DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Parts 93, 94, 95, and 96

[Docket No. APHIS–2006–0041]

RIN 0579–AC01

Bovine Spongiform Encephalopathy; Minimal-Risk Regions; Importation of Live Bovines and Products Derived From Bovines

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: We are amending the regulations regarding the importation of animals and animal products to establish conditions for the importation of the following commodities from regions that present a minimal risk of introducing bovine spongiform encephalopathy into the United States: Live bovines for any use born on or after a date determined by the Animal and Plant Health Inspection Service to be the date of effective enforcement of a ruminant-to-ruminant feed ban in the region of export; blood and blood products derived from bovines; and casings and part of the small intestine derived from bovines. We are making these amendments after conducting a risk assessment and comprehensive evaluation of the issues and concluding that such bovines and bovine products can be safely imported under the conditions described in this rule. This document also removes the delay in applicability of certain provisions of a final rule published in January 2005.

DATES: *Effective Date:* November 19, 2007.

FOR FURTHER INFORMATION CONTACT: For information regarding ruminant products, contact Dr. Karen James-Preston, Director, Technical Trade Services, Animal Products, National Center for Import and Export, VS, APHIS, 4700 River Road Unit 38, Riverdale, MD 20737–1231; (301) 734–4356.

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SUPPLEMENTARY INFORMATION:

Purpose

This document makes final a proposed rule that the Animal and Plant Health Inspection Service (APHIS) of the U.S. Department of Agriculture (USDA or the Department) published in the **Federal Register** on January 9, 2007 (72 FR 1101–1129, Docket No. APHIS–2006–0041). Additionally, it removes the delay of applicability of certain provisions of a final rule APHIS published in January 2005. The removal of delay is discussed below under the heading ''Removal of Partial Delay of Applicability of Provisions of January 2005 Final Rule.''

In our January 2007 proposed rule, we proposed to amend the regulations in 9 CFR parts 93, 94, 95, and 96 to establish conditions for the importation of the following commodities from regions that present a minimal risk of introducing bovine spongiform encephalopathy (BSE) into the United States: Live bovines for any use born on or after a date determined by APHIS to be the date of effective enforcement of a ruminant-to-ruminant feed ban in the region of export; blood and blood products derived from bovines; and casings and part of the small intestine derived from bovines.

In this document, we respond to public comments received on the proposed rule and its underlying risk assessment and other supporting analyses. Additionally, we discuss below the history of APHIS rulemaking related to BSE minimal-risk regions.

Background

APHIS 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 BSE, a chronic degenerative disease affecting the central nervous system of cattle.

With some exceptions, APHIS' regulations prohibit or restrict the importation of live ruminants and certain ruminant products and byproducts from the following three categories of regions with regard to BSE: (1) Those regions in which BSE is known to exist (listed in § 94.18(a)(1) of the regulations); (2) those regions that present an undue risk of introducing BSE into the United States 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 (listed in § 94.18(a)(2) of the regulations); and (3) those regions that present a minimal risk of introducing BSE into the United States via live ruminants and ruminant products and byproducts (listed in § 94.18(a)(3) of the regulations).

Chronology of Federal Register Publications Regarding BSE Minimal-Risk Regions

We added the § 94.18(a)(3) category (BSE minimal-risk regions) to the regulations in a final rule published in the **Federal Register** on January 4, 2005 (70 FR 459–553, Docket No. 03–080–3). In the final rule, we specified which commodities may be imported from BSE minimal-risk regions and under what conditions, and recognized Canada as a BSE minimal-risk region. (At this time, Canada is the only recognized BSE minimal-risk region.)

The January 2005 final rule was based on a proposed rule we published in the **Federal Register** on November 4, 2003 (68 FR 62386–62405, Docket No. 03–080–1). On December 25, 2003, less than 2 weeks before the close of the comment period for our proposed rule, a case of BSE in a dairy cow of Canadian origin in Washington State was verified by an international reference laboratory.

In response to comments from the public requesting an extension of the comment period and in order to give the public an additional opportunity to comment on the proposed rule in light of this development, on March 8, 2004, we published a document in the **Federal Register** (69 FR 10633–10636, Docket No. 03–080–2) reopening the comment period.

On January 4, 2005, along with the final rule, we published in the **Federal Register** a notice (70 FR 554, Docket No. 03–080–4) announcing the availability of, and requesting comments on, a final environmental assessment (EA) regarding the potential impact on the quality of the human environment due to the importation of ruminants and ruminant products and byproducts from Canada under the conditions specified in the final rule. On January 21, 2005, we published in the **Federal Register** a notice (70 FR 3183–3184, Docket No. 03–080–5) announcing the availability of a corrected version of the EA for public review and comment. On April 8, 2005, we published in the **Federal Register** a finding (70 FR 18252–18262, Docket No. 03–080–7) that the provisions of the final rule would not

have a significant impact on the quality of the human environment.

On March 11, 2005, we published a document in the **Federal Register** that gave notice that the Secretary of Agriculture was delaying until further notice the implementation of certain provisions of the final rule with regard to certain commodities (70 FR 12112–12113, Docket No. 03–080–6).

On November 28, 2005, we published in the **Federal Register** an interim rule (70 FR 71213–71218, Docket No. 03–080–8) that amended certain provisions established by the January 2005 final rule. The interim rule broadened the list of who is authorized to break seals on conveyances and allows transloading under supervision of products transiting the United States.

On March 14, 2006, we published in the **Federal Register** a technical amendment (71 FR 12994–12998, Docket No. 03–080–9) that clarified our intent with regard to certain provisions in the January 2005 final rule and corrected several inconsistencies within the rule.

On August 9, 2006, we published in the **Federal Register** a proposed rule (71 FR 45439–45444, Docket No. APHIS–2006–0026) that proposed to amend the provisions established by the January 2005 final rule by removing several restrictions regarding the identification of animals and the processing of ruminant materials from BSE minimal-risk regions, and by relieving BSE-based restrictions on hide-derived gelatin from BSE minimal-risk regions. We solicited comments concerning our proposal for 60 days ending October 10, 2006. On November 9, 2006, we published a document in the **Federal Register** (71 FR 65758–65759, Docket No. APHIS–2006–0026) reopening and extended the comment period until November 24, 2006. We received a total of 10 comments by that date. We are considering the issues raised by the commenters and will address them in a separate rulemaking document.

Scope of the January 2005 Final Rule

The regulations established by the January 2005 final rule and subsequent amendments have allowed the importation from BSE minimal-risk regions of live bovines that are under 30 months of age when imported and when slaughtered and that have been subject to a ruminant feed ban equivalent to that in place in the United States.

We did not attempt, for that rulemaking, to assess the BSE risk associated with the importation of live bovines 30 months of age or older from a BSE minimal-risk region. Our March 8, 2004, document that reopened the comment period on the November 2003 proposed rule stated that APHIS was evaluating the appropriate approach with regard to the importation of live animals 30 months of age or older from BSE minimal-risk regions, and would address that issue in a supplemental rulemaking proposal in the **Federal Register**. The provisions in our January 9, 2007, proposed rule regarding live bovines were the result of that evaluation.

The regulations established by the January 2005 final rule also provided for the importation of the following commodities derived from bovines of any age: (1) Meat, meat food products, and meat byproducts; (2) whole or half carcasses; (3) offal; (4) tallow composed of less than 0.15 percent insoluble impurities that are not otherwise eligible for importation under § 95.4(a)(1)(i) of the regulations; and (5) gelatin derived from bones of bovines that is not otherwise eligible for importation under § 94.18(c) of the regulations.

The January 2005 final rule and subsequent amendments did not change the regulations concerning the importation of blood and blood products from regions listed in § 94.18(a); the requirements for the importation of blood and blood products from BSE minimal-risk regions remain the same as the requirements for importation of blood and blood products from other regions listed in § 94.18(a)—only serum and serum albumin have been eligible for importation. The January 2005 final rule also did not change the regulations concerning the importation of bovine casings (defined as intestines, stomachs, esophagi, and urinary bladders) from regions listed in § 94.18(a); the requirements for the importation of bovine casings from BSE minimal-risk regions remain the same as the requirements for importation of bovine casings from other regions listed in § 94.18(a)—only bovine stomachs are eligible for importation.

The January 2005 final rule and subsequent amendments allowed trade to resume in many, but not all, of the commodities that had been prohibited importation from Canada following detection of a BSE-infected cow in Canada in May 2003. Following our January 2005 final rule, we continued to consider the BSE risk associated with older bovines and other bovine products from BSE minimal-risk regions—and Canada in particular—including bovine blood and blood products, bovine small intestine other than the distal ileum, and bovine casings, and included provisions in our January 2007 proposed rule for the importation of those commodities.[1]

Peer Review of APHIS' Risk Assessment

As part of this rulemaking, APHIS conducted an assessment that evaluated the animal health risk to the United States of BSE—i.e., the likelihood of establishment and the potential impacts of cases that may occur even without establishment—as a result of importing the bovine commodities considered in this rule (APHIS 2006b). Our assessment concluded that, over the 20 years of the analysis, the BSE risk to the United States is negligible. We made the risk assessment available for public review and comment at the time the proposed rule was published.

In addition to making the risk assessment available for review and comment by the general public, we requested an external, formal, independent peer review of the assessment by recognized experts in the field, consistent with guidelines of the U.S. Office of Management and Budget (OMB 2004). The objective of the peer review was to determine whether the risk assessment was scientifically sound, transparent, and consistent with international standards (e.g., those by the OIE); the application of external assessments or models was appropriate; and the assumptions were justified, supported and reasonable. Comments submitted by the public on the proposed rule were submitted to the peer reviewers for their consideration. The peer review process was coordinated by an independent private contractor.

The full peer review report may be viewed at *http://www.aphis.usda.gov/peer_review/peer_review_agenda.shtml.* Additionally, we have included below, under the heading ''Final Report from Peer Review of APHIS' Risk Assessment and Responses to Peer Reviewer Questions and Recommendations,'' APHIS' responses to reviewer comments that we consider representative of the content-related questions and recommendations of the report, and our response to those questions and recommendations. In summary, the

[1] The regulations regarding BSE minimal-risk regions apply to bison as well as cattle. In §§ 93.400, 94.0, and 95.1 of the regulations, *bovine* is defined as *Bos taurus, Bos indicus,* and *Bison bison.* Although the research and other data cited in this rulemaking refer to bovines other than bison (i.e., to ''cattle''), there is no evidence to indicate that the BSE susceptibility of bison differs from that of cattle. We therefore assume that our conclusions based on cattle-specific evidence discussed in this rulemaking are also applicable to bison. Given that no cases of BSE have been detected in bison, this is likely a conservative assumption. The provisions of this rule apply to bovines as defined in the regulations, which include bison.

reviewers found that the methods used in the risk assessment were scientifically rigorous in terms of using existing literature and models appropriately and making sound assumptions and that the risk assessment itself adhered to international risk assessment standards. The reviewers also agreed with the conclusion that the likelihood of establishment of BSE in the U.S. cattle population is negligible.

In addition to being supportive of the methods, evidence, and conclusions presented by APHIS in the risk assessment, the reviewers made several useful suggestions for its improvement. We made several clarifications and updates in consideration of these comments. While we expect that the changes improve the transparency and accuracy of the document, they do not alter our conclusion that the risk to the United States of BSE—i.e., the likelihood of establishment and the potential impacts of cases that may occur even without establishment—resulting from the changes outlined in the proposed rule is negligible.

Removal of Partial Delay of Applicability of Provisions of January 2005 Final Rule

Our January 2005 final rule made eligible for importation from Canada meat that is derived from bovines slaughtered in BSE minimal-risk regions, as well as certain other specified commodities derived from such bovines, provided certain specified risk-mitigating conditions have been met. The risk analysis we conducted for that rulemaking indicated a low BSE risk from such commodities derived from bovines of any age if certain conditions are met (APHIS 2004). These conditions include the removal of those tissues considered at particular risk of containing the BSE agent in infected animals (specified risk materials, or SRMs). In that rulemaking, we discussed regulatory requirements implemented by FSIS in 2004 that banned SRMs from the human food supply in the United States, and we stated that the Canadian Government had established similar safeguards in Canada.

Consequently, we provided that meat, meat byproducts, meat food products, and offal derived from bovines are eligible for importation from BSE minimal-risk regions if the following conditions, as well as all other applicable requirements of the regulations, are met:

- The commodity is derived from bovines that have been subject to a ruminant feed ban equivalent to the requirements established by the U.S. Food and Drug Administration at 21 CFR 589.2000;
- The commodity is derived from bovines for which an air-injected stunning process was not used at slaughter; and
- The SRMs and small intestine of the bovines from which the commodity was derived were removed at slaughter.

Additionally we provided that tallow composed of less than 0.15 percent insoluble impurities that is not otherwise eligible for importation under 9 CFR 95.4(a)(1)(i), and gelatin derived from bones of bovines that is not otherwise eligible for importation under 9 CFR 94.18(c) are eligible for importation from BSE minimal-risk regions, provided certain specified conditions are met.

In the economic analysis we conducted for the January 2005 final rule, we evaluated the potential economic effects of implementing that rulemaking, including implementation of the provisions allowing the importation of meat and other commodities derived from bovines slaughtered in BSE minimal-risk regions (APHIS 2004a).

In March 2005, APHIS published a document in the **Federal Register** that, pursuant to an announcement by the Secretary of Agriculture on February 9, 2005, delayed the applicability of the provisions in our January 2005 final rule as they apply to the importation from Canada of the following commodities when derived from bovines 30 months of age or older when slaughtered: (1) Meat, meat food products, and meat byproducts other than liver; (2) whole or half carcasses; (3) offal; (4) tallow composed of less than 0.15 percent insoluble impurities that is not otherwise eligible for importation under 9 CFR 95.4(a)(1)(i); and (5) gelatin derived from bones of bovines that is not otherwise eligible for importation under 9 CFR 94.18(c).

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

Since the date of the partial delay of applicability of our January 2005 final rule, we have obtained additional information regarding all aspects of the issues that prompted the delay of applicability and have conducted additional analyses in line with the plan as described. The risk assessment for this final rule demonstrates the negligible BSE risk from the importation of additional classes of live cattle, including those 30 months of age or older. This includes acknowledging the potential risk pathway that could be available if the SRMs from infected imported cattle entered the ruminant feed supply in contravention of current feed regulations. The negligible risk from the importation of live older cattle therefore gives further support to the conclusion of the risk analysis conducted for our January 2005 final rule regarding meat and meat products derived from bovines of any age in BSE minimal-risk regions. Specifically, the risk is even lower for the importation of meat and meat products, as the SRMs will be removed in accordance with the regulations, than for live bovines.

Therefore, this document will remove the partial delay of applicability of the January 2005 final rule. The removal of the partial delay of applicability will become effective on the date that the other provisions of this document become applicable. Including the removal of the partial delay of applicability in this final rule and making it effective along with the other provisions of this rule will enable APHIS to more efficiently communicate the necessary implementation instructions to U.S. Customs and Border Protection and to APHIS field personnel. Additionally, it will provide commercial entities more flexibility in carrying out import planning based on the relative economic merits of importing live bovines or meat and other products derived from bovines.

Because, for reasons of efficiency for APHIS and the regulated community, the Secretary has decided to remove the delay in applicability as part of this document, we looked at the economic effects of doing so in combination with allowing the importation of bovines born on or after March 1, 1999. Although we previously analyzed the economic effects of allowing the importation of meat and other products derived from bovines 30 months of age

or older, the economic analysis for this rule provides an updated analysis.

Public Comments on the January 2007 Proposed Rule

We solicited comments concerning our January 2007 proposal for 60 days ending March 12, 2007. We received close to 400 comments by that date. The commenters included cattle industry and farm bureau associations, consumer groups, representatives of the Canadian Government and other foreign countries, State Departments of Agriculture, food processing companies, individual cattle producers, and other members of the public.

Subjects of Comments Received

A number of commenters supported the rule and recommended no changes to the proposed provisions. Other commenters supported the rule in general but recommended certain changes or actions. Other comments consisted only of recommended changes, objections to the rule in general or to specific provisions, or requests for clarification. We discuss below by topic the issues raised by commenters and our response to those comments.

General Opposition to Imports

Issue: A number of commenters expressed general opposition to the importation of any bovines or bovine products from BSE minimal-risk regions.

Response: It appears to us that these commenters are not addressing just our January 2007 proposed rule, but, rather, also the January 2005 final rule that recognized the category of BSE minimal-risk regions and established conditions for the importation of certain ruminants and ruminant products from such regions.

As we discussed in the January 2005 final rule, the comprehensive analysis and evaluation we conducted for that rulemaking led to the conclusion that the conditions specified in that rule for the importation of ruminants and ruminant products from BSE minimal-risk regions would be effective and would therefore protect against the introduction of BSE into the United States. Our January 2007 proposed rule considered expansion of the types of commodities allowed importation from BSE minimal-risk regions, based on an evaluation of the risk (i.e., the likelihood of establishment and the potential impacts of cases that may occur even without establishment) of importing from Canada live animals, blood and blood products, and the small intestine excluding distal ileum.) Given the determination of negligible BSE risk associated with the provisions of this final rule, and the findings associated with our 2005 final rule, there is no scientific basis for increasing restrictions from those already in effect or being established in this rule.

Issue: A number of commenters expressed opposition, without further explanation, to the importation from BSE minimal-risk regions of live bovines 30 months of age or older and to the importation of products derived from such bovines.

Response: We discussed in our January 2007 proposed rule the rationale for our proposal to allow the importation, under certain conditions, of live bovines 30 months or older from BSE minimal-risk regions. We discussed further the assessment of the disease risk of allowing such imports that we conducted before issuing our proposal. It is not clear to us which factors in our risk assessment or discussion of rationale were being addressed by those commenters who expressed general opposition to the importation of live bovines 30 months of age or older. We continue to consider the BSE risk from importing live bovines under the conditions specified in this rule to be negligible.

Issue: Several commenters who expressed opposition to the proposed rule expressed concern that the agent that causes BSE has yet to be fully characterized. The commenters stated that what we know about BSE is mostly supposition, which should be a compelling reason not to allow the importation of cattle from a region of known BSE outbreaks. One commenter stated that research recently conducted at Yale University suggests that one of the agents that activates BSE may be viral, which, according to the commenter, implies that a feed ban is effective only when the virus is not present or active.

Response: As one of the commenters noted, some researchers (Manuelidis *et al.*, 2007) suggest that diseases characterized as transmissible spongiform encephalopathies (TSEs), such as BSE, may be caused by viruses, although, at this point, no infection-specific nucleic acids have been identified.

Experimental data and epidemiological studies strongly suggest that contaminated feed containing ruminant proteins derived from infected animals was the source of the epidemic, and that the epidemic was perpetuated through the use of these materials in ruminant feed. APHIS considers that regardless of the characteristics of the BSE causal agent, it is clear that the epidemic was sustained and amplified by the recycling of BSE infected cattle into cattle feed. Despite the difficulty in definitively determining the causal agent of BSE, risk factors for transmission of the agent have been identified. The identification and characterization of these risk factors through epidemiological and experimental study have allowed the development of effective mitigations to prevent BSE spread. The development and demonstrated effectiveness of those mitigations does not require identification of the agent itself. We consider mitigation measures that address the risk factors for BSE to be effective regardless of the precise nature of the BSE agent.

Prevalence of BSE in Canada

Although the provisions of this rule apply to any region recognized by APHIS as a BSE minimal-risk region, at present APHIS recognizes only one country, Canada, as such a region. Therefore, in evaluating the BSE risk of implementing this rule, we conducted an assessment of the risk of importing bovines and bovine products from Canada under the provisions of our proposed rule (APHIS 2006b). In our risk assessment, we laid out the likely risk pathway (i.e., a series of occurrences or steps necessary for disease to enter and become established).

In conducting our risk assessment, one of the factors we took into account was the prevalence of BSE in Canada, since prevalence is one factor that affects the likelihood of a BSE-infected bovine being imported into the United States. We received a number of comments from the public that addressed our estimate of the prevalence of BSE in Canada. Although some of the comments supported our estimate of BSE prevalence in Canada, in general the commenters maintained that such prevalence is either higher than we estimated, may be increasing, or is uncertain, or that our methods of estimating it were flawed. The methodology we used to arrive at such estimates is discussed in detail in our risk assessment. However, to provide some context for the issues raised by commenters and discussed below, we summarize here the models that we used in conducting our assessment.

The number of BSE cases detected through surveillance understates the disease prevalence because exposed animals may be incubating disease and carrying infectious material in their tissues without presenting clinical symptoms. Like many transmissible spongiform encephalopathies (TSEs),

BSE has an incubation period of several years. Therefore, the disease is not detectable in its early stages with current technology. Moreover, surveillance will miss a proportion of detectable cases. Therefore, we applied statistical methods to the available epidemiologic and surveillance data to estimate, with attendant uncertainty, the prevalence of BSE in Canada.

We used two related, but distinct, methods to estimate BSE prevalence in Canada: the BSurvE model and the Bayesian Birth Cohort (BBC) model. Given its international prominence, we used the European Union (EU) BSurvE model (Wilesmith *et al.*, 2004, 2005), recently developed for the purpose of estimating BSE prevalence in national herds. The BSurvE model is noteworthy for its sound epidemiologic structure, including stratifying cattle by age and cause of death (i.e., healthy slaughter, fallen stock, casualty slaughter, or clinical suspect) and accounting for the relative likelihood of detecting BSE in various strata (EFSA 2004). The BSurvE model structure calculates BSE surveillance point values (random sample size equivalents) represented by targeted Canadian sampling of certain groups of cattle in which BSE cases are more likely to be detected. This approach allows for the inclusion of infected, but undetected, cases (such as young animals in the early stages of incubation) in the estimate, which would be ignored by conventional methods.

The other prevalence estimation model that we used is the BBC model. This model uses the BSurvE model structure and incorporates additional information. Unlike BSurvE, the BBC model adopts a Bayesian statistical framework to incorporate prior information about the decreased incidence of BSE observed in animals born after a feed ban equivalent to the initial ruminant-to-ruminant feed ban introduced in the United Kingdom in 1988.

Issue: One commenter stated that BSE has become ''firmly established'' in Canada.

Response: We disagree with the comment, which we consider to erroneously equate disease presence, which may be transient, with disease establishment. In epidemiology, an infectious disease has become established in a population when the disease is perpetuated in the population without the need for reintroduction from an external source. For example, OIE's sister agency, the international Commission on Phytosanitary Measures (CPM) defines plant pest establishment as ''the perpetuation, for the foreseeable future, of a nonindigenous biological agent within an area after entry'' (CPM 2001). With the implementation and continuation of a feed ban in Canada, all evidence points toward eventual eradication, rather than perpetuation of BSE in that country.

Issue: One commenter stated that, since the time APHIS published its January 2005 final rule classifying Canada as a BSE minimal-risk region, the Agency has presented no new evidence that would support allowing the importation from Canada of the additional commodities discussed in the proposed rule. In fact, stated the commenter, evidence points to Canada having a higher prevalence of BSE than APHIS had previously determined.

Response: As discussed in our January 2007 proposed rule, we revisited our earlier conclusions and policies by conducting a rigorous risk assessment based on current available scientific knowledge of the disease. We used peer reviewed risk assessment models in our analysis to estimate the prevalence of the disease in Canada and to analyze the likelihood of BSE establishment in the United States and the potential impacts of cases that may occur even without establishment as a result of the importation into the United States of the bovine commodities considered in this rule. The risk assessment itself was peer reviewed by experts in the field. As noted above, the reviewers agreed with the conclusion that the risk of establishment of BSE in the U.S. cattle population is negligible and noted that several assumptions in the risk assessment actually over-estimate the risk, so the overall finding that the BSE risk is negligible is reasonable. Based on the results of the risk assessment, we concluded that we could safely import Canadian cattle born on or after March 1, 1999, blood and blood products, and small intestines, excluding the distal ileum.

Issue: Several commenters raised questions about the ability to statistically determine BSE prevalence ''trends'' in Canada, but reached different conclusions. Some commenters stated that the trajectory of BSE prevalence in Canada cannot be determined by available surveillance data and that, therefore, BSE prevalence in Canada may be increasing. On the other hand, another commenter requested that APHIS make clear that, despite the Agency's use of the BSurvE Prevalence B estimate, prevalence should not be assumed constant over time. The commenter requested that APHIS emphasize that lack of statistical evidence that prevalence varies from cohort to cohort is likely the result of inadequate statistical power,[2] and that, nevertheless, BSE prevalence in Canada is most likely decreasing.

Response: In our risk assessment for this rule, we acknowledge that, given the rarity of BSE cases in Canada, the surveillance data are unlikely to provide adequate statistical power to detect any trend. However, as discussed in the risk assessment, we consider it likely that the prevalence of BSE in Canada will decrease over time. With so few total BSE cases observed in Canada, the statistical power to detect differences in prevalence between cohorts is low. The peer reviewers of our risk assessment concur with our conclusion. (RTI 2007, pp. 6–26, 6–27).

Issue: One commenter estimated the Canadian BSE prevalence to be 6.4 cases per million cattle. Further, the commenter stated that this prevalence estimate is smaller than the risk estimate provided by one of APHIS' own risk assessments for a more pessimistic value of the misfeeding rate. The commenter suggested that this discrepancy reflects optimistic modeling assumptions in APHIS' risk assessment.

Response: We disagree with the commenter's analysis. Although the commenter's alternative prevalence estimate, based on a simple extrapolation method, falls within the 90 percent confidence interval [3] of APHIS' BSurvE Prevalence B estimate (2.4 to 6.8 cases per million adult cattle) with an expected value of 3.9 per million case per million adult cattle (APHIS 2006c, table 5), it is based on different assumptions. Based on an analysis of BSE testing in the EU in 2001 and 2002, the commenter's prevalence estimate assumes that targeted ''risk cattle'' are only 10 times more likely to test positive for BSE than non-targeted routinely slaughtered cattle. Considering the BSE testing conducted in the EU during 2001–2004 (EC 2005a, table 3, p. 23), cattle in the

[2] The power of a statistical test is the probability of rejecting the null hypothesis when it is false. The power depends on the test level of significance, the magnitude of effect under the alternative hypothesis, sample size, and variability in the population. Rice (1988, pp.361–364) describes the calculation of statistical power for comparing two independent samples.

[3] A confidence interval is a statistical range with a specified probability that a given parameter lies within the range. For example, the 90 percent confidence interval of a distribution indicates the range of values that we are 90 percent certain include the parameter value of interest. It extends from the 5th percentile, or 5 percent confidence level, at the low end of the distribution of the 95th percentile, or 95 percent confidence level at the high end of the distribution. Similarly, a 95 percent confidence interval would extend from the2.5 percent confidence level to the 97.5 percent confidence level.

European BSE risk animals category (emergency slaughter, clinical suspects, and fallen stock) are 22 times more likely to test BSE positive than cattle in the healthy slaughter category. Using the commenter's simple extrapolation method and these more up-to-date data on BSE test positive ratio, the resulting BSE prevalence estimate would be 2.9 per million cattle. Although actually lower than the expected value for the BSurvE estimate, this value also falls within the 90 percent confidence interval of the Agency's BSurvE Prevalence B estimate, described above. APHIS calculated both the BSurvE Prevalence B estimate and the Bayesian Birth Cohort (BBC) prevalence estimate, but judged the latter to better characterize the BSE prevalence in Canada over the next 20 years, due to the expected downward pressure exerted on the disease by a feed ban.

With regard to the commenter's suggestion of a discrepancy, the commenter provides no specific reference to ''the risk estimate provided by one of APHIS' own risk assessments,'' but appears to refer to the main body of the 2005 report of Cohen and Gray (available at *http://www.fsis.usda.gov/PDF/BSE_Risk_Assess_Report_2005.pdf*), which was prepared for the USDA's Food Safety and Inspection Service (FSIS). Cohen and Gray (2005) do not estimate Canadian BSE prevalence, but rather the effect of introducing 500 BSE-infected cattle into the United States, and the pessimistic misfeeding assumption estimates that introduction would result in an expected 2,600 new cases over 20 years. There is no discrepancy because this aspect of the Cohen and Gray 2005 report is not relevant to our estimate of Canadian BSE prevalence.

Issue: Based on APHIS'' statements that animals are infected within their first year, and that feed produced prior to the feed ban would not be available for longer than a year, one commenter stated that additional undetected infected animals must have existed and been rendered in order to provide infectivity to detected cases. Therefore, stated the commenter, adding in these ''undetected'' animals raises the number of Canada's known and measurable BSE cases rises from 10 to 14, and APHIS' estimate of BSE prevalence in Canada based on 10 animals is low.

Response: We disagree with the commenter's analysis and conclusion, which assumes that we did not take into account the possibility of undetected cases of BSE in arriving at our prevalence estimate. APHIS' estimate of the prevalence of BSE in Canada was adjusted to account for cases that would not be tested and for false negative test results. Also, although the bulk of feed will be consumed within a year after it is produced, residual infectivity may remain in the feed supply chain for an extended period. For example, examination of BSE cases in animals born in the United Kingdom after the 1996 ''reinforced feed ban'' suggests that these animals may have been infected from the persistence of the BSE agent in residual feed in storage bins (SEAC 2005).

Issue: One commenter suggested that it is likely that Canada has numerous cattle over 30 months of age that are presently incubating the BSE disease, rather than just a few (4.1) as suggested by APHIS.

Response: The estimate of 4.1 BSE-infected animals in the standing Canadian adult cattle population was based on the expected BSE prevalence in Canada under the BBC model. Using the estimated prevalence under BSurvE Prevalence B resulted in an estimate of 23.2 BSE-infected animals in the standing Canadian adult cattle population. Although, quantitatively, our risk assessment did not assume a decline in BSE prevalence over the next 20 years, we qualitatively consider such a decline to be likely because of continued compliance with the feed ban. Therefore, in assessing the BSE risk associated with imports from Canada over the next 20 years, we consider the result of the BBC model to be the more applicable prevalence estimate for use in our quantitative exposure model.

Issue: One commenter indicated that although it is unclear whether the APHIS estimates of Canadian BSE prevalence included the BSE case confirmed on August 23, 2006, the APHIS estimates certainly do not take into account the case confirmed on February 7, 2007.

Response: We estimated Canadian BSE prevalence based on a 7-year surveillance period through August 15, 2006. This surveillance period included the detection of nine BSE cases of Canadian origin reported through August 2006. Through surveillance conducted from August 16, 2006, through April 2007, Canada detected one BSE case born in 2000 and another born in 2001 (CFIA 2007). The BSE prevalence estimation methods used by APHIS (2006a) require detailed data to stratify tested cattle by age and cause of death (healthy slaughter, fallen stock, casualty slaughter, or clinical suspect) that are unavailable for the more recent surveillance period. However, we can assess the sensitivity of our previous Canadian BSE prevalence estimates by adding the two additional cases without changing the BSE surveillance points accumulated by Canada during the 7-year surveillance period through August 15, 2006 (APHIS 2006a, table 4).[4] This approach results in a revised table of BSurvE points and BSE cases by birth year cohort that reflects a total of 11 BSE cases of Canadian origin reported through April 2007 (APHIS 2007, table i).

Using the same methods described in USDA's estimate of BSE prevalence in Canada (APHIS 2006c), we obtain updated Canadian BSE prevalence estimates:

- BSurvE Prevalence B: 90 percent confidence interval = 3.0–8.0 cases per million adult cattle
- Bayesian Birth Cohort (BBC, Winbugs): 90 percent confidence interval = 0.47–1.2 cases per million adult cattle

Because the updated confidence intervals contain the previous expected value estimates of 0.68 per million (BBC) and 3.9 per million (BSurvE Prevalence B) (APHIS 2006c), we conclude that the prevalence estimate is not sensitive to the addition of the two additional BSE cases discovered in Canada in August 2006 and February 2007.

Issue: One commenter stated that APHIS' expectation that the prevalence of BSE in Canada will continue to decline from its present minimal level does not acknowledge that the prevalence of BSE in Canada right now is very uncertain. The commenter's independent estimate of the current Canadian BSE prevalence is ''on the order of 4–6 per million.''

Response: APHIS' risk assessment addresses the uncertainty in the prevalence of BSE in Canada by considering estimates that differ by more than a factor of five (APHIS 2006b). The BBC prevalence estimate has an expected value of 0.68 cases per million adult cattle.[5] The BSurvE Prevalence B estimate has an expected value of 3.9 per million. The

[4] In the BsurveE model, specific ''point values'' are assigned to each test sample, based on the surveillance stream or subpopulation of animals from which it was collected, as well as the likelihood of detecting infected cattle in that subpopulation. A sample from the specific surveillance subpopulation where BSE is most likely to be detected—*i.e.*, a middle adult clinical suspect—provides the most surveillance points. Conversely, a sample from the subpopulation where BSE is least likely to be detected—generally routine slaughter—provides the least points.

[5] The BBC model provides a more precise estimate of BSE prevalence in Canada by combining the epidemiologic theory and application of surveillance data underlying the BSurvE model with additional information about the effect of the feed ban on prevalence.

commenter's own method of estimation—''on the order of 4–6 per million——provides an estimate on the same order of magnitude as the BSurvE Prevalence B estimate of current prevalence. In either case, prevalence is extremely low.

Issue: One commenter stated that, although APHIS estimates that BSE prevalence in Canada is about 6.8 or more times greater than in the United States (0.68 vs. 0.1 per million), this does not adjust for the important fact that the first BSE case in the United States was imported from Canada.

Response: The APHIS October 2006 estimate of BSE prevalence in Canada is based on the nine BSE cases of Canadian origin that had been confirmed in North America as of August 23, 2006. This total includes a case of BSE that was confirmed in Washington State on December 25, 2003 (APHIS 2006c, p. 1). The estimate of BSE prevalence in the United States excludes this case.

Issue: One commenter stated that the calculation of BSE prevalence in Canada used in APHIS' risk assessment excluded the European-born case detected in 1993.

Response: The 1993 Canadian BSE case of European origin was likely part of the original exogenous source of BSE infectivity introduced into Canada that caused the subsequent generation of indigenous cases. Imported cases of BSE reflect an exposure to the disease that occurred elsewhere, and, therefore, are not generally included in estimates of prevalence that reflect native exposure. Similarly, when APHIS estimated the prevalence of BSE in the United States, the BSE-infected cow of Canadian origin that was detected in Washington State in December 2003 was excluded from the analysis, because it was an imported animal. In addition, as noted in APHIS' estimation of BSE prevalence in Canada (APHIS 2006c, p. 5), in accordance with OIE guidelines (which indicate that surveillance points totals taken into account in assessing a country's BSE risk be accumulated over a maximum of 7 consecutive years), the estimated prevalence of BSE in Canada is based on surveillance data accumulated over a 7-year period beginning August 16, 1999. The 1993 case predates the OIE 7-year period.

Issue: One commenter indicated that APHIS should not take action on the proposal until real surveillance data (not model-based predictions) show that the BSE problem has abated. The commenter stated further that denying Canada's BSE problem, or assuming it away with unvalidated and incorrect risk modeling assumptions, does not responsibly manage BSE risks to the United States.

Response: We disagree with the commenter. In low BSE prevalence populations such as Canada, surveillance at levels that meet or even greatly exceed OIE guidelines provide insufficient statistical power to reliably detect changes in BSE prevalence over time. In other words, starting with a very low number of infected animals makes it very difficult to statistically demonstrate decreases in that number, even when testing a relatively large number of animals.

The OIE Guidelines for BSE Surveillance (Type A) call for countries to accumulate 300,000 BSE surveillance points over 7 consecutive years in order to detect with 95 percent confidence a prevalence level of at least one case of BSE per 100,000 animals (OIE 2006, Appendix 3.8.4).

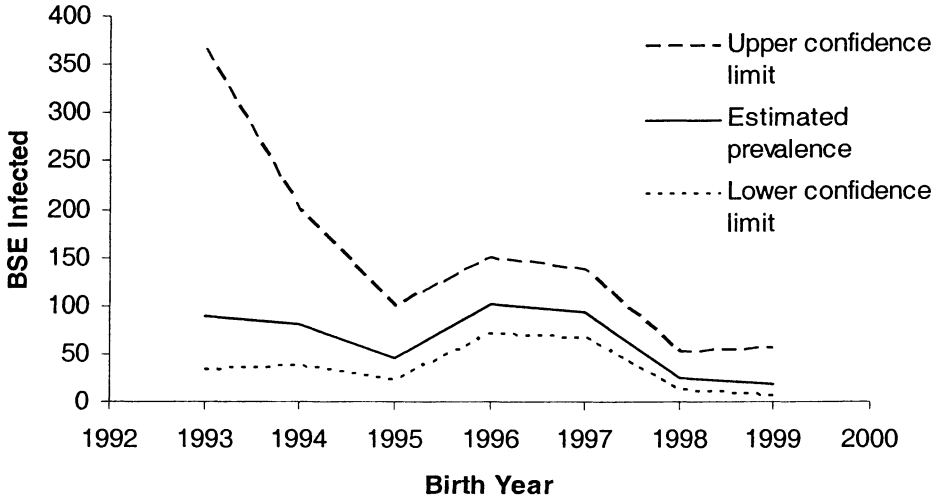
To illustrate the comparative difficulty in demonstrating trends in low versus high prevalence populations, consider two hypothetical countries that have accumulated 1 million BSE surveillance points for each of two cohorts: Animals born before and animals born after the introduction of a ruminant-to-ruminant feed ban. Under this scenario, sampling levels in both countries far exceed the OIE guidelines. Assume, however, that the two countries differ with respect to their initial prevalence—i.e., the initial prevalence in ''Country A'' is 1 infected animal per 10,000 animals, while that in ''Country B'' is 1 infected animal per 100,000 animals.

For a given surveillance level, the statistical power of a hypothesis test can be evaluated as a function of the supposed change in BSE prevalence between cohort 1 (pre-feed ban) and cohort 2 (post-feed ban). The conventional minimum statistical power criterion is 80 percent. In other words, the probability that a statistical analysis will detect a true difference across groups should be at least 80 percent. The conventional significance level is 5 percent, meaning that we would conclude that a result was nonrandom if it were 5 percent or less likely to occur by chance alone. In our hypothetical scenario, the power of the surveillance in the country with higher prevalence, Country A, to detect a 50 percent decline in BSE prevalence is 98 percent. In comparison, the power of the surveillance in the lower prevalence Country B to detect a 50 percent decline in BSE prevalence is only 25 percent. In other words, if the Country B feed ban actually led to a 50 percent decline in BSE prevalence and the equivalent of 2 million random samples were collected (6.7 times the level under the OIE guidelines), there would still be a 75 percent chance of concluding that the prevalence was unchanged from its initial level of 1 infected animal per 100,000 animals.

An important implication of the low statistical power of sampling in low prevalence populations is that BSE surveillance data are unlikely to provide a purely statistical basis for making a determination about the date when a specific intervention (e.g., a ruminant-to-ruminant feed ban) becomes effective, even when large amounts of surveillance data are available. For example, according to the OIE (2007a), the annual incidence of reported BSE cases in the Netherlands dropped from 13.2 to 0.8 per million adult cattle from 2001–2005.[6] Despite the EU BSE surveillance requirements for testing all risk animals over 24 months of age and all healthy slaughter cattle over 30 months of age, Figure 1 shows that application of the BSurvE (Prevalence A) model to Netherlands BSE surveillance data does not yield sufficient statistical power to draw clear distinctions among birth year cohorts as prevalence declines (Figure 1).

[6] The OIE Terrestrial Animal Code (Chapter 1.1.1., Article 1.1.1.1) defines incidence as ''the number of new cases or outbreaks of a disease that occur in a population at risk in a particular geographical area within a defined time interval (OIE 2006b).''

Figure 1. Application of BSurvE to Netherlands BSE surveillance data



Source: Heres et al. (2005, table 4.1)

Note that, in figure 1, there is a decrease in estimated prevalence between 1998 birth-year cohorts and 1999 birth-year cohorts, while, at the same time, there is an increase in the upper confidence limit. This apparent paradox is indicative of another shortcoming of relying on surveillance data alone to determine whether BSE prevalence has been reduced. Because fewer animals from the most recent birth year cohorts are tested when sent to slaughter, uncertainty about the prevalence in the most recent cohorts is much greater than in older cohorts. Furthermore, the lower likelihood of detecting BSE in young infected animals means that the young animals that are tested contribute relatively little to reducing uncertainty in the true (as opposed to apparent) BSE prevalence. These two sources of uncertainty in young birth cohorts (low numbers of animals tested, and little value in the surveillance data that are gathered from them) cause an asymmetrical increase in the upper limit of the confidence interval compared to the lower confidence limit. This effect on the upper confidence limit on BSE prevalence is most pronounced for the most recent birth year cohorts which are less likely to be tested and will not have lived long enough to manifest BSE, even if they have been infected. Wilesmith *et al.* (2004, figure 3) further illustrates this same concept.

Consequently, if the effectiveness of a country's safeguards against BSE amplification were determined strictly by setting a tolerance for the upper confidence limit on BSE prevalence associated with the ''real surveillance data,'' one might reach the incorrect conclusion that prevalence is increasing, when in actuality, the result is simply due to testing fewer and younger animals in the most recent birth year cohorts. Finally, relying solely on surveillance data fails to account for under reporting of disease due to the lack of diagnostic sensitivity to detect BSE at an early stage of disease. By accounting for the possibility of false negative test results, epidemiologic models such as BSurvE are recognized as providing a more accurate estimate of true BSE prevalence than the apparent prevalence measured by surveillance data alone.

Issue: One commenter stated that the output from the BSurvE model used by Canada in 2005 grossly underestimated Canada's 2006 and 2007 BSE prevalence and, therefore, the BSurvE model is unreliable for estimating Canada's BSE prevalence. The commenter stated further that, at the minimum, APHIS should determine the erroneous inputs that resulted in the failed prediction in 2005 and correct them.

Response: In the risk assessment conducted for this rulemaking, APHIS used its own prevalence estimate, not that of the Canadian Food Inspection Agency's (CFIA's) 2006 prevalence estimate, which was not based on BSurvE, but on a modified version that appears similar to the APHIS BBC model. The commenter cites CFIA's Assessment of the North American BSE Cases Diagnosed from 2003–2005 (Part II), which states that ''when the BSurvE model was recently applied to Canada's statistics and adjusted to account for the effectiveness of the 1997 feed ban (based on experiences with the 1988 feed ban in the United Kingdom), the resulting prediction was that it could be expected that three infected animals remain within the national herd'' (CFIA 2006, p. 13).

APHIS' estimation of BSE prevalence in Canada (APHIS 2006c) is that the expected prevalence values under the BBC and BSurvE Prevalence B models correspond to an expected number of BSE-infected animals in the standing Canadian adult cattle population of 4.1 and 23.2, respectively. APHIS further explains that it is important to note that this range of prevalence estimates represents uncertainty and not variability. BSE-infected animals are recruited into and exit from the adult cattle population over time, but at a given point in time, the number of infected animals in the population is a fixed but uncertain value.

