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9 CFR Part 93, et al.

Bovine Spongiform Encephalopathy; Minimal-Risk Regions and Importation of Commodities; Finding of No Significant Impact and Affirmation of Final Rule; Final Rule

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Parts 93, 94, 95, and 98

[Docket No. 03–080–7]

RIN 0579–AB73

Bovine Spongiform Encephalopathy; Minimal-Risk Regions and Importation of Commodities; Finding of No Significant Impact and Affirmation of Final Rule

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Affirmation of final rule.

SUMMARY: We are publishing a finding of no significant impact for a final rule concerning bovine spongiform encephalopathy minimal risk regions published January 4, 2005, and, based on that finding, we are affirming the provisions of the final rule. The finding of no significant impact is based on an environmental assessment that documented our review and analysis of potential environmental impacts associated with the final rule and our review of issues raised by the public regarding the environmental assessment. Together, the environmental assessment and our review of the issues raised provide a basis for our conclusion that the provisions of the final rule will not have a significant impact on the quality of the human environment and support our affirmation of the final rule.

DATES: The final rule published January 4, 2005 (70 FR 460), with a partial delay of applicability published March 11, 2005 (70 FR 12112), was effective March 7, 2005. This affirmation of the final rule is effective April 8, 2005.

ADDRESSES: The environmental assessment on which this finding of no significant impact is based may be accessed by any of the following methods:

- On the EDOCKET Web site at *http://docket.epa.gov/edkfed/do/EDKStaff CollectionDetailView?objectId=0b0007d48055a20d.*
- On the APHIS Web site at *http://www.aphis.usda.gov/lpa/issues/bse/bse.html.*
- In the APHIS Reading Room in room 1141 of the USDA South Building, 14th Street and Independence Avenue, SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 690–2817 before coming.
- You may request paper copies of the environmental assessment and the finding of no significant impact by calling or writing to the person listed under **FOR FURTHER INFORMATION CONTACT**. Please refer to the titles of these documents when requesting copies.

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

SUPPLEMENTARY INFORMATION:

Background

On November 4, 2003, the Animal and Plant Health Inspection Service (APHIS) published in the **Federal Register** and requested comment on a proposed rule (68 FR 62386–62405, Docket No. 03–080–1) to amend the regulations regarding the importation of animals and animal products to recognize a category of regions that present a minimal risk of introducing bovine spongiform encephalopathy (BSE) into the United States via live ruminants and ruminant products, and to add Canada to this category. The proposed rule also included provisions for the importation of certain live ruminants and ruminant products and byproducts from Canada under certain conditions. Also on November 4, 2003, we made available for public comment an 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 under the conditions of the proposed rule. We carefully considered all comments that addressed the EA, along with those that addressed the proposed rule itself.

On January 4, 2005, we published in the **Federal Register** (70 FR 460–553, Docket No. 03–080–3) a final rule to the proposed rule, to become effective March 7, 2005.[1]

Also in the January 4, 2005, issue of the **Federal Register**, we published a notice (70 FR 554, Docket No. 03–080–4) announcing the availability of, and requesting comments on, a final 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. APHIS' review and analysis of the potential environmental impacts associated with those importations were documented in the final EA, titled ''Rulemaking to Establish Criteria for the Importation of Designated Ruminants and Ruminant Products from Canada into the United States, Final Environmental Assessment (December 2004).'' We announced that the EA would be available to the public for review and comment until February 3, 2005.

We became aware, however, that the version of the EA that was made available on January 4, 2005, contained some transcription errors that resulted in the omission of several references to an updated APHIS risk analysis regarding the final rule, as well as the incorrect formatting of several source citations. We corrected those errors and, on January 21, 2005, published a notice in the **Federal Register** (70 FR 3183–3184, Docket No. 03–080–5) announcing the availability to the public of the corrected EA and extending the comment period on the EA until February 17, 2005.

We reviewed and considered all issues raised by commenters on the final EA. Of the issues raised by the commenters, some addressed the potential effects of the rule on the environment, while others addressed issues unrelated to such potential effects. Most of these issues had been raised by commenters on the proposed rule and had been previously considered and addressed in our final rule and supporting analyses.

Additionally, shortly after issuance of the final rule, the Ranchers-Cattlemen Action Legal Fund, United Stockgrowers of America (R–CALF), filed a complaint challenging the rule in the United States District Court for the District of Montana. In that complaint, R–CALF raised several issues regarding the EA that it had not included in either its comments on the proposed rule or in any comment on the final EA. In addition, no other commenter on the EA raised those potential environmental impact issues. Nonetheless, we addressed those issues in our finding of no significant impact (FONSI), discussed below.

We carefully considered environmental issues throughout the rulemaking. Based on the EA and on our review of the comments received on the original and final EAs, on the proposed rule, and in litigation, we have determined that the provisions of our January 4, 2005, final rule will not

[1] On March 11, 2005, the Department published a document in the **Federal Register** (70 FR 12112–12113, Docket No. 03–080–6), effective March 7, 2005, that delayed until further notice the applicability of certain provisions of the final rule. On March 2, 2005, Judge Richard F. Cebull of the U.S. District Court for the District of Montana ordered that the implementation of the final rule is preliminarily enjoined.

significantly impact human health or the environment, and that there is no basis in the comments we received and the issues that have been raised to alter the rule. Therefore, we are affirming the final rule as published.

Our FONSI is included in this document under the heading ''Bovine Spongiform Encephalopathy: Minimal-Risk Regions and Importation of Commodities (Final Rule; APHIS Docket No. 03–080–3), Finding of No Significant Impact.'' The FONSI includes a discussion of the comments received on the final EA. The EA and FONSI may also be accessed by any of the means listed above under the heading **ADDRESSES**.

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

Bovine Spongiform Encephalopathy; Minimal-Risk Regions and Importation of Commodities (Final Rule; APHIS Docket No. 03–080–3)

Finding of No Significant Impact

United States Department of Agriculture, Animal and Plant Health Inspection Service, Veterinary Services, National Center for Import and Export, Technical Trade Services, 4700 River Road, Unit 38, Riverdale, MD 20737

This finding concludes the environmental assessment process undertaken for the rulemaking, Bovine Spongiform Encephalopathy; Minimal-Risk Regions and Importation of Commodities (''MRR rule''). An environmental assessment (''EA''), dated October 2003, was prepared for this rulemaking and it was made available to the public for comment on November 4, 2003. Comments on the EA were received and carefully considered. A final EA was completed and it was made available to the public on January 4, 2005, for a 30-day comment period. On January 21, 2005, a corrected final EA was made available to the public and the comment period was extended for an additional 14 days until February 17, 2005. The corrected final EA had no changes or additions to the version issued on January 4, 2005, other than some specific references to the latest risk analysis for the MRR rule that had been inadvertently omitted from the final EA. This finding summarizes and incorporates by reference the final EA.

