Rules and Regulations

Federal Register
Vol. 70, No. 239
Wednesday, December 14, 2005

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Part 94

[Docket No. 05–004–2]

RIN 0579–AB93

Importation of Whole Cuts of Boneless Beef From Japan

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: We are amending the regulations governing the importation of meat and other edible animal products by allowing, under certain conditions, the importation of whole cuts of boneless beef from Japan. We are taking this action in response to a request from the Government of Japan and after conducting a risk analysis and considering public comments. This action will allow the importation of beef from Japan while continuing to protect against the introduction of bovine spongiform encephalopathy into the United States.

EFFECTIVE DATE: December 12, 2005, 11:30 a.m.

FOR FURTHER INFORMATION CONTACT: Dr. Gary Colgrove, Director, National Center for Import and Export, VS, APHIS, 4700 River Road Unit 38, Riverdale, MD 20737–1231; (301) 734–4356.

SUPPLEMENTARY INFORMATION:

Background

The Animal and Plant Health Inspection Service (APHIS) of the United States Department of Agriculture (USDA or the 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.

On August 18, 2005, we published in the **Federal Register** (70 FR 48494–48500, Docket No. 05–004–1) a proposed rule to amend the regulations governing the importation of meat and other edible animal products by allowing, under certain conditions, the importation of whole cuts of boneless beef from Japan. In that document, we explained that the proposed rule was developed in response to a request from the Government of Japan and after conducting an analysis of the risk that indicated that whole cuts of boneless beef that are derived from cattle born, raised, and slaughtered in Japan, could be imported into the United States, provided that the following conditions have been met:

- The beef is prepared in an establishment that is eligible to have its products imported into the United States under the Federal Meat Inspection Act (FMIA) (21 U.S.C. 601 *et seq.*) and the regulations in 9 CFR 327.2 and the beef meets all other applicable requirements of the FMIA and regulations thereunder (9 CFR chapter III), including the requirements for removal of specified risk materials (SRMs) and the prohibition on the use of air-injection stunning devices prior to slaughter on cattle from which the beef is derived.
- The beef is derived from cattle that were not subjected to a pithing process at slaughter.
- An authorized veterinary official of the Government of Japan certifies on an original certificate that the above conditions have been met.

In our August 2005 proposed rule we explained that these conditions would continue to protect against the introduction of BSE into the United States.

We solicited comments concerning the proposed rule and supporting risk analysis for 30 days ending September 19, 2005. We received 28 comments by that date. They were from cattlemen's associations, producers, representatives of foreign governments, and private citizens.

A number of commenters supported the rule in general but recommended certain changes to the proposed provisions. Others comments consisted only of recommended changes, objections to the rule in general or to specific provisions, or requests for clarification. In general, the comments we received on the proposed rule can be categorized as follows:

- Comments on the risk analysis;
- Comments on the economic analysis;
- Comments on the environmental analysis;
- Comments on the proposed standards for the importation of whole cuts of boneless beef from Japan; and
- Comments on miscellaneous issues related to the proposed rule.

We discuss these comments by topic below.

Risk Analysis for the Rulemaking

Incubation Period and Distribution of BSE in Cattle

Issue: One commenter stated that the APHIS risk analysis relied on outdated and incomplete scientific evidence to conclude that BSE infectivity is confined only to certain tissues and that infectivity in such tissues does not occur until cattle reach the age of 32 months. The commenter requested that, before APHIS proceeds with this rulemaking, the Agency explain: (1) Why cattle under 30 months of age do not present a risk of BSE, (2) why it is appropriate to base risk management strategies on equivocal science, (3) why additional risk mitigation measures are not needed to address the equivocal nature of the science, and (4) why APHIS is not imposing additional measures to address the potential risk of BSE infectivity in tissues that have not been designated by the USDA's Food Safety and Inspection Service (FSIS) as SRMs.

Response: We consider the BSE research upon which we based the proposed rule and this final rule to be substantial and current, and consider the mitigation measures in this rule to be appropriate based on the research. We discussed the research upon which we based this rulemaking in the risk document we made available with our August 2005 proposed rule. The key points are as follows:

The scope of this rulemaking is limited to whole cuts of boneless beef derived from cattle born, raised, and slaughtered in Japan. BSE infectivity has never been demonstrated in the muscle tissue of cattle experimentally or naturally infected with BSE at any stage of the disease. In tissues that have demonstrated BSE infectivity, pathogenesis studies have illustrated that levels of infectious BSE agent in certain tissues vary with the age of an animal. Infectivity was not detected in most tissues in cattle until at least 32 months post-exposure. The exception to this is the distal ileum (a part of the intestines), where infectivity was confirmed in experimentally infected cattle as early as 6 months post-exposure, and the tonsils, where infectivity was confirmed at 10 months post-exposure. Consistent with requirements established by FSIS and contained in 9 CFR part 310, we proposed to require the removal of tissues that have demonstrated BSE infectivity. (FSIS is the public health agency within USDA responsible for ensuring the food safety of beef.) These tissues (referred to as specified risk materials or SRMs) are 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 dorsal root ganglia of cattle 30 months of age and older, and the tonsils and distal ileum of the small intestine of all cattle. In addition to requiring the removal of SRMs, we proposed mitigation measures to address the potential risk of cross-contamination of the beef with SRMs. These requirements are based on currently available science and are consistent with the international guidelines on BSE established by the World Organization for Animal Health (formerly known as the Office International des Epizooties (OIE)), which is recognized by the World Trade Organization (WTO) as the international organization responsible for the development of standards, guidelines, and recommendations with respect to animal health and zoonoses (diseases that are transmissible from animals to humans).[1] For these reasons, we are not making any changes to the rule based on this comment.

Peripheral Nerves

Issue: Two commenters stated that the underlying assumption of the proposed rule, that whole cuts of boneless beef from Japan will not contain tissues that may carry the BSE agent, is no longer valid because researchers have found peripheral nervous system tissues, including facial and sciatic nerves, that contain BSE infectivity.[2] One of these commenters requested APHIS to explain whether and what additional mitigation measures are needed to reduce the risks that these tissues may be present in Japanese beef. This commenter further requested an additional comment period to obtain public comment regarding the manner by which APHIS intends to treat this new scientific finding.

Response: APHIS is familiar with the results of the study mentioned by the commenters in which mice, genetically engineered to be highly susceptible to BSE and to overexpress the bovine prion protein, were inoculated with tissues from a BSE-infected cow. This study demonstrated low levels of infectivity in the mouse assay in the facial and sciatic nerves of the peripheral nervous system. APHIS has evaluated these findings in the context of the potential occurrence of infectivity in the peripheral nerves of cattle and the corresponding risks of the presence of infectivity in such tissues resulting in cattle or human exposure to the BSE agent. The results from these experiments in genetically engineered mice should be interpreted with caution, as the findings may be influenced by the overexpression of prion proteins and may not accurately predict the natural distribution of BSE infectivity in cattle. Further, the overexpression of prion proteins in transgenic mice may not accurately mimic the natural disease process because the transgenic overexpressing mice have been shown to develop spontaneous lethal neurological disease involving spongiform changes in the brain and muscle degeneration.[3] In addition, the route of administration to the mice was both intraperitoneal and intracerebral, which are two very efficient routes of infection as compared to oral consumption. Given these factors, APHIS has determined that the finding of BSE infectivity in facial and sciatic nerves of the transgenic mice is not directly applicable to cattle naturally infected with BSE. Therefore, we do not consider it necessary to make any adjustments to the risk analysis for this rulemaking or to extend the comment period to solicit additional public comment on this issue.

Blood

Issue: Two commenters expressed concern that there has been a limited amount of research conducted on BSE infectivity in blood. One of these commenters cited a report that discussed, among other things, the detection of infectivity in sheep experimentally infected with BSE via blood transfusions.[4] This commenter also stated that the agent that causes Creutzfeldt-Jakob disease (CJD), a chronic and fatal neurodegenerative disease of humans, was detected in blood, and questioned whether the BSE agent could be detected in blood as well. The other commenter cited a study that detected infectivity in hamsters experimentally infected with scrapie.[5] This commenter requested that APHIS ban the use of blood in cattle feed.

Response: As stated in our risk analysis, the pathogenesis studies of naturally and experimentally infected cattle have not detected BSE infectivity in blood.

The first study mentioned by the commenter above demonstrated transmission of disease from sheep experimentally infected with BSE to another sheep via blood transfusions. We note that there are widely acknowledged differences between the distribution of BSE infectivity in the tissues of cattle and sheep. In addition, there is a significant difference in susceptibility to infection based on the route of transmission. Infection via oral consumption may be 10,000 times less efficient than infection via intravenous injection, such as a blood transfusion.

Both the United Kingdom's Department for Environment, Food and Rural Affairs' Spongiform Encephalopathy Advisory Committee (SEAC) and the European Commission's Scientific Steering Committee (SSC), which are scientific advisory committees, evaluated the findings of transmission of infectivity via blood transfusions in sheep experimentally infected with BSE and concluded that

[1] The OIE guidelines for trade in terrestrial animals (mammals, birds, and bees) are detailed in the Terrestrial Animal Health Code (available on the Internet at *http://www.oie.int*). The guidelines on BSE are contained in Chapter 2.3.13 of the Code and supplemented by Appendix 3.8.4 of the Code.

[2] Bushmann, A., and Gruschup, M.; Highly Bovine Spongiform Encephalopathy-Sensitive Transgenic Mice Confirm the Essential Restriction of Infectivity to the Nervous System in Clinically Diseased Cattle. The Journal of Infectious Diseases, 192: 934–42, September 1, 2005.

[3] Westaway, D., et al.; (1994) Degeneration of Skeletal Muscle, Peripheral Nerves, and the Central Nervous System in Transgenic Mice Overexpressing Wild-type Prion Proteins. Cell 76, 117–129.

[4] Pattison, J., et al.; UK Strategy for Research and Development on Human and Animal Health Aspects of Transmissible Spongiform Encephalopathies, 2005–2008. Available at *http://www.mrc.ac.uk/pdf-about-tse_uk_strategy_june2005.pdf.*

[5] Castilla, J., et al.; Detection of Prions in Blood. Nature Medicine, doi: 10.1038/nm1286, August 28, 2005, at 3.

these findings did not indicate that additional mitigation measures were necessary to protect public health.[6] Therefore, based on currently available information, APHIS considers it unlikely that the experimental observations in sheep reflect a biologically significant event for cattle or affect the safety of whole cuts of boneless beef derived from cattle born, raised, and slaughtered in Japan.