Assuming the overall probability of infection remains constant over time, the actual number of infected cattle in the population at any given point in time would still vary randomly about the mean. This variability is incorporated in the model supporting the exposure assessment for live bovines by means of the Poisson variability distribution. Assuming a fixed mean prevalence of 4.1 and 23.2 BSE infected animals in the standing adult cattle population in Canada, the 95th percentile of the Poisson distribution are 7 and 31 BSE-infected animals in any given year, respectively. We note that these numbers are greater than the

five BSE cases detected in Canada in 2006, which means that the greatest number of Canadian BSE cases identified in a single surveillance year is lower than even the 95th percentile of distribution.

Issue: One commenter stated that, if the United States were finding BSE cases at the same rate as in Canada, this would translate into roughly 40 BSE cases detected in the United States since January 2006, which would be regarded as a large number. The commenter stated further that, at this time, the BSE situation in Canada does not appear to be improving.

Response: We do not agree with the commenter. The commenter's conclusion appears to be based on a cursory estimate and does not provide an accurate comparison of BSE cases detected in Canada with a comparable number that would have been detected in the United States, given the larger U.S. cattle population. The commenter's comparison fails to take into account other years of surveillance, as well as the age and surveillance stream of tested animals. These data are extremely important for estimating BSE prevalence. A comparison based solely on the number of detected cases ignores infected animals with unapparent or undetected infections.

Table 1 provides a direct comparison of the estimated BSE prevalence in the current standing adult cattle population of the United States and Canada, respectively, using identical estimation methods (APHIS 2006a; 2006c).

TABLE 1.—COMPARISON OF ESTIMATED BSE PREVALENCE IN THE CURRENT STANDING ADULT CATTLE POPULATION OF U.S. AND CANADA

Country	BSE Prevalence Estimation Method	
	BSurvE prevalence B	BBC
	Expected value	
US	0.18×10^{-6}	0.10×10^{-6}
Canada	3.9×10^{-6} ...	0.68×10^{-6}

Despite the higher estimated BSE prevalence in the current standing adult cattle population in Canada compared to the prevalence of BSE in the standing adult cattle population in the United States, APHIS finds that, because of the extremely low BSE prevalence in Canada and the high levels of BSE controls in both Canada and the United States, the risk to the United States (i.e., the likelihood of establishment of BSE in the United States and the potential impacts of cases that may occur even without establishment) as a result of importing from Canada the bovine commodities considered in this rule is negligible (APHIS 2006b). Furthermore, as stated in our risk assessment, we expect that the prevalence of BSE in Canada will decrease continuously over the next several years. Peer reviewers of our risk assessment agreed (RTI 2007).

Issue: One commenter stated that Canada's ratio of positive cases per 10,000 cattle tested exceeds the ratio of 22 of the 25 EU-member countries; that only the ratios for the United Kingdom, Portugal, and Spain exceed Canada's 2006 ratio. The commenter noted further that even the countries of Ireland, Germany, and France, each of which are considered to have had widespread BSE exposure, have a lower ratio for positive cases detected per 10,000 head tested than does Canada. Another commenter stated that Canada's BSE prevalence is higher than that for Denmark, Belgium, and Austria, and is comparable to the rate in Germany. This commenter, who estimated the Canadian BSE prevalence to be 6.4 cases per million cattle, stated further that no one considers countries with a reported BSE rate of 1 to 2 cases per million animals (e.g., Denmark, Belgium and Austria) to have a minimal BSE risk, and that Canada is not a BSE minimal-risk region in any ordinary sense.

Response: The commenters' statements ignore important differences in BSE surveillance and cattle populations among countries, and a comparison based simply on the proportion of positive cases per number of cattle tested is inconsistent with the prevalence estimate approach taken by one of the commenters, as well as the prevalence estimate used by APHIS. Although calculating the proportion of infected animals detected per number of tested animals can serve as a useful tool, depending on the purpose for the calculation, it is not an estimate of prevalence. Rather, prevalence is defined as the number of infected animals in the total population at a given point in time. On the other hand, the calculation conducted by the commenter who referred to the ratio of positive cases per 10,000 cattle tested is similar to that conducted by the U.S. Department of Health and Human Services, Centers for Disease Control and Prevention (CDC). In May 2007, using data similar to that analyzed by APHIS for this rulemaking, CDC calculated the proportion of Canadian-born BSE cases identified by Canadian authorities in relation to the total number of animals tested in that country. CDC then made a like calculation regarding BSE cases in U.S.-born cattle and compared the Canadian and U.S. results (CDC 2007). Unlike the estimate used by APHIS in the risk assessment for this rule, the CDC calculation is not an estimate of the prevalence of BSE in Canada, nor of the prevalence in the United States. Although the type of calculations conducted by CDC can be useful in comparing relative proportions of BSE detections per number of cattle tested, they do not, as noted above, constitute an estimate of prevalence.

The number of disease detections per total number of animals tested can be influenced by the criteria used for choosing animals for testing. For instance, Canada, like the United States, conducts targeted BSE surveillance, sampling those animals where disease is most likely to be detected if present. In contrast, EU countries routinely test large numbers of healthy animals at slaughter. Approximately 80 percent of cattle tested for BSE in the EU during 2001–2004 were healthy slaughtered animals, but ''risk animals'' were 22 times more likely to test positive (EC 2005a). One study (Giovannini *et al.*, 2005) estimates the true prevalence of BSE infection in several EU countries. Based on BSE testing in 2001, although Denmark, Finland, and the Netherlands had a lower proportion of positives per test than Canada, the estimated prevalences from this study for those three countries were higher than the expected values of our Canadian BSE prevalence estimates using the BBC estimation method (0.68 cases per million adult cattle) or BSurveE Prevalence B (3.9 cases per million adult cattle). Giovannini *et al.* (2005) estimated the following 90 percent confidence intervals for the prevalence of BSE infection: Denmark, 9 to 38 cases per million animals; Finland, 29 to 110 cases per million animals; and Netherlands, 8 to 34 cases per million animals. The methods used by APHIS to estimate Canada's BSE prevalence, including the BSurvE model developed by the EU Transmissible Spongiform Encephalopathies Community Reference Laboratory, account for the cattle population demographics, the age and surveillance category of animals tested, and the insensitivity of BSE diagnostics with regard to detection of the disease at an early stage of development.

The comments are based on an inappropriate comparison of a statistical estimate of the true BSE prevalence in Canada to the crude rate. Table 2 below compares the crude reported BSE rates in all five countries in 2005. Comparing the reported BSE rate of Canada to those of the countries listed by the commenters shows that Canada's

reported rate is at least an order of magnitude below that of the others.

TABLE 2.—REPORTED BSE RATES IN 5 COUNTRIES

Country	Reported BSE cases per million adult cattle—2005
Canada	0.145
Denmark	1.289
Belgium	1.448
Austria	2.114
Germany	4.965

Source: OIE (2007a).

The problem with comparing the crude reported rate of BSE detection to the estimated true BSE prevalence is illustrated by the situation in Belgium. The reported rate of BSE in Belgium peaked in the 2001 surveillance year at 28.22 cases detected per million adult cattle (OIE 2007a). In comparison, Saegerman *et al.* (2004) applied the BSurvE model to the Belgian BSE surveillance data and estimated that the actual BSE prevalence in Belgium peaked at approximately 400 cases per million adult cattle in the 1995 birth year cohort. (The lag between the 1995 birth year and the 2001 surveillance year is consistent with the long BSE incubation period.)

With regard to the comment that countries with 1 to 2 cases per million animals are not considered to present minimal risk, APHIS notes that, prior to the 2005 revisions in the OIE guidelines on BSE, countries with a reported BSE rate of 1 to 2 cases per million animals could satisfy the prevalence criterion for the pre-2005 OIE BSE minimal-risk classification. Under the 2004 OIE Terrestrial Animal Health Code (Article 2.3.13.5), the criteria for a BSE minimal-risk country included a reported rate of less than two cases per million during each of the last four consecutive 12-month periods within the cattle population over 24 months of age. The OIE Code was modified in 2005 to include a revised country categorization system which more accurately reflected current scientific understanding of BSE. These modifications streamlined the number of country categories to three (negligible, controlled, or undetermined BSE risk) and also eliminated the numeric prevalence criteria for classifying the BSE risk status. The previous OIE minimal-risk category is now incorporated into the controlled risk category. We note that in 2007, the OIE recognized Switzerland as a BSE controlled risk region. Switzerland had a reported rate of 5.4 BSE cases per million adult animals in 2006 (OIE 2007a), greater than the 1 to 2 cases per million animals cited by the commenters.

APHIS disagrees with the commenter's statement that Canada does not qualify as a BSE minimal-risk region. APHIS regulations at § 94.0 define the standards for a region to be designated as a minimal-risk region. These include the standard that the region maintain ''risk mitigation measures adequate to prevent widespread exposure and/or establishment of the disease.'' Canada continues to meet this standard. The commenters provided no specific evidence to document how or why Canada does not meet the APHIS standards.

Issue: One commenter stated that the prior information [information using data from the United Kingdom feed ban] incorporated into the Bayesian models used to estimate prevalence of BSE-infected cattle in Canada may have resulted in estimates that are biased downward (to a limited degree) from the true burden. However, stated the commenter, the Bayesian models used to estimate prevalence in Canada (as of August 2006) are basically sound and a better approach than relying on the BSurvE Prevalence B estimate. Further, said the commenter, given the proviso that the models could overestimate the effectiveness of the feed ban, it is most likely that the actual prevalence of infected animals is between 0.68 and 3.9 animals per million adult cattle. The commenter stated that because it is likely that the Canadian feed ban was at least as effective as the initial United Kingdom feed ban, and based on available data, the true BSE prevalence in Canada is probably substantially closer to 0.68 cases per million animals than to 3.9 cases per million animals.

Conversely, several commenters suggested that APHIS rejected the higher prevalence estimate of the BSurvE model for the lower prevalence estimate of the BBC model, and that the BBC model prevalence estimate is not realistic in light of recent data.

Response: Although APHIS considered the results of both the BSurvE and the BBC prevalence estimation models, we consider the result of the BBC model as the more likely prevalence estimate to apply to the assessment of BSE risks associated with imports from Canada over the next 20 years in our quantitative exposure model, for the following reasons. APHIS estimated Canadian BSE prevalence based on surveillance conducted through August 15, 2006. (**Note:** This time period includes all cases of Canadian origin reported through August 2006 (APHIS 2006c).) From August 16, 2006, through April 2007, Canada accumulated approximately 44,980 additional BSE samples and detected two BSE cases (one confirmed on February 7, 2007, and another confirmed on May 2, 2007). Based on the negative binomial likelihood ratio, which considers the number of negative tests prior to one or more positives, the BSurvE Prevalence B estimate (with expected value of 3.9 cases per million animals) is indeed far more likely to be true than is the BBC prevalence estimate (with an expected value of 0.68 cases per million animals) for the current standing Canadian cattle population. However, the primary purpose of characterizing BSE prevalence in Canada's current standing herd (APHIS 2006c) was not to discuss or assume its implications for the present, but rather, to estimate prevalence for use as an input for the Harvard exposure model used in the Exposure Assessment of the analysis. Because BSE has a long amplification cycle (it takes an average of 7 years from the time that one animal is exposed, to the time that another might be exposed from infectivity produced by the first animal), the Harvard model is typically run with 20-year simulations to include roughly 3 amplification cycles. The prevalence estimates contained in APHIS' estimation of BSE prevalence in Canada (APHIS 2006c) are applied, unchanged, to the cattle imports projected over the next 20 years (2007–2026). Since we expect that the true prevalence will drop from its current level (whatever that may be), we anticipate that the lower, BBC estimate is a more realistic prediction (or even an overestimate) of average prevalence levels over this time frame. Consequently, APHIS considers the result of the BBC model, which incorporates the effect of a feed ban, to be better for application to the quantitative assessment of BSE risks associated with imports from Canada over this time period. In order to determine the impact of this assumption on the results, we applied the BSurvE estimate to the exposure model. We note that the likelihood of BSE establishment remained negligible (R_0 of 0.079, which is far less than 1), as did the potential impact of cases even without establishment (less than 4 clinical cases) over the 20 years of the analysis.

Issue: One commenter suggested that the APHIS risk model is not trustworthy because it has not been shown to have predictive validity and does not explain or predict a sustained flow of BSE cases from one geographic area (the Alberta region in Canada).

Response: It is not clear to us from the comment which model the commenter is referring to. Consequently, in this response, we discuss the Harvard model and the prevalence models used by APHIS. In either case, we disagree with the commenter's conclusion that the APHIS risk model is not trustworthy. The plausibility of the Harvard model was established by comparing its predictions for Switzerland against the observed progression of BSE within that country's cattle herd (Cohen *et al.*, 2003). It is not clear from the comment how the predictive validity of an infectious disease model is to be demonstrated over a 20-year time horizon, or how the model has failed to explain or predict the observed data. Regarding a sustained flow of BSE cases from one geographic area, assuming a constant proportion of BSE infected cattle in the herd, more BSE cases are found where large cattle populations exist.

As we discuss above in response to another issue raised by commenters, APHIS' estimation of BSE prevalence in Canada (APHIS 2006c) concludes that the expected prevalence values under the BBC and BSurvE Prevalence B models correspond to an expected number of BSE-infected animals in the standing Canadian adult cattle population of 4.1 and 23.2, respectively. Further, the prevalence estimates represent uncertainty and not variability. At any given point in time, the number of infected animals in the population is a fixed (although uncertain) value, although over time the actual number of infected cattle in the population would vary randomly about the mean of the probability distribution, as BSE-infected animals are recruited into and exit from the adult cattle population (i.e., some are newly infected and some die). Even assuming that the probability of infection remains constant, over time the actual number of infected cattle in the population would vary. This variability is incorporated in the model supporting our exposure assessment for live bovines by means of the Poisson variability distribution. Assuming a fixed mean prevalence of 4.1 and 23.2 BSE-infected animals in the standing adult cattle population in Canada, the 95th percentile of the Poisson distribution is respectively 7 and 31 BSE-infected animals in any given year. As we noted above, these numbers are greater than the five BSE cases detected in Canada in 2006, which means that the greatest number of Canadian BSE cases identified in a single surveillance year is lower than even the 95th percentile of distribution. While this observation does not statistically validate (confirm) the APHIS estimates of Canadian BSE prevalence, neither does it invalidate them, as the commenter seems to suggest. Furthermore, the prevalence estimates are applied not only to the current standing population, but also to the next 20 years.

BSE Data From the United Kingdom

In our January 2007 proposed rule and its supporting risk assessment, we discussed data associated with a ruminant-to-ruminant feed ban in the United Kingdom and indicated that experience in the United Kingdom demonstrates that implementation of a ruminant-to-ruminant feed ban causes BSE prevalence to decrease. We noted that animal feed restrictions were implemented in the United Kingdom in 1988, when the use of ruminant MBM in ruminant animal feed was banned. In September 1990, the use of specified bovine offals was banned for use in any animal feed. This ban prohibited the use in any animal feed of bovine tissues with the highest potential concentration of infectivity. In 1994, the use of mammalian protein—not just ruminant protein—was banned from ruminant feed. In 1996, feeding of any farmed livestock, including fish and horses, with mammalian MBM was completely banned. As a result of reducing the recycling of infectivity, the annual incidence of BSE fell by 99.4 percent, from 36,680 in 1992 to 203 in 2005 (DEFRA 2006b). There is, therefore, every reason to expect downward pressure on the prevalence of BSE in any country that implements a feed ban.

Issue: One commenter stated that, of 180,986 confirmed cases of BSE in Great Britain, the year of birth of the infected animal is unknown in 43,342 cases, and the large percentage of animals whose birth year is unknown casts doubt on the ability to determine the timeframe of an effective feed ban and, and further, makes it doubtful that all BSE-infected cattle in Canada are going to show clinical signs of the disease only if they were born before March 1, 1999. The commenter also stated that Japan has reported cattle as young as possibly 20 months of age or younger as testing positive for BSE.

Response: It is not clear to us how the information presented by the commenter supports the conclusions the commenter reached. However, we consider it useful to provide some clarification regarding the information presented. With regard to the proportion of BSE cases in Great Britain for which the date of birth is unknown, our risk assessment included a sensitivity analysis that takes into account that general source of uncertainty. (Sensitivity analysis evaluates the degree to which changes in the assumptions used in a model affect the model's results.) We made no assumptions as to whether Great Britain's feed ban is or has been effective, but applied the same proportional drop in cases observed in the United Kingdom to the Bayesian analysis that was performed to estimate BSE prevalence in Canada's standing cattle herd.

The commenter's statement that it is doubtful that only animals born before March 1, 1999, would show clinical signs of BSE indicates a potential confusion between the likelihood of exposure as expressed in terms of the date of the effectively enforced feed ban (and, thus, the potential for exposure) and the likelihood of an exposed animal developing clinical signs (which is based on age and amount of exposure, and the amount of time that has elapsed since exposure). In neither our risk assessment nor our proposed rule do we conclude that only infected animals born before March 1, 1999, would show clinical signs of the disease. Based on Canada's system of regulations, compliance and enforcement, and the length of time we expect pre-feed ban feed to persist in the system, we conclude that animals born on or after March 1, 1999, have an extremely low likelihood of exposure to BSE. Any animal, however, exposed to an infectious dose of the BSE agent and allowed to live to the end of its incubation period, would likely exhibit clinical signs.

Regarding the age of cattle diagnosed with BSE in Japan, the comment did not contain sufficient information for us to determine and respond to the relevance of the statement to the remainder of the comment.

Issue: One commenter questioned the effectiveness of APHIS' use of United Kingdom surveillance numerators to estimate Canada's BSE prevalence. Specifically, the commenter stated that ''Nowhere * * * is incidence reported. Cases (without reference to a population at risk) are used. This may be important because the manner in which BSE cases were counted changed over time in the [United Kingdom].''

Response: We acknowledge that changes over time in BSE surveillance and in the size and demographics of the cattle population do contribute to the uncertainty about the efficacy of the initial, ruminant-to-ruminant feed ban introduced in the United Kingdom in 1998. However, the United Kingdom's Department for Environment, Food, and

Rural Affairs (DEFRA) does not report BSE surveillance results by birth year and surveillance class (e.g., active or passive surveillance, animal health status). Ideally, such data could be entered into BSurvE or a similar model to estimate true BSE prevalence for all United Kingdom birth year cohorts since the onset of the epidemic. This process would permit not only an improved estimate of the effect of the initial feed ban but also of the incremental impact of additional measures that were subsequently introduced. DEFRA has reported back-calculation model estimates of true BSE prevalence in cohorts born after 1995 to assess the effects of the ''reinforced feed ban'' introduced by the United Kingdom in August 1996 (DEFRA 2005, 2006b). However, we are unaware of any published estimates of true BSE prevalence in the United Kingdom for the 1987–1995 birth year cohorts based on up-to-date surveillance results.

Issue: One commenter stated that APHIS is wrong to assume that the United Kingdom data regarding the effectiveness of the feed ban can be applied directly to the situation in Canada.

Response: We acknowledge that the applicability to Canada of the data from the initial United Kingdom ruminant-to-ruminant feed ban is uncertain. Nonetheless, the United Kingdom's experience and data are important and useful to our risk assessment and analyses. In addition, the Peer Review Report (RTI 2007, p. ES–2) noted that ''[all reviewers] agreed that the evidence from the United Kingdom * * * and Europe that the feed ban is effective is reasonable to consider in the case of Canada.''

Issue: Several commenters noted the differences in the feed bans in the United Kingdom and Canada in stating that it is not valid to draw conclusions about the likely prevalence of BSE in Canada by extrapolating from the rate of decline in BSE cases in the United Kingdom following implementation of a feed ban there. The commenters noted that (until expanded this July) the feed ban in Canada prohibited the feeding of ruminant material to ruminants. In contrast, said one commenter, significant declines in the number of confirmed BSE cases in the United Kingdom did not occur until the United Kingdom took stronger measures, ultimately banning the feeding of all mammalian protein to food animals in 2001. The commenter suggested that the United Kingdom's experience in particular clearly shows that ruminant-to-ruminant feed bans do not drastically curtail the number of confirmed BSE cases and that much stronger measures are needed to eradicate the disease.

Response: The comments appear to confuse the absolute level of BSE in the United Kingdom with its rate of decline. The comments also ignore the BSE incubation period and the effects of other concurrent measures, trends, and events in the United Kingdom. The number of BSE cases in United Kingdom birth year cohorts (all cattle born in a given year) has continued to decline since peaking in 1987. With the exception of the 1996 birth year cohort, it is not readily apparent that there has been any significant change in the rate of decline in birth year cohort prevalence after the United Kingdom introduced the initial ruminant-to-ruminant feed ban in 1988 (figure 2). As of March 1, 2007, the United Kingdom had confirmed two BSE cases in animals born after 2001, but due to the long BSE incubation period, it is reasonable to expect that ongoing surveillance may detect additional cases in animals born after 1998.

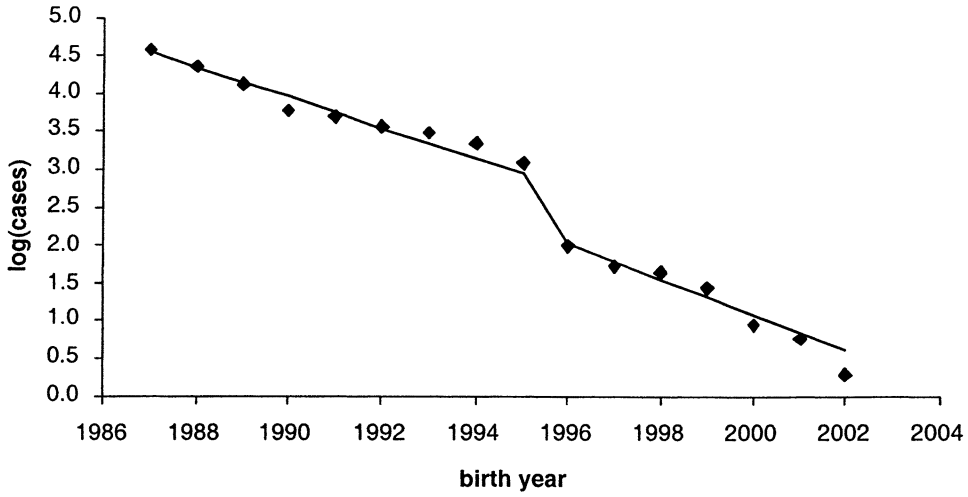
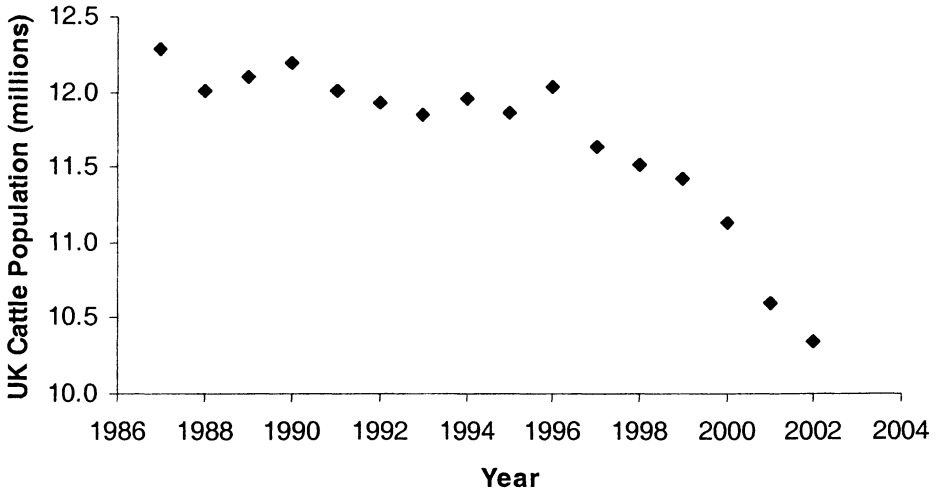


Figure 2.--Reduction in BSE cases in the United Kingdom by birth year, 1987-2002.

Source: DEFRA 2007a.

Shortly after the emergence of vCJD was publicly recognized in March 1996, the United Kingdom introduced several BSE-related measures, including the ban on the use of mammalian MBM in feed for all farm animals (the ''reinforced feed ban''), a selective cull, and the over-30-month rule limiting the age of animals that could be slaughtered for food. As shown in figure 3, the size of the United Kingdom cattle population began a marked decline in 1996, punctuated by a drop associated with the foot and mouth disease (FMD) outbreak in 2001.

Figure 3.--United Kingdom Cattle Population, 1987-2002



Source: DEFRA (2007b).

In addition to the declining cattle population size, other confounding variables, such as changes in cattle population demographics and BSE surveillance practices, make it difficult to ascertain the independent or marginal effect of any single measure on the decline of BSE in United Kingdom birth year cohorts. At this time, it appears that the confluence of events and measures of 1996 may have hastened the waning of BSE in the United Kingdom, but the decline was underway in 1988.

Issue: One commenter indicated that scientific studies in France and Britain have found that, after a ruminant-to-ruminant feed ban was put into place, the subsequent incidence of BSE was correlated to pig density, and that the new Canadian BSE feed rule, to be implemented in July 2007, is, according to the commenter, similar to, but weaker than, the September 1990 United Kingdom SBO [Specified Bovine Offals] ban. The commenter stated that, by not following the lead of the United Kingdom [and banning the feeding of all mammalian protein to food animals], the proposed CFIA SRM ban may reduce but will not eliminate the risk of BSE in Canada.

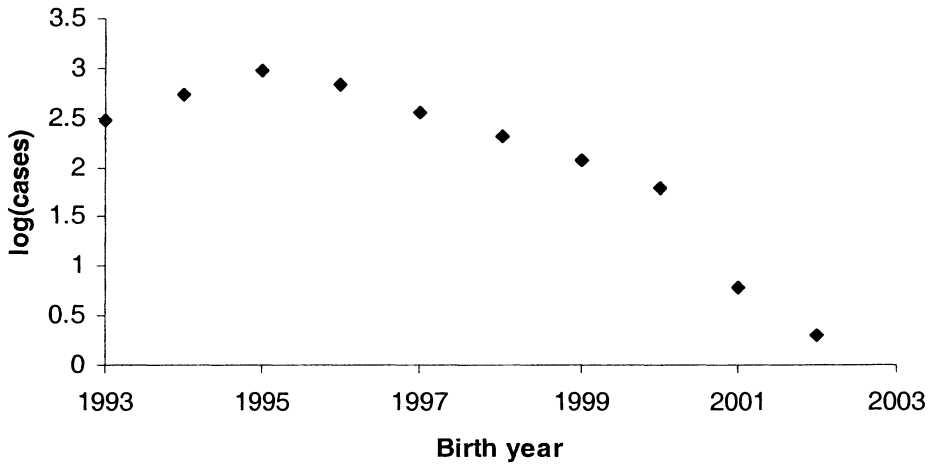
Response: Two studies—Abrial *et al.* (2005) and Stevenson *et al.* (2005)—indicate a correlation between cases of BSE born after a ruminant-to-ruminant feed ban was implemented and areas of higher pig density in France and Britain. These studies indicate the potential for cross-contamination of livestock feeds after ruminant-derived protein was excluded from ruminant feed. Eventually, each country and the EU adopted regulations prohibiting the inclusion of any animal protein in livestock feed. At this time, however, it is not possible to ascertain the extent, if any, to which establishment of a more restrictive feed ban had any impact on the rate of BSE decline in EU Member States beyond the feed controls already in effect.

As discussed previously, the number of BSE cases in United Kingdom birth year cohorts began to decline in 1988, the year the initial ruminant-to-ruminant feed ban was introduced. Although France initially introduced a ban on mammalian MBM in cattle feed in July 1990—not a ruminant-to-ruminant feed ban—the European Commission Scientific Steering Committee concluded that the French feed ban adopted in 1990 ''was likely not effectively enforced until 1994/1995.'' (ECSSC 2000, p. 30). Based on testing in 2001–2002, Bonnardiere *et al.* (2004) found a significant increase in French BSE prevalence between the July 1993–June 1994 and July 1994–June 1995 cohorts, followed by a significant decrease in BSE prevalence in birth cohorts born in France after June 1995. More recently, active surveillance during 2001–2005 also indicates that the number of BSE cases per cohort peaked in France in the 1995 birth year cohort and declined thereafter (EC 2006, table B20).

In Europe more generally, based on active surveillance during 2001–2005, the number of BSE cases per birth year cohort in the original EU Member States (EU 15), excluding the United Kingdom, was on the decline after the 1995 birth year cohort. In June 1994, the EU banned the feeding of mammalian MBM to ruminants. However, among EU members, only Belgium, Germany, Greece, Italy, Luxembourg, and Spain had no feed ban in place prior to the 1994 EU-wide measure (Court of Auditors 2001). In June 2005, the European Commission issued the ''Report on the Monitoring and Testing of Ruminants for the Presence of Transmissible Spongiform Encephalopathy in the EU in 2004'' and observed that the impact of the 2001 ''total feed ban'' (EU Regulation 999/2001) cannot yet be assessed due to the long BSE incubation period. As noted in the discussion of the decline of BSE in the United Kingdom, it is reasonable to expect that ongoing surveillance may detect additional cases in animals born after 1998.

The conclusion of our risk assessment that, over the 20 years of the analysis, the risk to the United States (i.e., the likelihood of establishment and the potential impacts of cases that may occur even without establishment of BSE) as a result of importing from Canada the bovine commodities considered in this rule is negligible, is not predicated on the eradication of BSE in Canada.

Figure 4.--Year of birth distribution in BSE cases detected in the EU-15 (excluding United Kingdom) during 2001-2005



Source: EC (2006, table B20).

Issue: One commenter indicated that year-of-birth data collected by the EU shows that, based on the number of BSE cases detected in the United Kingdom since 2001, there was a steady increase in the number of BSE-positive cattle born in the United Kingdom after its 1988 feed ban, beginning with cattle born in the year 1990.

Response: We disagree with the commenter. Since July 2001, when the EU-wide active BSE surveillance program commenced, an increasing proportion of the total BSE cases in the United Kingdom have been detected as a result of targeted (active) surveillance (DEFRA 2006b, figure 4.3). However, as shown by the EC (EC 2006, chart B1), the vast majority of BSE cases in the United Kingdom were detected by surveillance prior to 2001. Based on all available United Kingdom BSE surveillance data (DEFRA 2007), the number of BSE cases in United Kingdom birth year cohorts began to decline in 1988, the year the initial ruminant-to-ruminant feed ban was introduced.

For the reasons discussed above, we continue to consider it appropriate to apply our estimates of BSE prevalence in Canada to our risk assessment. As noted above, we used two related, but distinct, methods to estimate BSE prevalence in Canada, and addressed the uncertainty in the prevalence of BSE in Canada by considering prevalence estimates that differ by more than a factor of five. Although we consider the BSurvE Prevalence B estimate to be far more likely to be true than is the BBC estimate for the current standing Canadian cattle population, we consider the result of the BBC model as the more likely prevalence estimate to apply to the assessment of BSE risks associated with imports from Canada over the next 20 years.

Feed Ban in Canada

As discussed above, in our January 2007 proposed rule, we proposed to allow the importation of live bovines from BSE minimal-risk regions if the animals were born on or after a date determined by APHIS to be the date on and after which a ruminant-to-ruminant feed ban in the region of export has been effectively enforced. We noted that experience around the world in countries with BSE has demonstrated that feed bans are effective control measures, and that the incidence of BSE worldwide continues to decline because of these measures (OIE 2007a).

We indicated that, because of the demonstrated efficacy of an effectively enforced feed ban in reducing the possibility of exposure of cattle to the BSE agent, the OIE provides guidelines for trade in live cattle from regions that have reported BSE if such regions have an effective feed ban in place, provided the cattle were born after the date when the feed ban was effectively enforced (OIE *Terrestrial Animal Health Code*, Chapter 2.3.13). We proposed to consider March 1, 1999, as the date on and after which a feed ban has been effectively enforced in Canada. A number of commenters addressed Canadian enforcement of its feed ban, and also addressed the date we proposed to consider as the date of effective enforcement of a feed ban in Canada. Although some commenters specifically supported March 1, 1999, as the date of effective enforcement of a ruminant-to-ruminant feed ban in Canada, a number of other commenters disagreed that Canada was effectively enforcing a feed ban as of that date. Some commenters suggested alternative dates or time frames.

Issue: Several commenters stated that APHIS' determinations of the level of compliance with the Canadian feed ban and the time at which compliance was achieved are arbitrary and scientifically indeterminable.

Response: We disagree with the commenters. In January 2005, USDA sent a team to Canada to assess Canada's feed ban and its feed inspection program to determine whether the control measures put in place by the Canadian Government were achieving compliance with that country's regulations. APHIS conducted an extensive review of the feed ban in Canada. As part of its review, APHIS

analyzed CFIA's description of past cases of BSE in Canada, as well as historical inspection and compliance data related to the feed ban for the previous 3 years, educational materials, published notices, and the report of the International Review Team that was submitted to the U.S. Secretary of Agriculture in February 2004. Additionally, the U.S. team accompanied the CFIA inspection staff on inspections of randomly selected commercial feed mills and rendering facilities. At the facilities, the U.S. team observed the application of the inspection standards, observed manufacturing techniques, and discussed processes with facility personnel involved in various steps of feed manufacturing. In its report, the team concluded that Canada has a robust inspection program, that overall compliance with the feed ban in Canada is good, and that the feed ban is reducing the risk of transmission of BSE in the Canadian cattle population (USDA 2005). The team's findings support our conclusions regarding the level of compliance with the feed ban in Canada.

Issue: In our January 2007 proposed rule, in discussing our rationale for considering March 1, 1999, to be the date of effective enforcement of a feed ban in Canada, we stated that a 12-month period would generally be sufficient to allow purchased feed products that may contain MBM to be completely used. One commenter expressed uncertainty about that estimation and suggested that it might be advisable for APHIS to conduct a quantitative assessment of compliance with the feed ban to determine the date of its effective enforcement.

Response: We recognize uncertainty regarding the precise date on which Canada achieved effective enforcement of its feed ban, but we note that, given the extremely low prevalence of BSE in Canada along with the safeguards in the United States, the impact on the overall risk of a slightly earlier or later date would be minimal. Although reducing uncertainty can, at times, be achieved by performing more rigorous quantitative analyses, before attempting to reduce the uncertainty regarding any given factor or parameter—such as the precise date on which Canada achieved effective enforcement of its feed ban—it is important to examine the significance of the parameter to the overall risk result.

Issue: Several commenters stated that APHIS' calculation of the amount of time necessary for ruminant feed to cycle through the Canadian feeding system is irrelevant in the absence of effective enforcement of feed-ban regulations in Canada. The commenters stated that it was not until between 2000 and 2002 that Canada implemented inspections of feed and rendering facilities.

Response: The commenters' statement is not accurate. Inspections of rendering facilities and feed mills in Canada began immediately with the implementation of the feed ban in that country in August 1997. Rendering facilities were required to obtain an annual permit to operate, and issuance of a permit required an inspection of the facility. In addition, CFIA immediately began a program for inspection of commercial feed mills. All commercial feed mills were inspected in the first year after the implementation of the feed ban, with none of the feed mills found to be including prohibited material in ruminant feed. Thereafter, feed mills were on a 3-year inspection interval until 2002, when annual inspection of commercial feed mills was initiated.

Issue: A number of commenters stated that the diagnosis of BSE in cattle born after the establishment of a feed ban in Canada demonstrates that Canada's feed ban is either ineffective or not effectively enforced.

Response: We disagree with the commenters' conclusion. The commenters suggest that, in order for the Canadian feed ban to be considered effective, BSE surveillance data would have to demonstrate that the likelihood of BSE transmission in that country has been eliminated. However, as noted in our risk assessment, Canadian BSE surveillance data do not provide a statistical basis for distinguishing BSE prevalence among birth year cohorts (APHIS 2006b, p. 12); the overall prevalence is so low that distinguishing any difference is nearly impossible. In other words, the data cannot distinguish any significant difference in prevalence among animals born in different years, which would have been one way to demonstrate the effect of a feed ban (e.g., if the feed ban were implemented at the beginning of 1997, surveillance data showing a higher BSE prevalence in animals born in 1996 than in animals born in 1997 would support the effectiveness of the feed ban). However, in the absence of a feed ban that reduced exposure to BSE, we would expect the prevalence of the disease to increase over time. We have no evidence that such an increase has occurred, but we do have data that the feed ban is being enforced.

Furthermore, as we discussed in our risk assessment, detection of BSE in an animal born after the date a feed ban was implemented does not indicate an overall failure of the measures in place to stem transmission of the disease in that country. Most other countries that have experienced cases of BSE, have reported similar cases. Of 25 countries that have reported indigenous BSE cases, only 4 reported no cases in 2005–06 (OIE 2007). Human error is expected, which is why the feed ban is comprised of a number of interrelated measures that have a cumulative effect. Our risk assessment does not assume 100 percent compliance with all measures all of the time. We discussed factors related to the feed ban in Canada since before its implementation in 1997. We considered activities related to inspection and compliance with the feed ban, the rendering industry, the risk of cross-contamination, education activities and industry awareness, and on-farm practices that might contribute to the efficacy of the feed ban. In addition, we highlighted the fact that since the implementation of the feed ban on August 4, 1997, CFIA has continued to revise and strengthen its processes and procedures to further enhance the effectiveness of the feed ban. Canada's July 2007 modification of its feed ban to remove SRMs from all animal feeds, pet food, and fertilizer is a good example of such enhancements. We concluded that compliance with the feed ban measures in Canada continues to increase as the program evolves and that all of these factors have resulted in a cumulative reduction in the risk that Canadian cattle will be exposed to the BSE agent.

Issue: Several commenters stated that Canada cannot demonstrate that it has effectively prevented the feeding of ruminant material to cattle over the past 8 years. Commenters stated that eight or nine Canadian feedlots were discovered to still be feeding banned bone meal products, and that, because of their violations of the feed ban, 30,000 Canadian cattle were under quarantine. Additionally, one commenter stated that in March 2007, nine farms in Saskatchewan and as many as 8,000 cattle, deer, and other ruminants were quarantined after ruminant MBM was accidentally shipped to those farms from a Saskatoon feed mill. Another commenter stated that, in December 2006, Canada's Minister of Agriculture and Agri-Food acknowledged that up to 10,000 head of Canadian cattle on 113 different farms in the Provinces of Ottawa and Quebec had recently been fed feed contaminated with ruminant material.

Response: APHIS is aware of the incidents reported in late 2006 and in March 2007 and considered such incidences very carefully in its evaluation of the effectiveness of the

feed ban. However, it is not clear to us what the commenters are referring to regarding 30,000 Canadian cattle under quarantine.

It should be noted that the use of the term ''contaminated'' above refers to the potential inclusion in ruminant feed of MBM derived from ruminants, but not to the feeding of known BSE-contaminated material to ruminants. Feed control systems, including those in the United States, are inherently subject to human error such as occurred in these incidents. These compliance errors require follow up and correction by CFIA, just as in the United States such incidents would necessitate follow-up by the U.S. Human Health and Services, Food and Drug Administration (FDA). Following detection of these occurrences, CFIA conducted a detailed investigation and traced all potentially contaminated feed. CFIA accounted for and disposed of all feed that did not enter the distribution channels, and feed already distributed to farms was removed, disposed of, and replaced. CFIA conducted risk assessments to help evaluate the possibility that new cases of BSE would occur due to the contamination of feed with prohibited material, and concluded that the overall risk was negligible. Even though this finding indicated that it was highly unlikely that animals exposed to the involved feed would develop BSE in the coming years, in those instances where exposure to the feed could not be ruled out, the CFIA has excluded these animals and their meat and byproducts from export eligibility. This measure was established to meet the technical requirements of various trading partners and does not affect the movement or marketing of these animals within Canada. These findings, together with Canada's rapid and comprehensive response to the incidents, reinforces our confidence in the effective enforcement of Canada's ruminant feed ban.[7]

Issue: Some commenters questioned the effectiveness of Canada's feed ban, given evidence of contamination of ruminant feed with MBM derived from ruminants. One commenter stated that, in the five cases of cattle born after March 1, 1999, where investigations of BSE in Canadian cattle have been completed, the reported cause of BSE infectivity centered on ruminant MBM used in non-ruminant feeds cross-contaminating ruminant feeds, either during processing at the feed mill or during transport. Given that four animals were born after March 1, 1999, the commenters indicated that great care must be given to the analysis of these animals in the risk assessment and did not feel that APHIS thoroughly examined the cases.

Response: We agree with the commenters that the investigations of BSE in animals born in Canada in 2000 and 2002 suggest that these animals were most likely exposed during their first year of life to feed contaminated during processing (CFIA 2006a). Reports of the investigations identified incidents of concern in which ruminant feed was processed or transported immediately following the handling of nonruminant feed containing prohibited material. Such incidents were in contravention of Canadian regulations, which require flushing and/or clean-out between batches if ruminant feed is processed on the same lines as feed containing prohibited material.

We considered the issue of cross-contamination and concluded that Canada has implemented measures to prevent cross-contamination of ruminant feed with prohibited materials in the rendering and feed manufacturing industries are essential for implementation of an effective feed ban. We also considered other factors—including the regulatory actions taken to implement the feed ban, education and industry awareness efforts, inspection and compliance activities, and on-farm feeding practices—in our overall evaluation to determine the date the feed ban was effectively enforced in Canada and, based on those factors, identified March 1, 1999 as the date of effective enforcement of the feed ban.

APHIS did not specifically address each individual case of BSE in Canada in the risk assessment, as the available details of each epidemiological investigation did not contribute to the overall risk estimation. The risk estimation was based on consideration of all factors relevant in the risk pathway. These included consideration of the current Canadian feed ban, with explicit recognition that cases born after the feed ban was implemented in August 1997, or after the March 1, 1999 date have occurred and could continue to occur. The prevalence estimate acknowledges that BSE is present in Canada, albeit at a very low level. The risk reduction factors in the United States, including feed ban regulatory activities similar to those in Canada, were considered in the exposure assessment. The combination of all of these factors, including recognition that human error can occur in any step of the pathway, supported the conclusion that the risk to the United States of BSE—i.e, the likelihood of establishment and the potential impact of cases that may occur even without establishment—as a result of importing from Canada the bovine commodities considered in this rule is negligible.

Issue: One commenter stated that Canada has experienced an increase in the number of BSE cases since it instituted a feed ban in 1997.

Response: It appears that the commenter is equating the number of detected cases of BSE with the number of infected animals in a national herd. However, an increased number of detections of BSE does not necessarily mean an increase in prevalence. A BSE detection rate is dependent not only on prevalence, but also on intensity of surveillance. An increased number of BSE cases have been detected in Canada as that country has increased surveillance for the disease. As noted above, an APHIS analysis of the Canadian BSE surveillance data did not find a statistical basis for distinguishing BSE prevalence among birth year cohorts.

Issue: A number of commenters referred to the number of BSE cases in cattle born in Canada after March 1, 1999, as evidence that the date should not be accepted as the date of an effectively enforced feed ban. Commenters requested that APHIS reassess the proposed rule in light of recent diagnoses of such cattle.