Thirteen comments were received in response to our request for comments on the final EA. One was submitted by a state farm bureau federation with certain specific suggestions. This comment counseled caution in implementing the rule for the following reasons. It pointed to the four confirmed cases of bovine spongiform encephalopathy (BSE) in cows of Canadian origin'particularly the most recent diagnosis in a cow that was determined to have been born after implementation of a feed ban in Canada—and recommended that USDA confirm that the Canadian feed ban is being effectively enforced before resuming imports of Canadian cattle under 30 months of age and beef from such younger cattle. Additionally, the comment requested that an effective feed ban have been in place in Canada for a full 8 years before cattle over 30 months of age, and meat from such cattle, are allowed to be imported into the United States. It recommended further review of Canada's surveillance program and asked whether the current level of surveillance in Canada is adequate. The comment supported the animal identification provisions in the rule and recommended that appropriate steps be taken to ensure that all imported cattle were slaughtered before 30 months of age. Finally, the comment noted concerns, which we believe are outside the scope of the environmental assessment, about consumer confidence, our ability to regain access to export markets, and potential impacts on producer returns.

One comment, filed by an individual consumer of beef products who asserted he was not associated with any cattle production or processing business, raised five concerns or issues. These included that there was no quantitative risk assessment in the EA, concern about the duration and effectiveness of Canada's feed ban, concern about the tissues defined as specified risk materials (SRMs) under international standards, concern that public health risk was not adequately analyzed in light of recent diagnoses of BSE in Canada and the levels of feed ban compliance and surveillance in that country, and, finally, a recommendation that an environmental impact statement be completed to study the effect of BSE and TSE disease agents in soil, water, air, and the food chain.

Eight comments—one from a South Dakota organization, one from an Oregon organization, and six from individuals, including an assistant state veterinarian—raised a generally similar array of concerns. The thrust of these eight comments is that the commenters believe the risk of introducing BSE into the United States weighs against implementation of the rule. The comments noted support for maintaining the current prohibitions on imports of live animals and beef products from Canada, concerns about the effect of importation into the United States of Canadian cattle and cattle products on U.S. export markets, concern about the effectiveness of the Canadian feed ban and the adequacy of Canada's surveillance program, concerns about feeding animal protein of any kind to cows or sheep, a recommendation for country-of-origin labeling, and support for testing for BSE all cattle of Canadian origin that are in the United States. Again, certain of these issues are outside the scope of the EA. Several of the comments also raised questions about the implications of the most recently confirmed BSE-positive animals in Canada on January 2 and January 11, 2005, including the fact that one of these animals was born shortly after implementation of the Canadian feed ban in 1997.

A comment from a pharmaceutical association noted the importance of animal-derived materials in numerous products. This comment was received on February 24, 2005, 7 days after the close of the extended comment period for the final EA. Nevertheless, because, as the commenter pointed out, it had commented in a timely fashion on the proposed rule and its EA comment was intended to update its recommendations based on recent developments, we will respond to this comment. The comment supported the need to revise what it termed the ''binary system'' of BSE classification of countries and the adoption of what it termed a science-based approach to identifying minimal-risk regions for BSE as outlined in the rule. The comment, therefore, supported implementation of the rule. It recommended permanently identifying cattle from Canada and distinguishing Canadian and U.S.-origin cattle for the sourcing of bovine raw materials, which would allow companies to make sourcing decisions to satisfy BSE regulatory requirements in the countries to which these companies would ship their products. The association supported the implementation of a national animal identification system.

One comment took issue with the notation in the final EA that alkaline hydrolysis tissue digesters were a preferred method of disposal for BSE-contaminated carcasses. It took issue with that conclusion and suggested the commenter's validated protocol and

process for enzymatic prion degradation was perhaps equally effective. We acknowledge this comment and would welcome more information and data regarding this technology. It is our view, however, that it does not raise an issue that requires discussion in this document. One comment urged the lifting of the prohibitions on camelids because camelids have no demonstrated history of being susceptible to any type of TSE and because these animals are not used for human consumption. We agree with this comment and note that the MRR rule so provided.

Of the issues raised by the commenters, many concerned topics other than the potential effects of the rule on the environment (for example, comments regarding country-of-origin labeling, market access, and consumer confidence). These issues had been raised by commenters on the proposed rule and were considered and addressed by APHIS in its final rule and supporting analyses. Likewise, most of the commenters who did address the potential effects of the rule on the environment raised issues that had already been raised and addressed at considerable length in the final rule and supporting analyses. This fact illustrates the substantial identity of the central animal and public health issues of the rule and the issues evaluated in the environmental assessments.

It is important to note that issues raised in relation to the two most recent BSE-positive cows in Canada on January 2 and January 11, 2005, will be discussed below. Certain commenters observed that these incidents would call into question the effectiveness and adequate duration of the Canadian feed ban. Because these incidents occurred either after or immediately before the publication of the final EA, we welcome the opportunity to respond in this document.

On January 4, 2005, APHIS issued a final rule to amend regulations regarding the importation of animals and animal products to establish a category of regions that present a minimal-risk of introducing BSE into the United States by way of live ruminants and ruminant products and byproducts, and to add Canada to that category. (70 FR 460–553.) The final rule also established conditions for the importation of certain live ruminants and ruminant products and byproducts from minimal-risk regions. Under the Animal Health Protection Act (7 U.S.C. 8301 *et seq.*), the Secretary of Agriculture may prohibit or restrict the importation or entry of any animal, article, or means of conveyance, or use of any means of conveyance or facility, if the Secretary determines that the prohibition or restriction is necessary to prevent the introduction into or dissemination within the United States of any pest or disease of livestock. (7 U.S.C. 8303.) The MRR rule will regulate the importation of ruminants and ruminant products and byproducts from Canada in a manner that prevents the introduction of BSE into the United States.

