**DEPARTMENT OF AGRICULTURE**

**Food Safety and Inspection Service**

**9 CFR Parts 309, 310, and 318**

**[Docket No. 03–025F]**

**RIN 0583–AC88**

# Prohibition of the Use of Specified Risk Materials for Human Food and Requirements for the Disposition of Non-Ambulatory Disabled Cattle; Prohibition of the Use of Certain Stunning Devices Used To Immobilize Cattle During Slaughter

**AGENCY:** Food Safety and Inspection Service, USDA.

**ACTION:** Affirmation of interim final rules with amendments.

**SUMMARY:** The Food Safety and Inspection Service (FSIS) is affirming, with changes, the interim final rule ''*Prohibition of the Use of Specified Risk Materials for Human Food and Requirements for the Disposition of Non-Ambulatory Cattle,*'' which was published in the **Federal Register** on January 12, 2004. The Agency is also affirming the interim final rule ''*Prohibition of the Use of Certain Stunning Devices Used to Immobilize Cattle During Slaughter,*'' also published on January 12, 2004. FSIS issued these interim final rules in response to the confirmation on December 23, 2003, of bovine spongiform encephalopathy (BSE) in an imported dairy cow in Washington State. FSIS is taking this action to make permanent interim measures implemented by the Agency to minimize human exposure to cattle materials that could potentially contain the BSE agent.

**DATES:** This final rule is effective October 1, 2007. Comments on the information presented under ''Paperwork Reduction Act'' must be received by September 11, 2007.

**FOR FURTHER INFORMATION CONTACT:** Dr. Daniel Engeljohn, Deputy Assistant Administrator, Office of Policy, Program, and Employee Development, FSIS, U.S. Department of Agriculture, 1400 Independence Avenue, SW., Washington, DC 20250–3700, (202) 205–0495.

**SUPPLEMENTARY INFORMATION:**

## Background

On January 12, 2004, FSIS issued a series of three interim final rules to minimize human exposure to materials that scientific studies have demonstrated have the potential to contain the BSE agent in cattle infected with that disease. Scientific and epidemiological studies have linked the human disease variant Cruetzfelt-Jacob Disease (vCJD) to exposure to BSE, most likely through human consumption of beef products contaminated with the BSE agent. FSIS issued the rules in response to the diagnosis on December 23, 2003, of BSE in an imported dairy cow in Washington State. The animal had been imported from Canada.

One of the rules, ''Prohibition of the Use of Specified Risk Materials for Human Food and Requirements for the Disposition of Non-ambulatory Disabled Cattle'' (69 FR 1862, January 12, 2004) (also referred to as ''the SRM interim final rule''), designates certain materials from cattle as specified risk materials (SRMs), declares that SRMs are inedible, and prohibits the use of these materials for human food (9 CFR 310.22(a) and 9 CFR 310.22(b)). The SRM interim final rule also requires that establishments that slaughter cattle, and establishments that process the carcasses or parts of cattle, develop, implement, and maintain written procedures for the removal, segregation, and disposition of SRMs and incorporate these procedures into their HACCP plans or Sanitation Standard Operating Procedures (SOPs) or other prerequisite programs (9 CFR 310.22(d)).

The materials identified as SRMs in the FSIS SRM interim final rule are 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) from cattle 30 months of age and older, and the distal ileum of the small intestine and tonsils from all cattle (9 CFR 310.22(a)). The SRM interim final rule declares that SRMs are inedible because they present a sufficient risk of exposing humans to the BSE agent so as to render them ''unfit for human food'' within the meaning of section 1(m)(3) of the adulteration provisions of the Federal Meat Inspection Act (FMIA) (21 U.S.C. 601(m)(3)).

The SRM interim final rule designates the distal ileum from all cattle as an SRM because BSE infectivity has been confirmed in the distal ileum in the early stages of the disease. To ensure effective removal of the distal ileum, the SRM interim final rule originally required that the entire small intestine be removed and disposed of as inedible. However, in the preamble to the SRM interim final rule, FSIS noted that beef processors may be able to effectively remove the distal ileum from the rest of the small intestine and requested comments on this issue (69 FR 1862, 1869). The Agency again requested comments on this issue in an advance notice of proposed rulemaking published in July 2004 (''Federal Measures To Mitigate BSE Risks: Considerations for Further Action'' (69 FR 42287, 42296)).

In response to these requests, FSIS received several comments that described detailed procedures on how to remove the distal ileum from the small intestine. On the basis of these comments, FSIS evaluated this issue and determined that processors have the technology to effectively remove the distal ileum from the rest of the small intestine. Therefore, on September 7, 2005, FSIS issued an amendment to the SRM interim final rule to permit, under specific conditions, the use of beef small intestine, excluding the distal ileum, for human food (70 FR 53043).

In addition to prohibiting SRMs for use as human food, the SRM interim final rule also prohibits the slaughter for human food of non-ambulatory disabled cattle that are offered for slaughter. FSIS prohibited the slaughter of these non-ambulatory disabled cattle because surveillance data from European countries in which BSE has been detected indicate that non-ambulatory cattle are among the cattle that have a greater incidence of BSE than healthy slaughter cattle. Furthermore, because the typical clinical signs of BSE often cannot be distinguished from the typical clinical signs of other diseases and conditions that affect non-ambulatory cattle, FSIS determined that non-ambulatory disabled cattle present a sufficient risk of introducing the BSE agent into the human food supply so as to render the carcasses of these animals unfit for human food under section 1(m)(3) of the FMIA. The SRM interim final rule requires that all non-ambulatory disabled cattle that are offered for slaughter be condemned (9 CFR 309.3(e)).

In addition to the SRM interim final rule, FSIS published two other interim final rules in response to the confirmation of BSE in the cow in Washington State. One of the rules, *Prohibition of the Use of Certain Stunning Devices Used to Immobilize Cattle During Slaughter* (69 FR 1885) (also referred to as ''the air-injection stunning interim final rule''), prohibits the use of captive bolt stunning devices that deliberately inject air into the cranial cavity of cattle. The other rule, ''Meat Produced by Advanced Meat/Bone Separation Machinery and Meat Recovery (AMR) Systems'' (69 FR 1874) (also referred to as ''the AMR interim final rule''), establishes requirements for meat produced using AMR systems. In this document, FSIS is affirming

without amendment the air-injection stunning interim final rule. Because the AMR interim final rule contains several non-BSE related provisions, FSIS intends to affirm and, if necessary, amend that interim final rule in a separate document that will be published in the **Federal Register** at a later date.

Since FSIS issued the SRM, AMR, and air-injection stunning interim final rules, the Agency has implemented a number of programs to train its inspection personnel and help plants comply with new requirements. FSIS has issued several notices to its inspection personnel that detail specific aspects of the regulations, including BSE surveillance activities in cooperation with USDA's Animal and Plant Health Inspection Service (APHIS). In 2004, FSIS held five teaching workshops around the country to help primarily small and very small plants understand the regulations and help ensure compliance. As part of a continuing outreach effort to small and very small plants, FSIS produced workshop training materials, which remain available on the FSIS Web site. Additionally, FSIS developed a training CD and accompanying materials called ''The ABC's of BSE,'' which were released as part of FSIS' distance learning program.

FSIS is confident it is successfully carrying out its mission to protect public health by strictly enforcing safeguards designed to protect Americans from BSE. FSIS will continuously evaluate its policies and procedures to ensure that they remain based on the most up-to-date science available.

Since FSIS issued the interim final rules described above, two native cases of BSE have been confirmed in the United States. In June 2005, the disease was confirmed in a 12 year-old cow born and raised on a ranch in Texas. In March 2006, a second case was confirmed in a cow on a farm in Alabama. Experts confirmed through dentition that this animal was at least 10 years old. Both animals were born before the Food and Drug Administration (FDA) issued its 1997 prohibition on the feeding of most mammalian protein to ruminants.

**Opportunities To Comment**

When it issued the interim final rules described above, FSIS gave the public until April 12, 2004, to submit comments on the rules. The comment period was later extended to May 7, 2004 (69 FR 18245, April 7, 2004). In addition, on July 14, 2004, APHIS, FSIS, and FDA issued an Advance Notice of Proposed Rulemaking (ANPR), ''Federal Measures To Mitigate BSE Risks: Considerations for Further Action,'' (also referred to as ''the APHIS/FSIS/FDA ANPR'') that provided another opportunity for interested parties to comment on certain issues raised in the SRM interim final rule (69 FR 42287). The comment period for the APHIS/FSIS/FDA ANPR closed on September 13, 2004. In addition, when FSIS amended the SRM interim final rule to permit the use of beef small intestine, excluding the distal ileum, for human food, it gave the public until November 7, 2005, to comment on the issues raised in that rulemaking (70 FR 53043).

In developing this final rule to affirm the SRM and air-injection stunning interim final rules, FSIS considered all comments received in response to the documents described above. Based on its continued analysis of the issues, and on information provided by comments, FSIS has made certain changes to the SRM interim final rule. Those changes are summarized below and are discussed in detail in the Agency's responses to comments. As noted above, FSIS is affirming the interim provisions of the air-injection stunning interim final rule without amendment.

**Summary of Amendments to SRM Interim Final Rule**

In this final rule, FSIS is affirming the provisions in the SRM interim final rule and, in addition, is amending the rule to:

- Clarify that non-ambulatory disabled cattle that are offered for slaughter must be condemned but that FSIS inspection personnel will determine on a case-by-case basis the disposition of cattle that become non-ambulatory after they have passed ante-mortem inspection;
- Clarify that veal calves that are unable to rise from a recumbent position because they are tired or cold may be set apart and held for treatment;
- Exclude from the definition of SRMs materials from cattle from countries that can demonstrate that their BSE risk status can reasonably be expected to provide the same level of protection from human exposure to the BSE agent as prohibiting SRMs for use as human food does in the United States;
- Require that the spinal cord from cattle 30 months of age and older be removed from the carcass at the establishment where the animal was slaughtered;
- Clarify that an establishment's procedure for the removal, segregation, and disposition of SRMs must address potential contamination of edible materials with SRMs before, during, and after entry into the official establishment;
- Codify requirements for the sanitation of equipment used to cut through SRMs; and
- Specify the conditions under which slaughter establishments may ship carcasses or parts of carcasses that contain vertebral columns from cattle 30 months of age and older to another federally-inspected establishment for further processing.

**Comments and Responses**

FSIS received approximately 23,000 comments in response to the January 2004 interim final rules, the APHIS/FSIS/FDA ANPR, and the September 2005 amendment to the SRM interim final rule. Among the commenters were dairy farmers, cattle producers, meat processors, importers and exporters of meat products and by-products, members of Congress, representatives of State governments, representatives of foreign governments, organizations that represent livestock producers, organizations that represent meat processors, consumer advocacy organizations, animal welfare advocacy organizations, members of the restaurant industry, members of the academic community, private consultants, and private citizens. Most of the comments were submitted by animal welfare organizations and citizens concerned about the welfare of animals. Approximately 150 comments were submitted by entities other than animal welfare organizations or citizens concerned about the welfare of animals. The following are the issues raised by the comments and FSIS' response.

**Prohibition on the Slaughter of Non-Ambulatory Disabled Cattle**

*Comment:* Most of the comments received in response to the SRM interim final rule supported the prohibition on the slaughter of non-ambulatory disabled cattle for human food. Some of these comments stated that such a prohibition is needed to prevent human exposure to the BSE agent. These comments were from members of the restaurant industry, consumer advocacy organizations, animal welfare organizations, and a private consultant. Most supported the prohibition because, as described in the preamble to the SRM interim final rule, surveillance data from the European Union indicate that cattle that cannot rise from a recumbent position are among the cattle that have a greater incidence of BSE than healthy slaughter cattle. One comment noted that non-ambulatory cattle accounted for over half of the detected BSE cases

in both the European Union and Switzerland in 2003. The comment included references to support this statement.

Many comments also supported the prohibition on the slaughter of non-ambulatory cattle because the typical clinical signs of BSE may not always be observed in a non-ambulatory animal. According to the comments, determining the reason that an animal is non-ambulatory is often extremely difficult, if not impossible, without a full diagnostic work-up. One comment noted that neurological, metabolic, or other diseases that affect coordination and other aspects of gait often predispose an animal to injuries, such as broken limbs or soft tissue damage. The comment stated that if an animal is non-ambulatory because of a broken leg or torn ligament, the injury may be the prominent or sole presenting sign. The comment asserted that, without a complete diagnostic work-up and history of disease progression, the true underlying cause of the non-ambulatory condition may be impossible to ascertain.

This same comment also included a list of clinical signs of BSE from the United Kingdom's Department for Environment, Food, and Rural Affairs (DEFRA) Web site. The comment observed that the vast majority of signs (apprehensiveness; nervousness; reluctance to cross concrete, turn corners, enter yards, go through doorways, or permit milking; occasional kicking when milked; head shyness; high stepping gait, particularly hind legs; difficulties in rising; tremors; loss of condition, weight, or milk yield) would be difficult, if not impossible, to observe in a non-ambulatory animal.

Some comments argued that the previous system of clinical examination of non-ambulatory disabled cattle is not adequate to determine the disposition of cattle with regard to BSE. The comments asserted that when the SRM interim rule was issued, both cases of BSE that had been detected in North America at that point were non-ambulatory cattle that had been observed by veterinarians prior to slaughter, and neither had been identified as a BSE clinical suspect.

One comment stated that although the objective of the prohibition on the slaughter of non-ambulatory disabled cattle for human food is to minimize human exposure to the BSE agent, such a measure may also safeguard against other foodborne diseases, drug residues, and bioterrorism.

Most comments that opposed the prohibition on the slaughter of non-ambulatory disabled cattle asserted that prohibiting the slaughter of all non-ambulatory cattle for human food is overly broad and not necessary to protect the public. These comments were submitted by individual farmers, cattle producers, custom slaughter operations, small meat processors, trade associations that represent cattle producers, trade associations that represent meat processors, and State Departments of Agriculture.

One comment argued that the provisions in the SRM interim final rule associated with non-ambulatory disabled cattle do not take into consideration the basis for the animal's non-ambulatory status or the risk mitigation measures implemented by the U.S. government to prevent the spread of the BSE agent in the U.S. human and cattle populations. Several comments stated that the fact that an animal cannot rise from a recumbent position or walk does not necessarily render its carcass unfit for human food. Some of the comments argued that otherwise healthy cattle that are non-ambulatory solely due to an acute injury, such as a broken leg or torn ligament, are no more likely to test positive for BSE than healthy slaughter cattle. These comments asserted that the carcasses of these cattle pose little risk of exposing humans to the BSE agent.

Some comments stated that Federal and state veterinarians are able to readily discern through ante-mortem or post-mortem inspection whether an animal has suffered an acute injury or is affected with a pathological condition. One comment submitted detailed guidance on establishing the clinical signs consistent with cattle suspected of having BSE. According to the comment, the guidance was developed by veterinarians that have extensive experience dealing with cattle with confirmed BSE. The comment stated that while these veterinarians noted that the clinical signs of BSE are subtle, the document establishes clear and objective guidelines for determining clinical risk factors.

One comment noted that, although the SRM interim final rule cited epidemiological data from the European Union that suggests that animals that generally fit the description of ''non-ambulatory'' are among the animals most likely to test positive for BSE, there remain significant differences among countries concerning the definition of this class of cattle. As an example, the comment provided BSE surveillance data from Switzerland that indicates that there was no difference between the BSE prevalence rate of cattle in the ''sick slaughter'' category and those from the general ''healthy population'' within the Swiss cattle herd in 2002. The comment also noted that the Swiss study cited in the SRM interim final rule that demonstrates an increased likelihood of detecting BSE in targeted testing of fallen stock and emergency-slaughtered animals compared to the general population of healthy animals only looked at cattle over 24 months of age.

Some comments recommended that FSIS limit the prohibition on the slaughter of non-ambulatory disabled cattle to the specific subgroup of cattle that are most likely to present a higher risk of testing positive for BSE. According to the comments, these would be cattle that are 30 months of age and older whose non-ambulatory status cannot be attributed to an acute injury. Many of these comments suggested that FSIS allow non-ambulatory disabled cattle younger than 30 months that are unable to rise or walk due to an acute injury to be used for human food if the animal passes ante-mortem inspection and the carcass passes post-mortem inspection.

In addition to the comments described above, on July 7, 2005, the Humane Society of the United States, Farm Sanctuary, and a private citizen petitioned FSIS to take action to issue a final rule to prohibit the slaughter of non-ambulatory disabled cattle for human food. According to the petition, the confirmation on June 24, 2005, of a second case of BSE in a non-ambulatory animal in the United States demonstrates that the issuance of a final rule to prohibit the slaughter of these animals cannot be delayed any further. The petition asserted that FSIS should promptly issue a permanent ban on the slaughter of non-ambulatory disabled cattle to ensure that the U.S food supply is safe, export markets for beef remain open, and animals are treated in a humane and compassionate manner.

*Response:* After careful consideration of this issue and the comments received in response to the SRM interim final rule, FSIS has decided to affirm the prohibition on the slaughter of non-ambulatory disabled cattle offered for slaughter for human food. As discussed in the preamble to the SRM interim final rule, surveillance data from the European Union indicate that cattle that cannot rise from a recumbent position are among the cattle that have a greater prevalence of BSE than healthy slaughter cattle and the typical clinical signs of BSE may not always be observed when cattle are non-ambulatory.

As noted by some of the comments, the clinical signs of BSE are often subtle, and many typical signs, such as

gait disturbances, can only be observed in an animal that is able to rise from a recumbent position and walk. FSIS agrees that if an animal with clinical BSE is non-ambulatory due to an acute injury, such as a broken leg or torn ligament, the injury may be the prominent or sole presenting sign. Furthermore, the fact that there have been confirmed cases of BSE in North America in non-ambulatory cattle that had been observed by veterinarians prior to slaughter that had not been identified as BSE clinical suspects provides evidence that the underlying reason for an animal's non-ambulatory condition cannot always be accurately ascertained when these animals are presented for slaughter.

As noted by one comment, the non-ambulatory disabled cattle that are more likely to test positive for BSE may differ depending on how a particular country defines this class of animals. However, to minimize the risk that clinical signs of BSE may not be observed in non-ambulatory cattle, FSIS is affirming the SRM interim final rule's definition of non-ambulatory disabled livestock as livestock that cannot rise from a recumbent position or that cannot walk, including, but not limited to, those with broken appendages, severed tendons or ligaments, nerve paralysis, fractured vertebral column, or metabolic conditions.

This final rule affirms the requirement that non-ambulatory disabled cattle offered for slaughter be condemned but also clarifies that FSIS inspection personnel will determine on a case-by-case basis the disposition of cattle that become non-ambulatory after they have passed ante-mortem inspection. This amendment reflects current Agency practice as described in FSIS Notice 5–04, ''Interim Guidance for Non-Ambulatory Disabled Cattle and Age Determination'' (originally issued January 12, 2004, extension of effective date January 17, 2006) and FSIS Notice 05–06, ''Re-Examination of Bovine that become Non-Ambulatory after Passing Ante-Mortem Inspection'' (January 18, 2006)).

FSIS Notices 5–04 and 05–06 instruct FSIS PHVs on the actions they are to take when cattle become non-ambulatory after they have passed ante-mortem inspection. These notices provide that FSIS PHVs are to permit cattle that have passed ante-mortem inspection but that become non-ambulatory prior to slaughter from an acute injury to proceed to slaughter and post-mortem inspection if the PHV can verify that the animal suffered an acute injury. Under FSIS Notice 05–06, PHVs are to tag these cattle as ''U.S. suspects.'' If PHVs cannot verify that an animal that has passed ante-mortem inspection but that becomes non-ambulatory prior to slaughter suffered an acute injury, FSIS Notice 05–06 instructs the PHV to tag the animal as ''U.S. condemned.''

While FSIS agrees that non-ambulatory cattle younger than 30 months are less likely to present a risk of introducing the BSE agent into the human food supply than non-ambulatory disabled cattle that are 30 months of age and older, as explained in the preamble to the SRM interim final rule, although rare, there have been instances in which BSE has been confirmed in cattle younger than 30 months. Thus, FSIS has determined that it is prudent to continue to require the condemnation of cattle that exhibit some type of clinical abnormality that could be consistent with the end stages of BSE, regardless of the age of the animal.

As explained in the final regulatory impact analysis (FRIA) of this final rule, FSIS considered information presented in a recently updated version of the Harvard Risk Assessment (the 2005 model) in making its decision as to which measures are prudent for preventing potential human exposure to the BSE agent. Estimates generated using the 2005 model indicate that removal of SRMs is the most effective measure for preventing human exposure to the BSE agent and that such a measure would reduce, over a 20-year period, human exposure to the BSE agent by 99% from the baseline. The 2005 model also estimates that excluding non-ambulatory cattle from the human food supply would reduce, over a twenty-year period, human exposure to the BSE agent by approximately 3% from the baseline level.

Accordingly, FSIS has decided to affirm the prohibition on the slaughter of non-ambulatory disabled cattle because, as explained above, the typical clinical signs of BSE cannot always be observed in an animal that cannot rise from a recumbent position or walk, and BSE surveillance data from the European Union indicate that non-ambulatory disabled cattle are among the cattle sub-populations that have demonstrated the highest prevalence of BSE in countries where BSE has been identified. As discussed in the preamble to the SRM interim final rule, certain materials from cattle infected with BSE have demonstrated BSE infectivity a few months before the onset of clinical disease. Thus, it is not always possible to identify on ante-mortem inspection those cattle that are approaching the end stages of disease, which is when levels of the BSE agent are the highest. However, the Agency has determined that continuing to require the condemnation of cattle that exhibit some type of clinical abnormality that could be consistent with the end stages of BSE will reduce the potential for materials with infectious levels of the BSE agent to be introduced into the human food supply through the inadvertent contamination of edible tissue with SRMS.

Thus, after considering the available data on BSE and non-ambulatory disabled cattle, FSIS has determined that requiring the condemnation of these animals when they are offered for slaughter continues to be a prudent measure to prevent potential human exposure to the BSE agent.

*Comment:* Many comments argued that the prohibition on the slaughter of non-ambulatory disabled cattle for human food should not apply to non-ambulatory disabled cattle slaughtered or processed in custom operations for the owner's exclusive use if the animal is non-ambulatory as the result of an acute injury. Most of these comments were from farmers and owners of custom slaughter operations. Some of the comments suggested that FSIS allow the owner of the animal to present documentation at the time of slaughter to verify that the animal is non-ambulatory because of an acute injury. The comments suggested that this documentation could include an affidavit from a witness to the injury or from a state or local veterinarian that examined the animal shortly after the injury occurred. One comment suggested that the attending veterinarian for the farm where the animal was injured fill out an ante-mortem inspection form to document the reason for the animal's non-ambulatory condition. To ensure that non-ambulatory disabled cattle are non-ambulatory as the result of a recent injury, some comments suggested that FSIS limit the time that is permitted to elapse between the injury and the slaughter of the animal. One comment suggested that this time be limited to 12 hours.