Response: In the assessment of potential BSE risk we conducted for this rulemaking, we concluded that there is an extremely low likelihood that cattle born in Canada on or after March 1, 1999, will have been exposed to BSE. This conclusion does not mean that effective enforcement necessarily equals no instances of contravention of the feed ban, either accidentally or intentionally, just as isolated transgressions of U.S. laws do not necessarily constitute ineffective enforcement of those laws.

While specific incidents of cross-contamination can, and most likely will, happen, since no regulatory effort can ensure 100 percent compliance, the detection of BSE in several bovines in Canada born after March 1, 1999 does not negate the overall effect of the feed ban in decreasing the opportunities for transmission of disease. Empirical evidence from the United Kingdom has demonstrated, and simulation studies have reinforced, that implementation of a ruminant-to-ruminant feed ban leads to continued decrease in prevalence over time (Cohen, *et al.*, 2001; 2003; DEFRA 2006, EC 2003; 2005). Similar

[7] In the rulemaking for our 2005 final rule establishing criteria for recognition of a region as a BSE minimal-risk region, we discussed in detail our evaluation of Canada's veterinary infrastructure; disease history; practices for preventing widespread introduction, exposure, and/or establishment of BSE; and measures taken following detection of the disease (APHIS 2005).

effects of a feed ban have been seen in other countries in the EU, where there have been continued detections of BSE in cattle born after a feed ban is initially implemented. At the same time, however, the apparent number of cases of BSE identified in the EU–15 Member States has decreased every year since 2001. The available evidence leads firmly to the conclusion that animals born after the date of implementation of a ruminant-to-ruminant feed ban are far less likely to be exposed to the BSE agent (Heim and Kihm, 2003).

Issue: A number of commenters recommended various alternative dates or timeframes for consideration as the date of effective enforcement of a feed ban in Canada. Most of the commenters who recommended an alternative date expressed concern regarding the detection of BSE in bovines born in Canada after March 1, 1999.

The recommended alternative dates or timeframes included the following: July 1, 2007; the date of birth of the youngest bovine in Canada that has been determined to be BSE-positive; May 1, 2002; 5 to 7 years after the most recently diagnosed case of BSE in Canada; whenever Canada can verify 100 percent compliance with its ruminant-to-ruminant feed ban; a staggered system of dates that would increase the allowable age of bovines intended for importation from Canada as time progressed with no additional diagnoses of BSE in Canada.

Some of the commenters who suggested July 2007 as the date of effective enforcement based their recommendation on the fact that on July 12, 2007, Canada expanded its feed ban to prohibit the inclusion of SRMs in any animal feeds, pet foods, or fertilizers. One commenter asked how APHIS can be satisfied that the United States would be importing a safe product if Canada itself was not satisfied with the safeguards in place at the time the proposed rule was published, and subsequently took additional measures to strengthen its feed ban. A number of commenters recommended that the provisions of the proposed rule not be implemented until Canada bans all feeding of animal material to food animals. One commenter stated that July 2007 would be an appropriate point to begin the importation of breeding animals that have had exposure to processed animal feed, and that March 1, 1999 would be an acceptable date for bovines that have not been exposed to processed animal feeds—such as bison maintained by Parks Canada.

Several commenters, who expressed no animal health concerns with identifying March 1, 1999 as the date of effective enforcement of a feed ban in Canada, recommended that APHIS consider harmonizing the date chosen with the date Canada has identified as the effective date of a ruminant-to-ruminant feed ban in the United States, January 1, 1999.

Response: In prior rulemaking (APHIS 2005), we evaluated evidence (regulations in place based on statutory authority, adequate infrastructure to implement the regulations, and evidence of implementation and monitoring) in making the determination that compliance with the feed ban in Canada is good and concluded that the feed ban was effectively enforced. In our process of identifying the date of effective enforcement of a ruminant-to-ruminant feed ban in Canada, we considered Canada's implementation guidance and policies. For example, we considered the allowance of grace periods for certain aspects of the industry, in determining the practical implementation period for the feed regulations. Then we considered a sufficient time period subsequent to this implementation period to allow most feed products to cycle through the system, given the management practices in the country. We concluded, based on the above evaluations, that cattle born in Canada on or after March 1, 1999, can be imported into the United States with an extremely low likelihood that they have been exposed to the BSE agent.

As noted, a number of commenters recommended that APHIS consider July 2007, when Canada expanded its feed ban, as the date of effective enforcement of the Canadian feed ban. We consider the July 2007 expansion of the Canadian feed ban to be an enhancement of an already effective ban. CFIA, in explaining its rationale for the enhanced ban, emphasizes that, although surveillance results and investigations of BSE cases indicate that the feed ban in Canada has effectively reduced the spread of BSE since being implemented in 1997, even compliance with the ban's requirements left limited opportunities for contamination during manufacture, transportation, and storage that CFIA considered worth eliminating. In addition, the accidental misuse of feed on farms with multiple species could not be discounted. With the enhanced ban, CFIA projects that the eradication of BSE in Canada will be accelerated. Following such a regulatory path does not indicate that the feed ban in Canada prior to July 2007 was not effective or effectively enforced.

With regard to the recommendation that the date of effective enforcement of the Canadian feed ban be identified as the date of birth of the youngest bovine in Canada that has been determined to be BSE-positive, we do not consider such a change to be necessary or justified. The risk assessment we conducted for this rulemaking acknowledged that BSE exists in Canada and that there would likely be additional cases detected. March 1, 1999 was never intended to be an absolute cut-off point after which no new cases of BSE would be acceptable. The risk assessment concluded that, despite the likelihood of additional diagnoses of BSE in Canadian cattle, the proposed amendments would pose negligible risk to animal health and food safety in the United States. If an infected cow were to be imported into the United States, a series of strong safeguards would have to fail—in sequence—for that animal to pose any risk.

With regard to the recommendation that APHIS harmonize its identification of the effective enforcement date of a Canadian feed ban with the date identified by Canada as the date of effective enforcement in the United States, we do not agree that such a change would be appropriate or necessary. APHIS arrived at the March 1, 1999 date for effective enforcement of the feed ban in Canada by considering not only the date the feed ban was established in that country but also information provided by Canada regarding its implementation timetable, as well as feeding practices in that country. It does not necessarily follow that implementation events in the United States followed precisely the same track as those in Canada.

Issue: In our January 2007 proposed rule, we discussed the diagnosis of BSE in cattle in Canada born after March 1, 1999, and stated that ''such isolated incidents are not epidemiologically significant and do not contribute to further spread of BSE, especially when considered in light of the entire risk pathway and its attendant risk mitigations.''

Several commenters took issue with APHIS' description of the cases as ''isolated.'' Some commenters stated that ''isolated'' implies a solitary or separated condition, which cannot be said of the BSE cases recently confirmed in Canada. Further, other commenters stated the cases are linked by a trend in geographic location, with the last three cases occurring in the Province of Alberta. One commenter stated that of the nine cases of BSE detected in Canada, four occurred in cattle born after March 1, 1999, and that four of nine cases—or 44 percent—do not represent isolated cases and strongly disagreed that this date corresponds to

when Canada's feed ban became effectively enforced.

Response: We disagree with the comments, although we acknowledge that the term ''isolated'' could be interpreted in several ways. The use of the term in our proposed rule was not intended to imply that the cases were ''solitary or separated.'' Our use of the term ''isolated'' was intended to characterize the cases as being small in number and not indicative of a systemic failure of the feed ban in Canada, but rather the result of individual instances of error in contravention of the feed ban (*e.g.*, inadequate cleaning between handling of feed for non-ruminants and feed for ruminants).

For the reasons discussed above, we consider our determination that March 1, 1999 be deemed the date of effective enforcement of the feed ban in Canada to be reasonable, grounded firmly in the regulatory basis and operations of the ban in Canada, and entirely consistent with the science and with OIE guidelines. Accordingly, we are making no changes based on the comments.

Likelihood of Exposure of Cattle in the United States to BSE

The assessment is designed to estimate the likelihood of each of the multiple steps. Although we analyzed the likelihood of each individual step in the process occurring, we interpreted its significance in the context of the entire process.

As part of the risk assessment we conducted for our January 2007 proposed rule, we evaluated both the likelihood of ''release'' of the BSE agent into the United States and the likelihood of susceptible animals being exposed, given such release. We evaluated the pathways by which infected Canadian cattle, if imported, might expose U.S. cattle to BSE, and the likelihood that these pathways might lead to the establishment of the disease in the U.S. cattle population.

Several steps must take place for BSE to be transmitted to cattle in the United States from a bovine imported live from another country. A BSE-infected bovine must be imported into the United States; the infected bovine must die or be slaughtered; tissues from that animal that contain the infectious agent must be sent to a rendering facility; the infectivity present in these tissues must survive inactivation in the rendering process; the resulting meat-and-bone meal (MBM) containing the abnormal prion protein must be incorporated into feed; and this feed must be fed to cattle at a level adequate to infect the cattle. (The amount of infectious material required in feed for cattle to become infected is dependent on the age of the cattle; younger cattle are more susceptible to BSE and require less BSE-contaminated feed to become infected (Arnold and Wilesmith, 2004). We indicated in our risk assessment that the nature and likelihood of these pathways depend in large part on mitigations acting in series and in parallel that reduce the likelihood that BSE will be established in the United States.

A number of commenters addressed the issues of the likelihood of release of the BSE agent into the United States and the likelihood of exposure of U.S. cattle to BSE due to the importation of bovines from Canada. In general, the commenters said that we had underestimated the likelihood of release and/or exposure, or questioned one or more elements of our assessment.

Issue: One commenter, whose statements were referenced and supported by a second commenter, discussed the geographic distribution of BSE cases in Canada and expressed concern that Canada's experience demonstrates that certain locations in the United States might be more susceptible to BSE establishment than others. The commenter stated that events in Canada indicate that an average risk estimate is meaningless for BSE and demonstrates how ''hot spots'' (*i.e.*, locations that are more susceptible to spread of disease and, therefore, that have a localized higher BSE prevalence) allow BSE to propagate and spread. The commenter stated that the model-based predictions in APHIS' risk assessment are useless because the models do not account for geographic and other sources of heterogeneity and pointed to Alberta as a BSE hot spot. Further, the commenter indicated that the APHIS risk assessment has not provided any real data or relevant analyses related to BSE hot spot development and that APHIS has not quantified the risks that imports will create localized BSE hot spots in the United States. The commenter calculated that, if 5 percent of U.S. locations are potential hot spots, and 1 million animals are imported each year with six of them BSE-positive, the expected probability of at least one hot spot being activated in the United States is at least 77.7 percent.

Response: We disagree with the commenters. The available evidence provides no basis for distinguishing BSE prevalence among Canadian provinces. The commenter who singled out Alberta provides no analysis to support the hypothesis that the BSE prevalence in Alberta is higher than in other provinces. Through May 2007, reported BSE cases have originated in three western Provinces: Alberta (8 cases), British Columbia (2 cases), and Manitoba (1 case). No cases have been reported through May 2007 in the eastern Provinces. Intuition might suggest that the BSE prevalence is higher in Alberta. However, Alberta contains approximately 40 percent of the Canadian cattle herd. Other factors being equal, BSE is more likely to be detected in regions with large cattle populations.

Apart from the detected cases, geographically disaggregated data on BSE surveillance and Canadian cattle population demographics are not available. However, assuming that the total BSurvE points accumulated through August 15, 2006 (APHIS 2006c, table 4) were collected proportionally to the cattle population size in each province, table 3 presents the allocation of the random sample size equivalents (BSurvE points).

TABLE 3.—ALLOCATION OF BSURVE POINTS AMONG PROVINCES PROPORTIONAL TO HERD SIZE

Province	Cattle (000)*	Percent	BSurvE points	BSE cases**
Alberta	6,300.0	38.8	594,858.4	7
Manitoba	1,720.0	10.6	162,405.8	1
British Columbia	830.0	5.1	78,370.2	1
Saskatchewan	3,450.0	21.2	325,755.8	0+
Ontario	2,203.9	13.6	208,096.6	0
Quebec	1,455.0	9.0	137,384.0	0
Nova Scotia	107.0	0.7	10,103.2	0
New Brunswick	90.5	0.6	8,545.2	0
Prince Edward Island	84.5	0.5	7,978.7	0
Newfoundland	9.1	0.1	.....	.....

TABLE 3.—ALLOCATION OF BSURVE POINTS AMONG PROVINCES PROPORTIONAL TO HERD SIZE—Continued

Province	Cattle (000)*	Percent	BSurvE points	BSE cases**
Labrador	.....	.....	859.2	.....
Total	16,250.0	.....	1,534,357	9

*Source: Statistics Canada (2007).
**BSE cases reported through August 2006 were included in APHIS (2006c).
+The BSE case confirmed in May 2003 was born in Saskatchewan but reported in Alberta.

Based on this allocation of evidence, a binomial likelihood ratio test (Fleiss *et al.*, 2003) fails to reject the hypothesis that the provinces have the same BSE prevalence. That is, the result provides no basis for concluding that BSE prevalence varies among provinces. Depending on the method used to estimate provincial BSE prevalence, the test indicates that 11 to 20 BSE cases would have to have been observed in Alberta (or 4 to 7 cases in British Columbia) before rejection of the hypothesis.

The commenters provide no data or analysis related to BSE hot-spot development. APHIS' risk assessment discusses the apparent geographic clustering of Canadian BSE cases reported through August 2006 in three western provinces: Alberta, British Columbia, and Manitoba (APHIS 2006b, pp. 12–13). (In addition, the May 2003 case reported in Alberta was born in Saskatchewan.) However, APHIS also noted that the Manitoba BSE case was phenotypically different than the previously detected BSE cases of Canadian origin (APHIS 2006b). In addition, in its risk assessment, APHIS considered the CFIA report (CFIA 2006) that discusses geographic and temporal BSE clustering theories. APHIS concluded that the detection of further clusters (*i.e.*, linked cases) that might be defined in the future cannot be ruled out and did not assume that any Canadian provinces are BSE-free. While BSE case investigations may reveal associations among individual cases, such as a common feed source, the question of clustering is scale dependent. At a local scale, there may be associations between individual cases, but at a regional or national scale, the clusters themselves may be geographically dispersed. In addition, the geographic disease dispersal pattern may change over time due to the movement of cattle.

Further, the commenter provides no evidence or analysis to support the hypothesized sources of heterogeneity. On the contrary, disaggregating the available surveillance data into numerous strata to account for hypothetical sources of heterogeneity (geography, market class, etc.) generates substantial uncertainty within strata by diluting the sample size. One consequence of this practice (commonly called over-stratification) would be to inflate the upper confidence level risk estimates within putative strata (e.g., Alberta beef cattle).

With regard to quantifying the likelihood of imports creating localized hot spots in the United States, the commenter provides no data or analysis, and cites no existing scientific literature, in support of the hypothesis that some U.S. cattle-producing areas are—on average—more susceptible than others to the establishment of BSE. While such spatial heterogeneity is theoretically plausible, APHIS is unaware of any empirical data that would provide a statistical basis for distinguishing BSE susceptibility among U.S. cattle-producing locations. Although the commenter claims that the APHIS analysis represents an average risk estimate, the assessment does consider random variability on the national scale in the BSE reproductive rate (R_0) and the number of infected animals under each scenario or set of assumptions (APHIS 2006b). In essence, the commenter argues for a more disaggregated risk model that has random variability at the local level (in which regions are assumed to vary significantly from one another) rather than at the national level, but the comment does not provide any evidence in support of the hypothesis that such local differences (spatial heterogeneity) either exist, can be distinguished from a random distribution, or are of sufficient magnitude that they need to be accounted for by the model.

Finally, the commenter's calculation of a 77.7 percent probability of at least one U.S. hot spot being activated rests on two assumptions. First, the commenter assumes that the prevalence of BSE in Canada exceeds the APHIS prevalence estimate by a factor of 10. There is no evidence to support this assumption. Second, the commenter assumes that there is a 5 percent probability that Canadian cattle would be introduced into pockets within the United States where R_0 exceeds unity. (If R_0 exceeds unity (one), the disease will tend to spread. Conversely, if R_0 is less than unity, the number of cases will tend to decline over time, and ultimately the disease will die out.) Other than asserting the existence of such pockets and that 5 percent of U.S. locations may be hot spots, the commenter provides no evidence to support this contention. Even if the comment did provide such evidence, it would have to show that in such pockets the value of R0 substantially exceeds 1 in order for there to be evidence that a substantial impact is likely. For example, if $R_0 = 1.1$ and each generation of the disease (i.e., the time between infection of an animal and that animal's subsequent infection of another animal) lasts just 2 years, it would take 40 years for the disease prevalence to climb from 1 animal to 7. Finally, the commenter's suggestion supposes that no action would be taken to address vulnerabilities in a susceptible pocket if BSE did materialize. This assumption is inconsistent with APHIS' policy and record.

Issue: One commenter asked whether the expected number of imported animals by class (i.e., the intended use of the animal, such as for breeding, immediate slaughter, or feeding and then slaughter) needed to be validated or explored in the sensitivity analysis.

Response: We projected the expected number of imported animals by class because an animal's usage will govern at what age it goes to slaughter. How long a bovine lives will, in turn, have an effect on the animal's likelihood of developing detectable levels of BSE infectivity. The projected numbers of imports by age and use class used in our risk assessment were prepared for APHIS by USDA ERS. These values are based on USDA baseline projections, with specific factors considered based on the regulatory changes proposed. Additional details are provided in Appendix 1 of the Regulatory Impact Analysis and Final Regulatory Flexibility Analysis.

Although these estimates cannot be entirely certain, they are based on the input of experts in the fields of commodity projection and cattle markets iteratively refined with estimates from widely accepted models. Therefore, alternative plausible assumptions for the number of imported animals by class would not likely vary substantially from those based on the most current inputs. Hence, the import projections do not contribute significantly to uncertainty in the total estimated rate at which BSE may be introduced into the United States from Canada. In any case, new economic information based on market forces and age verification described above indicates that, compared to those used in the published risk assessment, the import projections should be revised downwards, especially estimates for the projected number of older cull animals. As a result, any potential release of BSE-infected animals should be lower than previously estimated. In addition, the key determinant of the impact of an introduction of BSE into the United States is its propensity to spread within the cattle herd. The risk assessment results indicate that, because the reproductive constant, R_0, remains consistently less than one, prevalence in the United States will tend to fall over time. (In order for the disease to spread, R_0 must exceed unity (one).)

Issue: One commenter stated that the incidence rate among just the older cattle covered by the proposed rule would be expected to be even higher than the overall incidence for all Canadian cattle slaughtered, thereby making the likely risk even greater.

Response: We are not certain what the commenter is referencing as ''overall incidence for all Canadian cattle slaughtered.'' We note that APHIS estimated the prevalence of BSE in the standing adult cattle population in Canada, not the BSE incidence in all Canadian cattle slaughtered. The Canadian BSE surveillance data provide no statistical basis for concluding that one birth-year cohort has a higher or lower BSE prevalence than another. Therefore, we assumed for our risk assessment that all animals in the current standing Canadian cattle population, including animals 30 months of age and older that are eligible for importation under this rule (as well animals that are not eligible for importation under this rule due to the birth-date requirement) have the same probability of BSE infection. However, it would not be surprising if animals born at an earlier date (i.e., either before or around the time the feed ban was implemented) have a greater likelihood of exposure to contaminated feed, and therefore could have a higher prevalence of BSE than animals born in later years. For this reason, we are restricting imports of live bovines from Canada to those born after the date when the country had an effectively enforced feed ban—which we have determined to be March 1, 1999. Additionally, of the live bovines we project will be imported following the effective date of this rule, greater than 80 percent of the animals are expected to be younger than 2 years of age at the time of importation.[8] Therefore, even if older animals had some significantly higher level of BSE prevalence (which is already reflected in the standing herd estimates), the fact that this rule excludes the importation from Canada of bovines born before March 1, 1999, along with the fact that the large majority of animals are expected to be young, would tend to decrease, rather than increase the overall risk from that which we have estimated.

Issue: One commenter indicated that Canada's BSE prevalence rate essentially guarantees (probability greater than 98 percent) that some BSE-positive cattle will enter the United States. Another commenter suggested that there is a 99.75 percent chance that one or more cattle that would test positive for BSE will be imported into the United States among the first million cattle that would be imported after adoption of the proposed rule.

Response: We note that prevalence refers to the proportion of BSE-infected animals, not the proportion of animals that would test positive for BSE. BSE-infected cattle are unlikely to test positive unless they are tested at a late stage of disease incubation.

Nevertheless, the commenter's estimated likelihood of entry of BSE-infected cattle is consistent with the APHIS risk assessment. The risk assessment clearly acknowledged the possibility of importing infected animals. Given the estimated current prevalence in Canada, table 7 in the risk assessment presents the projections for imports in the first year of implementation, including infected animals.

Issue: One commenter expressed doubt regarding the conclusion reached by the APHIS risk assessment that—because Canada's BSE prevalence will likely decrease over time, and because of the barriers to BSE transmission in the United States—the likelihood of BSE exposure and establishment in the U.S. cattle population as a consequence of the proposed rule is negligible. The commenter stated that the overlapping safeguarding measures described in the risk assessment have not prevented the continued spread of BSE in other countries (including Canada) that have relied on similar measures. The commenter further suggested that the measures have not been empirically tested or validated and cited the four Canadian BSE cases born in the years 2000 and 2002 as evidence that the measures are, in fact, ineffective to either reduce or prevent BSE infection.

Response: We disagree with the commenter's statements. Various data—epidemiological, modeling, and experimental—clearly demonstrate that the barriers discussed in the risk assessment and the proposed rule will decrease the risk of the introduction of BSE and its amplification. These barriers have been used internationally as strategies for the control and prevention of BSE. Furthermore, the barriers have demonstrated a striking effect in curtailing the epidemic and are responsible for the downward pressure on the prevalence of BSE observed in the United Kingdom and Europe. As described in the risk assessment: (1) Slaughter controls prevent the recycling of infectivity into human food and cattle feed; (2) rendering processes contribute to the inactivation of the BSE agent; and (3) feed controls prevent the recycling into cattle feed. In addition, there is epidemiological evidence of an age-related susceptibility to infection, which implies that the animal not only needs to be exposed to the BSE agent to become infected, but needs to be exposed with a sufficient dose at the time in its life that it is susceptible. For disease transmission to occur, the following events must happen in sequence: An infected animal dies or is slaughtered at a sufficiently late point in the incubation period to have significant infectivity present in certain tissues; those tissues go into the rendering system; some level of infectivity remains after the rendering process; the resulting protein is included in feed; and feed is fed to a ruminant in a sufficient amount at an age when it is susceptible. Although this could occur, the likelihood of it happening

[8] As discussed in the regulatory impact analysis APHIS conducted for this rule, most steers and heifers are ready for slaughter between 16 and 24 months of age, feeders are generally ready between 9 and 15 months of age, and vealers and light calves are slaughtered between less than 3 months and 8 months of age. In our analysis, we project that the total number of projected imports from Canada for these three categories of cattle in 2008 will be 987,000. This represents about 88 percent of the overall number of cattle projected to be imported from Canada in 2008. This percentage does not include imported replacement heifers and other breeding stock younger than 2 years of age.

repeatedly is negligible. This fact is demonstrated in the quantitative exposure model used in our risk assessment—i.e., transmission can occur, but it is not sufficient to sustain the disease (R_0 remains far less than one).

We reviewed Canada's feed production process (e.g., regulations in place based on statutory authority, infrastructure to implement the regulations, and compliance with the regulations). We used a peer-reviewed model to estimate the prevalence and determined that the prevalence in Canada is extremely low. We also used a peer-reviewed exposure model in our assessment of the risk (Cohen *et al.*, 2001; 2003). This model takes into consideration several parameter values that are based on experimental and epidemiological information related to BSE. These parameters represent key epidemiological elements related to the mechanisms by which BSE is transmitted. As we indicate in the exposure assessment, that assessment demonstrated that, because we expect Canada's prevalence to decrease over time, and because of the barriers to BSE transmission in the United States, the likelihood of BSE establishment in the U.S. cattle population is negligible. We reach the same conclusion even without assuming a drop in Canada's BSE prevalence over the next 20 years.

Issue: One commenter, in addressing risk mitigation measures in place in the United States, stated that several loopholes remain in the U.S. feed ban through which BSE infectivity could be introduced to cattle, despite recommendations from an APHIS TSE Working Group.

Response: APHIS has proceeded in a thorough and deliberative manner, in cooperation with FSIS and FDA, to determine the steps necessary to continue to protect animal and public health. APHIS has used a peer-reviewed model to assess the likelihood of exposure of cattle to BSE as a result of importing live cattle from Canada under the proposed rule (Cohen *et al.*, 2001; 2003). This model takes into consideration several parameter values relevant to the cattle production process, including what the commenter refers to as loopholes in the feed ban regulations. Even after considering these features of the U.S. system, the results indicate that the likelihood of BSE exposure and establishment in the U.S. cattle population as a consequence of infectivity introduced via imports from Canada is negligible.

Issue: One commenter stated that the models that Canada and the United States used in estimating BSE risk are not validated and have no predictive value. The commenter stated further that the predicted risks from the Harvard model would increase almost 15-fold if compliance is less than assumed in the base case.

Response: We disagree with the commenter's assessment of the quantitative exposure model we used in developing our risk assessment. As noted earlier, the plausibility of the model was established by comparing its predictions for Switzerland against the observed progression of BSE within that country's cattle herd (Cohen *et al.*, 2003). Although the model's performance in the United States has not been empirically evaluated (because there have been too few cases in the United States to do so), the use of models to characterize future risks is well-accepted in the scientific community.

The commenter cites an FSIS risk assessment (Cohen and Gray, 2005), which uses a version of the Harvard model, to argue that, if the misfeeding rate parameter is highly uncertain, the resulting range of results generated by the simulation model is likewise wide. As explained in the APHIS risk assessment, new information indicates that the original range of estimates for the misfeeding rate in the Harvard model as originally developed in 2001 were overly pessimistic. APHIS obtained new data and, using these new data in the Harvard model, reduced the range of the original estimates. Therefore, in APHIS' evaluation, the impact of misfeeding on the output of the model is much more modest.

Issue: One commenter asserted that APHIS' risk assessment model predicts low or ''negligible'' risks only if optimistic assumptions are made.

Response: APHIS disagrees with the commenter. The commenter simply cites the results of APHIS' own sensitivity analysis using ''pessimistic'' assumptions and provides no evidence or analysis demonstrating that the APHIS ''base case scenario'' assumptions are optimistic. APHIS combined qualitative and quantitative methods in its assessment of risk from live cattle. We qualitatively evaluated what we expect as the most likely scenario—prevalence drops in Canada over the next 20 years, resulting in decreases in potential release and exposure. While the commenter may consider this expectation an optimistic assumption, we do not and we note that this assumption is based on evidence from countries around the world that a feed ban provides continuous downward pressure on prevalence.

However, APHIS also considered other less likely (more pessimistic) scenarios, for which we assumed that the prevalence in Canada remained constant over the next 20 years, using a quantitative exposure model. The quantitative exposure model simulates the cattle management system in the United States, with assumptions made for certain variables, or parameters as input to this system. These parameters include BSE prevalence in Canada, which is an exogenous variable (and therefore, external to the U.S. system of mitigations), and many endogenous, or internal parameters. The endogenous parameters include various aspects of compliance with the FDA feed ban, how many carcasses enter the rendering system, what rendering processes are used, how rendered protein is incorporated into feed, and many other factors that can contribute to the spread of BSE. The values for each of these parameters basic assumptions that are meant to represent the most plausible and realistic representation of the U.S. system are reflected in the ''base case scenario.''

Assumptions regarding those parameters for which we have the least information (or the most uncertainty) were changed to more pessimistic, but still plausible, values in the sensitivity analysis, to evaluate the degree to which these changes would affect the results as compared to the base case. Given that at least one significant parameter—the constant prevalence of disease in Canada—was pessimistic even in the base case, we do not agree with the commenter's assertion that the quantitative model predicts low or negligible risk only if optimistic assumptions are used. Moreover, even under the more pessimistic scenario examined in the senstivity analysis, the reproductive rate of BSE (R_0) remains far below 1, indicating that the disease would not become established in the United States.

Issue: Several commenters stated that APHIS has not adequately considered the risk that imperfect compliance with U.S. SRM removal policies would have once we allow the importation of cattle over 30 months of age from Canada. One of the commenters stated further that APHIS provided no data or analysis in the proposed rule to address this series of known incidences of noncompliance.

Response: We disagree with the commenters. As noted in our risk assessment, the quantitative exposure model assumes that SRMs are effectively removed 99 percent of the time. This assumption is based on FSIS summaries of Noncompliance Records (NRs) performed from January 2004 to

May 2005 in about 6,000 federally inspected meat and poultry establishments. Based on these records, FSIS estimated that noncompliance with respect to SRM-related regulations had a frequency of less than 1 percent.

To explore the possible impact of assuming an arbitrary decrease (compared to the results of our exposure model) in SRM removal compliance on the availability of infectivity for human consumption, we can discuss the significance of an order of magnitude increase in available infectivity compared to our model's findings. First, we consider the results of that model, which used the unlikely assumption that prevalence in Canada (and thus the proportion of infected animals imported from Canada) remained constant over the next 20 years. In the model's scenario, the total amount of infectivity potentially available for human consumption over the 20 years of the analysis is 45 cattle oral infectious dose-50 units (ID_{50}s). (BSE infectivity is expressed in terms of cattle oral ID_{50}s. A cattle oral ID_{50} is defined as the amount of infectivity required to cause infection in 50 percent of an exposed cattle population (APHIS 2006)). The significance of cattle oral ID_{50} units to human exposure and susceptibility is not known; however, various studies suggest that the infectious agent may be 10 to 10,000 times less pathogenic in humans than in cattle because of a species barrier (EC SSC, 2000). Thus, if the cattle—human species barrier were 100, it would mean that 100 times more infective material would be required in order to have a similar probability of infecting a human as a bovine. Comer and Huntly (2003) estimated, after an evaluation of available literature, that 54 million bovine oral ID_{50} units were available for human consumption in Great Britain from 1980 to 2003. This extremely large amount of available infectivity has resulted in 165 cases of vCJD identified in the United Kingdom through April 2007, plus a few additional cases identified in other countries but attributed to exposure in the United Kingdom. When compared to the United Kingdom's BSE experience and the associated estimate of available bovine oral ID_{50} units, the expected, or average value of 45 cattle oral ID_{50} indicates that only a miniscule amount of the BSE infective agent that could possibly be available for potential human exposure in the United States over a 20-year period (APHIS 2006). (The potential for human exposure under this scenario is estimated at 1,200,000 times less in the United States than what the United Kingdom experienced during its BSE epidemic.) Even if compliance with the SRM ban were not as high as the 99 percent estimated in our exposure model, and we were to assume that the infectivity available for human consumption were increased by an order of magnitude (10x), it would still be far less than that estimated to have circulated in the United Kingdom and, we conclude, not to be of significance to human health.

Issue: One commenter stated that, although APHIS assumes that removal of SRMs from a bovine carcass will effectively shield consumers from exposure to BSE, numerous studies have demonstrated limitations on mitigating the risk of BSE exposure via SRM removal. In particular, the commenter stated that APHIS did not appropriately consider several studies (Buschmann, 2005; Iwamaru *et al.*, 2005; Hoffman, 2006) related to the distribution of SRMs, and that APHIS failed to explain why these uncertainties and concerns do not undermine its almost exclusive reliance on SRM removal requirements to protect American public health from potentially hazardous Canadian imports.

Response: We are aware of the studies cited by the commenter and do not agree that they question the efficacy of SRM removal. We acknowledge that studies using new methods that provide increased sensitivity will probably demonstrate the presence of PrP^{BSE} (the abnormal form of the prion protein) in various tissues. However, demonstrating the presence of PrP^{BSE} does not necessarily indicate the presence of BSE infectivity, especially if no infectivity is demonstrated via the most sensitive method available: Cattle-to-cattle exposure via intracerebral transmission. Therefore, one cannot automatically assume that a finding of PrP^{BSE} in a tissue means the tissue should be defined as an SRM. The OIE made this particular point in the *Terrestrial Animal Health Standards Commission Report, October 2006—Supporting Document for Chapter 2.3.13. Of the Terrestrial Animal Health Code on Bovine Spongiform Encephalopathy,* as follows:

> The availability of experimental infectivity data has significantly increased in recent years. During the same interval, extremely sensitive tests have been developed, including those employing highly sensitive transgenic mice strains and potentially more sensitive laboratory PrP detection methods. With the development of such highly sensitive methods, the probability of detection of PrP^{BSE} in tissues that are not currently listed as infectious is increasing. However, such findings need to be considered in context, and their relevance to establishing risk to consumers evaluated carefully when the quantity of PrP^{BSE} detected is potentially below the limit of detection of intracerebral (i.c.) cattle to cattle bioassay. By April 2007, 165 variant Creutzfeldt-Jakob Disease (vCJD) cases had been detected in the United Kingdom, a country where most probably the majority of the population was exposed to the BSE-agent. The latest models of the vCJD epidemic estimate that the potential scale of the clinical epidemic arising from food-borne exposure is unlikely to exceed 400 future cases in the United Kingdom (Clarke and Ghani, 2005). The relatively low number of predicted vCJD cases in relation to the massive exposure to the BSE agent is suggested to be due mainly to a significant species barrier between cattle and humans (Comer and Huntley, 2004; Bishop *et al.*, 2006).

APHIS is familiar with the results of the study (Buschmann, 2005) cited by the commenter in which tissues from a BSE-diseased cow were inoculated into genetically engineered (transgenic) mice that are highly susceptible to BSE and which over-express the bovine prion protein. Using this extremely sensitive mouse assay, this study demonstrated low levels of infectivity in the peripheral nervous system (*e.g.*, facial and sciatic nerves) of the infected cow. APHIS discussed these findings in its risk assessment and concluded that ''[g]iven all these factors there is not sufficient information to alter our understanding of the epidemiologically significant distribution of BSE infectivity in cattle.'' APHIS also acknowledges the results of Japanese studies in which PrP^{BSE} has been reported in the peripheral nerves of a case of BSE (Iwamaru *et al.*, 2005) and in some peripheral nerves of cattle slaughtered at abattoirs in Japan (Iwata *et al.*, 2006) by Western blot analyses. APHIS has also reviewed the German study in which infectivity was detected in the brainstem of an animal at 24 months post-infection (Hoffman, 2006). We have carefully considered all of these findings. USDA reviews and takes into consideration all BSE research for the definitions of SRMs, as does Canada and other countries internationally. As noted in the quote above, international policies regarding SRM removal have not changed based on the results of the studies discussed. Both the U.S. and Canadian policies regarding SRM removal are consistent with international standards.

Issue: One commenter referenced an FSIS study that found that the removal of SRMs can reduce human exposure to BSE by about 80 percent. The commenter stated that this level of protection is clearly inadequate to protect the United States from risks associated with the importation of older

cattle from Canada that represent an inherently higher risk for BSE. The commenter then referred to the sensitivity analysis APHIS conducted as part of its risk assessment, which incorporated a higher value for Canada's BSE prevalence than in the more likely base-case scenario. The commenter expressed concern that the sensitivity analysis revealed that 108 BSE infected cattle could be imported into the United States over the next 20 years and result in 12 new BSE cases in the United States.

Response: We disagree with the commenter regarding the significance and applicability of the cited study. In this response, we present a more appropriate study from which to draw useful inferences regarding the impacts of SRM removal.

The 2004 FSIS document referred to by the commenter—Preliminary Analysis of Interim Final Rules and An Interpretive Rule to Prevent the BSE Agent From Entering the U.S. Food Supply''—is an analysis intended to evaluate the major impacts of measures contained in the FSIS interim final rules published and implemented in January 2004. FSIS used the Harvard model in this analysis to estimate the benefits of these measures, specifically ''those [benefits] resulting from the reduction in human exposure to BSE infectivity.'' FSIS used this model to create a baseline estimate of potential human exposure and then evaluated three scenarios of risk mitigation options (*e.g.*, SRM removal) for comparison to the baseline. In each simulation, FSIS assumed that five infected animals were introduced into the United States in 2003, and then simulated the spread of BSE infectivity until 2020. The simulations of the risk mitigation measures were run assuming that the mitigations were implemented in 2004, *i.e.*, approximately 12 months after the introduction of infected animals. While the commenter is correct that this analysis demonstrated a reduction in potential human exposure of 80 percent, the comment does not accurately portray the context of this result. Given the assumptions used in the simulation (*i.e.*, the risk mitigation measures, including SRM removal, were not implemented until 12 months after introduction of infectivity), a certain amount of infectivity would have become available for human exposure before the mitigations measures were implemented in the model scenario. Therefore, the mitigation measures could never eliminate all of the infectivity available. Since all scenarios included at least some time in which the mitigations were not implemented, under the simulations, a certain amount of potential infectivity was allowed into inappropriate channels, such as human food. Because none of these scenarios incorporated the more realistic assumption that the mitigations were implemented (even imperfectly) throughout the simulation period, it is inappropriate to use this analysis as a citation for the level of public health protection provided by risk mitigation measures in place in the United States.

A more appropriate analysis for understanding the role of SRM removal in potential human exposure to BSE infectivity would be the FSIS update of the same Harvard simulation model that was available for public comment in 2006. APHIS cites the analysis in the risk assessment conducted for this rulemaking as Cohen and Gray (2005). This updated model used the ''base case'' as the circumstances in the United States prior to December 2003, and simulated the response of the U.S. system for 20 years following the import of BSE-infected cattle. FSIS' updated model estimated the impact of various risk management measures, including measures that were adopted, considered, or proposed by various agencies and groups. These simulations, where the risk mitigation was applied during the entire simulation, as opposed to the simulation in the analysis cited by the commenter (in which it was not), indicated that removing SRMs, as currently defined by FSIS, reduced potential human exposure by more than 99 percent, on average. This report also stated that ''[i]t is worth noting that these measures reduce what is already a small exposure in absolute terms.''

Issue: One commenter stated that SRM removal requirements have not been in place long enough for an effect to be determined, due to the exceedingly long incubation periods assumed for humans. The commenter stated further that the experience of other countries in which BSE has been detected (except for Canada) cannot be used to demonstrate that SRM removal is highly effective, because other countries have more stringent SRM removal requirements than do Canada and the United States and their experience is not applicable for predicting risk in the United States.

Response: The commenter appears to be questioning two points—first, whether SRM removal is actually highly effective in protecting public health, and second, whether experience in Europe can be used as a comparison for expectations in North America.

The commenter is correct in that there has been no specific controlled study that clearly and unequivocally demonstrates the effectiveness of SRM restrictions on protecting public health. The absence of such a study does not negate the fact, however, that substantial epidemiological and case evidence clearly indicate the success of such control measures. It is widely and generally accepted internationally, including by such international bodies such as the World Health Organization (WHO) and the OIE, that the primary public health protective measure regarding BSE is the removal of SRMs from the human food supply (WHO, 2002).

The OIE Scientific Revue notes the following: ''Excluding SRM from the human food chain effectively minimizes the risk of human exposure and is the most important measure taken to protect consumers. Failure to remove SRMs would probably expose a large number of consumers to an unnecessary risk.'' (Heim and Kihm, 2003). This point is also widely acknowledged in scientific literature, including articles cited by the commenter. For example, Bradley and Liberski (2004) conclude that ''risks to humans from infected cattle are now remote so long as the [bans on the use of SRMs in human food] are rigorously enforced.'' Fox and Peterson (2004) conclude that ''[a]doption of the human [specified bovine offal] ban in the United Kingdom in 1989 is probably the only example in the BSE story of a government going beyond expert opinion in taking a precautionary measure. It turned out to be the correct decision, and likely saved thousands of people from exposure to the disease.''

Simulation models and analysis conducted in the United Kingdom support the assumption that primary exposure sources for people were SRMs in the food supply prior to imposed restrictions. These models have been updated and revised repeatedly since the original identification of vCJD and the link to BSE in cattle (Ghani and others, 1998, 2000, 2001, 2003, 2005). They incorporate assumptions for all the parameters that could influence the course of vCJD in the United Kingdom—including assumptions about primary exposure from dietary sources, calculations about how many infected cattle may have been slaughtered at different points in time, what tissues from those animals were available for consumption, and what restrictions were imposed on the tissues and types of products available for consumption. The models are updated routinely to incorporate new information about vCJD cases as they are reported.

These models have been used to predict the course of the vCJD epidemic in the United Kingdom. Initially, the

projections were fairly high with considerable uncertainty. As more information is incorporated into the models, these projections continue to decline and the uncertainty levels also decrease. The number of clinical cases of vCJD in the United Kingdom has continued to decline since an apparent peak in 2000 (Andrews, 2007). This decline is consistent with projections made from the models, thus validating some of the assumptions used in the models. As an example, Cooper and Bird (2003) assume that the primary sources of exposure are the consumption of meat products—including mechanically separated meat and head meat—that were most likely contaminated with SRMs such as spinal cord, dorsal root ganglia, and brain. Restrictions on the inclusion of spinal cord and brain, among other tissues, were initially imposed in the United Kingdom in 1989. Restrictions on the production of mechanically separated meat, which included a significant level of infectivity from dorsal root ganglia, were imposed in the United Kingdom in 1995. Cooper and Bird (2003) concluded that ''[t]here is remarkable similarity between the age distribution and gender of simulated and observed vCJD patients, which supports (but does not prove) our assumption about the primary sources of exposure to BSE.''

The commenter notes the ''exceedingly long incubation periods assumed for humans.'' More recent updates of the models described previously have included estimates of the mean incubation period for vCJD (Ghani *et al.*, 2003) and estimated the mean incubation period for vCJD at 12.6 years when using the accumulated case data from confirmed vCJD cases. When additional information was added from results of a screening study performed on appendix and tonsil tissues, the mean incubation period was 16.7 years when fitted to this data. From this evidence, we can conclude that even the longer mean incubation period of 16.7 years would allow sufficient time to demonstrate the effect of SRM restrictions on the outbreak, since the initial SRM restrictions were imposed in 1989. We note that all vCJD cases that have been genotyped to date, with one exception, have been of the homozygous methionine (MM) genotype at codon 129 of the human prion protein gene. It is estimated that approximately 40 percent of the Caucasian population is homozygous methionine, with approximately 10 percent valine homozygous, and the remaining 50 percent heterozygous. While the effect of genotype on vCJD is still unknown, we can evaluate scenarios in the MM genotype as an example of epidemic progression, because this genotype may be the most susceptible and/or have shorter incubation periods than other genotypes.

The second point the commenter raises is whether there would be significant differences in potential public health exposure due to the different definitions of SRMs in Europe and North America (Canada and the United States). While these definitions identify essentially the same tissues, European regulations define tissues such as brain and spinal cord as SRMs in animals greater than 12 months of age, where North American regulations define these tissues as SRMs in animals greater than 30 months of age.

