The Harvard study divided potential sources of human exposure to BSE infectivity into two categories: specific high-risk tissues and contamination of low risk tissues with high-risk tissues. Specific high-risk tissues identified by Harvard, in order of infectivity, include: brain, spinal cord, DRG, distal ileum, and the trigeminal ganglia and other tissues found in the head (*e.g.*, eyes). Since brain and spinal cord of cattle infected with BSE contain most of the BSE infectivity in the animal, the Harvard study concluded that, if BSE were present in the United States, human consumption of bovine brains and spinal cords would be an obvious source of exposure to the BSE agent.

The Harvard study identified the production of meat through the use of AMR systems as the most important means by which low risk tissue can become contaminated with high-risk tissues because AMR systems can leave spinal cord and DRG in the recovered meat. Assuming that there is no SRM ban in place, the Harvard study estimated that beef AMR product could account for approximately 57% of the potential human exposure to the BSE agent.

Specified Risk Materials (SRMs)

Materials designated as SRMs. In determining which materials of cattle should be removed from the human food supply, FSIS considered the data on the age distribution of confirmed BSE cases in the United Kingdom, the findings of the pathogenesis studies conducted in the United Kingdom, and the findings of the BSE risk analysis conducted by Harvard.

After considering the factors mentioned above, together with the fact that a case of BSE was recently confirmed in the United States, FSIS has decided to designate the brain, skull, eyes, trigeminal ganglia, spinal cord, vertebral column (excluding the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae, and the wings of the sacrum), and DRG of cattle 30 months of age and older, and the tonsils and distal ileum of all cattle as SRMs, declare them inedible, and prohibit their use for human food. The Agency believes that removing these materials from the human food supply is a prudent and appropriate measure for preventing human exposure to the BSE agent in the United States.

Except for the skull and vertebral column (excluding the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae, and the wings of the sacrum) of cattle 30 months of age and older, the materials listed as SRMs in this interim final rule are all materials that have demonstrated infectivity in cattle naturally or experimentally infected with BSE. Thus, in this rule, FSIS is designating all materials from cattle that have demonstrated BSE infectivity as SRMs, regardless of the level or proportion of infectivity contained in each tissue.

Although the skull or vertebral column of cattle infected with BSE have not demonstrated infectivity, the skull contains the eyes, trigeminal ganglia, and brain, and the vertebral column contains DRG and spinal cord. Thus, because they contain high-risk tissues, FSIS is including 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 in the list of SRMs that the Agency is declaring inedible and prohibiting for human food. Head meat, cheek meat, and tongue are not part of the skull. Therefore, under this interim final rule, these materials may continue to be used for human food, provided they are not contaminated with SRM. Unlike other parts of the vertebral column, the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae, and the wings of the sacrum do not contain spinal cord or DRG. Therefore, FSIS is excluding these parts of the vertebral column from the materials designated as SRMs. Under this interim final rule, bone-in beef from cattle 30 months of age and older may be prepared from these sections of the vertebral column. These sections of the vertebral column may also be used as a source material for products produced from edible rendering.

The Harvard study identified the production of meat through the use of AMR systems as the most important means by which low risk tissue can become contaminated with high-risk tissues, such as spinal cord and DRG. Furthermore, as discussed above, although FSIS and the regulated industry have taken actions to prevent the incorporation of spinal cord and, in some instances, DRG, in beef AMR products, FSIS continues to detect spinal cord and DRG in its routine regulatory sampling of this product. By designating 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 as SRM and prohibiting its use for human food, FSIS will ensure that spinal cord and DRG from cattle 30 months of age and older are not incorporated into beef AMR product.

The Harvard study determined that some potential exposure to BSE infectivity would result from the presence of spinal cord and DRG in certain bone-in cuts of beef, such as T-bone steaks. By designating 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 as SRM and prohibiting its use for human food FSIS will ensure that bone-in cuts of meat from cattle 30 months of age and older will not contain spinal cord or DRG.

The Harvard study did not address potential human exposure to the BSE agent through beef stocks, broths, or other products produced from the edible rendering process. However, it is possible that, when vertebral column bones are used as a source material for products produced from edible rendering, spinal cord and DRG could become dislodged from the vertebral bones and incorporated into the final product. By designating 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 as SRM and prohibiting its use for human food FSIS will ensure that spinal cord and DRG from cattle 30 months of age and older will not be incorporated into beef products produced from the edible rendering process.

