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9 CFR Part 301, 309, et al.
Prohibition of the Use of Specified Risk Materials for Human Food and Requirements for the Disposition of Non-Ambulatory Disabled Cattle; Meat Produced by Advanced Meat/Bone Separation Machinery and Meat Recovery (AMR) Systems; Prohibition of the Use of Certain Stunning Devices Used To Immobilize Cattle During Slaughter; Bovine Spongiform Encephalopathy Surveillance Program; Interim Final Rules and Notice

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Parts 309, 310, 311, 318, and 319

[Docket No. 03-025IF]

Prohibition of the Use of Specified Risk Materials for Human Food and Requirements for the Disposition of Non-Ambulatory Disabled Cattle

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Interim final rule and request for comments.

SUMMARY: The Food Safety and Inspection Service (FSIS) is amending the Federal meat inspection regulations to designate the brain, skull, eyes, trigeminal ganglia, spinal cord, vertebral column (excluding the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae, and the wings of the sacrum), and dorsal root ganglia (DRG) of cattle 30 months of age and older, and the tonsils and distal ileum of the small intestine of all cattle, as "specified risk materials" (SRMs). The Agency is declaring that SRMs are inedible and prohibiting their use for human food. In addition, FSIS is requiring that all non-ambulatory disabled cattle presented for slaughter be condemned. The Agency is requiring that federally-inspected establishments that slaughter cattle and federally-inspected establishments that process the carcasses or parts of cattle develop, implement, and maintain written procedures for the removal, segregation, and disposition of SRMs. Establishments must incorporate these procedures into their HACCP plans or in their Sanitation SOPs or other prerequisite program. FSIS is taking this action in response to the diagnosis on December 23, 2003, by the U.S. Department of Agriculture of a positive case of bovine spongiform encephalopathy (BSE) in an adult Holstein cow in the State of Washington. This action will minimize human exposure to materials that scientific studies have demonstrated as containing the BSE agent in cattle infected with the disease. Infectivity has never been demonstrated in the muscle tissue of cattle experimentally or naturally infected with BSE at any stage of the disease.

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 #03-025IF, Room 102, Cotton Annex, 300 12th and 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. Reference materials that are not copyrighted will also be available 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.

SUPPLEMENTARY INFORMATION:

Background

Under the Federal Meat Inspection Act (FMIA) (21 U.S.C. 601 *et seq.*), FSIS issues regulations governing the production of meat and meat food products prepared for distribution in commerce. The regulations, along with FSIS inspection programs, are designed to ensure that meat and meat food products are safe, wholesome, unadulterated, and properly marked, labeled, and packaged. The FMIA prohibits anyone from selling, transporting, offering for sale or transportation, or receiving for transportation in commerce, any adulterated or misbranded meat or meat food product (21 U.S.C. 610).

Under the FMIA, a meat food product is adulterated if, among other circumstances, it bears or contains any poisonous or deleterious substance that may render it injurious to health (21 U.S.C. 601(m)(1)) or if it is for any reason unsound, unhealthful, unwholesome, or unfit for human food (21 U.S.C. 601(m)(3)). The FMIA requires that FSIS inspect the carcasses, parts of carcasses, and meat food products of all cattle, sheep, swine, goats, horses, mules, or other equines that are capable for use as human food to ensure that such articles are not adulterated (21 U.S.C. 604, 606). If the carcasses, parts of carcasses, and meat food products are found, upon inspection, to be not adulterated, FSIS marks them as "Inspected and passed" (21 U.S.C. 604, 606, 607). The FMIA gives FSIS broad authority to promulgate such rules and regulations as are necessary to carry out the provisions of the Act (21 U.S.C. 621).

As discussed in greater detail below, infectivity has been confirmed in the brain, trigeminal ganglia, tonsils, spinal cord, DRG, and distal ileum of the small intestine of cattle experimentally infected with BSE, and in the brain, spinal cord, and eyes of cattle infected with BSE under field conditions. Data on the age distribution of clinical cases of BSE in the field reported in the United Kingdom indicate that clinical BSE disease has rarely been reported in cattle younger than 30 months of age.