In the past few years, significant consideration has been given to the age limits on SRMs and their appropriateness. Additional information obtained from new research findings has contributed to these evaluations. Scientists in Europe have specifically examined these findings as part of their consideration on the age limit in cattle for the removal of SRMs (EFSA, 2005; 2007). In each of these opinions, they conclude that any likely detectable infectivity in the central nervous system (CNS)—including the SRMs in question—appears at about 75 percent of the incubation time. These opinions also note that the experimental low-dose scenarios are more likely to resemble the actual field exposure. The low-dose research scenarios are those in which calves were exposed orally to 1 gram of highly infective brain tissue, rather than the 100 grams used in the high-dose scenario. Experimental attack rate studies indicate that the incubation period for the low-dose scenario has a mean of 60 months, with a range of 45 to 73 months (Wells *et al.*, 2007). Using the low end of this range of incubation period, and assuming that infectivity is present in the CNS at 75 percent of the incubation period, they predict that infectivity would be sub-detectable or still absent in CNS in cattle aged 33 months.

In the United Kingdom, even including cases from the height of the BSE epidemic there, which are believed to have had shorter incubation periods than more recent cases, the peak age at onset of clinical signs was 5 to 6 years. This age of clinical onset is consistent with an assumption that the average incubation period in the United Kingdom has been about 60 months. The average age of animals identified with disease in the EU is higher than this—the average was 86 months in 2001 and has increased since then. This evidence indicates that considering certain tissues in bovines 30 months of age or older to be SRMs, and removing and disposing of those tissues, would eliminate the majority of infectivity present, and removing and disposing of these same tissues from bovines between 12 and 30 months of age would not provide any significant additional protection.

This same point is illustrated in various models. Comer and Huntly (2003) modeled the potential human exposure available in the United Kingdom from 1980 through 2002. They concluded that an estimated total of 54 million bovine oral ID_{50} units could have been consumed in that timeframe. This period included both the beginning of the epidemic in cattle, before the disease was recognized and public health control measures were established, and later in the epidemic when control measures were developed and instituted. Comer and Huntly also concluded that 99.4 percent of this estimated exposure was from animals older than 30 months of age. Therefore, SRM restrictions from animals greater than 30 months would reduce the vast majority of potential exposure.

In summary, we are in agreement with the conclusion that has been widely reached and that has generally been accepted internationally, that the primary public health protective measure regarding BSE is the removal of SRMs from the human food supply.

Issue: One commenter stated that APHIS' assertion that the rendering process is important in the inactivation of the BSE agent is overstated.

Response: As we stated in our January 2007 proposed rule, we recognize that standard rendering processes do not completely inactivate the BSE agent, and that rendered protein such as MBM derived from infected animals may remain contaminated. However, the rendering process is an important factor in BSE risk reduction for two reasons.

First, standard rendering processes will inactivate significant levels of any BSE infectivity that might remain in materials sent to rendering by subjecting the material to intense heat and pressure. The risk assessment conducted for this rulemaking noted that the rendering process has proven to be effective in reducing the level of infectivity. This is based on data regarding inactivation by various rendering methods (Taylor *et al.*, 1995; Taylor *et al.*, 1997). The assumptions on this point used in the quantitative exposure model have been previously explained (Cohen *et al.*, 2002, 2003) and include a range from 0 logs reduction in infectivity in a vacuum rendering

system to 3.1 logs reduction in a batch system. The proportions of cattle rendered in the various systems were also explained, with the majority of rendering (90 percent) done in either a continuous/fat-added system (providing a 2.0 log or 99 percent reduction) or a continuous/no-fat-added system (providing a 1.0 log or a 90 percent reduction). On average, the rendering process inactivates 1.4 logs of infectivity, or greater than 97 percent.

Additionally, rendering serves as a critical control point in redirecting ruminant proteins away from cattle feed. In the risk assessment we conducted for this rulemaking, we explained that the rendering process will contribute to the prevention of BSE as part of a series of sequential barriers, rather than as an independent barrier.

Issue: One commenter expressed concerns about plate waste as a potential pathway for BSE infection of U.S. cattle, because the proposed rule did not prohibit the feeding of plate waste, including beef, to cattle. The commenter referred to APHIS' risk analysis that accompanied the rulemaking related to the importation of boneless beef from Japan (70 FR 73905–73919, Docket No. 05–004–2), which concluded that the plate-waste pathway did not present a significant BSE risk, and stated that the conclusion reached in that risk assessment would not be applicable regarding beef from Canada, because the expected amount of product from Canada would be much greater than that projected for importation from Japan.

Response: We do not agree with the commenter that plate waste is a potentially significant BSE pathway due to this rule. In the risk analysis we conducted for the rule related to the importation of boneless beef from Japan, we discussed direct and indirect exposure pathways by which such beef might expose U.S. cattle to BSE if the product contained the BSE agent. In addition, we stated in unequivocal terms that the primary factors limiting the likelihood that whole cuts of boneless beef imported from Japan would expose the U.S. cattle population to BSE are (1) the inherently low risk of the product, (2) measures to prevent contamination, which would be the same for any beef from cattle from Canada that might become plate waste, and (3) the fact that the product is unlikely to be fed to cattle.

Although we recognized in our rulemaking for boneless beef from Japan that the product (inherently low-risk boneless beef) is not intended for animal consumption, we evaluated pathways by which some small fraction of the product might inadvertently be fed to cattle. We considered the possible pathways to include restaurant trimmings and plate waste, and the direct feeding of human food waste to cattle. We further evaluated pathways by which home food waste and plate waste can be fed directly to cattle, and we did not identify any epidemiologically significant pathways for exposure of the U.S. cattle population. Specifically for plate waste, which is allowed to be incorporated into ruminant feed, we considered that the amount of meat in the plate waste would be insignificant (Cohen *et al.*, 2001; 2003). Furthermore, because FDA requires that the plate waste be further heat processed for feed, it may be subject to rendering processes that will inactivate significant levels of the agent, further reducing the level of infectivity in the rendered product. (Cohen *et al.*, 2001; 2003).

The inherent (low risk) characteristic of the product imported under the Japan rule, coupled with the measures to prevent contamination of the product and the fact that the product is unlikely to be fed to cattle, were the primary factors in our evaluation. We did not dismiss any risk based on quantity. We considered the level of imports specifically under that rule as an additional limiting factor for any infectious material, if present, in the product.

Canadian cattle imported under this final rule will be slaughtered for edible meat production at slaughter plants within the United States and would be subject to FSIS' slaughter restrictions. These restrictions include ante-mortem inspection and prohibition of the slaughter of downer animals. In addition, FSIS requires the removal of SRMs, which is a critical risk measure preventing contamination of edible meat with BSE infectivity. We consider these measures, combined with the fact the edible meat is inherently low risk for the BSE agent, to be sufficient to mitigate the risk of exposing U.S. cattle to the BSE agent, if present, via plate waste.

Issue: One commenter noted that a peer reviewer of the 2005 Harvard Risk Assessment of Bovine Spongiform Encephalopathy Update: Phase IA suggested lowering the estimate that, at ante-mortem inspection, a Federal inspector will identify BSE symptoms in infected animals 90 percent of the time. The commenter stated further that the Canadian BSE cases have not been clinical suspects.

Response: The FSIS revision of the ante-mortem assumptions demonstrates that the assumed ante-mortem detection rate does not strongly influence the results of the analysis. The commenter noted that cutting the detection rates to 50 percent (ambulatory animals) and 25 percent (non-ambulatory animals) increases the projected number of infected animals by approximately 5 percent. Importantly from the perspective of APHIS, this revision had a limited impact on R_0. The revised FSIS assessment (dated December 26, 2006) included several changes relative to the original FSIS assessment (dated October 31, 2005).[9] The mean value of R_0 increased from 0.24 in the original FSIS assessment to a mean value of 0.27 in the revised FSIS assessment. The 95th percentile estimate for R0 increased from 0.45 in the original FSIS analysis to 0.48 in the revised FSIS analysis. In conclusion, the FSIS analysis indicates that changing the ante-mortem assumptions does not appreciably alter the projected spread of BSE. On the basis of the FSIS finding, APHIS concludes that a change in the ante-mortem detection rate of this magnitude does not qualitatively alter APHIS' conclusions, and therefore does not merit revision to the simulation model.

Issue: One commenter cited published literature described in the risk assessment to point out the levels (in grams) of highly infective brain tissue that resulted in infection of calves following experimental oral exposure. The commenter then asked if, after gauging what dosage is necessary to transmit BSE orally, the risk to each animal should be calculated based on the number of times it has a feeding.

Response: There is no need to revise the model in response to this comment for the following reasons. First, the model does not assume any threshold below which exposure to BSE would pose zero risk of infection. Second, and as a result of the first point, the model assumes that every exposure event incrementally contributes to the risk of infection.

Issue: One commenter noted that the number of infected animals that survive sufficiently long enough to develop clinical disease is always small in the exposure assessment (even under very pessimistic assumptions), and that, presumably, clinical animals will come primarily from those animals characterized as ''beef repro'' and ''dairy'' (APHIS 2006b, table 5). The commenter questioned whether the estimates of animals imported in these classes of animals and their time-

[9] The original and the revised FSIS assessments may be viewed at *http://www.fsis.usda.gov/Science/Risk_Assessments/index.asp.*

dependent removal (death, slaughter, and cull) rates from the population before clinical signs develop were realistic and validated.

Response: This comment appears to consist of two parts. In the first, the commenter asks if the estimates of numbers of imported breeding animals are realistic and valid, and in the second, the commenter asks if the time-dependent removal of these animals is realistic and valid. Because different sources of evidence support these two components of the question, we address them individually in the following discussion.

As we explained in response to another comment, our estimates of imports of all cattle classes, including breeding animals, were developed by USDA, ERS. They are based on a well-accepted, iterative method involving expert opinion and country-commodity specific modeling. Based on the above description of this process, we expect that alternative plausible assumptions for the number of imported breeding animals would not likely vary substantially from those based on the most current inputs.

With regard to the commenter's questions about time-dependent removal of these animals (i.e., at what point animals are removed from the cattle population by, e.g., slaughter) APHIS notes that imported animals are integrated into the U.S. herd and thus are removed (slaughtered) using the same distribution used for native-born U.S. cattle. The slaughter parameter used in the Harvard model (Cohen *et al.*, 2003) ''represents the probability that cattle will be sent to slaughter. This probability depends on the [animal's] type of production, age, and gender (e.g., steers and heifers are sent to slaughter earlier than dairy cows or reproductive beef animals).'' The developers of the model based the associated assumptions for the parameter on the following sources, listed in Cohen *et al.* 2003: USDA (U.S. Department of Agriculture 1998a), Radostits *et al.*, 1994, and several personal communications (Clay 2001; Crandall 2001; Pinter 2001). The model and its parameters have been subject to previous peer review and have been found to be realistic.

Issue: One commenter expressed concern that, if an undetected BSE-infected cow were imported into a family herd and, upon becoming incapacitated, were sent to a local small rural facility to be processed into beef for the cow's owners, BSE could enter the food chain.

Response: The commenter seems to be concerned about the possibility of BSE entering the human food chain after a cow is slaughtered for personal use at a custom slaughter facility. However, such usage would be in contravention of FSIS regulations. FSIS prohibitions on the use of SRMs for human food apply to cattle slaughtered for personal use at custom facilities, as does FSIS' prohibition of the use of all non-ambulatory disabled cattle in the human food chain (FSIS 2007).

Issue: A number of commenters recommended that the provisions of the proposed rule not be implemented unless focused testing for BSE of cattle imported from a BSE minimal-risk region is carried out at slaughter. A number of commenters recommended that any bovine 30 months of age or older imported into the United States from a BSE minimal-risk region be tested for BSE before being used for food. Several commenters recommended that USDA require testing for BSE of all cattle imported to the United States from countries in which BSE has been diagnosed, such as Canada. One commenter recommended that the proposed rule not be implemented until rapid-test technology for BSE is provided to all U.S. slaughtering facilities. Another commenter recommended that USDA allow slaughter establishments to conduct additional tests to satisfy consumer demands.

Response: Our peer-reviewed risk assessment concluded that the likelihood of BSE release from cattle imported from Canada is likely to be extremely low because (1) the prevalence of BSE in Canada is extremely low, and (2) measures requiring imported animals to be born on or after March 1, 1999, will further decrease the likelihood that those animals had been exposed to infectious material. Moreover, the exposure assessment for live animals qualitatively indicates that because of the barriers to BSE transmission in the United States, the likelihood of BSE exposure and establishment in the U.S. cattle population as a consequence of infectivity introduced via imports from Canada is negligible.

Further, although we understand the interest expressed by some commenters in testing certain cattle for slaughter, such comprehensive testing would not necessarily yield accurate or useful results. Current testing methodology can detect a positive case of BSE only a few months before the animal begins to demonstrate clinical signs. The incubation period for BSE—the time between initial infection and the manifestation of clinical signs—is generally very long—on average about 5 years, which means that there is a long period during which testing an infected animal would produce negative but incorrect results, especially if the animal is clinically normal. The import projections anticipate that the majority of animals imported for immediate slaughter and/or for feeding and subsequent slaughter are young animals, generally slaughtered at less than 30 months of age. Since current tests only determine the presence of BSE shortly before the likely onset of symptoms, testing young, apparently normal animals is not an effective use of the tests. In addition, since SRM removal requirements are in place, testing apparently normal animals at slaughter does not provide any significant additional public health protective measure. Heim and Kihm (2003) note that it is questionable whether testing all animals at slaughter provides any measurable increase in consumer safety. Additionally, they note that such testing can be counter-productive since measures such as SRM removal may not be sufficiently emphasized due to the perceived total reliability of the testing. Given that testing of clinically normal, apparently healthy cattle does not provide meaningful data, combined with the conclusions of the risk assessment concerning the extremely low likelihood of release and negligible likelihood of exposure and establishment in the U.S. cattle population, testing these animals at slaughter as commenters suggest is not appropriate at this time.

Issue: A number of commenters stated that APHIS should not expand the types of bovines allowed importation from a BSE minimal-risk region until it can be shown that the current U.S. regulations are being adequately enforced. Several commenters cited as an example of inadequate enforcement an incident involving the importation and movement to slaughter in the United States of Canadian cattle over 30 months of age. Of those commenters, some expressed concern regarding the time it took to trace the animals back.

Several commenters stated that records from Washington State suggest that Washington and several other States are having difficulty tracking hundreds of cattle that arrive from Canada each week. Other commenters stated that a number of cows entered the United States from Canada without ear tag identification or certificates of health, or had eartag identification that did not match the accompanying health certificate.

Response: The commenters referenced an alleged violation of the regulations in which imported Canadian feeder cattle

were reportedly sold through an auction market in the United States. A detailed investigation into the incident demonstrated that the animals in question were legally imported for immediate slaughter.

Commenters also referenced issues that State authorities identified in tracking imported animals. Certain States instituted policies or regulations that required additional movement controls and verification beyond the APHIS import requirements. In these instances, it is the responsibility of the State authorities to monitor compliance with their regulations and to follow up on any reported violations. APHIS can assist in resolving issues if requested.

APHIS port veterinarians inspect all live animal shipments entering the United States. These inspections include careful review of the health certificate accompanying the animals and a visual inspection of the animals. Live cattle presented at the port of entry with no accompanying valid health certificate are denied entry. We are not aware of any instances where shipments of cattle have entered through a designated port of entry without a health certificate. We recognize that animals can lose eartags at various points in the process and have established procedures to reapply eartags with appropriate documentation. In addition, apparent transposition of digits or similar errors in recording eartag numbers can often be addressed during consultation with CFIA and/or the private veterinarian involved.

APHIS is not aware of significant or repeated violations of the existing APHIS import regulations, and no evidence of such violations has been provided by the commenters concerned. Individual instances of errors or violations can, and have, occurred. These are investigated and dealt with appropriately. At no time have any of these errors presented a significant threat to animal or public health.

Issue: One commenter stated that the animal health risk assessment does not address the risks to the U.S. cattle industry, or to human health, of having additional BSE cases discovered in the United States.

Response: We disagree with the commenter. In our risk assessment, we addressed both the likelihood and the consequences of the adverse event of concern. We examined the likelihood of BSE becoming established in the United States, as well as the incremental consequences that may occur for every additional case that might be detected as a result of implementing the proposed rule. As discussed in the consequences section of the risk assessment, based on the responses to cases discovered in the United States since the initial finding of BSE in Canada in 2003, we do not expect additional costs (such as further closure of export markets or reduction in domestic consumption). When combined with the expected number of clinical cases, the resulting risk estimation is negligible, as discussed in the risk estimation section of the risk assessment. Determining what portion of the finding of negligible risk might be borne by the U.S. cattle industry, as the commenter requests, is unnecessary for the purposes of our risk assessment. Because we have determined the overall risk to be negligible, we do not consider it warranted to subdivide what is already a negligible risk in assessing its potential impact on various sectors.

The overall economic consequences of the proposed rule on trade were addressed by the Preliminary Regulatory Impact Analysis that was conducted for the proposed rule. That document concluded that, although larger net welfare benefits may be realized under the scenario of no restriction by date of birth on live bovine imports, the proposed rule is preferable because it would pose a lower risk of BSE infectivity entering the United States via imports of live bovines from Canada. In response to public comments, the revision of this analysis published with the final rule has further examined the welfare effects on certain sub-categories of the cattle industry.

As noted, the risk assessment specifically examines animal health, not human health. However, there would be no impact of detected cases on human health, because such animals would be removed from the human food supply. The risk assessment did, however, note the following and indicated that additional discussion of the human health aspects were included in the environmental assessment. ''Thus, although human health is not the focus of this assessment, we note that, even our quantitative model, which includes multiple sources of risk over-estimation, indicates that, over the 20 years of the analysis, only 45 cattle oral infectious dose-50 (ID_{50}) units will be available for human exposure.'' In comparison, as discussed above, Comer and Huntly (2003) estimated that 54 million bovine oral ID_{50} units were available for human consumption in Great Britain from 1980 to 2003. This extremely large amount of available infectivity has resulted in 165 cases of vCJD identified in the United Kingdom through April 2007, plus a few additional cases identified in other countries but attributed to exposure in the United Kingdom. When compared to the United Kingdom's BSE experience and the associated estimate of available bovine oral ID_{50} units, the expected, or average value of 45 cattle oral ID_{50} would result in a miniscule amount of the BSE infective agent that could possibly be available for potential human exposure in the United States over a 20-year period (APHIS 2006). The potential for human exposure under this scenario is estimated at 1,200,000 times less in the United States than what the United Kingdom experienced during its BSE epidemic. Whereas potential human exposure to infectivity is expected to be miniscule and epidemiologically insignificant, exposure (and hence potential human health impacts) due to detected cases would be nonexistent; detected cases of BSE are removed from the food supply.

OIE Guidelines

The OIE is recognized by the World Trade Organization (WTO) as the international organization responsible for development and periodic review of standards, guidelines, and recommendations with respect to animal health and zoonoses (diseases that are transmissible from animals to humans). The OIE guidelines provide a science-based reference document for international trade in animals and animal products. The OIE guidelines for trade in terrestrial animals (mammals, birds, and bees) are detailed in the Terrestrial Animal Health Code (OIE, 2006a). The OIE guidelines on BSE are contained in Chapter 2.3.13 of the Terrestrial Animal Health Code and are supplemented by Appendix 3.8.4 of the Code.

Some commenters stated that our proposed rule was inconsistent with OIE guidelines. We discuss below those areas addressed by the commenters.

Issue: Several commenters stated that the proposed rule is inconsistent with OIE guidelines because it did not require'as the commenters stated OIE guidelines recommend—that for countries that do not have an effectively enforced feed ban that is reducing the incidence of BSE, the vertebrae and all other SRMs be removed from cattle over 12 months of age.

Response: The OIE-recommended guidelines regarding BSE contain criteria for categorizing the risk of a country as either negligible risk, controlled risk, or undetermined risk. The basis for categorization encompasses several factors, including a risk assessment, surveillance efforts, regulatory structure for notifiable diseases, and education and awareness efforts. Canada has an effectively enforced feed ban. Further, Canada has been categorized by the OIE as

controlled risk (OIE 2007b), rather than as undetermined risk as implied by the commenters. The OIE guidelines recommend that certain SRMs be removed from cattle over 30 months of age for exports from countries that are considered controlled risk, and cattle over 12 months of age for exports from countries that are considered undetermined risk.

Issue: Several commenters stated that the proposed rule did not comply with OIE guidelines for either controlled risk or undetermined risk countries regarding the birth date of cattle in relation to the date of effective enforcement of a feed ban. The commenters stated that the OIE recommends that cattle not be exported from a country of undetermined risk for BSE, which the commenters stated Canada qualifies as, unless the cattle were born at least 2 years after the feed ban was effectively enforced. Nor, said the commenters, did the proposed rule meet the OIE guidelines that cattle not be exported from a controlled risk country until after the date a feed ban was effectively enforced.

Response: We disagree with the commenters. As noted previously, the OIE has categorized Canada as controlled risk. Our proposed changes are consistent with the OIE guidelines for trade in live animals from a controlled risk region. As part of the risk analysis that APHIS conducted in conjunction with its January 2005 final rule that recognized Canada as a BSE minimal-risk region, APHIS evaluated a series of measures introduced in Canada to prevent the feeding of ruminant proteins to ruminant animals. USDA considered the compliance activities reported by CFIA as well as epidemiological information in concluding that compliance with the feed ban was good, and that the feed ban was effectively enforced.

The OIE guidelines do not define how to determine the date the feed ban was effectively enforced. APHIS identified March 1, 1999, as the date of effective enforcement of the feed ban in Canada based on a careful evaluation of the full panoply of features employed by the feed ban and consideration of regulatory enforcement actions (i.e., a practical implementation period) and sufficient additional time to allow previously manufactured feed to cycle through the system.

Issue: Several commenters stated that APHIS published the proposed rule despite the fact that Canada does not meet OIE guidelines for testing for BSE, and requested that APHIS withdraw or delay this rulemaking until Canada significantly increases its BSE testing. One commenter stated that, to meet OIE testing guidelines, Canada needs to test with negative results 187,000 consecutively targeted cattle with a BSE risk equal to that in the casualty slaughter age between 4 and 7 years, in order to be confident that the BSE prevalence in Canada is not more than 1 in 100,000. However, said the commenter, Canada tested only 143,528 total cattle in the period from 2004 through February 12, 2007, with 8 positive cases found during that period.

Response: We disagree with the conclusions and assertions of the commenters. The OIE Terrestrial Animal Health Code, 2006, Appendix 3.8.4, contains guidelines for BSE surveillance. These guidelines describe a weighted points system for BSE surveillance samples and suggest total points targets for what is considered as either Type A or Type B surveillance. As noted in the Code, ''The application of Type A surveillance will allow the detection of BSE around a design prevalence of at least one case per 100,000 in the adult cattle population in the country, zone or compartment of concern, at a confidence level of 95 percent.'' Based on this definition, we assume the comments described above refer to Type A surveillance. The points target for Type A surveillance in a country such as Canada with an adult cattle population of more than 1,000,000 is 300,000 points, to be obtained over a 7-year period.

Under the OIE guidelines, specific ''point values'' are assigned to each sample, based on the surveillance stream or subpopulation of animals from which it was collected, as well as the likelihood of detecting infected cattle in that subpopulation. Table 4, below, outlines the point values for samples obtained from the different surveillance streams:

SURVEILLANCE POINT VALUES FOR SAMPLES COLLECTED FROM ANIMALS IN THE GIVEN SUBPOPULATION AND AGE CATEGORY

Surveillance subpopulation			
Routine slaughter	Fallen stock	Casualty slaughter	Clinical suspect
Age >1 year and <2 years			
0.01	0.2	0.4	N/A
Age >2 years and <4 years (young adult)			
0.1	0.2	0.4	260
Age >4 years and <7 years (middle adult)			
0.2	0.9	1.6	750
Age >7 years and <9 years (older adult)			
0.1	0.4	0.7	220
Age >9 years (aged)			
0.0	0.1	0.2	45

As demonstrated in table 4, a sample from the specific surveillance subpopulation where BSE is most likely to be detected—i.e., a middle adult clinical suspect—provides the most surveillance points. Conversely, a sample from the subpopulation where BSE is least likely to be detected—

generally routine slaughter—provides the least points.

It appears that the commenter calculated the number of samples necessary from an assumed surveillance subpopulation. That is, if a country samples only middle adult casualty slaughter animals at 1.6 points per sample, it would need to sample 187,000 cattle in this specific subpopulation to obtain 300,000 points.

However, it is inaccurate to compare such a calculation to Canada's surveillance efforts. The commenter referred to surveillance conducted in Canada from 2004 through February 2007—a period of slightly more than 3 years. However, as noted, the OIE guidelines provide for points targets to be met over a 7-year period. Therefore, a valid comparison of the OIE guidelines and the testing conducted in Canada would need to be based on surveillance totals from, e.g., January 2000 through December 2006.

More significantly, the commenter appeared to assume that Canada is sampling only one specific surveillance stream—casualty slaughter animals from 4 to 7 years of age. Attachment 1 of the risk assessment conducted for this rulemaking—''Estimation of BSE Prevalence in Canada (APHIS 2006c)''—contains tables that allocate Canadian surveillance samples into the different surveillance streams. In every year from 1999 through August 2006, animals from three different surveillance streams—fallen stock, casualty slaughter, and clinical suspect—of all ages were sampled. Therefore, the points value for each sample will vary in line with the previously provided table. A summary of OIE points can be calculated from the information provided. For example, data from surveillance conducted in Canada in 2005 for only one surveillance stream—clinical suspect—show that, in that year, 2 clinical suspects less than 2 years old were sampled (0 points), 43 clinical suspects 2 to 3 years of age were sampled (11,180 points), 120 clinical suspects 4 to 6 years of age were sampled (90,000 points), 68 clinical suspects 7 to 8 years of age were sampled (14,960 points), and 194 clinical suspects greater than 9 years of age were sampled (8,730 points). Testing of the 194 clinical suspects sampled in 2005 provided a total of 124,870 points for this 1 surveillance stream in 1 year. The total number of OIE points accumulated by Canadian surveillance over the 7-year period ending at August 2006 is 922,176. This far exceeds the OIE point target of 300,000 points for Type A surveillance.

Issue: Several commenters stated that the proposed rule did not comply with the OIE guidelines with regard to the importation of SRMs. The commenters stated that the OIE recommends that SRMs not be imported for feed or fertilizer and the proposed rule would allow SRMs to be used for non-ruminant feed and fertilizer.

Response: The commenters are correct that the OIE guidelines recommend that certain tissues—SRMs—should not be traded. Specifically, the guidelines recommend that SRMs ''should not be traded for the preparation of food, feed, fertilizers, cosmetics, pharmaceuticals including biologicals, or medical devices.'' It also states that ''protein products, food, feed, fertilizers, cosmetics, pharmaceuticals or medical devices prepared using these commodities (unless covered by other Articles in this Chapter) should also not be traded.'' However, the Code also includes guidelines for trade in live cattle—from which such materials could be derived after export to the recipient country—from countries of any risk status, thus creating an apparent contradiction in recommendations.

We recognized in our risk assessment that SRMs from live cattle imported under these conditions could enter the U.S. system, similar to SRMs from U.S. cattle. The assessment acknowledges that SRMs from imported animals—just as those from domestic animals—can enter the rendering system in the United States, and the quantitative exposure model in the risk assessment specifically simulates this situation.

Certain rendered protein products—bone meal, for example—can be included in fertilizer. However, this is not a common practice in the United States, as the vast majority of rendered protein products are sold for use in animal feed. Raw or untreated tissues are not generally used as fertilizer, and in fact are often prohibited from being spread on land. Therefore, any consideration of risk from fertilizer would be an evaluation of the risk of cattle exposure to oral consumption of fertilizer that contains in part rendered protein.

Our quantitative exposure model evaluates the potential oral exposure of cattle to feed containing infected rendered protein products. It does not specifically model potential exposure through fertilizer. However, it assumes that all rendered ruminant protein products are sold for feed use. Therefore, any of the infectivity contained in rendered ruminant protein is simulated through the potential for direct feed exposure—either through misfeeding, cross-contamination, or poultry litter. Feed constitutes a more significant pathway than potential consumption of a component of a fertilizer product after it is spread on a pasture. Therefore, any potential exposure through fertilizer would be assumed to be far less than exposure through feed, which is modeled in the risk assessment.

For the reasons discussed above, we disagree that this rule is inconsistent with OIE guidelines. In those cases where one might see in the OIE guidelines an internal contradiction, that contradiction is much more apparent then real, and we consider this rule to be consistent with the intent and objectives of the guidelines. Therefore, we are making no changes based on the comments.

International BSE Classification of Canada and the United States

Issue: At the time APHIS was accepting public comments on its January 2007 proposed rule, the OIE was in the process of completing its evaluation of countries internationally to determine which BSE risk category would be appropriate to each country evaluated. Several commenters recommended that our proposed rule be delayed until the OIE released its determinations. Commenters stated that waiting for release of the OIE designations would allow the U.S. categorization of BSE minimal-risk regions to be made consistent with OIE guidelines. Additionally, stated some commenters, the proposed rule could negatively influence the OIE's BSE risk categorization of the United States. One commenter recommended that the rulemaking be postponed until the European Food Safety Authority (EFSA) announced its BSE risk categorization of various countries, including Canada.

Response: Under the OIE risk classification system, a country can be considered to be ''negligible risk,'' ''controlled risk,'' or ''undetermined risk'' with regard to BSE. Based on the risk classification of a country, the OIE provides guidelines for the safe trade of cattle and cattle products. As noted above, at the May 2007 annual General Session of the OIE International Committee, a list of countries recognized as being BSE controlled risk or negligible risk was confirmed. Both the United States and Canada were confirmed as BSE controlled risk countries (OIE 2007b).

Request To Allow Imports From the European Union

Issue: One commenter requested that APHIS implement OIE import guidelines regarding BSE or,

alternatively, recognize the European Union as a BSE minimal-risk region.

Response: As noted above, it is APHIS' intent to develop rulemaking that would incorporate OIE guidelines.

Commodities Eligible for Importation Under This Rule

We proposed to allow the importation, under certain conditions, of live bovines for any use born on or after a date determined by APHIS to be the date of effective enforcement of a ruminant-to-ruminant feed ban in the region of export; blood and blood products derived from bovines; and casings and part of the small intestine derived from bovines.

Although commenters addressed the provisions of our proposed rule regarding each of these commodities, the great majority of commenters focused on the potential importation of live bovines. We discuss below first the issues raised concerning live bovines, then the commenter issues regarding bovine blood and blood products and then those regarding the small intestine, including casings derived from the small intestine.

Those commenters who addressed the importation of live bovines discussed which bovines should be eligible for importation with regard to usage and date of birth, identification of the animals, verification that the animals are imported in compliance with the regulations, sealing of means of conveyance carrying the animals, and monitoring of imported cattle once in the United States.

Live Bovines

Date of Birth Eligibility

Issue: A number of commenters questioned how it will be determined whether a bovine intended for importation from Canada was born on or after March 1, 1999. The commenters stated that it will not be feasible to use dentition to determine the age of imported bovines, particularly in animals over 4 years of age. In many cases, said the commenters, Canadian veterinarians would have to accept producers' statements as the only source of verification of the age of the cattle. The commenters stated that the Canadian national cattle identification program was not made mandatory until 2002, and that it is still not mandatory in Canada to enter the entire birth date information into the database. Several commenters stated that it is nearly impossible to verify the actual age of older Canadian cattle, because the Canadian animal identification requirement applies only to cattle that leave the farm.

Response: The provisions in § 93.436(a)(3) and (b)(4) of this rule provide that bovines are not eligible for importation from a BSE minimal-risk region unless they are accompanied by certification that, among other things, the animals were born on or after March 1, 1999. As provided in § 93.405(a), such certification must be issued by a full-time salaried veterinary officer of the national government of the region of origin, or by a veterinarian designated by the national government of the region of origin and endorsed by a full-time salaried veterinary officer of the national government of the region of origin, representing that the veterinarian issuing the certificate was authorized to do so. It is incumbent upon the individual issuing or endorsing the certificate to ascertain whether an animal's date of birth can be determined with the accuracy necessary for such certification. As the commenters imply, dentition can be used to adequately determine the birth date of animals below about 4 years of age. Specifically, if an animal does not have all of its permanent teeth erupted, it is less than 4–5 years of age and therefore was born after March 1, 1999. However, if all permanent teeth are present and in wear, dentition does not provide an estimate of birth date specific enough to support certification that the animal was born on or after March 1, 1999.

We recognize that Canada's mandatory identification requirements did not take effect until 2002, and also that these requirements do not mandate that birth date information be entered into the database. However, we also note that provisions have been established for birth date information to be entered at any time, with appropriate documentation available to support such information. The number of these age-verification entries continues to increase, with over 3.5 million birth dates submitted to the Canadian Cattle Identification Agency (CCIA) database by late 2006 (CCIA, 2006). We recognize that it is likely that owners of some bovines may not be able to provide the documentation regarding an animal's birth date that is necessary for the required certification. In those cases, even if an animal was born on or after March 1, 1999, the animal would not be eligible for importation into the United States.

Permanent Identification of Country of Origin

Issue: Under the provisions of the proposed rule, cattle imported from Canada for other than immediate slaughter would have to be permanently and humanely identified before arrival at the port of entry with a distinct and legible mark identifying the exporting country. As proposed, acceptable means of permanent identification would include a mark applied with a freeze brand, hot iron, or other method; a tattoo applied to the inside of one ear of the animal, or other means of permanent identification if deemed adequate by the Administrator. For bovines imported from Canada, a brand would have to read ''CAN'' and a tattoo would have to read ''CAN.''

A number of commenters addressed the issue of permanent identification of bovines as to the country of export. Several commenters recommended that the regulations require that such identification be applied with a hot-iron brand, and that a ''hair brand'' not be considered acceptable means of identification.

Response: A hair brand would not meet the requirements of the regulations, in that it could not be depended upon to provide permanent identification of the animal's country of export. However, we do not consider it necessary to list in the regulations all the forms of identification that would not be considered adequate to meet the intent of the regulations.

Issue: Several commenters addressed the requirement for permanent identification of the country of export as it would apply to bison. The commenters stated that a brand on the right hip or an ear tattoo are not the preferred alternatives, because of unnecessary stress on the animals and handlers. The commenters stated that a more humane means of bison identification, such as electronic tags (dual tags if necessary), could readily meet the need of tracking the origin of the bison and the movement patterns in Canada and the United States.

Response: The type of identification recommended by the commenters would provide the individual unique identification required by the regulations to facilitate traceback of the animal. Although the current regulations in § 93.436 require that such identification be provided by an official eartag of the country of origin, in August 2006 we have proposed to allow for forms of individual identification other than eartags.[10]

[10] We proposed (71 FR 45439–45444, Docket No. APHIS–2006–0026) to allow the individual identification to be provided with some form of identification other than an eartag. We solicited comments concerning our proposal for 60 days ending October 10, 2006. On November 9, 2006, we published a document in the **Federal Register** (71

Continued

However, we consider it necessary that the animal also be marked in some permanent and easily visible way as having been imported from a BSE minimal-risk region. In the case of bison from Canada, this would be a brand or other permanent ''CAN'' mark on the right hip, an ear tattoo with the letters CAN, or some other means of permanent identification if deemed adequate by the Administrator to humanely identify the animal in a distinct and legible way as having been imported from the BSE minimal-risk exporting region. The type of identification recommended by the commenters would not allow for easily visible identification of the country of origin.

Issue: A number of commenters disagreed that an ear tattoo would be an effective permanent means of identifying the country of origin of a bovine. The commenters stated that tattoos applied inside an animal's ear frequently become illegible after a period of time, and further, that tattoos may not be visible without catching the animal and examining it in a chute or other restraint system. The commenters recommended that, if tattoos are allowed, the regulations require that animals so identified be restrained and examined in the country of export to confirm that the tattoo is legible and permanent, and that such confirmation be indicated on signed documentation accompanying the animals to the United States.

Response: As discussed in our proposed rule, we agree that tattoos might not be the most readily visible means of identification of live animals in groups of animals. However, the purpose of requiring permanent identification of the animal's country of export is to expedite initial identification of an animal's country of export in the event the animal is diagnosed with BSE. Such a diagnosis cannot be confirmed on a live animal. Once the animal has been euthanized or has otherwise died, an ear tattoo will be an effective means of identification.

Issue: Several commenters stated that the APHIS Administrator should be required, upon request, to evaluate alternative means of permanent identification and, if they are functionally equivalent to the existing methods, be required to approve them.

Response: Paragraph (b)(2)(iii) of § 93.436 (of this rule provides for such approval by the Administrator of alternative means of permanent identification.

Issue: Several commenters recommended that a hot-iron brand on the right hip be required on all cattle crossing the U.S. border.

Response: As noted above, we proposed to require a permanent mark identifying the animal's country of origin only for cattle imported from a BSE minimal-risk region for other than immediate slaughter. We do not consider it necessary for cattle imported from a BSE minimal-risk region for immediate slaughter to be permanently identified as to country of export. Such animals will be moved to the slaughtering establishment in a group and the movement documentation accompanying such animals will be sufficient to provide ready identification of the animals' country of origin.

Issue: One commenter recommended that the regulations require that each animal entering the United States have permanent identification by which the animal could be traced back to its farm of origin.

Response: The commenter's recommendation refers to two types of identification that are already addressed by this rule. In this rule, paragraphs (a)(2) and (b)(3) of § 93.436 already require each bovine imported into the United States from a BSE minimal-risk region to be officially identified with an official eartag that provides unique individual identification that is traceable to the premises of origin of the animal. (As noted above, we have proposed to allow for forms of individual identification other than eartags). This rule requires, further, that no person may alter, deface, remove, or otherwise tamper with the official identification while the animal is in the United States or moving into or through the United States, except that the identification may be removed at the time of slaughter.

In addition to the individual identification that allows for traceback to the animal's premises of origin, the regulations also require that all cattle imported from a BSE minimal-risk region be permanently identified as to country of origin as described above. As discussed above, we do not consider it necessary for bovines imported for immediate slaughter to have this additional permanent identification as to country of origin.

Issue: One commenter requested that APHIS provide details of its protocol and criteria for ensuring that all live cattle imported from Canada have permanent identification maintainable until harvest.

Response: In § 93.436(b) of this rule, we give examples of means of permanent identification that would be considered acceptable. Acceptable types of permanent identification include a mark applied with a freeze brand, hot iron, or other method, or a tattoo applied to the inside of one ear of the animal. Any other types of permanent identification approved by the Administrator would have to be as effective as the examples cited in providing a permanent, distinct, and legible mark.

Individual Identification of Bovines

Issue: One commenter recommended that all cattle imported from Canada that are not moved directly to slaughter be required to be identified by a low frequency ISO compliant radio frequency tag placed in the left ear.

Response: As noted above, we have proposed to provide for forms of individual identification other than eartags, provided the identification can be used to trace the animal back to its premises of origin. We do not consider it necessary to mandate the use of any particular technology for meeting that criterion.

Issue: One commenter recommended that the regulations require that animals intended for importation into the United States from a country with a verified case of BSE be enrolled in a third-party source and age identification program that uses individual electronic identification devices.

Response: With regard to bovines intended for importation into the United States from a BSE minimal-risk region, the regulations already require that such animals be individually identified with unique identification that enables traceback to the premises of origin of the animal. Additionally, under this rule, bovines imported from Canada must be accompanied by certification issued or endorsed by the Canadian Government that the animals were born on or after March 1, 1999. After having evaluated the veterinary infrastructure of countries wishing to import animals and animal products into the United States, APHIS accepts official certification from those countries that commodities intended for export to the United States are in compliance with U.S. import regulations, just as U.S. trading partners rely on official U.S. certification that products exported from the United States meet the recipient country's requirements.

Sealing of Means of Conveyance

Issue: The regulations for importing live bovines from BSE minimal-risk regions have required that the bovines

FR 65758–65759, Docket No. APHIS–2006–0026) reopening and extended the comment period until November 24, 2006. We received a total of 10 comments by that date. We are considering the issues raised by the commenters and will address them in a separate rulemaking document.

be imported in a means of conveyance sealed in the region of origin with seals of the national government of the region of origin. In our proposed rule, we proposed to remove the requirement that bovines imported into the United States from BSE minimal-risk regions for other than immediate slaughter enter the country in sealed conveyances. We additionally proposed to remove the requirement that means of conveyance carrying bovines into the United States from minimal-risk regions for immediate slaughter be sealed in the region of export and to require instead that means of conveyance carrying bovines into the United States from Canada be sealed at the U.S. port of entry with seals of the U.S. Government.

Several commenters specifically supported the proposed change to require sealing of means of conveyance at the port of entry, rather than in the country of export.

One commenter stated that the proposed change to require sealing at the port of entry would allow APHIS less oversight of shipments and less opportunity to ensure that each animal in the shipment is accurately identified and of the appropriate age.

Several commenters recommended that APHIS specify which country or agency will be responsible for sealing a means of conveyance at the port of entry.

Response: We disagree that requiring sealing of means of conveyance at the port of entry will allow APHIS less oversight of shipments or cause decreased ability to ensure that the animals are being shipped in compliance with the regulations. The primary verification that the animals meet the requirements of the regulations will remain as it has been—i.e., certification by the country of export that the requirements of the regulations have been met.

However, we believe it is necessary to continue to require sealing of means of conveyance transporting bovines from Canada to immediate slaughter as a mitigative measure against diseases other than BSE. Cattle imported from Canada for immediate slaughter are not subject to tuberculosis and brucellosis testing requirements that would otherwise be applied to animals imported into the United States. Therefore, we would continue to require that such cattle be moved directly to slaughter in a sealed means of conveyance. (APHIS had been requiring such sealing at the port of entry even before our November 2003 proposal regarding BSE. However, the requirement for sealing was being done as APHIS policy, and was not specified in the regulations.)

As the commenters noted, this rule will remove the requirement that the sealing of the means of conveyance be done in the region of export. That requirement was included in the January 2005 final rule in response to comments from members of the public who expressed concern that requiring sealing at the port of entry could be harmful to the welfare and quality of the animals, due to delays at the port of entry. Under the provisions of this proposed rule, however, we do not expect undue delays of shipments at the port of entry. When a means of conveyance carrying bovines for immediate slaughter arrives at the U.S. port of entry, APHIS inspectors would confirm that the animals are as described on the certificate that must accompany the animals being imported, but generally would not require that the animals be offloaded from the means of conveyance. Therefore, requiring that the sealing of the means of conveyance take place at the port of entry would not cause measurable delay of the shipment. Further, sealing at the port of entry rather than in the region of export will reduce the time the animals will need to be contained in a sealed means of conveyance and reduce the likelihood that a seal will need to be broken between the time it is applied and the arrival of the animals at a slaughtering establishment.

We do not consider it necessary to specify which agency will seal means of conveyance at the port of entry with seals of the U.S. Government. In each case, the means of conveyance will be sealed by an APHIS employee.

Movement of Cattle for Other Than Immediate Slaughter

Issue: Some commenters who opposed allowing the importation from Canada of bovines 30 months of age or older urged the continuation of the current restrictions on movement in the United States of cattle moved to a feedlot, as well as continuation of the current requirements regarding sealing of conveyances carrying such animals and the requirement that the animals be accompanied by an APHIS-issued movement permit.

