comment. In addition, we have determined that the South American cactus moth is present in the State of Mississippi, which we did not include in the quarantined area in our proposal to establish regulations for South American cactus moth. We are reopening the comment period on that proposal to allow interested persons to submit comments on the addition of Mississippi to the proposed quarantined area, as well as on other aspects of the proposal.

DATES: We will consider all comments that we receive on or before October 20, 2008.

ADDRESSES: You may submit comments by either of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov/fdmspublic/component/main?main=DocketDetail&d=APHIS_2006_0153* to submit or view comments and to view supporting and related materials available electronically.
- *Postal Mail/Commercial Delivery:* Please send two copies of your comment to Docket No. APHIS 2006 0153, Regulatory Analysis and Development, PPD, APHIS, Station 3A 03.8, 4700 River Road, Unit 118, Riverdale, MD 20737–1238. Please state that your comment refers to Docket No. APHIS 2006 0153.

Reading Room: You may read any comments that we receive on this docket in our reading room. The reading room is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 690–2817 before coming.

Other Information: Additional information about APHIS and its programs is available on the Internet at *http://www.aphis.usda.gov*.

FOR FURTHER INFORMATION CONTACT: Dr. Robyn Rose, National Program Lead, Emergency and Domestic Programs, PPQ, APHIS, 4700 River Rd., Unit 26, Riverdale, MD 20737–1236; (301) 734–7121.

SUPPLEMENTARY INFORMATION:

Background

The South American cactus moth (*Cactoblastis cactorum*) is a grayish-brown moth with a wingspan of 22 to 35 millimeters (approximately 0.86 to 1.4 inches) that is indigenous to Argentina, southern Brazil, Paraguay, and Uruguay. It is a serious quarantine pest of *Opuntia* spp., and an occasional pest of *Nopalea* spp., *Cylindropuntia* spp., and *Consolea* spp., four closely related genera of the family Cactaceae. After an incubation period following mating, the female South American cactus moth deposits an egg stick resembling a cactus spine on the host plant. The egg stick, which consists of 70 to 90 eggs, hatches in 25 to 30 days and the larvae bore into the cactus pad to feed, eventually hollowing it out and killing the plant. Within a short period of time, the South American cactus moth can destroy whole stands of cactus.

On February 11, 2008, the Animal and Plant Health Inspection Service (APHIS) published in the **Federal Register** (73 FR 7679–7686, Docket No. APHIS–2006–0153) a proposal to amend the domestic quarantine regulations to establish regulations to restrict the interstate movement of South American cactus moth host material, including nursery stock and plant parts for consumption, from infested areas of the United States.

In connection with this proposed rule, we have prepared an environmental assessment (EA) entitled ''Quarantine for the South American Cactus Moth, *Cactoblastis cactorum*, in Florida, South Carolina, Georgia, Alabama, and Mississippi.'' We are making this environmental assessment available to the public for review and comment. We will consider all comments that we receive on or before the date listed under the heading **DATES** at the beginning of this notice.

Since publication of the proposed rule, surveys conducted by the Mississippi Department of Agriculture and Commerce have confirmed the presence of South American cactus moth in the State of Mississippi. Therefore, we have determined that Mississippi should be added to the proposed list of quarantined areas in § 301.55–3(c). In addition, we would like to clarify our intention regarding the use of deltamethrin as a treatment. Although the ''Background'' section of the proposal listed deltamethrin as an acceptable treatment for South American cactus moth, the proposed regulatory text did not include deltamethrin. We do not have efficacy data for the use of this chemical on South American cactus moth; therefore we did not intend to approve deltamethrin as a treatment and it should not have been included as an acceptable treatment in the ''Background'' section.

Comments on the proposed rule were required to be received on or before April 11, 2008. We are reopening the comment period for the proposed rule for 30 days following publication of this notice. This action will allow interested persons to prepare and submit comments regarding the proposed addition of Mississippi to the list of States quarantined for South American cactus moth or other aspects of the proposed rule. We will also consider all comments received between April 11, 2008, and the date of this notice.

The environmental assessment, the proposed rule, and all previously received comments on the proposed rule may be viewed on the Regulations.gov Web site or in our reading room (see **ADDRESSES** above for a link to Regulations.gov and information on the location and hours of the reading room). You may request paper copies of the documents listed above by calling or writing to the person listed under **FOR FURTHER INFORMATION CONTACT**. Please refer to the title of the environmental assessment when requesting copies.

The environmental assessment has been prepared in accordance with: (1) The National Environmental Policy Act of 1969 (NEPA), as amended (42 U.S.C. 4321 *et seq.*), (2) regulations of the Council on Environmental Quality for implementing the procedural provisions of NEPA (40 CFR parts 1500–1508), (3) USDA regulations implementing NEPA (7 CFR part 1), and (4) APHIS' NEPA Implementing Procedures (7 CFR part 372).