Because of its proximity to the vertebral column, some hand-deboned meat may contain DRG depending on the technique used to recover the meat from the bone. Thus, hand-deboned meat from cattle could be a potential source of human exposure to DRG. FSIS is not aware of any data on the extent to which DRG are found in hand-deboned meat. FSIS is examining this issue in a study it is conducting to delineate the characteristics of hand-deboned meat. FSIS is not, at this time, prohibiting hand-deboned meat from the vertebral columns of cattle 30 months of age and older for use as human food. The Agency requests comments on this issue.

The SRMs prohibited for human food in this interim final rule are the same materials prohibited for use as human food by Canada, thus establishing a consistent standard in both countries. The Canadian SRMs include the skull, brain, trigeminal ganglia, eyes, tonsils, spinal cord, and DRG from cattle 30 months of age and older, and distal ileum from all cattle. Although the vertebral column (excluding the vertebrae of the tail, the transverse process of the thoracic and lumbar

vertebrae, and the wings of the sacrum) from cattle 30 months of age and older is not identified as SRM in the Canadian regulations, to ensure complete removal of potentially risky DRG from the human food supply, the Canadian Food Inspection Agency (CFIA) requires that the vertebral column of cattle 30 months of age and older, excluding the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae, and the wings of the sacrum, be removed and disposed of as inedible product (Meat Hygiene Directive 2003–18 (Amended), July 24 2003). The CFIA also prohibits the use of vertebral columns from cattle 30 months of age and older as a raw material in the preparation of mechanically separated meat or finely textured meat (Meat Hygiene Directive 2003–18 (Amended), July 24, 2003). The Canadian provisions for the removal of SRMs from the carcasses of cattle slaughtered in official Canadian establishments can be accessed on the Internet at *http://www.inspection.gc.ca/english/anima/meavia/mmopmmhv/chap4/annexne.shtml.*

The Canadian SRMs include the distal ileum from all cattle. However, the CFIA presently requires that the small intestine of all cattle be removed and disposed of as inedible product (Meat Hygiene Directive 2003–18 (Amended), July 24, 2003). Therefore, FSIS is designating, consistent with the Canadian rule, the distal ileum of the small intestine as SRM. To ensure that the distal ileum is completely removed from the carcass, FSIS is requiring that establishments remove the entire small intestine and that it be disposed of as inedible. Processors may be able to effectively remove just the distal ileum, and, accordingly, the Agency requests comments on this issue.

Rationale. Given the way that infectivity occurs in BSE-infected cattle, and the fact that a case of BSE has been detected in the United States, FSIS has determined that certain materials from cattle present sufficient risk of exposing humans to the BSE agent that it is prudent and appropriate to find that such materials are unfit for human food within the meaning of section 1(m)(3) of the FMIA (21 U.S.C. 601(m)(3)). For the reasons presented above, FSIS has concluded that 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 DRG of cattle 30 months of age and older, and the tonsils and distal ileum of all cattle.

The brain, skull, eyes, trigeminal ganglia, spinal cord, vertebral column (excluding the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae, and the wings of the sacrum), and DRG of cattle 30 months of age and older, and the tonsils and distal ileum of all cattle, present a persistent risk of exposing humans to the BSE agent because, in pre-clinical BSE-infected cattle, infectivity in most of these tissues is not readily ascertainable. Thus, humans could unknowingly be exposed to the BSE agent through consumption of these materials.

By designating the brain, skull, eyes, trigeminal ganglia, spinal cord, vertebral column (excluding the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae, and the wings of the sacrum), and DRG of cattle 30 months of age and older, and the tonsils and distal ileum of all cattle as SRMs, declaring that they are inedible, and prohibiting their use for human food, FSIS will ensure that materials that could present a significant risk to human health, but whose infectivity status cannot be readily ascertained, are excluded from the human food supply.

Procedures for the Removal, Segregation, and Disposition of SRMs

In this interim final rule, FSIS is requiring 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 (section 310.22(d)(1)). The Agency is not prescribing specific procedures that establishments must follow because FSIS believes that establishments should have the flexibility to implement the most appropriate procedures that will best achieve the requirements of this rule.