Response: The sealing and movement restrictions referred to by the commenters were included in our January 2005 final rule to ensure that live bovines from BSE minimal-risk regions were imported and slaughtered before the age of 30 months. At the time we published that final rule, we had not formally assessed the disease risk of allowing the importation of live bovines 30 months of age or older from BSE minimal-risk regions. Since that time, we have conducted an assessment of the risk of such importations, which we discussed in our January 2007 proposed rule and made available with that proposed rule. Our risk assessment indicates that there is a negligible likelihood of U.S. cattle being exposed to BSE and of BSE becoming established in the U.S. cattle population as a consequence of this rule.

Under this final rule, bovines from a BSE minimal-risk region will not have to be imported and slaughtered before they are 30 months of age. Therefore, it is not necessary to retain provisions in the regulations that were designed to help ensure that bovines imported from a BSE minimal-risk region are moved directly to a feedlot and then to slaughter as an easily identifiable group.

Request To Exempt Cattle for Immediate Slaughter From Birth Date Requirement

We proposed to require that live bovines imported from BSE minimal-risk regions have been born on or after the date recognized by APHIS as the date of effective implementation of a ruminant-to-ruminant feed ban in the region of export. We proposed to apply this requirement to all bovines imported from a BSE minimal-risk region, whether they are imported for immediate slaughter or for some other usage.

Issue: A number of commenters stated that the eligibility of cattle to be imported for immediate slaughter should not be dependent on when the animals were born. The commenters stated that such animals do not present a BSE risk justifying such a condition, and that APHIS has not demonstrated such a risk. Several commenters stated that the risk assessment APHIS conducted for the proposed rule is based on the premise that slaughter cattle will be eligible for importation from Canada no matter what their date of birth.

Additionally, commenters argued that requiring cattle moving directly to slaughter to have been born on or after March 1, 1999, would be inconsistent with the January 2005 final rule, which provided for the importation of beef derived from cattle of any age if requirements for the removal of SRMs are met. The commenters stated that allowing the importation of beef from cattle of any age while prohibiting the importation of cattle born before March 1, 1999, suggests that SRM removal can be accomplished more effectively in a foreign country than in the United States.

Commenters stated further that scientific evidence overwhelmingly demonstrates that the safety of food products derived from cattle is not dependent on the age of the animal, but on whether SRMs have been removed and disposed of. The commenters stated that complete control of cattle imported from BSE minimal-risk regions can be assured by requiring movement under Government seal, as we proposed. As an additional safeguard, stated the commenters, USDA regulations require that if an animal showing clinical signs of BSE risk is tested for the disease at slaughter, the carcass and parts derived from the animal cannot enter the food supply unless the animal tests negative for BSE.

Response: The commenters who recommended allowing the importation of cattle of any age from BSE minimal-risk regions, regardless of date of birth, raised several distinct issues in support of their recommendations. We agree with the commenters who stated that the removal and disposal of SRMs is the key factor in the food safety of products from bovines used for human consumption. However, the risk assessment conducted for the proposed rule specifically addressed the risk to animal health. The risk of transmission to U.S. cattle occurs when infectious tissues—most likely SRMs—inadvertently and/or in contradiction to U.S. feed regulations are rendered and included in ruminant feed and fed back to cattle. The risk of BSE-infected SRMs being present in the United States, while minimal, might be increased to some extent if cattle from BSE minimal-risk regions were allowed to be imported for immediate slaughter regardless of date of birth. The commenters are incorrect that our risk assessment did not take into account the date of birth of slaughter cattle. As described in the risk assessment, the requirement that animals for import be born after a certain date is one mitigation step that helps reduce the risk that infected animals will be imported, and therefore helps reduce the possibility that their SRMs will be incorporated into the ruminant feed chain in the United States.

Request for Restrictions on Use of Imported Cattle

Issue: As discussed above, we proposed to allow the importation of bovines from BSE minimal-risk regions for any use, provided the animals were born on or after the date recognized by APHIS as the date of effective implementation of a ruminant-to-ruminant feed ban in the region of export. This provision allows bovines to be imported for immediate slaughter or for some other usage, such as breeding or feeding and then slaughter. It differs from the regulations, that have been in place, which have limited the importation of bovines from BSE minimal-risk regions according to both the age of the animal and the intended usage of the animal in the United States (only those animals moved to immediate slaughter, or to one feedlot and then directly to slaughter, have been eligible for importation).

A number of commenters opposed the proposed removal of restrictions on how cattle imported from BSE minimal-risk regions may be used. Although most of these commenters did not object to the importation of cattle born on or after the date of effective implementation of a feed ban if the cattle were moved in a sealed means of conveyance directly to immediate slaughter, or to a single feedlot and then to slaughter, they expressed concern regarding the potential importation of cattle intended for breeding or as replacement animals in dairy herds.

Some of the commenters stated that BSE-infected cattle imported from BSE minimal-risk regions for breeding or herd replacement may not show clinical symptoms of BSE infection for many years, allowing BSE to incubate in U.S. cattle herds, and that an outbreak of BSE in the United States due to such imported cattle would be devastating to the U.S. dairy industry.

A commenter stated that, at the 95th percentile confidence for model simulations of Canadian BSE prevalence in the APHIS risk assessment, 180 new BSE cases occur over 20 years, and that 90 percent of these new cases would be expected to be in animals already infected with BSE when imported from Canada. Therefore, stated the commenter, almost all new cases of BSE expected in the United States will be from BSE-infected cattle imported from Canada and that any U.S.-born cases will be the result of importing breeding animals. Commenters stated further that, according to USDA, younger cattle are more susceptible to BSE and require less BSE-contaminated feed to become infected, and that since it is likely that younger cattle will be the ones imported for breeding or replacement purposes, the chance of introducing BSE into the United States from Canada is magnified.

Commenters stated that, although a series of risk mitigations are in place, these are different when it comes to animals imported for breeding versus those going directly to slaughter.

Response: The risk of BSE transmission to U.S. cattle occurs when infectious tissues—most likely SRMs—inadvertently and/or in contravention of U.S. feed regulations are rendered and included in ruminant feed and fed back to cattle. This risk is the same whether the animals were imported for immediate slaughter or were imported for breeding and are slaughtered later, and the series of risk mitigations or steps that prevent the transmission of BSE are the same, regardless of the purpose of the imported animal. While it is true that the level of infectivity in a BSE-infected bovine has been shown to increase as an animal ages, the amount of infectivity in, for example, a 7-year-old cow infected at 1 year of age would be the same at slaughter whether it was imported as a 1-year-old infected cow and used for breeding in the United States until it was 7 years old, or whether it was imported as a 7-year-old cull cow for immediate slaughter.

The U.S. feed ban prohibits the use of most mammalian protein in ruminant feed. The mammalian protein referenced could be derived from slaughterhouse offal—including SRMs—from animals imported for immediate slaughter, or from slaughterhouse offal derived from animals imported for breeding that have reached the end of their useful life in the United States. The protein could also be derived from the carcass of an animal imported for breeding that died other than by slaughter. The feed restrictions on the use of rendered protein derived from any of those scenarios would be exactly the same.

The commenters are correct that BSE-infected cattle may not show clinical signs for many years, due to the long incubation period for this disease as explained in the risk assessment. However, as long as the animals were born on or after March 1, 1999, the likelihood of any individual animal having been exposed to and infected with BSE, and subsequently releasing BSE infectivity into the United States, is negligible. There is no expected difference in the likelihood of BSE infection in two animals born on or after March 1, 1999, and raised in Canada, one imported into the United States as a young animal for breeding purposes and slaughtered at the end of its productive period, and one used as a breeding animal in Canada, and exported for immediate slaughter in the United States at the end of its productive period. Furthermore, BSE is not a contagious disease and does not spread by casual animal contact. Therefore, while an individual animal in a herd may be infected, that does not mean that other animals in that herd are at risk of becoming infected via spread from that animal.

Regarding the commenter's reference to our model simulation, we believe the commenter did not correctly interpret the results from the simulation. For sensitivity analysis 5 (pessimistic value for assumed BSE prevalence in Canada), the 95th percentile value for total infected cattle in the United States over a 20-year period amounts to 180 animals. The 95th percentile value for endogenous BSE-infected cattle over that period is 75, suggesting that 180 − 75 = 105 BSE cases are imported over that period, not 160 animals, as suggested by the commenter.[11]

Also, although our quantitative exposure models project that new cases of BSE in the United States would be transmissions secondary to the importation of infected cattle from Canada, we note that the United States has identified two indigenous cases of BSE. Given this fact, one cannot categorically state that any such cases identified ''will be from BSE-infected cattle directly imported from Canada.''

We explained in the risk assessment that there is an apparent age-susceptibility in regard to BSE, specifically noting that susceptibility in cattle declines with age. However, we disagree with the commenter's conclusion that, based on this fact, importing younger animals—specifically breeding animals as they are generally imported at less than 2 years of age—presents a magnified risk. Susceptibility is not the same as likelihood of being infected. As an example, the commenter's conclusion means that any animal born within the past 2 years would have a higher likelihood of being infected than an animal born 6 years ago. Given equal exposure a younger animal may be more susceptible to infection. However, as noted in the risk assessment, the overall prevalence in Canada is extremely low and BSE controls such as the feed ban are effectively enforced, so the chance that a given animal of any age had been exposed to an adequate amount of infectivity at a susceptible age i.e., the likelihood of being infected) is extremely small.

[11] Note that this estimate for the 95th percentile for imported cases (105) is approximate. The 95th percentile values for the total number of infected animals (180) and the number of endogenous cases (75) are estimated independently. In particular, all of the trials are first ranked according to the total number of endogenous cases, allowing identification of the 95th percentile value. The same is then done in order to identify the 95th percentile value for the total number of BSE cases. As a result, the 95th percentile values may be selected from different simulation trials. Because the number of endogenous cases influences the number of total cases, these two quantities are (imperfectly) correlated, however. That is, simulation trials that project a large number of endogenous cases also project a large total number of BSE cases. Hence, the actual 95th percentile value for the total number of imported BSE cases is likely to be similar to 105.

Monitoring of Imported Cattle

Issue: A number of commenters expressed concern that the proposed rule did not explicitly provide for a system to monitor the movement in the United States of cattle imported from BSE minimal-risk regions, specifically Canada. Some commenters limited their discussion to cattle 30 months of age or older. Commenters recommended that the regulations include an accounting procedure capable of monitoring the movement of imported animals from entry into the United States until slaughter, including changes in ownership of the animals.

Response: The regulations currently include movement conditions for bovines from BSE minimal-risk regions imported for other than immediate slaughter. Such bovines must be imported in a sealed conveyance and be moved directly from the port of entry to a feedlot identified on APHIS Form VS 17–130 or other movement documentation required by the regulations. The APHIS Form VS 17–130 or other movement documentation must identify the physical location of the feedlot, the individual responsible for the movement of the animals, and the individual identification of each animal. The bovines must remain at the feedlot until transported from the feedlot in sealed conveyances to a recognized slaughtering establishment for slaughter. While being moved to slaughter, the bovines must be accompanied by APHIS Form VS 1–27 or other movement documentation deemed acceptable by the Administrator, which must identify the physical location of the recognized slaughtering establishment, the individual responsible for the movement of the animals, the individual identification of each animal.

In our January 2007 proposed rule, however, we proposed to remove each of the above requirements from the regulations. The requirements described above were implemented solely to help ensure that cattle imported from BSE minimal-risk regions were slaughtered at less than 30 months of age—i.e., to preclude any diversion of the bovines to other uses in the United States that would result in a slaughter at some age 30 months or older.

We did not attempt, for that rulemaking, to assess the BSE risk associated with the importation of live bovines 30 months of age or older from a BSE minimal-risk region. However, as discussed in our January 2007 proposed rule and in this final rule, for this rulemaking we did assess the BSE risk associated with the importation of such animals, and concluded that the resulting BSE risk from the importation from Canada of bovines born on or after March 1, 1999—whether or not the bovines are 30 months of age or older when imported and slaughtered—would be negligible. Therefore, in our January 2007 proposed rule, we proposed to remove the requirement in § 93.436(a)(1) of the current regulations that live bovines imported from BSE minimal-risk regions be less than 30 months of age when ported into the United States and when slaughtered.

With the removal of the less-than-30-month age restriction on the importation of bovines from BSE minimal-risk region, any cattle imported from Canada—once certification has been presented to APHIS that the animals were born on or after March 1, 1999—will be able to be moved and handled in the United States in the same way as U.S.-born cattle.

Scientific evidence strongly indicates that BSE, unlike most transmissible diseases of cattle, is not transmitted from live animal to live animal. BSE is not a contagious disease and, therefore, is not spread through casual contact between animals. Scientists believe that the primary route of transmission requires that cattle ingest feed that has been contaminated with a sufficient amount of tissue from an infected animal. Therefore, even a BSE-infected bovine poses no BSE risk to other bovines unless those other bovines are fed BSE-contaminated materials from the infected animal. This route of transmission can be prevented by excluding potentially contaminated materials from ruminant feed, as is required in the United States.

If a bovine imported from a BSE minimal-risk region were diagnosed as being infected with the disease, from a biosecurity standpoint, it would not be necessary to know its record of movement while in the United States. However, we would proceed to trace the bovine back to its herd of origin, in order to identify birth cohorts of the animal. Traceback to the animal's premises of origin would be facilitated by the animal's unique individual identification, which is required under the current regulations and continues to be required by this rule, and which must be traceable to the premises of origin of the animal.

Issue: Several commenters stated that imports of bovines under the proposed rule should not be allowed until a mandatory cattle and premises identification program is implemented

throughout the United States. At the minimum, stated one commenter, USDA should amend the National Animal Identification System policy to allow for and integrate with mandatory identification when required for animal health programs.

Response: As discussed in the preceding response, one of the requirements for the importation of bovines from BSE minimal-risk regions is that each animal have unique individual identification that is not removed from the animal, except at slaughter. Such identification is in addition to any cattle or premises identification that might be carried out under the U.S. national animal identification system, and would facilitate tracing an imported bovine that is determined to be infected with BSE to its herd of origin.

For the reasons discussed above, we are making no changes based on the comments regarding the monitoring and identification of cattle imported into the United States from a BSE minimal-risk region.

Feed Cohorts of BSE-Infected Animals

Issue: Several commenters stated that the regulations should specifically prohibit the importation from BSE minimal-risk regions of feed cohorts of BSE-infected cattle.

Response: We do not consider it necessary to add such a provision to the regulations and are making no changes based on the comments. Our definition of a BSE minimal-risk region in § 94.0 of the regulations includes a requirement that such regions conduct an epidemiological investigation following detection of BSE sufficient to confirm the adequacy of measures to prevent the further introduction or spread of BSE, and continue to take such measures. We described such investigations in our January 2005 final rule, as well as in the proposed rule and the risk analysis for that rulemaking. This description noted that CFIA conducts comprehensive epidemiological investigations, and one component of these investigations is to trace feed cohorts of confirmed BSE-positive cattle, in accordance with OIE guidelines. As a result of these traces, feed cohorts that remain alive are euthanized and tested for BSE. Therefore, since such animals would be euthanized, there is no need to specifically prohibit their importation.

Maternal Transmission of BSE

Issue: One commenter stated that APHIS' policy of destroying progeny of BSE-positive cows, in accordance with OIE guidelines, demonstrates that APHIS acknowledges there is some risk of maternal transmission of BSE. The commenter expressed the opinion that APHIS' conclusion expressed in the proposed rule that infectivity is unlikely to localize to the fetal blood is based on scant scientific evidence that remains equivocal. The commenter stated that APHIS does not prescribe any action to mitigate the additional risk pathway of the importation of pregnant cattle and fetuses from pregnant cattle.

Response: We disagree with the commenter and are making no changes based on the comment. In the proposed rule, we pointed out that, based on scientific and epidemiological data, maternal transmission of BSE is unlikely to occur at any appreciable level. In fact, maternal transmission can be ruled out in the majority of the cases born after the 1996 ban in the United Kingdom of all animal protein from livestock feed (DEFRA 2007b). Additionally, modeling studies using data obtained from the United Kingdom epidemic show that even if maternal transmission occurred at very small levels, it could not sustain an epidemic.

The commenter states that the OIE continues to recognize the risk of maternal transmission. However, we note that the 2006 OIE guidelines contain no specific recommendations regarding the destruction of offspring of infected animals as part of an epidemiological investigation. These recommendations were removed after recognition that the possibility of maternal transmission is very low. In addition, the 2006 guidelines with regard to trade from controlled risk regions for BSE contain no specific restrictions regarding progeny of positive animals. While the 2006 guidelines did contain a restriction for progeny of positive animals with regard to trade with undetermined risk regions (i.e., ''cattle selected for export * * * are not the progeny of BSE suspect or confirmed females''), this reference was removed in the 2007 OIE general session. Therefore, all restrictions on the trade in progeny of BSE-positive animals have been removed from the current OIE guidelines. APHIS believes the weight of the scientific information and scientific consensus reflected in the OIE international guidelines support the conclusion that maternal transmission of BSE is unlikely to occur at any appreciable level, and that specific regulatory measures are not necessary or warranted.

SRM Removal

Issue: One commenter stated that USDA regulations should require the removal of all SRMs from cattle imported from Canada at 30 months of age or older.

Response: FSIS regulations require the removal of all SRMs from cattle slaughtered in the United States, regardless of the country of origin of the cattle. Therefore, the action requested by the commenter is already included as a requirement in USDA regulations for any cattle 30 months of age or older that would be imported from Canada.

Ports of Entry

Some commenters addressed the regulations that have required that live bovines imported from Canada enter the United States only through ports of entries listed as authorized ports in § 93.403 of the regulations. Some commenters expressed concern about the ability of the ports to handle shipments from Canada, while other commenters requested that the list of authorized ports be expanded.

Authorized Ports of Entry

Issue: Several commenters stated that the proposed rule should not be implemented until sufficient personnel, quarantine facilities, and testing capabilities are available at the U.S.-Canadian border to monitor imports and detect suspect animals.

Response: APHIS regulations require that live ruminants imported into the United States from Canada come through the border ports listed in § 93.403(b) (except as provided in special cases in § 93.403(f)). APHIS lists ports in § 93.403(b) only after determining that they have sufficient personnel and facilities to accommodate importations of live animals from Canada.

Border Ports in Alaska

Issue: Several commenters noted that none of the border ports listed in § 93.403(b) are on the border of Alaska and Canada and requested that the regulations provide for such a border port.

Response: The volume and frequency of live animal imports through the ports listed in § 93.403(b) justifies making Federal inspectors available on a regular basis. As noted above, § 93.403(f) of the regulations provides for the designation by the Administrator of other ports in special cases as necessary.

Historically, the volume and frequency of imports of ruminants from Canada directly into Alaska has not made it resource-effective to provide the Federal inspectors for such importations on a regular basis. Imports of bovines from Canada into Alaska under this rule will continue to be handled by special arrangements on an as-needed basis.

For the reasons discussed above, we are making no changes based on the comments.

Blood and Blood Products

Paragraph (a) of § 94.18 lists regions from which imports of ruminants and ruminant products are prohibited or restricted because of BSE. Those regions in which BSE is known to exist are listed in § 94.18(a)(1); those regions that present an undue risk of introducing BSE into the United States 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 are listed in § 94.18(a)(2); those regions that present a minimal risk of introducing BSE into the United States via live ruminants and ruminant products and byproducts are listed in § 94.18(a)(3).

The requirements for the importation of blood and blood products from BSE minimal-risk regions have been the same as the requirements for importation of blood and blood products from other regions listed in § 94.18(a)—only serum and serum albumin have been eligible for importation. In our January 2007 proposal, we proposed to allow the importation of blood and additional blood products from BSE minimal-risk regions provided certain conditions were met regarding the health of the animal from which the blood or blood products were derived, or—in the case of blood collected from a fetal calf—the health of the dam; the method of slaughter; the process of collection of blood; and certification of compliance with the regulations.

We received comments regarding the importation of bovine blood and blood products from BSE minimal-risk regions. Most of the commenters addressing this topic expressed concern regarding such importation, while others sought clarification as to allowable methods of collection of bovine blood intended for importation as blood or blood products into the United States.

Issue: Several commenters stated that the regulations should not allow the importation of cattle blood for use as animal feed. One commenter stated that a number of studies have shown prion transmission through blood, that there is evidence that TSE diseases are capable of crossing the species barrier, that the EU has banned all animal protein except meat and eggs from use in feed for any animal that enters the human food chain and the United States should do the same, and that what the commenter referred to as the EC report on the assessment of BSE risk in the United States specifically condemned the practice of intraspecies recycling of ruminant blood and blood products. Some commenters specifically expressed concern about the potential use of blood protein as a milk replacement or as animal feed, and the production of spray-dried blood plasma or blood meal for use in feed.

Response: As we discussed in detail in our risk assessment, in experiments examining tissues from BSE-infected cattle, no BSE infectivity was demonstrated in cattle blood or any tested derivatives (EC SSC 2002). Also as discussed in our risk assessment, the Scientific Steering Committee of the European Commission concluded that the finding of BSE infectivity in the blood of sheep could not be extrapolated to BSE in cattle (EC SSC 2002a). Further, the available evidence indicates that TSEs in other species, when found in the blood, are localized primarily to the cellular fractions. Although BSE has never been detected in any bovine blood or blood product, we expect even further risk reduction after removal of cellular fractions in the preparation of the most commonly imported bovine blood commodities. In addition, the mitigations included in this rule help prevent contamination of bovine blood and blood products with infectious tissues such as SRMs. Thus, there is no reason to prohibit the importation of cattle blood for use in animal feed. (We note that FDA has responsibility for determining which materials may be used in animal feed.) Finally, as discussed in our risk assessment, infection with BSE via the oral route is less efficient than by subcutaneous or intramuscular injection. Given that we have concluded that there is a negligible risk for exposure to bovine blood and blood products via the injectable route, the same conclusion holds for exposure via the oral route.

Issue: One commenter cited a report (Castilla *et al.*, 2005) regarding the first detection of scrapie prions in hamster blood, using a biochemical technique called protein misfolding cyclic amplification (PMCA).

Response: APHIS is making no changes in response to this comment. The study cited by the commenter does not present evidence about BSE infectivity in bovine blood. The cited study presents a technique for the rapid amplification and detection of scrapie prions in hamster blood. The study is notable because the novel detection method could be useful in the development of diagnostic methods. Previously, only the prion concentration in the brain and some lymphoid tissues was high enough for detection by routine biochemical detection.

However, APHIS does not assume that finding the presence of abnormal prion protein in a given tissue, especially at low levels, is equivalent to demonstrating infectivity of the tissue. APHIS notes that there are very sensitive bioassays in live animals for determining the infectivity of various tissues, such as that for BSE using intracerebral inoculation of transgenic mice expressing the bovine PrP. These methods, recently used by authors of the cited study and others (Espinosa *et al.*, 2007; EC SSC 2002) have reliably determined that, unlike sheep, mouse, and hamster blood, bovine blood from BSE-infected animals does not have demonstrable infectivity.

Issue: One commenter stated that the reference APHIS used in its risk assessment in discussing the lack of TSE infectivity in bovine blood—the European Commission Scientific Steering Committee report, 2002—is dated.

Response: We note that, in addition to the 2002 European Commission Scientific Steering Committee report the commenter refers to, a more recently published study (Espinosa *et al.*, 2007) provides evidence of lack of TSE infectivity in cattle blood. The 2007 study found that orally inoculating asymptomatic cattle with BSE resulted in BSE infectivity restricted to the nervous system, Peyer's patches, and tonsils, as had been reported previously for clinically affected cattle. The study involved collection of tissue at 20, 24, 27, 30, and 33 months post-challenge. Infectivity in brainstem and sciatic nerve was detectable only after 27 months, whereas Peyer's patches and tonsils were positive at every time point tested. Blood, urine, spleen, and skeletal muscle were negative for detectable infectivity throughout the study, using the very sensitive bioassay, intracerebral inoculation of transgenic mice expressing the bovine PrP, to assess infectivity.

Issue: In order to guard against BSE contamination of blood intended for importation into the United States from BSE minimal-risk regions—or blood products derived from such blood—we proposed to require that the blood be collected in a closed system (in which the blood is conveyed directly from the animal in a closed conduit to a closed receptacle) or in an otherwise hygienic manner that prevents contamination of the blood with SRMs.

Several commenters stated that, because of current line speeds in beef slaughter facilities, a closed collection

system is not practical and would be cost prohibitive for production of spray-dried blood plasma or blood meal. The commenters stated that industry associations of both renderers and spray-dried blood and plasma producers in the United States and Canada have developed and implemented guidelines and a code of practice designed to minimize the risk of contamination. One of the commenters stated that the manufacture of spray-dried blood products involves concentration of the liquid plasma with reverse osmosis or ultra-filtration, followed by atomization of the concentrated liquid in a heated drying container. According to the commenter, because the filtration and spray drying equipment will operate inefficiently if the feed liquid contains particulate material, a number of pre-filtration steps to remove particulate contamination are included in the production of spray-dried blood products. The commenter stated that the combination of the filtration system with manufacturing standards results in a system that meets the requirements of the regulations for collection ''in an otherwise hygienic manner that prevents contamination of the blood with SRMs.''

Several other commenters recommended that the regulations specifically provide for the adoption of alternative, less restrictive mitigation measures should the Administrator determine they are scientifically justified.

Response: As noted above, our proposed rule provided for collection in an otherwise hygienic manner that prevents contamination of the blood with SRMs, in lieu of using a closed system for the collection of blood. APHIS will determine whether an alternative process collects blood in a hygienic manner that prevents contamination of the blood with SRMs upon request by a party that such a determination be made. The request for determination must include a description of the proposed alternative method of collection.

Based on information received from the industry and an evaluation of industry capabilities, APHIS would consider the following to be an example of an acceptable alternative collection process at a slaughter facility: After the animal has passed ante-mortem inspection and is stunned, a long midline cut is made in the skin on the ventral part of the neck. A specially designed bucket—with two barbs that allow it to hang on the hide and that has been treated with anticoagulant prior to use—is inserted into the cut, so that the opening of the bucket, an oval-shaped area that conforms to the shape of the cut, is essentially inside the skin. As the animal moves down the line, another cut is made with a clean knife inside the skin opening, cutting the arteries and veins through the thoracic inlet for exsanguinations. The carcass travels down the rail while the blood drains. The bucket is mechanically removed by a conveyor at the end of this line. The conveyor carries the bucket into a separate room (separate from the kill floor), and empties the bucket into a vat with a screen to pick out any clots. The blood in the vat is then centrifuged, and the cells are piped to a dryer in another part of the plant, while the plasma is held in large refrigerated vats prior to transfer to another processing facility. The empty bucket travels through a pre-wash that removes any remaining blood, then through a disinfectant wash. Before reentering the collection process, the cleaned and disinfected bucket is treated with a measured amount of anticoagulant.

For the reasons discussed above, we are making no changes based on these comments to the proposed requirements for importing blood or blood products.

Small Intestine

The regulations in § 94.19 have required that meat, meat byproducts, and meat food products derived from bovines that have been in a BSE minimal-risk region be derived from bovines from which the SRMs and the small intestine were removed at slaughter. The regulations at § 95.4(g) have applied this same requirement to offal derived from bovines from BSE minimal-risk regions. Section 94.0 defines SRMs as ''those bovine parts considered to be at particular risk of containing the bovine spongiform encephalopathy (BSE) agent in infected animals, as listed in the FSIS regulations at 9 CFR 310.22(a).''

The regulations require removal of the entire small intestine, even though only part of the small intestine (the distal ileum) has been determined to be an SRM, to ensure removal of the distal ileum.

In our January 2007 proposed rule, we proposed to remove the requirements for removal of the entire small intestine. We proposed, instead, to require removal of 80 inches of the uncoiled and trimmed small intestine, as measured from the cecocolic junction, unless the processing establishment has demonstrated that an alternative method is effective in ensuring complete removal of the distal ileum. We explained that this proposed change is consistent with the definition of SRMs in the FSIS regulations at 9 CFR 310.22(a).

Some commenters who addressed the topic of the removal of the distal ileum and other parts of the small intestine requested that the regulations be made more stringent than at present, while others expressed the view that our proposed regulations were too restrictive.

Issue: Several commenters addressed our proposed change regarding removal of the small intestine. One commenter recommended not only that the regulations continue to require the removal of the small intestine, but that we require that the large intestine be removed as well. The commenter stated that the European Commission Scientific Steering Committee stated that, because slaughterhouse contamination of other intestinal areas with matter from the distal ileum cannot be avoided, it is prudent to remove the entire small and large intestines. Additionally, stated the commenter, the International Review Team (IRT) that issued a report to the U.S. Secretary of Agriculture in February 2004 called for the banning the entire intestine—from anus to pylorus—from human and animal food, from cattle of any age.

Response: The issue of how much of the intestines should be removed to ensure removal of the distal ileum to prevent contamination with the BSE agent was also raised in response to rulemaking documents published in the **Federal Register** by FSIS and FDA. The agencies' responses to those comments were published in interim final rules published in the **Federal Register** on September 7, 2005. (FSIS Docket No., 03–025IFA, 70 FR 53043–53050, and FDA Docket No. 2004N–0081, 70 FR 53063–53069). We concur with FSIS and FDA that, although the EU prohibits the entire intestine from use in food, the data we are aware of indicating BSE infectivity along the entire intestine is from other species, and may not represent the distribution of infectivity in cattle infected with BSE, as evidenced by studies with bovine tissues.

In cattle, infectivity has been found in the distal ileum in tissue assay from cattle experimentally given BSE (Wells *et al.*, 1994). In such cattle, positive Peyer's patches were found by immunohistochemistry only in the distal ileum, and in cattle with naturally occurring and experimental BSE, positive myenteric plexus neurons were found only in the distal ileum (Terry *et al.*, 2003). The duodenum of cattle experimentally given BSE has not demonstrated infectivity when tested by mouse bioassay and has been negative

for the presence of abnormal prions when examined by immunohistochemistry during all stages of the pathogenesis of the disease (Wells, 1994). Few samples of jejunum have been tested, but those that have been tested were negative for the presence of abnormal prions when examined by immunohistochemistry (Terry *et al.*, 2003). In a bioassay of tissues from cattle with naturally occurring BSE, no infectivity was found in the splanchnic nerve, rumen, omasum, abomasum, proximal small intestine, proximal colon, distal colon, and rectum, or in the distal small intestine (EU SSC 2002).

The study by Terry and others indicated that the myenteric plexus of the distal ileum contained some abnormal prion protein in neurons (Terry *et al.*, 2003). Since the myenteric plexus extends throughout the small intestine, we acknowledge the possibility that infectivity might exist in the myenteric plexus of the jejunum or the duodenum. However, if infectivity in intestinal tissues (other than distal ileum) exists, it is below the level of detection by both mouse and cattle bioassay. Given the relative efficacies of these experimental modes of transmission compared to oral exposure at doses estimated to have occurred in the field, we conclude that intestine other than the distal ileum is highly unlikely to contain epidemiologically significant levels of infectivity, if any infectivity is present at all.

We do not agree that slaughterhouse contamination of other intestinal areas with matter from the distal ileum cannot be avoided. FSIS is responsible for ensuring the adequacy and effectiveness of procedures for removing the distal ileum in slaughterhouses. The FSIS regulations require that establishments develop, implement, and maintain written procedures for the removal, segregation, and disposition of SRMs, and that they incorporate these procedures into their HACCP (Hazard Analysis and Critical Control Point) plans, sanitation standard operating procedures, or other required programs (9 CFR 310.22(d)(1)). These procedures must ensure that SRMs, including the distal ileum, are completely removed from the carcass, segregated from edible products, and disposed of in an appropriate manner as prescribed by 9 CFR 314.1 and 9 CFR 314.3 (*i.e.*, used for inedible rendering, incinerated, or denatured). Regions wishing to export meat and meat products to the United States must follow processing practices equivalent to those of FSIS.

With regard to the IRT report referenced by the commenter, the recommendation for removal of the entire intestine, from anus to pylorus, was meant to apply in the United States only if the risk of BSE had not been determined to be minimal, based on aggressive surveillance. Aggressive surveillance conducted in both the United States and Canada indicate a very low prevalence of BSE. Therefore, the recommendation of the IRT for removal of the entire intestine of all cattle does not apply. As discussed above, scientific evidence does not support the designation of the entire intestine as an SRM.

Issue: Several commenters stated that the regulations should require that only the distal ileum be removed, rather than an additional 80 inches of small intestine. The commenters stated that APHIS has not established that it is necessary to excise so much additional intestine. At a minimum, stated the commenters, the regulations should allow the Administrator to approve effective alternatives in ensuring complete removal of the distal ileum.

Response: As discussed in our proposed rule, removal of the distal ileum as well as an additional portion of the small intestine is consistent with FSIS and FDA requirements to ensure removal of the distal ileum. APHIS concurs with FSIS and FDA that, unless demonstrated otherwise, to ensure complete removal of the distal ileum, it is prudent to require removal of 80 inches of the uncoiled and trimmed small intestine as measured from the cecocolic junction. We concur that this standard will ensure removal of the distal ileum despite differences in length of the intestinal tract or its segments between breeds or variations from animal to animal of the same breed. However, we recognize, as do FSIS and FDA, that alternative means of ensuring removal of the distal ileum may exist, and current APHIS regulations provide for such alternative means.

For the reasons discussed above, we are making no changes based on these comments to the proposed requirements regarding removal of part of the small intestine.

Bovine Tongue

Issue: One commenter stated that USDA's assumption that removal of a fraction of the small intestine and the tonsils removes any potential for transmission to humans is unjustified, given that APHIS has not evaluated the potential for contamination of tongue with tonsil tissue. The commenter also stated that APHIS claims this possibility is eliminated by current slaughter techniques, and stated further that such an assumption is contradicted by facts (i.e., scientists who examined over 250 bovine tongues intended for human consumption found tonsillar tissue in the vast majority—in some cases, ''even after the most rigorous trimming of the root of the tongue'' (Wells *et al.*, 2005). The commenter stated that APHIS cannot simply assume this risk away by stating, without record support, that it is eliminated.

Response: We are making no changes based on the comment. Wells *et al.* (2005) state the following:

> However, the trace level of infectivity so far detected in tonsillar tissue and the localization of the lingual tonsillar lymphoid tissue, together with the current SRM legislation for the removal of tonsil from cattle carcasses and the low and diminishing prevalence of BSE in the UK suggest that the risk of human exposure to infected tonsil is now remote. It seems likely that under these circumstances any additional trimming of the tongue would result in an immeasurable reduction in the risk. * * *

In other words, the study cited by the commenter does not present a strong case for additional risk measures. The study, in fact, indicates the opposite conclusion.

Moreover, even before the SRM requirements were implemented in January 2004, FSIS did not consider tonsil to be edible tissue—it was previously required to be removed. As noted in FSIS Notice 50–04:

> In the preamble to 9 CFR 310.22, FSIS stated that tonsils of all livestock species, including cattle, were already required to be removed and were prohibited for use as ingredients in meat food products under 9 CFR 318.6(b)(6). The accepted practice for removing the tonsils from livestock has been to remove all visible tonsils. In cattle, this includes separation of the palatine tonsils and lingual tonsils from the tongue (in establishments that harvest the tongue for human food) by a transverse cut caudal (just behind) the last vallate papillae. * * * FSIS expected that establishments would continue to remove tonsils from cattle in accordance with the procedures that they had implemented to comply with 9 CFR 318.6(b)(6) * * *. Establishments that slaughter cattle should have been following these practices before tonsils were designated as SRMs. (FSIS, 2004).

APHIS' quantitative exposure model included an update that acknowledged the potential infectivity in tonsils and clearly added these as an SRM, with the acknowledgment that they could still be potentially available for human consumption. In fact, the output tables from the model runs show the potential ID_{50}s derived from tonsils and available for human consumption over the 20-year period of the analysis. These values are obviously very low, ranging from

0.026 ID_{50}s in the base case scenario to 0.16 ID_{50}s in sensitivity analysis 6 (in which all uncertain parameters were simultaneously set to their corresponding pessimistic level). Such very small values are not surprising given the low likelihood of infectivity in the tissue itself. These possible exposure routes were therefore explicitly modeled and not ''assumed away.'' Moreover, although our model predicts a vanishingly low level of possible human exposure via tonsils, we have not stated that the risk is ''eliminated,'' as was suggested in the comment.

Issue: A number of commenters urged that, before this rule is implemented, a plan should be in place for the removal and mitigation of any potential risk factors that might arise from the introduction of the BSE agent into the United States because of the importation of a BSE-infected cow.

Response: We are making no changes based on the comments. The safeguards in the United States regarding any BSE-infected cow that might be imported from a BSE minimal-risk region are the same that are in place to deal with a BSE-infected cow of any source, including any of U.S. origin that might be detected. These mitigations are simulated in the quantitative exposure model used in the risk assessment for this rule.

The primary animal-health mitigation measure is the feed ban implemented by the FDA in 1997. This feed ban is the most important measure to prevent the transmission of disease to cattle. In addition to the regulatory restrictions imposed by the feed ban, other industry practices—such as rendering processes that inactivate a significant proportion of BSE infectious agent present in raw material—and biological processes—such as age susceptibility to infection—also help to mitigate the transmission of disease to animals.

Public or human health protective measures are maintained by both the FSIS and the FDA. The most important public health protective measure is the removal from the human food supply of SRMs. Other controls include prohibiting air-injection stunning of slaughter cattle; requiring additional process controls in advanced meat-recovery systems; forbidding the use of mechanically separated meat in human food; and prohibiting nonambulatory disabled cattle from the human food chain. Additionally, protection from BSE and other disease is achieved through ante-mortem inspection of slaughter cattle and the exclusion of animals with any clinical signs of neurological disease or other abnormalities.

If a BSE-positive bovine were identified in the United States, APHIS would lead an epidemiological investigation that would include the tracing of birth cohorts of the infected animal. Birth cohorts are those animals that could have been exposed to the same feed as the infected animal, and include those bovines that were born on the same premises as the infected animal during the 12-month period immediately before the birth of the infected animal or during the 12-month period immediately after the birth of the infected animal. They would also include other bovines raised on the premises at the time the infected animal was there. Any birth cohorts located would be prevented from entering the human or animal feed chains. In addition to the APHIS epidemiological investigation, FDA would conduct an extensive feed investigation to help determine the potential source of the infection.

With regard to commodities eligible for importation from BSE minimal-risk regions under this rule, we have concluded that such commodities can be imported with a negligible BSE risk to the United States.

The Role of States

Several commenters discussed the role U.S. States should play regarding bovines imported from BSE minimal-risk regions.

Issue: Commenters stated that CFIA and APHIS should provide the State veterinarian in the U.S. State that is receiving such bovines with all animal health and identification documentation before the animal is imported. Commenters requested further that the regulations require all importers of cattle over 30 months of age from BSE minimal-risk regions to report all movements of the animal to the department of agriculture of the recipient State before the animal is moved into or through the State.

Response: As noted above, the purpose of the current APHIS regulations with regard to BSE, and those in this rule, is to allow the importation into the United States of commodities that can be imported with a negligible likelihood of the BSE exposure and establishment in the U.S. cattle population as a consequence of eligible imports from Canada. We do not consider the extensive recordkeeping and paperwork requirements suggested by the commenters to be warranted or justified by science and are making no changes in response to the comments.

Issue: Commenters recommended that APHIS authorize each State Veterinarian to ensure that the animal health and identification requirements of the APHIS regulations are met, and recommended further that, in the event the State determines noncompliance with the APHIS regulations, USDA support the enforcement actions of the State officials.

Response: APHIS has a historical and ongoing working relationship with State animal health officials to protect livestock in the United States from both foreign diseases and diseases endemic to the United States. This ongoing cooperation has enabled the United States to protect this country's livestock from a variety of diseases, including BSE. It has not been necessary to specify this working relationship in the APHIS regulations, and we do not consider it warranted to do so for any one disease. However, APHIS emphasizes that it values highly its cooperative efforts with State animal health officials and welcomes a continuing exchange of information and support in carrying out our mutual missions.

Potential Economic Effects of the Proposed Rule

A large number of commenters addressed the potential economic effects of the proposed rule. Most of these commenters expressed concern that the proposed rule would have an unacceptable negative impact on U.S. entities. Some of the commenters took issue with the economic analysis we conducted for our proposed rule.

Issue: Many commenters recommended that APHIS withdraw or restrict implementation of this rule because of its potential negative economic effects on the U.S. livestock and livestock product industry, due to the potential significant influx of cattle from Canada over a short period of time. A number of commenters requested that the rule not take effect until USDA has developed and implemented an orderly market transition plan to reduce the negative effect of the rule on U.S. cattle producers. One commenter stated that such a plan should include gradually accepting imports, so as not to overload the U.S. cattle supply and crash those markets. Further, commenters recommended that APHIS delay implementation of the rule until all U.S. export markets that were closed due to the December 2003 detection in an imported cow in Washington State are reopened.

Response: APHIS does not have the statutory authority to restrict trade based purely on its potential economic impact, market access effects, or

quantity of products expected to be imported. Under the Animal Health Protection Act, the Secretary of Agriculture 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. This authority has been delegated to APHIS.

We note that this rule, and our January 2005 final rule, do not make any commodities eligible for importation from Canada that were not already allowed importation prior to May 2003, when a BSE-infected cow was diagnosed in Canada. One difference between the current situation and pre-May 2003, however, is that certain of the commodities that are now eligible for importation, or that will become eligible when this rule becomes effective, are subject to risk mitigating importation conditions appropriate to the fact that BSE has been detected in Canada and that we consider that country a minimal-risk region for BSE. As noted above, both Canada and the United States have been classified as controlled risk countries for BSE under the OIE guidelines. Additionally, even under these rules, there are some commodities (e.g., cattle born before March 1, 1999) that continue to be ineligible for importation into the United States. Nevertheless, this rulemaking and our January 2005 final rule represent to a great extent a return to trade patterns that existed between the United States and Canada for many years previously. As discussed in the January 2007 proposal for this rule, in this final rule, and in the risk assessment for this rule, we have determined that the commodities eligible for importation from Canada under this rulemaking can be imported into the United States under the conditions specified with a negligible BSE risk to the United States.

With regard to exports markets that were closed to U.S. beef following the December 2003 detection of BSE in a cow of Canadian origin in Washington State, U.S. Government agencies are actively negotiating with trading partners to reestablish our export markets. After the 2003 detection of an imported BSE-infected cow in Washington State, many of the 114 nations that imported U.S. beef banned our beef and live animals, despite the apparent lack of scientific basis for such measures. The efforts of multiple U.S. Government agencies have succeeded in removing bans in over half of those markets, including our largest export market, Japan. U.S. Government agencies continue to work to reopen or further open markets where restrictions remain; the results of these negotiations are posted on the USDA APHIS Web site (*http://www.aphis.usda.gov*).

Issue: Some commenters took issue with the economic analysis that we conducted for our January 2007 proposed rule. One commenter stated that the economic analysis ignored any multiplier effects (i.e., the impact of a change in the level of economic activity in one sector on other sectors of the economy and on households in terms of employment and income) that would come from the broader economic impacts on the beef wholesale sector.