The rule defines a BSE minimal-risk region as one that:

1. Maintains, and, in the case of regions where BSE was detected, had in place prior to the detection of BSE in an indigenous ruminant, risk mitigation measures adequate to prevent widespread exposure and/or establishment of the disease. Such measures include the following:

- Restrictions on the importation of animals sufficient to minimize the possibility of infected ruminants being imported into the region, and on the importation of animal products and animal feed containing ruminant protein sufficient to minimize the possibility of ruminants in the region being exposed to BSE;
- Surveillance for BSE at levels that meet or exceed recommendations of the World Organization for Animal Health (Office International des Epizooties or OIE) for surveillance for BSE; and
- A ruminant-to-ruminant feed ban that is in place and is effectively enforced.

2. In regions where BSE was detected, conducted an epidemiological investigation following detection of BSE sufficient to confirm the adequacy of measures to prevent the further introduction or spread of BSE, and continues to take such measures.

3. In regions where BSE was detected, took additional risk mitigation measures, as necessary, following the BSE outbreak based on risk analysis of the outbreak, and continues to take such measures.

These standards are based upon, and are consistent with, international guidelines issued by OIE. For a full analysis and discussion of these standards, see APHIS' November 4, 2003, proposed rule (68 FR 62388–62389) (please note that some revisions were made to the wording of the proposed standards in the final rule) and the update to our risk analysis.[2]

APHIS conducted a comprehensive examination and evaluation of all the relevant risk factors in determining whether Canada qualified as a BSE minimal-risk region. A complete discussion of this evaluation can be found in the risk analysis.[3] In summary, APHIS determined that Canada met the standards for a BSE minimal-risk region because:

1. Canada has implemented comprehensive, effective measures for preventing BSE introduction and the potential for spread within Canada in order to minimize the possibility that infected ruminants, ruminant products, byproducts, or contaminated feedstuffs enter the country. The potential for introduction of the BSE agent into Canada has been limited by import restrictions on meat-and-bone meal (MBM) and live animals. Canada's Animal Disease and Protection Regulations (1978) and Health of Animals Regulations (1991) prohibited importation of MBM from countries other than the United States and, later, from Australia and New Zealand. These rules were first initiated in response to foot-and-mouth disease and later extended to address BSE issues. Canada has not imported live cattle from the United Kingdom (UK) since 1990. In 1994, an import ban was imposed on all countries where BSE had been detected in native cattle, and from 1996 live cattle could only be imported from countries that Canada designated as free from BSE following a comprehensive risk assessment. After detection of BSE in an imported animal in 1993, Canada traced and destroyed and incinerated or repatriated all surviving cattle imported from the UK.

2. Canada has an adult cattle population of approximately 5.5 million cattle older than 24 months of age. The 2004 OIE Code, Appendix 3.8.4, references adult cattle populations as those greater than 30 months and recommends examining at least 300 samples per year from high-risk animals in a country with an adult cattle population of 5 million, or 336 samples per year in a country with an adult cattle population of 7 million. Even though the adult cattle population in Canada is defined as greater than 24 months of age and OIE defines it as greater than 30 months, Canada has met or exceeded this level of surveillance for the past 7 years, thus exceeding the OIE guidelines. Since 1992, the surveillance has been targeted surveillance, with samples obtained from adult animals exhibiting some type of clinical signs or considered high risk for other reasons that could be considered consistent with BSE. From January 2004 through March

[2] See "Analysis of Risk-Update for the Final Rule: Bovine Spongiform Encephalopathy; Minimal Risk Regions and Importation of Commodities, December 2004." pp. 2–5. This update can be viewed on the Internet at *http://www.aphis.usda.gov/lpa/issues/bse/bse.html.*

[3] Ibid, pp. 5–18.

2005, over 37,000 samples were obtained. Canadian Food Inspection Agency (CFIA) officials have stated that this surveillance program is designed to detect one case of BSE in one million adult cattle.

3. Since August 4, 1997, Canada has implemented a ruminant-to-ruminant feed ban that is comparable to that existing in the United States and prohibits the feeding of proteins from ruminant species to ruminant animals. Based on CFIA inspections since 2003, virtually 100 percent of Canadian rendering facilities are in compliance with the ruminant-to-ruminant feed ban requirements applicable to this industry. With regard to inspections of feed mills, CFIA reported that, for an annual inspection period of April to March, the fraction of mills reportedly in compliance was 92 percent, 99 percent, and 95 percent for 2002, 2003, and 2004, respectively.[4] CFIA has identified noncompliance of ''immediate concern'' in fewer than 2 percent of feed mills inspected during 2003–2004. Those instances of noncompliance of ''immediate concern'' are dealt with rapidly when identified. Noncompliance of ''immediate concern'' includes situations where direct contamination of ruminant feed with prohibited materials has occurred, as identified through inspections of production documents or visual observation, and where a lack of appropriate written procedures, records, or product labeling by feed manufacturers may expose ruminants to prohibited animal proteins. Accordingly, it is clear that Canada's feed ban is effective.

4. Canada conducted rigorous epidemiological investigations after the BSE cases were detected in May 2003 and December 2003 and after the detections in January 2005.[5] In all but the most recent detection, the cases were animals that were born before the implementation of the feed ban in 1997, with exposure assumed to occur prior to or near the time of the imposition of the feed regulations. The cow in the last detected case was born within a year after implementation of the Canadian feed ban. Although a specific source of infection was not identified, the most likely possibility was the introduction of a low level of infectivity into the animal feed supply originating from an infected animal imported from the UK in the period between 1982 and 1989. These investigations have resulted in the destruction and sampling of a large number of potentially exposed cattle, and results from all testing have yielded no further evidence of infection. CFIA has traced and destroyed the majority of surviving cattle that were birth cohorts of each of the cases of Canadian origin.

5. CFIA imposed new regulations to further strengthen its safeguards against BSE. Measures taken included requiring the removal of bovine SRMs; enhancing enforcement activities associated with the existing cattle identification system; and increasing the level of BSE testing.