Some comments stated that prohibiting the owners of non-ambulatory disabled cattle from having these animals slaughtered or processed in custom operations for their personal use will result in the slaughter and processing of non-ambulatory disabled cattle on the farm under insanitary conditions and without proper refrigeration, which will create a greater risk to public health than allowing these animals to be slaughtered or their products prepared in custom operations.

Other comments questioned FSIS' ability to enforce the prohibition on the slaughter of non-ambulatory disabled cattle in custom facilities, given that products produced in these facilities are exempt from the inspection requirements of the FMIA.

Some comments questioned FSIS' legal authority to prohibit the slaughter or processing of non-ambulatory disabled cattle in custom facilities for the personal use of the owner of the animal. Most of these comments were submitted by representatives of State Departments of Agriculture. These comments argued that: (1) The term ''adulterated'' as used in the FMIA only applies to carcasses, parts thereof, meat, and meat food products, and not to live animals that have not received ante-mortem inspection by a government veterinarian; (2) the FMIA exempts the slaughter of livestock and the processing of their carcasses and parts for the personal use of the owner from the inspection requirements of the FMIA; and therefore, (3) animals slaughtered in custom operations cannot be condemned by FSIS because they are not inspected. Some of these comments also asserted that a government prohibition on the slaughter or processing of any animal raised by an individual for his or her own personal use amounts to a seizure of property without just compensation.

*Response:* FSIS has determined that it cannot permit the custom slaughter or preparation of products of non-ambulatory disabled cattle for human food even if it is for the owner's exclusive use because the Agency considers the carcasses of these animals to be adulterated.

As explained in the background section of this document, when it issued the SRM interim final rule, FSIS determined that non-ambulatory disabled cattle present a sufficient risk of introducing the BSE agent into the human food supply so as to render the carcasses of these animals ''unfit for human food'' under section 1(m)(3) of the adulteration provisions of the FMIA. To prevent the use of adulterated carcasses for human food, the SRM interim final rule requires that all non-ambulatory disabled cattle offered for slaughter be condemned on ante-mortem inspection (9 CFR 309.3(e)).

Although the custom slaughter and preparation of products of cattle and other livestock are exempt from inspection under section 23(a) of the FMIA, meat and meat food products prepared in custom operations are still subject to the FMIA's adulteration and misbranding provisions (21 U.S.C. 623(a), 21 U.S.C. 623(d)). Thus, while FSIS inspectors are not present in custom facilities to condemn non-ambulatory disabled cattle that are offered for slaughter, custom operators are effectively prohibited from slaughtering or preparing products of non-ambulatory disabled cattle, because the carcasses of these animals are considered unfit for human food.

Therefore, FSIS not only disagrees with the comments that assert that it lacks the legal authority to prohibit the custom slaughter or preparation of products of non-ambulatory disabled cattle, the Agency has concluded that the FMIA requires that the carcasses of these animals be prohibited for human food regardless of whether the animal is slaughtered in a custom operation for the owner's exclusive use or in an official establishment for distribution in commerce.

As discussed above, while this final rule requires that all non-ambulatory disabled cattle that are offered for slaughter be condemned, it also clarifies that FSIS inspection personnel will determine the disposition of cattle that become non-ambulatory after they have passed ante-mortem inspection on a case-by-case basis (9 CFR 309.3(e)). Thus, as explained above, FSIS PHVs may permit cattle that have passed ante-mortem inspection but that become non-ambulatory because of an acute injury prior to slaughter to proceed to slaughter and post-mortem inspection if the PHV can verify that the animal suffered an acute injury.

As noted above, FSIS inspectors are not present in custom operations to examine cattle that become non-ambulatory after they have been offered for slaughter. However, if an animal becomes non-ambulatory from an acute injury after its owner has delivered it to a custom operation for slaughter, the custom operator may slaughter the animal for human food if both the operator and the owner of the animal did not observe any other clinical abnormalities that could be consistent with BSE before the animal sustained the acute injury.

*Comment:* Some comments suggested that, instead of prohibiting the slaughter of all non-ambulatory disabled cattle, FSIS should require that all non-ambulatory disabled cattle be tested for BSE, and if the test result is negative, the Agency should allow the carcass to be used for human food. The comments noted that FSIS' ''test and hold'' policy, which requires that the carcasses of cattle tested for BSE be retained until the test results are known, would apply. Some comments stated that FSIS should facilitate the testing of non-ambulatory disabled cattle on the farm and use the results to determine the disposition or marketing of the animal.

Other comments agreed with FSIS' conclusion in the SRM interim final rule that, because of limitations in the available testing methods, testing non-ambulatory cattle for BSE would not provide the same level of protection from human exposure to BSE as excluding non-ambulatory disabled cattle from the human food supply.

*Response:* FSIS disagrees with the comments that suggested that it should permit non-ambulatory disabled cattle that test negative for BSE to be slaughtered for human food. As was explained in the preamble to the SRM interim final rule, under the BSE tests that are available today, certain tissues of cattle infected with BSE may contain the BSE agent even though the diagnostic test does not indicate that the animal has the disease. Thus, FSIS has determined that the BSE tests that are available today are not appropriate for use as a food safety measure.

*Comment:* Some comments argued that since SRMs are the only materials in which BSE infectivity has been confirmed, rather than prohibiting the slaughter of non-ambulatory disabled cattle, FSIS should require that all materials that have been designated as SRMs be removed from non-ambulatory disabled cattle regardless of the age of the animal. As stated by the comments, removal of SRMs is the action that has the greatest impact on ensuring that materials that may contain the BSE agent do not enter the human food supply.

*Response:* Although the BSE agent has only been confirmed in certain materials of cattle infected with BSE, unintentional contamination of edible materials with SRMs could potentially occur during slaughter and processing. As noted above, non-ambulatory disabled cattle are among the cattle that are more likely to test positive for the BSE agent than healthy slaughter cattle. Thus, these animals are more likely to be in the end stages of the disease, which is when infective tissues are known to contain the highest levels of the BSE agent. Therefore, FSIS has determined that requiring the condemnation of cattle that exhibit some type of clinical abnormality that could be consistent with BSE will reduce the potential for materials with infectious levels of the BSE agent to be introduced into the human food supply through the inadvertent contamination of edible tissue with SRMs.

*Comment:* Some comments stated that the prohibition on the slaughter of non-ambulatory disabled cattle will hamper USDA's surveillance testing for BSE by

removing access to these animals at slaughter establishments.

*Response:* Experience with APHIS' testing for BSE has demonstrated that this has not been the case. Surveillance for BSE in the United States has always targeted those cattle populations where the disease is most likely to be found. The goal of APHIS' enhanced BSE surveillance program, which began on June 1, 2004, was a one-time effort designed to give a snapshot of the cattle population in the United States and to help define whether BSE is present in the cattle population and, if so, at what level. The program tested as many animals in the targeted population as possible over a 12- to 18-month period. Although there have been fewer non-ambulatory disabled cattle available for testing at official slaughter establishments since FSIS issued the SRM interim final rule, APHIS has increased the number of samples collected from non-ambulatory and other high-risk cattle at farms, slaughter facilities, rendering facilities, livestock auctions, veterinary clinics, and public health laboratories.

As discussed in more detail below, based on the information obtained through both the enhanced surveillance program and the BSE surveillance conducted by the United States in the 5 years before the enhanced surveillance program was implemented, USDA has concluded that the prevalence of BSE in the United States is extremely low. Therefore, in July 2006, USDA's APHIS announced that it would begin transitioning its enhanced BSE surveillance program to an ongoing surveillance program (*http://www.aphis.usda.gov/newsroom/hot_issues/bse/downloads/BSE_ongoing_surv_plan_final_71406%20.pdf*). APHIS' ongoing BSE surveillance program, which samples approximately 40,000 animals each year, continues to sample the cattle populations where the disease is most likely to be found. The targeted population for APHIS' ongoing surveillance includes cattle exhibiting signs of CNS disorders or any other signs that may be associated with BSE, including emaciation or injury, and dead cattle, as well as non-ambulatory cattle. Samples from the targeted population are being taken from the same locations as those used during the enhanced surveillance program.

*Comment:* A few comments requested that FSIS clarify that the prohibition on the slaughter of non-ambulatory disabled cattle does not apply to veal calves that are unable to stand on arrival at the slaughter establishment because they are tired or cold. The comments stated that FSIS should allow the establishment to rest these animals or warm them up prior to ante-mortem inspection. Other comments stated that cattle that have become non-ambulatory for reasons related to stress or fatigue, and have no other clinical signs associated with BSE, should be given the opportunity to recover from the fatigue to determine if they can become ambulatory.

*Response:* The prohibition on the slaughter of non-ambulatory disabled cattle applies to all cattle that are offered for slaughter, including veal calves. However, the regulations that prescribe requirements for the disposition of condemned livestock permit livestock condemned on account of certain conditions to be set apart and held for treatment (9 CFR 309.13 (b)). These animals are permitted to proceed through normal slaughter procedures if, following treatment, FSIS inspection personnel find that the condition that required condemnation has resolved.

Since it issued the SRM interim final rule, FSIS has permitted veal calves that cannot stand because they are tired or cold to be set aside for treatment. In this final rule, FSIS is revising 9 CFR 309.13 to clarify that this is an accepted practice. The regulations that prescribe requirements for the disposition of condemned livestock also permit condemned livestock to be released for a purpose other than slaughter if permission is obtained by the local, State, or Federal official that has jurisdiction over the movement of the animal (9 CFR 309.13). Thus, cattle and calves that are unable to stand when they arrive at slaughter may, if permission is obtained, be released from the establishment for treatment.

*Comment:* Several comments from cattle farmers and ranchers asserted that the prohibition on the slaughter of non-ambulatory disabled cattle has placed a serious economic burden on livestock owners. Many of these comments, particularly those from dairy farmers, stated that prior to the implementation of the new regulations, when a healthy cow suffered an acute injury, farmers were able to send the animal to slaughter and receive compensation for it. According to the comments, as a result of the rule, livestock owners must not only incur a loss when a healthy animal becomes non-ambulatory, but also incur costs associated with destroying the animal and disposing of its carcass.

Several comments from small meat processors and custom operations said that the prohibition on the slaughter of non-ambulatory disabled cattle places a serious economic burden on them. These comments stated that because they do not slaughter or process a large number of animals, they stand to lose a significant source of revenue, and some stated that a prohibition on the slaughter of non-ambulatory disabled cattle will cause them to go out of business.

*Response:* FSIS acknowledges that prohibiting the slaughter of all non-ambulatory disabled cattle offered for slaughter has certain economic effects on farmers, small meat processors, and custom operators. However, as discussed above, the carcasses of non-ambulatory disabled cattle offered for slaughter are adulterated and as such cannot be used for human food. The final regulatory impact analysis section of this document contains a more complete description of the economic impact of prohibiting the slaughter of non-ambulatory disabled cattle for human food.

**Materials Designated as SRMs**

*Comment:* Several comments concurred with the list of materials that FSIS designated as SRMs. Some comments indicated that removal of these materials is supported by the Harvard Risk Assessment.

One comment stated that the 30-month cut-off for exclusion of SRMs provides very strong protection of human health, given that fewer than 0.01% of BSE cases have been recorded in cattle under 30 months of age. The comment also said that in regions such as North America, where BSE is very rare, and where measures to prevent its spread have been in place for a number of years, it is improbable that cattle will be exposed to high doses of the BSE agent. Therefore, the commenter postulates that short incubation periods are unlikely in the United States, which makes a 30-month age cut-off for SRMs adequate and reasonable.

*Response:* FSIS agrees that the current scientific understanding supports these comments. As explained in more detail below, FSIS is affirming the 30-month age and older classification for certain SRMS.

*Comment:* Some comments stated that the materials designated as SRMs if they are from cattle 30 months of age and older should be considered SRMs if they are from cattle 12 months of age and older. The comments asserted that the pathogenesis of BSE is not clearly understood, and that there is still scientific uncertainty regarding when during the incubation period infectivity occurs. The comments noted that cattle as young as 21 months have tested positive for BSE in both Japan and the United Kingdom.

Some of the comments also noted that the post-mortem tests that are available today are only capable of identifying the presence of the BSE agent near the end of the incubation period. As stated by the comments, cattle younger than 30 months of age in the early stages of BSE that do not test positive for the disease may still be harboring the BSE agent.

Some comments argued that permitting the brain or spinal cord from cattle of any age for human food carries an unjustifiable risk of exposing humans to the BSE agent. These comments suggested that FSIS prohibit brain and spinal cord from all cattle for human food.

*Response:* In the SRM interim final rule, FSIS designated all materials that have demonstrated BSE infectivity as SRMs, regardless of the level or proportion of infectivity contained in each tissue. However, because BSE infectivity has only been confirmed in certain tissues when cattle are approaching the end of the disease incubation period, or after cattle have developed overt clinical disease, FSIS designated some tissues as SRMs only if they are from cattle 30 months of age and older. As discussed in detail in the preamble to the SRM interim final rule and in the APHIS/FSIS/FDA ANPR, the Agency has determined that a 30-month-and-older age classification for certain SRMs is reasonable because BSE surveillance data from European countries demonstrate that cattle younger than 30 months are unlikely to be in the later stages of BSE and, thus, are unlikely to contain high levels of BSE infectivity. Materials that have demonstrated infectivity in the early stages of disease are SRMs regardless of the age of the animal. In addition, prevalence estimates from USDA's APHIS enhanced BSE surveillance program also support the 30 month-and-older age classification for certain SRMs. BSE surveillance data from the European Union and the United States are discussed below.

FSIS is aware of the cases of BSE in animals 21 and 23 months of age reported by Japan mentioned by the comments. FSIS took comment on the significance of these cases. The response to those comments is provided later in the preamble to this final rule. In short, a report issued by the European Food Safety Authority (EFSA), Scientific Panel on Biological Hazards, states that ''it is unclear whether the very young cases [reported in Japan] were adequately identified and formally confirmed.'' [1]

*BSE surveillance in the European Union.* As discussed in the preamble to the SRM interim final rule and the APHIS/FSIS/FDA ANPR, although rare, BSE has been confirmed in cattle younger than 30 months. As explained in those documents, the occurrence of BSE in young animals is most likely the result of exposure to a high infective dose of the BSE agent at a young age.

BSE surveillance data from the European Union indicate that most cases of BSE detected in animals younger than 30 months involve cattle that were most likely exposed to the BSE agent at a time when their countries-of-origin had significant levels of circulating BSE infectivity. As the level of BSE disease in the European Union has decreased, so has the number of confirmed cases in cattle younger than 30 months.[2] This most likely reflects a reduction in the amount of circulating BSE infectivity that occurred after full implementation by most E.U. countries of measures to prevent the spread of BSE.

These analyses of BSE surveillance data from the European Union indicate that when disease prevalence is low, and effective measures for preventing the spread of BSE are in place, it is unlikely that there will be a sufficient amount of circulating BSE infectivity to result in clinical cases in young animals.

*BSE surveillance in the United States.* As discussed below, analysis of USDA's APHIS BSE surveillance testing program has led FSIS to conclude that the BSE prevalence in the United States is extremely low. Based on the low estimated prevalence of BSE in the United States, FSIS has determined that U.S. cattle younger than 30 months are unlikely to contain high levels of the BSE agent and that a 30-month-and-older age classification for certain SRMs remains appropriate for the United States.

USDA's APHIS has conducted surveillance for BSE disease since 1990. Surveillance has always targeted those cattle populations where the disease is most likely to be found. The level of surveillance in the United States has increased steadily from 1990 and jumped significantly in 2004 when USDA implemented enhanced surveillance following the detection of BSE in an imported cow in December 2003.

As stated above, the goal of USDA's enhanced BSE surveillance program, which began on June 1, 2004, was to test as many animals in the targeted population as possible over a 12- to 18-month period. This program was designed to provide a snapshot of the domestic cattle population to help define whether BSE is present in the United States and, if so, at what level.

Based on the information gained during both the enhanced surveillance program and the BSE surveillance conducted in the United States in the five years before the enhanced surveillance program was implemented, APHIS recently concluded that the prevalence of the disease in this country is extremely low, less than one case per million adult cattle. Two models were used to estimate the prevalence, and the most likely values calculated by these models estimate that the number of cases is between 4 and 7 infected animals out of 42 million adult cattle.[3] APHIS' analysis was submitted to the scrutiny of a peer review process, and the expert panel agreed with the appropriateness of APHIS' assumptions and the factors it considered, as well as with the estimate of BSE prevalence. APHIS has transitioned into an ongoing BSE surveillance program designed to test a targeted sample of approximately 40,000 targeted animals each year, a level consistent with international animal health standards.[4]

*Comment:* Some commenters indicated that expanding the list of SRMs to include materials from cattle 12 months of age and older is consistent with recommendations made in a report by an international expert BSE panel (the International Review Team or IRT) that was convened at the request of the

[1] The EFSA Journal 2005 220, 1–21, Annex to the Opinion, Report of the Working Group on the assessment of the age limit in cattle for the removal of certain specified risk materials (SRM) (see 1.2.3. Age distribution of young BSE cases outside the EU, p. 11). Available on the Internet at: *http://www.efsa.eu.int/science/biohaz/biohaz_opinions/opinion_annexes/933/biohaz_report_ej220_srmremove_en1.pdf.*

[2] European Commission (EC), 2005; Report on the monitoring and testing of ruminants for the presence of transmissible spongiform encephalopathy (TSE) in 2004, European Commission Health and Consumer Protection Directorate-General; European Commission (EC), 2004; Report on the monitoring and testing of ruminants for the presence of transmissible spongiform encephalopathy (TSE) in 2003, European Commission Health and Consumer Protection Directorate-General; European Commission (EC), 2003; Report on the monitoring and testing of ruminants for the presence of transmissible spongiform encephalopathy (TSE) in 2002, European Commission Health and Consumer Protection Directorate-General (*http://europa.eu.int/comm/food/food/biosafety/bse/mthly_reps_en.htm).*

[3] ''An Estimate of the Prevalence of BSE in the United States,'' Animal and Plant Health Inspection Service, USDA, July 20, 2006. Available on the Internet at: *http://www.aphis.usda.gov/peer_review/content/printable_version/BSE_Prevalance_scientific_doc_after.pdf.*

[4] OIE Terrestrial Animal Health Code 2006, Appendix 3.8.4, Surveillance for Bovine Spongiform Encephalopathy.

Secretary of Agriculture to review actions taken by the United States in response to a single finding of BSE. The commenters noted that the IRT report recommended that the brain, skull, spinal cord, and vertebral column of all cattle over 12 months be excluded from both the human food and animal food chains unless aggressive surveillance proves the BSE risk in the USA to be minimal according to [former] standards of the World Organization for Animal Health (the OIE). [5]

*Response:* As noted by the commenters, the IRT report did recommend that the brain, skull, spinal cord, and vertebral column of all cattle over 12 months be excluded from both the human food and animal food chains unless aggressive surveillance indicates otherwise. However, as discussed above, USDA's APHIS has conducted the aggressive surveillance recommended by the IRT, and the extremely low prevalence estimates, in conjunction with the E.U. experience, provide evidence that a 30-month-and-older age classification for certain SRMs is a prudent measure for preventing human exposure to the BSE agent in the United States. The 30-month-and-older age classification for SRMs that have demonstrated BSE infectivity in the end stages of the disease incubation is accepted internationally in BSE standards set by various countries and is consistent with OIE recommendations.

In addition, FSIS' regulations contain measures that reduce the potential for cattle younger than 30 months to introduce the BSE agent into the human food supply. Under 9 CFR 309.4 of the ante-mortem inspection regulations, all livestock with signs of a neurological disease must be condemned. Thus, the regulations prohibit the slaughter of those cattle younger than 30 months having any characteristics consistent with the end stages of BSE, i.e., those with clinical signs consistent with the disease. Furthermore, the prohibition on the slaughter of non-ambulatory disabled cattle, which FSIS is affirming in this document, ensures that non-ambulatory cattle younger than 30 months that may have clinical signs consistent with BSE that are difficult to observe do not enter the human food supply. Thus, the regulations require the condemnation of all cattle that exhibit some type of clinical abnormality that could be consistent with the end stages of BSE, regardless of the age of the animal.

*Comment:* One comment noted that a recently published study suggests that there may be another form of transmissible spongiform encephalopathy in cattle, referred to as bovine amyloidotic spongiform encephalopathy (BASE). According to the comment, given the possibility of an additional strain of BSE, together with the continued lack of scientific understanding concerning the pathogenesis of the disease, FSIS must minimize human exposure to all animal materials that could potentially harbor the BSE agent. The comment argued that as long as there is uncertainty, SRMs from cattle over 12 months of age should be excluded from both the human and animal food chain.

*Response:* There is very little data on the BASE strain of BSE described by the comment. The data that are available do not indicate that cattle with this form of BSE are more likely to contain high levels of the infective agent early in the incubation period than cattle with the ''typical'' BSE strain. Further study on the BASE form of BSE is needed to determine its significance.

*Comment:* One comment stated that a ban on SRMs regardless of the age of the animal would significantly improve enforcement of the regulations and would eliminate the need to determine the age of each animal offered for slaughter. Another comment said that the only plausible explanation for not prohibiting SRMs from cattle of all ages is an implicit cost/benefit analysis. According to the comment, the FMIA does not allow the Agency to rely on a cost/benefit analysis. It requires that the Agency remove all adulterated materials from the market.

*Response:* FSIS disagrees with these comments. With regard to the comment that stated that the FMIA requires that the Agency remove all adulterated materials from the market without consideration of costs or benefits, the SRM interim final rule does require that all adulterated materials be excluded from the human food supply. Under the SRM interim final rule, certain materials are only considered adulterated if they are from cattle 30 months of age and older.

FSIS disagrees that prohibiting materials designated as SRMs for human food regardless of the age of the animal is needed to improve enforcement of the regulations, as was suggested by one of the comments. Under the regulations, establishments must develop, implement, and maintain written procedures to ensure that SRMs are completely removed from the carcass, segregated from edible materials, and disposed of as inedible. FSIS is responsible for ensuring that the establishment's procedures are adequate and effective, and is responsible for taking appropriate action if they are not. As discussed in more detail later in this document, the Agency has developed effective procedures for verifying the age of cattle offered for slaughter.