The study on scrapie-infected hamsters noted by the commenter describes a process by which the abnormal prion protein can be amplified and detected using current testing methods, such as a Western blot. In this study, blood from hamsters experimentally infected with a scrapie strain was collected when the animals demonstrated clinical signs of disease. These blood samples were incubated with excess normal prion protein from brain tissue for multiple cycles. If abnormal protein is present in blood, it will convert the normal brain prion to abnormal prion, yielding an increased amount of abnormal prion that can be more easily detected. In this manner, the presence of abnormal prion protein in the initial blood samples, which was present in levels too low to detect using routine test methods, was demonstrated. While this finding has many possibilities related to the development of diagnostic tests, it does not demonstrate BSE infectivity in blood. We also note that the international community largely considers that studies using transmissible spongiform encephalopathies (TSEs) other than BSE in non-bovine animals cannot be directly extrapolated to BSE in cattle because of the significant interactions between the host species and the prion strain involved.

Feed regulations in the United States are under the authority of the Food and Drug Administration (FDA), not APHIS. Therefore, the commenter's request that APHIS ban the use of blood in cattle feed falls outside the scope of this rulemaking. For these reasons, we are not making any changes to the rule based on these comments.

Low Dose Exposure

Issue: One commenter cited new research indicating that infection by the disease agent that causes BSE may be reached through the accumulation of subinfectious doses over time.[7] The commenter expressed concern that this finding undercuts the risk analysis prepared for this rulemaking, which, according to the commenter, discussed evidence that BSE infectivity is caused by the consumption of a single dose of infected tissue and that a low dose exposure has a longer incubation period. This commenter requested APHIS to explain the impact of these findings on its assessment of the risk posed by the importation of boneless beef from Japan.

Response: Our risk analysis does not state, as stated by the commenter, that ''BSE infectivity is caused by the consumption of a single dose of infected tissue.'' Our risk analysis states that ''the incubation period [of the BSE agent] is inversely related to dose (i.e., low dose exposures have a long incubation period before clinical signs of disease become apparent).'' This statement is based on research conducted on BSE and is not meant to make a statement about the number of doses necessary for cattle to become affected by the BSE agent. Further, the findings noted by the commenter would not affect the critical evaluation of risk on which our mitigation measures are based. This rule will allow the importation of whole cuts of boneless beef derived from cattle. Regardless of the infective dose or period of incubation, BSE infectivity has never been demonstrated in the muscle tissue of cattle experimentally or naturally infected with BSE at any stage of the disease. Therefore, we are not making any changes to the rule based on this comment.

Findings Related to Tissue Inflammation

Issue: One commenter requested that APHIS discuss the implications of a recent study[8] indicating that inflammation may act as a modifier of natural and iatrogenic (experimental) prion transmission to other organs and tissues not presently listed as SRMs and whether those findings necessitate the implementation of additional risk mitigation measures to reduce the risk of introducing BSE into the United States from Japan.

Response: APHIS reviewed the study referred to by the commenter. The study authors present results that show that chronic lymphocytic inflammation enabled prion accumulation in certain otherwise prion-free organs. The study authors postulate that chronic inflammatory condition may act to modify natural and iatrogenic prion transmission by expanding tissue distribution of prions. According to the authors, in the inflammatory conditions studied, expression in two specific types of lymphotoxins and a secondary lymphoid organ chemokine in certain tissues was enough to establish ''unexpected'' prion reservoirs. APHIS reviewed the findings from this study, which used transgenic mice, in the context of the potential occurrence in cattle. We do not believe that the study results can be extrapolated to cattle naturally infected with BSE. First, the study used several transgenic and spontaneous mouse models of chronic inflammation that were inoculated with scrapie infectivity rather than BSE infectivity. The pathogenesis and infectivity distribution of the scrapie agent in mice is different from the BSE agent in cattle. Second, the mice in this study were injected with scrapie prions through intraperitoneal and/or intracerebral routes of inoculation, which are much more efficient routes than oral consumption of a disease agent, the natural route for exposure of cattle to the BSE agent. Finally, the study authors themselves did not claim that the mouse models and results obtained in the study represent a model for the pathogenesis of BSE in cattle. They stated that direct evidence from similar studies using the BSE agent in cattle are needed prior to concluding that chronic inflammatory conditions in cattle can alter the distribution of the BSE agent. Therefore, we are making no changes in the rule in response to this comment.

TSE Working Group

Issue: One commenter stated that the proposed rule and supporting risk analysis should be evaluated by APHIS' TSE Working Group. The commenter further requested that APHIS make available to the public a report of the TSE Working Group's evaluation of the risk of BSE arising from the proposed rule along with the Group's recommendations regarding the actions that should be taken in response to these risks.

Response: APHIS has proceeded in a thorough and deliberative manner, in cooperation with FSIS and FDA, to define the steps necessary to protect animal and public health. The APHIS

[6] Spongiform Encephalopathy Advisory Committee, Oct. 19, 2000, Summary of SEAC Committee Meeting 29 September 2000. Available at *http://www.defra.gov.uk/news/seac/seac500.htm.*

European Commission Scientific Steering Committee; The Implications of the Recent Papers on Transmission of BSE by Blood Transfusion in Sheep (Houston et al., 2000; Hunter et al., 2002), Adopted by the SSC at its Meeting of 12–13 September. Available at *http://europa.eu.int/comm/food/fs/sc/ssc/out280_en.pdf.*

[7] Jacquemot, C., et al.; High Incidence of Scrapie Induced by Repeated Injections of Subinfectious Prion Doses. Journal of Virology, July 2005, p. 8904–8908.

[8] Heikenwalder, M., et al.; Chronic Lymphocytic Inflammation Specifies the Organ Tropism of Prions. Science, Vol. 37, February 18, 2005, 1107–1110.

TSE Working Group consists of APHIS employees with expertise in veterinary science, epidemiology, import/export issue management, pathobiology, veterinary biologics, and TSE program management. The group has met in the past to assist and make recommendations to the Deputy Administrator for APHIS' Veterinary Services, as well as other managers, regarding animal health programs. The TSE Working Group is not solely responsible for evaluating information and data regarding BSE/TSE import regulations. That said, members of the TSE Working Group who have special expertise in BSE participated in the development of the risk analysis, either as contributing writers or reviewers of the document. Their input was, therefore, considered by the Agency during development of the proposed rule. Under these circumstances, we do not believe it would be appropriate for the TSE Working Group to take on the role suggested by the commenter.

Harvard-Tuskegee Investigation of BSE Risk in the United States

In April 1998, USDA contracted with the Harvard Center for Risk Analysis (HCRA) at Harvard University and the Center for Computational Epidemiology at Tuskegee University to conduct a comprehensive investigation of BSE risk in the United States. The report,[9] widely referred to as the Harvard Risk Assessment or the Harvard Study, is referred to in this document as the Harvard-Tuskegee Study. It was completed in 2001 and released by the USDA. Following a peer review of the Harvard-Tuskegee Study in 2002, the authors responded to the peer review comments and released a revised risk assessment in 2003.[10]

Issue: One commenter expressed concern about the Harvard-Tuskegee Study. In our risk analysis, we refer to the Harvard-Tuskegee Study in our discussion of the risks associated with plate waste. The commenter disagreed with the study's conclusion that the risk of BSE becoming established in the United States is ''extremely unlikely.'' Specifically, this commenter noted that, with respect to the United States' potential exposure to BSE before the 1989 import ban and 1997 feed ban, the Harvard-Tuskegee Study stated that, ''Exposure to infectivity among U.S. cattle could not have been substantial because in the years prior to the 1997 FDA feed ban, such exposure would have eventually resulted in a substantial number of clinical cases, a prediction that is inconsistent with the fact that BSE has not been identified in the United States to date. There is therefore, a small chance that BSE could have been introduced into the U.S. and remained undetected.'' The commenter stated that the detection of a 12-year-old BSE-positive cow native to the United States in June 2005 proves that the Harvard-Tuskegee Study's assumption was in error, and that the chance that BSE could have been introduced into the United States was not small. The commenter also stated that, until and unless the Secretary revises the Harvard-Tuskegee Study to correct the known, erroneous assumptions underpinning the study, the Harvard-Tuskegee Study is an inappropriate tool for accurately ascertaining the degree of increased risk the United States would be subject to under the proposed rule.

Response: We disagree with this commenter's interpretation of the Harvard-Tuskegee Study's conclusion regarding the risk of BSE establishment in the United States. First, the text extracted from the Harvard-Tuskegee Study and quoted by the commenter states that ''* * * such exposure would have eventually resulted in a substantial number of clinical cases * * *.'' We do not consider one native case of BSE to constitute a substantial number. In addition, the model used by the Harvard-Tuskegee Study did not rely on a zero probability of BSE incidence in the United States. The detection of BSE in a 12-year-old cow does not invalidate the conclusions of the study nor our conclusions about the level of risk posed by the importation of beef from Japan under the proposed conditions. Furthermore, because this rule applies only to whole cuts of boneless beef, and muscle tissue of cattle has never demonstrated BSE infectivity, it is highly unlikely that this meat will introduce BSE into the United States. The Harvard-Tuskegee Study is referenced in the risk analysis only to address this already remote risk.

APHIS considers the assumptions underpinning the study to be valid and based on currently available science. As mentioned above, the USDA commissioned the HCRA and the Center for Computational Epidemiology at Tuskegee University to conduct what we now refer to as the Harvard-Tuskegee Study in 1998. The objective of the Harvard-Tuskegee Study was to analyze and evaluate the measures implemented by the U.S. Government to prevent the spread of BSE in the United States and to reduce the potential exposure of Americans to the BSE agent. The Harvard-Tuskegee Study reviewed available scientific information related to BSE and other TSEs, assessed pathways by which BSE could potentially spread in the United States, and identified measures that could be taken to protect human and animal health in the United States. The Harvard-Tuskegee Study concluded that, if introduced, BSE is extremely unlikely to become established in the United States. The Harvard-Tuskegee Study also concluded that, should BSE enter the United States, only a small amount of potentially infective tissues would likely reach the human food supply and be available for human consumption. The HCRA recently revised its model using updated estimates for some of the model parameters, based on new data about compliance with feed restrictions. The results are even lower estimates of risk than previously predicted.

Risk of BSE in General

Issue: Several commenters expressed concern regarding the risk posed by boneless beef imported into the United States from Japan. One commenter asked why the U.S. Government would propose to allow the importation of boneless beef from Japan if there is any risk that it could introduce BSE into the United States. One commenter stated that APHIS failed to provide a basis for its conclusion that this increased risk is acceptable.