Authority: 7 U.S.C. 7701–7772 and 7781–7786; 7 CFR 2.22, 2.80, and 371.3. Section 301.75–15 issued under Sec. 204, Title II, Public Law 106–113, 113 Stat. 1501A 293; sections 301.75–15 and 301.75–16 issued under Sec. 203, Title II, Public Law 106–224, 114 Stat. 400 (7 U.S.C. 1421 note).

Done in Washington, DC, this 12th day of September 2008.

Kevin Shea,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. E8–21816 Filed 9–17–08; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Parts 94 and 95

[Docket No. APHIS–2008–0093]

Bovine Spongiform Encephalopathy; Minimal-Risk Regions and Importation of Meat, Meat Byproducts, and Meat Food Products Derived From Bovines 30 Months of Age or Older

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Request for comments.

SUMMARY: This document requests comment on the removal of the delay of applicability of certain provisions of the rule entitled ''Bovine Spongiform Encephalopathy; Minimal-Risk Regions and Importation of Commodities,'' published in the **Federal Register** on January 4, 2005, 70 FR 460–553. The delay of applicability was removed in a final rule entitled ''Bovine Spongiform Encephalopathy; Minimal-Risk Regions; Importation of Live Bovines and Products Derived from Bovines,'' published in the **Federal Register** on September 18, 2007, 72 FR 53314–53379.

DATES: We will consider all comments that we receive on or before November 17, 2008.

ADDRESSES: You may submit comments by either of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov/fdmspublic/component/main?main=DocketDetail&d=APHIS–2008–0093* to submit or view comments and to view supporting and related materials available electronically.
- *Postal Mail/Commercial Delivery:* Please send two copies of your comment to Docket No. APHIS–2008–0093, Regulatory Analysis and Development, PPD, APHIS, Station 3A–03.8, 4700 River Road Unit 118, Riverdale, MD 20737–1238. Please state that your comment refers to Docket No. APHIS–2008–0093.

Reading Room: You may read any comments that we receive on this docket, as well as APHIS supporting materials referenced in this docket, in our reading room. The reading room is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue, SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 690–2817 before coming.

Other Information: Additional information about APHIS and its programs is available on the Internet at *http://www.aphis.usda.gov*.

FOR FURTHER INFORMATION CONTACT: Dr. Lisa Ferguson, ASEP Director, National Center for Animal Health Programs, VS, APHIS, 4700 River Road Unit 46, Riverdale, MD 20737–1231; (301) 734–6188.

SUPPLEMENTARY INFORMATION:

Background

The Animal and Plant Health Inspection Service (APHIS) of the U.S. Department of Agriculture (USDA or Department) regulates the importation of animals and animal products into the United States to guard against the introduction of animal diseases. The regulations in 9 CFR parts 93, 94, 95, and 96 (referred to below as the regulations) govern the importation of certain animals, birds, poultry, meat, other animal products and byproducts, hay, and straw into the United States in order to prevent the introduction of various animal diseases, including bovine spongiform encephalopathy (BSE), a chronic degenerative disease affecting the central nervous system of cattle.

Nature of BSE

BSE belongs to the family of diseases known as transmissible spongiform encephalopathies (TSEs). All TSEs affect the central nervous system of infected animals. However, the distribution of infectivity in the body of the animal and mode of transmission differ according to the species and the TSE agent. In addition to BSE, TSEs include, among other diseases, scrapie in sheep and goats, chronic wasting disease in deer and elk, and Creutzfeldt-Jakob disease in humans.

The agent that causes BSE has yet to be fully characterized. The theory that is most accepted in the international scientific community is that the agent is an abnormal form of a normal protein known as cellular prion protein. The BSE agent does not evoke a traditional immune response or inflammatory reaction in host animals. BSE is confirmed by post-mortem examination of an animal's brain tissue, which may include detection of the abnormal form of the prion protein in the brain tissues. The pathogenic form of the protein is both less soluble and more resistant to degradation than the normal form. The BSE agent is resistant to heat and to normal sterilization processes.

BSE is not a contagious disease, and therefore is not spread through casual contact between animals. Scientists believe that the primary route of transmission is through ingestion of feed that has been contaminated with a sufficient amount of tissue from an infected animal. This route of transmission can be prevented by excluding potentially contaminated materials from ruminant feed.

Roles of Different Agencies

APHIS, an animal health agency within USDA, promulgates its regulations regarding BSE under the authority of the Animal Health Protection Act (7 U.S.C. 8301 *et seq.*), which gives the Secretary broad discretion to regulate the importation of animals and animal products if necessary to protect the health of U.S. livestock.