Establishments are responsible for ensuring that SRMs are completely removed from the carcass, segregated from edible products, and disposed in an appropriate manner. Establishments must address their control procedures in their HACCP plans, Sanitation SOPs, or other prerequisite programs. FSIS will ensure the adequacy and effectiveness of the establishment's procedures.

This interim final rule also requires (section 310.22(d)(4)) that establishments that slaughter cattle and establishments that process the carcasses or parts of cattle maintain daily records that document the implementation and monitoring of their procedures for the removal, segregation, and disposition of SRMs, and that the establishments make these records available to FSIS personnel on request.

FSIS will develop compliance guidelines for use by very small and small establishments to assist them in the development of validated methods for meeting the requirements of this interim final rule. FSIS believes that the use of the Canadian guidance on SRM removal generally is acceptable. FSIS will assess whether additional guidance is necessary (see the FSIS docket room and the FSIS Web site for the link to the Canadian and other compliance guidance information).

Verification of the Age of Cattle

Most of the materials that FSIS is prohibiting for use as human food in this rulemaking are from cattle 30 months of age and older. Thus, FSIS is prescribing the method that inspection program personnel will use to determine the age of cattle slaughtered in official establishments, to verify that the establishments are effectively segregating SRMs from edible materials.

The Agency is aware of two methods that can be used to verify the age of cattle slaughtered in official establishments: (1) Documentation that identifies the age of the animal, such as a birth certificate, cattle passport, or some other form of identification, that is presented with the animal when it arrives for slaughter, and (2) examination of the dentition of the animal to determine whether 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). The Agency has decided to use a combination of both methods.

If the establishment has records that document the age of the cattle slaughtered in the facility, FSIS inspection program personnel will examine the records. If the inspection program personnel conclude that the records are accurate and reliable, they will accept the records as verification of the age of the cattle. However, if FSIS inspection program personnel examine the records and find significant reasons for questioning their validity, they will verify the age of the cattle through dental examination. If the establishment does not have records that document the age of the cattle presented for slaughter, or the inspection program personnel have any reason to question the age of the animals, the Agency will verify age through dental examination.

In 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 were derived. If the establishment does not have records that document the age of the cattle from which the carcasses were derived, it must handle all carcasses and parts of carcasses as if they came from cattle 30 months of age and older.

Although there are various methods of cattle identification in the United States, there is no national cattle identification system. Thus, there is currently no uniform standard of documentation that FSIS can rely on to accurately verify the age of cattle slaughtered in official establishments. On December 30, 2003, the Secretary of Agriculture announced that the USDA will implement a system of national animal identification. The development of such a system has been underway for more than a year and a half to achieve uniformity, consistency, and efficiency across this national system.

FSIS has developed instructions for use by its inspection personnel in verifying the age of cattle that is available for viewing by the public in the FSIS docket room and posted on the FSIS Web site.

Non-Ambulatory Disabled Cattle

Current regulatory requirements. FSIS' regulations prohibit for use as human food all livestock, including cattle, with clinical signs of a CNS disorder (9 CFR 309.4) and livestock that are in a dying condition or that died otherwise than by slaughter (9 CFR 309.3). Under the current regulation, all seriously crippled livestock and livestock commonly termed "downers" presented for slaughter are automatically suspected of being affected with a disease or condition that may require condemnation of the animal, in whole or in part, and are identified as "U.S. Suspects" (9 CFR 309.2(b)). Such animals are examined at ante-mortem inspection by an FSIS veterinarian, and a record of the veterinarian's clinical findings accompanies the carcass to post-mortem inspection if the animal is not condemned on ante-mortem inspection.

Post-mortem inspections of the carcasses of "U.S. Suspect" livestock are performed by veterinarians rather than by food inspectors, and the results of this inspection are recorded. "U.S. Suspects," unless otherwise released pursuant to 9 CFR 309.2(p), must be set apart and slaughtered separately (9 CFR 309.2(n)). If, on post-mortem inspection, the meat and meat food products from such animals are found to be not adulterated, such products may be used for human food (9 CFR 311.1).