*Comment:* One comment noted that in its 2002 ''Current Thinking Paper'' on BSE, FSIS identified prohibiting the brain and spinal cords from cattle 24 months of age and older for human food, and prohibiting the vertebral column from cattle 24 months of age and older as a source material in mechanical meat recovery systems, as measures that the Agency was considering implementing to minimize potential human exposure to the BSE agent. The comment stated that FSIS must offer some justification as to why the Agency determined that a 30-month age cut-off for SRMs is appropriate in preventing potential human exposure to the BSE agent when it had previously stated that a 24-month age cut-off was necessary to protect public health.

Another comment stated that Germany, Italy, and France test all cattle older than 24 month of age that are slaughtered for human food for BSE. According to the comment, this suggests that these countries have concluded that there is a significant risk that cattle between 24 and 30 months of age may transmit the BSE agent to humans.

*Response:* FSIS made its ''current thinking paper'' on BSE available to the public January 17, 2002. The 24-month age cut-off for SRMs as described in that document was based on the best information available at the time and was intended to address the fact that, in rare instances, BSE had been confirmed in cattle younger than 30 months in the European Union.[6]

However, the E.U. BSE surveillance data that were available at the time that FSIS issued the paper were limited because they generally reflected cases detected by means of traditional passive surveillance.[7] In January 2001, the European Union implemented more systematic testing for BSE, which has increased the number of BSE cases detected. Thus, more complete

[5] The OIE guidelines no longer provide for a minimal BSE risk category. Since the IRT issued its report, the OIE has revised its BSE risk categories. OIE now has three BSE risk categories instead of five: negligible risk, controlled risk, and undetermined risk.

[6] Food Safety and Inspection Service (FSIS): Current Thinking On Measures That Could Be Implemented To Minimize Human Exposure To Materials That Could Potentially Contain the Bovine Spongiform Encephalopathy Agent, January 15, 2002 (see page 8). Available on the Internet at *http://www.fsis.usda.gov/oa/topics/bse_thinking.htm.*

[7] Frequently asked questions about BSE. 6 April 2001. Europa Web site: *http://europa.eu.int/comm/food/fs/bse/bse20_en.html.*

information on the age distribution of confirmed BSE cases has become available since FSIS issued its current thinking paper.

The E.U. BSE surveillance data that are available today indicate that BSE is unlikely to be confirmed in animals younger than 30 months in the European Union, which, as explained above, most likely reflects a reduction in the amount of circulating BSE infectivity that occurred after full implementation by most E.U. countries of measures to prevent the spread of BSE. For example, in E.U. BSE surveillance testing conducted in 2002, 2003, and 2004, none of the 4,355 animals that tested positive for BSE were younger than 30 months.[8] A total of 31,514,999 BSE tests were conducted in those years. In addition, as discussed above, the extremely low BSE prevalence estimates obtained from APHIS' analysis of its BSE surveillance data reinforce the conclusion that a 30-month-and-older age classification for certain SRMs is a prudent measure for preventing human exposure to the BSE agent as opposed to the 24-month age cut-off that the Agency was contemplating when it issued its current thinking paper.

As noted by one comment, Germany, Italy, and France require that cattle older than 24 months be tested for BSE if they are slaughtered for human food. However, testing for BSE conducted in these countries from 2001 through 2004 has detected only two animals younger than 30 months of age, and both were detected in 2001.[9] Of note is that these animals were 28 and 29 months of age. Furthermore, measures implemented by other European countries appear to recognize that cattle older than 30 months present the greatest risk of introducing the BSE agent into the human food supply. Under the E.U. regulations, cattle over 30 months of age must be tested for BSE if they are slaughtered for human food.[10] In addition, since 1996, the United Kingdom has prohibited the slaughter of cattle over 30 months of age for human food. This prohibition was recently replaced with a program that permits cattle over 30 months to be used for human food if these animals test negative for BSE (except for cattle born before August 1, 1996).[11] In the United Kingdom and the rest of the European Union, SRMs must still be removed from animals that test negative for BSE.

*Comment:* A few comments stated that FSIS should designate bone marrow as an SRM even though pathogenesis studies have not conclusively demonstrated that bone marrow contains BSE infectivity. The comments stated that FSIS should not wait for a ''conclusive'' study to take action to prevent human exposure to a potential source of BSE infectivity. One comment stated that the FMIA mandates a precautionary approach that does not require conclusive demonstration that a meat food product will cause adverse health effects.

*Response:* FSIS has reviewed the available research with regard to BSE infectivity in bone marrow and has determined that it does not support designating bone marrow as an SRM.

As noted in the preamble to the SRM interim final rule, in pathogenesis studies conducted in the United Kingdom, bone marrow from one set of cattle demonstrated BSE infectivity 38 months post oral exposure to the BSE agent.[12] However, because bone marrow from cattle sacrificed at earlier (32 and 36 months) and later (40 months) intervals post exposure to the BSE agent did not demonstrate infectivity, these findings are considered inconclusive. The infectivity at 38 months was detected through use of a mouse bioassay and occurred after the cattle had developed clinical signs of disease.

BSE infectivity in bone marrow has also been tested using a more sensitive cattle bioassay. In November 2003, the U.K. Spongiform Encephalopathy Advisory Committee (SEAC) reported that in the cattle bioassay, no infectivity had been reported in bone marrow of cattle up to 55–56 months post exposure to the BSE agent.[13] SEAC concluded that research from the cattle bioassay indicate that the level of infectivity in the bone marrow is at most very low, and that the single positive finding from the mouse bioassay may be an experimental artifact but cannot be discounted.

On the basis of the information on BSE infectivity in bone marrow that is described above, FSIS has concluded that there is insufficient evidence to indicate that bone marrow should be designated as an SRM. FSIS will continue to follow the research with regard to BSE infectivity in bone marrow. However, even if there is weak infectivity in the bone marrow of cattle, it likely presents little risk of exposing humans to the BSE agent because FSIS requires condemnation of the cattle most likely to contain infectivity, i.e., those with clinical signs of disease and non-ambulatory animals.

*Comment:* Some comments suggested that FSIS prohibit organs in close proximity to SRMs, such as the dura mater, hypophysis, pineal gland, and cerebrospinal fluid, for human food. One comment noted that the dura was harvested but not tested in pathogenesis studies conducted in the United Kingdom. According to the comment, the dura's close association with the brain and spinal cord, along with the documented evidence of its role in the human-to-human transmission of CJD, has prompted scientists to designate bovine dura as a high-risk tissue. The comment also noted that if the dura is not removed and disposed of as inedible prior to processing, it may come loose and be incorporated into ground product or contaminate surfaces where de-boning occurs.

*Response:* FSIS agrees that, because of their close association to the CNS, the dura mater and CSF from cattle 30 months of age and older could potentially come in contact with SRMs; contamination could result from such contact if the animal had BSE. While the dura and CSF are not designated as SRMs, establishments are required to address the potential for edible products to become contaminated with SRMs in their procedures for the removal, segregation, and disposition of SRMS.

[8] European Commission (EC), 2005; Report on the monitoring and testing of ruminants for the presence of transmissible spongiform encephalopathy (TSE) in 2004, European Commission Health and Consumer Protection Directorate-General; European Commission (EC), 2004; Report on the monitoring and testing of ruminants for the presence of transmissible spongiform encephalopathy (TSE) in 2003, European Commission Health and Consumer Protection Directorate-General; European Commission (EC), 2003; Report on the monitoring and testing of ruminants for the presence of transmissible spongiform encephalopathy (TSE) in 2002, European Commission Health and Consumer Protection Directorate-General (*http://europa.eu.int/comm/food/food/biosafety/bse/mthly_reps_en.htm).*

[9] European Commission (EC), 2002; Report on the monitoring and testing of ruminants for the presence of transmissible spongiform encephalopathy (TSE) in 2001, European Commission Health and Consumer Protection Directorate-General (*http://europa.eu.int/comm/food/food/biosafety/bse/mthly_reps_bse2001_en.htm).*

[10] Commission Regulation (EC) No 1248/2001 of 22 June 2001 amending Regulation (EC) No 999/2001 of the European Parliament and of the Council as regards epidemio-surveillance and testing of transmissible spongiform encephalopathies.

[11] United Kingdom, Department for Environment Food and Regulatory Affairs (DEFRA) Web site at *http://www.defra.gov.uk/animalh/bse/otm/index.html* (accessed November 2005).

[12] Wells GA, Hawkins DA, Green RB, Spencer YI, Dexter I, Dawson M. 1999, Limited detection of sternal bone marrow infectivity in the clinical phase of experimental Bovine Spongiform Encephalopathy (BSE). Vet Rec. Mar 13: 144 (11): 292–4.

[13] Eightieth Meeting of the Spongiform Encephalopathy Advisory Committee Meeting, November 2003. Available on the Internet at: *www.seac.gov.uk/minutes/final80.pdf.*

Anatomically, the hypophysis and pineal gland are part of the brain and thus must be removed from the carcass when the brain is removed.

*Comment:* A few comments suggested that FSIS designate bovine spleen and pancreas as SRMs.

*Response:* Neither the spleen nor pancreas from cattle has demonstrated BSE infectivity, nor are they closely associated with any materials that have been designated as SRMs. Therefore, the spleen and pancreas from cattle are not SRMs.

*Comment:* One comment stated that FSIS should designate the entire head from cattle 30 months of age and older as SRM and require that the cheek and head meat of cattle 12 months of age and older be removed before the skull is fragmented or split.

*Response:* The SRM interim final rule designates potentially infective materials, as well as certain materials that are closely associated with potentially infective materials, from cattle 30 months of age and older as SRMs. Furthermore, under the SRM interim final rule, establishments are required to address contamination of all edible materials, which would include head meat, with SRMs in their procedures for the removal, segregation, and disposition of SRMs. Therefore, FSIS has concluded that it is not necessary to designate the entire head from cattle 30 months of age and older as an SRM.

None of the materials located in the head of cattle younger than 30 months of age are considered SRMs. Therefore, FSIS does not believe that it is necessary to prescribe procedures for the removal of head meat from cattle younger than 30 months in order to minimize potential human exposure to the BSE agent.

*Comment:* One comment stated that FSIS must better articulate its rationale for excluding other areas of the carcass from the list of SRMs. According to the comment, there is scientific evidence to indicate that the BSE agent is not confined to the brain and spinal cords of cattle, and that it can be found in several other compartments and extra-CNS spinal nerve centers. The comment criticized FSIS for not including a discussion on whether peripheral nerves coursing throughout the carcass may potentially contain BSE infectivity.

*Response:* As discussed in the preamble to the SRM interim final rule, available data on the development and distribution of tissue infectivity in BSE-infected cattle are incomplete, and most of what is known comes from the pathogenesis studies conducted in the United Kingdom (69 FR 1862, 1864, January 12, 2004). When it issued the SRM interim final rule, FSIS noted that while the results of the pathogenesis 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, these studies did not determine the rate at which the BSE agent increases in the tissues that have demonstrated infectivity or identify the tissues that the BSE agent must pass through to reach its ultimate destination. Of the peripheral nervous tissues tested in the pathogenesis studies, only the DRG and trigeminal ganglia demonstrated infectivity, which occurred late in the disease incubation and in cattle with clinical disease.

After FSIS issued the SRM interim final rule, a study in which highly BSE-susceptible transgenic mice challenged with a variety of tissue samples from a clinically diseased cow was published.[14] Of the tissues sampled in this study, infectivity was confirmed in the CNS, as well as in the optic nerve and the retina. In addition, samples of the facial and sciatic nerve of the peripheral nervous system (PNS) also demonstrated infectivity, although at lower levels than the CNS tissues. The study also tested tissue samples from the radial nerve of the PNS and reported no demonstrated infectivity at the time of publication.

While both the U.K. pathogenesis study and the study involving the highly BSE-susceptible transgenic mouse bioassay described above demonstrate that BSE infectivity may occur in certain PNS tissues of cattle in the end stages of BSE disease, FSIS has determined that these studies do not provide conclusive evidence that peripheral nerves coursing throughout the carcass contain BSE infectivity. In both studies, the PNS tissues that demonstrated BSE infectivity were closely associated with the CNS, and infectivity was only detected in these tissues late in the disease incubation, or when cattle had overt clinical disease. While FSIS acknowledges that these findings do not exclude the possibility that other parts of the PNS may contain infectivity at some point in the course of BSE disease, the Agency believes that the fact that infectivity has only been confirmed in PNS tissues that are closely associated with the CNS indicates that if BSE infectivity does occur in other parts of the PNS, it is most likely at low or undetectable levels.

Thus, based on the available research, FSIS believes that the primary tissues of concern for spreading the BSE agent have been identified. FSIS will continue to follow the results of future studies on BSE to further refine this determination and inform its policies with regard to BSE.

*Comment:* Several comments requested that FSIS continue to designate the spinal cord and DRG from cattle 30 months of age and older as SRMs but remove the vertebral column from the list of materials designated as SRMs. The comments stated that designation of vertebral column as SRM because of its proximity to the DRG is not scientifically justifiable. The comments asserted that technologies can be developed to effectively remove DRG without requiring removal of the vertebral column. One comment stated that the regulatory intent of designating the vertebral column as SRM can be achieved by designating spinal cord and DRG as SRMs and adding the following sentence: ''Unless the establishment can demonstrate through scientific methods that the spinal cord and DRG have been completely removed, the entire vertebral column (excluding the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae, and the wings of the sacrum) shall be removed.''

*Response:* While the comments submitted on this issue suggested that technologies can be developed to remove the DRG without requiring removal of certain parts of the vertebral column, they did not provide any evidence to demonstrate that such technologies exist or how establishments would accomplish removal of DRG without removing sections of the vertebral column. Therefore, under this final rule, the vertebral column (excluding the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae, and the wings of the sacrum) from cattle 30 months of age and older is among the materials designated as SRM. The Agency will reconsider this issue if this technology becomes available.

*Comment:* Some comments stated that vertebral bones should not be SRMs if they are part of a bone-in cut of meat. According to one comment, establishments should already have or, if they do not, could easily implement procedures for the thorough removal of the spinal cord and sheath from the vertebral column. The comment stated that the remaining DRG are contained within the vertebral bones and as such are not likely to be consumed by

[14] Buschmann, A, Groschup, MH. Highly Bovine Spongiform Encephalopahty-Sensitive Transgenic Mice Confirm the Essential Restriction of Infectivity to the Nervous System in Clinically Diseased Cattle. Journal of Infectious Disease, 2005; 192:934–42.

humans unless they are processed using AMR technology. As noted by the comment, another regulation issued by FSIS, i.e., the AMR interim final rule, prohibits the use of vertebral columns from cattle 30 months of age and older in the production of AMR product. The comment stated that allowing vertebral bones from cattle 30 months of age and older to remain in traditional cuts, like T-bone steaks, will not result in any increased risk of consumer exposure to the BSE agent.

Some comments stated that requiring the removal of the vertebral column from cattle 30 months of age and older imposes costs on farmers and small processors and has raised consumer satisfaction issues. One comment noted that the United Kingdom lifted its ban on bone-in beef because scientists concluded that the potential risk of human exposure to the BSE agent from bone-in beef was insignificant.

*Response:* FSIS disagrees that vertebral bones should not be SRMs if they are part of a bone-in cut of meat. As noted by the comments, most establishments have the technology to completely remove the spinal cord from the vertebral column, but FSIS is not aware of any that have the technology to remove the DRG without removing parts of the vertebral column.

Although the DRG are located within the vertebral bones, FSIS has determined that because they could potentially become dislodged during consumption of bone-in beef products, the DRG from cattle 30 months of age and older are still a potential source of human exposure to the BSE agent. An updated risk assessment conducted for USDA by the Harvard Center for Risk Analysis (the 2005 Harvard model) determined that consumption of bone-in-beef could account for 23% of the total potential human exposure to the BSE agent on average (based on the conditions as they existed in 2003 and assuming the introduction of 10 infected cows).[15] The 2005 Harvard BSE Update assumes that the total infectivity in bone-in-beef is the sum of the contribution of spinal cord contained in these cuts of meat and the DRG attached to the bones.

With regard to the comment that the United Kingdom has lifted its bone-in-beef ban, the United Kingdom does not permit for use as human food bone-in-beef derived from parts of the vertebral column that have been designated as SRMs. The vertebral column (excluding the vertebrae of the tail, the spinous and transverse processes of the cervical, thoracic and lumbar vertebrae and the median sacral crest, the wings of the sacrum, but including the DRG) from cattle over 24 months is considered an SRM in the United Kingdom.[16]

*Comment:* Comments submitted on whether FSIS should require that the entire small intestine be removed to ensure effective removal of the distal ileum were addressed in the amendment to the SRM interim final rule issued on September 7, 2005 (70 FR 53043). FSIS received seven comments in response to the amended interim final rule. Most were supportive of the Agency's decision to permit the use of beef small intestine, excluding the distal ileum, for human food. Some asserted that FSIS only considered comments submitted by the casing and meat processing industry.

*Response:* FSIS in fact carefully considered all comments on removal of the distal ileum that were submitted in response to the SRM interim final rule and the APHIS/FSIS/FDA ANPR and addressed the issues raised by the comments in the September 7, 2005 amendment to the SRM interim final rule (see 70 FR 53043).

*Comment:* Since FSIS issued the amendment to the SRM interim final rule that permits, under certain conditions, beef small intestine, excluding the distal ileum, for use as human food, establishments interested in harvesting the small intestine for human food have requested that the Agency clarify whether procedures that involve removal of the small intestine without uncoiling it comply with the requirements of the rule if the establishment can verify that, when it is uncoiled, the part of the small intestine that is not harvested for human food measures at least 80 inches from where the distal ileum attaches to the cecum.

*Response:* 9 CFR 310.22(a)(3)(ii) of the amended SRM interim final rule provides that the small intestine may be used for human food if the distal ileum is removed by a procedure that removes at least 80 inches of the uncoiled and trimmed small intestine as measured from the ceco-colic junction and progressing proximally towards the jejunum or by a procedure that the establishment demonstrates is effective in ensuring complete removal of the distal ileum. Procedures in which the small intestine is harvested without uncoiling it are likely to comply with 9 CFR 310.22(a)(3)(ii) if the establishment can verify that when it is uncoiled, the portion of the intestine that was not harvested for human food measures at least 80 inches from the ceco-colic junction progressing proximally towards the jejunum.

**Requirements for the Removal, Segregation, and Disposition of SRMs**

*Comment:* Some comments stated that FSIS should prescribe specific procedures for the removal, segregation, and disposition of SRMs rather than rely on private industry to implement appropriate procedures that will best achieve the requirements of the interim final rule. One comment stated that in the interim final rule, FSIS did not specify who would approve the procedures for the removal, segregation, and disposition of SRMs in the establishment's HACCP plan or Sanitation SOP.

*Response:* As noted in the preamble to the SRM interim final rule, FSIS did not prescribe specific procedures for the removal, segregation, and disposition of SRMs because the Agency believes that establishments should have the flexibility to implement the most appropriate procedures that will best achieve the requirements of the rule. The regulations recognize that procedures that are appropriate for some establishments to ensure that SRMs are completely removed from the carcass, segregated from edible materials, and disposed of as inedible may not be effective when used in other establishments. Therefore, FSIS disagrees that it should prescribe specific procedures for the removal, segregation, and disposition of SRMs.

While FSIS does not approve an establishment's procedures for the removal, segregation, and disposition of SRMs, the Agency is responsible for ensuring that these procedures are adequate and effective. If FSIS inspection personnel determine that an establishment's procedures are not effective in excluding SRMs from the human food supply, the Agency will take appropriate action.

*Comment:* One comment suggested that FSIS require that establishments address SRMs in their HACCP plans, and that the Agency create a regulatory sampling program to verify that edible portions of carcasses are not contaminated with SRMs. The comment stated that the program could be similar to the testing program required for establishments that use AMR technology.

*Response:* The regulations require that establishments address SRMs as part of their food safety systems, i.e., in their

[15] Harvard Center for Risk Analysis, '' Harvard Risk Assessment of Bovine Spongiform Encephalopathy Phase IA.,'' 2005. Available for viewing by the public in the FSIS docket room and on the FSIS Web site at: *http://www.fsis.usda.gov/Science/Risk_Assessments/index.asp#bse.*

[16] United Kingdom Food Standards Agency (FSA) 2005, Web site *http://www.food.gov.uk/bse/what/beef/controls.*

HACCP plans or Sanitation SOPs or other prerequisite programs. To ensure that SRMs are not present in meat products, FSIS inspection personnel verify that establishments are removing SRMs in a manner that does not result in contamination of edible tissues. Unlike AMR products, gross contamination of beef carcasses and solid cuts of meat with SRMs can often be detected visually. Therefore, FSIS has determined that it is not necessary to establish a verification sampling program for SRM removal at this time.

*Comment:* One comment requested that FSIS exclude references to HACCP in 9 CFR 310.22(d)(1) because there is no scientific basis for determining that abnormal prions are a hazard reasonably likely to occur when conducting a hazard analysis. The comment stated that removal of SRMs would be better covered in an establishment's Sanitation SOPs or other prerequisite program.

*Response:* When conducting a hazard analysis, some establishments may determine that SRMs are a hazard that is reasonably likely to occur and that should be addressed in the HACCP plan. Other establishments may determine that it is more appropriate to address the removal and disposition of SRMs in their Sanitation SOPs or other prerequisite programs. Thus, because FSIS believes that establishments should have the flexibility to implement the most appropriate procedures that will best achieve the requirements of this rule, the Agency is not removing references to HACCP in this final rule.

*Comment:* Some comments suggested that FSIS prescribe and supervise the methods of destruction for SRMs rather than leave those choices to the producers, slaughterers, or processors. One comment stated that because the rule does not specify how SRM disposal must be accomplished, FSIS cannot assure that once removed, SRMs are consistently disposed of in a manner that will not introduce the BSE agent into the environment. One comment noted that alkaline hydrolysis at elevated temperatures is the most effective and environmentally responsible method of destroying materials that could potentially contain the BSE agent. Another comment stated that FSIS did not evaluate alternative methods of disposition for SRMs or the consequences of each alternative.