Because variant Creutzfeldt-Jakob Disease (vCJD) in humans has been linked to exposure to the BSE agent, APHIS collaborates with other Federal agencies with regulatory responsibility for assuring food safety and the protection of human health to implement a comprehensive coordinated U.S. response to BSE. Within USDA, protecting human health from the risks of BSE is carried out by the Food Safety and Inspection Service (FSIS), the agency charged with responsibility for administering the Federal Meat Inspection Act, which was enacted to ensure that meat and meat food products distributed in commerce are wholesome, not adulterated, and properly marked, labeled, and packaged. The USDA agencies carry out their programs in close coordination with the following Centers of the Food and Drug Administration (FDA) of the U.S. Department of Health and Human Services: The Center for Veterinary Medicine regarding animal feed; the Center for Food Safety and Applied Nutrition regarding foods other than meat, poultry, and egg products; and other Centers regarding drugs, biologics, and devices containing bovine material. These agencies collaborate, issuing regulations under their respective authorities.

Tissue Localization

Some bovine tissues have demonstrated infectivity, whereas others have not. Most of the information on the development and distribution of tissue infectivity in BSE-infected cattle has been derived from experimental pathogenesis studies conducted in the United Kingdom (Wells, *et al.*, 1994; 1996; 1998; 1999; 2005). In these studies, cattle were deliberately infected with BSE through oral exposure to the brain tissue of cattle with confirmed BSE. Subsets of the experimentally infected cattle were killed at regular intervals as the disease progressed. At each interval, the tissues of the infected cattle were examined for histopathological changes consistent with BSE and for abnormal prion proteins. Also, at each interval, a mouse assay was done—i.e., tissues of the BSE infected cattle were injected intracerebrally and intraperitoneally into mice to identify those tissues of cattle containing infectivity.

The pathogenesis studies involved 30 animals, each of which received a single dose of 100g of infected brain at 4 months of age (Wells, *et al.*, 1994; 1996;

1998; 1999; 2005). This dose is probably 10–100 times greater than that associated with field exposure via feed (DEFRA 2005). The studies demonstrate that in cattle infected with BSE, the total amount of infectivity in the animal, as well as the distribution of infectivity in the animal's body, change over time (Wells, *et al.*, 1994; 1996; 1998; 1999; 2005). The highest levels of infectivity were detected in the brain and spinal cord at the end stages of disease. Some cattle exhibited clinical signs of BSE as early as 35 months after oral exposure to the BSE agent. By 37 months after oral exposure, all five animals that were still alive demonstrated clinical evidence of BSE. Infectivity was found in cattle with clinical signs of BSE in the brain, spinal cord, dorsal root ganglia (DRG),[1] trigeminal ganglia, and the distal ileum of the small intestine.

BSE infectivity was demonstrated in the brain, spinal cord, and DRG as early as 32 months after oral exposure to the BSE agent in some cattle (Wells, *et al.*, 1994; 1996; 1998; 1999; 2005). Infectivity was demonstrated in these tissues 3 months before animals began to develop clinical signs of the disease. Infectivity was demonstrated in the distal ileum of cattle 6 to 18 months after oral exposure to the BSE agent and again at 38 months and 40 months after oral exposure. A similar, more recent, study (Espinosa, *et al.*, 2007) examined the infectivity of tissues from these same animals by intracerebral inoculation of highly sensitive transgenic mice overexpressing bovine PrP. This study's findings were similar to those of Wells, *et al.*, described above. In addition, infectivity in the sciatic nerve was found at low levels only after 30 months from exposure. No detectable infectivity was found in the spleen, skeletal muscle, blood or urine of asymptomatic cattle.

As explained by the United Kingdom's Department for Environment, Food and Rural Affairs (DEFRA) and by the European Commission's Scientific Steering Committee, a second phase of the pathogenesis studies, which used a cattle bioassay as an endpoint, was conducted to ensure that low levels of infectivity that may not have been detected in the first phase using the mouse bioassay were not missed (DEFRA 2006; EC SSC 2002). This second phase of the study was completed in March 2007 (Gerald Wells, personal communication, 2008).

In the cattle bioassay, tissues from the same cattle orally exposed to BSE in the earlier pathogenesis studies were injected directly into the brain of BSE-free cattle (DEFRA 2005). This method is considered to be several hundred-fold more sensitive in detecting BSE infectivity than the mouse bioassay (DEFRA 2005). Preliminary results from the cattle bioassay study demonstrate that, in addition to the materials that were found to contain infectivity when the mouse bioassay was used, the tonsils of calves 10 months after oral exposure to the BSE agent also contain infectivity. However, because only one of five animals injected with tonsil material from infected animals developed clinical BSE at 45 months post-inoculation, the level of infectivity in the tonsils appears to be very low.