Canada has provided comprehensive information throughout this rulemaking regarding its BSE status and the actions it has taken to protect animal and public health and food safety. The most recent Canadian status update can be accessed through the CFIA 2 Web site at *http://www.inspection.gc.ca/english/anima/heasan/disemala/bseesb/200503canadae.shtml.*

In summary, the essential factors that led us to conclude that Canada qualified as a BSE minimal-risk region include longstanding Canadian import restrictions, an effective ban on the feeding of ruminant protein to ruminants, the quality of Canada's surveillance and monitoring program, and other measures, such as the required removal of SRMs from cattle at the time of slaughter and enhanced enforcement of Canada's existing mandatory cattle identification system.

APHIS has concluded that the animal and public health measures that Canada has in place to prevent BSE, combined with existing U.S. domestic safeguards and additional safeguards provided in the final rule, provide the utmost protection to U.S. consumers and livestock. With respect to Canadian cattle, the MRR rule will allow the importation of:

- Bovines, for immediate slaughter, or for feeding, as long as they are slaughtered at less than 30 months of age;
- Meat from bovines; and
- Certain other products and byproducts, including bovine livers and tongues, gelatin, and tallow.

The final rule provides the following additional requirements for live Canadian feeder cattle that will ensure they are slaughtered before they reach 30 months of age:

- Feeder cattle must be permanently marked with a brand to identify the BSE minimal-risk region of origin before entering the United States. Feeder cattle exported from Canada will be branded with ''C/AN'';
- Cattle must be individually identified with an ear tag before entering the United States. This ear tag allows the animal to be traced back to the premises of origin (birth herd);
- Information must be included on the cattle's animal health certification, relating to animal identification, origin, destination, and responsible parties;
- Cattle must be moved to feedlots in sealed containers and cannot go to more than one feedlot; and
- SRMs will be removed from Canadian cattle slaughtered in the United States in accordance with FSIS regulations.

Based on our risk analyses, APHIS concluded that the cumulative effect of all of the measures in place in Canada and the United States, and the additional measures imposed by the final rule, is an extremely effective set of interlocking, overlapping and sequential barriers to the introduction and establishment of BSE in the United States.[6] The preceding discussion and conclusions provide the foundation for the finding of no significant impact described below.

The final rule was scheduled to become effective on March 7, 2005. On February 9, 2005, the Secretary of Agriculture announced that the provisions of the final rule allowing the importation of beef products from cattle over 30 months of age would be delayed.[7] On March 2, 2005, the United States District Court for the District of Montana issued a preliminary injunction that enjoined implementation of the MRR rule.

Pursuant to the National Environmental Policy Act (NEPA) (42 U.S.C. 4321 *et seq.*), the purpose of an environmental assessment is to provide sufficient information and analysis to agency decision makers to allow them to determine whether the proposed agency action will have a significant effect on the human environment. If a determination is made that the action would have a significant effect on the human environment, the agency is obligated to prepare an environmental impact statement. If a determination is made that the action will not have a significant effect on the human environment, a finding of no significant impact is issued.

The two EAs issued for the MRR rule considered two alternatives: (1) The ''No

[4] Canadian Food Inspection Agency (CFIA). Memorandum from Dr. Brian Evans, Chief Veterinary Officer, to Dr. John Clifford, Deputy Administrator, VS, APHIS. July 30, 2004.

[5] Canadian reports of the investigations can be accessed at *http://www.inspection.gc.ca/english/anima/heasan/disemala/bseesb/bseesbindexe.shtml.*

[6] See ''Analysis of Risk-Update for the Final Rule: Bovine Spongiform Encephalopathy; Minimal Risk Regions and Importation of Commodities, December 2004.'' pp. 25–27.

[7] On March 11, 2005, APHIS published a notice in the **Federal Register** delaying the applicability of the provisions of the rule relating to beef products and byproducts from bovines 30 months of age or older (70 FR 12112).

Action'' alternative, which would maintain the continued regulatory prohibition of the importation of ruminants, ruminant products, ruminant by-products from Canada and from any other country or region that could eventually be classified as a BSE minimal-risk region pursuant to the rulemaking and (2) the preferred alternative, which will allow for the importation of certain ruminant products and by-products and certain ruminants, providing the country or region seeking recognition as a BSE minimal-risk region demonstrates that it meets the relevant factors consistent with standards recommended by the OIE.

The environmental issues involved in this rulemaking, including those raised in comments on the two EAs as well as in litigation, are discussed below.

A. The Degree to Which the Action May Affect Public Health or Safety

The introduction of BSE into the United States has the potential to affect both human and animal health. BSE, commonly known as ''mad cow disease,'' is a disease that belongs to a family of mostly very rare diseases known as TSEs. Cases of BSE in cattle were first reported in the UK in 1986. To date, over 95 percent of all known BSE cases worldwide have occurred in the UK. Within cattle herds, BSE is not contagious and does not spread from animal to animal. It is spread to cattle primarily through the consumption of animal feed containing protein from ruminants infected with BSE. In 1996, a new disease, variant Creutzfeldt-Jakob disease or vCJD, was detected in humans and linked to the BSE epidemic in cattle. Consumption of cattle products contaminated with the BSE agent is reported to be the cause of vCJD. Approximately 153 cases of vCJD have been identified worldwide and 95 percent of these cases have been linked to exposure in the UK. When compared with the significant number of cattle exposed to BSE, the relatively small number of cases of vCJD indicates a substantial species barrier that protects humans from widespread illness due to BSE exposure.

As previously discussed, the MRR rule amends APHIS' regulations to allow the importation of certain ruminants, ruminant products and by-products from regions that pose a minimal risk for BSE. The rule will preclude introduction of BSE into the United States and will ensure the protection of domestic livestock and the food supply. The MRR rule is fully consistent with the guidelines and recommendations of the OIE for trade in animals and animal products from BSE-affected countries.

In determining whether it was necessary to continue the prohibitions and restrictions on imports from Canada pursuant to the Animal Health Protection Act, APHIS analyzed the risks associated with such imports. The analysis is consistent with OIE guidelines and the internationally recommended components for animal health import risk analysis. The risk analysis drew on a number of sources of information, including: Previous analyses of risk conducted by APHIS; scientific literature; results of epidemiological investigations; data provided by the Canadian Government; a quantitative analysis of the risk of BSE in Canada; quantitative analyses of the consequences of BSE being introduced into the United States; measures implemented by USDA's Food Safety and Inspection Service (FSIS) and the U.S. Department of Health and Human Services' Food and Drug Administration (FDA) to protect against human exposure to the BSE agent in the United States; reports by international review teams; and the BSE guidelines adopted by the OIE. The determination to allow imports of certain Canadian ruminants and ruminant products was based on a thorough evaluation of the BSE risk in Canada, the potential for BSE infectivity to be introduced into the United States, the potential spread of BSE in cattle and possible human exposure if BSE infectivity were introduced into the United States, and the likelihood that BSE could become established in the United States.