Response: Zero risk is virtually, if not absolutely, impossible to achieve. If we were to make trade dependent on zero risk, foreign, as well as interstate, trade in animals and animal products would cease. Consistent with international trade agreements, such as the WTO's ''Agreement on the Application of Sanitary and Phytosanitary Measures'' (WTO–SPS Agreement) and the North American Free Trade Agreement, APHIS agrees that measures to protect human,

[9] Harvard Center for Risk Analysis, Harvard School of Public Health, and Center for Computational Epidemiology, College of Veterinary Medicine, Tuskegee University; Evaluation of the Potential for Bovine Spongiform Encephalopathy in the United States. Available at *http://www.aphis.usda.gov/lpa/issues/bse/risk_assessment/mainreporttext.pdf, 2001.*

[10] Research Triangle Institute; Review of the Evaluation of the Potential for Bovine Spongiform Encephalopathy in the United States. Accessed online at *http://www.aphis.usda.gov/lpa/issues/bse/BSE_Peer_Review.pdf, 2002.*

Harvard Center for Risk Analysis, Harvard School of Public Health; Evaluation of the Potential for Bovine Spongiform Encephalopathy in the United States: Response to Reviewer Comments Submitted by Research Triangle Institute. Available at *http://www.aphis.usda.gov/lpa/issues/bse/ResponsetoComments.pdf, 2003.*

Harvard Center for Risk Analysis, Harvard School of Public Health, and Center for Computational Epidemiology, College of Veterinary Medicine, Tuskegee University; Evaluation of the Potential for Bovine Spongiform Encephalopathy in the United States. Available at *http://www.aphis.usda.gov/lpa/issues/bse/madcow.pdf, 2003.*

animal, and plant health should be no more trade restrictive than necessary to achieve an appropriate level of protection. Under these agreements, participating nations, including the United States and U.S. trading partners, have agreed to base their measures, such as conditions for importation, on science-based risk assessments and international standards.

As discussed in our risk analysis, BSE infectivity has never been demonstrated in the muscle tissue of cattle experimentally or naturally infected with BSE at any stage of the disease. Therefore, if BSE is present in a country's cattle population, as it is in Japan, the most significant risk mitigation measure for ensuring the safety of whole cuts of boneless beef is the prevention of cross-contamination of the beef with SRMs during stunning and slaughter of cattle. The proposed rule and this final rule include mitigation measures that address such risks and are consistent with the international guidelines on BSE established by the OIE.

U.S. Feed Ban

Issue: One commenter stated that the level of risk posed by beef imported from Japan is unacceptable because the U.S. feed ban could potentially result in the recycling of BSE in the United States. This commenter requested that APHIS define ''small fraction'' and ''highly diluted'' in our statements in the risk analysis about the amount of imported beef that might, hypothetically, be fed to cattle, and the potential concentration of any BSE agent, if present, that might be available. The commenter further questioned whether these terms describe an infectious level below 0.001 gram, which is the amount of infected tissue research has shown to cause BSE infectivity. In addition, the commenter asked how many doses may be expected to enter the animal food chain, if the dose is greater than 0.001 gram.

Response: We disagree that the current feed regulations could result in the recycling of BSE if introduced into the United States by whole cuts of boneless beef from Japan. In our risk analysis, we considered possible direct and indirect pathways by which whole cuts of boneless beef imported from Japan might expose U.S. cattle to BSE if the product contained the BSE agent. We discussed these pathways in the context of barriers that exist to prevent these types of exposures. Our discussion of these barriers was specifically prefaced by the fact that whole cuts of boneless beef are an inherently low risk commodity because BSE infectivity has never been demonstrated in muscle tissue in cattle. In fact, we clearly stated that the primary barriers limiting the likelihood that whole cuts of boneless beef imported from Japan would expose the U.S. cattle population to BSE are the inherently low risk of the product, the mitigation measures included in this rule to prevent contamination, and the fact that the product is unlikely to be fed to cattle. We further stated that although the product is not intended for animal consumption, we evaluated pathways by which some small fraction or amount of the product might inadvertently be fed to cattle.

The amount of boneless beef that would be imported from Japan is relatively small and the amount of material likely to be disposed of is even smaller, given that household and restaurant food waste are rarely, if ever, fed to cattle or rendered. These types of waste become municipal garbage and are disposed of in landfills. Further, because the FDA requires that plate waste be further heat processed before it can be incorporated into ruminant feed, any potential plate waste derived from boneless beef from Japan would most likely be subject to rendering processes that would inactivate significant levels of the BSE agent, thereby further reducing the level of infectivity in the feed. Therefore, our risk analysis concluded that it is extremely unlikely that imported material containing an infectious level of the BSE agent will enter the ruminant feed chain. Because we do not consider these pathways to be epidemiologically significant for exposure of the U.S. cattle population to BSE infectivity in products imported under this rule, we do not believe it is necessary to quantify a level of infectious material that is theoretically possible, but highly unlikely, to be present. For these reasons, we are making no changes to the rule in response to this comment.

With regard to the commenter's request for APHIS to define ''small fraction'' and ''highly diluted,'' in our statements in the risk analysis about the amount of imported beef that might, hypothetically, be fed to cattle, these terms were used to describe a small amount of material and a small amount of material that is not concentrated, respectively.

Issue: One commenter stated that APHIS' reliance upon heat-processed rendering to inactivate BSE infectivity is misplaced because the Harvard-Tuskegee Study makes no definitive finding that the rendering processes used in the United States will inactivate the BSE agent. This commenter stated that, in order to meet its duty to protect the livestock in the United States from the introduction of BSE, the FDA must first modify the U.S. feed ban to prevent the possible recycling of any BSE infectivity imported from Japan. According to the commenter, the U.S. feed ban includes exceptions for the feeding of blood, poultry litter, and plate waste, the feeding of SRMs to farmed animals, and does not require segregated facilities in the manufacturing of animal feed. This commenter stated that these elements of the feed ban must be eliminated before APHIS begins accepting beef or cattle from any country where BSE is known to exist, including Japan.

Response: The model used by the Harvard-Tuskegee Study included assumptions about the types of rendering processes used in the United States, and the amount of material subjected to these processes. There are only a limited number of rendering processes in use, and research has demonstrated that, with one exception, these processes inactivate significant levels of the BSE agent. The one type of rendering system that does not inactivate significant levels of the BSE agent, the low-temperature vacuum system, is not widely used in the United States, if at all. In fact, the Harvard-Tuskegee Study assumed that only 5 percent of cattle carcasses rendered in the United States may be subject to this process. APHIS does not rely solely on this inactivation, however, in the analysis. A series of barriers, of which inactivation at rendering is only one, must each be crossed in sequence for transmission of BSE to occur. In fact, inactivation by rendering would only be relevant if BSE-contaminated beef entered the United States and entered the ruminant feed supply. Our analysis shows that neither event is likely.

With regard to the commenter's statement that the FDA must modify and broaden the U.S. feed ban to prevent the possible recycling of any BSE infectivity imported from Japan, the Harvard-Tuskegee Study demonstrates that with the existing feed ban, even with incomplete compliance, the level of transmission of BSE from infected animals is minimal, if it occurs at all. This rule only allows the importation of whole cuts of boneless beef, a product that presents a very low risk of BSE infectivity. Even if beef were imported with infectivity, all of the sequential barriers to transmission-of which the feed ban is only one-must be crossed in order for transmission to occur. Therefore, we are making no changes to the rule in response to this comment.

Cross-Contamination

Issue: One commenter expressed concern that the current FSIS regulations and policies do not fully address the possibility of cross-contamination between SRMs and edible product in plants that predominately slaughter cattle over 30 months of age. This commenter stated that, although the current policies address the use of separate equipment in cattle under 30 months versus those that are over this age, they do not specifically address the issue of dedicated equipment for the removal and trim of SRMs in plants slaughtering over-30-month-old cattle. The commenter urged the USDA to include more specific requirements in its regulations to prevent cross contamination between SRMs and edible products. The commenter stated that these should include, but not be limited to, requiring the use of separate equipment, such as knives and blades, and utilizing effective TSE disinfection procedures for equipment used to handle SRMs.

Response: The FSIS regulations contained in 9 CFR part 310 require that establishments that slaughter/process cattle develop, implement, and maintain written procedures for the removal, segregation, and disposition of SRMs. These procedures address appropriately potential cross-contamination of edible product with SRMs. FSIS inspectors are responsible for verifying the effectiveness of the establishment's procedures. If FSIS personnel determine that an establishment's procedures are not effective in preventing cross-contamination, the inspectors will take appropriate action.

Issue: One commenter expressed concern that infective tissue could potentially contaminate additional carcasses via the use of saws in carcass splitting. This commenter stated that this risk is too great for consumers and the U.S. cattle industry. Another commenter requested that APHIS explain the risk of introducing BSE into the United States that may result from the potential for boneless beef to be contaminated with BSE-infected tissues during the carcass-splitting process.

Response: As discussed in our risk analysis, cross-contamination events represent potential pathways to contaminate whole cuts of boneless beef. One potential event for such beef is cross-contamination of carcasses with spinal cord during carcass splitting, as the saw cuts the carcass in half.

FSIS has determined that the Japanese meat inspection system is equivalent to that of the United States, and that the slaughter mitigations applied in both systems would work similarly to reduce the potential for contamination of whole cuts of boneless beef. For example, the Japanese establishments, like U.S. establishments, remove the vertebral column as a unit to reduce the likelihood of potentially infective tissues contaminating the beef. The establishments also remove spinal cord dura matter and wash the dressed carcasses after splitting, and inspectors confirm that the carcasses are free of all visually detectable evidence of contamination by spinal cord fragments. Some establishments in Japan carry out suction removal of spinal cords prior to carcass splitting, which further reduces the risk of contamination. Finally, it should be noted that the whole cuts of boneless beef that will be imported into the United States from Japan are trimmed further, which again reduces any potential for contamination.

Issue: One commenter stated that the proposed rule is arbitrary and capricious because APHIS has not quantified the number of infectious doses of BSE-infected material that can be expected to contaminate boneless beef based on the scientifically known occurrence of contamination resulting from carcass splitting. This commenter stated that APHIS provides no basis for its conclusion that the increased risk associated with importing meat from Japan that may be contaminated with high risk tissues is acceptable.