In cattle experimentally infected with BSE, infectivity has been confirmed in the distal ileum at various stages of the disease process and as early as 6 months after oral exposure to the BSE agent. The tonsils of experimentally infected cattle have demonstrated apparently weak infectivity as early as 10 months after oral exposure to the BSE agent. The other tissues in which BSE infectivity has been confirmed have demonstrated infectivity at the end stages of disease, which, in experimentally infected cattle, was 32 months after exposure to the BSE agent and later. The brain, trigeminal ganglia, tonsils, DRG, and distal ileum are materials of experimentally infected cattle in which infectivity has been confirmed before the onset of clinical disease.

Based on these findings, FSIS has concluded that the brain, skull, eyes, trigeminal ganglia, spinal cord, vertebral column (excluding the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae, and the wings of the sacrum), and DRG of cattle 30 months of age and older, and the tonsils and distal ileum of the small intestine of all cattle are unfit for human food under section 1(m)(3) of the FMIA (21 U.S.C 601(m)(3)). Therefore, FSIS is designating these materials as SRMs, declaring that they are inedible and, pursuant to its authority to promulgate regulations necessary to carry out the provisions of the FMIA, prohibiting their use for human food.

Because there are currently no restrictions on the incorporation of spinal cord and DRG into MS(Beef) meat food product, such product may contain concentrated amounts of these high-risk tissues. Therefore FSIS has concluded that, like the SRMs described above, MS(Beef) is unfit for human food under section 1(m)(3) of the FMIA (21 U.S.C. 601(m)(3)).

As discussed in detail below, surveillance data from European countries in which BSE has been detected indicate that non-ambulatory cattle are among the animals that have a greater incidence of BSE than other cattle. Surveillance data also indicate that clinical signs of BSE cannot always be observed in non-ambulatory cattle. Furthermore, due to limitations in the testing methods for BSE that are available today, certain tissues of cattle

infected with BSE may contain BSE infectivity even though the diagnostic test does not indicate that the animal has the disease. For the reasons presented above, FSIS believes that non-ambulatory disabled cattle present a risk of introducing the BSE agent into the human food supply. Therefore, FSIS has determined that the carcasses of non-ambulatory disabled cattle are unfit for human food under section 1(m)(3) of the FMIA and that all non-ambulatory disabled cattle that are presented for slaughter should be condemned.

By declaring SRMs and MS(Beef) inedible and prohibiting their use for human food, and by condemning all non-ambulatory disabled cattle, 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 identified in this document are unfit for human food. Thus, the status of most 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 and establishments that process the carcasses or parts of cattle will reassess their HACCP plans in accordance with 9 CFR 417.4(a)(3) to address SRMs.

BSE and Variant Creutzfeldt-Jakob Disease

BSE is a progressive degenerative disease that affects the central nervous system (CNS) of adult cattle. BSE belongs to the family of diseases known as transmissible spongiform encephalopathies (TSEs), which include, among other diseases, scrapie in sheep and goats, chronic wasting disease (CWD) in deer and elk, and Cruetzfeldt-Jakob disease (CJD) in humans. The typical incubation period (the time from when an animal becomes infected until it first shows disease signs) for BSE is believed to be from two to eight years. BSE was first documented in the United Kingdom in 1986 and has since been identified in approximately 21 other countries in Europe. BSE has also been confirmed in some non-European countries, including Japan, Israel, and Canada.

On December 23, 2003, USDA announced a presumptive diagnosis of BSE in an adult Holstein cow from Washington State. Samples were taken from the cow on December 9 as part of USDA's BSE surveillance program. The BSE diagnosis was made on December 22 and 23 by histopathology and immunohistochemical testing at the National Veterinary Services Laboratory, Ames, Iowa. On December 25, 2003, the International Reference Laboratory in Weybridge, England confirmed the diagnosis of BSE.

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 also been implicated. The agent is highly resistant to heat, ultraviolet light, ionizing radiation, and common disinfectants that normally inactivate viruses or bacteria.