*Response:* The SRM interim final rule requires that SRMs be handled and disposed of in accordance with 9 CFR part 314.1 or 9 CFR 314.3 of FSIS' regulations for the handling and disposition of condemned or other inedible products at official establishments (see 9 CFR part 314). For establishments that have the appropriate facilities, condemned or other inedible carcasses or parts must be disposed of by inedible rendering (also referred to as ''tanking'') in accordance with the procedure prescribed by 9 CFR 314.1. Under 9 CFR 314.3, those establishments that do not have tanking facilities may dispose of condemned or other inedible carcasses or parts by incineration or by denaturing using crude carbolic acid, cresylic disinfectant a formula consisting of one part DF&C No. 3 green coloring, 40 parts water, 40 parts liquid detergent, and 40 parts oil of citronella, or any other proprietary substance approved by the Administrator.

The purpose of the prescribed methods of disposal of condemned or other inedible carcasses and parts in FSIS' regulations is to ensure that condemned and other inedible materials are rendered incapable of use as human food. After these materials have been subjected to an inedible rendering process, incinerated, or denatured, further disposition is conducted in accordance with applicable Federal, state, and local laws and regulations. FSIS works with other governmental entities to ensure that the disposition of SRMs and other inedible materials complies with environmental requirements.

*Comment:* Some comments requested that FSIS develop compliance guidelines on the removal, segregation, and disposition of SRMs specifically for the U.S. meat packing industry.

*Response:* FSIS has posted compliance guidance materials for its BSE-related rules on the FSIS Technical Services Center Web page at: *http://www.fsis.usda.gov/About_FSIS/Technical_Service_Center/index.asp.*

In addition, after it issued the SRM interim final rule, FSIS held a series of teaching workshops from January through March 2004 to discuss the actions that the Agency had taken to prevent human exposure to the BSE agent. These workshops were designed to assist small and very small plants to understand the requirements of the measures implemented by FSIS to prevent human exposure to the BSE agent. Materials provided at these workshops are available on the FSIS Web site at: *http://www.fsis.usda.gov/Science/Workshop_SmallPlants_BSE/index.asp.*

**Shipment of Carcasses and Parts That Contain Vertebral Columns**

9 CFR 310.22(e) of the SRM interim final rule (which has been re-designated as 9 CFR 310.22(h) in this final rule) provides that materials designated as SRMs will be deemed to be from cattle 30 months of age and older unless the establishment can demonstrate that the materials are from an animal that was younger than 30 months at the time of slaughter. In the preamble to the SRM interim final rule, FSIS explained that for establishments that only process the carcasses and parts of carcasses of cattle, the Agency will verify age through establishment records that document the age of the cattle from which the carcasses or parts were derived (60 FR 1861, 1869–1870, January 12, 2004). The preamble also states that if an establishment that processes the carcasses or parts of cattle does not have records that document the age of the cattle from which the carcasses were derived, it must handle all carcasses and parts as if they were from cattle 30 months of age and older.

FSIS permits federally-inspected establishments that slaughter cattle to ship carcasses and parts that contain vertebral columns from cattle that were 30 months of age and older at the time of slaughter to another federally-inspected establishment for processing if both establishments have controls in place to ensure that the SRM portions of the vertebral column are removed and properly disposed of. When beef carcasses or parts that contain SRM vertebral columns are transported from one official establishment to another, both the transporting establishment and the receiving establishment must develop and maintain documentation and on-going verification to ensure that the SRMs are removed, segregated from edible materials, and disposed of as inedible. If establishments have implemented appropriate controls, FSIS inspection personnel at the shipping establishment will apply the mark of inspection to carcasses or parts that contain SRM vertebral bones as an accommodation to facilitate their transport to a processing facility where the SRMs can be removed and properly disposed of.

To assist with implementation of the SRM interim final rule, FSIS issued an FSIS notice that instructs its inspection program personnel on how to verify the effectiveness of controls adopted by establishments that transport or receive cattle carcasses or parts that contain vertebral columns from cattle 30 months of age and older (see FSIS Notice 68–05, ''Verification Activities at Establishments that Transport or Receive Cattle Carcasses or Parts with Vertebral Columns that Contain Specified Risk Materials (SRMs),'' October 6, 2005). FSIS Notice 68–05 instructs inspection program personnel at establishments that transport for

further processing carcasses or parts of carcasses that contain vertebral columns from cattle that were 30 months of age and older at the time of slaughter to verify that the establishment: (1) Maintains control of the carcasses or parts while they are in transit (through companies seals or under FSIS control); (2) ensures that the carcasses or parts are accompanied by documentation that clearly identifies that the carcasses or parts are from cattle that were 30 months of age and older at the time of slaughter or that clearly states that the vertebral column must be removed and disposed of as an SRM; (3) maintains records that identify the official establishment that received the carcasses or parts; (4) incorporates its procedures into its HACCP System. FSIS Notice 68–05 also provides that inspectors at establishments that process cattle carcasses and parts are to verify that the establishment (1) has implemented controls to identify carcasses or parts that contain vertebral columns with SRM portions; (2) has implemented controls to ensure that the SRM portions of the vertebral column are properly handled and disposed of; (3) has incorporated its controls into its HACCP System; and (4) maintains records that verify that the SRM portions of the vertebral column were removed and disposed of as inedible.

In January 2006, the USDA Office of the Inspector General (OIG) issued an audit report that found that establishments transporting carcasses and parts from cattle 30 months and older often did not have appropriate controls and procedures in place to ensure that SRMs were removed and properly disposed of by downstream processors.[17] The report provided an example of a receiving establishment that received a bill of lading from the transporting establishment that identified four carcasses as being from cattle that were 30 months or older at the time of slaughter when there were actually 11 such carcasses.

Following are the comments submitted on this issue and FSIS' response. As discussed in detail below, after considering the comments submitted on this issue, and the findings in the OIG report, FSIS has decided to codify and strengthens the requirements that must be satisfied for a federally-inspected establishment to ship beef carcasses that contain vertebral columns from cattle that were 30 months of age and older at the time of slaughter to another federally-inspected establishments for further processing.

*Comments:* Some comments argued that it is not necessary to require that processors provide documentation from their suppliers to demonstrate that beef carcasses or parts that contain vertebral bones are from cattle that were younger than 30 months of age at the time of slaughter. According to these comments, the fact that carcasses or parts bear the USDA mark of inspection is sufficient to verify that they are from cattle that were younger than 30 months at the time of slaughter because FSIS only applies the mark of inspection to carcasses or parts if they do not contain SRMs or, for carcasses or parts that do contain SRMs, if the establishment has controls in place to ensure that the SRMs will be removed at the processing establishment.

*Response:* As indicated in the OIG report described above, carcasses or parts transported to a processing facility may not always be accompanied by documentation that properly identifies which carcasses or parts are from cattle that were 30 months and older at the time of slaughter. Thus, to ensure that SRM vertebral columns do not inadvertently enter the human food supply, FSIS has determined that processors must either obtain documentation from their suppliers to demonstrate that carcasses or parts are from cattle that were younger than 30 months at the time of slaughter or handle all carcasses and parts as if they were from cattle 30 months and older.

Under this final rule, it is the establishment's responsibility to demonstrate that beef carcasses or parts are from cattle that were younger than 30 months of age at the time of slaughter. An establishment that merely indicates that carcasses or parts bear the USDA mark of inspection has not met this responsibility. If the establishment cannot demonstrate, through documentation from the supplier, that beef carcasses or parts are from cattle that were younger than 30 months at the time of slaughter, it must handle all carcasses and parts for which this documentation is not provided as if they were from cattle 30 months of age and older.

*Comment:* Some comments argued that FSIS should not allow the shipment of beef carcasses that contain SRMs to bear the mark of inspection even if the establishment has a program in place to ensure that SRMs will be removed by the receiving establishment. According to the comments, the only way to ensure that vertebral columns from cattle 30 months of age and older do not inadvertently enter the food supply is to require that these materials be removed at the time of slaughter. The comments noted that identifying marks on carcasses could be obliterated or altered, and identification and tracking information could be lost as the carcasses pass from slaughterhouse to the processor. One comment said that allowing beef carcasses and parts that contain SRMs to bear the mark of inspection could erode public confidence in the mark of inspection as a symbol of meat safety.

One comment suggested that if FSIS were to reject the suggestion to require that the vertebral column be removed at the time of slaughter, the Agency should make it clear that carcasses with SRMs must not be shipped to uninspected establishments, such as retail stores or restaurants. The comment stated that such a prohibition should be in the final rule, not in an FSIS internal document, such as an FSIS notice or directive.

*Response:* As stated above, after considering this issue, and the findings of the OIG audit report, FSIS has decided to continue to permit, and to codify and strengthen the requirements that must be satisfied for federally-inspected establishments to ship beef carcasses that contain vertebral columns from cattle that were 30 months of age and older at the time of slaughter to other federally-inspected establishments for further processing. As discussed above, FSIS currently permits this practice if both establishments have implemented controls to ensure that the vertebral column (excluding the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae, and the wings of the sacrum), is removed from the carcass and disposed of as inedible at the receiving establishment. To ensure that SRMs are removed to the greatest extent possible at slaughter, the Agency is amending the SRM interim final rule to clarify that the spinal cord from cattle 30 months of age and older must be removed at the establishment where the animals were slaughtered. Thus, under this final rule, the only SRMs that are permitted to be transported from one federally-inspected facility to another are vertebral columns and the DRG contained in the vertebral columns.

In addition, to ensure that beef carcasses or parts that contain vertebral bones from cattle that were 30 months of age and older at the time of slaughter do not inadvertently enter the human food supply, this final rule strengthens

[17] Animal and Plant Health Inspection Service Bovine Spongiform Encephalopathy (BSE) Surveillance Program—Phase II and Food Safety and Inspection Service Controls over BSE Sampling, Specified Risk Materials, and Advanced Meat Recovery Product—Phase III (Report no. 50601–10–KC, January 2006). Available on the Internet at: *http://www.usda.gov/oig/webdocs/50601–10-KC.pdf.*

and codifies the conditions under which establishments will be permitted to ship these carcasses or parts for further processing. Under this final rule, FSIS will permit slaughter establishments to ship beef carcasses or parts that contain vertebral columns from cattle 30 months of age and older for further processing if the slaughter establishment: (1) Maintains control of the carcasses or parts while they are in transit (e.g., through company seals) or ensures that the carcasses or parts move under FSIS control (e.g., under USDA seal or accompanied by FSIS Form 7350–1); (2) ensures that the carcasses or parts are accompanied by documentation that clearly states that the carcasses or parts contain vertebral columns from cattle that were 30 months of age or older at the time of slaughter; (3) maintains records that identify the official establishment that received the carcasses or parts; and (4) maintains records that verify that the official establishment that received the carcasses or parts removed the SRM portions of the vertebral column and disposed of them as inedible.

The first three requirements described above codify the conditions that FSIS inspection personnel at establishments that transport carcasses or parts that contain SRM vertebral columns are instructed to verify under FSIS Notice 68–05. Thus, these requirements reflect current practices. However, the fourth condition, which requires that shipping establishments maintain records that verify that the official establishment that received carcasses or parts from cattle 30 months and older removed and properly disposed of the SRMs, is a new requirement designed to strengthen existing controls. Because this new provision establishes a new recordkeeping requirement, it has been submitted to OMB for approval. This provision will not become effective until OMB approves the information and recordkeeping requirements. More detailed information on the information and recordkeeping requirements associated with this final rule, including instructions for submitting comments on these requirements, are described in the Paperwork Reduction Act Section of this document.

FSIS is adopting this additional control on the transportation of carcasses and parts that contain SRM vertebral columns, in part, in response to the OIG audit report described above. As noted above, the OIG report found that establishments transporting carcasses and parts from cattle 30 months and older often did not have appropriate controls and procedures in place to ensure that SRMs were removed and properly disposed of by downstream processors. This new provision addresses this finding by establishing an addition control that transporting establishments must implement to ensure that receiving establishments are removing and properly disposing of SRMs.

In addition, requiring that transporting establishments maintain records that verify that the receiving establishment removed and properly disposed of SRMs is consistent with other Agency policies that address situations in which products are transported from an official establishment to another facility for processing or disposition. For example, establishments that transport non-intact beef products that test positive or presumptive positive for *E. coli* O157:H7 to another official establishment, or a landfill or rendering operation, for further processing or disposal must obtain documentation from the receiving operation that indicates that the product was properly processed or disposed of.

As requested by the comment, for clarification, federally-inspected establishments are not permitted to ship for further processing beef carcasses or parts that contain vertebral columns from cattle 30 months of age and older to establishments that are not under Federal inspection, such as retail stores, restaurants, or state-inspected processing establishments. The SRMs must be removed in the Federal system.[18] Establishments that receive beef carcasses or parts for further processing are required to address removal of the vertebral column from cattle 30 months of age and older in their procedures for the removal, segregation, and disposition of SRMs.

**Sanitation and Cross-Contamination**

To assist with implementation of the SRM interim final rule, FSIS developed procedures to verify that cross-contamination of edible tissue with SRMs was reduced to the maximum extent practical in facilities that slaughter cattle, and in facilities that process the carcasses or parts of cattle, that are both younger than 30 months of age and that are 30 months of age and older (see FSIS Notice 10–04, ''Questions and Answers Regarding the Age Determination of Cattle and Sanitation,'' January 29, 2004, reissued January 2005). Under these procedures, if an establishment uses dedicated equipment to cut through SRMs, or if it segregates cattle 30 months of age and older from cattle younger than 30 months of age, then the establishment may use routine operational sanitation procedures (i.e., no special sanitation procedures are required). If the establishment does not segregate cattle 30 months of age and older from younger cattle, equipment used to cut through SRMs must be cleaned and sanitized before it is used on carcasses or parts from cattle younger than 30 months of age.

When it issued FSIS Notice 10–04, FSIS determined that, because of the multiple risk mitigation measures implemented in the United States to prevent the spread of BSE, these procedures reduce to the maximum extent practical cross-contamination of carcasses with high-risk tissues. However, to assist in determining whether it should strengthen these measures, FSIS requested further comment on this issue in the joint ANPR issued by APHIS, FSIS, and FDA on July 14, 2004, (see ''Federal Measures To Mitigate BSE Risks: Considerations for Further Action,'' 69 FR 42287, 42290). The Agency also issued a press release during the comment period for the SRM interim final rule that specifically requested public comment on methods to prevent cross-contamination of carcasses with SRMs.

*Comment:* Most of the comments received on this issue agreed that establishments must have a system in place to prevent cross-contamination between edible materials and SRMs. Some of the comments agreed with the current FSIS procedures that permit sanitation of equipment by establishments between the processing of carcasses or parts of carcasses from cattle 30 months of age and older and those from cattle younger than this age. According to the comments, while the cleaning and sanitizing procedures that are available will not inactivate the BSE agent, these procedures are adequate to prevent cross-contamination due to the multiple risk mitigation measures implemented by the U.S. government to prevent the spread of BSE. One comment stated that separate or dedicated equipment is not necessary if proper cleaning and sanitizing procedures are in place and documented.

Other comments argued that, until effective decontamination procedures are developed, FSIS should require that establishments use dedicated and visually coded equipment for the severing and removal of SRMs. Some

[18] State-inspected establishments are permitted to transport for further processing carcasses or parts that contain vertebral columns from cattle 30 months of age and older to other State-inspected establishments in the same State if the State enforces requirements that are at least equal to those imposed under the FMIA.

comments indicated that if dedicated equipment is not used, FSIS should require separate slaughter and processing lines for cattle 30 months and older and cattle younger than 30 months.

One comment included a CD–ROM with suggestions and practices to reduce cross-contamination during slaughter. Among the suggested practices were capping the stun hole, using separate equipment for the severing and removal of SRMs, keeping saws clean to prevent build-up of SRMs, using both high and low stations for removal of the spinal cord, removing both the spinal cord and dura on the kill floor, and taking care of mis-split carcasses on the kill floor.

One comment suggested that FSIS require that the spinal cord be removed on the slaughter floor using dedicated equipment. The comment argued that once spinal cord or other CNS tissue enters the boning room and contaminates the tables and equipment, the potential risk from BSE is already there and removal at this point is not completely sufficient.

*Response:* After considering the comments submitted on this issue, FSIS has decided to continue its current practices for verifying the effectiveness of establishments' procedures for preventing cross-contamination of edible tissue with SRMs. The Agency has concluded that, within the context of the probability that SRMs from slaughtered cattle would carry infectivity (i.e., removal of cattle most likely to have BSE and the extremely low prevalence of BSE in the United States), the current procedures appropriately reduce the potential for cross-contamination of carcasses with SRMs. To ensure that establishments conduct what the Agency has determined are appropriate sanitation procedures for equipment used to sever SRMs, the Agency is also codifying the sanitation procedures described in FSIS Notice 10–04.

Therefore, under this final rule, if an establishment does not segregate the carcasses and parts from cattle 30 months of age and older from the carcasses and parts from cattle younger than 30 months during processing operations it must either use dedicated equipment to cut through SRMs or clean and sanitize equipment used to cut through SRMs before the equipment is used on carcasses or parts from cattle younger than 30 months of age. Establishments that use dedicated equipment to cut through SRMs may continue to conduct routine operational sanitation procedures between carcasses. Establishments that segregate the carcasses and parts of cattle 30 months of age and older from cattle younger than 30 months, and that process the carcasses and parts from the younger animals first, may conduct routine operational sanitation procedures on equipment used to cut through SRMs.

Furthermore, establishments must address potential contamination of edible products with SRMs, including tonsils and the distal ileum from all cattle, as well as CNS and CNS-type tissues from cattle 30 months of age and older, in their procedures for the removal, segregation, and disposition of SRMs.

As discussed in detail above, the estimated prevalence of BSE in the United States is extremely low, and FSIS prohibits the slaughter of cattle that, if infected with BSE, are most likely to contain high levels of the BSE agent, i.e., cattle with CNS signs and non-ambulatory cattle. Thus, because cattle slaughtered in U.S. establishments are highly unlikely to be in the end stages of BSE, equipment used to slaughter or process U.S. cattle is highly unlikely to become contaminated with the BSE agent. Therefore, given the extremely low estimated U.S. BSE prevalence, FSIS has determined that the sanitation procedures prescribed in this rule are appropriate for preventing potential contamination of carcasses with the BSE agent. The Agency agrees with the comment that stated that separate or dedicated equipment is not necessary if proper cleaning and sanitizing procedures are in place and documented.

*Comment:* One comment stated that new technologies must be developed to detect both SRMs and the BSE agent on equipment and finished products to permit establishments to conduct testing to verify that no contamination with SRMs or prion proteins has occurred. The Agency supports the development of new technologies to detect SRMs and the BSE agent on equipment and finished products and agrees that this type of technology would be useful in verifying that no contamination with SRMs or prion proteins has occurred. While FSIS is not aware of any accurate or practical technologies that could be used to determine whether equipment or carcasses have been contaminated with SRMs or prion proteins, the Agency will continue to follow research on the development of these kinds of technologies.

*Comment:* One comment suggested that, to prevent edible products from coming into contact with SRMs during transport, FSIS should prohibit SRMs from being transported in the same vehicle as cattle parts destined for human food.

*Response:* FSIS is amending the SRM interim final rule to clarify that establishments must address contamination of edible materials with SRMs before, during, and after entry into the establishment in their procedures for the removal, segregation, and disposition of SRMs. This provision ensures that procedures for the removal, segregation, and disposition of SRMs are consistent with 9 CFR 417.3(a) of the HACCP regulations, which require that an establishment's hazard analysis include food safety hazards that can occur before, during, and after entry into the establishment.

**Age Verification**

In the preamble to the SRM interim final rule, FSIS stated that if the establishment has accurate records that document the age of the cattle slaughtered in the facility, FSIS inspection program personnel would accept these records as verification of the age of the cattle. If the establishment does not have records that document the age of the cattle presented for slaughter, the Agency verifies age through dental examination. Under its age verification procedures, FSIS deems cattle to be 30 months of age and older if at least one of the second set of permanent incisors has erupted (the permanent incisors of cattle erupt from 24 through 30 months of age).

*Comment:* Several comments concurred with FSIS' procedures for verifying the age of cattle through dental examination. The comments noted that determining age based on eruption of one of the 2nd set of permanent incisors is a conservative and appropriate approach. One commenter, a trade association that represents cattle producers, conducted research to determine whether FSIS' standard for verifying the age of cattle is the appropriate standard for today's cattle and concluded that, given the lack of a standard method for documenting age, the FSIS dentition guidelines are the best alternative. The commenter stated that it will be adding to this research, and if the data show that a new standard is appropriate, it will share the results with FSIS and propose a change in policy. The commenter also noted that it is working with the industry to develop a standard document that can be used by producers to verify the age of cattle that will be accepted by slaughter establishments and FSIS.

*Response:* FSIS agrees with these comments and supports the need for further research on methods for estimating the age of cattle when

reliable documentation is not available. The Agency also supports the development of a standard document that can be used to verify the age of cattle at slaughter.

*Comment:* Some comments disagreed with FSIS' method for verifying the age of cattle through dentition. Most of the comments asserted that the method is inaccurate because many cattle have all four permanent incisors by the time they are 24 months old. According to the comments, under FSIS' method for aging cattle, many cattle are deemed to be 30 months of age and older when they are probably 24 months or less. One comment noted that dentition varies from herd-to-herd and animal-to-animal due to genetics, diets, and the varied geographic locations in which animals are raised. Another comment indicated that the dentition standards used by FSIS were established more than 50 years ago and do not reflect the advancements in animal genetics that may account for early maturity, nor do they reflect the development of new hybrid breeds over the past 50 years.

One comment questioned the amount of research that FSIS completed when developing its guidelines for verifying age through dentition. The comment said that, according to a leading veterinary medicine anatomy textbook, the permanent incisors of cattle erupt from 18 to 48 months rather than 24 months to 30 months of age. The comment went on to note that another veterinary text states that the second pair of permanent incisors is fully developed, and the gingiva at the base of the third deciduous incisors is receding from the gum line, when the animal is approximately 29½ months of age. The comment asserted that these guidelines would provide a more accurate method to verify the age of cattle than the method adopted by FSIS.

Another comment stated that good veterinary practice recognizes that cattle develop their first set of permanent incisors at 18 to 24 months, their second set at 24 to 30 months, and their third set at 30 to 42 months. The comment asserted that it would be more accurate for FSIS to verify the age of cattle based on the eruption of the fifth permanent incisor rather then the eruption of the third permanent incisor. Another comment also suggested that FSIS deem cattle to be 30 months of age and older based on the eruption of the fourth set of permanent incisors.