BSE infectivity has not been demonstrated in the muscle tissue of BSE-infected cattle examined in these studies through either the mouse bioassay or the cattle assays (Wells 1996; 2005; personal communication 2008). All assays of the skeletal muscle pools were completed in March 2007 (Wells, personal communication 2008).

In addition to these studies on experimentally infected cattle, distribution of tissue infectivity has also been studied in cattle exposed to BSE under field conditions. In these animals, at the end stages of the incubation period with demonstrated clinical signs, BSE infectivity has been confirmed by mouse bioassay only in the brain, spinal cord, and retina of the eye (EC SSC 2001).

In a recent study, mice, genetically engineered to be highly susceptible to BSE and to overexpress the bovine prion protein, were inoculated with tissues from an end-stage clinically affected BSE-infected cow (Buschmann and Groschup, 2005). The sensitivity of these mice to infection is significantly greater than other mice panels used in bio-assays, and the sensitivity is even greater than that of cattle by approximately tenfold. This study demonstrated low levels of infectivity in the facial and sciatic nerves of the peripheral nervous system when injected into these highly sensitive mice. While this study, and the 2007 study by Espinosa, *et al.*, produced interesting findings that can help further characterize the pathogenesis of BSE, they cannot be extrapolated into the context of the risk presented by natural (*i.e.*, field) exposure pathways. The findings may be influenced by the overexpression of prion proteins in these genetically engineered mice. Any apparent levels of infectivity are low in these extremely sensitive mice and would be even lower in other species such as cattle. Moreover, the route of administration to the mice was both intraperitoneal and intracerebral, both of which are very efficient routes of infection as compared to oral consumption.

Tissues that have demonstrated infectivity, and thus are likely to contain the infectious BSE agent in infected cattle, are brain, tonsil, spinal cord, eyes, trigeminal ganglia, DRG, and distal ileum. Approximately 90 percent of the infectivity is associated with the brain, spinal column, DRG, and trigeminal ganglia. The remaining 10 percent is associated with the infectivity in the distal ileum. In BSE, as with other TSEs, the total amount of infectivity in an animal increases throughout the incubation period, reaching the highest load at the end of that period, very close to the death of the animal. Infectivity is considered to increase exponentially, reaching 4.5 logs less than a clinical case at 50 percent of the incubation period and 3 logs less than a clinical case by 70 percent of the incubation period (Comer and Huntly, 2003).

All of this research has contributed to the definition of which tissues should be deemed specified risk materials (SRMs). Both the types of tissues, and the understanding of the progression of the infectivity throughout the incubation period contribute to the definition of SRMs. Affiliated tissues or structures such as skull or vertebral column are also considered risk materials because of the difficulty in separating out small tissues such as DRG from the vertebral column. The risks associated with tissue localization can be mitigated by excluding SRMs from the food or feed chain or by excluding them completely from importation. FSIS and FDA regulations regarding SRMs are based on this scientific knowledge and an understanding of the mitigative effects of exclusion of SRMs (FSIS, 2004; 2004a; 2004b; 2005; 2007; FDA, 2004; 2005; 2007; 2008).

There are some studies available that report finding the presence of the abnormal prion protein in various tissues (Buschmann and Groschup, 2005; Masujin *et al.*, 2007). As new methods are developed that provide increased sensitivity to detect abnormal PrP, such demonstrations of the presence of abnormal PrP in various tissues may continue. However, demonstrating the presence of PrP^{BSE} does not necessarily indicate the presence of BSE infectivity, especially if no infectivity is demonstrated via the

[1] DRG are clusters of nerve cells attached to the spinal cord that are contained within the bones of the vertebral column. ''DRG'' as used in this document has the same meaning as the term ''dorsal spinal nerve root ganglia.'' Trigeminal ganglia are clusters of nerve cells connected to the brain that lie close to the exterior of the skull.

most direct method available: cattle-to-cattle exposure via intracerebral inoculation. Therefore, one cannot automatically assume that a finding of PrP^{BSE} in a tissue means the tissue should be considered infectious or should be considered an SRM. As noted by the World Organization for Animal Health (OIE), the international standard-setting organization for guidelines related to animal health:

> The availability of experimental infectivity data has significantly increased in recent years. During the same interval, extremely sensitive tests have been developed, including those employing highly sensitive transgenic mice strains and potentially more sensitive laboratory PrP detection methods. With the development of such highly sensitive methods, the probability of detection of PrP^{BSE} in tissues that are not currently listed as infectious is increasing. However, such findings need to be considered in context, and their relevance to establishing risk to consumers evaluated carefully when the quantity of PrP^{BSE} detected is potentially below the limit of detection of intracerebral cattle to cattle bioassay (OIE TAHSC, 2006).

