BSE and a new variant of CJD, commonly referred to as variant CJD (vCJD). While it is not certain how BSE may be spread to humans, evidence indicates that humans may acquire vCJD by consuming parts of cattle that contain the BSE agent.

The U.S government has taken a number of actions to prevent the spread of BSE into the U.S. Since 1989, the USDA's Animal and Plant Health Inspection Service (APHIS) has prohibited the importation of live cattle and certain animal products from cattle, including rendered protein products, from the United Kingdom and certain other countries where BSE is known to exist. In 1997, because of concerns about widespread risk factors and inadequate surveillance for BSE in many European countries, these importation restrictions were extended to include all of the countries in Europe. As of December 7, 2000, APHIS has prohibited all imports of rendered animal protein products, regardless of species, from BSE-restricted countries because of concerns that feed intended for cattle may have been cross-contaminated with the BSE agent.

APHIS leads an ongoing, comprehensive, interagency surveillance system for BSE in the U.S. and, in cooperation with FSIS, has drafted an emergency response plan to be used in the event that BSE is identified in the U.S. BSE was, in fact, identified in a cow in Washington State on December 23, 2003; as a result, the plan was immediately put into effect. Other Federal agencies also have contingency plans that work in concert with the USDA plan. In 1997, the Food and Drug Administration (FDA) issued a final rule prohibiting the use of most mammalian protein in animal feeds for cattle and other ruminants. Under the FDA's rule, animal feed manufacturers must keep records sufficient to track any material that contains prohibited protein (prohibited material) throughout its receipt, processing, and distribution, must have processes in place to prevent co-mingling between ruminant feed and non-ruminant feed containing prohibited materials, and must ensure that non-ruminant feed containing prohibited materials is labeled conspicuously with the statement "Do not feed to cattle and other ruminants." These regulations are intended to prevent the spread of BSE in U.S. cattle through feed contaminated with the BSE agent. In addition, the Centers for Disease Control and Prevention (CDC) leads a surveillance program for vCJD in the U.S.

On November 30, 2001, the USDA released the results of a risk assessment on BSE conducted by the Harvard Center for Risk Analysis that evaluates the ways BSE could spread in the U.S. (Ref. 1, available for viewing by the public in the FSIS Docket room and on the Internet at *http://www.fsis.usda.gov/OA/topics/bse.htm).* The Harvard study also provides government agencies with a science-based approach to evaluate measures already in place to prevent the spread of BSE into the U.S. and to identify additional actions that should be taken to minimize the risk of BSE. The Harvard study shows that early prevention systems put into place by the USDA and the Department of Health and Human Services (HHS) would prevent BSE from spreading throughout the country.

Although the Harvard study found that the U.S. was highly resistant to the spread of BSE, as previously mentioned, the USDA response to BSE has always been proactive and preventive. Therefore, in response to the Harvard study, on November 30, 2001, the Secretary of Agriculture announced a series of actions that the Department would take to strengthen its BSE prevention programs and to maintain the government's vigilance against the spread of BSE. One of these actions was to issue a proposed rule to prohibit the use of certain stunning devices used to immobilize cattle during slaughter. This action was identified because certain methods used to stun cattle (*i.e.*, render them unconscious before they are slaughtered) have been found to force visible pieces of CNS tissue, known as macro-emboli, into the circulatory system of stunned cattle. Most of the infectivity in cattle that have BSE is found in the CNS tissue, *i.e.*, brain and spinal cord.

Stunning and the Humane Methods of Slaughter Act

Section 3(b) of the Federal Meat Inspection Act (FMIA) (21 U.S.C. 603(b)) requires that any cattle or other livestock species slaughtered or handled in connection with slaughter under Federal inspection be handled in accordance with the provisions of the Humane Methods of Slaughter Act (HMSA) (7 U.S.C. 1901–1906). The HMSA states that "* * * it is * * * the policy of the United States that the slaughtering of livestock and the handling of livestock in connection with slaughter shall be carried out only by humane methods" (7 U.S.C. 1901). The HMSA requires that livestock be rendered insensible to pain before being shackled, hoisted, thrown, cast, or cut (unless they are slaughtered and handled in connection with slaughter in accordance with certain specified religious ritual requirements) (7 U.S.C. 1902, 1906). The HMSA also authorizes the Secretary of Agriculture (and FSIS by delegation) to designate methods of slaughter and handling in connection with slaughter that conform to the policy of the HMSA (7 U.S.C. 1904(b)).

Pursuant to the authority granted under the HMSA, FSIS promulgated regulations that prescribe requirements for the humane treatment of livestock. These regulations, which are codified at 9 CFR part 313, identify, among other things, humane methods of stunning for specified livestock species (*see* 9 CFR 313.5, 9 CFR 313.15, 9 CFR 313.30). 9 CFR 313.15 sets forth the requirements for the use of captive bolt stunning for livestock. There are two types of captive bolt stunners, penetrative and non-penetrative. Both are permitted to be used to stun cattle prior to bleeding. In addition, the FSIS post-mortem inspection regulations, at 9 CFR 310.13, specifically list air-injection captive bolt stunning as an approved method for injecting air into the carcasses or parts of carcasses of livestock (9 CFR 310.13(a)(2)(iv)(C)).