A great deal is now known about BSE. There is a strong scientific consensus about the BSE agent, the mechanisms for its spread, and the tissues that are most likely to harbor the infective agent. Scientific research, backed by practical experience, has resulted in a defined series of measures that countries can use to keep the BSE agent out of the food and feed chain and thus ensure the safety of animal and public health. APHIS has concluded that such measures are in place in Canada and the United States. The risk analysis contains a comprehensive discussion of the facts and circumstances relevant to Canada's BSE status and of the mitigation measures in place in both Canada and the United States that will ensure that BSE is not introduced into the United States. The critical country-of-origin factors leading to APHIS' conclusion and this finding of no significant impact are:

1. *Import Restrictions*—Canada has implemented effective methods for preventing the introduction of BSE into its herd by restricting the importation of live ruminants and meat-and-bone meal from any country that had not been recognized as BSE-free following a comprehensive risk assessment.

2. *Surveillance*—Canada has been actively monitoring for BSE in its herd since 1992 and has met or exceeded the OIE recommended level of BSE surveillance for the past 7 years. The number of cattle tested annually has steadily increased over the years, and in 2003, approximately 5,700 cattle were tested. In 2004, more than 23,500 animals were tested. In 2005, more than 14,000 samples were tested as of March 23.

3. *Feed Ban*—Canada and the United States implemented substantially identical feed bans simultaneously in 1997 that prohibit the feeding of mammalian protein to ruminants. Canada's feed ban is more stringent than the feed ban in the United States, as it prohibits the use of plate waste and poultry litter in ruminant feed. The Canadian feed ban has been effective and has a strong compliance and enforcement component. It is also important to note that Canada established its feed ban 6 years before identifying its first case of BSE in May 2003.

4. *Epidemiological Investigations*—Canada has the capacity to conduct, and has conducted, rigorous investigations of its BSE findings. These investigations have included trace-outs of cattle that may have been exposed to the same feed sources as infected cattle and of rendered protein products that could have included the tissues from the infected animals. These investigations have been successful due in part to the mandatory cattle identification program in Canada.

5. *Removal of SRMs*—Both Canada and the United States require the removal at slaughter of SRMs—those tissues most likely to harbor the BSE infective agent—and prohibit the use of SRMs in human food.

In addition, there are several biological factors that support the finding herein with specific reference to the importation of live animals and animal products. These factors include: The age of the animal, tissue distribution and infectivity, and feed source and exposure. Our findings with respect to these factors are detailed in the final risk analysis associated with this final rule.[8] Furthermore, as explained in the exposure assessment

[8] See ''Analysis of Risk—Update for the Final Rule: Bovine Spongiform Encephalopathy; Minimal Risk Regions and Importation of Commodities, December 2004,'' pp. 11–17.

component of the risk analysis, our evaluation of slaughter controls in place in both the United States and Canada, rendering inactivation factors, feed manufacturing controls both in the United States and Canada, and of the likelihood that an animal would ingest an infectious dose and would develop the disease provides further support for our finding of no significant impact.

Finally, the additional post-entry mitigation measures imposed by the final rule enhance protection of animal and human health and further ensure that there will be no significant impacts. The MRR rule requires that live cattle under 30 months of age can only enter the United States for immediate slaughter or for feeding and slaughter. Movement of these cattle is carefully controlled by requiring each animal to have permanent identification that identifies its country of origin, and a special permit designed to account for the inventory of cattle consigned to their point of destination. The rule, therefore, ensures that those cattle are identified and remain accounted for through slaughter.

Based on all these factors, APHIS concluded that there was no scientific basis to believe that the importation from Canada of live ruminants (including cattle less than 30 months of age) and ruminant products (including beef products and byproducts) in accordance with the conditions required in the rule pose any risk of introducing BSE into the United States. For all the reasons discussed in section VI.A. of the final EA, the safeguards in place in both the United States and Canada, coupled with the additional risk mitigation measures required in the MRR rule fully protect both animal and public health.

B. The Degree to Which the Effects on the Quality of the Human Environment Are Likely To Be Highly Controversial or the Degree to Which the Possible Effects on the Human Environment Are Highly Uncertain or Involve Unique or Unknown Risks

Controversy exists when substantial questions are raised as to whether an action may cause significant degradation of an environmental factor. In the context of an EA under NEPA, controversy refers not to the existence of public opposition, but to a substantial dispute about the size, nature, or effect of the action. Even if an action is projected to have a controversial effect, the agency nonetheless has the discretion to be guided by the expertise and judgment, as well as the practical experience, of its own experts. There is a presumption in favor of the agency's expert advice and guidance.

In the case of the MRR rule, there is no significant controversy with regard to the science underlying the mitigation measures that form the basis of the rule, and the effectiveness of the mitigation measures that are in place in Canada and the United States or prescribed as additional requirements in this rule. While questions remain about BSE and research continues on BSE as it does for many animal diseases, there is substantial knowledge about the disease and effective mitigation measures, and a solid scientific consensus among animal health experts both in the United States and internationally. Based upon this substantial body of scientific research, field epidemiological investigations and years of practical experience and observations by animal health authorities, very effective measures have been identified to prevent the introduction and spread of BSE and these measures have been put in place in the United States and Canada and are embodied in the MRR rule.

Two principal concerns are expressed in comments filed on the EA in opposition to the MRR rule. First is the perceived risk that BSE would be introduced into domestic cattle and, second, that vCJD could occur as a result of such introduction or through the import of meat products from Canada. APHIS has concluded that the MRR rule will preclude the introduction of BSE and that the comprehensive animal and public health measures in place in Canada and in the United States will prevent these effects from occurring. In this regard, we must note that while APHIS' principal responsibilities encompass animal and plant health, FSIS and the FDA are the agencies principally responsible for public health and food safety. Both of these agencies have implemented regulations to ensure that the BSE agent does not enter either the human or the ruminant food chain.[9] In developing the MRR rule and in preparing the EA, APHIS consulted with both FSIS and FDA.