In 1996, a newly recognized form of the human disease CJD, referred to as vCJD, was reported in the United Kingdom. Scientific and epidemiological studies have linked vCJD to exposure to BSE, probably through human consumption of beef products contaminated with the agent that causes BSE (Ref. 1–5 available for viewing by the public in the FSIS Docket Room). To date, approximately 150 probable and confirmed cases of vCJD have been reported worldwide.

The Centers for Disease Control and Prevention (CDC) leads a surveillance system for vCJD in the United States, and as of December, 2003, the disease has never been detected in residents of the United States that have never lived in or traveled to the United Kingdom for extended periods of time. In 2002, a probable case of vCJD was reported in a Florida resident who lived in the United Kingdom during the BSE epidemic. Epidemiological data indicate that the patient was likely exposed to the BSE agent before moving to the United States. (Ref. 6 available for viewing by the public in the FSIS Docket Room).

The United States government has implemented a number of measures to prevent BSE from entering the United States and to prevent the spread of the disease should it be introduced into the United States. Since 1989, USDA's Animal and Plant Health Inspection Service (APHIS) has prohibited the importation of live cattle and certain cattle products, including rendered protein products, from countries where BSE is known to exist. In 1997, due to 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. In 1997, FDA prohibited the use of most mammalian protein in the manufacture of animal feeds given to cattle and other ruminants. In December 2000, APHIS prohibited all imports of rendered animal protein products, regardless of species, from BSE-restricted countries because of concern that feed intended for cattle may have been cross-contaminated with the BSE agent. In addition, APHIS leads an ongoing, comprehensive, interagency surveillance system for BSE in the United States and, in cooperation with FSIS, has drafted an emergency response plan to be used in the event that BSE is identified in the United States. This plan was activated when the BSE test for the cow in Washington State came back presumptive positive on December 23, 2003. Other Federal agencies also have contingency plans that work in concert with the USDA plan.

BSE Infectivity

Animal age. The distribution and amount of the BSE agent in cattle infected with BSE is not known with certainty. It is generally accepted that in animals with clinical BSE disease, the brain and spinal cord contain the greatest concentration of the BSE agent, and that the quantity of the agent increases as the animals progress through the incubation period to the development of clinical disease. Thus, the total infective load in cattle in the early stages of the incubation period is believed to be much lower than in cattle approaching the end of the incubation period or in those cattle with overt clinical BSE. As stated above, the typical incubation period for BSE is believed to be between two to eight years.

Information on the age at which cattle develop clinical BSE under field conditions, *i.e.*, commercially reared cattle not part of a specially designed experiment, can be useful in identifying those cattle that, if infected with the BSE agent, are most likely to contain the highest levels of 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 (Ref. 7, available for viewing by the public in the FSIS Docket Room). These data demonstrate that the age at which cattle develop clinical disease varies. The data from the United Kingdom show a gradual increase in the number of clinical BSE cases with increasing age, and that the number of confirmed cases peaks at 5 years of age. The lower ranges of this age distribution include some cattle younger than 30 months of age.

The age distribution data show that, of the cattle that developed clinical BSE in the field, only 0.01% were less than 30 months of age. Thus, 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 hence, are less likely to contain high levels of BSE infectivity. Research demonstrates that the incubation period for BSE appears to be linked to the infectious dose of the BSE agent received, *i.e.*, the larger the infectious dose received the shorter the incubation period (Ref. 8, available for viewing by the public in the FSIS docket room). Thus, given these observations, scientists that have studied the disease believe that the occurrence of BSE in young cattle is most likely the result of exposure to a very large dose of the BSE agent at a very young age.

Detection of BSE in cattle younger than 30 months of age. In October 2003, Japan reported a BSE case in a 23-month old bull, the 8th BSE case confirmed in that country. Earlier cases confirmed in Japan were in cattle over 5 years of age. This recent case apparently did not have clinical signs of disease and was detected as part of Japan's regular surveillance for BSE in which all cattle slaughtered for human consumption are screened for the disease. In reporting on this BSE case, Japanese officials stated that tests suggested that the form of the BSE agent found in the affected animal was atypical, and that they planned to conduct further studies on this form of the disease. A similar form of the atypical agent detected in the Japanese animal has been reported in two BSE cases in Italy. However the Italian animals were 11 and 12 years old. Japan has reported importing feed from Italy.