Within USDA, APHIS and FSIS review and consider carefully, on an ongoing basis, all BSE research regarding the definition of SRMs, as do other countries that participate in OIE. International guidelines regarding SRM definition and removal have not changed based on the results of the studies noted above that report finding the presence of the abnormal prion protein in various tissues. U.S. regulations regarding SRM removal are consistent with international guidelines.

Prior to 2005, when the APHIS final rule on BSE minimal-risk regions (70 FR 460–553, Docket No. 03–080–3) became effective, APHIS' import regulations regarding BSE considered three categories of regions with regard to BSE—(1) those in which BSE is known to exist, (2) those that present an undue risk of BSE, and (3) all regions not listed in either of the other two categories. Imports from BSE-affected regions and those considered to present an undue risk are governed by the same set of restrictions, including a prohibition on the importation of meat, meat products, and edible products other than meat (except for milk and milk products and gelatin under certain conditions). All other regions were not subject to any import restrictions because of BSE.

Beginning in 2003, APHIS commenced a rulemaking process to update our BSE regulations to reflect the latest scientific data and knowledge of the disease. In a document published in the **Federal Register** on November 4, 2003 (68 FR 62386–62405, Docket No. 03–080–1), APHIS proposed to establish a category of regions that present a minimal risk of introducing BSE into the United States via live ruminants and ruminant products and byproducts, and to add Canada to this category. The proposal also set forth conditions for the importation of certain live ruminants and ruminant products and byproducts from BSE minimal-risk regions. Among the conditions for the importation of meat from BSE minimal-risk regions was that the meat be derived from bovines less than 30 months of age when slaughtered. This age restriction was a measure to guard against the importation of, or contamination of meat through contact with, tissues other than meat that have the potential of containing high levels of BSE infectivity.

On December 25, 2003, less than 2 weeks before the close of the comment period for the proposed rule, a case of BSE in a dairy cow of Canadian origin in Washington State was verified by an international reference laboratory. Subsequently, both FSIS and FDA implemented significant additional measures in the United States to protect human health. In addition, APHIS commenced an enhanced BSE surveillance program to determine the incidence of the disease in the United States.

The measures taken by FSIS included declaring SRMs to be inedible and requiring their removal from cattle at slaughter. FSIS designated as SRMs the brain, skull, eyes, trigeminal ganglia, spinal cord, vertebral column (excluding the vertebrae of the tail, the transverse process of the thoracic and lumbar vertebrae, and the wings of the sacrum), and DRG of cattle 30 months of age or older, and the tonsils and distal ileum of the small intestine of all cattle. To ensure effective removal of the distal ileum, FSIS also required that the entire small intestine be removed and be disposed of as inedible.[2] FSIS also required all slaughtering and processing establishments to develop, implement, and maintain written procedures for the removal, segregation, and disposition of SRMS. Establishments were specifically required to implement procedures to address the potential contamination of edible materials with SRMs before, during, and after entry into the establishment. FSIS did not restrict the age of cattle eligible for slaughter, because the removal of SRMs effectively mitigates the BSE risk to humans associated with cattle that pass both ante-mortem and post-mortem inspections (*i.e.*, apparently healthy cattle).

Pursuant to the Federal Meat Inspection Act, countries that export meat to the United States must implement food safety requirements that are equivalent to those in place in the United States. To be eligible to export beef to the United States, a country must have in place a system to effectively keep SRMs out of the production chain and to prevent cross-contamination of beef with SRMs. FSIS has determined that the SRM requirements implemented by Canada in July 2003 are equivalent to FSIS' requirements. Additionally, FDA's feed ban prohibits most mammalian protein, including ruminant protein, from entering the ruminant feed chain in the United States.

On March 8, 2004, we published a document in the **Federal Register** (69 FR 10633–10636, Docket No. 03–080–2) explaining the effects on our proposed rule of the detection of BSE in the State of Washington in a cow imported from Canada and of the additional measures taken by FSIS, APHIS, and FDA. That document explained why the detection of an imported BSE-infected cow did not alter the conclusions we had reached in our original risk assessment. It explained further that, in fact, the resulting additional measures put in place by FSIS provided a basis for removing from the proposed provisions an age restriction on cattle from which meat would be derived for export to the United States. Accordingly, we proposed to allow the importation of beef derived from cattle of any age. To give the public additional time to comment on the proposal in light of these developments, we reopened and extended the comment period for an additional 30 days.