This rule is based upon and is fully consistent with an international scientific consensus that is embodied in the guidelines and recommendations of the OIE. OIE is the internationally recognized authority on animal health issues and currently has 167 member countries, including the United States and Canada. OIE develops and publishes standards, guidelines and recommendations for international trade in animals and animal products. These standards and guidelines are recognized by the World Trade Organization as the reference international animal health rules for animal diseases and zoonoses and they are codified in the Terrestrial Animal Health Code and the Aquatic Animal Health Code. The standards, guidelines and recommendations are developed by specialist commissions and experts based on the latest and best available scientific research and data and are adopted by consensus of the OIE member countries. The aim of the Terrestrial Animal Health Code is to facilitate the safe international trade of animals and animal products. This is achieved through recommendations on risk management measures for specific diseases to be used by national veterinary authorities or other competent authorities of importing and exporting countries when establishing health regulations for the safe importation of animals and animal products. The aim of the OIE's work in this regard is to avoid the transfer of agents pathogenic for animals and humans, without the imposition of unjustified trade restrictions. With respect to the OIE guidelines for BSE, it is important to note that the OIE does not recommend that an importing country completely ban the importation of live cattle and meat products even when the importing country determines that the exporting country has a high BSE risk status. For the details of the BSE chapter of the Terrestrial Animal Health Code, see *http://www.oie.int/eng/publicat/en_code.htm.*

Many of the 13 commenters on the final EA opposed implementation of the MRR rule out of a concern that BSE would be introduced into the United States, a concern raised in part by the 2 confirmed cases of BSE in Canada in January 2005. These commenters did not elaborate on the basis for their concern or whether they disagreed with the scientific foundation of the MRR rule. On the other hand, some commenters who expressed concerns about the implementation of the MRR rule acknowledged, implicitly or explicitly, the validity of the scientific

[9] See: FSIS' interim final rule published in the **Federal Register** on January 12, 2004, titled ''Prohibition on the Use of Specified Risk Materials for Human Food and Requirements for the Disposition of Non-Ambulatory Disabled Cattle'' (69 FR 1874–1885, FSIS Docket No. 03–025IF,); FDA interim final rule published in the **Federal Register** on July 14, 2004, titled ''Use of Materials Derived from Cattle in Human Food and Cosmetics'' (69 FR 42255, FDA Docket No. 2004N–0081); FDA's ruminant feed regulations in 21 CFR 589.2000; and an advance notice of proposed rulemaking issued jointly by FDA, FSIS, and APHIS in the **Federal Register** on July 14, 2004, titled ''Federal Measures to Mitigate BSE Risks: Considerations for Further Action'' (69 FR 42288–42300, FDA Docket No. 2004N–0264, FSIS Docket No. 04–021ANPR, APHIS Docket No. 04–047–1).

approach embodied in the rule but urged the agency to ensure that the measures the agency relies upon have been effectively implemented. For example, the state farm bureau federation urged that USDA ''investigate and confirm'' that the current feed ban is being effectively enforced prior to opening the border with Canada. Additionally, the federation urged that USDA assess whether Canada's surveillance program is adequate.

Four cases of BSE have been detected in Canadian-origin cattle. The first two positive cases were detected in 2003 and two cases have been detected in 2005. On January 2, 2005, Canada announced that it had confirmed a case of BSE in an 8-year-old dairy cow in Alberta, Canada.

The following week, on January 11, 2005, Canada announced that it had confirmed a case of BSE in a beef cow in Alberta that was born shortly after the implementation of the feed ban in 1997. Because the cow was born shortly after the implementation of the feed ban and, in addition, to determine if there were any previously unidentified potential links, the USDA sent two technical teams to Canada to evaluate the circumstances surrounding these two recent BSE findings. One team, consisting of USDA and FDA officials, was responsible for conducting an in-depth assessment of Canada's feed ban, and the other team focused on the epidemiological investigations of the positive cases.

In preparing the MRR rule, Canada's compliance with the feed ban was thoroughly considered and discussed. Canada implemented its feed ban in 1997 to prohibit the feeding of most mammalian protein to ruminants. Canada's feed ban is virtually identical to the feed ban in place in the United States, except that Canada has extended its ban by prohibiting plate waste and poultry litter from being fed to ruminants. APHIS concluded, based on this thorough assessment, that Canada has had an effective feed ban in place in the rendering, feed manufacturing and livestock industries. (70 FR 467–468, APHIS Docket No. 03–080–3; ''Analysis of Risk-Update for the Final Rule: Bovine Spongiform Encephalopathy; Minimal Risk Regions and Importation of Commodities, December 2004,'' pp. 7–10; see also BSE in Canada Status Update—March, 2005, which can be found at *http://www.inspection.gc.ca/english/anima/heasan/disemala/bseesb/200503canadae.shtml.)*

On February 25, 2005, USDA published its assessment of the Canadian feed ban. The team concluded, based on its review of inspection records for the last 3 years and on-site inspections of commercial feed mills and rendering facilities, that Canada has a robust inspection program with strong enforcement, that overall compliance with the feed ban is good, and that the feed ban is effectively reducing the risk of transmission of BSE. (*http://www.aphis.usda.gov/lpa/issues/bse/bse.html.*) The team's report confirmed the APHIS evaluation of Canada's feed ban which supported the MRR rule.

It is important to note that in 1997, BSE had not been detected in North America, and the feed bans implemented by Canada and the United States were precautionary measures. As a result, neither government required that existing feed stocks be recalled. In Canada specifically, the feed ban was implemented with provisions for a phase-in period so that existing stocks of feed material could be depleted. It is likely that the Canadian feed ban took some time to be implemented completely throughout the feed manufacturing industry, as did the United States' feed ban. This would be expected in implementing a new, comprehensive regulatory program.