In early November 2003, shortly after reporting the confirmation of BSE in a 23-month-old animal, Japan reported that BSE was confirmed in a 21-month-old animal. The 21-month-old animal is Japan's 9th reported case of BSE. Like the 23-month-old animal, this animal apparently did not have clinical signs of disease. However, the abnormal prion protein detected in this animal does not appear to be the same as the apparently atypical form detected in the 23-month-old animal. Japanese officials reported that they will be conducting testing to determine if the tissues of these relatively young cattle that were recently found positive for BSE contain BSE infectivity.

The immediate implications of the recent detection of BSE in two animals younger than 24 months of age in Japan, one of which has an apparently atypical form of the disease, are not readily apparent at this time. Although rare, confirmed cases of BSE in animals younger than 30 months of age have also been reported in the United Kingdom and in some other European countries. As stated earlier in this document, a confirmed case of BSE in an animal less than 30 months of age generally implies that the animal was exposed to a large dose of the infective agent at a young age. From 1988 to 1996, during the height of the BSE epidemic in the United Kingdom when large amounts of infective agent were being circulated among cattle herds, 19 clinical cases of BSE were confirmed in cattle younger than 30 months of age (Ref. 9, available for viewing by the public in the FSIS docket room). The youngest confirmed case of BSE was in the United Kingdom in an animal with clinical disease at 20 months of age in 1992. However, as of September 30, 2003, no cases of BSE in cattle younger than 30 months of age have been detected in the United Kingdom since 1996, and only 3 cases have been found in European animals less than 30 months of age since 2001.

FSIS requests comment on the potential implications, if any, of the reported 21- and 23-month-old cases of BSE in Japan. The Agency is also requesting comments on whether, and if so how, it should modify the measures in this rulemaking to address the fact that, in rare instances, BSE has been confirmed in cattle younger than 30 months of age.

Infective tissues. Available data on the development and distribution of tissue infectivity in BSE-infected cattle are incomplete. Most of what is known comes from pathogenesis studies conducted in the United Kingdom (Ref. 10, 11, 12 available for viewing by the public in the FSIS Docket Room). In these studies, cattle were deliberately infected with BSE through oral exposure to the brains of cattle with confirmed BSE. The experimentally infected cattle were killed at regular intervals as the disease developed, and at each interval the tissues of the infected cattle were examined for histopathological changes consistent with BSE and for abnormal prion proteins. At each interval, tissues of the BSE infected cattle were also injected into mice to identify those tissues of cattle capable of transmitting the disease.

The pathogenesis studies involved a small number of cattle (30 animals) that received a large, uniform dose of the BSE agent at a very young age (4 months). Thus, the findings may not reflect the development and distribution of infectivity of cattle exposed to the BSE under field conditions, where the level and age of exposure to the BSE agent are unpredictable. Furthermore, the pathogenesis studies did not determine the rate at which the BSE agent increases in the tissues that have demonstrated infectivity or the tissues that the agent must pass through to reach its ultimate destination in the animal after it is ingested. However, the results of these studies are useful in that they provide experimental evidence of the distribution of the infective agent in BSE-infected cattle at various stages of the disease.

The pathogenesis studies demonstrate that in cattle infected with BSE, the total amount of infectivity in the animal, as well as the distribution of infectivity in the animal's body, change over time, with the highest levels of infectivity detected in the brain and spinal cord at the end stages of disease. In the studies, some cattle exhibited clinical signs of BSE as early as 35 months post oral exposure to the BSE agent. By 37 months post oral exposure, all of the 5 animals that were still alive demonstrated clinical evidence of BSE (animals had been serially sacrificed at set intervals). In cattle with clinical BSE, infectivity was demonstrated in the brain, spinal cord, DRG, trigeminal ganglia, and the distal ileum of the small intestine. (DRG are clusters of nerve cells attached to the spinal cord that are contained within the bones of the vertebral column. "DRG" as used in this document has the same meaning as the term "dorsal spinal nerve root ganglia." Trigeminal ganglia are clusters of nerve cells connected to the brain that lie close to the exterior of the skull.)