Response: We used the multi-sector model in our economic analysis to examine impacts for the major vertically linked marketing channels for beef and other livestock products. We estimate consumer surplus for the beef sector will increase by 1 to 1.3 percent at the retail level in scenario 3 of the economic analysis. Indirect downstream effects on income and employment are not modeled; however, we do not believe APHIS is required to analyze the impacts of regulation on every sector of the economy that may be indirectly affected by these changes. As in many regulations, opportunity costs imposed on one sector of the economy are often passed on to other sectors of the economy. We anticipate that there may be indirect economic benefits to communities where, for example, cull cattle imported from Canada result in increased slaughter plant employment. In other communities, there may be income and employment losses due to reduced spending by producers who face a fall in prices for cull cattle. These impacts are expected to be small on a national basis, although they may show some geographic concentration. Overall, the effects of this rule are expected to reflect a return to trade circumstances similar to those that existed prior to May 2003.

Issue: One commenter indicated that APHIS acknowledged the sensitive nature of the results of the economic analysis based on the parameters (elasticities) used to drive the economic model and requested public comment on those parameter assumptions. The commenter stated that APHIS should have done a literature search for studies that report on these parameters and should have made those reported parameters available, in order to provide policy analysts with fuller knowledge to assess the accuracy of the results reached by APHIS.

Response: APHIS agrees that this would be useful information to provide for those interested in the impact analysis. The two tables that follow summarize our overview of demand and supply elasticities estimated or used in published research. The referenced sources are identified in a footnote following the tables.[12] The elasticities we use in the economic analysis fall within a reasonable range of the elasticities found in these various sources.

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[12] Arnade, C.,and K. Jones. ''Modeling the Cattle Replacement Decision.'' Paper prepared for presentation at the *American Agricultural Economics Association Meeting,* Montreal, Canada, July 27–30, 2003.

Brester, G.W., J.M. Marsh, and V.H. Smith. ''The Impacts on U.S. and Canadian Slaughter and Feeder Cattle Prices of a U.S. Import Tariff on Canadian Slaughter Cattle.'' *Can. J. Agr. Econ.* 50(March 2002), pp. 51–66.

Brester, G.W. ''Estimation of the U.S. Import Demand Elasticity for Beef: The Importance of Disaggregation.'' *Rev. Agr. Econ.* 18(January 1996), pp. 31–42.

Brester, G.W., and M.K. Wohlgenant. ''Estimating Interrelated Demands for Meats Using New Measures for Ground and Table Cut Beef.'' *Amer. J. Agr. Econ.* 73(November 1991), pp. 1182–94.

Marsh, J.M. ''Impacts of Declining U.S. Retail Beef Demand on Farm-Level Beef Prices and Production.'' *Amer. J. Agr. Econ.* 85(November 2003), pp. 902–13.

Marsh, J.M. ''Estimating Intertemporal Supply Response in the Fed Beef Market.'' *Amer. J. Agr. Econ.* 76(August 1994), pp. 444–53.

Marsh, J.M. ''USDA Data Revisions of Choice Beef Prices and Price Spreads: Implications for Estimating Demand Responses.'' *J. Agr. and Res. Econ.* 17(December 1992), pp. 323–34.

Wohlgenant, M.K. ''Demand for Farm Output in a Complete System of Demand Functions.'' *Amer. J. Agr. Econ.* 71(May 1989), pp. 241–52.

DEMAND ELASTICITIES

	Feeder Placements	Retail Beef	Replacements	Nonfed Beef[a,b]	Fed Beef[b]	Beef[b]	Slaughter Cattle[c]
Arnade and Jones (2003)							
Short Run			-2.300				
Long Run			-2 770				
Brester, Marsh, and Smith (2002)							-1 790
Brester (1996)						-0.700	
Brester and Wohlgenant (1991)				-2 543	-1.155		
Marsh (2003)		-0.670					
Marsh (1994)							
Short Run	-0 255						
Intermediate Run	-0 887						
Long Run	-2 760						
Marsh (1992)							-0.650
Wohlgenant (1989)							-0 760

[a]Nonfed beef is defined as beef from bulls, cows, and grass-fattened steers and heifers.

[b]This is a compensated elasticity.

[c]This is an import demand elasticity

SUPPLY ELASTICITIES

	Fed Marketing	Slaughter	Feeder	Calves	Cull Cows
Arnade and Jones (2003)					
Short Run				0.391	0.430
Long Run				0.417	0.460
Marsh (2003)					
Short Run			0.220		
Long Run		0.593	2.820		
Marsh (1994)					
Short Run	-0.170				
Intermediate Run	0.606				
Long Run	3.240				

Issue: One commenter stated that the type of ''welfare'' analysis APHIS used in its economic analysis is invalid because it relies upon the unscientific concept of interpersonal utility comparison.

Response: We disagree. Our economic analysis does not attempt to make interpersonal utility comparisons. We recognize that an additional dollar of income provides a different level of utility to every individual. APHIS uses techniques that are quite standard in welfare and trade economics; we estimate changes in consumer and producer surplus that may result from projected changes in cattle and beef imports from Canada under different scenarios. For a given transaction, consumer surplus refers to the value that the purchase of the good provides the buyer over and above its price. Producer surplus refers to the value that the sale of the same good provides the seller over and above the lowest price at which he would have been willing to sell it.

The estimated changes in welfare and prices are generalized across all entities that would take part in transactions concerning the particular commodity at hand, such as the purchase and sale of cull cattle. We make no attempt to evaluate impacts on income distribution or the utility gained or lost by individual market participants. In a transaction, the buyer and the seller both gain utility, as individually determined, compared to their next best alternatives. Otherwise the transaction wouldn't occur. But for some entities, the ''gain'' in utility may be, in fact, a smaller welfare loss than the participant anticipates would be incurred without the transaction (e.g., selling a cull animal rather than keeping it past the optimal point of sale, even though the price has declined). Commodity-wide changes in welfare (changes in consumer and producer surplus) reflect the changes in utility across all buyers and sellers of the commodity.

The common measure of value and, therefore, of changes in welfare is, of course, the dollar. Our analysis appropriately uses changes in consumer and producer surplus, expressed in dollars, to evaluate net benefits of this rule and other scenarios considered. As pointed out in the Office of Management and Budget's Circular A–4, a distinctive feature of benefit-cost analysis is that both benefits and costs are expressed in monetary measures, which allows a common measure for evaluation of different regulatory options.[13]

Issue: One commenter stated that the economic analysis for the proposed rule is invalidated by its assumption that import numbers will be exogenous, rather than determined within the context of a dynamic North American livestock market.

Response: APHIS disagrees. We agree that the North American livestock market is a dynamic system, with the interplay of changing prices and changing supply and demand quantities continually redefining market equilibria. The projected imports from Canada may be exogenous to the particular model we used to estimate domestic impacts; however, they are derived from USDA baseline projections and anticipated market changes that reflect the fluidity of interacting markets. In other words, the impacts were not modeled as external exogenous shocks, but rather as rational responses to changing market conditions. We also note that every model is an abstraction from reality that relies upon selected exogenously determined values and parameters. Our import projections are

[13] Office of Management and Budget, Circular No. A–4, Regulatory Analysis, September 17, 2003. *http://www.whitehouse.gov/omb/circulars/a004/a-4.pdf*

well based in theory and market considerations. Imports of Canadian cull cattle will be newly reestablished by the rule, and effects for the other modeled commodities will derive from the resumption of the cull cattle imports. The principal model we use to evaluate expected effects of the rule is a net trade model, and its operation is driven by projected changes in net trade.

Issue: One commenter stated that our economic analysis overstates consumer benefits associated with the availability of cull cattle for slaughter in the United States, because it does not adequately account for substitution among the modeled products in both the United States and Canada.

Response: Consumer welfare benefits are expected to be gained under the rule by buyers of processing beef at the wholesale level. Lean processing beef from cull cattle and trimmings from fed beef are complementary goods that are combined to produce ground beef. At the level of the retail shopper, there is a degree of substitution between ground beef and fed beef cuts, but this relationship is not expected to significantly influence the estimated consumer benefits attributable to the rule.

As part of the economic analysis for the final rule, we simulate substitution among livestock products in response to relative price changes. The simulations yield measures of consumer welfare changes at the retail level. Results of this analysis indicate that, with the rule under scenario 3 as discussed in our economic analysis and in the summary of that analysis in this document (entry of Canadian cattle born on or after March 1, 1999, and resumption of imports of beef from Canadian cattle slaughtered at 30 months of age or older), consumer surplus for the beef sector at the retail level will increase by 1 to 1.3 percent compared to a 2006 baseline.

Issue: One commenter stated that, based on normal culling rates, the January 2007 herd size, the modernization and expansion of Canada's slaughter plants, and the increased use of Canadian beef in the Canadian domestic market, the number of animals that might be available for export is considerably lower than the number estimated by USDA. The commenter calculated that the number of older, age verified, beef and dairy animals that might be eligible for export would total about 471,000 head annually, consisting of approximately 250,000 dairy cows, 154,000 beef cows, and 67,000 bulls. The commenter noted that the estimate of 471,000 head should be viewed as an upper bound and that, if confirmation of an animal's age proves to be a complex procedure, that number would be reduced.

One commenter stated that, in assessing the potential economic effects of this rulemaking, the use of any historical references regarding trade flows and regional basis levels to assess potential impacts are not likely to be of much use, due to changes in cattle usage. The commenter stated that the vast majority of Canadian cull cows and bulls will be converted into beef in Canada, and, after subtracting the elimination of the supplemental tariff rate quota (TRQ) supplies, the balance could be exported to the United States depending on the influence of the exchange rate. (''TRQ'' is the total annual quantity of a commodity that can be imported at a lower tariff rate, excluding imports from NAFTA countries. Canada's supplemental TRQ beef supplies were quantities of beef above the tariff rate quota that were allowed by Canada to enter at the lower tariff rate. In eliminating supplemental TRQ certificates—that is, by not allowing additional beef imports at a lower tariff rate, Canada is relying to a greater extent on domestic production and less on imports.)

Response: We have considered these observations carefully and reassessed the proposed rule import projections and, as a result, have revised our economic analysis based on a smaller quantity of cull cattle projected to be imported from Canada. Although the modernization and expansion of Canada's slaughter plants and increased reliance on Canadian beef in the Canadian domestic market will tend to dampen cull cattle imports from that country, we expect the major reason for a smaller number of imports will be the requirement that the cattle be verified as having been born on or after March 1, 1999. In the preliminary regulatory impact analysis (RIA) we conducted for our January 2007 proposed rule, we projected that cull cattle imports from Canada in 2008, for example, would total 657,000 head (586,000 cows and 71,000 bulls and stags). In scenario 3 of the final RIA, however, we are projecting cull cattle imports in 2008 totaling 75,000 head (63,000 cows and 12,000 bulls and stags). We believe that the commenter who estimated that there would be approximately 471,000 older cattle eligible for import from Canada, and who acknowledged that number was an upper bound estimate, did not fully consider the extent to which the age verification requirement would reduce the number of eligible cattle. Of the cull cattle that might be imported by the United States if there were no age restriction and no age verification requirement, only about one-fourth are expected to be eligible for importation in 2008 under this rule, and only about one-half may be eligible by 2012.

Issue: One comment stated that APHIS did not provide an explanation in its economic analysis for the different percentages of cattle over 30 months of age and of such cattle plus beef from cattle over 30 months of age assumed to displace other processing beef imports.

Response: We agree that it is reasonable to expect, for all of the scenarios set forth in the economic analysis, that a consistent percentage of Canadian imports across the scenarios would displace other imports. We have revised the final RIA accordingly. In this final rule, we estimate that 25 percent of cull cattle imports from Canada (scenarios 1 and 2 in our economic analysis) and 25 percent of cull cattle and beef derived from cattle 30 months of age or older (OTM beef) from Canada (scenario 3 in our economic analysis) will displace U.S. processing beef imports from elsewhere. The estimate of 25 percent comes from simulations of the multi-sector model and takes into account interactions of the processing beef sector with the beef cattle and dairy cattle sectors. The model allows cattle prices to adjust to an increase in beef imports from one source (in this case, cull cattle and OTM beef imports from Canada), spreading the market response across both beef and cattle. This interaction dampens the beef price decline and reduces the amount of displacement below that would be expected to occur by considering only the market for processing beef. We also examine the sensitivity of the impacts to changes in the quantities of cull cattle and processing beef imported from Canada that displace processing beef from elsewhere: The RIA presents results assuming 50 percent of the imports from Canada displace imports from elsewhere as well as results assuming none of the imports from Canada displace other imports.

Issue: Several commenters, in addressing the potential economic effects of this rulemaking, stated that the time of year a final rule would go into effect is an extremely important variable in assessing its initial economic impact. One commenter stated that U.S. cull cow marketings are highly seasonal because the majority of calves are born in the spring and the decisions to retain cows are generally made during the fall. As a result, the months of October, November, December, and January are typically lowest for cull cow prices. Another commenter stated that implementation of the rule in the fall of

2007 (post-weaning) would likely result in a larger impact on U.S. cull cow prices in the very short term.

Response: We agree with the commenters that, in the short term, the timing of the resumption of imports of cull cattle and processing beef from Canada could have an impact on producers' monthly revenues. Historically, cull cow slaughter in the United States is highest in the months of October, November, December, and January. As the commenters noted, because of this, cull cow prices are typically lower in these months. Limited data prevent analysis on a monthly basis of price changes in response to projected cull cattle imports from Canada. However, we do acknowledge that, because of the larger number of cull cattle marketed per month, during October through January, a slight price decline during this period would result in larger total monthly revenue losses for U.S. producers than during the other months of the year. This seasonal difference in monthly revenue losses would not be large on an annual basis.

This outcome is demonstrated in research conducted at Montana State University (Brester *et al.*, 2007). This study examined effects of additional cull cattle slaughter using two scenarios: One in which Canadian cull cattle imports return to pre-2003 levels and do not displace beef imports from other countries, and a second in which 50 percent of cull cattle and processing beef imports from Canada displace beef imports from Uruguay. The changes in U.S. cull cattle prices estimated for these two scenarios are declines of $1.55 per cwt and $0.78 per cwt, respectively. The average of the price changes reported in the Montana State study, $1.17 per cwt (2.5 percent of the 2006 average U.S. cull cow price of $47.56 per cwt), would correspond to 25 percent of imports from Canada displacing processing beef imports from other countries, which is the percentage share used in the economic analysis for this final rule.

As reported by Brester *et al.* for the period, 2000–2006, monthly cull cattle sales averaged 488,000 head, October through January, compared to an average of 434,000 head per month, February through September. Based on the Montana State study results, a 25 percent level of displacement would correspond to a decrease in total monthly revenue for cow-calf producers of $5,956,500, October through January, and $5,297,000, February through September. In other words, there would be an additional revenue loss of $659,000 (12 percent) per month, October through January.

We project in our economic analysis a baseline for beef and dairy cow slaughter in 2008 totaling 5,084,000 head, and a nominal 2008 price of $54.19 per cwt. Based on an average live slaughter weight of 1,050 pounds, total baseline gross revenue from the sale of cull cows in 2008 would be $2.89 billion. The increase in producer losses because of increased cull cattle sales occurring during the months of October through January, rather than during the months of, February through September, based on the Montana State study results, would total less than 0.1 percent of the projected baseline annual revenue from cow slaughter.[14]

While we recognize that the timing of the resumption of cull cattle imports from Canada may influence the size of the short-term impacts for producers, differences in revenue losses due to the timing of the implementation of the rule are considerably smaller when considered on an annual basis. Our analysis is in terms of annual cattle import projections and, therefore, yields annual price and welfare effects. The within-year distribution of effects is smoothed in the annual estimate.

Issue: Many commenters addressed the issue of the potential economic impact on U.S. cattle producers should a bovine of Canadian origin be diagnosed in the United States as BSE-infected. A number of the commenters expressed general concern regarding such a potential impact, and suggested that APHIS' analysis of the potential economic effects of the proposed rule was incomplete because it did not consider such impacts. Commenters stated that such impacts have been large in other countries and could overwhelm the effects estimated by APHIS if a BSE-infected animal imported into the United States under the provisions of this rule caused the spread of BSE in the United States, and that a comprehensive economic analysis should include consideration of the demand reactions that would be triggered by identification of additional Canadian-born BSE cases in the United States, even at the low levels projected in APHIS' risk assessment.

Other comments stated that the cost associated with the projected importation of up to 160 BSE-infected cattle into the U.S. (based on APHIS' estimate for the 95th percentile of confidence) over 20 years, or the projected 2 to 20 U.S.-born infected cattle, should have been considered. Several commenters expressed concern that the existence of 21 to 180 cases of BSE-infected animals could substantially undercut demand for beef, as it has done in Europe, or dairy, if the public begins to identify BSE with the older dairy breeding stock that are most at risk of manifesting the disease.

A number of commenters expressed concern regarding the potential economic impact of the detection in the United States of a Canadian-born BSE-infected cow on U.S. export markets. Commenters stated that the reaction of the beef markets to the first U.S. case of BSE—despite that cow's being of Canadian origin—demonstrates the very substantial potential costs to U.S. cattle industries of introducing even a limited number of infected animals into the U.S. herd. Commenters stated that APHIS should examine such potential economic impacts.

Response: Expected economic impacts if new cases of BSE were to occur in the U.S. cattle population because of the rule are addressed in the consequence assessment portion of the risk assessment we conducted for this rulemaking. The consequence assessment notes that effects of BSE include a variety of costs. Some costs are long-term; others are one-time costs uniquely associated with new cases.

The major long-term cost for the United States due to the diagnosis of BSE in a cow of Canadian origin in Washington State in December 2003 has been reduced access since then to beef export markets. Principal Asian markets, in particular, remain largely restricted. In 2003, the value of U.S. exports of beef and beef by-products (as measured by the 33 ''beef only'' Census Bureau categories) totaled over $3.9 billion, of which the value of sales to Asian markets totaled $2.4 billion. In 2004, these totals had fallen to $863 million and $16 million, respectively. In 2006, the value of U.S. beef and beef by-product exports worldwide was $2.1 billion, and exports to Asia were valued at $197 million.[15]

Trade impacts tend to decline over time as exporting and importing countries find ways to resume mutually beneficial trade while maintaining the safety of the beef supply. The OIE has developed international science-based

[14] An additional revenue loss of $659,000 per month, October through January, multiplied by the four months, yields an additional annual revenue loss of $2,636,000. This amount divided by the total baseline revenue from cow slaughter projected in the regulatory impact analysis of $2,892,770,580 (5,084,000 cows slaughtered, at a price of $54.19 per cwt and an average weight of 1,050 pounds) yields an additional revenue loss on an annual basis of 0.09 percent.

[15] Compiled by APHIS using data from the Department of Commerce, U.S. Census Bureau, Foreign Trade Statistics.

animal health standards to permit safe international trade in beef from countries that have BSE, based on the risk level of such countries. The OIE has classified both the United State and Canada as controlled risk countries for BSE.

We anticipate that the economic impact of any additional cases of BSE-infected cows imported from Canada will likely be minimal. As noted above, after the 2003 detection of BSE in Washington State, many of the 114 nations which imported U.S. beef banned our beef and live animals, but over half—including our largest export market, Japan—have resumed importing U.S. beef (USDA 2006).[16] The joint U.S.-Japan press statement for resuming trade in beef and beef products after market closures in response to finding BSE in the United States noted that the United States has a ''robust'' food safety system, and stated that ''identification of a few additional BSE cases will not result in market closures and disruption of beef trade patterns without scientific foundations'' (USDA 2004). Adherence to science is imperative to expanding trade opportunities and maintaining existing market access. Continued import bans by other countries without sufficient scientific basis to warrant such measures, and maintained without adequate assessment of specific risks, may not be consistent with international trade obligations, and U.S. Government agencies continue to work to reopen such markets.

One of the potential incremental costs of the detection of BSE in an imported cow is the regulatory expense of investigating such cases and paying indemnity for animals that are destroyed. Based on the U.S. experience with native BSE cases that have been detected, the regulatory costs per case total approximately $250,000 for epidemiological investigations and indemnification of depopulated animals.

The potential domestic market effects of any new cases of BSE are difficult to predict. However, as described in the consequence assessment in our risk assessment, there is little reason to expect that additional U.S. cases of BSE would have a significant impact on U.S. beef consumption, based on past experience.

Although the first U.S. discovery of BSE, a cow of Canadian origin, resulted in major restrictions on U.S. beef exports, that case and subsequent cases have not, to use the commenter's term, ''substantially undercut'' U.S. demand for beef or dairy products. Studies show that any negative consumer response to the discoveries of BSE in Canada and the United States in May and December 2003, respectively, was neither significant nor long-lasting.

Consumer opinion surveys as summarized by Coffey *et al.* (2005) indicated that between 14 and 29 percent of respondents reported reducing their beef consumption. However, as Kuchler and Tegene (2006) point out, survey responses may systematically differ from actual market behavior. Coffey *et al.* found that, in the months following the December 2003 BSE discovery, consumer demand for beef increased.

Vickner, Bailey, and Dustin (2006) analyzed weekly grocery store purchases, from May 9, 2004, to May 1, 2005. The authors studied the impact of BSE announcements on consumer demand for beef in Utah over this time period and found that Utah consumers were not responsive to BSE announcements during that period. Kuchler and Tegene found similar results on a national scale. The authors studied three separate markets, including fresh beef from grocery store meat counters, frozen beef, and frankfurters. The study concluded that the announcement of the finding of BSE in a Washington State cow may have reduced purchases of fresh and frozen beef over a 2-week period, but had no impact on purchases of frankfurters. A similar announcement for the finding of BSE in Canada had no noticeable impact on beef purchases in the United States.

Although various consumer studies have concluded that discovery of additional cases of BSE in the United States may lead to decreased consumption of beef, the market has not substantiated this conclusion. In the first year after the December 2003 BSE discovery, beef consumption increased. While consumption in 2005 was above 1998 levels, consumer demand started to decline. This decline was likely due to a combination of factors, including increased supplies of poultry and a slowing of growth in consumers' disposable incomes (Mintert, 2006). There is no evidence to suggest a decline in consumption related to the confirmation of additional cases of BSE in the United States.

Issue: Several commenters stated that APHIS' economic analysis does not consider potential demand changes regarding exports of U.S. beef that could result from implementation of the proposed rule. A number of commenters expressed concern that the rulemaking would exacerbate the limited access of U.S. beef to world markets and harm the ability of the United States to restore lost export markets. Commenters stated that imports of Canadian cattle and beef are currently banned by 35 countries, including the important U.S. export markets of the Republic of Korea, Singapore, and Taiwan, and that APHIS should not consider relaxing its BSE import restrictions in light of ongoing international concerns regarding the safety of Canadian beef and cattle. Other commenters stated that the United States should allow imports only of classes of cattle and beef that U.S. export markets are willing to accept from the United States.

Several commenters expressed concern that, should Mexico cease accepting imports of cattle and beef from Canada, the commingling of Canadian and U.S. cattle and beef products would negatively affect the reopening of Mexico to U.S. live breeding cattle and the present export of processed beef to Mexico.

Response: The commenters raise the concern that, by allowing Canadian cattle born on or after March 1, 1999, to be imported into the United States, U.S. beef export markets will become more restrictive. Various countries have enacted different levels of restriction on beef imports from the United States and Canada. However, we expect any restrictions placed on beef from the United States and Canada by an importing country to become more uniform, as discussed below, and, therefore, for the rule to have little effect on U.S. beef export markets.

The reason for the expected uniformity is the May 2007 OIE decision to classify both Canada and the United States as BSE controlled risk countries. By this decision, the OIE recognized the effectiveness of the science-based mitigations and interlocking safeguards in both countries. This classification is expected to help the beef industries in both the United States and Canada to expand their access to export markets.

Issue: One commenter stated that APHIS' economic analysis does not truly analyze the potential ''consumer welfare'' of the rulemaking. The commenter stated that the closest the analysis gets to considering the consumer is its consideration of wholesale buyers of processing beef and fed beef—whom the commenter stated APHIS should identify as the primary beneficiary of the rule.

Response: The principal model that we use to estimate welfare effects resulting from the rule does not extend beyond the wholesale level to retailers and end buyers of beef. We

[16] The temporary closure of the U.S. export market to Japan in January 2006 was in response to a specific commodity concern and not to the likelihood of BSE infection in the U.S. herd.

acknowledge this modeling choice in our discussion of sector impacts in the analysis for the final rule, and note that benefits received at the wholesale level can be expected to be at least partly distributed downstream to retailers and final buyers, depending on the levels of competition. Nevertheless APHIS believes this modeling choice is consistent with standard RIA practices, as recommended by OMB Circular A–4, and that it adequately identifies the impact of this regulatory action.

APHIS agrees, however, that some indication of the distribution of benefits in different product markets would be an interesting addition to the model. As part of the economic analysis for the final rule, we simulate substitution among livestock products in response to relative price changes using a multi-sector model. Although meant simply to be illustrative and subject to considerable uncertainty, included in the simulations is a derivation of consumer welfare changes at the retail level. Results of this analysis suggest that consumer surplus for buyers of beef at the retail level may increase by 1.0 to 1.3 percent compared to a 2006 baseline.

Issue: One commenter stated that APHIS should also broaden the model used in the economic analysis to account for cull animal producers, so that welfare implications to producers of U.S. cull animals and processing beef could be separated from those of the packers. The commenter stated that APHIS' analysis includes no single estimate of the economic impact of the rule on cow-calf producers resulting from the change in value and demand for U.S. cattle.

A number of cow-calf producers provided estimates of the potential economic impact of the proposed rule on their individual operations.

Response: In our regulatory flexibility analysis for this final rule, we present a sector-based analysis that includes a separate consideration of impacts of the rule for the cow-calf and dairy sector. The sector analysis uses the measures of welfare change estimated for cull cattle/processing beef, feeder cattle, fed cattle, and fed beef, distributing these changes among the commodities' principal buyers and sellers.

Concerning the numerous comments we received regarding economic impacts of the rule on individual livestock producers, we acknowledge that analysis does not fully identify the distribution of all of the possible effects on the vast array of different types of entities that comprise the cattle and beef industries. Because of the different choices made by market participants, it would be difficult, if not impossible, to design such an analysis. For example, some large firms likely also act as wholesalers and distributors, and may be participants in fed cattle, feeder cattle, and other markets. The analysis APHIS has produced does identify the direct impacts of the regulation on the industry; the results of our analysis are based on baseline quantities and prices and import projections that are well supported by historical trends and economic research. The models that we use to estimate price and welfare effects are also well-grounded in theory and utilize methodologies widely accepted by economists. We are confident that the results of the analysis appropriately depict expected net effects of the rule for the modeled commodities.

Issue: Commenters noted that APHIS estimated that 46,800 Canadian dairy breeding animals could be imported annually into the United States as a result of this rulemaking. The commenters expressed concern that these animals would have a negative impact on the effectiveness of the Cooperatives Working Together (CWT) herd retirement program, which the commenters noted is funded by voluntary dairy producer assessments. (CWT is a national program, organized by dairy farmers, with the goal of reducing milk supply and demand imbalances and, in doing so, of delivering a significant return on farmers' investments through higher, more stable, milk prices.)

The commenters stated that the proposed rule would have the effect of having U.S. dairy farmers assessed to reduce the U.S. dairy cattle herd, while, at the same time, cattle are being imported from Canada to replace those animals.

One commenter stated that APHIS should have made the effort to incorporate ''expected future net returns,'' as well as impacts on milk prices, into an analysis of breeding cattle imports, and that the economic analysis should have modeled impacts on the milk market, and resulting impacts on producer incomes and the price of milk cows. Commenters expressed the opinion that APHIS failed to meet its obligations under Executive Order 12866 and the Regulatory Flexibility Act in its economic analysis by not performing the required analyses regarding imported dairy replacement animals.

Response: We do not expect imports of dairy animals from Canada to add significantly to the U.S. national herd, but, rather, to serve as an additional source of replacement animals. Dairy breeding cattle replacements imported from Canada during 1992 to 2002 represented about 1.1 percent of U.S. dairy heifer replacements over this period. We have no reason to expect the supply of Canadian heifer replacements to be greater than historical levels. In fact, the numbers of dairy heifer replacements present on all cattle operations in Canada have been in decline in recent years, from 512,000 on January 1, 2003, to 476,300 on January 1, 2007. The number of operations that specialize in raising heifers has also decreased. In Ontario and Quebec, there were 487 of these operations on January 1, 2003, and only 296 on January 1, 2005.[17] The currency exchange rate is also less favorable to Canadian exports than it was prior to 2003.

There is no evidence that imports of dairy cattle from Canada have historically had any significant effect on the U.S. cow herd, U.S. dairy heifer prices, or U.S. milk prices. The U.S. milk herd declined from about 9.7 million head in 1992 to about 9.1 million in 2002. The number of U.S. milk cow replacements[18] remained essentially steady, fluctuating between 4 million and 4.1 million head over that same time period.[19] An empirical investigation by Mussell, *et al.* (2006)[20] concluded that imports from Canada prior to 2003 had no statistically significant impact on the U.S. dairy herd. Imports of dairy heifers from Canada were also found to have no statistically significant impact on U.S. heifer prices in the United States, nor on U.S. milk prices.

As noted by commenters, a producer dairy herd retirement initiative called CWT is currently underway.[21] The number of imported dairy breeding cattle projected in our economic analysis for the proposed rule was based on historical import levels prior to formation of CWT. Imports of dairy heifers are driven by the demand for replacement animals, relative prices, and the exchange rate. If dairy farmers are dedicated to reducing the national

[17] Ontario and Quebec account for approximately two-thirds of the dairy cattle inventory in Canada. Source: Statistics Canada, as cited in Al Mussell, Graeme Hedley, Don Ault, and David Bullock, ''Role and Impact of Renewed Canada—U.S. Trade in Dairy Heifers and Dairy Breeding Stock,'' George Morris Centre, Informa Economics, February 2006. *http://www.informaecon.com/*

[18] Heifers 500 pounds and over kept for milk cow replacements. Source: Agricultural Statistics, National Agricultural Statistics Service, USDA.

[19] In table 17 of the preliminary Regulatory Impact Analysis that accompanied our January 2007 proposed rule (Docket No. APHIS 2006–0041), under column ''Average Annual U.S. Heifer Replacements'' the numbers for Beef and Dairy were transposed.

[20] Mussell, *et al.* (February 2006).

[21] *http://www.cwt.coop*

dairy herd, they may purchase fewer replacement animals and the import projections may be overstated. However, if a replacement dairy heifer from Canada can be purchased at a lower price than a domestic one, then it is to the producer's (and industry's) advantage for the Canadian replacement to be purchased and a domestically raised animal to be retired. Therefore, APHIS disagrees with the commenters' claims that dairy producers will somehow be worse off with this rulemaking. As a lower priced replacement heifer would represent a lower priced input into the production of dairy products, standard economic theory indicates that producers and consumers will be better off.

Issue: One commenter stated that APHIS' economic analysis indicates that imports of dairy cattle from Canada would be expected to represent ''only'' 1.1 percent of the annual U.S. dairy heifer crop. The commenter stated that, although APHIS labels this percentage as small, a short-term change in the milking herd of 1 percent can change milk prices by 10 percent or more.

Response: We agree that a 1 percent increase in the national dairy herd (and a corresponding increase in milk production) may result in a decline in milk prices. However, as we discuss above, imports of dairy animals from Canada that occur should serve as an additional source of replacement animals, rather than adding entirely to the national milking herd. First, we would reiterate that imports are voluntary; we believe any projected imports of dairy heifers would be undertaken because the cost saving associated with the import would be greater than any decrease in revenue due to relative price declines resulting from higher production and lower prices. We further note that we believe the comment overestimated the expected price declines due to this regulatory change. The projected number of imported dairy cattle is equivalent to 1 percent of the dairy heifer crop and not 1 percent of the entire milking herd, which is more than twice the size of the annual dairy heifer crop. Projected imports of dairy heifer replacements and other breeding cattle represent approximately 0.45 percent of the milking herd.

In 2006, the farm-milk supply produced from 9.1 million dairy cows was 181.8 billion pounds of milk (19,951 pounds per cow) at an all-milk price of $12.90 per cwt, which is a weighted average of the fluid grade milk price of $12.92 per cwt and the manufacturing grade milk price of $12.21 per cwt. An increase in the size of the milking herd would increase milk production.

If all 47,800[22] dairy heifers projected to be imported from Canada were to constitute an addition to the U.S. milking herd, they would represent a 0.5 percent increase over the 2006 U.S. herd size. This increase would correspond to a change in milk production of approximately 0.5 percent.[23] We would expect the short-run effects (more inelastic supply) of such an increase in the U.S. milking herd to be larger than the longer term effects (more elastic supply). Assuming a short-run supply elasticity of milk of 0.15 and a demand elasticity of −0.30,[24] a 0.5 percent increase in milk production is estimated to decrease the milk price by 15 cents per cwt. This translates into a 1.2 percent price decline. As supply becomes more elastic, the price decline resulting from a 0.5 percent increase in production becomes smaller. Assuming a longer run supply elasticity of 0.50 would lead to an estimated decline in price of 9 cents per cwt, or 0.7 percent.

This example of potential effects on milk prices due to changes in the size of the U.S. milking herd assumes that the projected imports of Canadian breeding cattle would be absorbed into the U.S. milking herd in their entirety, thereby slightly expanding the overall size of the U.S. milking herd. An analysis of scenario 3 as discussed in our economic analysis and in the summary of that analysis in this document (entry of Canadian cattle born on or after March 1, 1999, and resumption of imports of beef from Canadian cattle slaughtered at 30 months of age or older) using the multi-sector model indicates that dairy producers may experience price declines of 1.3 to 1.7 percent for dairy cattle, due to the small number projected to be imported from Canada. These imports translate into an increase in U.S. milk production of 0.1 percent or less, and a decline in the price of milk and increase in consumer surplus of less than 0.1 percent.

[22] Projected annual imports 2008–2012.

[23] Assuming the additional heifers produce milk at the same average rate reported for the U.S. herd in 2006.

[24] Milk supply elasticities of 0.12 in year 1 and 2.46 in year 10 are cited in Chavas, J.P., and R.M Klemme, ''Aggregate Milk Supply Response and Investment Behavior on U.S. Dairy Farms,'' *American Journal of Agricultural Economics* 78 (February 1986). A total dairy product demand elasticity of −0.31 is cited in Haidacher, R.C., J.R. Blaylock, and L.H. Meyers. ''Consumer Demand for Dairy Products, A Summary Analysis.'' USDA Economic Research Service, Agriculture Information Bulletin 537 (March 1988).

Issue: One commenter noted that the importation of live animals from Canada has enabled many U.S. plants to better utilize their slaughter capacity, allowing them to maximize plant efficiencies. The commenter stated that allowing the resumption of imports of older animals to the United States, as envisaged in the proposed rule, might enable some previously closed plants to reopen.

Response: The resumption of cull cattle imports from Canada will provide increased throughput for U.S. slaughter plants, especially those that principally slaughter and process cull animals. While the cattle from Canada will enable these businesses to more fully utilize their available capacities, we do not anticipate the effects to be highly significant. Nor are we aware of plants that have closed and will be reopened due to reestablished cull cattle imports. Our analysis for scenario 3 as discussed in our economic analysis and in the summary of that analysis in this document (entry of Canadian cattle born on or after March 1, 1999, and resumption of imports of beef from Canadian cattle slaughtered at 30 months of age or older) indicates that the additional numbers of cull cattle marketed over the 5 years, 2008–2012, will not increase substantially. Compared to projected U.S. baseline slaughter numbers averaging 5.4 million head of cows and 570,000 head of bulls and stags over the 5-year period, imports of Canadian cows and bulls/stags are projected to average 89,400 head and 16,600 head over the same period, representing 1.7 percent and 2.9 percent of the baseline quantities. These percentages in fact overstate the expected impact of the rule in terms of cull cattle slaughter because they do not take into account the effect of expected price declines on domestic sales. Notwithstanding this cautious assessment of the extent to which the rule will benefit U.S. facilities, the slaughter industry is expected to benefit from improved operating efficiencies.

Issue: One commenter stated that APHIS' economic analysis for the proposed rule did not consider the economic implications of the combination of the rule and Canada's implementation of its expanded feed ban on July 12, 2007, which bans the inclusion of SRMs in any animal feeds, pet foods, and fertilizers. The commenter stated that, under the expanded Canadian feed ban, SRMs in Canada will have little or no economic value. Instead, said the commenter, the materials will generate a disposal cost, thereby providing increased incentive for Canadian producers to ''send all their cattle over 30 months of age to the

U.S. for slaughter where the SRMs can continue to be used as ingredients in other U.S. animal feed, pet food, and fertilizer * * *. The result would be an even greater supply of imported Canadian cattle than what APHIS presently predicts and a correspondingly greater decline in U.S. cattle prices.''

Response: We acknowledge that Canada's July 2007 expansion of its feed ban eliminates the value of SRMs for producers of cattle slaughtered in Canada, and we agree that the continued use of SRMs in the United States for rendered purposes other than as a component of ruminant feed will contribute to a difference in prices paid for cattle at slaughter in Canada and the United States. Because SRMs are defined more broadly for cattle 30 months of age or older than for animals under 30 months of age, this effect on relative prices in the two countries will be more notable for cull cattle. For all cattle, the tonsils and distal ileum are considered SRMs, whereas for cattle 30 months of age or older, SRMs also include the brain, skull, eyes, trigeminal ganglia, spinal cord, vertebral column (excluding the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae, and the wings of the sacrum), and dorsal root ganglia.

However, even for cull cattle, the value of rendered SRMs is relatively minor in comparison to the total value of the slaughtered animal. In a 2005 analysis of economic impacts of alternative FDA animal feed regulations, the value of SRMs was estimated using a 4-year average of byproduct market prices.[25] For cattle slaughtered at greater than 30 months of age, the value of SRMs used in MBM products was valued at $2.35 per animal, and the value of SRMs used for tallow was valued at $2.19 per animal. Thus, the total value of SRMs from cull cattle used as rendered byproducts is estimated to be less than $5 per animal. Given a projected 2008 nominal value of about $569 per cow, the income from SRMs gained by selling the animal in the United States rather than in Canada will represent less than 1 percent of the projected price of the animal at slaughter.[26] Canada's July 2007 feed ban may make the U.S. market more attractive, but not appreciably.

Issue: One commenter stated that APHIS' analysis of the projected economic effects of the rule should be revised to take into account the handling of increased amounts of SRMs.

Response: In the regulatory impact analysis we conducted for this rule, projected prices for processing beef and fed beef incorporate animal slaughter and meat packing costs, including costs of handling SRMs. Costs and returns per animal of handling SRMs are not expected to change for slaughtering facilities because of the rule and therefore do not require specific analysis. Copies of the full amended analysis may be viewed on the APHIS Web site (*http://www.aphis.usda.gov/newsroom/hot_issues/bse/index.shtml*), or be obtained by contacting the person listed under **FOR FURTHER INFORMATION CONTACT**.

Environmental Assessment for the Rulemaking

Consistent with the National Environmental Policy Act of 1969 (NEPA), as amended (42 U.S.C. 4321 *et seq.*), regulations of the Council on Environmental Quality (CEQ) for implementing the procedural provisions of NEPA (40 CFR parts 1500–1508), and APHIS' NEPA implementing procedures (7 CFR part 372), we prepared an environmental assessment (EA) regarding the potential impact on the quality of the human environment due to the importation of live bovines and products derived from bovines under the conditions specified in our proposed rule. We made the EA available to the public and accepted public comment on its provisions. We discuss below the issues raised by commenters who addressed the EA.

Issue: One commenter stated that the EA that APHIS conducted for the proposed rule did not adequately discuss the impact of air emissions from additional truck round-trips entering the United States that would result from importation of cattle 30 months of age and older from Canada. The commenter stated that USDA apparently did not consider the fact that these emissions would be concentrated in relatively small parts of the country. Further, said the commenter, the EA's discussion of air pollutants and mitigation measures is limited to those pollutants regulated under the Clean Air Act and does not recognize what the commenter described as substantial emissions of greenhouse gases that could result from the additional truck trips.

Response: Our EA estimated that the number of additional cattle that would be available for importation into the United States as a result of this rule would result in a 0.05–0.16 percent increase in truck transports, compared to the annual truck transport baseline, discussed below. However, more recent data from ERS indicate that the number of additional cattle that would be available and eligible for import from Canada as a result of this rulemaking initially will be less than the number we used in the calculations for our October 2006 EA. Consequently, the estimated number of truck transports initially will also be less, as will the emissions generated by such transports.

In the finding of no significant impact (FONSI) (APHIS 2005a) that APHIS made in conjunction with our January 2005 final rule, we discussed truck transports for cattle under 30 months of age. Prior to implementation of that final rule, the projected number of imports of cattle under 30 months of age would have caused the resumption of about 35,000 truck transports. The FONSI for our January 2005 final rule determined that the result of environmental impacts from resuming 35,000 trucks transports would be *de minimus.* Afterward, based on a decrease in the projected number of available imported animals under 30 months of age, the estimated number of truck transports projected to be resumed was adjusted downward to range between 19,460 to 22,140 annually.

As discussed in the EA for this final rule, for cattle born on or after March 1, 1999, cattle import numbers are projected to range between 130,000 to 446,000 over a 20-year period after implementation of this rule. The number of associated truck transports that would resume for this rule would range from 2,600 to 8,920. When added to the truck transports resumed as a result of our January 2005 final rule, the total number of projected resumed truck transports is still within the amount described in the FONSI for our January 2005 final rule as *de minimus.* Additionally, that projected number is within the number of truck transports for cattle trade that occurred between Canada and the United States before such trade was temporarily halted in May 2003.

As we stated in our EA, the transport of cattle could occur through any of 20 U.S.-Canadian border ports specifically equipped to handle cattle. These ports are not confined to one region of the United States, but stretch across nine northern border States from Washington to Vermont. Market patterns and geographic issues can cause fluctuations in the availability and importation of cattle. Availability of cattle for

[25] ''Economic Impacts of Alternative Changes to the FDA Regulation of Animal Feeds to Address the Risk of Bovine Spongiform Encephalopathy: Final Report.'' Submitted by Eastern Research Group, Inc. to the Office of Policy and Planning, Food and Drug Administration, July 25, 2005.

[26] Boning utility cow, Sioux Falls, price of $54.19 per cwt, multiplied by an average weight of 1,050 pounds yields an average value of $569 per animal. Assuming a total value per cow for rendered SRMs of five dollars: $5/$569 = 0.0088.

importation also can vary depending upon the time of year and geographic location. For example, most feeder cattle are imported through certain western ports from areas with the highest cattle population in Canada, and more feeder cattle may become available in the fall when ranchers wean calves and sell them. Cull cattle for immediate slaughter historically have come through different ports than feeder cattle, including some eastern ports. Emissions from trucks importing cattle from Canada could affect any of the 20 locations at the U.S.-Canadian border and any location between transport origination and destination.