*Response:* FSIS acknowledges that under the Agency's age verification procedures some cattle younger than 30 months will be deemed to be 30 months of age and older. As noted by the comments, dentition may vary from herd-to-herd and animal-to-animal depending on genetics, diet, and the geographic locations. However, despite its limitations, the Agency has determined that the dentition evaluation adopted in these rules is the best and most practical means of estimating the age of cattle at slaughter in the absence of reliable records. Thus, FSIS will continue to use current dentition evaluation procedures to verify the age of cattle when records are not available.

The procedures adopted by FSIS to verify the age of cattle offered for slaughter are based on data from veterinary anatomy texts and academic articles.[19] These sources indicate that the second set of permanent incisors erupt when cattle are between 24 to 30 months of age. Based on this information, FSIS adopted a conservative approach and considers cattle in which at least one of the second set of permanent incisors has erupted to be 30 months of age or older. This approach is accepted internationally and is consistent with the dentition standards used in Canada.[20]

*Comment:* Some comments strongly suggested that FSIS inspection personnel rely more heavily on producer documentation to verify the age of cattle. Some comments requested that FSIS restate the pre-eminence of documented birth records over approximating age through dentition. The comments stated that FSIS should not use dentition to verify supportable documentation, such as breeding or birth records.

*Response:* If establishments use accurate and reliable documentation to determine the age of cattle at slaughter, FSIS will not use dentition to verify the accuracy of the records. After it issued the SRM interim final rule, FSIS issued FSIS Notice 10–04 ''Questions and Answers Regarding the Age Determination of Cattle and Sanitation'' (January 29, 2004) to clarify that documentation will be the primary means to determine the age of cattle at slaughter. The notice makes clear that if reliable documentation is provided at slaughter, FSIS inspectors should not use dentition to verify the age of cattle.

*Comment:* Some comments requested that FSIS clarify the type of records that the Agency considers acceptable for determining age. The comments suggested that herd calving record books be included as acceptable evidence of age.

*Response:* The FSIS Notice described above (FSIS Notice 10–04) describes the type of documents that can be used to provide an accurate and reliable basis for determining the age of cattle. Included among the acceptable forms of documentation are records that certify that an entire herd was born on a farm during a specific time ( e.g., certification that a group of Angus cattle were born during the calving season of Spring 200X or Fall 200X), together with information from the feedlot that identifies each animal individually (e.g., eartags). As provided in the notice, when calving birthing ranges are provided, the oldest possible age based on the ranges should be assigned to the group of cattle.

*Comment:* Some comments asserted that FSIS' method for verifying the age of cattle frequently overestimates the age of cattle that are younger than 30 months, resulting in an economic loss to cattle producers. One comment stated that certain meatpackers have indicated that they intend to deduct 15 cents per pound per head for any animal that is determined to be over 30 months of age by dentition. According to the comment, the implementation of the rule is devaluing a group of cattle (heiferettes) that previously returned a premium over their current class (cull cows). The comment also noted that after Canada implemented similar procedures for determining the age of cattle offered for slaughter, cattle in Canada with more than two permanent incisors are now being sold for a total prices of 8 to 20 cents (Canadian) per pound live weight.

This same comment stated that cattle feeders are losing nearly $200.00 per head for any animal found to have more than two permanent incisors, which is a per head loss of nearly 20%. The comment also claimed that ranchers are losing up to $360.00 per head for any animal found to have more than two permanent incisors, which amounts to a per head loss of nearly 50%. The comment estimated that the costs associated with FSIS' method for verifying the age of cattle using dentition will cost the cattle producing industry in excess of $1,035,936,000.00. One comment submitted by a rancher indicated that he takes a discount of $60.00 to $100.00 per head on cattle deemed to be 30 months of age and older, which could force him to discontinue his business unless he is able to purchase cattle that have documentation of age.

[19] See references to the FSIS Technical Services Center document ''Using Dentition to Age Cattle, '' which is available on the FSIS Web site at: *http://www.fsis.usda.gov/Frame/FrameRedirect.asp?main=http://www.fsis.usda.gov/OFO/TSC/bse_information.htm.*

[20] Canadian Food Inspection Agency, Meat Hygiene Directive, Chapter 4, Annex IV. Available on the Internet at *http://www.inspection.gc.ca/english/anima/meavia/mmopmmhv/chap4/annexne.shtml.*

*Response:* FSIS discusses in detail the economic impacts of age verification in the final regulatory impact analysis (FRIA) of this final rule. The FRIA explains that generally, in any group of steers and heifers, some cattle will appear to be 30 months of age and older based on dentition even if all of the animals in the group are younger than 30 months of age. The FRIA states that estimates of the proportion of steers and heifers that will appear to be 30 months of age and older based on dentition range from 1 to 5 percent (Hodges and Seward, 2004).

The FRIA notes that after FSIS implemented the SRM interim final rule, the USDA Market News Service (of the Agricultural Marketing Service (AMS)) began to report discounts for cattle 30 months of age and older (including those determined by dentition). Weekly values have ranged from $35 to $50 per cwt (carcass weight), which translates to an approximate discount of $175 to $250 per head for a 500-pound cow or bull carcass ( e.g., on the lower end, $35 per cwt times 5 cwt equates to $175).

The comments on this issue and the analysis in the FRIA demonstrate the advantage of using accurate records rather than dentition to determine the age of cattle. Nonetheless, while FSIS' dentition standards are conservative, the Agency has determined that they are the most appropriate way to estimate the age of cattle in the absence of accurate documentation. As mentioned above, the dentition standards adopted by the Agency are internationally accepted and based on data from veterinary anatomy texts and academic articles. These standards are also objective and practical to implement. Furthermore, according to one study, determining physiological maturity by the number of permanent incisors may be a more accurate technique of sorting beef carcasses into less variable age groups than the USDA bone ossification-based maturity system used for beef grading.[21]

If cattle producers are interested in preventing potential financial losses associated with the use of dentition to estimate the age of their cattle, they may prefer to maintain records that can be used to accurately document the age of their animals. As stated above, if reliable documentation is available at slaughter, FSIS inspectors will rely on documentation, not dentition, to verify the age of cattle.

*Comment:* One comment stated that dentition should only be used to verify the age of cattle imported into the United States from countries that are not classified as ''BSE-free,'' such as Canada. The comment asserted that because the United States has never had a native case of BSE,[22] the use of dentition to age U.S. cattle unnecessarily penalizes American producers and feeders without offering any substantial public health benefits to the public or long term benefits to cattle producers.

*Response:* As discussed earlier in this document, two native cases of BSE have been confirmed in the United States since FSIS issued the SRM interim final rule. Therefore, the statement that the United States has never had a native case of BSE is no longer accurate. Furthermore, FSIS disagrees that its dentition evaluation procedures unnecessarily penalize American producers and feeders. As discussed in detail above, although the dentition standards adopted by FSIS may be conservative, the Agency has determined that these standards are the most appropriate means to estimate the age of cattle at slaughter in the absence of accurate documentation.

*Comment:* One comment was submitted by a company that has developed a new technology that it claims will permit the creation of secure and auditable records of the dentition of cattle when they arrive at the feedlot. According to the company, these records would allow slaughter establishments to determine the age of cattle offered for slaughter on the basis of dental exam at the feedlot.

According to the comment, literature shows that the standard error of the association of age with dentition is smaller with animals at younger ages. The comment asserted that because cattle usually enter feedlots between 10 and 16 months of age, dentition exam could be used more accurately at those ages to assign a maximum possible age. Since the dentition exam on these cattle would typically show no permanent incisor eruption, the comment suggested that cattle with no permanent incisors upon arrival to the feedlot be assigned a maximum age of 24 months. Then, said the commenter, cattle with an auditable record of their dentition examination at the feedlot could be deemed as being under 30 months of age at slaughter if their dentition examination upon arrival to the feedlot showed no permanent incisors and if they are sent to slaughter within six months of their arrival at the feedlot.

The comment noted that it has already submitted a notification to the FSIS New Technology Staff (NTS) of its new technology. The commenter submitted a copy of a letter from the FSIS NTS stating that the NTS has no objection to the use of the new technology. However, as stated in the letter, the regulations and implementing notice do not include documentation of dentition examination prior to slaughter as a method for verifying the age of cattle presented for slaughter. Therefore, the comment requested that FSIS allow the use of its new technology as a method to verify the age of cattle presented for slaughter.

*Response:* FSIS considers auditable records of the dentition examination of cattle at the feedlot as a form of documentation that can be used to estimate the age of cattle at slaughter. Thus, the Agency does not object to the use of the technology described above to verify the age of cattle offered for slaughter. To assist with implementation of this final rule, FSIS intends update the guidance provided in FSIS Notice 10–04 to issue to clarify that auditable records of dentition examination on the feedlot are an acceptable form of documentation for verifying the age of cattle.

**Importation of Products From Countries With a ''Negligible BSE Risk''**

Comment: FSIS received a number of comments from countries that export meat food products to the United States, as well as from importers of meat food products, requesting that FSIS exempt countries that present a ''negligible BSE risk'' from the requirements of the SRM interim final rule.[23] According to the comments, a country's negligible BSE risk status provides the same level of protection from human exposure to the BSE agent as does exclusion of SRMs and non-ambulatory disabled cattle from the human food supply in the United States.

The comments asserted that application of the SRM interim final rule to all establishments that export meat food products to the United States regardless of a country's BSE risk status is without scientific justification and requires that certain countries implement costly and unnecessary

[21] Lawrence, TE, 2001. A comparison of the USDA ossification-based maturity system to a system based on dentition, J. Anim. Sci., 79:1683–1690.

[22] This statement reflects the situation at the time that FSIS issued the SRM interim final rule.

[23] The comments requested that FSIS exempt countries with a ''BSE-free'' or ''provisionally free'' risk status. However, the OIE BSE risk categories have been revised since FSIS issued the SRM interim final rule. To reflect these revisions, instead of referring to countries as having a ''BSE-free'' or ''provisionally free,'' risk status, FSIS will use the term ''negligible BSE risk.''

measures. According to the comments, application of the U.S. BSE measures to countries that can demonstrate that they present a negligible BSE risk violates the World Trade Organization Agreement on the Application of Sanitary and Phytosanitary Measures (the SPS Agreement) because it is more trade restrictive than necessary to achieve the appropriate level of sanitary protection required by the United States.

Many comments noted that providing an exemption for countries with a negligible BSE risk would be consistent with guidelines established by the OIE, which recommend that countries restrict the importation of potentially infective materials on the basis of the BSE risk classification of the region of origin. Some comments stated that providing an exemption for countries with a negligible BSE risk would be consistent with the position already adopted by Canada. The comments also stated that exempting countries with a negligible BSE risk would be consistent with U.S. efforts to achieve uniformity and consistency in international standards. As noted by the comments, E.U. regulations exclude from the definition of SRMs materials from animals from countries that fall within the European Union's lowest risk range of BSE risk categories.

Many of the comments also submitted information on standards that FSIS could use to determine a foreign country's BSE risk status. Some comments suggested that FSIS apply guidelines for determining the BSE risk status of a country or zone established by the OIE. The comments stated that FSIS could rely on evaluations conducted by the OIE Ad-hoc Group for BSE to determine whether a country meets the OIE criteria for negligible BSE risk status, or the Agency could conduct its own evaluations using the OIE criteria. Some comments suggested that FSIS adopt criteria similar to the criteria used by Canada for determining whether a country qualifies for an exemption from that country's BSE-related requirements. Other comments recommended that FSIS consider countries to have a negligible BSE risk if they are not listed by APHIS in 9 CFR 94.18(a) as regions that present a risk of introducing BSE into the United States. One comment suggested that, if a country's BSE risk is to be evaluated by U.S. authorities, one U.S. agency should be responsible for conducting the assessment. According to the comment, USDA's APHIS would be the most appropriate agency because of it has experience in conducting this type of evaluation.

*Response:* FSIS has been persuaded by these comments. The Agency agrees that it is possible for a country's BSE risk status to provide the same level of protection from human exposure to the BSE agent as excluding SRMs from the human food supply does in the United States. The Agency also agrees that restricting the importation of potentially infective materials on the basis of the BSE risk of the region of origin is more consistent with international guidelines than an approach that does not consider a country's BSE risk.

Therefore, after careful consideration of this issue and the comments received in response to the SRM interim final rule and the APHIS/FSIS/FDA ANPR, FSIS has decided to amend the SRM interim final rule to exclude from the definition of SRMs materials from cattle from foreign countries that can demonstrate that their BSE risk status can reasonably be expected to provide the same level of protection from human exposure to the BSE agent as prohibiting SRMs for use as human food does in the United States.[24]

Section 20 of the FMIA prohibits the importation of carcasses, parts, meat, and meat food products that are adulterated or misbranded, and that do not comply with all other requirements of the FMIA and its implementing regulations (21 U.S.C. 620(a)). Under the FMIA, the Secretary of Agriculture (and FSIS by delegation) is authorized to treat as equivalent to a U.S. requirement, an alternative measure proposed by an exporting country if the country provides scientific evidence or other information, in accordance with risk assessment methodologies agreed to by the Secretary and the exporting country, to demonstrate that the alternative measure achieves the level of protection that the Secretary considers appropriate (21 U.S.C. 620(e)(1)(B)).

FSIS' import regulations specify that a country's eligibility to export meat and meat products to the United States must be based on an equivalence evaluation (9 CFR 327.2(a)). To determine equivalence, FSIS conducts two types of evaluations. The Agency conducts an initial evaluation to determine whether a foreign meat inspection system is equivalent in the case of a country that is not presently eligible to export meat products to the United States. FSIS also conducts evaluations to determine whether an individual sanitary measure is equivalent in the case of a country that has already established its equivalence and is requesting that FSIS recognize an alternative method of eliminating or abating a particular food safety hazard.[25]

The initial equivalence evaluations of foreign meat inspection systems are a prerequisite for trade. Countries that have completed this initial equivalence process and that are eligible to export meat and meat products to the United States are listed under 9 CFR 327.2(b) of FSIS' import regulations. After a country is listed in 9 CFR 327.2(b) as eligible to export meat and meat products to the United States, the country may request that FSIS conduct an evaluation to determine whether an alternative sanitary measure proposed by the country is equivalent to a U.S. requirement. FSIS will allow a country to adopt an alternative sanitary measure if the country provides sufficient scientific evidence to demonstrate that the alternative measure achieves the same level of protection that is provided by the U.S. requirement.

FSIS adopted regulations that prescribe requirements for the removal, segregation, and disposition of SRMs as a measure to prevent potential human exposure to the BSE agent. When it issued the SRM interim final rule, FSIS explained that because of the way that BSE infectivity occurs in BSE-infected cattle, and the fact that a case of BSE has been detected in an imported animal in the United States, the Agency has determined that certain materials from cattle present a sufficient risk of exposing humans to the BSE agent that is prudent and appropriate to find that these materials are unfit for human food within the meaning of section 1(m)(3) of the adulteration provisions of FMIA. As discussed earlier in this document, since FSIS issued the SRM interim final rule, BSE has been confirmed in two native U.S. animals. Thus, given these additional cases, FSIS has concluded that the materials designated as SRMs in this final rule continue to present a sufficient risk of exposing humans to the BSE agent so as to render them ''unfit for human food'' under the FMIA.

However, not all countries have the same situation with regard to BSE as the United States. Based on past import histories, import controls, animal health risk mitigations, animal surveillance, and other factors, some countries may be able to demonstrate that their BSE risk status is such that materials from their cattle population that would be designated as SRMs in the United States do not present a sufficient risk of

[24] Materials may be derived from any animal from the country's cattle population if the animal has been inspected and passed for human food.

[25] FSIS may also consider an alternative sanitary measure as part of an initial equivalence evaluation if the applicant country were to propose alternative sanitary measures as part of its initial equivalence submission.

exposing humans to the BSE agent to render these materials ''unfit for human food'' as defined under the adulteration provisions of the FMIA. Thus, the BSE risk status of these countries would accomplish the same objective as the U.S. requirement for the removal, segregation, and disposition of SRMs, which is to prevent human exposure to the BSE agent.

Therefore, because the BSE risk status of certain countries may be equivalent to U.S. requirements with regard to SRMs, FSIS has decided to exclude from the definition of SRMs, materials from cattle from a country that can demonstrate that its BSE risk status can reasonably be expected to provide the same level of protection from human exposure to the BSE agent as excluding SRMs from the human food supply does in the United States. Because a country's BSE risk status would be considered as an individual alternative sanitary measure to the U.S. requirement for the removal, segregation, and disposition of SRMs, only those countries that are listed in 9 CFR 327.2(b) as eligible to export meat and meat products to the United States are eligible to request this exemption.

When FSIS implements a measure to eliminate or abate a food safety hazard, an exporting country must either adopt the same measure or notify the Agency that it proposes to apply a different measure that provides the same level of protection. Thus, countries that believe that they are eligible to have materials from their cattle excluded from FSIS' definition of SRMs should notify FSIS' Office of International Affairs (OIA) and provide that office with sufficient scientific evidence to support its claimed BSE risk status. FSIS will then develop criteria to evaluate the equivalence request.

In developing equivalence criteria, FSIS will consider evidence that the country proposes to submit in support of its BSE risk status, including a BSE risk status evaluation, if one was conducted, or any other supporting documentation. An exporting country may submit an evaluation of its BSE risk status conducted by the OIE, another country, or any other appropriate entity. Countries may also conduct their own evaluations. However, any evaluation and supporting documentation submitted by a country must contain sufficient scientific evidence to demonstrate that the country's BSE risk status can reasonably be expected to achieve the same level of protection from human exposure to the BSE agent as excluding SRMs from human food does in the United States.

An evaluation of a country's BSE risk status would consider whether appropriate measures are in place to manage identified risks. This would include consideration of import policies and import history to determine the likelihood of the introduction of BSE into the country. It could also include (among other things) consideration of any of the following: effective surveillance efforts; measures to identify and effectively control pathways for the amplification of BSE; appropriate awareness programs; effective epidemiological investigations as necessary, with appropriate tracing, control and destruction of risk animals; continuing risk considerations with corresponding revisions of existing mitigations; appropriate public health control measures commensurate with risk; and the infrastructure sufficient to define and implement any of the above.

As part of the equivalence process, FSIS officials with technical program expertise and, where appropriate, technical experts from other agencies, such as APHIS and FDA, consider the evidence provided by an exporting country to demonstrate that its alternative sanitary measure provides the same level of protection as the U.S. measure. During the process, FSIS may request more information from the country to facilitate the evaluation. Upon completion of the review process, FSIS makes an equivalence determination and notifies the exporting country of its decision. The Agency also provides the basis for the decision, whether positive or negative. FSIS documents the equivalence process.

In addition to equivalence requirements, FSIS' import regulations also provide that compliance with the conditions for importation of products under FSIS' regulations does not excuse the need for compliance with applicable requirements under other laws, including the provisions in APHIS' regulations that prohibit or restrict the importation of certain animals and animal products for animal health purposes (9 CFR 327.2(b)). Thus, foreign countries that comply with all of FSIS' requirements with regard to BSE must also comply with any requirements related to BSE imposed by APHIS and FDA. Therefore, to ensure, to the greatest extent possible, that FSIS' import policies with regard to BSE are consistent with policies implemented by USDA's APHIS and HHS' FDA, FSIS intends to consult with these agencies whenever a country requests to have materials from its cattle population excluded from FSIS' definition of SRMs.

As part of this consultation process, FSIS may request that technical experts from APHIS and FDA review the BSE risk evaluation and other evidence of equivalence submitted by the exporting country. FSIS will consider APHIS' and FDA's conclusions as to whether information submitted by the exporting country provides sufficient scientific evidence to support the country's claimed BSE risk status. FSIS will also consider whether APHIS or FDA impose any BSE-related restrictions on imports from the country and, if so, the basis for those restrictions.

After FSIS is finished considering the evidence submitted by a country in support of its BSE risk status, the Agency will: (1) Recognize that the country's BSE risk status is equivalent to excluding SRMs from the human food supply in the United States or (2) request more information to facilitate consideration of the submission or (3) reject equivalence of the country's BSE risk status and provide appropriate reasons for that decision. FSIS will notify the exporting country of its judgment within a reasonable period of time, although the time that it takes FSIS to complete its equivalence determination may vary depending on the evidence submitted by the country and its specific situation with regard to BSE. FSIS will also provide the country with basis for its decision should the judgment be that the country's BSE risk status is not equivalent.

FSIS retains a sovereign right to decide whether the exporting country's sanitary measure is equivalent to its own provided that the process is fair and transparent and the decision is based on sufficient scientific evidence. Exporting countries must receive an equivalence determination from FSIS before any alternative sanitary measure is implemented in the country. Following a judgment of alternative sanitary measure equivalence based upon document analysis, FSIS will verify on-site during the next regularly scheduled audit that the alternative sanitary measure has been appropriately implemented. Thereafter, FSIS and the exporting country should advise each other of any changes in their programs or infrastructure that may affect the original determination of equivalence.

In addition, after FSIS completes its initial equivalence determination, the Agency uses a three-part process to verify that an exporting country's meat inspection system and proposed alternative sanitary measures continue to be equivalent. The first part of this process is a recurring document analysis, which is used to gradually repeat and update initial equivalence determinations. The second is on-site meat inspection system audits

conducted at least annually in every country that exports meat and poultry products to the United States. The third is port-of-entry re-inspections in which FSIS randomly samples meat product as they enter the United States. These re-inspections provide evidence of how the foreign inspection system is functioning.

Because FSIS, APHIS, and FDA have different regulatory responsibilities, it is not practical for one U.S. Government agency to be responsible for conducting all aspects of every evaluation of a foreign country's BSE risk. However, FSIS' approach for considering evidence of an exporting country's claimed BSE risk status is consistent with the approach used by USDA's APHIS to determine a foreign country's animal health risk status related to BSE. When it considers a country's BSE risk, APHIS evaluates an individual country's specific situation and analyzes risk based on the overall effectiveness of actions taken by the country to prevent the introduction and spread of BSE. APHIS also takes into consideration the OIE guidelines, as well as evaluations conducted by other countries.

FSIS has determined that the type of comprehensive approach used by APHIS to consider a country's animal health risk status is also an appropriate approach for FSIS to use to determine whether materials from cattle from countries considered to be of negligible risk will present no greater risk of exposing humans to the BSE agent than do beef products permitted for human food in the United States, including those materials that would be designated as SRMs if they were from cattle from the United States.

*Comment:* One comment suggested that the prohibition on the slaughter of non-ambulatory disabled cattle may have been motivated to some degree by animal welfare objectives in that automatic condemnation of these animals will deter attempts to ship non-ambulatory cattle and perhaps persuade truckers to do more to prevent injury during transport. The comment stated that if this is the case, some countries have implemented alternative measures that address the animal welfare implications associated with the transportation of non-ambulatory animals. According to the comment, when making equivalence determinations, FSIS should give due consideration to countries, such as Canada, that prohibit non-ambulatory animals from leaving the farm.