In one set of animals, infectivity was demonstrated in the bone marrow at 38 months post exposure, but these findings were not conclusive. At this time, bone marrow is not designated as SRM. However, in today's **Federal Register**, FSIS is announcing new requirements to limit the presence of bone marrow in meat produced from AMR systems, with iron as a marker. This action is not a food safety measure at this time but is related to misbranding.

In some cattle in the studies, BSE infectivity was demonstrated in the brain, spinal cord, and DRG as early as 32 months post oral exposure to the BSE agent. In addition, infectivity was demonstrated in these tissues three months before animals began to develop clinical signs of the disease. Infectivity was demonstrated in the distal ileum of cattle 6 to 18 months post oral exposure to the BSE agent and again at 38 months and 40 months post oral exposure.

A second phase of the pathogenesis studies that uses a cattle bioassay is being conducted to ensure that low levels of infectivity that may not have

been detected in the first phase using the mouse bioassay are not missed. The cattle bioassay, in which tissues from cattle deliberately infected with BSE are injected directly into the brains of BSE-free cattle, is considered to be several hundred-fold more sensitive in detecting BSE infectivity than the mouse bioassay. Preliminary results from the cattle bioassay demonstrate that, in addition to the materials that were found to contain infectivity when the mouse bioassay was used, the tonsils of calves 10 months post oral exposure to the BSE agent contain infectivity. However, because only one of five animals injected with infected tonsil material developed clinical BSE at 45 months post-inoculation, the level of infectivity in the tonsils appears to be very low. The second phase of the study is still underway and is not expected to be completed for several more years. (Ref. 8 and 13, available for viewing by the public in the FSIS Docket Room).

In cattle infected with BSE under field conditions, BSE infectivity has been confirmed in the brain, spinal cord, and retina of the eye at the end stages of the disease (Ref. 8 available for viewing by the public in the FSIS Docket Room).

BSE infectivity has never been demonstrated in the muscle tissue of cattle experimentally or naturally infected with the disease at any stage of the disease.

Proportion of infectivity in certain tissues. In 2001, the European Commission's Scientific Steering Committee (SSC), a scientific 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% of the total infectivity in the animal and the spinal cord contains 25.6% of the total infectivity (Ref. 14 available for viewing by the public in the FSIS Docket Room). Thus, the brain and spinal cord of cattle with clinical BSE are estimated to contain nearly 90% of the total infectivity in the animal. According to the SSC, the remaining proportion of infectivity in a typical animal with clinical BSE is found in the DRG (3.8%), the trigeminal ganglia (2.6%), the distal ileum (3.3%), the spleen (0.3%), and the eyes (0.04%).[1] However, as mentioned above, in experimentally infected cattle BSE infectivity has been demonstrated in the distal ileum as early as 6 to 18 months post oral exposure to the BSE agent and in the tonsils as early as 10 months post exposure. Thus, in younger cattle infected with BSE, these materials apparently present the greatest risk of exposing humans to the BSE agent.

[1] For this study, low levels of infectivity were assumed for the spleen and eyes based on scrapie experiments. The spleen has not demonstrated infectivity in cattle.

Current Regulatory Requirements for Potentially Infective Materials

Under FSIS' regulations, most of the materials that have demonstrated BSE infectivity in cattle with clinical disease, *i.e.*, brain, eyes, trigeminal ganglia, spinal cord, DRG, and the distal ileum of the small intestine, may currently be used in some way for human food. The brains of all livestock species, including the brains of cattle, are permitted for human food, with the exception of brains from animals stunned by lead, sponge iron, or frangible bullets (9 CFR 310.18(b)). Unprocessed cattle brains are typically sold chilled, frozen, or canned, and are consumed as a variety meat. Cattle brains may also be used as a by-product ingredient in certain processed products. When used as a by-product ingredient, cattle brains must be listed in the ingredients statement on the labeling of the product and declared by species (9 CFR 317.2(f)(1)).