Non-ambulatory cattle and BSE. Surveillance data from European countries in which BSE has been detected, indicate that cattle with clinical signs of a CNS disorder, dead cattle, and cattle that can not rise from a recumbent position (in Europe these cattle are distinguished either as "fallen stock" if not for human consumption or "emergency slaughter" cattle if for human consumption) have a greater incidence of BSE than healthy slaughter cattle. For example, in 2002 the EU reported that for healthy cattle 55–60 months of age, there were 0.55 positive tests for BSE per 10,000 animals tested compared with 3.05 positive tests for BSE per 10,000 cattle tested for the high-risk cattle (*i.e.*, fallen stock, emergency slaughter and animals that show clinical signs of BSE on ante-mortem inspection) (Ref. 18, available for viewing by the public in the FSIS docket room). In addition, an analysis of a targeted screening program for BSE in Switzerland found that when high-risk cattle were targeted for BSE testing, the odds of finding a BSE case was 49 times higher in fallen stock and 58 times higher in emergency-slaughtered cattle than in cattle tested under passive surveillance, *i.e.*, clinical BSE suspects reported to the veterinary authorities (Ref. 19, available for viewing by the public in the FSIS docket room). This study also found that the BSE cases detected through targeted screening of high risk animals were on average four months younger than the BSE cases detected through passive surveillance of clinical suspects.

Surveillance for BSE in Europe has also shown that the typical clinical signs associated with BSE cannot always be observed in non-ambulatory cattle infected with BSE because the signs of BSE often cannot be differentiated from the typical clinical signs of the many other diseases and conditions affecting non-ambulatory cattle. Furthermore, as discussed in greater detail below, there are limitations with the diagnostic tests for BSE that are available today. Under the current testing methods, which are conducted on sections of the brain or spinal cord, certain tissues of cattle infected with BSE, such as the distal ileum and tonsils, may contain BSE infectivity even though the diagnostic test does not show that the animal has the disease. Thus, permitting the carcasses of non-ambulatory cattle to be used for human food if the animal tests negative for BSE will not provide the same level of protection against human exposure to the BSE agent that prohibiting these cattle from entering the human food supply will.

Revised regulatory requirements. Because they present a risk of introducing the BSE agent into the human food supply, FSIS has determined that the carcasses of non-ambulatory disabled cattle are unfit for human food under section 1(m)(3) of the FMIA and that all non-ambulatory disabled cattle that are presented for slaughter should be condemned. Therefore, FSIS is amending its ante-mortem inspection regulations to require the condemnation of non-ambulatory disabled cattle presented for slaughter.

Specifically, FSIS is amending the regulations that prescribe requirements for "U.S. Suspect" livestock in 9 CFR 309.2 by replacing the reference to "animals commonly termed 'downers'" in § 309.2(b) with the term "non-ambulatory disabled livestock." FSIS is making this modification because there is currently no regulatory definition of "downer" and the Agency believes that the term "non-ambulatory disabled" more accurately describes the cattle that it believes should be prohibited for human food. "Non-ambulatory disabled livestock" is defined 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. Thus, this definition includes livestock that are non-ambulatory due to an acute injury in route to the slaughter facility, such as a broken leg, as well as livestock that are non-ambulatory due to an underlying pathological condition.

FSIS is excluding all non-ambulatory disabled cattle from the human food supply, regardless of the reason for their non-ambulatory status or the time at which they became non-ambulatory. Thus, if an animal becomes non-ambulatory in route to the establishment due to an acute injury, it must be humanely removed from the truck, humanely euthanized, and the carcass properly disposed of. Likewise, cattle that become non-ambulatory on the establishment premises, such as an animal that breaks its leg as it is unloaded from the truck, are also required to be humanely moved, humanely euthanized, and the carcass properly disposed of.

FSIS is also amending the regulations that prescribe requirements for dead, dying, disabled, or diseased and similar livestock in 9 CFR 309.3 to require that non-ambulatory disabled cattle be condemned and disposed of in accordance with 9 CFR 309.13. Unless another provision in part 309 applies, under § 309.13, condemned livestock must be killed by the establishment, if

not already dead. Such animals cannot be taken into the establishment to be slaughtered or dressed, or conveyed into any department of the establishment that is used for edible products. The carcasses of condemned livestock must be disposed of in the manner provided for in part 314.

Under part 314, condemned carcasses must be disposed of by "tanking," *i.e.*, inedible rendering (9 CFR 314.1). For those establishments that do not have facilities for tanking, condemned carcasses may be disposed of by incineration or denatured by crude carbolic acid, cresylic disinfectant, a formula consisting of one part FD&C No. 3 green coloring, 40 parts water, 40 parts liquid detergent, and 40 parts oil of citronella, or any other proprietary material approved by the Administrator of FSIS (9 CFR 314.3). The Agency is aware that many establishments use activated charcoal to denature inedible materials. Therefore, FSIS recognizes activated charcoal as a proprietary substance approved by the Administrator.