In determining if the impacts from truck transport emissions from carrying additional cattle as a result of this rule could result in a significant impact on the environment, a baseline of the annual overall truck transports was used. In this case, the baseline used for comparison was for all incoming trucks from Canada to the United States through 20 approved ports of entry where cattle can transit to determine whether the increase in the numbers of imported cattle would cause a significant increase in air emissions. The comparison of the baseline (the average number of heavy-duty truck crossings annually between the U.S.-Canadian border) to the number of truck transports estimated for cattle 30 months of age and older that would be available to be imported from Canada annually shows that the increase in the number of truck transports would not be significant.

To a great extent, projecting the specific air emissions that would result from implementation of this rule would be speculative. Emissions vary according to many different factors, including type of truck engine, the year the engine was manufactured, fuel properties, the type of hauler and weight of the load, the grade of the highways on the transport routes, the distance traveled, speed and acceleration, and the amount of wait time at the border ports. Due to the comparatively small amount of truck transports (ranging from 2,600 to 8,920) that are projected to result from this rule in relation to the baseline, speculating on the specific air emissions that would result from this rule would not result in information indicating that the indirect impacts, unassociated with the scope of this rule, would contribute to significant adverse impacts on the environment from resuming imports from Canada of cattle over 30 months of age born on or after March 1, 1999.

The method of transporting cattle and the type of vehicle to be used are not mandated by APHIS regulations. Emissions from the transport of cattle, or of any commodity moved by modern transport methods, are unavoidable. However, measures to reduce the impacts from vehicle emissions are enforced by environmental statutes, such as the Clean Air Act, at both the State and Federal levels and have been reported to be effective in regulating and decreasing vehicle emissions. Mitigations for vehicle emissions are under the jurisdiction of the U.S. Environmental Protection Agency and State government agencies and are outside of the mission of APHIS.

The commenter is correct that the EA did not discuss the contribution of greenhouse gases from the transport trucks that would be used to import cattle and did not discuss mitigation measures for greenhouse gases. We note that draft guidance provided to Federal agencies from the Council on Environmental Quality with regard to consideration of global climatic change in environmental documents calls for consideration, in the context of NEPA, of how major Federal actions could influence the emissions and sinks of greenhouse gases and how climate change could potentially influence such actions.[27] We interpret that this guidance does not apply to this rulemaking because it is not a major Federal action that could influence the emissions and sinks of greenhouse gases .[28]

Issue: One commenter stated that APHIS' EA did not assess the environmental impact of holding and feeding in the United States each year hundreds of thousands of Canadian cattle 30 months of age or older.

Response: Approximately 34 million head of cattle are slaughtered in the United States each year. Approximately 0.13 to 0.45 million additional head of cattle would be available annually and eligible for importation from Canada under this rulemaking. The majority of cattle that we anticipate being imported from Canada and held in feedlots will be cattle under 30 months of age that are already allowed importation from Canada under our January 2005 final rule. The majority of additional cattle that we expect to be imported as a result of this rulemaking would consist of cows, bulls, and stags imported directly for slaughter that would remain in a holding facility of the slaughter facilities for approximately 1 to 2 days before slaughter. A small percentage of the remainder of the cattle that we expect to be imported as a result of this rulemaking would consist of breeding cattle (for example, dairy or beef cows and heifers and bulls) that would be integrated into a cattle herd for an indefinite period of time. Thus, for purposes of the EA, the cattle that would be imported would not be held in feedlots for a long duration and would not contribute to an increase to the baseline of the number of cattle produced in the United States and held and fed in feedlots each year.

Pollutant discharges and emissions from holding cattle in feedlots are unavoidable; however, measures to reduce the impacts from feedlot discharges and emissions are enforced by environmental statutes, such as the Clean Water Act and the Clean Air Act, at both the State and Federal levels. Requirements for mitigating pollutant discharges and emissions, under the jurisdiction of Federal and State government agencies, are intended to protect the human environment of the United States.

Issue: One commenter expressed the opinion that our EA was inadequate because, according to the commenter, it failed to explain why the potential for widespread distribution of infectious BSE prion proteins is not a significant environmental impact. The commenter expressed concern that blood and SRMs that will be collected when cattle of Canadian origin that are over 30 months of age are slaughtered can be used as fertilizer and be spread on the ground (and ingested as well as running off into streams) on farms throughout the United States. The commenter stated further that the EA did not assess the environmental impact of distributing infectious BSE prion proteins in animal feed that will be used (and spilled, disposed of, and excreted) on farms across the United States. The commenter stated that OIE guidelines prohibit trade in SRMs for use in fertilizer, as well as trade in fertilizer contaminated with SRMs.

Response: The commenter did not specify, and it is not clear to us, in what manner the commenter anticipates prions being widely distributed through animal feed and fertilizer and having a significant impact on the quality of the human environment. Scientists believe that the primary route of BSE

[27] Memorandum to All Federal NEPA Liaisons, dated October 8, 1997, from Dinah Bear, General Counsel, Executive Office of the President, Council on Environmental Quality, with attached draft memorandum from Kathleen A. McGinty, Chairman, on Guidance Regarding Consideration of Global Climatic Change in Environmental Documents Prepared Pursuant to the National Environmental Policy Act.

[28] A sink is, simply speaking, the converse of a source. Instead of releasing carbon into the atmosphere as is done when fossil fuels or wood are burned, sinks absorb carbon and lock it in. The most obvious examples are trees and other plants.

transmission in cattle requires that an animal ingest feed that has been contaminated with a sufficient amount of tissue from an infected animal. In humans, vCJD, a chronic and fatal neurodegenerative disease of humans, has been linked via scientific and epidemiological studies to exposure to the BSE agent, most likely through consumption of cattle products contaminated with the BSE agent. Therefore, our assumption is that the commenter's primary concern regarding the potential impact of feed and fertilizer on the environment is the potential consumption of BSE-contaminated feed or fertilizer by ruminants or humans. We also consider it possible that the commenter is concerned about the potential for the BSE agent to be consumed by animals other than ruminants, excreted by those animals, and subsequently consumed by ruminants or humans.

The commenter stated that APHIS inadequately assessed the potential environmental impact of contaminated feed and fertilizer. We disagree with the commenter. Our EA evaluated the potential impact of the proposed rule on the physical environment, public health, and endangered species, as well as cumulative impacts of any of the above. The EA referenced and discussed the conclusions of the risk assessment we conducted for this rulemaking, in which we assessed the likelihood that U.S. cattle would be exposed to the BSE agent as a result of this rule. Our risk assessment examined the likelihood of exposure of ruminants to BSE via feed.

Our evaluation of risk included an understanding that SRMs from live cattle imported under the conditions of the proposed rule would enter the U.S. rendering system, in the same fashion that SRMs from cattle of U.S. origin are generally disposed of. The protein products from the rendering system could then be incorporated into either animal feed or fertilizer. We assumed in the risk assessment that the vast majority of rendered protein products are sold for use in animal feed. The commenter makes this assumption as well, stating that ''* * * SRMs can be used as a protein source for animal feed other than ruminant feed, and it is reasonable to assume that they will be, given the favorable economics of this use as compared to SRM disposal.''

The quantitative exposure model used in the risk assessment specifically simulated potential exposures through feed—either through ruminant feed that was mislabeled or cross-contaminated, through other animal feed that was misfed to ruminants, or directly through poultry litter that could contain spilled feed and be fed back to cattle. These pathways are the most direct exposure of cattle that could occur.

We disagree with the commenter's assertion that APHIS did not consider ''spilled, disposed of, or excreted'' animal feed as a potential pathway of BSE transmission. The poultry litter pathway modeled in the quantitative exposure model specifically addresses spilled and even undigested excreted feed, with very conservative assumptions about potential infectivity retained in such feed. The issue of feed being ''disposed of'' is addressed through the misfeeding component of the model, which incorporates situations where non-ruminant feed is fed directly to cattle. These situations would include those where a producer either mistakenly or intentionally feeds non-ruminant feed to ruminants. Mislabeling and misfeeding components would include situations where non-ruminant feed is sold for salvage value. We are not aware of similar situations where litter or waste from other species—for example, swine litter—that contains quantities of either spilled or undigested feed is routinely used for cattle feed. Further, there is no evidence to date of environmental contamination (e.g., via fecal or other bodily excretions) being a route of transmission of BSE. Therefore, we do not consider there to be potentially significant pathways for exposure of susceptible animals to BSE-contaminated feed that were not considered in the risk assessment.

With regard to potential exposure of humans to the BSE agent, there is no evidence, anecdotal or otherwise, to suggest any likelihood of BSE-contaminated animal feed, spilled or excreted, being consumed by humans, and we consider the risk of such exposure to be negligible.

The commenter also stated that the EA should have examined the potential impact on the environment of BSE-contaminated fertilizer. As noted above, although rendered protein can be a component of fertilizer, such usage is not common because most rendered proteins are sold for use in feed. Any consideration of animal health exposure from fertilizer would be an evaluation of the risk of cattle exposure to BSE through oral consumption of fertilizer that contains rendered protein. Our quantitative exposure model evaluates the potential oral exposure of cattle to feed containing such rendered protein. It does not specifically model potential exposure through fertilizer. However, it assumes that all rendered ruminant protein products are sold for feed use. Therefore, any of the infectivity contained in rendered ruminant protein is already simulated through the potential for direct feed exposure. This is a more direct pathway than any potential consumption of a component of a fertilizer product, some undefined time after it was spread on a pasture. Therefore, any potential exposure through fertilizer would be assumed to be far less than the exposure the model already takes into account through the consumption of feed.

It appears that the commenter is suggesting that raw, untreated SRMs might be spread directly on land as fertilizer. Raw or untreated tissues are not generally used as fertilizer, and, in fact, are often prohibited from being spread on land through environmental regulations on carcass/offal disposal and solid waste disposal. Therefore, this risk pathway was not considered in our risk assessment.

With regard to the likelihood of exposure of humans to the BSE agent through fertilizer, we are assuming the commenter is not referring to potential consumption by humans of fertilizer, and is referring instead to some other method of BSE transmission to humans through fertilizer. As noted above, there is no evidence to date of environmental contamination being a route of transmission of BSE.

Regarding the commenter's statement that OIE guidelines recommend that trade not be carried out in SRMs for use in fertilizer, as well as trade in fertilizer contaminated with SRMs, the primary purpose of such guidelines is to reduce the possibility of the consumption by cattle of such product due to mislabeling or misdirection of shipments—e.g., through having SRM-derived protein for fertilizer mistakenly sent to a feed mill.

Other Issues

A number of commenters raised other issues that did not address the provisions of the proposed rule.

Requests Regarding the Importation of Additional Commodities

We received comments that requested that bovine commodities not specifically addressed in our proposed rule be made eligible for importation into the United States.

Issue: Several commenters requested that U.S. regulations with regard to BSE allow the importation of the same commodities that Canada considers eligible for importation from the United States.

Response: Although in most cases, Canadian and U.S. import restrictions regarding BSE are comparable, we do not consider it practical or advisable to

attempt to mirror the regulations of another country, given differences in regulatory approach, structure, and authority.

Issue: Commenters requested that the current regulations be amended to allow the importation from BSE minimal-risk regions of rendered feed products—including bovine-derived meat-and-bone meal and blood meal—that are manufactured in compliance with U.S. regulations if the products can be determined to meet the health protection objectives of the recommended standards of the OIE.

Response: The recommended standards of the OIE clearly state that ruminant-derived rendered protein should not be traded from either controlled risk or undetermined risk countries.

For the reasons discussed above, we are making no changes based on these comments.

APHIS's Use of the Term ''Minimal-Risk Region''

Issue: Several commenters requested that APHIS discontinue classifying and referring to countries as ''BSE minimal-risk regions.'' The commenters stated that APHIS's definition of ''minimal-risk regions'' does not follow the scientific terminology of the OIE, which classifies countries with regard to BSE risk as ''negligible,'' ''controlled,'' or ''undetermined.'' One commenter stated that APHIS's classification of BSE minimal-risk regions may create confusion and be seen as not accepting the OIE categorization criteria.

Response: At the time APHIS published its January 2005 final rule to recognize a category of BSE minimal-risk regions, the OIE guidelines regarding BSE provided for five possible BSE classifications for regions. For each classification, the guidelines recommended different export conditions for live animals and products, based on the risk presented by the region. Although APHIS did not incorporate the text of OIE's BSE guidelines into its January 2005 rule, the agency based its standards regarding BSE minimal-risk regions on these guidelines. Although we are making no changes based on the comments, it is APHIS's intent to develop rulemaking that would more closely employ terminology used in the current OIE standards.

BSE Surveillance in the United States

Issue: Several commenters expressed general concern with the effectiveness of the current BSE testing program in the United States. One commenter stated that a report issued by the U.S. Office of the Inspector General (OIG) called into question USDA's ability to adequately detect BSE, even before the most recent reduction in the U.S. surveillance program. The commenter stated that an OIG report pointed to the voluntary nature of the surveillance program and the program's sampling protocols as indicators that the surveillance program may not have been providing an accurate picture of BSE prevalence in the United States. The report also noted that the surveillance program, which focused on high-risk cows, did not account for emerging evidence that BSE has been detected in seemingly healthy animals.

Response: We assume the commenters are referring to an OIG audit report issued in August 2004. This audit was conducted prior to the implementation of the enhanced surveillance program and, therefore, was limited in the conclusions that could be made about the performance of that effort. The report stated the following: ''Our review was limited because implementation plans have not been finalized and APHIS has not yet been able to address some of the questions we have raised.'' Nevertheless, APHIS responded to the recommendations provided by OIG and addressed the issues raised. A second audit report was issued in January 2006, covering both the surveillance program and FSIS' controls on SRM requirements and advanced meat recovery products. This report included a recommendation, among others, for transparency in the analysis and conclusions derived from the data obtained during the surveillance efforts. APHIS has subsequently completed and released a detailed summary of the data obtained during the enhanced surveillance effort, and an estimate of the prevalence of BSE in the United States adult cattle population. This analysis concluded that the prevalence of the disease in this country is extremely low, less than 1 case per million adult cattle. Two models were used to estimate the prevalence, and the most likely values calculated by these models for the estimated number of cases were 4 or 7 infected animals out of 42 million adult cattle. APHIS' analysis was submitted to the scrutiny of a peer review process, and the expert panel agreed with the appropriateness of APHIS' assumptions and the factors it considered, as well as with the estimate of BSE prevalence.

Country-of-Origin Labeling

A number of commenters recommended that APHIS postpone implementation of this rule until mandatory country-of-origin labeling, as prescribed by the 2002 Farm Bill, is in place in this country.

Response: On May 13, 2002, President Bush signed into law the Farm Security and Rural Investment Act of 2002, more commonly known as the 2002 Farm Bill. One of its many initiatives requires country of origin labeling (COOL) for beef, lamb, pork, fish, perishable agricultural commodities and peanuts. On January 27, 2004, President Bush signed Public Law 108–199 which delays the implementation of mandatory COOL for all covered commodities except wild and farm-raised fish and shellfish until September 30, 2006. On November 10, 2005, President Bush signed Public Law 109–97, which delays the implementation for all covered commodities except wild and farm-raised and shellfish until September 30, 2008. As described in the legislation, program implementation is the responsibility of USDA's Agricultural Marketing Service.

The COOL program, when fully implemented, will address the 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.''

Comments on Other Issues Outside the Scope of This Rulemaking

A number of other comments also addressed topics outside the scope of the proposed rule. These comments included the following issues: Concern that the examination and euthanization of cattle be carried out in a humane fashion; a request to extend the U.S. ban on the slaughter of nonambulatory cattle to include all livestock species; recommendations regarding the type of penalties USDA should impose for noncompliance with the regulations; comparison of U.S. and Canadian regulations regarding the rendering of cattle slaughtered on-farm; the importation of composted bovine manure from BSE minimal-risk regions; a request to allow the importation of breeding stock and embryos of small ruminants, such as sheep; a request that the USDA allow the importation from BSE minimal-risk regions of up to 5 kilograms of bovine meat and meat

products for personal use without certification; and concerns regarding diseases other than BSE.

For the reasons discussed above, we are making no changes to the proposed rule based on these comments.

Final Report From Peer Review of APHIS' Risk Assessment and Responses to Peer Reviewer Questions and Recommendations

As discussed above under the heading ''Peer Review of APHIS' Risk Assessment,'' we requested an external, formal, and independent peer review of our risk assessment by recognized experts in the field. The objective of the peer review was to determine whether the risk assessment was scientifically sound, transparent, and consistent with international standards (e.g., those developed by OIE); the application of external assessments or models was appropriate; and the assumptions were justified, supported and reasonable. In summary, the reviewers found that the methods used in the risk assessment were scientifically rigorous in terms of using existing literature and models appropriately and making sound assumptions and that the risk assessment itself adhered to international risk assessment standards. The reviewers also agreed with the conclusion that the likelihood of establishment of BSE in the U.S. cattle population is negligible. They also asked a variety of questions and suggested minor refinements. APHIS' full response to the comments and recommendation of the peer reviewers may be viewed on the APHIS Web site (*http://www.aphis.usda.gov/newsroom/hot_issues/bse/index.shtml*).

Some of the questions raised by peer reviewers were also posed in public comments on our proposed rule and are addressed above in our responses to public comments. In addition, we set forth here certain other questions and recommendations from peer reviewers that we consider representative of the content-related questions and recommendations of the report, and our response to those questions and recommendations.

Issue: A reviewer suggested that we more explicitly list the specific risks to be addressed in the assessment.

Response: The risk of BSE evaluated in the assessment is the expected impact of importing from Canada live animals, blood and blood products, and small intestines excluding distal ileum. These impacts include the potential for establishment of BSE in the United States and the projected consequences of any additional cases that might occur even without establishment. The risk was evaluated qualitatively for all commodities and also quantitatively for additional live animal import scenarios. For the latter, the likelihood of establishment is measured by the disease reproductive rate (R_0). We also simulated the total number of animals in the United States that might become infected with BSE as a result of the importation of live bovines from Canada over the 20 years. Of the infected animals, those that we assumed might have economic impacts were only the animals expected to live long enough to display clinical signs, as these are the most likely to be detectable with current testing methods. We have added this clarification to the Introduction of the revised risk assessment.

Issue: A reviewer suggested that the analysis needs to acknowledge the exogenous sources of BSE into Canada. As phrased by the reviewer:

> For the assumption that BSE prevalence in Canada would decrease over the next 20 years until the disease is eradicated, the authors relied on compelling evidence from the U.K. experience with the ruminant feed ban and the resulting dramatic decrease in BSE prevalence in cattle. However, this did not address any issues associated with exogenous sources of BSE into Canada (imports from other BSE-affected countries). The Canadian prevalence model used for this analysis appears to assume no new exogenous sources of BSE. The dilution of risk due to current practices that reduce the likelihood of spread of prions through the Canadian cattle herd make this risk minimal at best, but it should be addressed for the sake of completeness.

Response: The prevalence estimation models use BSE surveillance data (test results from dead or slaughtered cattle) as inputs and therefore cannot differentiate whether the source of infectivity is endogenous (recycled) or exogenous (introduced). Also, because they are based on actual surveillance data, they cannot attempt to predict any changes in Canadian BSE prevalence over the next 20 years. The qualitative prediction of a drop in prevalence is based on the experience in the United Kingdom and does not assume that no additional infectivity can be introduced. In addition, the results of the U.S. Harvard model presented in our risk assessment illustrate that, despite the recurrent release of ''exogenous infectivity'' (in this case, from Canada), the reproductive constant, R_0, remains well below one, indicating that the mitigations in place (particularly the ruminant feed ban) are effective in driving disease prevalence downward. Since the feed ban in Canada is very similar to that in the United States, we expect that any additional infectivity that may potentially enter Canada would fail to alter our predictions of a decrease in prevalence over time. For these reasons, we do not explicitly address the source of BSE infectivity in Canada as either endogenous or exogenous.

Issue: A reviewer suggested that we address the amount of uncertainty that is associated with the conclusion that the likelihood of releasing BSE into the United States from Canada via importation of live bovines is extremely low. He suggested that we report and use the 95th confidence levels throughout the assessment.

Response: Uncertainty between prevalence estimation models (BBC or BSurvE) is greater than the statistical uncertainty within prevalence estimation models (represented by confidence levels for a given model). Therefore, uncertainty about prevalence is addressed by considering the two expected (average) prevalence estimates obtained with different models. The reviewer also commented that the expectation that prevalence remains stable at the lower level estimated by the BBC model over the next 20 years is ''a very pessimistic assumption.'' Similarly, another reviewer stated that it is ''very reasonable'' to assume that BSE prevalence in Canada will decrease over the next 20 years until the disease is eradicated . If these assertions are correct, then assuming that prevalence remains stable at the 95 percent (or 99 percent) confidence level estimated by the BSurvE model over the next 20 years would simply result in a more extremely pessimistic assumption. A reviewer commented: ''It should'be pointed out that the other pessimistic assumptions in the Exposure Assessment model (for example no decrease in BSE prevalence over the next 20 years) would likely override any underestimate of the present BSE prevalence due to using the mean BBC prevalence estimate.'' For the reasons noted above, we have elected not to rerun the exposure model using the 95 (or 99) percent confidence level.

Issue: A reviewer commented that ''[o]ne argument that might be made is that introduction will not lead to an establishment of a cycle of infection but may extend the temporal occurrence of the number of cases of BSE in the U.S. Are there any adverse economic effect[s] associated with this outcome? One possibility is that testing levels might need to be maintained for a longer time than if there were no more introduced and detected BSE cases. Market access and prices for beef and beef products might also be adversely affected.''

Response: The APHIS risk assessment did not consider endogenous levels of

BSE in the U.S. cattle herd; however, continuous exogenous inputs of BSE infectivity from Canada (as is assumed in the less likely quantitative scenarios of the risk assessment) or any other source would extend the time to eradication of the disease in the United States. Although the incremental duration of the extended time to eradication is unknown, we expect that it would have little or no practical effect on the potential economic impacts of BSE in the United States. We note that the exposure model, which incorporates several risk-inflating assumptions, estimates that, over the 20 years of the analysis, there will be less than one clinical case of BSE in the United States as a result of the cattle imported from Canada. Given that the United States has already detected three BSE cases (two in native cattle), we do not expect any incremental impact (from a lengthened period of testing or from additional market impacts) of this very small number of potential additional cases. This point is described in detail in the consequence section of our risk assessment.

Issue: One reviewer requested greater attention to uncertainty throughout the document. The reviewer stated, in reference to our risk assessment, that ''uncertainty is consistently underplayed if not ignored'' and ''it would perhaps be useful to actually list the sources of uncertainty in each of the sections. Another commenter suggested that we list all the model inputs considered to be variable.

Response: We disagree with the reviewers. Though not always addressed as distinct lists, uncertainty and varibiality are incorporated throughout the risk assessment. The models used in the risk assessment are complex with a large number of inputs, which, as for most models, may be somewhat uncertain and/or variable. However, preparing a comprehensive list of uncertain and/or variable risk assessment model inputs is not necessary. In our judgment, the inputs are better discussed in the context of how they are used in the model.

All of the BSE prevalence estimation model inputs represent best available estimates of either a variability distribution (e.g., BSE incubation period, cattle age structure) or a parameter value (e.g., number of adult animals in the herd, age of a BSE tested animal). Consequently, the calculated confidence intervals represent statistical uncertainty about current BSE prevalence related to random sampling error. The major source of uncertainty regarding BSE prevalence in the current standing cattle population was considered to be the effect of the Canadian feed ban. This uncertainty was addressed by considering two BSE prevalence estimation models: The BBC model, which incorporates an estimate of the effect of the feed ban based on evidence from the United Kingdom, and the BSurvE Prevalence B model, which makes no assumptions about the effect of the feed ban. Variability also entered into the prevalence calculation in that the BBC prevalence model assumes that birth year cohort prevalence declined during the first five years after Canada introduced a feed ban in 1997. Thereafter, both the BBC and BSurvE models were used to obtain the expected proportion of BSE infected animals, which is assumed to remain constant over time in the quantitative risk analysis.

Another component of the release assessment, for which uncertainty has not been addressed, is the projection of imports. These projections were prepared by USDA ERS and were based on USDA baseline projections and a broad array of expert opinion. Because they are projections, they are uncertain. This uncertainty has been reduced somewhat by incorporating more recent data into the 2007 import projections, prepared for the final rule. Based on these updates, we expect lower numbers of older animals to be imported in the early years of the rule's implementation. The total imports over the entire 20 years of the analysis are only slightly (125,000 animals) higher than the original and so do not confer significant additional magnitude of release ($125{,}000*0.68*10^{-6}$=0.085 cases; $125{,}000*3.9*10^{-6}$=0.49 cases). Therefore, although the import projections are somewhat uncertain, reduction of this uncertainty has not significantly changed our release estimates or conclusions.

The projections used in the original analysis incorporated temporal variability across years due to the cattle cycle. The variability considered did not include possible but less likely extremes (shocks), such as a temporary spike in slaughter rates due to severe weather.

The parameters for the exposure model have been described in earlier documents (Cohen, *et al.*, 2003). These documents explicitly examined the effects of uncertainty in key parameters in their respective sensitivity analyses. The version of the Harvard model performed for this rule included a sensitivity analysis to examine the uncertainty of several parameters—some of which were included in earlier models, and some of which were new parameters (e.g., the amount of chicken litter incorporated into ruminant feed) and the Canadian BSE prevalence estimate) (APHIS 2007a). Of the uncertain parameters examined, Canadian BSE prevalence over the next 20 years was the most significant source of uncertainty for the model. This uncertainty contains two components: The estimate of prevalence in Canada's current standing cattle population, and how prevalence of BSE in Canada will change over time. This latter component was not treated quantitatively, and its uncertainty was therefore not explicitly analyzed in the sensitivity analysis. Variability in this parameter was addressed, however. Assuming constant prevalence over the next 20 years, the simulated number of BSE infected cattle imported each year still varies, because it is a combination of the predicted import volume (which varies as described above), and the sampling variation (using a Poisson distribution) about the expected prevalence value. This source of variation has already been described in the risk assessment.

In conclusion, rather than perform a comprehensive uncertainty analysis in which all model inputs are treated as statistical distributions, we identified and evaluated the potential contributions to variability and uncertainty that we deemed most relevant to our analysis. Given that the uncertainty about the key inputs to the risk assessment models has been considered, we agree with the reviewers that further uncertainty analysis will not affect the conclusions of the risk assessment.

Adoption of this Final Rule

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

Applicability of the March 1, 1999, Date to Imports of Beef

Issue: Several commenters stated that it was not clear from the proposed rule whether the March 1, 1999, date of birth requirement for live bovines imported into the United States from Canada would apply as well to frozen beef products derived from cattle slaughtered in Canada and shipped to the United States. If the same effective date does not apply, stated the commenter, USDA should specify what date would be used for imported frozen beef products. One commenter stated that, in addition to prohibiting the importation of beef from cows born before March 1, 1999, the regulations should limit the importation of beef from BSE minimal-risk regions to that derived from cows slaughtered no earlier than March 1, 1999.

Response: We do not consider it necessary to address the importation of beef from BSE minimal-risk regions in this rulemaking, because the importation conditions for meat, meat byproducts, and meat food products derived from bovines were addressed in the rulemaking for our January 2005 final rule (in which we added the category of BSE minimal-risk regions to the regulations and specified which commodities may be imported from such regions). The risk analysis we conducted for that rulemaking indicated a low BSE risk from such commodities derived from bovines of any age if certain conditions are met. In that rulemaking, we discussed regulatory requirements implemented by FSIS in 2004 that banned SRMs from the human food supply in the United States, and we stated that the Canadian Government had established similar safeguards in Canada.

Consequently, we provided in § 94.19 of the regulations that meat, meat byproducts, and meat food products derived from bovines are eligible for importation from BSE minimal-risk regions if the following conditions, as well as all other applicable requirements of the regulations, are met:

- The commodity is derived from bovines that have been subject to a ruminant feed ban equivalent to the requirements established by the U.S. Food and Drug Administration at 21 CFR 589.2000;
- The commodity is derived from bovines for which an air-injected stunning process was not used at slaughter; and
- The SRMs and small intestine of the bovines from which the commodity was derived were removed at slaughter.

Because there is negligible risk from bovine meat, meat byproducts, and meat food products that meet the above requirements, there is no science-based reason to require that such commodities be derived from bovines born on or after March 1, 1999. As long as the commodities meet the conditions listed above (with the exception of the condition regarding small intestine as discussed in this rule), the regulations will allow for their importation into the United States. We note that the OIE guidelines for trade in fresh meat and meat products from cattle from controlled risk regions (both Canada and the United States are classified as BSE controlled risk regions under the OIE guidelines) recognize the negligible risk presented by such products as long as SRMs are removed, and, therefore, the guidelines do not recommend that the date of birth of the animal from which the commodity was derived be a condition for such trade.

Comments Regarding the Partial Delay in Applicability of the January 2005 Final Rule

Issue: As discussed above in this document, in March 2005, APHIS published a final rule in the **Federal Register** that, pursuant to an announcement by the Secretary of Agriculture in February 2005, delayed the applicability of the provisions in our January 2005 final rule as they apply to the importation from Canada of meat, meat food products, and meat byproducts (other than liver) when derived from bovines 30 months of age or older when slaughtered, as well as certain other bovine products when derived from bovines 30 months of age or older.

A number of commenters either questioned whether the delay in applicability would be lifted if our January 2007 proposed rule were made final, or requested that the delay be lifted.

Response: As discussed above, it is the Secretary's intent to remove the delay in applicability when this rule becomes effective.

Executive Order 12866 and Regulatory Flexibility Act

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

We have prepared an economic analysis for this rule. The economic analysis provides a cost-benefit analysis as required by Executive Order 12866 and a final regulatory flexibility analysis that examines the potential economic effects on small entities as required by section 604 of the Regulatory Flexibility Act. The economic analysis is summarized below. Copies of the full analysis may be viewed on the APHIS Web site (*http://www.aphis.usda.gov/newsroom/hot_issues/bse/index.shtml*), or be obtained by contacting the persons listed under **FOR FURTHER INFORMATION CONTACT.**

This rule will allow the importation, under certain conditions, of the following commodities from BSE minimal-risk regions (currently only Canada):

- Live bovines that were born on or after March 1, 1999;
- Bovine small intestines, minus the distal ileum;
- Bovine casings; and
- Bovine blood and blood products.

APHIS has determined that the previous restrictions are not warranted by scientific research and evidence, and that they are unnecessary for maintaining a negligible risk (i.e., the likelihood of establishment and the potential impacts of cases that may occur even without establishment) to the United States via imports of live bovines and bovine products from such regions.

Additionally, this rule removes the delay of applicability of provisions of our January 2005 final rule regarding the importation of meat, meat products, and meat byproducts derived from bovines in Canada that were 30 months of age or older when slaughtered.

This regulatory impact analysis (RIA) addresses expected economic effects of allowing resumption of imports from Canada of the above commodities. Expected benefits and costs are examined in accordance with Executive Order 12866. Expected economic impacts for small entities are also evaluated, as required by the Regulatory Flexibility Act. Our analysis indicates that benefits of the rule will exceed costs overall. Effects for Canadian and other foreign entities are not addressed in this analysis. However, the Agency expects reestablished access to U.S. markets to benefit Canadian producers and suppliers of commodities included in the rule.

Analytical Approach

The approach and models used in this analysis are the same as were applied in the preliminary RIA that we prepared for our January 2007 proposed rule. Impacts for cattle for feeding or for immediate slaughter and impacts for beef are quantitatively modeled. Impacts for other affected commodities—breeding cattle including dairy, vealers and slaughter calves, bison, bovine casings and small intestine products, and bovine blood and blood products—are examined largely qualitatively. For the modeled cattle and beef, we project a 5-year baseline, 2008–2012, against which we measure expected price and welfare effects of projected levels of cattle and beef imports from Canada. We evaluate price and welfare effects for the three scenarios that were considered in the preliminary RIA, as follows:

- Scenario 1: Allow imports of Canadian cattle born on or after March 1, 1999;
- Scenario 2: Allow imports of Canadian cattle unrestricted by date of birth; and
- Scenario 3: The same as scenario 1, with the addition of the resumption of imports of beef from Canadian cattle

slaughtered at 30 months or older (called over-30-month, or OTM beef).

As a fourth scenario, we consider imports of Canadian cattle unrestricted by date of birth, with the resumption of OTM beef imports. Projected imports under this scenario 4 are described, but the expected impacts are not evaluated, for reasons explained below.

Beginning with baseline quantities and prices, we compute effects of the projected changes in imports from Canada for four commodity categories: Cull cattle/processing beef, feeder cattle, fed cattle, and fed beef. The resumption of cull cattle imports is expected to affect the slaughter mix in Canada, and that change in the slaughter mix will be reflected in changes in the mix of exports to the United States.

As part of this adjustment, for example, we expect that more fed steers and heifers will be slaughtered in Canada and fewer will be exported to the United States than if cull cattle imports were not reestablished. Canada's cattle inventory increased rapidly following the diagnosis of BSE in a Canadian cow in May 2003 and Canada's subsequent loss of export markets for cattle and beef. In response, Canada's slaughter capacity expanded. Beginning in July 2005, with the resumption of imports by the United States of Canadian feeder cattle and fed cattle, some Canadian plants continued to utilize their expanded slaughter capacity by shifting to increased cull cattle slaughter. Canadian cull cattle slaughter would likely continue to expand if the United States were to remain closed to imports of Canadian cull cattle. However, with this rule, we can expect some substitution in Canada of cull cattle slaughter by fed cattle slaughter.

Importation of fewer fed cattle from Canada, all things equal, will cause the price of fed cattle in the United States to rise. We estimate the expected increase in price and, because of the price rise, the decrease in the quantity of fed cattle demanded by U.S. slaughter and packing establishments and the increase in the quantity of fed cattle supplied by U.S. feedlots. The analysis yields measures of welfare change, which in this example are in terms of surplus losses for U.S. buyers and surplus gains for U.S. sellers of fed cattle.

For each of the first three scenarios, we compute impacts for the modeled commodities using the Baseline Analysis System (BAS) model.[29] Impacts are also summed for each scenario. The BAS model is a net trade, non-spatial partial equilibrium model. Partial equilibrium means that the model results are based on maintaining a commodity-price equilibrium in a limited portion of an overall economy. Commodities not explicitly included in the model are assumed to have a negligible influence on the results. The simple summation of the separate partial equilibrium results using the BAS model does not take into account market dynamics, but does provide a reasonable approximation of the combined welfare effects for each scenario.

We also examine impacts more broadly using a multi-sector model that takes into account substitution among livestock products in response to relative price changes.[30] This model maps interactions among the grain, animal, and animal products industries. It takes into account substitution among livestock products in response to relative price changes, incorporates foreign trade, and yields expected price and revenue effects. The simulated multi-sector impacts tend to be smaller than the BAS model results because the model linkages specified between the livestock production and processing sectors capture at least some of the flexibility that industry enterprises exhibit when adjusting to supply shocks. These results support our expectation that broader impacts of the rule will be limited.

Baseline quantities and prices and imports from Canada have been projected by staff of USDA ERS, Market and Trade Economics Division, Animal Products, Grains, and Oil Seeds Branch, based on their expert knowledge and reference to ''USDA Agricultural Baseline Projections to 2016,'' United States Department of Agriculture, Interagency Agricultural Projections Committee, Baseline Report OCE–2007–1, February 2007.[31]

Projected Imports From Canada

Scenario 1. Table A shows the projected changes in cattle and fed beef imports from Canada under scenario 1 (in which imports of Canadian cattle born on or after March 1, 1999, are allowed). Under this scenario, cull cattle imports from Canada are projected to total 104,000 head in 2008 and average 147,800 head over the 5-year period of analysis. These import numbers are considerably smaller than were projected in the preliminary RIA because we now have a better understanding of the extent to which the birth-date restriction and age-verification requirement may limit the number of cull cattle eligible for import. Annual declines in feeder cattle and fed cattle imports are projected to average 6,800 head and 56,800 head, respectively. These declines correspond to projected changes in the overall Canadian cattle inventory, with the import volumes for fed cattle further adjusted downward to reflect greater competition from Canadian packers due to the resumption of U.S. imports of cull cattle. Yearly fed beef imports are projected to increase by an average of 45.8 million pounds, carcass weight equivalent.

All of the changes under scenario 1 are small when compared to the commodities' projected U.S. baseline supplies. The changes in imports for feeder cattle, fed cattle, and fed beef imports, in particular, are projected to be only fractions of 1 percent of baseline supplies. Under scenario 1, the number of cull cattle projected to be imported in 2008 is less than 2 percent of projected U.S. baseline cull cattle slaughter quantities. Over the period of analysis, cull cattle imports are projected to average 2.5 percent of baseline quantities. Cull cattle imports are projected to increase in the latter years of the analysis, and even more so in subsequent years, as higher percentages of Canada's cull cattle inventory are able to be verified as having been born on or after March 1, 1999. A relative increase in the number of cull cattle imported over time is projected to be associated with, in turn, a relative decrease in the quantity of fed cattle imports and a relative increase in the quantity of fed beef imports.

Baseline projections over the 5-year period, 2008–2012, show the United States importing a little over 40 percent of its supply of processing beef. A share

[29] A complete description of the model is provided in: Forsythe, K.W. ''An Economic Model for Routine Analysis of the Welfare Effects of Regulatory Changes.'' V3.00. U.S. Department of Agriculture, Animal and Plant Health Inspection Service, Veterinary Services, Centers for Epidemiology and Animal Health. April 20, 2005 (draft). *http://www.aphis.usda.gov/peer_review/content/printable_version/bas_model_econOnly_apr20.pdf*

[30] Four examples of studies based on this type of model are: Paarlberg, P.L., A.H. Seitzinger, and J.G. Lee, ''Economic Impacts of Regionalization of a Highly Pathogenic Avian Influenza Outbreak in the United States,'' *Journal of Agricultural and Applied Economics,* forthcoming. Paarlberg, P.L. ''Agricultural Export Subsidies and Intermediate Goods Trade,'' *American Journal of Agricultural Economics.* 77, 1(1995): 119–128. Paarlberg, P.L., J.G. Lee, and A.H. Seitzinger. ''Potential Revenue Impact of an Outbreak of Foot-and-Mouth Disease in the United States,'' *Journal of the American Veterinary Medical Association.* 220, 7(April 1, 2002): 988–992. Sanyal, K.K. and R.W. Jones. ''The Theory of Trade in Middle Products,'' *American Economic Review.* 72(1982): 16–31.

[31] *http://www.usda.gov/oce/commodity/ag_baseline.htm*

of the cull cattle imported from Canada will yield processing beef that will substitute for processing beef that otherwise would be imported from other countries, while a share of the imported cull cattle will yield processing beef that will replace a quantity of processing beef that would otherwise be domestically supplied, as U.S. producers respond to lower prices. The remaining share of cull cattle imports will yield processing beef that will represent a net increase in U.S. processing beef supplies.

We use 25 percent as the percentage of cull cattle imports from Canada projected to displace U.S. processing beef imports from elsewhere. The 25 percent share is estimated using the multi-sector model and takes into account the interactions of the beef processing sector with the beef cattle and dairy cattle sectors. For comparison, we also compute price and welfare effects assuming that 50 percent of cull cattle imported from Canada displace processing beef imports, and assuming, alternatively, that none of the imported cull cattle displace processing beef imports.

Scenario 2. In Table B, we show the projected changes in cattle and fed beef imports from Canada under scenario 2 (in which imports of Canadian cattle unrestricted by birth date are allowed). Under this scenario, imports of cull cattle and changes in imports of fed cattle and fed beef are all projected to be much larger than in scenario 1. Feeder cattle imports are projected to be the same under all of the scenarios. Projected cull cattle imports in scenario 2 average 459,800 head per year over the period of analysis, or 7.8 percent of U.S. baseline slaughter quantities. This amount is more than three times cull cattle imports projected in scenario 1. The fed cattle and fed beef changes remain a fraction of 1 percent of the U.S. baseline supplies, but are also larger. The increased number of cull cattle imported in this scenario is projected to be associated with larger declines in fed cattle imports and larger increases in the fed beef imports. We again estimate that 25 percent of cull cattle imports from Canada under this scenario displace processing beef imports from other sources. Price and welfare analyses assuming that 50 percent of the imported cull cattle displace processing beef imports and that none of the cull cattle displace processing beef imports are also presented.

Scenario 3. Table C shows the projected changes in cattle and beef imports from Canada under scenario 3 (in which imports of Canadian cattle born on or after March 1, 1999, are allowed and imports of OTM beef resume). In scenario 3, impacts derive from the resumption of OTM beef imports as well as the cull cattle imports from Canada. Projected cull cattle imports are lower than in scenario 1 (averaging 106,000 head per year over the 5-year period, compared to 147,800 head) because of the entry of OTM beef. Similarly, changes in projected fed cattle and fed beef imports are somewhat smaller than the changes projected in scenario 1. Processing beef imports from Canada under scenario 3 are projected to average 254.6 million pounds per year, carcass weight equivalent, or about 4.1 percent of the U.S. baseline supply. The quantity of processing beef imported is projected to decline and the quantity of cull cattle imported is projected to increase in the latter years of the 5-year period, as an increasing number of cull cattle become eligible for importation—i.e., can be verified as having been born on or after March 1, 1999. Under scenario 3, and considering imports of cull cattle (based on the cattle's processing beef equivalence) and processing beef as a single market, 77 percent of cull cattle and processing beef imports from Canada are projected to enter the United States as OTM beef over the 5-year period of the analysis, while 23 percent of these imports are projected to enter as cull cattle. Consistent with scenarios 1 and 2, we use 25 percent as the share of the cull cattle and OTM beef imports from Canada that displaces processing beef imports from other countries. We also present the price and welfare effects assuming that either 50 percent or none of the cull cattle and OTM beef imports from Canada displace processing beef imports from elsewhere.

Scenario 4. In table D, we show the projected changes in cattle and fed beef imports from Canada under scenario 4 (in which imports of Canadian cattle unrestricted by birth date are allowed and imports of OTM beef resume). As in scenario 2, imports of cull cattle and changes in imports of fed cattle and fed beef are all projected to be larger than in scenarios 1 and 3.

Projected cull cattle imports in scenario 4 average 328,200 head per year over the period of analysis, or 5.5 percent of U.S. baseline slaughter quantities. The fed cattle and fed beef changes remain a fraction of 1 percent of the U.S. baseline supplies.