Cattle brains are also permitted to be used as a source material in edible rendering. Edible rendering involves the processing of materials inspected and passed for human food into products, such as edible oils, meals, beef extracts, beef protein, beef broths, beef stocks, and beef flavorings. Many of these products are regulated by FSIS and FDA.

Given the invariable presence of bone splinters, detached spinal cords from all livestock species, including cattle, are prohibited for use in the preparation of edible products (9 CFR 318.6(b)(4)). However, detached spinal cords may be used as a raw material in edible rendering (9 CFR 318.6(b)(4)). The labeling of extracts prepared from brains, spinal cords, or other organs or parts of the carcass other than fresh meat from all livestock species, including cattle, must include the true name of the parts from which the product was prepared, *e.g.*, "extract from beef brain" (9 CFR 317.8(b)(15)).

Vertebral columns from cattle contain both spinal cord and DRG. FSIS' regulations do not require that the spinal cord or DRG of cattle be removed from the vertebral column at the time of slaughter. Thus, some bone-in beef products may contain spinal cord, DRG, or both.

Bones from the vertebral column of cattle are permitted to be used as source materials in the production of processed products manufactured from edible rendering. When the vertebral columns from cattle are used in the production of such products, spinal cord and DRG that remain attached to the vertebral column could potentially become dislodged and incorporated into the final product. Under the FSIS regulations, the labeling of the final product is not required to disclose the fact that the product may contain spinal cord or DRG.

Bones from the vertebral column of cattle are also permitted for use as a source material in meat recovery systems that use pressure to separate beef muscle tissue from bones. When the vertebral columns are used as a source material in these systems, spinal cord and DRG may become dislodged from the vertebral bones and incorporated into the final product. The use of vertebral columns in systems that mechanically separate meat and meat products from bone, and the labeling requirements for such products, are discussed in greater detail below.

Casings made from the small intestine, including the distal ileum, of cattle are permitted to be used as containers for meat food products (9 CFR 318.6(b)(1)). Cattle intestines, including the distal ileum, are also permitted for use as ingredients in meat food products that do not have an FSIS prescribed standard of identity, provided that the products are properly labeled (9 CFR 318.6(b)(8)).

FSIS' regulations do not prohibit the use of cattle eyes for human food, although direct consumption of such materials is uncommon in the United States. The tonsils of all livestock species, including cattle, are prohibited for use as ingredients of meat food products (9 CFR 318.6(b)(6)). The trigeminal ganglia of cattle are not sold directly as consumer products. However, the heads of cattle (commonly referred to as "market heads") are permitted for use as human food and are sold to retail establishments where they are used to produce edible products. Some retail establishments sell market heads of cattle directly to consumers. Cattle market heads contain skull, eyes, trigeminal ganglia, and fragments of brains.

Meat that has been trimmed from the head and cheeks of cattle is permitted to be used in FSIS-regulated products, although some product standards place certain restrictions on the use of head and cheek meat (for examples see 9 CFR 319.81, 9 CFR 319.199, 9 CFR 319.300 9 CFR 319.301, and 9 CFR.303) Head or cheek meat may contain CNS materials if the meat is not removed before the skull is fragmented or split. Although rare, the skulls of cattle are sometimes

intentionally split to remove materials contained within the cranial cavity, such as the pituitary gland. The skulls of cattle are sometimes unintentionally fragmented, and the brains of the animals exposed, when a mechanical device is used to remove horns from cattle. In some instances, in addition to the fragmentation that occurs during horn removal, the brain has also been penetrated by the captive bolt of a stun gun, which results in a hole with weeping material that may contain CNS tissue. In these cases, when the head and cheek meat are removed, the heads of the cattle may be manipulated in such a way as to potentially contaminate the meat. Contamination of head or cheek meat with trigeminal ganglia is unlikely because the trigeminal ganglia are embedded within the skull and are not likely to be removed when the meat is harvested.