Response: We disagree with the comment. Our proposed rule and the risk analysis are scientifically sound. Many regulatory decisions do not depend on numerical calculations or quantifications. What is important is a careful, comprehensive characterization and evaluation of the risk involved. Such an evaluation has been accomplished by APHIS and is consistent with the methodology used in the risk analysis for this rulemaking. With respect to the commenter's specific concern, *i.e.*, the quantification of infectious doses of BSE-infected material that can be expected to contaminate whole cuts of boneless beef, there currently is no reliable information to support a precise quantification of a human infectious dose. However, there is a wide body of independently verifiable scientific evidence regarding BSE, including how to control and eliminate the disease. This rule requires mitigation measures consistent with that information.

Issue: One commenter expressed concern that the proposal did not address the risk of acceptable methods of stunning (other than air-injection stunning and pithing, which are prohibited under this rule). This commenter cited a report by the European Commission's TSE BSE Ad Hoc Group that noted a theoretical risk that, when a healthy animal that nevertheless has infectivity in the brain is stunned using a penetrative method, there is the possibility that the bolt of the gun could be contaminated and could introduce that infectivity into one or more sequentially stunned animals, if stunned with the same gun.[11] The commenter requested APHIS to specifically address what measures it will put in place to address this risk.

Response: We acknowledge the theoretical possibility that infectivity in the brain of a BSE-infected bovine could potentially be transferred from the head of one animal to the head of another animal through the use of penetrating stunning methods. However, there is currently no evidence that such contamination occurs during the slaughter process. Further, as discussed in the background section of our August 2005 proposed rule, we use the term, ''whole cuts of boneless beef,'' to refer to meat derived from the skeletal muscle of a bovine carcass, excluding all parts of the animal's head and diaphragm. These restrictions ensure that penetrative stunning methods not prohibited under this rule are not a risk factor for whole cuts of boneless beef from Japan.

BSE Incidence in Japan

Issue: One commenter stated that the proposed rule did not take into consideration the present and future BSE incidence rate in Japan. This commenter stated that the rule should require that Japan demonstrate that the incidence of BSE is declining and that no new cases are discovered in animals born after the implementation of the feed ban. The commenter stated that sufficient time has not yet lapsed since Japan implemented its feed ban and other risk mitigation measures to determine whether such measures have effectively arrested the spread of BSE. Another commenter stated that Japanese beef is not safe based on the incidence of BSE in Japan. Finally, one commenter stated that Japan should be proven to be free from BSE for 7 years before the United States should consider importing from Japan.

Response: We concur that at present it is not possible to know with certainty whether any additional animals in Japan are infected with BSE. However, as documented in our risk analysis, we

[11] Scientific Report on Stunning Methods and BSE Risks, TSE BSE Ad Hoc Group, European Commission, December 13, 2001, at 41.

analyzed the likelihood that whole cuts of boneless beef imported from Japan would: (1) Contain infectious levels of the BSE agent; and (2) present a risk of exposing U.S. consumers or cattle to BSE, if the imported beef product was contaminated with BSE. Based on the potential pathways, we then determined appropriate mitigation measures to address the risks associated with whole cuts of boneless beef imported from Japan. BSE infectivity has never been demonstrated in the muscle tissue of cattle infected with BSE at any stage of the disease. Therefore, the most significant risk management strategy for ensuring the safety of whole cuts of boneless beef is the prevention of cross-contamination of the beef with SRMs during stunning and slaughter of the animal. Mitigation measures that prevent contamination of such beef involve procedures for the removal of SRMs and carcass splitting and prohibitions on air-injection stunning and pithing. This rule requires such mitigation measures. While our risk analysis considered the incidence of BSE in Japan in its discussion of the OIE recommendations on BSE, it did not play a central role in our evaluation of the risk posed by whole cuts of boneless beef. Our evaluation was based on the nature of the commodity and the potential pathways for exposure.

Economic Analysis

Issue: One commenter asked what assurances there are in the rule that Wagyu beef will be the only beef exported, since Japan also produces Holstein beef, which appears to be where Japan is experiencing the highest rate of BSE.

Response: This rule allows the importation of whole cuts of boneless beef from all cattle breeds, including Holstein, provided that certain conditions are met. These conditions, which include removal of SRMs and prohibitions on the use of air-injection stunning and pithing, will continue to protect against the introduction of BSE into the United States, regardless of the breed of cattle from which the beef is derived. As a practical matter, the export of Holstein beef to the United States is unlikely, since it is unlikely that Japan will try to compete in the U.S. import market for lower-grade beef from culled dairy cattle against such established suppliers as Australia and New Zealand. We expect only Wagyu beef to be imported under the rule.

Issue: One commenter stated that the impact of the rule on the domestic Wagyu beef industry should be thoroughly analyzed because this rule has the potential to have the most impact on that segment of the beef industry.

Response: Our assessment of the rule's potential impact on U.S. producers of Wagyu beef was as thorough as possible given the available data. In the proposed rule, we stated that we did not have all of the data necessary for a comprehensive analysis, and invited the public to provide information that would enable us to better assess the rule's potential impact, including information on the number of domestic Wagyu producers and their production. None of the comments received from the public in response to the proposed rule included that information.

Issue: One commenter stated that domestic producers will lose economically from this rule because the initial regulatory flexibility analysis noted that consumers may benefit if the price of domestic Wagyu beef goes down due to the resumption of trade in Japanese boneless beef.

Response: The economic impact of the rule on domestic Wagyu producers is unclear. This is because the extent to which Wagyu beef imports from Japan and domestically produced Kobe-style beef compete for the same group of buyers is not known. It is conceivable that demand for, and prices of, domestic Kobe-style beef could decline if consumers switched to Wagyu beef from Japan once that product becomes available in the U.S. market. On the other hand, it is possible that the importation of Wagyu beef from Japan could stimulate additional interest in, and demand for, high-end beef in general, thereby benefitting U.S. producers of Kobe-style beef. That domestic Kobe-style beef will likely sell at a lower average price than Wagyu beef from Japan suggests that the two commodities are not perfect substitutes.

Issue: One commenter expressed concern that the most serious economic impact of the rule has not been addressed, that is, the possibility of an American consumer contracting variant CJD (vCJD), which has been linked via scientific and epidemiological studies to exposure to the BSE agent. The commenter stated that this rule would unfairly reduce demand for beef from American cattle producers because country of origin labeling has not yet been enforced and consumers will not be able to differentiate Japanese beef from American beef.

Response: The possibility of an American consumer contracting vCJD from infected meat imported from Japan is extremely unlikely. FSIS, which assessed the human health risks associated with the rule, concluded that the beef imported under the conditions described in the rule will pose no greater level of risk as products produced for human consumption in the United States. Matters relating to country of origin labeling are beyond the scope of this rule.

Environmental Assessment

Issue: One commenter stated that APHIS should prepare an environmental impact statement (EIS) that shows the effects of a range of potential risks including low risk, moderate risk, and high risk.

Response: APHIS prepared an environmental assessment in order to determine whether or not there could be significant environmental impacts associated with allowing the importation of whole cuts of boneless beef from Japan based upon conditions specified in the rulemaking. The purpose of an environmental assessment is to provide sufficient information and analysis to agency decisionmakers to allow them to determine whether a proposed agency action will have a significant effect on the human environment, including public health and safety. The decisionmaker reviews the environmental assessment and any associated public comments and then makes a determination on whether there will be adverse impacts significantly affecting the human environment. This determination is based on the consequences of associated risks and on safeguards that are designed to prevent those risks from occurring and causing significant adverse impacts on the human environment. If a determination is made that a proposed action would have a significant effect on the human environment, the agency is obligated to prepare an EIS. If a determination is made that the action will not have a significant effect on the human environment, a finding of no significant impact is issued in connection with any final rule and an environmental impact statement is unnecessary. That is the case with this rulemaking.

Issue: The same commenter stated that the proposed rule should be afforded even greater scrutiny from an environmental perspective than APHIS afforded the minimal risk region rule because of the cumulative effects of the two rules.

Response: The minimal-risk region rule (see 70 FR 360–553, Docket No. 03–080–3, January 4, 2005) allows the importation of live bovines less than 30 months of age when imported and when slaughtered, sheep and goats less than 12 months of age when imported and when slaughtered, and certain bovine meat, meat byproducts, and meat food

products, from regions recognized as minimal-risk for BSE, provided that certain conditions are met. The environmental assessment for the minimal-risk region rule and a review of the issues raised by public comment provided the basis for a finding of no significant impact on the quality of the human environment, *i.e.*, public health and safety (see 70 FR 18252–18262, Docket No. 03–080–7, April 8, 2005). The rule for Japanese beef will only allow whole cuts of boneless beef, which have not demonstrated BSE infectivity at any stage of the disease. The conditions contained in this rule for whole cuts of boneless beef, such as the appropriate removal of SRMs from the carcass, address the potential risk for BSE contamination. Thus, it is highly unlikely that the importation of such beef from Japan would result in the introduction of BSE into the United States. Therefore, from an environmental perspective, an environmental assessment is the appropriate level of environmental documentation.

Proposed Regulations

BSE Regulations (General Approach)

Issue: Several commenters expressed concern that APHIS' import policy with regard to BSE and, more specifically, BSE-related restrictions for the importation of whole cuts of boneless beef from Japan, seems to differ from its regionalization approach found in the current BSE regulations and the general policy with regard to recognition of regions for other foreign animal diseases. One commenter stated that, with most diseases, APHIS does not allow importation until adequate surveillance has been done to prove freedom of a region from the disease. However, with regard to BSE, stated the commenter, APHIS allows imports from a region until a case of BSE is identified in that region. The commenter stated that APHIS should define standards for all levels of trade with various countries concerning BSE. The commenter suggested that APHIS conduct or peer review the proper risk evaluations to determine a country's BSE risk category based upon OIE guidance and to classify all countries that have not been evaluated as undetermined risk regions.

Similarly, another commenter expressed concern that APHIS does not have a standard for protecting the United States against the introduction and spread of BSE, and potentially other communicable diseases, because Japan does not meet the criteria for a minimal-risk region. Finally, one commenter stated that no reason was provided in the proposal for APHIS' departure from previous policies to deny the importation of commodities from BSE-affected regions.

Response: With regard to trade from BSE-affected regions, § 94.18(a)(1) lists regions where BSE is known to exist. Paragraph (a)(2) of § 94.18 lists regions that present an undue risk of BSE because their import requirements are less restrictive than those that would be acceptable for import into the United States and/or because the regions have inadequate surveillance for BSE. Additionally, § 94.18(a)(3) lists regions that present a minimal risk of introducing BSE into the United States. APHIS prohibits the importation of live ruminants and certain ruminant products and byproducts both from regions where BSE is known to exist (and that are not considered BSE minimal-risk regions) and from regions of undue risk, even though BSE has not been diagnosed in a native animal in the latter regions. The minimal-risk regions rule provided the basis for allowing the importation of various commodities from regions in which BSE has been detected but that have been evaluated as minimal-risk regions for BSE.