TABLE A.—PROJECTED CHANGES IN IMPORTS OF CULL CATTLE, FEEDER CATTLE, FED CATTLE, FED BEEF, AND PROCESSING BEEF FROM CANADA UNDER SCENARIO 1, AND PROJECTED CHANGES IN IMPORTS FROM CANADA AS A PERCENTAGE OF THE PROJECTED U.S. BASELINE SUPPLIES, 2008–2012

	2008	2009	2010	2011	2012
Projected changes in imports from Canada:					
Cull cattle (thousand head)	104	110	113	187	225
Feeder cattle (thousand head)	−1	9	−5	−16	−21
Fed cattle (thousand head)	−30	−4	−43	−93	−114
Fed beef (million pounds, carcass weight equivalent)	24	3	35	75	92
Processing beef (million pounds, carcass weight equivalent)	0	0	0	0	0
Projected changes in imports from Canada as a percentage of the projected U.S. baseline supply:					
Cull cattle	1.8%	1.9%	1.9%	3.1%	3.7%
Feeder cattle	nil	nil	nil	nil	−0.1%
Fed cattle	−0.1%	nil	−0.1%	−0.3%	−0.4%
Fed beef	0.1%	nil	0.2%	0.3%	0.4%
Processing beef	0	0	0	0	0

TABLE B.—PROJECTED CHANGES IN IMPORTS OF CULL CATTLE, FEEDER CATTLE, FED CATTLE, FED BEEF, AND PROCESSING BEEF FROM CANADA UNDER SCENARIO 2, AND PROJECTED CHANGES IN IMPORTS FROM CANADA AS A PERCENTAGE OF THE PROJECTED U.S. BASELINE SUPPLIES, 2008–2012

	2008	2009	2010	2011	2012
Projected changes in imports from Canada:					
Cull cattle (thousand head)	459	459	459	460	462
Feeder cattle (thousand head)	−1	9	−5	−16	−21
Fed cattle (thousand head)	−119	−91	−129	−161	−173
Fed beef (million pounds, carcass weight equivalent)	96	74	105	131	140
Processing beef (million pounds, carcass weight equivalent)	0	0	0	0	0
Projected changes in imports from Canada as a percentage of the projected U.S. baseline supply:					
Cull cattle	8.2%	7.8%	7.6%	7.6%	7.6%
Feeder cattle	nil	nil	nil	nil	−0.1
Fed cattle	−0.4%	−0.3%	−0.4%	−0.5%	−0.6%
Fed beef	0.4%	0.3%	0.5%	0.6%	0.6%
Processing beef	0	0	0	0	0

TABLE C.—PROJECTED CHANGES IN IMPORTS OF CULL CATTLE, FEEDER CATTLE, FED CATTLE, FED BEEF, AND PROCESSING BEEF FROM CANADA UNDER SCENARIO 3 AND PROJECTED CHANGES IN IMPORTS FROM CANADA AS A PERCENTAGE OF THE PROJECTED U.S. BASELINE SUPPLIES, 2008–2012

	2008	2009	2010	2011	2012
Projected changes in imports from Canada:					
Cull cattle (thousand head)	75	79	81	134	161
Feeder cattle (thousand head)	−1	9	−5	−16	−21
Fed cattle (thousand head)	−23	4	−34	−80	−98
Fed beef (million pounds, carcass weight equivalent)	18	−3	28	65	79
Processing beef (million pounds, carcass weight equivalent)	277	273	272	234	217
Projected changes in imports from Canada as a percentage of the projected U.S. baseline supply:					
Cull cattle	1.3%	1.3%	1.3%	2.2%	2.7%
Feeder cattle	nil	nil	nil	nil	−0.1
Fed cattle	−0.1%	nil	−0.1%	−0.3%	−0.3%
Fed beef	0.1%	nil	0.1%	0.3%	0.3%
Processing beef	4.7%	4.5%	4.4%	3.7%	3.4%

TABLE D.—PROJECTED CHANGES IN IMPORTS OF CULL CATTLE, FEEDER CATTLE, FED CATTLE, FED BEEF, AND PROCESSING BEEF FROM CANADA UNDER SCENARIO 4, AND PROJECTED CHANGES IN IMPORTS FROM CANADA AS A PERCENTAGE OF THE PROJECTED U.S. BASELINE SUPPLIES, 2008–2012

	2008	2009	2010	2011	2012
Projected changes in imports from Canada:					
Cull cattle (thousand head)	328	328	327	328	330
Feeder cattle (thousand head)	−1	9	−5	−16	−21
Fed cattle (thousand head)	−86	−58	−96	−129	−140
Fed beef (million pounds, carcass weight equivalent)	70	47	78	104	114
Processing beef (million pounds, carcass weight equivalent)	94	94	94	94	95
Projected changes in imports from Canada as a percentage of the projected U.S. baseline supply:					
Cull cattle	5.8%	5.6%	5.4%	5.4%	5.4%
Feeder cattle	nil	nil	nil	nil	−0.1%
Fed cattle	−0.3%	−0.2%	−0.3%	−0.4%	−0.5%
Fed beef	0.3%	0.2%	0.3%	0.5%	0.5%
Processing beef	1.6%	1.5%	1.5%	1.5%	1.5%

Effects for Commodities Not Analyzed Using the BAS Model

Five categories of commodities that will be affected by this rule have not been included in the modeled quantitative analysis described above. They are: Breeding cattle, including dairy; vealers and slaughter calves; bison; bovine casings and small intestine products; and bovine blood and blood products. Projected imports of breeding cattle including dairy, and projected changes in imports of vealers, slaughter calves, and bison, are relatively small, suggesting that impacts on affected U.S. entities will not be significant. For bovine casings, small intestine products, and blood and blood products, the analysis is constrained by a scarcity of information about the quantities that would be imported and levels of U.S. production and consumption.

With regard to dairy producers, we do not expect imports of dairy cattle from Canada to add significantly to the U.S. herd, but rather to serve as an additional

source of replacement animals. From 1992 to 2002, U.S. producers annually raised about 4.1 million dairy replacement heifers and about 5.9 million beef replacement heifers. The average number of Canadian breeding cattle imported during that period (including bulls) totaled only 0.5 percent of these combined quantities. The breeding cattle imports from Canada during this period represented about 1.1 percent of dairy heifer replacements and less than 0.1 percent of beef heifer replacements. Imports of dairy cows and heifers from Canada are projected to be similar to their historic levels, 1992–2002, averaging 47,800 head per year over the period of analysis in all of the scenarios.

Analysis using the multi-sector model indicates that, in scenario 3, dairy producers may experience price declines of 1.3 to 1.7 percent for dairy cattle due to the small number projected to be imported from Canada. These imports translate into an increase in U.S. milk production of 0.1 percent or less, and a decline in the price of milk and increase in consumer surplus of less than 0.1 percent. As sellers of cull cattle, dairy producers as well as beef producers are expected to be negatively affected by the price decline for cull cattle due to this rule.

We expect market effects for vealers and slaughter calves to be insignificant, given the small change in the number projected to be imported from Canada. The decline in imports is projected in scenario 3 to average only 6 percent, or 3,000 head per year.

A larger number of bison are projected to be imported than was projected in the preliminary RIA. Reestablished imports of Canadian breeding bison will be the principal impact of this rule for that industry. Yearly imports of breeding bison are projected to average 1,200 head, and are expected to represent about 1 percent of U.S. breeding bison, assuming the composition of the national bison herd is similar to that of the national cattle herd.

This rule may directly affect the U.S. supply of bovine casings and small intestine products through resumption of imports from Canada, and may affect it indirectly through changes in U.S. cattle slaughter numbers and the reestablished importation of Canadian bovine small intestines, minus the distal ileum. For scenario 3, the annual supply of bovine casings produced from additional U.S. cattle slaughter is projected to increase on average over the period of analysis by less than 0.2 percent.

Fetal bovine serum (FBS) is the most important blood product that will be affected by this rule. Resumption of commercial imports of FBS from Canada, directly as serum and indirectly through increased U.S. pregnant cow slaughter, is expected to benefit FBS users, given current strong demand for this blood product in the United States.

Expected Impacts for Modeled Commodities

In this summary, prices and welfare impacts are expressed in 2007 dollars; price and quantity averages and percentage averages are over the 5-year period of analysis, 2008–2012; annualized values are discounted at 3 percent; and beef prices and quantities are in carcass weight equivalent. Percentage changes in prices and estimated welfare effects are shown in table E.

Scenario 1. In this scenario, buyers of cull cattle and processing beef can be expected to benefit from welfare gains and sellers of cull cattle and processing beef can be expected to bear welfare losses due to the cull cattle imports. For this commodity, the estimated annualized consumer gains are $90.3 million, producer losses are $53.2 million, and net benefits are $37.1 million.

Welfare changes for the cull cattle/processing beef category dominate the modeled effects in all of the scenarios. The relatively large impacts are not unexpected, given that this is the one modeled commodity category for which imports from Canada would be newly reestablished and projected changes from the baseline are much larger than for the other commodities. The numbers of cull cattle projected to be imported in scenario 1, averaging 124,800 cows and 23,000 bulls and stags per year, are much larger than the projected average annual declines in imports of Canadian fed cattle (56,800 head) and feeder cattle (6,800 head).

Another reason the welfare effects computed for the cull cattle/processing beef category are large is the inelastic demand (−0.40) compared to the price elasticities of demand—i.e., buyers' responsiveness to changes in price—for the other modeled commodities (feeder cattle, –0.88; fed cattle, −0.76; fed beef, −0.60). In the preliminary RIA, we examined the significance of processing beef's more inelastic demand by considering welfare changes for the cull cattle/processing beef category when a price elasticity of demand of −0.60 is used, that is, the same elasticity as for fed beef. This exercise found that all impacts—consumer gains, producer losses, net benefits, and price declines—are reduced by nearly one-fifth when a price elasticity of demand of −0.60 is used in place of −0.40. The price elasticity of demand is an important determinant of the magnitude of welfare and price changes for the cull cattle/processing beef category.

Lastly, the large difference between consumer welfare gains and producer welfare losses for the cull cattle/processing beef category can be attributed to the fact that the United States is projected to import about 40 percent of its supply of processing beef over the period of analysis. In modeling the welfare effects, demand (defined as U.S. consumption) is much larger than supply (defined as U.S. production minus exports). Consequently the change in consumer surplus is large compared to the change in producer surplus because the effects are estimated only for U.S. entities.

Slightly fewer feeder cattle are projected to be imported from Canada in scenario 1 than would otherwise enter, and the analysis indicates small gains in producer welfare (higher prices and less competition from Canadian suppliers) and small losses in consumer welfare for this commodity (higher prices and fewer feeder cattle available for purchase). Estimated annualized values are producer gains of $3.6 million, consumer losses of $3.8 million, and net losses of $0.2 million.

As with feeder cattle, fewer fed cattle are projected to be imported under scenario 1 than would otherwise be imported. Once again, producers (sellers of fed cattle for slaughter) would benefit from welfare gains and consumers (buyers of fed cattle for slaughter) would bear welfare losses. Estimated annualized values are producer gains of $43.6 million, consumer losses of $44.7 million, and net losses of about $1.1 million.

Scenario 1 is projected to result in increased imports of Canadian fed beef ranging from an additional 3 million pounds in 2009 to 92 million pounds in 2012. Estimated annualized values are consumer gains of $48.8 million, producer losses of $46.8 million, and net gains of $2 million.

The analysis shows annualized combined welfare changes under scenario 1 as consumer gains of $90.6 million and producer losses of $52.7 million, yielding net benefits of $37.9 million. As can be seen in table E, the combined annualized values of consumer welfare losses for feeder cattle and fed cattle are similar to the consumer welfare gains for fed beef. Combined consumer welfare gains are very similar to the consumer welfare gains estimated for the cull cattle/processing beef category. A similar but opposite outcome is evident with

respect to producer welfare changes, with combined gains for feeder cattle and fed cattle somewhat larger than the producer welfare losses for fed beef. The result is combined producer welfare losses that are close to the producer welfare losses estimated for cull cattle/processing beef. Under scenario 1, the combined annualized net welfare benefits, $37.9 million, are only slightly more than the $37.1 million in net benefits estimated for cull cattle/processing beef.

TABLE E.—COMPARISON OF PERCENTAGE PRICE CHANGES AND ANNUALIZED WELFARE EFFECTS FOR SCENARIOS 1, 2, AND 3 BY COMMODITY CATEGORY, 2008–2012, DISCOUNTED AT 3 PERCENT, 2007 DOLLARS

Commodity category	Scenario	Percentage change in price	Change in consumer welfare	Change in producer welfare	Net welfare change
			Thousand dollars		
Cull cattle/Processing beef	1	−1.4%	90,307	−53,207	37,100
	2	−4.5%	286,936	−165,615	121,320
	3	−4.5%	286,912	−165,603	121,308
Feeder cattle	1	nil	−3,795	3,605	−190
	2	nil	−3,795	3,605	−190
	3	nil	−3,795	3,605	−190
Fed cattle	1	0.1%	−44,703	43,636	−1,066
	2	0.3%	−107,513	105,101	−2,412
	3	0.1%	−36,263	35,388	−874
Fed beef	1	−0.1%	48,800	−46,757	2,044
	2	−0.3%	117,459	−112,426	5,033
	3	−0.1%	39,791	−38,131	1,660
Categories combined	1	.....	90,609	−52,723	37,888
	2	.....	293,087	−169,335	123,751
	3	.....	286,645	−164,741	121,904

The three import scenarios considered in this table are (1) Canadian cattle born on or after March 1, 1999; (2) Canadian cattle unrestricted by date of birth; and (3) Canadian cattle born on or after March 1, 1999, plus resumption of imports of meat from Canadian cattle slaughtered at 30 months or older. The percentage change in price is the average annual change over the 5-year period. Welfare changes may not sum due to rounding.

Scenario 2. Because of the significantly larger number of cull cattle projected to be imported in scenario 2, the estimated price and welfare effects are also much larger than for scenario 1. Table E shows these differences, with the percentage changes in price about three times greater in all cases (other than for feeder cattle, for which imports are projected to be the same in all scenarios). Whereas the combined net benefit in scenario 1 is estimated to be an annualized $37.9 million, in scenario 2 it is $123.8 million.

As described in the risk assessment, transmission of BSE requires that bovines ingest feed that contains the infectious agent. The OIE establishes standards for the international trade in animals and animal products. It recommends that cattle be imported from a controlled risk region for BSE only if the cattle selected for export were born after that date from which a ban on the feeding of ruminants with meat-and-bone meal and greaves (the residue left after animal fat or tallow has been rendered) derived from ruminants had been effectively enforced. In May 2007, the OIE classified both the United States and Canada as BSE controlled risk regions.

On August 4, 1997, Canada issued regulations prohibiting the use of mammalian protein in ruminant feeds. Implementation of the feed ban was a gradual process, with producers, feed mills, retailers, and feed manufacturers given grace periods before they were required to be in full compliance with the regulations. It is believed that this implementation period may have lasted 6 months, making February 1998 a more realistic date on which the ban can be considered to have gone into effect.

APHIS considers that a period of 1 year following the full implementation of the feed ban allowed sufficient time for the measures taken by Canada to have their desired effect. Therefore, APHIS concludes that there is an extremely low likelihood that cattle born in Canada on or after March 1, 1999, will have been exposed to the BSE agent via feed. Therefore, these animals have an extremely low likelihood of being infected and can be imported into the United States for any purpose.

We do not have a quantitative estimate of the additional risk posed by importation of Canadian cattle born before March 1, 1999. The importance of a feed ban as a risk mitigation measure is demonstrated in science and experience, and is incorporated into the OIE guidelines. We conclude that there could be some degree of increased likelihood of BSE infectivity entering the United States via imports of live bovines from Canada under scenario 2, compared to the very low likelihood posed in scenario 1, because of the greater likelihood of cattle born prior to the effective enforcement of a feed ban having been exposed to infectivity.

Scenario 3. The price and welfare effects under scenario 3 are similar to the effects under scenario 2 for cull cattle/processing beef, but more like the scenario 1 effects for fed cattle and fed beef (table E). This outcome is expected because scenario 3 includes reestablishment of OTM beef imports from Canada. Combined net welfare benefits for scenarios 2 and 3 are very similar, with the projected cull cattle imports in scenario 2 and the projected imports of cull cattle and OTM beef in scenario 3 both based on cattle and beef import quantities prior to May 2003. The additional quantities of cull cattle/processing beef in scenarios 2 and 3 are essentially the same, entering as live cattle in scenario 2 and as beef in scenario 3.

The BSE risk mitigations under scenario 3 are comparable to those under scenario 1. The restriction on live bovine imports by date of birth, age verification, and other safeguard measures are the same in both cases. Consequently, as in scenario 1, the likelihood of BSE infectivity entering the United States via imports of live bovines from Canada in this scenario is

extremely low. Resumption of OTM beef imports from Canada will not affect the likelihood of BSE infectivity entering the United States because SRMs will be removed and disposed of in Canada.

Scenario 4. A fourth scenario, as indicated above, would be to allow entry of Canadian cattle unrestricted by birth date, along with resumption of OTM beef imports from Canada. A quantitative analysis of expected price and welfare effects for this particular scenario was not performed. When we compare projected imports under this scenario with those projected for scenario 3, we find the differences in combined cattle and beef imports to be very small and conclude that the welfare effects for this scenario would be very similar to the effects of scenario 3.

Cull cattle imports from Canada are projected to average about 328,000 head per year under scenario 4, compared to 106,000 head per year under scenario 3. Conversely, annual processing beef imports under scenario 4 are projected to average 94 million pounds, carcass weight equivalent, compared to 255 million pounds for scenario 3.

Similar differences between the two scenarios are projected for fed cattle and fed beef imports. The larger number of cull cattle that would be imported from Canada under scenario 4 could be expected to be associated with increased fed cattle slaughter in Canada, with fewer fed cattle and more fed beef exported to the United States. Under scenario 4, fed cattle imports from Canada are projected to average about 624,000 head per year, compared to 679,000 head per year under scenario 3. Annual fed beef imports under scenario 4 are projected to average 992 million pounds, compared to 947 million pounds for scenario 3.

The average annual net difference between scenarios 3 and 4 in projected cull cattle and processing beef imports from Canada, after converting the cull cattle to processing beef, is about 700,000 pounds (330.8 million pounds in scenario 3, and 330.1 million pounds in scenario 4). This amount represents about 0.2 percent of projected cull cattle/processing beef imports under scenario 3. For fed cattle and fed beef imports from Canada, the average annual net difference between scenarios 3 and 4 after converting the fed cattle to fed beef, is about 1.3 million pounds (1,483.7 million pounds in scenario 3, and 1,485.0 million pounds in scenario 4). This amount represents about 0.1 percent of the projected fed cattle and fed beef imports under scenario 3. Hence, we conclude that the overall welfare effects of scenario 4 would be very similar to those for scenario 3.

Effects on Small Entities

There were no significant issues raised in public comment on the initial regulatory flexibility analysis (RFA) for this rulemaking. However, as described below, the majority of businesses that may be affected by this rule are small entities. Therefore, while none of the comments received on the proposed rule raised specific issues regarding the initial RFA, comments on the preliminary RIA can be inferred to express small-entity concerns.

Topics that received public comment and that concerned the estimated economic impacts of the proposed rule included modeling issues; the timing of the rule's implementation; consequences of a BSE occurrence; and impacts of the rule for consumers, cow-calf producers, the dairy industry, and the packing industry, and on beef exports. These comments are addressed in the Agency's responses that are included as part of the final rule.

Small entities comprise the majority of the establishments engaged in the production, processing, and sale of the commodities affected by this rule. These small entities number at least in the hundreds of thousands, with cow-calf and dairy producers comprising the largest single industry sector share. The entities are classified within the following industries according to the North American Industry Classification System: Beef Cattle Ranching and Farming (NAICS 112111), Dairy Cattle and Milk Production (NAICS 112120), All Other Animal Production (NAICS 112990), Cattle Feedlots (NAICS 112112), Animal (except Poultry) Slaughtering (NAICS 311611), Meat Processed from Carcasses (NAICS 311612), Meat and Meat Product Merchant Wholesalers (NAICS 424470), Supermarkets and Other Grocery (except Convenience) Stores (NAICS 445110), Meat Markets (NAICS 445210), In-Vitro Diagnostic Substance Manufacturing (NAICS 325413), and Biological Product (except Diagnostic) Manufacturing (NAICS 325414).

We are unable to determine the extent to which cull cattle prices may fall because of the rule. Assuming that the price decline for cull cattle is proportional to the estimated price decline for processing beef, cow-calf and dairy producers in scenario 3 may experience a fall in price for cull cattle of 4.7 percent in 2008, and an average price decline of 4.5 percent ($4.61 per cwt). To place this average price decline in perspective, we consider the effect it may have on gross earnings of small-entity cow-calf operations. Based on data from the 2002 Census of Agriculture, the average value of cattle and calves sold by small-entity beef cow operations was about $26,600.[32] The projected 2008 price for a culled cow is $54.19 per cwt.[33] Assuming the cow weighs 1,100 pounds, its price in 2008 would be $596.09 per head. A 4.7 percent decline would result in a price of $568.07. Presumably, most of a cow-calf operation's revenue is earned from the sale of calves. If one-half of an operation's revenue were to derive from the sale of cull cattle, the reduction in revenue attributable to the decline in the price of cull cattle in scenario 3 would total about $625 for the year.[34]

For dairy enterprises, the expected price decline for cull cattle because of imports from Canada is expected to have a small effect on their incomes because most revenue (over 86 percent in 2002) is earned from the sale of milk and other dairy products.[35] The average per animal value of cattle and calves sold by small-entity dairy cow operations in 2002 was about $453. A price decline of 4.7 percent, notwithstanding the fact that not all of the animals sold would be cull cattle, would mean a decrease in annual revenue for the average small-entity dairy operation of about $1,040, assuming no change in the number of cattle sold.[36] This forgone income would represent a decline in average revenue of about 0.6 percent.[37]

The scenario 3 analysis indicates that decreases in the price of fed beef due to increased fed beef imports from Canada are expected to be very small, resulting in a loss for the average meat packing and processing establishment of less than 0.2 percent of average revenue (18 cents per cwt, with projected baseline fed beef prices averaging $151.80 per cwt). Effects for those packers and processors that utilize processing beef will be larger, due to the resumption of cull cattle and OTM beef imports from

[32] USDA, NASS. 2002 Census of Agriculture, Volume 1, Chapter 1, Table 16. The $26,000 average is for operations with fewer than 1,000 head. *http://www.nass.usda.gov/Census_of_Agriculture/index.asp*

[33] Boning utility cow (Sioux Falls) nominal price.

[34] ($26,600/2) (0.047) = $625.10.

[35] USDA, NASS, 2002 Census of Agriculture, Volume 1, Chapter 1, Table 17. For small-entity producers, revenue from cattle and calf sales totaled $1.7 billion and revenue from dairy product sales totaled $11.2 billion. *http://www.nass.usda.gov/Census_of_Agriculture/index.asp*

[36] In 2002, the average revenue from cattle sales for small-entity dairy operations was $22,197 ($453 per head multiplied by 49 head). ($22,197)(0.047) = $1,043.26.

[37] $1,043 divided by $175,912 (average income for small dairy farms from combined dairy product and cattle sales) equals 0.59 percent.

Canada. Annual prices of processing beef are expected to fall by an average of $4.61 per cwt in scenario 3. This decline in price will benefit establishments that use processing beef to produce ground beef for the wholesale market. Conversely, establishments that sell processing beef will be negatively affected by the expected price decline.

In response to public comments on the preliminary RIA, we include an evaluation of welfare effects by industry sector for scenario 3. While this evaluation is admittedly broad, it provides an indication of the extent to which major sectors of the cattle and beef industries may be affected. We group the entities that we expect to be directly affected into four generalized categories: cow-calf and dairy producers, feedlot establishments, slaughter and packing establishments, and wholesaler and successive establishments. Admittedly, this simple categorization does not capture the many complexities of the cattle and beef industries, but it does provide a level of specification sufficient for examining expected effects for the industries' principal stages of economic activity. In reality, businesses combine the slaughter, packing, processing, and wholesaling functions in various ways. This consideration of sector-level effects indicates that cow-calf and dairy producers and slaughter and packing establishments are expected to incur net welfare losses, while feedlots and wholesalers are expected to accrue net welfare gains.

Currently, bovines imported from Canada are restricted to animals that are slaughtered at less than 30 months of age. Bovines not imported for immediate slaughter must be moved from the port of entry to a feedlot in a sealed means of conveyance and from the feedlot to a recognized slaughtering establishment again in a sealed means of conveyance. The animals may not be moved to more than one feedlot. With this rule, these movement restrictions will no longer be imposed. Canadian bovines imported other than for immediate slaughter will be able to be moved any number of times to any destinations in unsealed means of conveyance.

Under this rule, feeder bovines imported from BSE minimal-risk regions will not need to be accompanied by APHIS Form VS 17–130, which currently is used to identify the feedlot of destination. (The name of the individual responsible for the movement of an imported animal and individual identification of the animal will still be required information on the accompanying health certificate.) APHIS estimates that the time saved by entities no longer needing to acquire APHIS Form VS 17–130 will total approximately 40,000 hours per year.[38] Also under this rule, bovines of Canadian origin moved from a U.S. feedlot to a slaughtering establishment will not need to be accompanied by APHIS Form VS 1–27. APHIS estimates the same total time savings by entities no longer needing to acquire APHIS Form VS 1–27: 40,000 hours per year.

Removal of these movement and paperwork requirements will benefit buyers and sellers of Canadian-origin bovines. Many of the beneficiaries are likely to be small entities, given their predominance among beef and dairy operations and feedlot establishments. Affected businesses will be able to take advantage of a broader range of transactional opportunities than previously. For example, the sale of a young steer first for backgrounding, then for confined feeding at one or more facilities, and finally for slaughter may enable the original and subsequent owners of the animal to better maximize returns compared to current marketing possibilities. While we are not able to quantify impacts of removing current movement restrictions on Canadian cattle imports, we expect their removal will benefit the cattle industry across-the-board.

The Agency has identified alternatives to the rule and analyzed them in this RIA. We have found that the chosen alternative (scenario 3) best strikes the balance of continuing to provide an acceptable level of protection against BSE infectivity entering the United States via imports of live bovine and bovine product imports, while removing unnecessary prohibitions on the importation of certain commodities from Canada. Without this rule, restrictions on U.S. importation of certain Canadian bovine commodities that are without scientific merit would continue. With this rule, importation of these Canadian commodities will be allowed to resume under certain conditions and the BSE risk to the United States via imports of live bovines and bovine products from Canada will be negligible.

Small Business Regulatory Enforcement Fairness Act of 1996

This rule has been designated by the Administrator, Office of Information and Regulatory Affairs, Office of Management and Budget, as a major rule under the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801–808). Accordingly, the effective date of this rule has been delayed the required 60 days pending congressional review.

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 live bovines and of bovine products as 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 Decisionmaker 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 APHIS Web site (*http://www.aphis.usda.gov/newsroom/hot_issues/bse/index.shtml*), or be obtained by contacting the person listed under **FOR FURTHER INFORMATION CONTACT**. 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

[38] This approximation is based on 1,000 entities filling out Form VS 17–130 on 20 occasions per year, with each form requiring two hours. The estimated total time saved by not having to complete Form VS 1–27 is calculated on this same basis.

writing to the individuals 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.*).

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List of Subjects

9 CFR Part 93

Animal diseases, Imports, Livestock, Poultry and poultry products, Quarantine, Reporting and recordkeeping requirements.

9 CFR Part 94

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

9 CFR Part 95

Animal feeds, Hay, Imports, Livestock, Reporting and recordkeeping requirements, Straw, Transportation.

9 CFR Part 96

Imports, Livestock, Reporting and recordkeeping requirements.

■ Accordingly, we are amending 9 CFR parts 93, 94, 95, and 96 as follows:

PART 93—IMPORTATION OF CERTAIN ANIMALS, BIRDS, AND POULTRY, AND CERTAIN ANIMAL, BIRD, AND POULTRY PRODUCTS; REQUIREMENTS FOR MEANS OF CONVEYANCE AND SHIPPING CONTAINERS

■ 1. The authority citation for part 93 continues to read as follows:

Authority: 7 U.S.C. 1622 and 8301–8317; 21 U.S.C. 136 and 136a; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.4.

§ 93.405 [Amended]

■ 2. In § 93.405, paragraph (a)(4) is amended by removing the words ''feedlot or recognized slaughtering establishment'' and adding in their place the words ''destination''.

■ 3. Section 93.419 is amended as follows:

■ a. Paragraphs (b) and (c) are revised to read as set forth below.

■ b. Paragraph (d) is redesignated as paragraph (e).

■ c. A new paragraph (d) is added to read as set forth below.

■ d. In newly redesignated paragraph (e)(2), the reference to ''paragraph (d)(7)'' is removed and a reference to ''paragraph (e)(7)'' is added in its place.

§ 93.419 Sheep and goats from Canada.

* * * * *

(b) If the sheep or goats are unaccompanied by the certificate

required by paragraph (a) of this section, or if they are found upon inspection at the port of entry to be affected with or exposed to a communicable disease, they shall be refused entry and shall be handled or quarantined, or otherwise disposed of, as the Administrator may direct.

(c) Any sheep or goats imported from Canada must not be pregnant, must be less than 12 months of age when imported into the United States and when slaughtered, must be from a flock or herd subject to a ruminant feed ban equivalent to the requirements established by the U.S. Food and Drug Administration at 21 CFR 589.2000, and must be individually identified by an official Canadian Food Inspection Agency eartag, applied before the animal's arrival at the port of entry into the United States, that is determined by the Administrator to meet standards equivalent to those for official eartags in the United States as defined in § 71.1 of this chapter and to be traceable to the premises of origin of the animal. No person may alter, deface, remove, or otherwise tamper with the individual identification while the animal is in the United States or moving into or through the United States, except that the identification may be removed at the time of slaughter. The animals must be accompanied by the certification issued in accordance with § 93.405 that states, in addition to the statements required by § 93.405, that the conditions of this paragraph have been met. Additionally, for sheep and goats imported for immediate slaughter, the certificate must state that the conditions of paragraphs (d)(1) through (d)(3) of this section have been met, and, for sheep and goats imported for other than immediate slaughter, the certificate must state that the conditions of paragraphs (e)(1) and (e)(2) of this section have been met.

(d) *Sheep and goats imported for immediate slaughter.* Sheep and goats imported from Canada for immediate slaughter must be imported only through a port of entry listed in § 93.403(b) or as provided for in § 93.403(f) in a means of conveyance sealed in Canada with seals of the Canadian Government, and must be moved directly as a group from the port of entry to a recognized slaughtering establishment for slaughter as a group. The sheep and goats shall be inspected at the port of entry and otherwise handled in accordance with § 93.408. The seals on the means of conveyance must be broken only at the port of entry by the APHIS port veterinarian or at the recognized slaughtering establishment by an authorized USDA representative. If the seals are broken by the APHIS port veterinarian at the port of entry, the means of conveyance must be resealed with seals of the U.S. Government before being moved to the recognized slaughtering establishment. The shipment must be accompanied from the port of entry to the recognized slaughtering establishment by APHIS Form VS 17–33, which must include the location of the recognized slaughtering establishment. Additionally, the sheep and goats must meet the following conditions:

(1) The animals have not tested positive for and are not suspect for a transmissible spongiform encephalopathy;

(2) The animals have not resided in a flock or herd that has been diagnosed with BSE; and

(3) The animals' movement is not restricted within Canada as a result of exposure to a transmissible spongiform encephalopathy.

* * * * *

■ 4. Section 93.420 is revised to read as follows:

§ 93.420 Ruminants from Canada for immediate slaughter other than bovines, sheep, and goats.

The requirements for the importation of sheep and goats from Canada for immediate slaughter are contained in § 93.419. The requirements for the importation of bovines from Canada for immediate slaughter are contained in § 93.436. All other ruminants imported from Canada for immediate slaughter, in addition to meeting all other applicable requirements of this part, must be imported only through a port of entry listed in § 93.403(b) or as provided for in § 93.403(f) to a recognized slaughtering establishment for slaughter, in conveyances that must be sealed with seals of the U.S. Government at the port of entry. The seals may be broken only at a recognized slaughtering establishment in the United States by an authorized USDA representative. The shipment must be accompanied from the port of entry to the recognized slaughtering establishment by APHIS Form VS 17–33, which must include the location of the recognized slaughtering establishment. Such ruminants shall be inspected at the port of entry and otherwise handled in accordance with § 93.408.

(Approved by the Office of Management and Budget under control number 0579–0277)

■ 5. Section 93.436 is amended as follows:

■ a. Paragraphs (a) and (b) are revised to read as set forth below.

■ b. In paragraph (c), the reference to ''§§ 93.419(c) and 93.420'' is removed and a reference to ''§§ 93.405 and 93.419'' is added in its place.

§ 93.436 Ruminants from regions of minimal risk for BSE.

* * * * *

(a) *Bovines for immediate slaughter.* Bovines from a region listed in § 94.18(a)(3) of this subchapter may be imported for immediate slaughter under the following conditions:

(1) The bovines must have been born on or after a date determined by APHIS to be the date of effective enforcement of a ruminant-to-ruminant feed ban in the region of export. For bovines imported from Canada, that date is March 1, 1999.

(2) Each bovine must be individually identified by an official eartag of the country of origin, applied before the animal's arrival at the port of entry into the United States, that is determined by the Administrator to meet standards equivalent to those for official eartags in this chapter and to be traceable to the premises of origin of the animal. No person may alter, deface, remove, or otherwise tamper with the official identification while the animal is in the United States or moving into or through the United States, except that the identification may be removed at the time of slaughter;

(3) The bovines must be accompanied by a certificate issued in accordance with § 93.405 that states, in addition to the statements required by § 93.405, that the conditions of paragraphs (a)(1) and (a)(2) of this section have been met;

(4) The bovines must be imported only through a port of entry listed in § 93.403(b) or as provided for in § 93.403(f). The bovines shall be inspected at the port of entry and otherwise handled in accordance with § 93.408;

(5) The bovines must be moved directly from the port of entry to a recognized slaughtering establishment. Bovines imported from Canada must be moved to the slaughtering establishment in conveyances that are sealed with seals of the U.S. Government at the port of entry. The seals may be broken only at the recognized slaughtering establishment by an authorized USDA representative; and

(6) The bovines must be accompanied from the port of entry to the recognized slaughtering establishment by APHIS Form VS 17–33.

(b) *Bovines for other than immediate slaughter.* Bovines from a region listed in § 94.18(a)(3) of this subchapter may be imported for other than immediate

slaughter under the following conditions:

(1) The bovines must have been born on or after a date determined by APHIS to be the date of effective enforcement of a ruminant-to-ruminant feed ban in the region of export. For bovines imported from Canada, that date is March 1, 1999.

(2) The bovines must be permanently and humanely identified before arrival at the port of entry with a distinct and legible mark identifying the exporting country. Acceptable means of permanent identification include the following:

(i) A mark properly applied with a freeze brand, hot iron, or other method, and easily visible on the live animal and on the carcass before skinning. Such a mark must be not less than 2 inches nor more than 3 inches high, and must be applied to each animal's right hip, high on the tail-head (over the junction of the sacral and first cocygeal vertebrae). Bovines exported from Canada so marked must be marked with ''C∧N'';

(ii) A tattoo with letters identifying the exporting country must be applied to the inside of one ear of the animal. For bovines exported from Canada, the tattoo must read ''CAN'';

(iii) Other means of permanent identification upon request if deemed adequate by the Administrator to humanely identify the animal in a distinct and legible way as having been imported from the BSE minimal-risk exporting region.

(3) Each bovine must be individually identified by an official eartag of the country of origin, applied before the animal's arrival at the port of entry into the United States, that is determined by the Administrator to meet standards equivalent to those for official eartags in § 71.1 of this chapter and to be traceable to the premises of origin of the animal. No person may alter, deface, remove, or otherwise tamper with the official identification while the animal is in the United States or moving into or through the United States, except that the identification may be removed at the time of slaughter;

(4) The bovines must be accompanied by a certificate issued in accordance with § 93.405 that states, in addition to the statements required by § 93.405, that the conditions of paragraphs (a)(1) and (a)(2) of this section have been met; and

(5) The bovines must be imported only through a port of entry listed in § 93.403(b) or as provided for in § 93.403(f).

* * * * *

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

■ 6. 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.

§ 94.19 [Amended]

■ 7. Section 94.19 is amended as follows:

■ a. By removing the words ''and small intestine'' each time they appear in paragraphs (a)(2), (b)(2), and (f).

■ b. By removing the Note to paragraph (a).

■ c. By removing the Note to paragraph (b).

■ d. By removing the Note to paragraph (f).

PART 95—SANITARY CONTROL OF ANIMAL BYPRODUCTS (EXCEPT CASINGS), AND HAY AND STRAW, OFFERED FOR ENTRY INTO THE UNITED STATES

■ 8. The authority citation for part 95 continues to read as follows:

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

■ 9. Section 95.4 is amended as follows:

■ a. The section heading and paragraph (a) introductory text are revised to read as set forth below.

■ b. Paragraphs (a)(1)(ii) and (a)(1)(iv) are revised to read as set forth below.

■ c. In paragraph (b), the words ''paragraphs (d) and (h)'' are removed and the words ''paragraphs (d), (e), and (i)'' are added in their place.

■ d. Paragraph (d) introductory text is revised to read as set forth below.

■ e. The ''Note to paragraph (f)'' and the ''Note to paragraph (g)'' are removed.

■ f. Paragraphs (e) through (h) are redesignated as paragraphs (f) through (i), respectively.

■ g. The ''Note'' currently following newly redesignated paragraph (f) is redesignated as ''Note to paragraph (f)''.

■ h. New paragraph (e) is added to read as set forth below.

■ i. In newly redesignated paragraph (h)(1)(i), the words ''and small intestine'' are removed.

■ j. In newly redesignated paragraph (i) introductory text, the words ''paragraphs (h)(1) through (h)(3)'' are removed and the words ''paragraphs (i)(1) through (i)(3)'' are added in their place, and the words ''paragraphs (h)(1) through (h)(4)'' are removed and the words ''paragraphs (i)(1) through (i)(4)'' are added in their place.

■ k. In newly redesignated paragraph (i)(4)(iii), the reference to ''paragraph (h)(2)'' is removed and a reference to ''paragraph (i)(1)'' is added in its place.

§ 95.4 Restrictions on the importation of processed animal protein, offal, tankage, fat, glands, certain tallow other than tallow derivatives, and blood and blood products due to bovine spongiform encephalopathy.

(a) Except as provided in paragraphs (c) through (i) of this section, the importation of the following is prohibited:

(1) * * *

(ii) Glands, unprocessed fat tissue, and blood and blood products derived from ruminants;

* * * * *

(iv) Derivatives of glands and blood and blood products derived from ruminants.

* * * * *

(d) Except as provided in paragraph (e) of this section, the importation of serum albumin, serocolostrum, amniotic liquids or extracts, and placental liquids derived from ruminants that have been in any region listed in § 94.18(a) of this chapter, and collagen and collagen products that meet any of the conditions listed in paragraphs (a)(1) through (a)(3) of this section, is prohibited unless the following conditions have been met:

* * * * *

(e) Bovine blood and blood products that are otherwise prohibited importation under paragraph (a)(1) or (d) of this section may be imported into the United States if they meet the following conditions:

(1) For blood collected at slaughter and for products derived from blood collected at slaughter:

(i) The blood was collected in a closed system in which the blood was conveyed directly from the animal in a closed conduit to a closed receptacle, or was collected otherwise in a hygienic manner that prevents contamination of the blood with SRMs.

(ii) The slaughtered animal passed ante-mortem inspection and was not subjected to a pithing process or to a stunning process with a device injecting compressed air or gas into the cranial cavity;

(2) For fetal bovine serum:

(i) The blood from which the fetal bovine serum was derived was collected in a closed system in which the blood was conveyed directly from the animal in a closed conduit to a closed

receptacle, or was collected otherwise in a hygienic manner that prevents contamination of the blood with SRMs;

(ii) The dam of the fetal calf passed ante-mortem inspection and was not subjected to a pithing process or to a stunning process with a device injecting compressed air or gas into the cranial cavity;

(iii) The uterus was removed from the dam's abdominal cavity intact and taken to a separate area sufficiently removed from the slaughtering area of the facility to ensure that the fetal blood was not contaminated with SRMs when collected.

(3) For blood collected from live donor bovines and for products derived from blood collected from live donor bovines:

(i) The blood was collected in a closed system in which the blood was conveyed directly from the animal in a closed conduit to a closed receptacle, or was collected otherwise in a hygienic manner that prevents contamination of the blood with SRMs;

(ii) The donor animal was free of clinical signs of disease.

(4) Each shipment to the United States is accompanied by an original certificate signed by a full-time salaried veterinary officer of the national government of the region of origin, or issued by a veterinarian designated by or accredited by the national government of the region of origin, representing that the veterinarian issuing the certificate was authorized to do so. The certificate must state that the requirements of paragraph (e)(1), (e)(2), or (e)(3) of this section, as applicable, have been met.

* * * * *

PART 96—RESTRICTION OF IMPORTATIONS OF FOREIGN ANIMAL CASINGS OFFERED FOR ENTRY INTO THE UNITED STATES

■ 10. The authority citation for part 96 continues to read as follows:

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

■ 11. In § 96.1, definitions of *Food and Drug Administration* and *Food Safety and Inspection Service* are added, in alphabetical order, to read as follows:

§ 96.1 Definitions.

* * * * *

Food and Drug Administration. The Food and Drug Administration of the United States Department of Health and Human Services.

Food Safety and Inspection Service. The Food Safety and Inspection Service of the United States Department of Agriculture.

* * * * *

■ 12. In § 96.2, paragraph (b) is revised to read as follows:

§ 96.2 Prohibition of casings due to African swine fever and bovine spongiform encephalopathy.

* * * * *

(b) *Ruminant casings.* The importation of casings, except stomachs, from ruminants that originated in or were processed in any region listed in § 94.18(a) of this subchapter is prohibited, except as provided in paragraphs (b)(1) and (b)(2) of this section:

(1) Casings that are derived from sheep that were slaughtered in a region listed in § 94.18(a)(3) of this subchapter at less than 12 months of age and that were from a flock subject to a ruminant feed ban equivalent to the requirements established by the U.S. Food and Drug Administration at 21 CFR 589.2000 may be imported.

(2) Casings that are derived from bovines that were slaughtered in a region listed in § 94.18(a)(3) of this subchapter may be imported, provided, if the casings are derived from the small intestine, the casings are derived from that part of the small intestine that is eligible for use as human food in accordance with the requirements established by the Food Safety and Inspection Service at 9 CFR 310.22 and the Food and Drug Administration at 21 CFR 189.5.

(3) Casings imported in accordance with either paragraph (b)(1) or (b)(2) of this section must be accompanied by a certificate that:

(i) States that the casings meet the conditions of this section;

(ii) Is written in English;

(iii) Is signed by an individual eligible to issue the certificate required under § 96.3; and

(iv) Is presented to an authorized inspector at the port of entry.

* * * * *

■ 13. In § 96.3, paragraph (d) is revised to read as follows:

§ 96.3 Certificate for animal casings.

* * * * *

(d) In addition to meeting the requirements of this section, the certificate accompanying sheep casings from a region listed in § 94.18(a)(3) of this subchapter must state that the casings meet the requirements of § 96.2(b)(1), and the certificate accompanying bovine casings from a region listed in § 94.18(a)(3) of this subchapter must state that the casings meet the requirements of § 96.2(b)(2).

* * * * *

Done in Washington, DC, this 12th day of September 2007.

Charles D. Lambert,

Acting Under Secretary for Marketing and Regulatory Programs.

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