With respect to the two most recent positive BSE cases, the Canadian government confirmed that the animal identified as positive on January 2nd was exposed to feed rations containing meat and bone meal that was produced prior to the 1997 feed ban. This animal was born in October 1996 and was exposed to rations that contained meat and bone meal in early 1997, before the feed ban was implemented. In the case confirmed on January 11th, the Canadian investigation concluded that BSE may have been transmitted to the affected animal through feed produced shortly after the feed ban was implemented. As described in the previous paragraph, since an extensive change in industry practices cannot be expected to be completed immediately, a finding of BSE in an animal born shortly after the feed ban would not be unexpected and would not be inconsistent with the risk analysis supporting the final rule. (See BSE in Canada Status Update—March, 2005, which can be found at *http://www.inspection.gc.ca/english/anima/heasan/disemala/bseesb/200503canadae.shtml.* See also the summary report of the CFIA investigation of the January 2, 2005, case of BSE at *http://www.inspection.gc.ca/english/anima/heasan/disemala/bseesb/ab2005/2investe.shtml* and the summary report of the CFIA investigation of the January 11, 2005, case of BSE at *http://www.inspection.gc.ca/english/anima/heasan/disemala/bseesb/ab2005/3investe.shtml.*)

The possibility of additional BSE positive animals was understood and carefully considered by APHIS in the risk analysis and in our determination that Canada qualifies as a minimal-risk region. In our final rule (70 FR 514), we acknowledged the possibility that additional BSE-infected cattle might exist in Canada and explained the reason for our confidence that the number of such additional infected animals, if any, would be small. First, Canada has not imported ruminant MBM from any country with BSE since 1978. Second, Canada has prohibited the feeding of ruminant MBM to ruminants since 1997, and CFIA has verified high levels of compliance with the feed ban by routine inspections of both renderers and feed mills. Third, Canada has traced and destroyed all remaining cattle imported from the UK. Fourth, Canada has traced and destroyed the majority of the cattle that comprised the birth cohorts of the two initial Canadian BSE cases, as it has subsequently done with the birth cohorts of the two most recent cases. Fifth, Canada has conducted surveillance for BSE since 1992 and has conducted targeted surveillance at levels that have met or exceeded OIE guidelines since 1995.

As we explained in our final rule, even if BSE-infected cattle do remain in Canada, they are likely to be older animals that were exposed before Canada's feed ban in 1997. Because this rule requires that imported animals be less than 30 months old, such animals could not legally enter the United States under this rule. Further, even if an infected animal did enter the United States, the science, the research, and the experience of animal and public health authorities, supported by the Harvard-Tuskegee Study indicates it would be very unlikely to lead to the introduction of BSE into domestic cattle or to human exposure to the BSE agent.

Several commenters on the EA questioned Canada's feed ban due to press reports published in December 2004 that revealed that animal protein of undetermined origin had been found by CFIA in ruminant feed. As part of its ongoing compliance and enforcement program, the CFIA conducted a small feed sampling and testing program to evaluate the usefulness of direct microscopy. CFIA concluded that microscopy was not capable of distinguishing between animal tissues that pose no animal health risk and those that are prohibited under Canada's

feed ban regulations. In following up on the microscopy results, the CFIA concluded the great majority of samples did not contain prohibited material. Of the 110 samples tested, 65 samples were of Canadian origin, 44 samples were from the United States, and one was from France. Of the 65 samples of Canadian origin, the CFIA was unable to rule out the possibility that some incidental level of prohibited material may have been present in 11 samples. Of the 45 imported samples, animal material was detected in 18. With respect to the Canadian origin samples, the CFIA has taken action to ensure that the establishments involved have improved their recordkeeping, flushing, and/or sequencing procedures. (*http://www.inspection.gc.ca/english/anima/feebet/rumin/microe.shtml*.) Based on our extensive experience and interaction with CFIA program officials over many years, the thorough Canadian report on the microscopy sampling and testing program, as well as the results of the APHIS feed team inquiry, APHIS has concluded that the Canadian feed ban is effective and will accomplish its objective of reducing and eliminating any BSE infectivity that may remain in Canada.

As noted above, several commenters expressed concern that the MRR rule could result in the introduction of BSE into the domestic herd and that vCJD could occur as a result of such introduction or through the import of meat products from Canada. With regard to this concern, there is a solid scientific consensus regarding our knowledge of the cattle tissues that contain BSE infectivity and our knowledge of the modes of transmission of that infectivity. While it is likely that ongoing research will increase our knowledge of the disease agent, APHIS, along with FSIS and FDA, are confident that the measures in place will protect animal and human health. In addition, it seems clear that there is a significant species barrier that protects humans from illness due to exposure to the BSE agent. European scientists working on the outbreak in the UK and subsequent BSE research have suggested that the amount of infective tissue required to infect humans may be 10,000 times greater than the amount needed to infect cattle. During the epidemic in the UK, it was estimated that there were approximately 1 million infected animals and yet, to date, there have been only approximately 153 vCJD cases worldwide, 95 percent of which have occurred in the UK. Current research does not suggest the need for further food safety mitigations and does not alter the conclusion that the appropriate tissues that can carry levels of infectivity sufficient to cause human or animal illness are, in fact, being removed from the animal and human food supply under U.S. and Canadian regulations.

One commenter suggested the need for further assessment of the persistence of the BSE agent in soil, water and air. To date, there is no evidence of environmental transmission of the BSE agent. While such transmission could be theoretically possible, epidemiological reviews do not indicate that such transmissions, even if they occurred, would be a significant issue. In the UK, which has experienced the largest and most significant outbreak, early epidemiological investigations pinpointed feed as the route of transmission. In response to these findings, the UK authorities instituted feed ban regulations that have been strengthened over the years. The feed restrictions have clearly had an effect in preventing transmission of disease, with the number of cases identified annually continuing to decrease from a peak in 1992–1993. Investigations have been done on animals born after the reinforced ban went into effect. These have included evaluating all possible routes of transmission, and they continue to conclude that environmental contamination is an unlikely risk factor. Therefore, based on the best available science, the ability of the BSE agent to persist in soil, water and air is not a significant issue.

While there is evidence that scrapie disease in sheep and chronic wasting disease (CWD) in cervids can be transmitted by environmental contamination, there is no basis for extrapolating these data to BSE in cattle. Research has demonstrated that the distribution of scrapie infectivity in sheep is different than the BSE agent in cattle. For example, infectivity has been found in the placenta of sheep infected with scrapie. This contributes to the lateral transmission (animal-to-animal) of scrapie in sheep, and if placental tissue remains in the environment, it can contribute to environmental contamination. Conversely, in cattle infected with BSE, no infectivity has been demonstrated in placenta and there is no evidence of lateral transmission of the disease. Similarly, animal-to-animal contact appears to contribute to the spread of CWD in cervids, and environmental contamination also appears to be a factor, although the specific means of transmission is unknown. However, these findings cannot be extrapolated to cattle with BSE, as there is no evidence of lateral transmission of BSE or of transmission by environmental contamination.