On January 4, 2005, we published in the **Federal Register** (70 FR 460–553, Docket No. 03–080–3) a final rule that established the criteria for BSE minimal-risk regions, listed Canada as a BSE minimal-risk region, and specified importation requirements for live animals, and meat products and byproducts. The final rule allowed the importation of meat from bovines of any age, as we had proposed on March 8, 2004. The final rule was scheduled to become effective on March 7, 2005.[3]

[2] On September 7, 2005, FSIS published in the **Federal Register** an interim final rule that allowed for use as human food, under certain conditions, beef small intestine, excluding the distal ileum, derived from cattle slaughtered in official U.S. establishments or in certified foreign establishments in countries listed by FSIS in 9 CFR 327.2(b) as eligible to export meat products to the United States.

[3] On March 2, 2005, Judge Richard F. Cebull of the U.S. District Court for the District of Montana ordered that the implementation of APHIS' January

In January 2005, BSE was confirmed in two cows in Canada.

On March 11, 2005, APHIS published a document in the **Federal Register** (70 FR 12112–12113, Docket No. 03–080–6) that, pursuant to an announcement by the Secretary of Agriculture on February 9, 2005, delayed the applicability of the provisions of the January 2005 final rule as they applied to the importation from Canada of the following commodities when derived from bovines 30 months of age or older when slaughtered: (1) Meat, meat food products, and meat byproducts other than liver; (2) whole or half carcasses; (3) offal; (4) tallow composed of less than 0.15 percent insoluble impurities that is not otherwise eligible for importation under 9 CFR 95.4(a)(1)(i); and (5) gelatin derived from bones of bovines that is not otherwise eligible for importation under 9 CFR 94.18(c).

In his February 9, 2005, announcement, the Secretary stated that because ongoing investigations into the recent finds of BSE in Canada in animals over 30 months of age were not complete, he felt it prudent to delay the effective date for allowing imports of meat from bovines 30 months of age and over. He also indicated that the delay of applicability would address concerns that the January 2005 final rule allowed the importation of meat from bovines 30 months of age or older, while continuing to prohibit the importation of live cattle 30 months of age or older for processing in the United States. The Secretary stated that the Department would consider and develop a plan—based on the latest scientific information and with the protection of public and animal health as the highest priority—to allow imports of live bovines 30 months of age or older.

In January 2005, an APHIS team visited Canada to evaluate the epidemiology of the North American BSE cases that had been identified at that time. This team concluded that the information available suggested a localized exposure, based on the relatively small geographical location, the temporal association, and the clustering of cases. The team also evaluated the likelihood of higher-risk animal or feed exposure to the United States at that time, and concluded that the U.S. feed ban and other mitigations had effectively minimized the risk of transmission or amplification of the BSE agent (USDA, 2005). In addition, also in January 2005, USDA sent a team to Canada to assess Canada's feed ban and its feed inspection program to determine whether the control measures put in place by the Canadian Government were achieving compliance with that country's regulations. APHIS conducted an extensive review of the feed ban in Canada and concluded that Canada has a robust inspection program, that overall compliance with the feed ban in Canada was good, and that the feed ban was reducing the risk of transmission of BSE in the Canadian cattle population (USDA, 2005a).

On January 9, 2007, we published a proposed rule in the **Federal Register** (72 FR 1101–1129, Docket No. APHIS–2006–0041) to, among other things, establish conditions for the importation from BSE minimal-risk regions of live bovines for any use born on or after a date determined by APHIS to be the date of effective enforcement of a ruminant-to-ruminant feed ban in the region of export.[4]

We conducted an assessment of the risk to U.S. livestock of allowing the importation of live bovines according to the provisions of the proposed rule from Canada—currently the only region recognized as a BSE minimal-risk region by APHIS. That risk assessment incorporated and built on information from all of the previous analyses, including the 2005 reports of the feed ban team and the epidemiological investigation team. In the risk assessment, we evaluated both the likelihood of ''release'' of the BSE agent into the United States and the likelihood of susceptible animals being exposed, given such release. We evaluated the pathways by which infected Canadian cattle, if imported, might expose U.S. cattle to BSE, and the likelihood that these pathways might lead to the establishment of the disease in the U.S. cattle population. We concluded that the likelihood of BSE exposure and establishment in the U.S. cattle population as a consequence of imports under the proposed rule was negligible.