Meat Produced Using Advanced Meat Recovery Systems and Mechanically Separated (Species) Meat Food Product

Advanced Meat Recovery. Advanced Meat Recovery (AMR) is a technology that enables processors to remove the 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.

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 tissue in beef AMR products (referred to as the 2002 Beef AMR Survey) (Ref. 15 and 16, available for viewing by the public in the FSIS docket room and on the Internet at *http://www.fsis.usda.gov/oa/topics/AMRAnalysis.pdf and http://www.fsis.usda.gov/OA/topics/AMRSurvey.pdf).* 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 tissue, 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 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 (Ref. 15 and 16, available for viewing by the public in the FSIS docket room), 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 detected 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.

Under the current regulations, AMR product that contains DRG is not misbranded and can be identified as meat. However, given the nature of DRG, and the fact that BSE has been confirmed in a cow in the United States, FSIS has reconsidered its approach to this tissue and is issuing a separate interim final rule on AMR systems in this edition of the **Federal Register** that reflects recent developments that have occurred with regard to BSE. The interim final rule on AMR systems also establishes non-compliance criteria to discern "meat" from non-meat product.

Mechanically Separated (MS)(Beef). MS(Beef) meat food product is a finely comminuted product resulting from the mechanical separation and removal of most of the bone from attached skeletal muscle of cattle carcasses and parts of carcasses that meets the specifications contained in 9 CFR 319.5, the regulation that prescribes the standard of identity for MS(Species). Unlike AMR systems in which bone and bone products are not purposefully incorporated in the final meat product, MS(Species) systems are designed to purposefully incorporate significant amounts of bone and bone components in the resulting meat food product. The specifications for product identified as MS(Species) in 9 CFR 319.5 do not establish limits on the incorporation of spinal cord or DRG into this product. Although beef products produced using AMR systems that contain spinal cord cannot be identified as meat, if these products meet the specifications contained in 9 CFR 319.5, they are permitted to be labeled as MS(Beef).

Under the current regulations, MS(Species) product is permitted for use as an ingredient in other processed meat and poultry products in limited amounts (9 CFR 319.6). When MS(Beef) is used as an ingredient in meat or poultry products, it must be identified in the ingredients statement as

MS(Beef). However, the fact that MS(Beef) may contain spinal cord or DRG is not required to be conveyed on the labeling of MS(Beef) product or processed products that contain MS(Beef).

The fact that MS(beef) has been permitted to include spinal cord and DRG makes this product an obvious source of potential human exposure to the BSE agent. Given that a case of BSE was recently confirmed in the United States, FSIS believes that it is necessary to remove this high-risk product from the human food supply. Therefore, in this interim final rule, the Agency is banning the use of MS(beef) for human food. Accordingly, no product may bear the label (MS(Beef)). However, certain products from bones that do not contain CNS tissue, *e.g.*, long bones, that may contain excess bone solids or bone marrow may be produced but must be labeled with an appropriate common or usual name (refer to the interim final rule, "Meat Produced by Advanced Meat/Bone Separation Machinery and Meat Recovery Systems," docket number 03–038IF published in this edition of the **Federal Register**).

The Harvard Risk Assessment

In April 1998, USDA commissioned the Harvard Center for Risk Analysis to conduct an analysis and evaluation of the current measures implemented by the United States government to prevent the spread of BSE in the United States and to reduce the potential exposure of Americans to the BSE agent. The risk assessment (referred to below as the Harvard study) reviewed available scientific information related to BSE and other TSEs, assessed pathways by which BSE could potentially occur in the United States, and identified measures that could be taken to protect human and animal health in the United States (Ref. 17, 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 concluded that if introduced, due to the preventive measures currently in place in the United States, BSE is extremely unlikely to become established in the United States. Should BSE enter the United States, the Harvard study concluded that only a small amount of potentially infective tissues would likely reach the human food supply and be available for human consumption. The Harvard study expressed the amount of infectivity in terms of cattle oral ID50s for the purpose of quantifying both animal and human exposure to the BSE agent. A cattle oral ID50 is the amount of infectious tissue that would be expected to cause 50% of exposed cattle to develop BSE.