With respect to the issue about Japan meeting the requirements for a minimal-risk region as defined in § 94.0, as mentioned previously, the situation in Japan represents conditions consistent with a controlled-risk region as outlined in the OIE guidelines. We did not evaluate Japan as a minimal-risk region. This rule is commodity-based. The requirements for importing that commodity-whole cuts of boneless beef-protect against the introduction of BSE. Other provisions in APHIS' regulations address risks associated with other diseases. For example, if Japan were to experience an outbreak of foot-and-mouth disease, the requirements of § 94.4, which require cooking or curing, would apply.

With respect to the approach to BSE differing from the approach to other diseases, when it was newly discovered, BSE was limited in its geographic distribution to the United Kingdom and certain other countries in Europe. There was no evidence to suggest the disease existed elsewhere in the world. Designating regions as affected could be done quickly by interim rule as cases were detected. Evaluation of countries for lower risk status (*e.g.*, minimal risk or unaffected), usually involves a risk analysis as well as a rulemaking. The BSE approach (*i.e.*, designation as affected) is consistent with our approach to other diseases, such as African horsesickness, which has never been shown to exist in countries other than in Africa and some countries on the Arabian Peninsula. Also, in contrast to infectious diseases that can be diagnosed relatively quickly, BSE has an extremely long incubation period. Therefore, our regulations for BSE are designed to protect against the introduction of BSE from regions where BSE exists or that present an undue risk of introducing BSE.

An alternative approach to assigning status to a region is to follow a commodity-based approach in which mitigations are defined that are appropriate to the commodity (and the region, if relevant). Existing examples of this include the regulations in § 94.18(b) that allow for the importation of gelatin and milk under certain conditions from any region listed in § 94.18(a). Similarly, this rule will allow the importation of whole cuts of boneless beef from Japan, under the conditions contained in this rule, while continuing to protect against the introduction of BSE into the United States.

The import request submitted to APHIS by the Government of Japan lent itself to a commodity-based approach because it was limited in scope to boneless beef from Japanese cattle. Because Japan was not requesting the importation of live animals, we only considered the risk associated with the importation of that commodity, rather than the risk associated with the importation of live animals and other commodities from Japan. Because whole cuts of boneless beef present a low risk of BSE, we determined that it was not necessary to evaluate the country in light of the minimal-risk region criteria.

OIE Recommendations on BSE

Issue: Several commenters expressed concern that the proposed conditions for whole cuts of boneless beef from Japan are less restrictive than the recommended export conditions contained in Article 2.3.13.1 of the OIE's 2005 Terrestrial Animal Health Code for deboned skeletal muscle meat from anywhere. These commenters pointed out that the proposal did not require that the beef be derived from cattle that are less than 30 months of age and that the cattle be subject to ante- and post-mortem inspections and were not suspect or confirmed BSE cases. The commenters stated that these conditions are contained in the OIE recommendations for the export of deboned skeletal muscle meat from any region. One commenter requested that these additional restrictions be added to the rule. Finally, one commenter also noted that the proposed rule would allow for the importation of boneless beef from cattle over 30 months of age,

which is not allowed from minimal-risk regions.

Response: We appreciate the commenter's question regarding consistency with the current OIE recommendations on BSE. As discussed in the proposed rule and the risk analysis, the conditions for the importation of whole cuts of boneless beef from Japan are consistent with the recommendations for the export of meat and meat products from controlled-risk regions, which are contained in Article 2.3.13.10 of the OIE's 2005 Terrestrial Animal Health Code, not those recommendations for the export of deboned beef from any region. Unlike the OIE recommendations for the free trade of deboned beef from any region, the OIE recommendations for commodities exported from controlled-risk regions do not contain a 30-month-age restriction.

The OIE recommendations, as noted by the commenter, include conditions that the commodity be derived from cattle that were subject to ante- and post-mortem inspections and were not suspect or confirmed BSE cases. These requirements are consistent with FSIS requirements under the Federal Meat Inspection Act (FMIA). In 9 CFR parts 309 and 310, for example, FSIS requires that all livestock offered for slaughter must receive (and pass) ante- and post-mortem inspections. As part of FSIS' equivalence determination process, countries that export commodities to the United States must have meat inspection systems that provide the same level of protection as that provided by systems in the United States. Because the OIE recommendations noted by the commenter are already established requirements under FSIS' regulations, and are, moreover, requirements that pertain to all livestock regardless of the BSE risk status of a region, it was not necessary to include those same requirements in our regulations.

Issue: One commenter asked for clarification on how APHIS determined that Japan could be considered as having controlled-risk status under the OIE guidelines.

Response: APHIS personnel requested written documentation on the BSE status of and conditions in Japan and conducted a site visit to verify the information and gather additional data. We then evaluated the country-specific information in the context of the OIE recommendations on BSE and found that the BSE conditions in Japan are consistent with those conditions for a controlled-risk region contained in Article 2.3.13.4 of the 2005 Terrestrial Animal Health Code. For example, Japanese authorities had conducted an appropriate risk assessment to identify the historical and existing BSE risk factors; the country's surveillance program was consistent with Type A surveillance as defined by OIE in Appendix 3.8.4 of the Code; and the BSE conditions for controlled-risk regions relative to BSE cases, a feed ban, importation of meat-and-bone meal or greaves, epidemiological tracing, and disposition of affected and contact animals were met.

It is important to note that, while we considered the OIE recommendations on BSE in the development of the risk analysis, we based our mitigation measures on a careful analysis of the risk posed by the importation of whole cuts of boneless beef from Japan. BSE infectivity has never been demonstrated in the muscle tissue of cattle infected with BSE at any stage of the disease. Therefore, the most significant risk management strategy for ensuring the safety of whole cuts of boneless beef is the prevention of cross-contamination of the beef with SRMs during stunning and slaughter of the animal. Mitigation measures that prevent contamination of such beef involve procedures for the removal of SRMs and carcass splitting and prohibitions on air-injection stunning and pithing. This rule requires such mitigation measures.

Age Restriction

Issue: One commenter expressed concern that the proposal did not contain an age limitation on whole cuts of boneless beef from Japan and stated that there should be such a restriction, especially since Japan's control measures for BSE have not been in place for a long period of time. Other commenters stated that the lack of a 30-month age restriction on cattle from which the beef is derived for export from Japan is inconsistent with APHIS' rulemakings, specifically, the age restriction for cattle and cattle products contained in the minimal-risk rule. Some of these commenters stated that APHIS provided no justification for allowing imports of beef from animals over 30 months of age from Japan or any other country where BSE is known to exist.

Response: Prior to developing the proposed rule for this action, we analyzed the likelihood that boneless beef imported from Japan would: (1) Contain infectious levels of the BSE agent; and (2) present a risk of exposing U.S. consumers or cattle to BSE, if the imported beef was contaminated with BSE. Based on the potential pathways, APHIS then determined what mitigation measures should be imposed to address the risks associated with whole cuts of boneless beef from Japan. We did not attempt to classify Japan as a minimal-risk region, nor did we include live animals or other meat and meat products. Rather, we limited our analysis to the BSE risk associated with whole cuts of boneless beef. Scientific data show that BSE infectivity in the muscle tissue of cattle examined in either the mouse bioassay or the cattle assays have not been demonstrated to date, regardless of the age of the animal. For these reasons, we consider whole cuts of boneless beef to be inherently low-risk for BSE and determined that it can be safely traded provided that measures are taken to prevent cross-contamination during processing. Such measures are contained in this rule and an age restriction is not necessary.

County of Origin Labeling

Issue: A number of commenters recommended that country of origin labeling be required in the United States so that beef imported from Japan would be so labeled. Some commenters suggested APHIS postpone implementation of this rule until such labeling is in place in this country. Several commenters raised concerns about how the United States would be able to verify the requirement that the beef be derived from cattle born, raised, and slaughtered in Japan without a country of origin labeling requirement. Finally, one commenter expressed concern that, because the proposal did not contain a country-of-origin requirement, any stigma associated with imported Japanese beef would be transferred to the entire U.S. beef supply if the BSE or vCJD incidence in Japan increases.

Response: Under the Farm 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).[12] 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 identified criteria that these commodities must meet to be considered of U.S. origin. In November

[12] AMS USDA; Country of Origin Labeling—Current Status of Country of Origin Labeling. Available at *http://www.ams.usda.gov/cool/status.htm.*

2005, President Bush signed Public Law 109–197, which includes a provision to extend a previous delay of implementation of mandatory COOL for all covered commodities except wild and farm-raised fish and shellfish until September 2008. The COOL program, when implemented, will address the labeling concerns raised by commenters with regard to APHIS' proposed rule. APHIS does not consider it necessary to delay implementation of this rule until those labeling provisions are implemented. In its October 30, 2004, proposal, AMS noted, in discussing Section 10816 of Public Law 107–171 (7 U.S.C. 1638–1638d) regarding COOL that the ''intent of the law is to provide consumers with additional information on which to base their purchasing decisions. It is not a food safety or animal health measure. COOL is a retail labeling program and as such does not address food safety or animal health concerns.''

With respect to the concern expressed about verifying that the beef is derived from cattle born, raised, and slaughtered in Japan, this rule will require that an authorized veterinary official of the Government of Japan certify on an original certificate that the conditions contained in this rule have been met.

BSE Testing

Issue: One commenter requested that, before proceeding with this rule, APHIS explain why the rule does not require BSE testing of cattle slaughtered in Japan in the rule. This commenter stated that the use of rapid tests could assist in eliminating from the food chain clinically healthy cattle with PrP^{sc} (abnormal prion protein) in the central nervous system. The commenter stated that such a mandatory testing requirement must be included in any rule to resume imports from BSE-affected countries or else the United States would have no means of ensuring the continuation of current mitigation measures currently practiced in countries like Japan.

Response: We understand the interest expressed by some commenters in testing certain cattle for slaughter. However, no live animal tests exist for BSE and the currently available postmortem tests, although useful for disease surveillance (i.e., in determining the rate of disease in the cattle population), are not appropriate as food safety indicators. Studies have demonstrated that 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. Research also indicates that the incubation period for this disease—the time between initial infection and the manifestation of clinical signs—is generally very long, on the average of about 5 years. Accordingly, we know there is a long period during which, using the current methodology, testing an infected animal that has not demonstrated clinical signs of the disease or is not at the end of the incubation period would, incorrectly, produce negative results. If, however, the infected animal is already exhibiting some type of clinical signs that could be consistent with BSE, then the test is not likely to produce false negative results.