The regulations in 9 CFR 311.27 permit injured livestock to be slaughtered for humane reasons at hours when an inspector is not available to perform ante-mortem inspection, provided that the carcasses and parts of such animals are kept for inspection. To ensure that non-ambulatory disabled cattle are not slaughtered under this provision and their carcasses and parts used for human food, FSIS is amending 9 CFR 311.27 to prohibit the carcasses and parts of carcasses from cattle slaughtered on an emergency basis without ante-mortem inspection from being used for human food. Without performing ante-mortem inspection on cattle slaughtered on an emergency basis, FSIS inspection program personnel cannot determine whether the carcasses or parts from such cattle came from a non-ambulatory disabled animal, and thus cannot find that the carcasses and parts from these emergency slaughter cattle are not adulterated.

Testing Cattle for BSE

There is no sensitive and reliable live animal test for BSE, and the available post-mortem diagnostic tests can only indicate that cattle have the disease two to three months before the onset of clinical disease or after the onset of clinical disease. Given the limitations of the diagnostic tests available today, which are conducted on sections of the brain or spinal cord, certain tissues of cattle infected with BSE, such as distal ileum and small intestine, may contain BSE infectivity even though the diagnostic test will not show that the animal has the disease. Thus, exempting materials from cattle that test negative for BSE from the restrictions in this rulemaking will likely not provide the same level of protection as prohibiting those materials for use as human food.

Therefore, under this interim final rule, the use of specified risk materials from cattle is prohibited for human food regardless of whether the animal has been tested for BSE. FSIS requests comments on whether further consideration should be given to exempting cattle that have tested negative for BSE from the requirements contained in this interim final rule, and if so, what testing methods and protocols the Agency should accept as providing acceptable and reliable results.

Request for Comments

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

Emergency Action

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

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

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

Executive Order 12866 and Regulatory Flexibility Act

This rule has been reviewed under Executive Order 12866. It has been determined to be economically significant for purposes of Executive Order 12866 and therefore, has been reviewed by the Office of Management and Budget (OMB).

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

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

Executive Order 12988

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

Paperwork Reduction Act

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

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

Type of collection: New.

Abstract: In this interim final rule, FSIS is requiring that establishments that slaughter cattle and establishments that process the carcasses or parts of cattle develop written procedures for the removal, segregation, and disposition of SRMs. FSIS is also requiring that these 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. These records are needed for FSIS to verify the effectiveness of an establishment's procedures.

Estimate of burden: FSIS estimates that it will take establishments approximately 8 hours to develop written procedures for the removal, disposition, and segregation of SRMs. FSIS estimates that an establishment will spend about five minutes a day developing an average of nine monitoring records, which includes documentation of any corrective actions taken, and an additional two minutes a day to file each record.

Respondents: Official establishments that slaughter cattle and official establishments that process the carcasses or parts of cattle.

Estimated Number of Respondents: 2,500.

Estimated Number of Responses per Respondent: 2,701.

Estimated Total Annual Burden on Respondents: 807,500 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 collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility; (b) the accuracy of the Agency's estimate of the burden of the 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 30 days of the publication date of this interim 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 interim 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 recordkeeping 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 better ensure that minorities, women, and persons with disabilities are aware of this final interim final rule and are informed about the mechanism for providing their comments, FSIS will announce it and provide copies of this **Federal Register** publication in the FSIS Constituent Update. FSIS provides a weekly FSIS Constituent Update, which is communicated via fax to over 300 organizations and individuals. In addition, the update is available on line through the FSIS Web page located at *http://www.fsis.usda.gov.* The update is used to provide information regarding FSIS policies, procedures, regulations, **Federal Register** notices, FSIS public meetings, recalls, and any other types of information that could affect or would be of interest to our constituents/ stakeholders. The constituent fax list consists of industry, trade, and farm groups, consumer interest groups, allied health professionals, scientific professionals, and other individuals that have requested to be included. Through these various channels, FSIS is able to provide information to a much broader, more diverse audience. For more information and to be added to the constituent fax list, fax your request to the Congressional and Public Affairs Office, at (202) 720–5704.