*Response:* As discussed below, above, FSIS is affirming the prohibition on the slaughter of non-ambulatory disabled cattle because the Agency has determined that it is a prudent measure to prevent potential human exposure to the BSE agent. Thus, under this final rule, if a foreign country can demonstrate that its BSE risk status can reasonably be expected to achieve the same level of protection from potential human exposure to the BSE agent as requiring the condemnation of non-ambulatory disabled cattle that are offered for slaughter does in the United States, the country will not be required to prohibit the slaughter of all non-ambulatory disabled cattle for human food in order to be eligible to export beef products to the United States.

*Comment:* One comment asked how FSIS will provide assurance that products imported into the United States were produced in compliance with the requirements in the SRM interim final rule.

*Response:* FSIS ensures that imported meat in the U.S. marketplace is safe, wholesome, unadulterated, and properly labeled by (1) determining whether foreign countries and their establishments have implemented a food safety system and inspection requirements equivalent to those in the United States and (2) re-inspecting imported meat and poultry products from those countries through random sampling of shipments. The FSIS regulations in 9 CFR 327.2 provide that countries eligible to export meat to the United States must have a meat inspection system that has been determined by FSIS to be equivalent to the U.S. meat inspection system. The FSIS equivalence determination is based on a review of the foreign country's relevant laws and regulations and on an on-site audit of the foreign country's inspection system.

Once a country is listed as eligible to export meat and meat products to the United States, it is responsible for certifying individual exporting establishments to FSIS and for providing annual recertification documentation. FSIS regularly conducts on-site audits of the eligible foreign inspection systems to ensure they remain equivalent to the U.S. system.

**Air-Injection Stunning**

*Comment:* Most of the comments received in response to the air-injection stunning interim final rule were supportive and encouraged FSIS to make the interim provisions permanent. Some comments indicated that even though the U.S. beef slaughter industry no longer uses air-injection stunning devices, the regulation is still important to prohibit any future use of these devices and to ensure the safety of imported beef products into the United States.

One comment concurred with FSIS' decision to reject the option of a performance standard for CNS emboli that may occur after stunning. As noted by the comment, a performance standard and testing for CNS emboli would be costly and unwieldy to both industry and government enforcement officials.

*Response:* FSIS agrees with these comments. Accordingly, in this final rule, FSIS is adopting, without changes, the provisions of the air injection stunning interim final rule.

*Comment:* One comment noted that the Canadian Food Inspection Agency (CFIA) has prohibited the use of air-injection stunning equipment for any red meat species processed in federally-registered Canadian establishments since May 2000. The comment also indicated that CFIA prohibits the destruction of brain matter using a rod (referred to as ''pithing'') because this procedure can cause dislocation of portions of brain and release emboli into the circulatory system of stunned cattle.

*Response:* U.S. requirements for stunning cattle are consistent with the Canadian requirements. The pithing method of stunning is not permitted in the United States and it is not listed as an approved humane method of slaughter in 9 CFR part 313.

*Comment:* One comment criticized FSIS for not including a discussion of CNS micro-emboli in the preamble to the rule. According to the comment, trauma sufficient to cause unconsciousness will cause damage that ranges from contusions and ultra structural changes, including the disruption of the blood-brain barrier to frank tissue destruction and accompanying hemorrhage. The comment asserted that other types of stunning devices, such as penetrating captive bolt stunners that do not inject air and non-penetrating captive bolt stunners, may result in CNS micro-emboli.

*Response:* In the preamble to the air-injection stunning interim final rule, FSIS addressed the potential for captive bolt stunning devices that do not use air-injection to result in CNS micro-emboli in its discussion of the Harvard Risk Assessment study. In that discussion, the Agency noted that the original Harvard study (2001/2003) (also referred to as the Harvard-Tuskegee study) estimated that for each BSE-infected animal stunned with a standard captive bolt stunner (without air injection), there is a 50 percent probability that a very small fraction of the BSE agent will be transferred to the

blood (see 69 FR 1885, 1888). The Harvard-Tuskegee study assumes that this small fraction is what would be contained within micro-emboli that might occur. As noted in the discussion, the Harvard-Tuskegee study concluded that the stunning method used on cattle is not a major potential source of human exposure to the BSE agent, but that potential human exposure to the BSE agent would increase with greater use of air-injection stunning.

Since FSIS issued the air-injection stunning rule, information has become available to the Agency that indicates that the use of both penetrating and non-penetrating captive bolt stunning on cattle may result in CNS tissue emboli. A report of the EFSA Working Group on BSE risk from dissemination of brain particles in blood and carcass reported that recent studies have shown that brain damage caused by both penetrating and non-penetrating captive bolt stunning in cattle can result in occurrence of CNS tissue emboli in venous blood draining the head.[26] The EFSA report also concludes that while experimental studies have indicated that widespread distribution of CNS emboli via systemic arterial circulation may occur, this has not been confirmed under commercial conditions. The report recommends that further validation studies on the occurrence of stunning-associated CNS emboli be conducted under commercial conditions and that these studies should focus on the involvement of systemic arterial circulation in the distribution of CNS emboli.

Thus, further research is needed to assess how various methods used to stun cattle at slaughter in the United States affect the risk of potential human exposure to the BSE agent. The Agency supports the need for additional research on stunning methods and CNS emboli. FSIS will use the results of future studies to evaluate the stunning methods permitted for use on cattle in the United States and, if necessary, will take appropriate action to ensure that stunning devices are not a significant potential source of human exposure to the BSE agent.

*Comment:* One comment stated that if FSIS is not aware of any U.S. slaughter establishments that use air-injection stunning, why did the Agency issue a rule to prohibit this practice? The comment asserted that the rule appears to be unnecessary and may negatively affect consumer confidence in the safety of the U.S. beef production system.

*Response:* As indicated by one of the comments above, even though the U.S. beef slaughter industry no longer uses air-injection stunning devices on cattle, prohibiting the use of these devices is still important to ensure that they are not used in the future and to ensure the safety of imported beef products into the United States.

*Comment:* One comment asked how FSIS will ensure that certified foreign establishments in countries that permit the use of air-injection stunning are not using air injection stunning devices on cattle whose products are exported to the United States.

*Response:* Foreign countries that import meat food products into the United States must employ sanitary measures that can reasonably be expected to provide the same level of protection from human exposure to BSE that is achieved domestically. Therefore, foreign establishments that use air-injection stunning on cattle are prohibited from exporting meat food products to the United States. FSIS regularly conducts on-site audits of eligible foreign inspection systems to ensure they remain equivalent to the U.S. system.

**MS(Beef)**

*Comment:* Most comments submitted in response to the SRM interim final rule's prohibition on the use of MS(beef) for human food expressed support for this provision. Some comments suggested that instead of banning MS(beef), FSIS should consider prohibiting the use of cattle skulls and vertebral columns in the production of this product. One comment stated FSIS could revise the specifications for MS(beef) to prohibit the incorporation of CNS-type tissues and apply controls similar to those for beef produced using AMR systems.

*Response:* Because they are SRMs, skulls and vertebral columns (excluding the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae, and the wings of the sacrum) from cattle 30 months of age and older are prohibited for use as source materials in AMR systems. However, skulls and vertebral columns from cattle younger than 30 months are permitted to be used as a source material in AMR systems if they do not contain any CNS-type tissues. Under the AMR interim final rule, beef AMR product that does not qualify to be labeled or used as ''meat,'' but that meets the requirements of 9 CFR 319.5 (the requirements for MS(species)), may be used for human food if skulls or vertebral column bones that contain CNS-type tissues from cattle younger than 30 months of age were not used as a source material in the production of the product and the product does not contain spinal cord or DRG from bones of cattle younger than 30 months (9 CRF 318.24(c)(2)(iii)). While this product, which has the characteristics of MS(beef) without CNS-type tissues, cannot bear the name MS(beef), it may bear a common or usual name that is not false or misleading.

**Hand De-Boned Meat**

In the SRM interim final rule, FSIS noted that because of its proximity to the vertebral column, some hand de-boned meat may contain DRG depending on the technique used to remove the meat from the bone. The Agency requested comments on whether it should prohibit hand de-boned meat from the vertebral columns of cattle 30 months of age and older for use as human food (69 FR 1862, 1868).

*Comment:* Some comments stated that as long as standard boning procedures are followed, hand de-boned meat from the vertebral columns of cattle 30 months of age and older is safe and should not be prohibited for human food. One comment suggested that FSIS allow companies to determine whether hand de-boned meat from the vertebral bones of cattle 30 months of age and older is acceptable based on the individual design of the plant's HACCP plan. Another comment argued that FSIS should prohibit hand de-boned meat from the vertebral column of cattle 30 months of age and older for human food until data on whether it may contain DRG is more conclusive.

A comment submitted by the Canadian Food Inspection Agency (CFIA) noted that hand de-boning of parts of the vertebral column can result in DRG tissue being excised, particularly in the lumbar region. The comment stated that CFIA and Health Canada would welcome the opportunity to compare data with FSIS and to collaborate in an assessment of the risk associated with this practice and identification of appropriate risk management measures.

*Response:* After considering this issue, FSIS has determined that there are insufficient data to demonstrate that hand de-boned meat presents a risk of exposing humans to the BSE agent. Therefore, in this final rule, FSIS will continue to permit hand de-boned meat from the vertebral column of cattle 30 months of age and older for human food. However, because of the DRG's close association to the vertebral bones, the Agency requires that establishments

[26] Annex to the EFSA Journal (2004). Report of the EFSA Working Group on BSE risk from dissemination of brain particles in blood and carcasses, adopted on 21 October 2004. (pp. 16–17) (*http://www.efsa.eu.int*).

that produce hand de-boned beef from the vertebral column of cattle 30 months of age and older address the potential for contamination of edible materials with SRMs, including the DRG, in their procedures for the removal, segregation, and disposition of SRMs.

FSIS appreciates and accepts the CFIA's offer to compare data on the potential for DRG to become dislodged when meat is hand de-boned. The Agency intends to work with CFIA to further assess the risk associated with DRG in hand de-boned meat and to identify appropriate risk mitigation measures.

**BSE in Japanese Cattle Younger Than 30 Months**

*Comment:* In the preamble to the SRM interim final rule, FSIS requested comments on the implications, if any, of the reported 21- and 23-month-old cases of BSE in Japan (69 FR 1862, 1864). One comment submitted on this issue stated that it endorsed recommendations made by an OIE Expert Group convened in Paris on December 2, 2003. According to the comment, the OIE group concluded that the so-called atypical BSE cases reported in Japan were no cause for changes in the international standards for trade in cattle and cattle products.

Another comment suggested that FSIS investigate the findings of the 21- and 23-month old Japanese cattle that were reported as testing positive for BSE and publicly clarify that these results were reached using inadequate methodology. The comment asserted that the tissue samples from these animals were later confirmed as negative by the International Reference Laboratory in Weybridge, England.

*Response:* The two Japanese cases of BSE in animals 21- and 23-months old were reported in 2003 and were detected as part of Japan's program to test all cattle slaughtered for human food for BSE. While FSIS is not aware of any data to indicate that these animals were later confirmed as negative by the U.K. International Reference Laboratory, a report issued by the European Food Safety Authority (EFSA), Scientific Panel on Biological Hazards, states that ''it is unclear whether the very young cases [reported in Japan] were adequately identified and formally confirmed.'' [27] This same report concluded that these cases ''seem to be epidemiologically peculiar as their cohort would have been expected to yield further cases.'' FSIS has concluded that the available evidence surrounding the two very young cases of BSE reported in Japan is insufficient to support any changes in the measures implemented by FSIS to prevent human exposure to the BSE agent.

**Testing Cattle for BSE**

*Comment:* Some comments stated that all cattle offered for slaughter should be tested for BSE and their carcasses should be permitted for use as human food only if the test result is negative. The comments noted that the carcasses would be held pending the test result in accordance with FSIS' ''test and hold'' policy. Some comments suggested that cattle over 20 months of age be tested for BSE. Others suggested that testing be limited to cattle over 30 months. One comment stated that establishments should not be required to remove SRMs if an animal tests negative for BSE.

Other comments agreed with statements made by FSIS in the preamble to the SRM interim final rule on the limitations of available test methods for BSE. The comments agreed that removal of SRMs provides more protection from human exposure to the BSE agent than testing cattle for BSE at slaughter.

*Response:* As discussed in the SRM interim final rule, the BSE tests that are available today are not appropriate for use as a food safety measure. Thus, the Agency believes that cattle should only be tested for BSE at slaughter as part of USDA's surveillance for BSE. FSIS agrees with the comments that assert that removal of SRMs at slaughter provides more protection from human exposure to the BSE agent than testing cattle for BSE.

The earliest point at which current testing methods can detect a positive case of BSE is 2 to 3 months before the animal begins to demonstrate clinical signs. The incubation period for BSE—the time between initial infection and the manifestation of clinical signs—is generally very long, on average about 5 years. Therefore, there is a long period in the life of an infected animal when tests with the current methodology would not detect the disease. Thus, testing all slaughter cattle for BSE might offer misleading assurances to the public and to U.S. trading partners.

In contrast, the current test technology provides highly meaningful and reliable results when used for surveillance purposes on animals within USDA's targeted populations—specifically, adult animals exhibiting some type of clinical abnormality that could be consistent with BSE. This targeted approach is based on the assumption that if the disease is rare in the most likely population, it will be even more unlikely to be found in the non-targeted population. Thus, USDA's APHIS is able to calculate the estimated prevalence of BSE in the U.S. cattle population as a whole from fewer samples when those samples are drawn from the target population. The current testing technology enables APHIS to assess the prevalence within the context of surveillance and therefore the effectiveness of various risk mitigation measures that have been implemented.

*Comment:* A few comments stated that there is a need to develop improved tests for BSE. The comments stated that a live animal test must be developed so that cattle can be tested for BSE at slaughter. Another comment said that enhanced diagnostics for BSE must be developed to minimize the possibility of false negatives. The comment provided the example of the use of sodium phosphotungstic acid to preferentially precipitate prions. Another comment said that the discovery of a normal-appearing animal in Italy with an apparently new strain of BSE that may elude tests used in the United States underscores the need for more sensitive and rapid tests that are in widespread use in Europe.

*Response:* FSIS agrees and supports the development of improved BSE tests and agrees that there is a need for an accurate and reliable live animal test.

*Comment:* Some comments stated that USDA should permit private companies to test cattle for BSE at slaughter.

*Response:* USDA's APHIS is responsible for approving the use and distribution of approved BSE test kits. However, as stated above, FSIS believes that the BSE tests that are available today are not appropriate for use as a food safety measure.

**Reassess Measures as Needed**

*Comment:* Several comments suggested that FSIS make appropriate adjustments to the SRM interim final rule if new scientific findings or the results of the increased surveillance indicate that the regulations should be modified. The comments stated that if no additional cases of BSE are confirmed under APHIS' enhanced surveillance, FSIS should evaluate whether the removal of SRMs from cattle older than 30 months of age is warranted given the near-zero risk posed to the public and the high costs imposed on producers. One comment said that FSIS should rescind the SRM interim final rule if no additional BSE cases are confirmed in the United

[27] The EFSA Journal 2005 220, 1–21, Annex to the Opinion, Report of the Working Group on the assessment of the age limit in cattle for the removal of certain specified risk materials (SRM) (see 1.2.3. Age distribution of young BSE cases outside the EU, p. 11). Available on the Internet at: *http://www.efsa.eu.int/science/biohaz/biohaz_opinions/opinion_annexes/933/biohaz_report_ej220_srmremove_en1.pdf.*

States. Another stated that FSIS should permit the use of some, if not all, SRMs and permit vertebral bones from cattle 30 months of age and older in the production of beef AMR product if no additional cases are confirmed.

One comment said that any action to prevent human exposure to the BSE agent should be evaluated based on its public health outcome. According to the comment, a human health risk assessment should be conducted to determine the extent of public health protection that the SRM interim final rule provides before FSIS issues a final rule. Another comment stated that FSIS should leave the current measures in place regardless of the outcome of APHIS' enhanced BSE surveillance.

A few comments suggested that FSIS work with Canada and Mexico to harmonize BSE regulations in North America. One comment stated that FSIS should harmonize its requirements for SRM removal with the OIE standards to the maximum extent possible.

*Response:* FSIS will continue to evaluate the science, international standards for, and the risk of BSE in the United States on an ongoing basis to ensure that the measures implemented by the U.S. government to minimize potential human exposure to the BSE agent continue to provide the appropriate level of protection. The Agency, in coordination with APHIS and FDA, will make appropriate adjustments to this final rule if new scientific findings or information on the risk of BSE in the United States indicate that prescribed measures should be modified, added, or eliminated.

**Humane Handling of Livestock**

*Comment:* Most of the comments received in response to the SRM interim final rule were from animal welfare advocacy organizations and private citizens concerned about the welfare of animals. These comments expressed support for the interim prohibition on the slaughter of non-ambulatory disabled cattle for human food and requested that FSIS make it permanent. The comments also requested that FSIS extend the prohibition to cover all livestock species under FSIS'' jurisdiction, i.e., sheep, swine, goats, and horses and other equines, and to require that all non-ambulatory animals be immediately and humanely euthanized on arrival at a slaughter facility. According to the comments, a permanent prohibition on the slaughter of non-ambulatory disabled cattle and other non-ambulatory livestock is necessary to ensure that these animals are handled in a humane manner.

*Response:* FSIS has carefully considered the humane handling implications of the interim prohibition on the slaughter of non-ambulatory disabled cattle and has concluded that the comments have merit. Thus, the Agency has determined requiring the condemnation of non-ambulatory disabled cattle that are offered for slaughter may be necessary ensure that these animals are humanely handled in connection with slaughter as required under the Humane Methods of Slaughter Act (HMSA) of 1978 (7 U.S.C. 1901 *et seq.*).

However, because FSIS did not discuss issues related to the humane handling of non-ambulatory disabled cattle or other non-ambulatory disabled livestock that are offered for slaughter in the SRM interim final rule or in the July 14, 2004, FSIS/APHIS/FDA ANPR, this final rule affirms the prohibition on the slaughter of non-ambulatory disabled cattle that are offered for slaughter as a measure to prevent potential human exposure to the BSE agent. FSIS intends to initiate a separate action in which it will discuss measures that may be necessary to ensure that non-ambulatory disabled cattle and other non-ambulatory disabled livestock are humanely handling in connection with slaughter.

*Comment:* Some comments suggested that FSIS amend the regulations in 9 CFR 309.13 that permit condemned livestock to be set apart and treated, or to be released from the establishment premises if permission is granted, to exclude all non-ambulatory disabled livestock.

*Response:* FSIS disagrees with these comments. Some non-ambulatory livestock that have been condemned may be affected with reversible conditions. The Agency believes that livestock that are condemned on the account of conditions such as ketosis, swine erysipelas, leptospirosis, inflammatory conditions, or the other conditions identified under 9 CFR 309.13, should continue to be permitted to be set apart and held for treatment under supervision of an FSIS program employee or an official designated by the area supervisor.

*Comment:* Some comments noted that prohibiting the slaughter of non-ambulatory disabled cattle for human food provides an incentive for cattle producers and transporters to engage in responsible husbandry and management practices to prevent cattle from becoming non-ambulatory before they are slaughtered. One comment stated that USDA should prohibit the transport of non-ambulatory disabled cattle from the farm.

*Response:* Although the purpose of requiring the condemnation of non-ambulatory disabled cattle that are offered for slaughter is to prevent potential human exposure to the BSE agent, FSIS agrees with the comments that stated that prohibiting the slaughter of non-ambulatory disabled cattle may provide incentives for cattle producers to adopt animal husbandry practices that prevent cattle from becoming non-ambulatory. The Agency also agrees that it may provide incentives for transporters to handle cattle in a manner that prevents them from becoming non-ambulatory.

**Comments Concerning Livestock Other Than Cattle**

*Comment:* One comment asked that the slaughter of all non-ambulatory disabled livestock be prohibited to prevent potential human exposure to the BSE agent. The comment argued that, in addition to the BSE variant discovered in the cow in Washington State, there are likely other variants of BSE that afflict cattle, as well as other poorly understood or unidentified TSE variants that affect other livestock species. According to the comment, variants of BSE or other TSEs may be linked to cases of the classical or the ''sporadic'' form of CJD in the United States and elsewhere.

The comment also stated that researchers in the United Kingdom have recently discovered a type of scrapie that resembles BSE. The comment argued that scientists cannot rule out the possibility that this is a new form of BSE that has adapted to sheep. As stated by the comment, prion diseases in sheep can be transmitted from animal to animal and, as a result, a form of BSE acquired prior to the feed ban may be circulating in the United States. The comment also noted that TSE agents are more widely distributed in the tissues of sheep than they are in cattle.

The comment also argued that the fact that requirements in the interim final rule on AMR systems also apply to pork demonstrates that FSIS acknowledges that materials from livestock other than cattle may pose a BSE risk.

*Response:* When FSIS issued the SRM interim final rule, the prohibition on the slaughter of non-ambulatory disabled cattle for human food was limited to cattle because the Agency was not aware of any data to indicate that livestock other than cattle could contract BSE under natural conditions. Thus, the Agency did not believe that extending the prohibition on the slaughter of non-ambulatory disabled cattle to other livestock would be appropriate in this rulemaking.

On January 28, 2005, a suspected case of BSE in a goat slaughtered in France in 2002 was confirmed by a panel of European scientists.[28] In response to this finding, the European Commission proposed to increase testing for BSE among goats for at least six months to determine if this one positive case was an isolated incident. As of the date of the publication of this document, no additional cases of BSE have been confirmed under natural conditions in livestock species other than cattle. Therefore, the Agency has concluded that there are insufficient data to indicate that a prohibition on the slaughter of non-ambulatory disabled livestock other than cattle is needed to minimize human exposure to the BSE agent. The Agency will continue to follow the research with regard to BSE in livestock species other than cattle and will use the findings of future research to inform its policies with regard to BSE.

FSIS disagrees that requirements in the interim final rule on AMR systems indicate that the Agency acknowledges that materials from livestock other than cattle may pose a BSE risk. One of the objectives of the AMR interim final rule is to define the criteria that products produced using AMR systems must comply with to be represented as ''meat.'' The preamble to the AMR rule makes clear that the presence of ''CNS-type tissues,'' i.e., CNS tissue, DRG, and trigeminal ganglia, from livestock other than cattle 30 months of age and older in AMR product renders the product misbranded (69 FR 1874, 1881).