In our risk assessment, we explained that several steps must occur for BSE to be transmitted to cattle in the United States from a live bovine imported from another country. A BSE-infected bovine must be imported into the United States; the infected bovine must die or be slaughtered; tissues from that animal that contain the infectious agent (i.e., the SRMs) must be sent to a rendering facility; the infectivity present in these tissues must survive inactivation in the rendering process; the resulting meat-and-bone meal containing the abnormal prion protein must be incorporated into feed; and this feed must be fed to cattle, in contravention of FDA regulations, at a level adequate to infect the cattle. (The amount of infectious material required in feed for cattle to become infected is dependent on the age of the cattle; younger cattle are more susceptible to BSE and require less BSE-contaminated feed to become infected (Arnold and Wilesmith, 2004)). We explained in our risk assessment that some of the steps could occur in parallel—i.e., without the occurrence of other steps—while others would need to occur in series. Because the impact of any specific step would depend on its relationship to other steps, its importance to the likelihood of BSE transmission, and, in turn, the impact of disease mitigation measures at each step, cannot be understood in isolation from the rest of the pathway.

One component of our risk assessment was an estimate of the prevalence of BSE in Canada, which was conducted using the same methods as an earlier estimate of the prevalence of BSE in the United States. The results of this prevalence estimate were then used to inform the subsequent considerations and calculations in the risk assessment. Because the prevalence was not zero—i.e., we concluded and acknowledged that BSE is still present in Canada at low levels—the risk assessment consequently assumed that infected animals could be imported into the United States under the provisions of the proposed rule. Even with this assumption, our conclusion that the risk of the exposure of U.S. cattle and the establishment of BSE in the United States was negligible remained unchanged.

On September 18, 2007, we published in the **Federal Register** (72 FR 53314–53379, Docket No. APHIS–2006–0041) a

4, 2005, final rule be preliminarily enjoined. On July 14, 2005, the U.S. States Court of Appeals for the Ninth Circuit ordered that the preliminary injunction order be vacated and the case remanded to the District Court.

[4] Requiring that live bovines exported to the United States from BSE minimal-risk regions be born after the date of effective enforcement of a ruminant-to-ruminant feed ban is consistent with the standards of the World Organization for Animal Health (OIE) for the exportation of live bovines from countries classified by the OIE as having either a negligible or a controlled BSE risk. We consider effective enforcement to have been achieved after completion of the initial (or practical) period of implementation of a feed ban and after sufficient time has elapsed to allow most feed products to cycle through the system. The practical implementation period, which begins when the regulations are initially put in place, can be determined by evaluating implementation guidance and policies, such as allowing grace periods for certain aspects of the industry. In addition, the time necessary for initial education of industry and training of inspectors must be considered. After the practical implementation period is defined, we then consider the time necessary subsequent to practical implementation to allow most feed products to cycle through the system, given the management practices in the country. Effective enforcement does not necessarily mean that 100 percent compliance with the feed ban requirements will be achieved.

final rule that adopted the changes to the regulations we had proposed in January 2007. Additionally, the September 2007 final rule removed the partial delay of applicability of the January 2005 final rule with respect to meat and certain meat products and byproducts derived from cattle over 30 months of age. In our September 2007 final rule, we stated that, subsequent to implementation of the partial delay of applicability, ''we [had] obtained additional information regarding all aspects of the issues that prompted the delay of applicability and [had] conducted additional analyses'' as indicated by the Secretary in February 2005 to allow imports of live bovines 30 months of age or older (72 FR 53316).

As we concluded in our September 2007 final rule, the risk assessment for that final rule demonstrates the negligible BSE risk from the importation of additional classes of live bovines, including those 30 months of age or older. As explained previously, the risk of transmission of BSE occurs when SRMs from infected cattle enter the ruminant feed supply in contravention of current feed regulations. Since the risk is tied to those tissues that contain infectivity, if those tissues are excluded from import, the risk is mitigated. When live cattle are imported, the potential exists that, after their death, their SRMs could enter the ruminant feed supply. Even with this potential, the conclusion of the risk assessment was that such imports present a negligible risk of establishment of BSE in the United States. As noted above, one of the requirements for the importation of meat from bovines is that the SRMS be removed from the animals from which the meat is derived. In other words, the SRMs are excluded from import and would not even have the potential to enter the risk pathway in the United States. Therefore, the conclusion of negligible risk related to the importation of live older bovines gives further support to the conclusion of the risk analysis conducted for our January 2005 final rule regarding meat and meat products derived from bovines of any age in BSE minimal-risk regions. Specifically, the risk is even lower for the importation of meat and meat products than for live bovines.

The September 2007 final rule, which included the removal of the partial delay of applicability of the provisions of the January 2005 rule relating to meat derived from cattle 30 months of age or older, became effective on November 19, 2007.