Because the exact quantitative relationship between human exposure to the BSE agent and the likelihood of human disease is unknown, the Harvard study did not evaluate the quantitative likelihood that humans will develop vCJD if BSE were introduced into the United States.

The Harvard study also did not address potential human exposure to the BSE agent through products containing ingredients of bovine origin, such as some pharmaceuticals, gelatin, and beef stocks, extracts, and flavorings. Many of these products are derived through the edible rendering process. FSIS is working with FDA, the agency that regulates the use of these products, to address the impact of this issue.

The Harvard study identified three pathways or practices that could contribute most to either human exposure to the BSE agent or to the spread of BSE should it be introduced into the United States. The three pathways are:

- Noncompliance with FDA regulations prohibiting the use of certain proteins in feed for cattle and other ruminants;
- Rendering of animals that die on the farm and use (through illegal diversion or cross-contamination) of the rendered product in ruminant feed;
- Inclusion of high-risk tissue from cattle, such as brain and spinal cord, in edible products.

FDA and USDA's APHIS are taking action to address the first two pathways. FDA is enhancing its enforcement of the feed ban and is evaluating whether further rulemaking is needed (*see* Advance Notice of Proposed Rulemaking, "*Substances Prohibited From Use in Animal Food or Feed; Animal Proteins Prohibited in Ruminant Feed,*" 67 FR 67572, November 6, 2002). APHIS is developing approaches to control the potential risk that dead stock and non-ambulatory animals could serve as potential pathways for the spread of BSE (*see* Advance Notice of Proposed Rulemaking, "*Risk Reduction Strategies for Potential BSE Pathways Involving Downer Cattle and Dead Stock of Cattle and Other Species,*" 68 FR 2703, January 21, 2003). FSIS is prohibiting the use of certain materials from cattle for human food to address the third potential pathway identified in the Harvard study, the inclusion of high-risk tissues in edible product. In addition, in a separate rulemaking published in this edition of the **Federal Register**, FSIS is prohibiting the use of penetrative stunning devices that inject air into the cranial cavity of cattle to ensure that portions of the brain are not dislocated into the tissues of the carcass as a consequence of humanely stunning cattle during the slaughter process (*see* "*Prohibition on the Use of Certain Stunning Devices Used to Immobilize Cattle During Slaughter,*" Docket #01–033IF). Although FSIS is not aware of any cattle slaughter establishments in the United States that use air-injection stunning, research has shown that this practice poses a risk of exposing humans to materials that could contain the BSE agent. Given that a case of BSE was recently confirmed in the United States, FSIS believes that this prohibition is a necessary measure to help strengthen the U.S. Government's actions to prevent human exposure to the BSE agent.

The Harvard study concluded that, based on conditions as they existed in 2001, if 10 infected cows were introduced into the United States, on average, three additional new cases of BSE in cattle would be expected. In fact, Harvard predicted that there was a 75 to 95% chance that there would be no new cases at all. The extreme case (95th percentile of the distribution) predicted 11 new cases. However, in all cases, the system in 2001 was robust enough so that model predicts that the disease would be quickly cleared from the United States with virtually no chance that there would be any infected animals 20 years following the import of the 10 infected cattle.

The Harvard study concluded the greatest sources of potential human exposure to the BSE agent would be human consumption of cattle brain (26% of the total potential exposure on average), cattle spinal cord (5% of the total potential exposure on average), and beef products derived from AMR systems (57% of the total potential exposure on average). The Harvard study also determined that other potential human exposure routes to the BSE agent include consumption of bone-in beef (11% of the total potential exposure on average), and intestine (2% of the total potential exposure on average). However, as stated in the Harvard study report, these estimates are likely to overstate true human exposure because they represent the amount of infectivity presented for human consumption but do not take into account waste or actual consumption rate. For example, the reported quantity for potential exposure to infectivity in bone-in beef reflects the presence of spinal cord and DRG in a fraction of cuts like T-bone steaks, although the spinal cord and DRG may never be consumed in these cuts of meat.