*Comment:* A few comments stated that the change in the regulation that replaces ''seriously crippled animals commonly termed ''downers'' in § 309.2(b) with ''non-ambulatory disabled livestock'' unnecessarily and inappropriately broadens the rule's scope. The comments noted that the SRM interim final rule, as written, applies the definition of non-ambulatory disabled livestock to swine even though there is no scientific link between swine and BSE. The comment suggested that FSIS consider species-specific language that recognizes that swine or other amenable species can be ''temporarily disabled'' and still be suitable for slaughter for human food. The comment requested that FSIS amend the definition of non-ambulatory disabled livestock to recognize the differences in species and the conditions that may warrant the condemnation of those animals on a species and case-by-case basis.

*Response:* The definition of non-ambulatory disabled livestock does not broaden the scope of the rule to require the immediate condemnation of non-ambulatory disabled livestock other than cattle. The regulations at 9 CFR 309.2(b) provide that all seriously crippled animals and non-ambulatory disabled livestock shall be identified as U.S. Suspects unless they are required to be classed as condemned under 9 CFR 309.3. The regulations in 9 CFR 309.3 require that all non-ambulatory disabled cattle be condemned. However, non-ambulatory disabled livestock other than cattle may be identified as U.S. Suspects, set apart, and slaughtered separately from livestock that have passed ante-mortem inspection (9 CFR 309.2(n)). If an FSIS veterinarian finds that the meat and meat food products from a U.S. Suspect are not adulterated, these products may be used for human food (9 CFR 311.1).

**Animal Feed**

*Comment:* Several comments requested that FSIS prohibit the use of SRMs and non-ambulatory disabled cattle in animal feed and pet food. Other comments suggested that FSIS work with FDA to completely remove all SRMs, as well as non-ambulatory and dead stock from the animal feed chains. One comment stated that the U.S. government should ban the feeding of any mammalian protein to all mammals and prohibit the use of poultry litter in animal feed.

*Response:* The FDA is responsible for regulating animal food and feed in the United States. On October 6, 2005, FDA published a proposed rule to amend its animal feed regulations to prohibit from use in the food or feed of all animals certain high risk cattle materials that can potentially carry the BSE agent (''*Substances Prohibited From Use in Animal Food or Feed,*'' 70 FR 58570). The issues raised by these comments are addressed in that rulemaking. FSIS with APHIS will continue to work closely with FDA on its rulemaking.

**Surveillance, Disposal of Dead Cattle, and Cattle Identification**

*Comment:* Some comments noted that surveillance for BSE is essential for establishing the prevalence of the disease and for evaluating the effectiveness of control measures. One comment said that FSIS should test all high-risk cattle 30 months of age and older for BSE and randomly sample healthy cattle over 30 months of age to determine the true prevalence of the disease and to evaluate risk management measures in this country. One comment said that testing all non-ambulatory disabled cattle for BSE regardless of the reason for their non-ambulatory status may bias the representative population of potentially infected cattle. As stated by the comment, young injured cattle are unlikely to have BSE. Another comment suggested that USDA test all non-ambulatory disabled cattle.

One comment stated that USDA should require licensing of all entities, including farms and ranches, that dispose of cattle. As stated by the comment, FSIS has some authority over registration and recordkeeping of handlers of 4–D livestock and should explore extending this to disposal of these livestock to aid surveillance.

A few comments asserted that APHIS' BSE surveillance testing on the farm provides no incentive for farmers or ranchers to voluntarily subject their non-ambulatory cattle to testing. According to the comments, the program offers only risk and no compensation. The comments suggested that USDA establish a program for producers to submit animals that die on the farm for testing for BSE.

*Response:* USDA's APHIS has primary responsibility for BSE surveillance activities in the United States and is responsible for developing the BSE sampling protocols. We forwarded these comments to APHIS for consideration as they designed their current BSE surveillance program. As discussed above, APHIS has now transitioned to an ongoing BSE surveillance program, which samples approximately 40,000 animals each year, and continues to sample the cattle populations where the disease is most likely to be found. The targeted population for APHIS' ongoing surveillance includes cattle exhibiting signs of CNS disorders or any other signs that may be associated with BSE, including emaciation or injury, and dead cattle, as well as non-ambulatory cattle. Samples from the targeted population are taken from the same locations as those used during the enhanced surveillance program.

FSIS has and continues to assist APHIS in implementing its BSE surveillance program by, among other activities, collecting brain samples of all cattle condemned on ante-mortem inspection, including non-ambulatory disabled cattle and cattle that show signs of CNS disease, and verifying that ante-mortem condemned cattle that are to be tested by APHIS at an off-site sample collection location arrive at the location.

[28] Case of BSE in goat confirmed: Commission extends testing programme, Europa Web site, January 28. 2005. *http://europa.eu.int/rapid/pressReleasesAction.do?reference=IP/05/105&format=HTML&aged=0&language=EN&guiLanguage=fr.*

As noted by the comments, FSIS has some authority over registration and recordkeeping of handlers of 4–D livestock. FSIS does not believe further regulatory action is required as suggested by the comment.

*Comment:* One comment stated that USDA should develop, implement, and enforce safe and effective methods for destroying animals that are found to have a TSE. Another comment suggested that all dead cattle on farms be transported to a federally regulated facility for disposal.

*Response:* USDA's APHIS is the agency primarily responsible for ensuring the proper disposition of animals that have confirmed TSEs. At the same time, APHIS, FSIS, FDA, and the Environmental Protection Agency (EPA), coordinate efforts to ensure that the carcasses of animals with TSEs and other diseases are properly disposed of.

*Comment:* Several comments expressed support for a national cattle identification system. Some comments stated that USDA should implement an identification system for all livestock, not just cattle, and that is should be mandatory. One comment stated that animals at slaughter should be required to have identification records and that the records should be retained for 7 years.

*Response:* Since April 2004, USDA has been in the process of implementing the National Animal Identification System (NAIS), a voluntary animal identification and tracking system that will be used in all States and that will operate under national standards. When fully operational, the system will be capable of tracing a sick animal or group of animals back to the herd or premises that is the most likely source of infection. It will also be able to trace potentially exposed animals that were removed from that herd or premises. Information regarding the NAIS can be found on the Internet at: *http://animalid.aphis.usda.gov/nais/index.shtml.*

**Other Comments**

*Comment:* One comment suggested that FSIS require that the packaging of beef products bear labeling to warn the American public about the potential risk of BSE. Another comment stated that the labeling of products that contain brain or spinal cord from cattle younger than 30 months of age should include a warning about the potential BSE risk. Another comment said that country-of-origin labeling for meat products would be invaluable for tracking individual animals or herds implicated in disease transmission.

*Response:* As discussed in detail above, the estimated BSE prevalence in the United States is extremely low, less than one case per million cattle. On the basis of these prevalence estimates, in conjunction with effective implementation of the risk mitigation measures discussed here, FSIS has determined that beef and beef products produced in the United States are, and will remain, highly unlikely to be contaminated with the BSE agent. Therefore, the Agency disagrees that beef products or products that contain brain or spinal cord from cattle less than 30 months should bear warning labels about the potential BSE risk.

Under the Farm and Security and Rural Investment Act of 2002 and the 2002 Supplemental Appropriations Act, USDA is required to implement a mandatory country of origin labeling program (COOL).[29] USDA's Agricultural Marketing Service (AMS) published a proposed rule on the COOL program on October 30, 2003 (68 FR 61944–61985, Docket No. LS–03–04). Under the proposal, retailers would be required to notify their customers of the country of origin of all beef (including veal), lamb, pork, fish, and selected other perishable commodities being marketed in their stores. In addition, the AMS proposal identifies criteria that these commodities must meet to be considered of U.S. origin. In January 2004, President Bush signed Public Law 108–199, which included a provision to delay until September 2006 the implementation of mandatory COOL for all covered commodities except wild and farm-raised fish and shellfish. On November 10, 2005, President Bush signed Public Law 109–97, which delayed implementation of mandatory COOL for all covered commodities except wild and farm-raised fish and shellfish until September 30, 2008.

*Comment:* One comment stated that the U.S. government must trace CJD in humans.

*Response:* The U.S. Centers for Disease Control and Prevention (CDC) conducts surveillance and does tracing for CJD and other human TSEs in the United States. Information on surveillance for CJD in the United States is available on the CDC Web site at: *http://www.cdc.gov/ncidod/dvrd/vcjd/index.htm.*

*Comment:* One comment suggested that USDA encourage farmers to feed cattle natural, organic feed. Another comment stated that USDA should phase out all growing and raising of animals for human consumption.

*Response:* These comments are outside the scope of this rulemaking and outside the scope of FSIS' regulatory authority.

*Comment:* One comment requested that USDA eliminate the requirement that beef imported from Canada be processed on dedicated equipment if establishments slaughter cattle 30 months of age and older and cattle younger than 30 months in the same facility.

*Response:* This comment was addressed by APHIS in its final rule, ''*Bovine Spongiform Encephalopathy; Minimal-Risk Regions and Importation of Commodities*'' (70 FR 459–553, January 4, 2005). In that rulemaking, APHIS removed the proposed requirement that meat derived from bovines in a BSE minimal-risk region that are slaughtered in that region come from animals slaughtered at a facility that either slaughters only bovines less than 30 months of age or complies with an approved segregation process.

**2005 Risk Assessment**

*Background.* In the Final Regulatory Impact Analysis (FRIA) of this final rule, FSIS used an updated version of the 2001 and 2003 Harvard Risk Assessment models developed by the Harvard Center for Risk Analysis (HCRA) of the Harvard School of Public Health and the Center for Computational Epidemiology at Tuskegee University to develop baseline and mitigation estimates of potential human exposure to the BSE agent. The update is referred to here as ''the 2005 model.'' The Agency used estimates generated by the 2005 model to assess the benefits associated with the measures adopted in this final rule.

In the 2005 model, the HCRA developed a new baseline, analyzed the effects of the measures implemented by USDA and FDA in response to the confirmation of the BSE case in Washington State, and analyzed recommendations made by an international expert BSE panel that was convened at the request of the Secretary of Agriculture to review the actions taken by the United States in response to the confirmation of the BSE case in Washington State.

The authors submitted the 2005 model to FSIS in June 2005, and a peer review of the 2005 model and resulting assessment was completed in September 2005. The final products were submitted to FSIS following the peer review.

On July 12, 2006, FSIS published a notice in the **Federal Register** announcing that the Agency was making

[29] AMS USDA, ''Country of Origin Labeling—Current Status of Country of Origin Labeling,'' available at *http://www.ams.usda.gov/cool/status.htm.*

the 2005 Harvard BSE Update (i.e., the 2005 model) available to the public (71 FR 39282). In the notice, FSIS gave the public until August 11, 2006, to submit comments on the updated risk assessment. The notice also announced that the Agency would be holding a technical meeting to provide information on the 2005 model and resulting assessment. This meeting was held on July 25, 2006.

In response to a comment submitted on August 1, 2006, FSIS extended the comment period on the 2005 model to October 27, 2006, which is 45 days from the date on which the Agency made the transcript of the July 25, 2006, technical meeting publicly available. The transcripts of the public meeting were posted on the FSIS Web site on September 12, 2006 (*http://www.fsis.usda.gov/PDF/BSE_Transcript_072506.pdf*).

FSIS received six comments on the 2005 model. The commenters included a consumer advocacy organization, two animal welfare organizations, a cattle producer trade association, a consultant, and a private citizen. In response to some of these comments, revisions were made to the 2005 model.

This document refers to the analyses conducted before the 2005 model was revised in response to public comments as ''the pre-public comment runs of the 2005 model'' and the analyses that were conducted after the 2005 model was revised as ''the post-public comment runs of the 2005 model.'' Both the pre-public comment and post-public comment runs of the 2005 model are discussed below.

*Pre-public comment runs of the 2005 model.* The pre-public comment runs of the 2005 model use the base case provided by Harvard (i.e., prior to the revisions made in response to public comments). The pre-public comment runs yielded an estimated mean total potential human exposure of 3,800 cattle oral $ID_{50}$s to the BSE agent over 20 years following the hypothetical introduction of 500 BSE-infected cattle into the U.S. This base case yielded an average of 180 new BSE cases in the U.S. over 20 years.

The pre-public comment runs found that the food safety measures enacted by USDA all reduce potential human exposure to BSE infectivity but have little effect on spread of BSE in the cattle population. Removing non-ambulatory disabled cattle from the human food supply reduces predicted potential human exposure by about 3% (leaving a mean of 3,700 cattle oral $ID_{50}$s). The pre-public comment runs found that removing SRMs from cattle 30 months of age and older almost completely eliminates potential human exposure, reducing it to 11 cattle oral $ID_{50}$s. Prohibiting the use of skulls and vertebral columns from cattle 30 months of age and older in advanced meat recovery (AMR) systems reduces potential human exposure by approximately two-fifths to 2,200 $ID_{50}$s. It is worth noting that these are relative reductions to what is already a small risk in absolute terms, especially in light of the fact that these simulations reflect the assumed introduction of 500 infected cattle into the U.S. None of the combined measures yielded substantial improvements over their components.

The 2005 model evaluates two measures under consideration by FDA, including a prohibition on the use of ruminant blood in ruminant feed, and the requirement that plants producing both prohibited material (i.e., ruminant-derived material) and non-prohibited material use dedicated production lines. The pre-public comment runs indicate that neither of these actions would have much impact on the spread of BSE. The 2003 Harvard report concluded that blood contributes relatively little to the spread of BSE. Similarly, earlier work done by the HCRA suggests that cross-contamination is a relatively minor factor.

As discussed earlier in this document, the IRT (the International Review Subcommittee convened by the Secretary of Agriculture) suggested the possibility of a ban on SRMs from animals 12 months and older for both human food and animal feed. The 2005 model evaluates the impact of this ban assuming perfect compliance. The pre-public comment runs of the 2005 model suggest that this measure would reduce potential human exposure to the BSE agent by more than 99% relative to the base case. Because the model assumed that the ban also removes SRMs from dead stock prior to their rendering, the measure achieves a substantial reduction in the spread of BSE among cattle, decreasing the number of new infected BSE cases in the U.S. to 35 from 180. The pre-public comment runs found that the removal of all animal-derived protein from cattle feed, as suggested by the IRT, would decrease the number of new BSE cases from 180 to 170 over 20 years. The remaining cases result primarily from mis-feeding of rations containing ruminant proteins (feed intended for other species) to cattle. This measure has a small-predicted impact on potential human exposure.

*Post-public comment runs of the 2005 model.* For the post-public comment runs, the 2005 model was revised to incorporate poultry litter as a potential pathway for the spread of BSE in the United States. The model's revised base case assumes that 40% of prohibited meat and bone meal produced by either mixed or prohibited-only renderers is used in poultry feed. It also assumes that 1% of chicken litter is recycled back to cattle feed.

The poultry litter assumption is based on information provided by stakeholders to FDA. FDA shared this information with an interagency (APHIS, FDA, and FSIS) group that reviewed the data and incorporated them into the post-comment revisions of the 2005 model.

In addition, for the post-public comment runs, the 2005 model base case was revised to lower the rate that animals with clinical signs of BSE are detected on ante-mortem inspection. The 2005 post-public comment model's revised base case assumes that ante-mortem inspection detects 50% of ambulatory animals with clinical BSE signs, and 25% of non-ambulatory animals with clinical BSE signs. A revised sensitivity analysis investigates the impact of assuming ante-mortem inspection fails to detect any animals with clinical signs of BSE.

FSIS used the post-public comment revised base case and new mitigation measures to estimate of potential human exposure to the BSE agent. Like the base case used for the pre-public comment runs, the revised base case for the post-public comment runs does not reflect the measures to minimize human exposure to the BSE agent implemented by FSIS in the SRM interim final rule.

The post-public comment runs of the 2005 model lead to an increase in the estimated number of infected cattle and an increase in potential human exposure. Specifically, when the two modifications discussed above (i.e., inclusion of the poultry litter pathway and inclusion of the less optimistic assumptions regarding ante-mortem inspection) were added to the model, the base case from the post-public comment runs yielded an increase in the estimated mean total potential human exposure to the BSE agent over 20 years following the hypothetical introduction of 500 BSE-infected cattle into the U.S. from 3,800 to 6,600 cattle oral $ID_{50}$s. These modifications also resulted in an increase from 180 to 200 in the average number of new BSE cases in the U.S. over 20 years.

However, although both the number of BSE cases and the level of human exposure increased in the post-public comment runs, conclusions with regard to prohibiting the use of SRMs for human food remain the same. More specifically, even with the revised base

case, the post-public comment runs show that excluding the materials designated as SRMs in this final rule almost completely eliminates potential human exposure to the BSE agent if compliance is perfect. Similarly, the post-public comment runs found that neither lowering the age classification for SRMs from cattle 30 month of age and older to 12 months of age and older, nor from 30 months of age and older to 24 months of age and older, provides additional benefits in reducing the level of potential human exposure to the BSE agent. Thus, the results of the 2005 model, regardless of the base case used, have not led the Agency to change its conclusion that the measures adopted in this final rule are prudent for preventing potential human exposure to the BSE agent.

The 2005 pre-public comment and 2005 post-public comment models are available for viewing by the public on the FSIS Web site at: *http://www.fsis.usda.gov/Science/Risk_Assessments/index.asp.* Also available on the Web site are the comments received on the 2005 model, and FSIS' response to these comments.

**Summary of the Final Rule**

In this final rule, FSIS is affirming, with amendments, the SRM interim final rule. The Agency is also affirming the air-injection stunning interim final rule. As discussed earlier in this document, the Agency intends to affirm and, if necessary, amend the AMR interim final rule in a separate document that will be published in the **Federal Register** at a later date. In addition, FSIS also intends to address the humane handing implications of the slaughter of non-ambulatory disabled cattle and other non-ambulatory disabled livestock in a separate action.

In this final rule, FSIS is affirming, without amendment, the provisions in 9 CFR 309.2(b) of the SRM interim final rule which replace the term ''downer'' with ''non-ambulatory disabled livestock'' and which define ''non-ambulatory disabled livestock'' as livestock that cannot rise from a recumbent position or that cannot walk, including, but not limited to, those with broken appendages, severed tendons or ligaments, nerve paralysis, fractured vertebral column, or metabolic conditions. The Agency is revising paragraph 9 CFR 309.3(e) to clarify that non-ambulatory disabled cattle that are offered for slaughter must be condemned but that FSIS inspection personnel will determine the disposition of cattle that become non-ambulatory after they have passed ante-mortem inspection on a case-by-case basis. As discussed earlier in this document, this amendment reflects the current Agency practice.

In addition, FSIS is amending 9 CFR 309.13(b) of the regulations that prescribe requirements for the disposition of condemned livestock to add veal calves that cannot rise from a recumbent position or that cannot walk because they are tired or cold to the list of conditions for which condemned livestock may be set aside and treated.

FSIS is affirming, with amendments, the provisions of the SRM interim final rule that define SRMs and prescribe requirements for the handling and disposition of SRMS. The Agency is amending 9 CFR 310.22(a) to exclude from the definition of SRMs materials from cattle from foreign countries that can demonstrate that their BSE risk status can reasonably be expected to provide the same level of protection from human exposure to the BSE agent as prohibiting SRMs for use as human food does in the United States. As discussed earlier in this document, countries that believe that they have the appropriate BSE risk status to qualify for this exemption should submit evidence to support their claimed BSE risk to FSIS' Office of International Affairs.

FSIS is affirming without changes the list of materials designated as SRMs in 9 CFR 310.22(a)(1). These materials are 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 of cattle 30 months of age and older. 9 CFR 310.22(a)(2) designates the distal ileum of the small intestine and the tonsils of all cattle as SRMs. The Agency is removing 9 CFR 310.22(a)(3) and re-designating the provisions in that paragraph that prescribe the conditions under which the small intestine, excluding the distal ileum, from cattle may be used for human food as 9 CFR 310.22(d).

The Agency is affirming, with minor grammatical changes, 9 CFR 310.22(b), which declares that SRMs are inedible and prohibits their use for human food. FSIS is also affirming the provisions in 9 CFR 310.22(c) that specify that SRMs must be removed and disposed of as inedible in accordance with 9 CFR 314.1 or 9 CFR 314.3. In addition, the Agency is amending 9 CFR 310.22(c) to require that the spinal cord from cattle 30 months of age and older be removed from the carcass at the establishment where the animal was slaughtered.

FSIS is re-designating 9 CFR 310.22(d) of the SRM interim final rule, the requirements for the removal, segregation, and disposition of SRMs, as 9 CFR 310.22(e) and moving the conditions under which the small intestine, excluding the distal ileum, may be used for human food, formerly found in 9 CFR 310.22(a)(3), to 9 CFR 310.22(d).

Specifically, 9 CFR 310.22(d)(1) provides that the small intestine from cattle may be used for human food if it is derived from cattle that were inspected and passed in an official establishment in the United States, or in a certified foreign establishment, and it is otherwise eligible for importation into the United States under 9 CFR 327.1(b) of FSIS' import regulations (9 CFR 310.22(d)(1)(i)) and the distal ileum has been removed by a procedure that removes at least 80 inches of the uncoiled and trimmed small intestine as measured from the ceco-colic junction and progressing towards the jejunum or by a procedure that the establishment demonstrates is effective in ensuring complete removal of the distal ileum (9 CFR 310.22(d)(1)(ii)). FSIS is also amending 9 CFR 310.22(d)(1) to add a paragraph (d)(1)(iii), which clarifies that if the conditions described above are not met, the small intestine must be removed and disposed of as inedible.

9 CFR 310.22(d)(2) provides that requirements for the removal of the small intestine prescribed in 9 CFR 310.22(d)(1) do not apply to materials from cattle from countries that can demonstrate that their BSE risk status provides the same level of protection from human exposure to the BSE agent as prohibiting SRMs for use as human food does in the United States.

FSIS is re-designating paragraph 9 CFR 310.22(e) of the SRM interim final rule, which specifies that materials that are SRMs will be deemed to be from cattle 30 months of age and older unless the establishment can demonstrate through documentation that the materials are from an animal that was younger than 30 months of age at the time of slaughter, as 9 CFR 310.22(h). FSIS is affirming with minor grammatical changes, most of the requirements for the removal, segregation, and disposition of SRMs in 9 CFR 310.22(d) of the SRM interim final rule and re-designating them as 9 CFR 310.22(e). In 9 CFR 310.22(e)(1), the Agency is adding a provision to clarify that an establishment's procedures for the removal, segregation, and disposition of SRMs must address potential contamination of edible materials with SRMs before, during, and after entry into the establishment.