On July 3, 2008, Judge Lawrence L. Piersol of the U.S. District Court for the District of South Dakota, in response to a motion filed in that Court, ordered USDA to provide the public with notice and a further opportunity to comment on the provisions of our January 2005 final rule regarding the importation of beef from bovines 30 months of age or older when slaughtered, to consider comments made by interested parties, and to revise the rule as USDA deems necessary. In this document, we are providing such notice and further opportunity for comment. We will consider all comments that we receive by November 17, 2008.

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Authority: 7 U.S.C. 450, 7701–7772, and 8301–8317; 21 U.S.C. 136 and 136a; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.4.

Done in Washington, DC, this 12th day of September 2008.

Cindy J. Smith,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. E8–21786 Filed 9–17–08; 8:45 am]

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DEPARTMENT OF ENERGY

10 CFR Part 430

[Docket No. EERE–2008–BT–STD–0012]

RIN 1904–AB80

Energy Conservation Standards for Residential Refrigerators, Refrigerator-Freezers, and Freezers: Public Meeting and Availability of the Framework Document

AGENCY: Office of Energy Efficiency and Renewable Energy, Department of Energy.

ACTION: Notice of public meeting and availability of the framework document.

SUMMARY: DOE will hold an informal public meeting to discuss and receive comments on issues that it will address in this rulemaking proceeding. The Department is also initiating data collection for establishing energy conservation standards for residential refrigerators, refrigerator-freezers, and freezers. The Department also encourages written comments on these subjects. To inform stakeholders and facilitate this process, DOE has prepared a draft framework document, available at *http://www1.eere.energy.gov/buildings/appliance_standards/residential/refrigerators_freezers.html*.

DATES: The Department will hold a public meeting on Monday, September 29, 2008, from 9 a.m. to 5 p.m. in Washington, DC. Any person requesting to speak at the public meeting should submit such request along with a signed original and an electronic copy of the statements to be given at the public meeting before 4 p.m., Monday, September 22, 2008. Written comments are welcome, especially following the public meeting, and should be submitted by October 20, 2008.

ADDRESSES: The public meeting will be held at the U.S. Department of Energy, Forrestal Building, Room 8E–089, 1000 Independence Avenue, SW., Washington, DC 20585–0121. Please note that foreign nationals participating in the public meeting are subject to advance security screening procedures. If a foreign national wishes to participate in the public meeting, please inform DOE of this fact as soon as possible by contacting Ms. Brenda Edwards at (202) 586–2945 so that the necessary procedures can be completed.

Stakeholders may submit comments, identified by docket number EERE–2008–BT–STD–0012 and/or Regulation Identifier Number (RIN) 1904–AB80, by any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov*. Follow the instructions for submitting comments.
- *E-mail: ResRefFreez–2008–STD–0012@hq.doe.gov*. Include EERE–2008–BT–STD–0012 and/or RIN 1904–AB80 in the subject line of the message.
- *Mail:* Ms. Brenda Edwards, U.S. Department of Energy, Building Technologies Program, Mailstop EE–2J, Framework Document for Refrigerators, Refrigerator-Freezers, and Freezers, EERE–2008–BT–STD–0012 and/or RIN 1904–AB80, 1000 Independence Avenue, SW., Washington, DC 20585–0121. *Phone:* (202) 586–2945. Please submit one signed paper original.
- *Hand Delivery/Courier:* Ms. Brenda Edwards, U.S. Department of Energy, Building Technologies Program, 6th Floor, 950 L'Enfant Plaza, SW., Washington, DC 20024. Phone: (202) 586–2945. Please submit one signed paper original.

Instructions: All submissions received must include the agency name and docket number or RIN for this rulemaking.

Docket: For access to the docket to read background documents, a copy of the transcript of the public meeting, or comments received, go to the U.S. Department of Energy, 6th Floor, 950 L'Enfant Plaza, SW., Washington, DC 20024, between 9 a.m. and 4 p.m., Monday through Friday, except Federal holidays. For additional information about visiting the Resource Room, please call Ms. Brenda Edwards at (202) 586–2945. Please note that the Department's Freedom of Information Reading Room (formerly Room 1E–190 at the Forrestal Building) no longer houses rulemaking materials.

FOR FURTHER INFORMATION CONTACT: (1) Stephen Witkowski, U.S. Department of Energy, Office of Energy Efficiency and Renewable Energy, Building Technologies, EE–2J, 1000 Independence Avenue, SW., Washington, DC 20585–0121. *Phone:* (202) 586–7463. *e-mail: stephen.witkowski@ee.doe.gov*. (2) Michael Kido, U.S. Department of Energy, Office of General Counsel, GC–72, 1000 Independence Avenue, SW., Washington, DC 20585–0121. *Phone:* (202) 586–9507. *e-mail: michael.kido@hq.doe.gov*.

SUPPLEMENTARY INFORMATION: Part A of Title III of the Energy Policy and