BSE infectivity has never been demonstrated in the muscle tissue of cattle experimentally or naturally infected with BSE at any stage of the disease. Therefore, if BSE is present in a country's cattle population, the most significant risk mitigation measure for ensuring the safety of whole cuts of boneless beef is the prevention of cross-contamination of the beef with SRMs during stunning and slaughter of the animal. This rule includes such risk mitigation measures. For example, this rule requires the removal of SRMs and prohibits the use of air-injection stunning devices and pithing processes on cattle from which the beef is derived.

For these reasons, we do not consider the testing of bovines at slaughter to be scientifically justified or meaningful in the context of either human or animal health. Making this a criterion for the importation of beef from Japan would not contribute to human or animal health protection. A statistically and epidemiologically valid surveillance plan is crucial to monitoring the success of risk mitigation measures, such as a feed ban, but surveillance is not a mitigation measure.

Miscellaneous Comments

Harmonized Two-Way Trade

Issue: Many commenters requested that APHIS not finalize the proposed rule until two-way, harmonized trade can be resumed between the United States and Japan. These commenters expressed concern that Japan has not provided adequate assurances that U.S. producers will be allowed to export beef to Japan. Further, several of these commenters were concerned that U.S. producers would be subject to more stringent export conditions than those faced by exporters of boneless beef from Japan. For example, some commenters expressed concern that U.S. producers will only be allowed to export beef to Japan if the beef is derived from cattle less than 20 months of age. No such age restriction was contained in the proposed rule regarding the importation of boneless beef from Japan. These commenters stated that the export conditions for beef between the two nations should be the same.

In addition, one commenter noted that the proposed rule did not address potential impacts the rule could have on the United States' ability to restore the export markets that remain closed to the U.S. cattle and beef industries. This commenter asked if APHIS has consulted with South Korea and other importing nations that continue to ban U.S. beef and cattle to determine whether the rule would enhance or impede the reopening of these markets. This commenter expressed concern that the rule would be viewed by other nations as exposing the United States to an unacceptable risk. This commenter requested that APHIS provide the public with a list of nations that currently allow the importation of Japanese beef and stated that APHIS should not proceed with the rule until and unless a firm commitment is obtained from all countries that formerly accepted U.S. beef exports that they will-in a timely fashion-reopen their borders to U.S. beef, even if the U.S. resumes imports of Japanese beef.

Response: APHIS does not have authority to restrict trade based on its potential market access effects. Under its statutory authority, APHIS may prohibit or restrict the importation or entry of any animal or article when the agency determines it is necessary to prevent the introduction or dissemination of a pest or disease of livestock. However, APHIS is actively negotiating with trading partners to reestablish our export markets.

Trade With Other BSE-Affected Regions

Issue: One commenter suggested that APHIS make explicit in its final rule that, based on the logic and reference to the new OIE guidelines in the proposal, the United States is now ready to accept safe products from countries that have experienced BSE but have stringent risk mitigation measures in place, following separate risk analyses to be carried out by APHIS. This commenter stated that it expects APHIS is now prepared to use the same approach when evaluating a specific request to authorize the import of whole cuts of boneless beef from the European Union, in particular. In contrast, another commenter expressed concern that the rule would establish a precedent for allowing the importation of commodities from other BSE-affected regions that pose a greater risk of introducing BSE into the United States than does boneless beef from Japan.

Response: As mentioned above, under its statutory authority, APHIS may

prohibit or restrict the importation or entry of any animal or article when the agency determines it is necessary to prevent the introduction or dissemination of a pest or disease of livestock. When we receive a request from a country to allow the importation of commodities, we carefully and thoroughly consider the risk associated with the commodity and the country. In addition, APHIS is currently considering developing a comprehensive set of regulations consistent with the OIE recommendations on BSE.

Importation of Commodities From Minimal-Risk Regions and/or Canada

Issue: One commenter stated that the risk analysis and the OIE guidelines used in support of the proposed rule would also allow the importation of cattle over 30 months of age and beef from those cattle from any minimal-risk region. This commenter stated that, as a result, there is no justified reason to allow the importation of beef from Japan to enter the United States and not provide the same treatment for Canadian cattle and beef. The commenter stated that Canada and other minimal-risk regions should be afforded treatment consistent with Japan and that Canadian cattle over 30 months of age and beef derived from those cattle should be allowed to be imported by APHIS.

Response: APHIS recognizes that the OIE guidelines address the importation of live cattle over 30 months of age and beef from such cattle from regions of different status. However, the scope of this rulemaking is limited to whole cuts of boneless beef derived from cattle born, raised, and slaughtered in Japan. Therefore, the issue of imports of live cattle over 30 months of age and beef from those cattle from minimal-risk regions, including Canada, falls outside the scope of this rulemaking. Nevertheless, as noted in the minimal-risk region rule, APHIS is committed to dealing with the issue of imports of live bovines 30 months of age and over from Canada in further rulemaking.

Issue: One commenter stated that the BSE minimal-risk regions rule should be withdrawn, and that the U.S. geographical BSE risk assessment (GBR) should immediately be raised to BSE GBR IV. This commenter further requested that the United States adhere to the BSE GBR and that USDA work to enhance those assessments to include all animal TSEs.

Response: Consideration of changes to the minimal-risk rule are outside the scope of this rulemaking. The BSE GBRs are conducted by the European Commission. These assessments were initially begun in the late 1990's, under the auspices of the European Commission's Scientific Steering Committee (SSC). Since the functions of the former SSC have now been taken up by the European Food Safety Authority (EFSA), the GBR assessments are done under the EFSA. This assessment process is not a process supervised by the USDA or APHIS, and we cannot change any assessments previously done by the European Commission. It is not clear what the commenter means by requesting that the United States adhere to the BSE GBRs, as these are documents created internally by the European Union for its purposes. APHIS conducts its own risk assessments as necessary for specific rulemaking efforts, incorporating all available information. Such information may refer to an assessment conducted by the country requesting a regulatory change, but it generally would not depend on third party assessments.

The United States considers all animal TSEs in developing regulations related to BSE. However, it should be noted that the various animal TSEs are generally caused by different agents (i.e., scrapie in sheep is different from chronic wasting disease (CWD) in cervids, which is different from BSE in cattle) with different routes of transmission and unique characteristics. Sometimes these processes may be similar, but one cannot automatically assume, for example, that if a country has identified scrapie in sheep that they are therefore at significant risk for other animal TSEs such as CWD or BSE.

CJD and Domestic Compliance With FSIS' BSE-Related Regulations

Issue: One commenter noted that the number of probable and confirmed cases of vCJD cited in the proposed rule was greater than the number of cases cited in the minimal-risk regions final rule and raised questions regarding the significance of this increase in cases over a several month period. This commenter requested that APHIS provide a comparison between the number of deaths attributable to the consumption of beef contaminated with BSE and the number of deaths attributable to the consumption of beef contaminated with other food-borne contaminates such as *Escherichia coli* (*E. coli*) in order to place this increase in vCJD cases in context for the beef and cattle industries.

Response: To date, there have been a total of approximately 170 cases of vCJD reported worldwide since 1996. Most of these cases have been in the United Kingdom. In the United Kingdom, it is estimated that the incidence of deaths from vCJD reached a peak in mid-2000, with 28 deaths that year. For comparison, the Centers for Disease Control (CDC) estimates that foodborne diseases cause approximately 76 million illnesses, 350,000 hospitalizations, and 5,000 deaths in the United States alone each year. Of these, known pathogens account for an estimated 14 million illnesses, 60,000 hospitalizations, and 1,800 deaths annually. These estimates are not attributed to specific food products implicated in each outbreak, but rather to the specific pathogens. The variation in number of reported vCJD cases cited in our minimal-risk regions final rule and the proposed rule for this rulemaking and noted by the commenter is attributable to an update in figures obtained by APHIS and not a spike in the number of vCJD cases reported worldwide.

Issue: Two commenters raised questions regarding the origin of CJD in humans. One commenter noted that there are different strains of TSEs being discovered in ruminants, and that new atypical strains of TSE in cattle look similar to sporadic CJD in humans. Another commenter asked if APHIS has considered whether sporadic CJD in humans might be caused by atypical cases of TSEs that have been found in animals. This commenter further questioned whether blood and other tissues may carry BSE infectivity in cattle infected with atypical strains of the BSE agent or other TSE agents.

Response: Sporadic CJD is the most common form of CJD. It has been found in every country in the world where it has been looked for including countries that are generally considered by the international scientific community to be free of BSE and other TSEs (for example, Australia and New Zealand). In general, it affects about one person per million. No association between sporadic CJD and consumption of animal products in general and/or infected or contaminated bovine products has ever been documented. It is currently believed that sporadic CJD arises through the spontaneous conversion of PrP^{C} (normal cellular prion protein) to PrP^{SC} in an individual.[13] In contrast, atypical cases of BSE in cattle are rare and have been reported in only few countries that experience BSE, such as Italy, Belgium, Japan, and France. It has been speculated that the spontaneous or sporadic form of BSE could exist in cattle, as well as humans.[14]

[13] Stahl, N. and Prusiner, S.B.; (1991) FASEB–J. 5: 2799–807.

[14] Biacabe; 2004 EMBO reports, Vol. 5, No. 1.

APHIS agrees with the commenter that reports indicate that some of the atypical BSE cases, in particular the bovine amyloidotic spongiform encephalopathy (BASE), and sporadic CJD have similar PrP^{SC} patterns. APHIS evaluated the findings in the context of risk of exposure to cattle and humans. Currently, the relevance of the atypical cases is unknown, but at this time there is no indication that any control measures—such as feed bans or SRM requirements—should be modified based on these cases. Additionally, although atypical cases of BSE and sporadic CJD share similarities at this point, there is no evidence that they are linked.

Issue: One commenter expressed concern over the number of citations issued for various SRM violations during the June 2004 enhanced BSE surveillance program in the United States. This commenter questioned whether these incidents of noncompliance may have led to infective materials entering the human or animal food chains. This commenter cited the case of BSE detected in a 12-year-old cow in Texas as evidence that infective materials may have entered the food chain. The commenter suggested that noncompliance reports should be made more easily available to the public in the future.

Response: FSIS inspectors are responsible for verifying the effectiveness of an establishment's procedures. If FSIS personnel determine that an establishment's procedures are ineffective in preventing cross-contamination, the inspectors will take appropriate action. We note that none of the meat from the 12-year-old BSE-infected cow in Texas mentioned by the commenter entered the human food or animal feed chains.