FSIS is adding a new paragraph, 9 CFR 310.22(f), that prescribes requirements for the sanitation of

equipment used to cut through SRMs. 9 CFR 310.22(f)(1) prescribes requirements for establishments that do not segregate the carcasses or parts from cattle 30 months of age and older from the carcasses or parts from cattle younger than 30 months. 9 CFR 310.22(f)(1) requires that such establishments either (1) use dedicated equipment to cut through SRMs (9 CFR 310.22(f)(1)(i)) or (2) clean and sanitize equipment used to cut through SRMs before the equipment is used on carcasses or parts from cattle younger than 30 months (9 CFR 310.22(f)(1)(ii)). Under 9 CFR 310.22(f)(2), establishments that segregate the carcasses or parts from cattle 30 months of age and older from the carcasses or parts from cattle younger than 30 months, and that process the carcasses of the younger cattle first, may use routine operational sanitation procedures on equipment used to cut through SRMs.

FSIS is also adding a new paragraph 310.22(g) that specifies the conditions under which slaughter establishments may ship beef carcasses or parts that contain vertebral columns from cattle 30 months of age and older to another federally-inspected facility for further processing. FSIS is adding these provisions to ensure that establishments that ship carcasses or parts that contain vertebral columns from cattle that were 30 months of age and older at the time of slaughter implement the appropriate controls to prevent the inadvertent introduction of SRMs into the human food supply.

Under 9 CFR 310.22(g), establishments may ship carcasses or parts of carcasses that contain vertebral columns from cattle 30 months of age and older to another federally-inspected establishment for further processing if the establishment: (1) Maintains control of the carcasses or parts while these materials are in transit or ensures that the carcasses or parts move under FSIS control (310.22(g)(1)); (2) ensures that the carcasses or parts are accompanied by documentation that clearly states that they contain vertebral columns from cattle that were 30 months of age or older at the time of slaughter (9 CFR 310.22(g)(2)); (3) maintains records that identify the official establishment that received the carcasses or parts (9 CFR 310.22(g)(3)); and (4) maintains records that verify that the receiving establishment removed and properly disposed of the SRM portions of the vertebral column (9 CFR 310.22(g)(4)). Establishments that do not meet these conditions must remove the SRM portions of the vertebral column from cattle 30 months of age and older prior to shipping the carcass. Establishments that receive beef carcasses or parts must address removal of the vertebral column from cattle 30 months of age and older in their procedures for the removal, segregation, and disposition of SRMs.

FSIS is affirming without amendment the provisions in 9 CFR 311.27 of the SRM interim final rule that prohibit for use as human food the parts and carcasses of cattle slaughtered for humane reasons in the absence of an inspector. FSIS is affirming without amendment the interim provisions in 9 CFR 313.15(b)(2) and 9 CFR 310.13(a)(2)(iv)(C) that prohibit the use of stunning devices that deliberately inject compressed air into the cranial cavity of cattle.

FSIS is amending 9 CFR 318.6(b)(1) and 9 CFR 318.6(b)(8) to reflect the re-designation of the requirements on the use of the small intestine for human food from 9 CFR 310.2(a)(3) to 9 CFR 310.22(d). 9 CFR 318.6(b)(1) prescribes requirements for the use of animal casings as containers of meat food products and 9 CFR 318.6(b)(8) prescribes requirements for the use of intestines in meat food products and edible rendering. Finally, FSIS is affirming the prohibition on the use of MS (beef) for human food in 9 CFR 319.5(b).

**Executive Order 12866 and Regulatory Flexibility Act**

This final rule has been determined to be economically significant and, therefore, it has been reviewed by the Office of Management and Budget. This final rule affirms the air-injection stunning interim final rule and affirms, with changes, the SRM interim final rule. As discussed above, because the AMR interim final rule contains several non-BSE related provisions, FSIS intends to affirm and, if necessary, amend that interim final rule at a later date. The Agency will include a regulatory impact analysis of the final AMR rule at that time. The complete regulatory impact analysis for this final rule is available through the FSIS Web site at *http://www.fsis.usda.gov/regulations/2007_Interim_&_Final_Rules_Index/.*

**Summary of the Final Regulatory Impact Analysis**

In developing this Final Regulatory Impact Analysis (FRIA), FSIS reviewed the public comments received on the Preliminary Regulatory Impact Analysis (PRIA) and the interim final rules. In addition, FSIS developed and analyzed a set of regulatory alternatives for the FRIA.

The FRIA shows that the actions of this final rule require about 3,512 establishments that slaughter cattle or process bone-in beef products to take measures to minimize human exposure to cattle materials that could potentially contain the BSE agent. The FRIA estimates that the total annual average cost of the measure adopted in this final rule is $171.2 million annualized over 5 years at an interest rate of 7 percent.[30] The primary impacts of this final rule are the exclusion of SRMs from use in the human food supply; the prohibition of the slaughter of non-ambulatory disabled cattle that are offered for slaughter; and modifications of HACCP plans or Sanitation SOPs or other prerequisite programs and recordkeeping requirements. The FRIA found that there is no cost associated with the air-injection stunning final rule because air injection stunning devices are no longer in use in the United States.

The FRIA assesses the benefits of the measures adopted in this final rule. The measures adopted in this final rule are reasonable and necessary measures to ensure food safety. In doing so, they help to assure domestic and foreign consumers that the U.S. food supply is safe.

FSIS used the 2005 Harvard BSE Risk Assessment model, which is described above, to develop baseline and mitigation estimates of potential human exposure to the BSE agent for this rule. As discussed in detail above, the 2005 model was modified in response to comments.

Both the pre-public comment and post-public comment runs of the 2005 model estimated that the measures adopted in this final rule will result in a greater than 99 percent (at the mean) relative reduction in potential human exposure to the BSE agent when compliance is 100%. Because the amount of the BSE agent necessary to cause disease in humans is unknown, FSIS has not estimated monetary values for reductions in human morbidity and mortality associated with this final rule. No known cases of vCJD have been associated with consuming beef products in the United States.

[30] The estimated costs are higher compared with those estimated for the PRIA of the interim final rule because more establishments needed to take measures than what the PRIA anticipated. However, the PRIA accounted for the removal of the entire small intestine instead of just the distal ileum portion of the small intestine. The savings of only removing the distal ileum offset partially the extra costs of more establishments (state-inspected and custom-exempt) needing to take the measures contained in the final rule. FSIS changed the small intestine provision in September 2005.

The FRIA does estimate a benefit for the restoration of beef export markets (gross sales), which may, in part, have been affected by the measures implemented in this final rule. However, because of the many other factors that are also relevant to regained market access, the affects on the restoration of beef export markets that may be attributed to the measures implemented in this final rule are difficult to determine. In pre-BSE 2003, beef export markets totaled $3,861.9 million annually for veal, beef, and beef variety meats. Then, in post-BSE 2004, these beef export market sales dropped about 79 percent or $3,053.8 million to $808.1 million. However, in 2005, the U.S. had restored its beef export market sales to a total of $1,365.3 million. Compared to 2004, this is an increase of about 69 percent or $557.2 million in beef export market sales.

In addition, the FRIA shows that this final rule is cost-effective when compared to considered regulatory alternatives. Further, the FRIA addresses how this final rule affects about 3,278 very small, 197 small, and 37 large establishments of a total of about 3,512 establishments affected.[31]

FSIS expects that the aggregate beef price impacts of the measures contained in the final rule are not significant. FSIS estimates that the affected establishments have a relatively insignificant increase in operating costs, given that this increase is typically a relatively small share of the total operating costs affected. In addition, the removal of SRMs from the supply of variety meats is not expected to have a significant impact on prices, given the availability of substitutes (e.g., brains from cattle younger than 30 months of age, and the remaining small intestine excluding the distal ileum). Furthermore, FSIS estimates that only a relatively small share of the beef variety meat supply is affected. In addition, the removal of non-ambulatory disabled cattle from the food supply is not expected to have a significant impact on beef prices given the relatively small share of beef supply affected (less than 0.15 percent).

[31] FSIS defined small and very small establishments by its HACCP (Hazard Analysis and Critical Control Points) size definition. Establishments that have fewer than 10 employees or generate less than $2.5 million in annual sales are ''very small'' establishments; establishments that have between 10 and 499 employees or generate more than $2.5 million in annual sales are ''small'' establishments; and establishments that have 500 or more employees are ''large'' establishments. The size definition classification is different from the Small Business Administration's categorization of small and large business due to the unique nature of the meat and poultry slaughter and processing industry.

**Executive Order 12988**

This final rule has been reviewed under Executive Order 12988, Civil Justice Reform. In this final rule: (1) All state and local laws and regulations that are inconsistent with this rule will be pre-empted; (2) no retroactive effect will be given to this rule; and (3) administrative proceedings will not be required before parties may file suit in court challenging this rule.

**Paperwork Requirements**

In accordance with section 3507(j) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), FSIS has reviewed the information and recordkeeping requirements in this final rule and has determined that the paperwork requirements associated with the regulations that require that establishments develop written procedures for the removal, segregation, and disposition of SRMs, have already been accounted for in the Specified Risk Materials information collection approved by the Office of Management and Budget (OMB). FSIS has also determined that the paperwork requirements for the regulations that require that establishments maintain daily records sufficient to document the implementation and monitoring of their procedures for the removal, segregation, and disposition of SRMs, and any corrective actions taken, have also been accounted for in the Specified Risk Materials information collection approved by OMB. The OMB approval number for the Specified Risk Materials information collection is 0583–0129.

In this final rule, FSIS is adding a new regulation that requires that federally-inspected slaughter establishments that transport carcasses or parts that contain vertebral columns from cattle 30 months of age and older to another federally-inspected establishment for further processing maintain records that verify that the official establishment that received the carcasses or parts removed and properly disposed of the portions of the vertebral column designated as SRMs. This is a new recordkeeping requirement that FSIS has submitted to OMB for approval.

*Title:* ''Specified Risk Materials Transport Documentation''.

*Type of Collection:* New.

*Abstract:* In this final rule, FSIS is requiring that slaughter establishments that transport carcasses or parts that contain vertebral columns from cattle that were 30 months of age and older at the time of slaughter to another federally-inspected establishment for further processing maintain documentation that verifies that the receiving establishment removed and properly disposed of the SRM portions of the vertebral column. This is a new information and recordkeeping requirement.

Under the current regulations, establishments that slaughter cattle, and establishments that process the carcasses and parts of cattle, are required to maintain daily records sufficient to document the implementation and monitoring of their procedures for the removal, segregation, and disposition of SRMs. Under this final rule, establishments that transport carcasses or parts from cattle 30 months of age and older for further processing will have to obtain these records from the receiving establishment in order to verify that the receiving establishment removed and properly disposed of the SRMs.

*Estimate of burden:* FSIS estimates that it will take establishments that receive for further processing carcasses or parts that contain vertebral columns from cattle 30 months of age and older approximately 2 minutes a day to submit to the transporting establishment records that document the implementation and monitoring of the receiving establishment's procedures for the removal, segregation, and disposition of SRMs. FSIS estimates that it will take the transporting establishments approximately 2 minutes a day to file this documentation once it is received.

*Respondents:* Official establishments that transport vertebral columns from cattle that were 30 months of age and older to another official establishment for further processing, and official establishments that receive for further processing carcasses or parts that contain vertebral columns from cattle that were 30 months of age at the time of slaughter.

*Estimated Number of Respondents:* 70.

*Estimated Number of Responses per Respondent:* 300 annually.

*Estimated Total Annual Burden on Respondents:* 700 hours.

Copies of this information collection assessment can be obtained from John O'Connell, Paperwork Reduction Act Coordinator, Food Safety and Inspection Service, USDA, 112 Annex, 300 12th Street, SW., Washington, DC 20250.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of FSIS' functions, including whether the information will have practical utility; (b) the accuracy of FSIS' estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(c) ways to enhance the quality, utility, and clarity of the information to be collected; ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques, or other forms of information technology. Comments may be sent to both John O'Connell, Paperwork Reduction Act Coordinator, at the address provided above, and the Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20253.

To be most effective, comments should be sent to OMB within 60 days of the publication date of this final rule.

**Government Paperwork Elimination Act (GPEA)**

FSIS is committed to achieving the goals of the GPEA, which requires that Government agencies, in general, provide the public with the option of submitting information or transacting business electronically to the maximum extent possible. Under this final rule, records that document the implementation and monitoring of an establishment's procedures for the removal, segregation, and disposition of SRMs may be maintained on computers, provided that the establishment implements appropriate controls to ensure the integrity of the electronic data. Allowing establishments to comply with the required record-keeping requirements will reduce data collection time and information processing and handling by the regulated industry and FSIS.

**Additional Public Notification**

Public awareness of all segments of rulemaking and policy development is important. Consequently, in an effort to ensure that minorities, women, and persons with disabilities are aware of this rule, FSIS will announce it on-line through the FSIS Web page located at *http://www.fsis.usda.gov/regulations_&_policies/2007_Interim_&_Final_Rules_Index/index.asp.*

The Regulations.gov Web site is the central online rulemaking portal of the United States government. It is being offered as a public service to increase participation in the Federal government's regulatory activities. FSIS participates in Regulations.gov and will accept comments on documents published on the site. The site allows visitors to search by keyword or Department or Agency for rulemakings that allow for public comment. Each entry provides a quick link to a comment form so that visitors can type in their comments and submit them to FSIS. The Web site is located at *http://www.regulations.gov/.*

FSIS also will make copies of this **Federal Register** publication available through the FSIS Constituent Update, which is used to provide information regarding FSIS policies, procedures, regulations, **Federal Register** notices, public meetings, recalls, and other types of information that could affect or would be of interest to our constituents and stakeholders. The update is communicated via Listserv, a free e-mail subscription service consisting of industry, trade, and farm groups, consumer interest groups, allied health professionals, scientific professionals, and other individuals who have requested to be included. The update also is available on the FSIS Web page. Through Listserv and the Web page, FSIS is able to provide information to a much broader, more diverse audience.

In addition, FSIS offers an e-mail subscription service that provides an automatic and customized notification when popular pages are updated, including **Federal Register** publications and related documents. This service is available at *http://www.fsis.usda.gov/news_and_events/email_subscription/* and allows FSIS customers to sign up for subscription options across eight categories. Options range from recalls to export information to regulations, directives and notices. Customers can add or delete subscriptions themselves and have the option to password protect their account.

**List of Subjects**

*9 CFR Part 309*

Meat inspection.

*9 CFR Part 310*

Meat inspection, Meat and meat products, Reporting and recordkeeping requirements.

*9 CFR Part 318*

Meat inspection, Meat and meat products, recordkeeping requirements.

■ Accordingly, the interim final rules amending 9 CFR Chapter III, which were published on January 12, 2004, at 69 FR 1862 and 69 FR 1885, and amended on September 7, 2005, at 70 FR 53043, are adopted as a final rule with the following changes:

## PART 309—ANTE-MORTEM INSPECTION

■ 1. The authority citation for part 309 is revised to read as follows:

**Authority:** 21 U.S.C. 601–695; 7 CFR 2.18, 2.53.

■ 2. Section 309.3 is amended by revising paragraph (e) to read as follows:

**§ 309.3 Dead, dying, disabled, or diseased and similar livestock.**

* * * * *

(e) Non-ambulatory disabled cattle that are offered for slaughter must be condemned and disposed of in accordance with § 309.13. FSIS inspection personnel will determine the disposition of cattle that become non-ambulatory after they have passed ante-mortem inspection on a case-by-case basis.

■ 3. Paragraph (b) of § 309.13 is amended by adding a new second sentence to read as follows:

**§ 309.13 Disposition of condemned livestock.**

* * * * *

(b) * * * Veal calves that are unable to rise from a recumbent position and walk because they are tired or cold may also be set apart and held as provided in this paragraph. * * *

* * * * *

## PART 310—POST-MORTEM INSPECTION

■ 4. The authority citation for part 310 continues to read as follows:

**Authority:** 21 U.S.C. 601–695; 7 CFR 2.18, 2.53.

■ 5. Section 310.22 is revised to read as follows:

**§ 310.22 Specified risk materials from cattle and their handling and disposition.**

(a) The following materials from cattle are specified risk materials, except when they are from cattle from a country that can demonstrate that its bovine spongiform encephalopathy (BSE) risk status can reasonable be expected to provide the same level of protection from human exposure to the BSE agent as prohibiting specified risk materials for use as human food does in the United States:

(1) 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 from cattle 30 months of age and older and

(2) The distal ileum of the small intestine and the tonsils from all cattle.

(b) Specified risk materials are inedible and prohibited for use as human food.

(c) Specified risk materials must be removed from the carcasses of cattle, segregated from edible materials, and

disposed of in accordance with § 314.1 or § 314.3 of this subchapter. The spinal cord from cattle 30 months of age and older must be removed from the carcass at the establishment where the animal was slaughtered.

(d) *Requirements for use of the small intestine for human food.* (1) The small intestine from all cattle may be used for human food if:

(i) It is derived from cattle that were inspected and passed in an official establishment in the United States or in a certified foreign establishment in a country listed in 9 CFR 327.2(b) as eligible to export meat and meat products to the United States and it is otherwise eligible for importation under 9 CFR 327.1(b), and

(ii) The distal ileum is removed by a procedure that removes at least 80 inches of the uncoiled and trimmed small intestine as measured from the ceco-colic junction and progressing proximally towards the jejunum or by a procedure that the establishment demonstrates is effective in ensuring complete removal of the distal ileum.

(iii) If the conditions in paragraphs (d)(1)(i) or (ii) of this section are not met, the entire small intestine must be removed from the carcass, segregated from edible materials, and disposed of in accordance with §§ 314.1 or 314.3 of this subchapter.

(2) The requirements in paragraph (d)(1) of this section do not apply to materials from cattle from countries that can demonstrate that their BSE risk status can reasonably be expected to provide the same level of protection from human exposure to the BSE agent as prohibiting specified risk materials for use as human food does in the United States.

(e) *Procedures for the removal, segregation, and disposition of specified risk materials.* (1) Establishments that slaughter cattle and establishments that process the carcasses or parts of cattle must develop, implement, and maintain written procedures for the removal, segregation, and disposition of specified risk materials. These procedures must address potential contamination of edible materials with specified risk materials before, during, and after entry into the establishment. Establishments must incorporate their procedures for the removal, segregation, and disposition of specified risk materials into their HACCP plans or Sanitation SOPs or other prerequisite programs.

(2) Establishments that slaughter cattle and establishments that process the carcasses or parts of cattle must take appropriate corrective action when either the establishment or FSIS determines that the establishment's procedures for the removal, segregation, and disposition of specified risk materials, or the implementation or maintenance of these procedures, have failed to ensure that specified risk materials are adequately and effectively removed from the carcasses of cattle, segregated from edible materials, and disposed of in accordance with paragraph (c) of this section.

(3) Establishments that slaughter cattle and establishments that process the carcasses or parts of cattle must routinely evaluate the effectiveness of their procedures for the removal, segregation, and disposition of specified risk materials in preventing the use of these materials for human food and must revise the procedures as necessary whenever any changes occur that could affect the removal, segregation, and disposition of specified risk materials.

(4) *Recordkeeping requirements.* (i) Establishments that slaughter cattle and establishments that process the carcasses or parts of cattle must maintain daily records sufficient to document the implementation and monitoring of the procedures for the removal, segregation, and disposition of the materials listed in paragraph (a) of this section, and any corrective actions taken.

(ii) Records required by this section may be maintained on computers provided that the establishment implements appropriate controls to ensure the integrity of the electronic data.

(iii) Records required by this section must be retained for at least one year and must be accessible to FSIS. All such records must be maintained at the official establishment for 48 hours following completion, after which they may be maintained off-site provided such records can be made available to FSIS within 24 hours of request.

(f) *Sanitation of equipment used to cut through specified risk materials.* (1) If an establishment that slaughters cattle, or that processes the carcasses or parts from cattle, does not segregate the carcasses and parts from cattle 30 months of age and older from the carcasses and parts from cattle younger than 30 months during processing operations it must:

(i) Use dedicated equipment to cut through specified risk materials; or

(ii) Clean and sanitize equipment used to cut through specified risk materials before the equipment is used on carcasses or parts from cattle younger than 30 months of age.

(2) If an establishments that slaughters cattle, or that process the carcasses or parts from cattle, segregates the carcasses and parts of cattle 30 months of age and older from cattle younger than 30 months of age during processing operations, and processes the carcasses or parts from the cattle younger than 30 months first, it may use routine operational sanitation procedures on equipment used to cut through specified risk materials.

(g) Slaughter establishments may ship beef carcasses or parts that contain vertebral columns from cattle 30 months of age and older to another federally-inspected establishment for further processing if the establishment shipping these materials:

(1) Maintains control of the carcasses or parts while they are in transit or ensures that the carcasses or parts move under FSIS control;

(2) Ensures that the carcasses or parts are accompanied by documentation that clearly states that the carcasses or parts contain vertebral columns from cattle that were 30 months of age and older at the time of slaughter;

(3) Maintains records that identify the official establishment that received the carcasses or parts;

(4) Maintains records that verify that the official establishment that received the carcasses or parts removed the portions of the vertebral column designated as specified risk materials in paragraph (a)(1) of this section and disposed of them in accordance with § 314.1 or § 314.3 of this subchapter.

(h) The materials listed in paragraph (a)(1) of this section will be deemed to be from cattle 30 months of age and older unless the establishment can demonstrate through documentation that the materials are from an animal that was younger than 30 months of age at the time of slaughter.

## PART 318—ENTRY INTO OFFICIAL ESTABLISHMENTS; REINSPECTION AND PREPARATION OF PRODUCTS

■ 6. The authority citation for part 318 continues to read as follows:

**Authority:** 7 U.S.C. 38f, 450, 1901–1906; 21 U.S.C. 601–695; 7 CFR 2.18, 2.53.

### § 318.6 [Amended]

■ 7. Section 318.6 is amended as follows:

■ a. In the third and fourth sentences of paragraph (b)(1) remove ''9 CFR 310.22(a)(3)'' and add ''9 CFR 310.22(d)'' in its place.

■ b. In the second sentence in paragraph (b)(8) remove ''9 CFR 310.22(a)(3)'' and add ''9 CFR 310.22(d)'' in its place.

Done at Washington, DC, on July 5, 2007.

**David P. Goldman,**

*Acting Administrator.*

[FR Doc. 07–3350 Filed 7–12–07; 8:45 am]

**BILLING CODE 3410–DM–P**