References

The following sources are referred to in this document. All have been placed on display in the FSIS Docket Room (address above) and may be seen by interested persons between 8:30 a.m. and 4:30 p.m., Monday through Friday. Materials that are not copyright protected may also be accessed on the FSIS Web site as related documents to this interim final rule.

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List of Subjects

9 CFR Part 309

Ante-mortem inspection, Disposition of carcasses.

9 CFR Part 310

Post-mortem inspection, Disposition of carcasses.

9 CFR Part 311

Post-mortem inspection, Disposition of carcasses.

9 CFR Part 318

Entry into official establishments, reinspection and preparation of products.

9 CFR Part 319

Food grades and standards, Food labeling, Meat inspection.

■ For the reasons discussed in the preamble, FSIS is amending 9 CFR Chapter III as follows:

PART 309—ANTE-MORTEM INSPECTION

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

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

■ 2. Paragraph (b) of §309.2 is revised to read as follows:

§ 309.2 Livestock suspected of being diseased or affected with certain conditions; identifying suspects; disposition on post-mortem inspection or otherwise.

* * * * *

(b) All seriously crippled animals and non-ambulatory disabled livestock shall be identified as U.S. Suspects and disposed of as provided in § 311.1 of this subchapter unless they are required to be classed as condemned under § 309.3. Non-ambulatory disabled livestock are 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.

* * * * *

■ 3. Section 309.3 is revised by adding a new paragraph (e) to read as follows:

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

* * * * *

(e) Non-ambulatory disabled cattle shall be condemned and disposed of in accordance with § 309.13.

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. A new § 310.22 is added 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:

(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 of cattle 30 months of age and older;

(2) The tonsils of all cattle; and

(3) The distal ileum of all cattle. To ensure effective removal of the distal ileum, the establishment shall remove the entire small intestine, and shall dispose of it in accordance with §§ 314.1 or 314.3 of this subchapter.

(b) Specified risk materials are inedible and shall not be used for human food.

(c) Specified risk materials shall be disposed of in accordance with §§ 314.1 or 314.3 of this subchapter.

(d) 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 shall develop, implement, and maintain written procedures for the removal, segregation, and disposition of specified risk materials. The establishment shall incorporate such procedures into its HACCP plan or in its Sanitation SOP or other prerequisite program.

(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 such procedures, have failed to ensure that such materials are adequately and effectively removed from the carcass 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 shall 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 shall 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 shall 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 shall be retained for at least one year and shall be accessible to FSIS. All such records shall be maintained at the official establishment 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.

(e) 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 that the materials are from an animal that was younger than 30 months of age at the time of slaughter.

PART 311—DISPOSAL OF DISEASED OR OTHERWISE ADULTERATED CARCASSES AND PARTS

■ 6. The authority citation for part 311 continues to read as follows:

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

§311.27 [Amended]

■ 7. Section 311.27 is amended as follows:

■ a. By inserting "of all livestock except for cattle" in the first sentence after "the carcass and all parts" and before "shall be kept for inspection".

■ b. By adding the following new sentence at the end of the paragraph: "The parts and carcasses of cattle slaughtered in the absence of an inspector shall not be used for human food."

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

■ 8. The authority citation for part 318 is revised to read as follows:

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

§318.6 [Amended]

■ 9. Section 318.6 is amended as follows:

■ a. Paragraph (b)(1) is amended by removing the word "cattle" and adding the following new sentence at the end of the paragraph: "Casings from cattle may be used as containers of products provided the casings are not derived from the small intestine."

■ b. Paragraph (b)(4) is amended by adding the following new sentence at the end of the paragraph: "Detached spinal cords from cattle 30 months of age and older shall not be used as raw materials for edible rendering."

■ c. Paragraph (b)(8) is amended by adding the following new sentence at the end of the paragraph: "The small intestine of cattle shall not be used in any meat food products or for edible rendering."

PART 319—DEFINITIONS AND STANDARDS OF IDENTITY OR COMPOSITION

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

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

■ 11. Section 319.5 is amended as follows:

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

§319.5 Mechanically Separated Species.

* * * * *

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

* * * * *

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

Garry L. McKee,

Administrator.

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

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DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Parts 301, 318, and 320

[Docket No. 03–038IF]

RIN 0583–AC51

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

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Interim final rule and request for comment.

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

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

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

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

SUPPLEMENTARY INFORMATION:

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