Issue: One commenter stated that the domestic BSE mitigation measures, including the U.S. ruminant feed ban, border controls, and BSE surveillance program, must be strengthened in order to protect public health. The commenter further requested that USDA's Office of the Inspector General (OIG) hold an inquiry into the effectiveness of the BSE surveillance program.

Response: APHIS considers the measures in place to be adequate and based on the best available science. First, available evidence suggests that the feed ban which FDA implements is a critical safeguard against the spread of BSE in the United States. FDA has recently issued a proposed rule to further strengthen the feed ban (70 FR 58570–58601, October 6, 2005). Domestic BSE mitigation measures for border controls are based on risk analyses conducted using the best scientific information available. These are made available for public comment in association with regulations implementing these controls. The BSE surveillance program in the United States was developed by technical experts to help determine whether BSE is present in the U.S. cattle population, and if so, to help estimate at what level. The USDA's OIG is conducting an ongoing audit of the BSE surveillance program.

Other Comments

Issue: One commenter stated that there was no background or supporting information provided along with the proposed rule.

Response: The background information in support of the proposal was provided in our risk analysis and other supporting analyses that were made available to the public concurrent with the proposal. These documents remain available at *http://www.regulations.gov.*

Issue: Several commenters raised issues that fall outside the scope of this rulemaking, including the impact of eating meat on the health of American consumers, the relative quality of beef produced in Japan and the United States, and the necessity and market effects of importing beef from Japan when the United States produces beef domestically.

Response: APHIS does not have authority to restrict trade based on these considerations. Under its statutory authority, APHIS may prohibit or restrict the importation or entry of any animal or article when the Secretary determines it is necessary to prevent the introduction or dissemination of a pest or disease of livestock. While the United States does not have direct control over the quality of products produced in other countries, FSIS requires that the food it regulates be produced under conditions that will provide at least an equivalent level of safety as that produced in the United States. Therefore, we are not making any changes to the rule based on this comment.

Issue: One commenter stated that it would be helpful if the OIE or USDA would define ''controlled BSE-risk country'' and ''effectively enforced ban.''

Response: Article 2.3.13.4 of the OIE's 2005 Terrestrial Animal Health Code lists recommended conditions that a country, zone, or compartment should meet to be considered as controlled BSE risk. These conditions include a consideration of whether a country has identified indigenous cases of BSE and what risk mitigation measures have been imposed. Neither USDA nor the OIE have strictly defined an ''effectively enforced ban.'' The OIE has indicated that it may consider developing such a definition, but this process may take some time. USDA considers effective enforcement of the feed ban as an important measure to control BSE in a specific region. In previous rulemaking, we noted that determining whether a feed ban had been effectively enforced involved a review by APHIS of a number of interrelated factors, including: The existence of a program to gather compliance information and statistics; whether appropriate regulations are in place in the region; the adequacy of enforcement activities (*e.g.*, whether sufficient resources and commitment are dedicated to enforcing compliance); a high level of facility inspections and compliance; accountability of both inspectors and inspected facilities; and adequate recordkeeping.

Therefore, for the reasons given in the proposed rule and in this document, we are adopting the proposed rule as a final rule, without change.

Effective Date

This is a substantive rule that relieves restrictions and, pursuant to the provisions of 5 U.S.C. 553, may be made effective less than 30 days after publication in the **Federal Register**. The Administrator of the Animal and Plant Health Inspection Service has determined that immediate implementation of this rule is warranted to relieve certain restrictions on the importation of whole cuts of boneless beef from Japan that are no longer necessary.

Executive Order 12866 and Regulatory Flexibility Act

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

Under the Animal Health Protection Act of 2002 (7 U.S.C. 8301 *et seq.*), the Secretary of Agriculture is authorized to promulgate regulations that are necessary to prevent the introduction or dissemination of any pest or disease of livestock into the United States.

This final rule will amend the regulations governing the importation of meat and other edible animal products by allowing, under certain conditions, the importation of whole cuts of boneless beef derived from cattle born, raised, and slaughtered in Japan. This action is taken in response to a request

from the Government of Japan and after conducting an analysis of the risk that indicates that such beef can be imported from Japan under the conditions described in this final rule. These conditions will continue to protect against the introduction of BSE into the United States.

In accordance with 5 U.S.C. 604, we have performed a final regulatory flexibility analysis, which is summarized below, regarding the impact of this rule on small entities.[15] This analysis also serves as our cost-benefit analysis under Executive Order 12866.

We expect that this rule will have little or no economic impact on the majority of consumers and beef producers in the United States because the volume of beef imported from Japan is likely to be small and have only a minor impact on the overall domestic beef market.

In 2001, APHIS placed a ban on the importation of ruminants and most ruminant products from Japan following the confirmation of one case of BSE in a native-born animal in that country. Prior to that ban, U.S. imports of boneless beef from Japan were negligible when compared to total imports of that commodity. Over a 4-year period, 1997–2000, for example, the volume of U.S. imports of boneless beef from Japan—reported to be entirely fresh/chilled, as opposed to frozen—averaged a little less than 9 metric tons per year. This amount was less than 0.005 percent of average annual U.S. imports of fresh/chilled boneless beef worldwide for the same period (202,540 metric tons).[16] The average annual value of U.S. imports of boneless beef from Japan over this 4-year period was $808,000, less than 0.2 percent of the 4-year average annual value of U.S. imports of fresh/chilled boneless beef from all regions ($600 million). Including frozen boneless beef in the comparison over the same 4-year period diminishes Japan's annual average percentage share all the more, to about 0.001 percent of the quantity and about 0.05 percent of the value of all U.S. boneless beef imports. This impact would be further reduced if Japan's share of the U.S. total beef supply (domestic production plus imports minus exports, disregarding carryover stocks) were considered.

Based on the unit price of beef imported into the United States from Japan prior to the 2001 ban on the importation of ruminants and most ruminant products from Japan, it is assumed that all of the boneless beef imported from Japan prior to the ban was Wagyu beef. (The term ''Wagyu,'' which literally translates to Japanese cattle, refers to purebred Japanese Black or Japanese Brown breeds of cattle. Wagyu beef is a high-priced specialty meat widely acclaimed for its flavor and tenderness. ''Kobe beef'' refers to Wagyu beef that is produced in the Kobe area of Japan.) Japan also produces Holstein breed dairy cattle, but it is unlikely that Japan would try to compete in the U.S. import market for lower-grade beef from culled dairy cattle. Accordingly, we expect only Wagyu beef to be imported under the final rule.

We expect that Japan will continue to be a minor supplier of beef to the United States after this final rule becomes effective. We estimate that the volume of imports is likely to range between about 8 metric tons and 15 metric tons per year, a quantity aligned with import levels in the years immediately prior to the ban. There are three reasons for the small import volume. First, the demand for Japanese Wagyu beef in the United States will likely be small, because the beef is expensive. In October 2004, for example, the average actual selling price of Wagyu sirloin in Japanese supermarkets was just under $50 per pound.[17] The price of Japanese Wagyu beef would be higher in the United States because of transportation and other costs associated with the importation of the beef from Japan.

Second, Japanese agricultural officials have indicated to APHIS staff that they expect the volume of Wagyu exports to the United States to be approximately 10 metric tons per year. This quantity aligns with historic import levels, as described above, and would be well below the annual tariff rate quota for Japan of 200 metric tons.[18] Over the 10-year period from 1991 to 2000, U.S. imports of boneless beef—both fresh/chilled and frozen—from Japan never exceeded 27.0 metric tons in any one year.

Finally, Japan's boneless beef exports to countries other than the United States have also been minor. Over the 4-year period 1997–2000, Japan's exports of boneless beef to the world—both fresh/chilled and frozen—averaged only 81 metric tons per year, and the largest export volume in any one of those years was 95 metric tons (in 1999). For fresh/chilled boneless beef alone, the 4-year annual average was 37 metric tons, with no one year exceeding 47 metric tons.[19]

Because we expect that Japan will export only Wagyu beef under this final rule, this action has the potential to affect farmers and ranchers in the United States who raise Wagyu and Wagyu hybrid cattle for the high-end domestic beef market. However, the impact, if any, on these so-called ''Kobe-style'' beef producers is unclear, without an approximation of the quantity of Kobe-style beef sold in the United States and information on the extent to which the two products would directly compete. The number of these producers is unknown, but it is believed to be very small.

Cost-Benefit Analysis

Given the high price and small quantity of Wagyu beef expected to be imported, this final rule is likely to have little impact for most U.S. consumers. A relatively small segment of beef consumers will benefit because they would be allowed, once again, to buy this product in the United States. Importers, brokers and others in the United States who will participate in the importation of Wagyu beef from Japan also stand to benefit, due to the increased business activity.

U.S. beef producers, in general, will not be affected by this final rule; demand is expected to remain low reflecting pre-ban consumption patterns, with a minor impact on less expensive domestically produced beef. Any producer impact of the rule will likely fall upon producers of Kobe-style beef, and then only to the extent that the commodities will be competing for the same niche market.

In general, trade of a commodity increases social welfare. To the extent that consumer choice is broadened and the increased supply of the imported commodity leads to a price decline, gains in consumer surplus will outweigh losses in domestic producer surplus.[20] Although the rule's impact on

[15] A copy of the full economic analysis is available for review on the Regulations.gov Web site. Go to *http://www.regulations.gov,* click on the ''Advanced Search'' tab and select ''Docket Search.'' In the Docket ID field, enter APHIS–2005–0073 then click on ''Submit.'' The economic analysis will appear near the end of the resulting list of documents.

[16] Trade statistics, unless otherwise indicated, are taken from the World Trade Atlas or the Global Trade Atlas (Global Trade Information Services), which report data from the Department of Commerce, U.S. Bureau of the Census. The Harmonized Tariff Schedule (HTS) 6-digit code for fresh/chilled boneless beef cuts is 020130; the HTS code for frozen boneless beef is 020230.

[17] Source: ''Monthly Statistics,'' January 2005, Agricultural & Livestock Industries Corporation. The selling price was calculated using an exchange rate of 105 yen per U.S. dollar, and it is the price for Wagyu sirloin from all regions in Japan, including Kobe.

[18] Harmonized Tariff Schedule of the United States (2005), Chapter 2, Meat and Edible Meat Offal.

[19] Foreign Agricultural Service, USDA.

[20] Consumer surplus is the difference between the amount a consumer is willing to pay for a good and

Continued

the relatively small number of U.S. producers of Kobe-style beef is uncertain, it is expected to provide benefits to consumers (domestic importers, wholesalers, retailers, as well as final consumers) that will exceed any potential losses to domestic producers. The net welfare effect for the United States of reestablished Wagyu beef imports from Japan will be positive.

Effects on Small Entities

We do not expect that this final rule will have significant economic impact on a substantial number of small entities. As discussed above, this rule has the potential to primarily affect farmers and ranchers in the United States who produce Kobe-style beef. The number of these producers is unknown, but it is believed to be very small. The American Wagyu Association, a Wagyu breeder group, lists approximately 75 members in the United States.[21]

The size distribution of Kobe-style beef producers in the United States is also unknown, but it is reasonable to assume that most are small, under the U.S. Small Business Administration's (SBA) standards. This assumption is based on composite data for all beef producers in the United States. In 2002, there were 664,431 U.S. farms in North American Industry Classification System (NAICS) 112111, a classification comprised of establishments primarily engaged in raising cattle. Of the 664,431 farms, 659,009 (or 99 percent) had annual receipts that year of less than $500,000.[22] The SBA's small entity threshold for farms in NAICS 112111 is annual receipts of $750,000.

Executive Order 12988

This final rule has been reviewed under Executive Order 12988, Civil Justice Reform. This rule: (1) Preempts all 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.

National Environmental Policy Act

An environmental assessment and finding of no significant impact have been prepared for this final rule. The environmental assessment provides a basis for the conclusion that the importation of whole cuts of boneless beef from Japan under the conditions specified in this rule will not have a significant impact on the quality of the human environment. Based on the finding of no significant impact, the Administrator of the Animal and Plant Health Inspection Service has determined that an environmental impact statement need not be prepared.

The environmental assessment and finding of no significant impact were 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 1b), and (4) APHIS' NEPA Implementing Procedures (7 CFR part 372).

The environmental assessment and finding of no significant impact may be viewed on the Internet at *http://www.regulations.gov*. Go to *http://www.regulations.gov*, click on the ''Advanced Search'' tab and select ''Docket Search.'' In the Docket ID field, enter APHIS–2005–0073 then click on ''Submit.'' The environmental assessment and finding of no significant impact will appear near the end of the resulting list of documents. Copies of the environmental assessment and finding of no significant impact are also available for public inspection at USDA, room 1141, South Building, 14th Street and Independence Avenue SW., Washington, DC, between 8 a.m. and 4:30 p.m., Monday through Friday, except holidays. Persons wishing to inspect copies are requested to call ahead on (202) 690–2817 to facilitate entry into the reading room. In addition, copies may be obtained by writing to the individual listed under **FOR FURTHER INFORMATION CONTACT**.

Paperwork Reduction Act

This final rule contains no new information collection or recordkeeping requirements under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

List of Subjects in 9 CFR Part 94

Animal diseases, Imports, Livestock, Meat and meat products, Milk, Poultry and poultry products, Reporting and recordkeeping requirements.

■ Accordingly, we are amending 9 CFR part 94 as follows:

PART 94—RINDERPEST, FOOT-AND-MOUTH DISEASE, FOWL PEST (FOWL PLAGUE), EXOTIC NEWCASTLE DISEASE, AFRICAN SWINE FEVER, CLASSICAL SWINE FEVER, AND BOVINE SPONGIFORM ENCEPHALOPATHY: PROHIBITED AND RESTRICTED IMPORTATIONS

■ 1. The authority citation for part 94 continues to read as follows:

Authority: 7 U.S.C. 450, 7701–7772, 7781–7786, and 8301–8317; 21 U.S.C. 136 and 136a; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.4.

■ 2. In § 94.18, paragraph (b) is revised to read as follows:

§ 94.18 Restrictions on importation of meat and edible products from ruminants due to bovine spongiform encephalopathy.

* * * * *

(b) Except as provided in paragraph (d) of this section or in §§ 94.19 or 94.27, the importation of meat, meat products, and edible products other than meat (except for gelatin as provided in paragraph (c) of this section, milk, and milk products) from ruminants that have been in any of the regions listed in paragraph (a) of this section is prohibited.

* * * * *

■ 3. A new § 94.27 is added to read as follows:

§ 94.27 Importation of whole cuts of boneless beef from Japan.

Notwithstanding any other provisions of this part, whole cuts of boneless beef derived from cattle that were born, raised, and slaughtered in Japan may be imported into the United States under the following conditions:

(a) The beef is prepared in an establishment that is eligible to have its products imported into the United States under the Federal Meat Inspection Act (21 U.S.C. 601 *et seq.*) and the regulations in 9 CFR 327.2 and the beef meets all other applicable requirements of the Federal Meat Inspection Act and regulations thereunder (9 CFR chapter III), including the requirements for removal of SRMs and the prohibition on the use of air-injection stunning devices prior to slaughter on cattle from which the beef is derived.

(b) The beef is derived from cattle that were not subjected to a pithing process at slaughter.

(c) An authorized veterinary official of the Government of Japan certifies on an original certificate that the above conditions have been met.

---

the amount actually paid. Producer surplus is the amount a seller is paid for the good minus the seller's cost.

[21] Source: American Wagyu Association Web site.

[22] 2002 Census of Agriculture, National Agricultural Statistics Service.

Done in Washington, DC, this 12th day of December 2005.

Charles D. Lambert,

Acting Under Secretary for Marketing and Regulatory Programs.

[FR Doc. 05–24057 Filed 12–12–05; 11:30 am]

BILLING CODE 3410–34–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2005–23252; Directorate Identifier 2004–NM–146–AD; Amendment 39–14414; AD 2005–25–21]

RIN 2120–AA64

Airworthiness Directives; Airbus Model A330–243, –341, –342, and –343 Airplanes Equipped with Rolls-Royce RB211 TRENT 700 Engines

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Final rule; request for comments.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for certain Airbus Model A330–243, –341, –342, and –343 airplanes equipped with Rolls-Royce RB211 TRENT 700 engines. This AD requires modifying the cowl assemblies of the left- and right-hand thrust reversers. This AD results from a review of certification tests of the thrust reverser, which revealed that certain structural components within the C-duct need strengthening to meet high fatigue loads and maintain structural integrity. We are issuing this AD to prevent fatigue cracking of the hinges integrated into the 12 o'clock beam of the thrust reversers, which could result in separation of a thrust reverser from the airplane, and consequent reduced controllability of the airplane.

DATES: This AD becomes effective December 29, 2005.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in the AD as of December 29, 2005.

We must receive comments on this AD by February 13, 2006.

ADDRESSES: Use one of the following addresses to submit comments on this AD.

- DOT Docket Web site: Go to *http://dms.dot.gov* and follow the instructions for sending your comments electronically.
- Government-wide rulemaking Web site: Go to *http://www.regulations.gov* and follow the instructions for sending your comments electronically.
- Mail: Docket Management Facility; U.S. Department of Transportation, 400 Seventh Street, SW., Nassif Building, room PL–401, Washington, DC 20590.
- Fax: (202) 493–2251.
- Hand Delivery: Room PL–401 on the plaza level of the Nassif Building, 400 Seventh Street, SW., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Contact Airbus, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France, for the service information identified in this AD.

FOR FURTHER INFORMATION CONTACT: Tim Backman, Aerospace Engineer, International Branch, ANM–116, FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington 98055–4056; telephone (425) 227–2797; fax (425) 227–1149.

SUPPLEMENTARY INFORMATION:

Discussion

The Direction Générale de l'Aviation Civile (DGAC), which is the airworthiness authority for France, notified us that an unsafe condition may exist on certain Airbus Model A330–243, –341, –342, and –343 airplanes equipped with Rolls-Royce RB211 TRENT 700 engines. The DGAC advises that a review of certification tests of the thrust reverser revealed that certain structural components within the C-duct need strengthening to meet high fatigue loads and maintain structural integrity. Unexpected high loads were measured on the hinges integrated into the 12 o'clock beam of the thrust reverser; the 12 o'clock beam forms the upper edge of the C-duct of the thrust reverser on Rolls-Royce engines. This condition, if not corrected, could result in fatigue cracking of the hinges integrated into the 12 o'clock beam of the thrust reversers, separation of a thrust reverser from the airplane, and consequent reduced controllability of the airplane.

Relevant Service Information

Airbus has issued Service Bulletin A330–78–3010, Revision 03, dated April 28, 2004. The service bulletin describes procedures for modifying the cowl assemblies of the left- and right-hand thrust reversers. Accomplishing the actions specified in the service information is intended to adequately address the unsafe condition. The DGAC mandated the service information and issued French airworthiness directive F–2001–528 R2, dated June 23, 2004, to ensure the continued airworthiness of these airplanes in France.

The service bulletin refers to Rolls-Royce Service Bulletin RB.211–78–C899, Revision 3, dated May 7, 2004, as an additional source of service information for modifying the cowl assemblies of the left- and right-hand thrust reversers. The modification includes related investigative actions, and repair if necessary. The related investigative actions include certain inspections for discrepancies of the bores, bushings, plug holes, and cavity webs of the thrust reversers.

FAA's Determination and Requirements of This AD

These airplane models are manufactured in France and are type certificated for operation in the United States under the provisions of section 21.29 of the Federal Aviation Regulations (14 CFR 21.29) and the applicable bilateral airworthiness agreement. Pursuant to this bilateral airworthiness agreement, the DGAC has kept the FAA informed of the situation described above. We have examined the DGAC's findings, evaluated all pertinent information, and determined that we need to issue an AD for products of this type design that are certificated for operation in the United States.

Therefore, we are issuing this AD to prevent fatigue cracking of the hinges integrated into the 12 o'clock beam of the thrust reversers, which could result in separation of a thrust reverser from the airplane, and consequent reduced controllability of the airplane. This AD requires accomplishing the actions specified in the Airbus service information described previously except as discussed under ''Difference Among the AD, French Airworthiness Directive, and Airbus Service Information.''

Difference Among the AD, French Airworthiness Directive, and Airbus Service Information

The French airworthiness directive and the service information specify a modification that involves replacement of certain thrust reverser C-ducts with new ducts at or before specific total flight cycle thresholds. This AD requires you to replace the affected parts before the accumulation of those thresholds or within 6 months after the effective date of the AD, whichever is later. A table containing those flight cycle thresholds is specified in paragraph (f) of this AD. We have included a 6-month grace period to ensure that any airplane that is close to or has passed its applicable threshold (if imported and placed on the U.S. Register) is not grounded as of the effective date of the AD.