C. The Degree to Which the Action May Establish a Precedent for Future Action With Significant Effects or Represent a Decision in Principle About a Future Consideration

This criterion requires consideration of whether an action may establish an authoritative rule, pattern, or practice for similar cases that may follow and whether the precedent thereby established could have significant effects on the quality of the human environment.

The MRR rule establishes standards for recognizing regions as presenting a minimal risk of introducing BSE into the United States and provides for the importation of certain ruminants, ruminant products and byproducts from such regions. The minimal-risk region standards and import conditions established by APHIS are designed to prevent the introduction of BSE into the United States. These standards and conditions are buttressed by a series of interlocking, overlapping risk mitigations in place in the United States. The addition of this minimal-risk category to the agency's BSE rules will permit regions that believe they meet the standards to request recognition as a BSE minimal-risk region. We would expect and require that any such request will, in the first instance, comply with § 92.2 of the APHIS regulations, which contains the general procedures for requesting the recognition of regions. (9 CFR 92.2.) The MRR rule, however, designates Canada as the only minimal-risk region for BSE. Before another country or region would be recognized as a BSE minimal-risk region, APHIS would conduct an assessment of all risks involved. If the risk assessment indicated that the region meets the standards and appropriate requirements, APHIS would publish a proposal in the **Federal Register**. At that point, the public would have an opportunity to participate fully and all pertinent issues, questions, and concerns would be addressed in the rulemaking process. Needless to say, any unusual or unique facts or circumstances related to a particular region's request would be carefully evaluated by APHIS as well. For example, the animals or animal products allowed to be imported and the required risk mitigation measures could and would be tailored to each specific region considered. Accordingly, the MRR rule does not establish a precedent for future actions with significant effects or represent a decision in principle about future

approval of additional minimal-risk regions.

D. Whether the Action Is Related to Other Actions With Individually Insignificant but Cumulatively Significant Impacts

The term cumulative impact is defined as an impact on the environment that results from the incremental impact of the action when added to other past, present, and reasonably foreseeable future actions regardless of what agency or person undertakes such other actions. Cumulative impacts can result from individually minor but collectively significant actions taking place over a period of time.

The potential for harm to the quality of the human environment lies in the introduction of the BSE agent into the United States and subsequently finding its way into the animal and human food supply where it could be ingested and result in infection. For this chain of events to occur, the multiple animal and human health mitigation measures in place in Canada and the United States, as well as the additional mitigations prescribed by the MRR rule, would have to substantially fail. There is no basis to conclude that such a significant breakdown in the system of interlocking and overlapping measures could ever occur. Similarly, if the agency were to recognize any other regions as minimal-risk regions, there is no reason to believe that the mitigation measures and other requirements imposed in such a rulemaking would be any more likely to be breached and result in harm to animal or human health. It must be remembered that our MRR rule is designed to preclude the introduction of BSE into the United States and APHIS has concluded that the rule will achieve that result. Accordingly, there is no basis to believe that this action, or future actions that the agency may take, could result in cumulatively significant environmental impacts.

Additional Issues: Allegations of Environmental Impacts Raised in Litigation

Shortly after issuance of the final EA for the MRR rule, the Ranchers-Cattlemen Action Legal Fund, United Stockgrowers of America (''R–CALF''), filed a complaint challenging the rule in the United States District Court for the District of Montana. R–CALF alleged that the final EA was inadequate because, among other things, it failed to assess the environmental effects of transporting what we estimated would be as many as 2 million head of cattle from farms and feedlots in Canada to feedlots and slaughterhouses in the United States, as well as the environmental impacts of feeding and holding these additional feeder cattle until slaughter. Although the plaintiff filed several comments on the rule throughout this rulemaking proceeding, it did not include these concerns in these comments, nor did it file any comment on the final EA published on January 4, 2005. In addition, no other commenter on the EAs raised these potential environmental impact issues. Even though the alleged potential effects pose no significant environmental impact, and were not raised by R–CALF or any other commenter on the EA, we have addressed them below.

The two issues raised by R-CALF did not, and do not now, pose potentially significant impacts. Accordingly, they were not discussed in the final EA. First, it is important to note that the impacts or effects alleged by R-CALF to be significant are not brought about or caused by the MRR final rule. Second, it is also important to understand the MRR rule within the context of the economic relationship that has existed between Canada and the United States for many years. Since the 1970's, the U.S. and Canadian cattle and beef industries operated largely as an integrated North American industry, with both live cattle and processed beef flowing freely between the two countries. For years prior to May 2003, millions of head of live cattle crossed the border in one direction or the other. The two countries have become each other's largest trading partners in agricultural products.

In May 2003, as a result of the finding of BSE in Canada, APHIS published an interim rule to add Canada to the list of countries in which BSE exists. APHIS took this action as a temporary measure while it assessed the facts and circumstances surrounding the BSE situation in Canada. After evaluating the epidemiological investigation of the May 2003 BSE positive cow and after reviewing the BSE risk mitigation measures in place in Canada and the United States, USDA announced in August 2003 that it would begin issuing permits, pursuant to its existing regulations, to allow the importation of certain low-risk meat products from Canada. These products included boneless beef from cattle under 30 months of age, veal, and bovine liver. As a result, within 3 months, a substantial amount of trade in beef and beef products was resumed with Canada. In November 2003, APHIS issued a proposed rule that would again allow the importation of certain live animals, including cattle under 30 months of age, as well as all beef products from cattle under 30 months of age, from Canada. Therefore, the MRR rule would allow the restoration of trade in ruminants and ruminant products under approved mitigations after a temporary suspension of such trade.

The final economic analysis for the MRR rule estimated that as many as 2 million head of cattle could be imported from Canada in 2005, assuming implementation of the MRR rule at the beginning of the year. This estimate was based on historical cattle import data from 2001 and 2002, an estimated backlog of cattle in Canada as a result of the temporary closure of the border to live cattle in 2003, and an estimate of the number of cattle under 30 months of age that would be available for importation into the United States because of an increase in the number of older cattle that would be slaughtered in Canada for the export of beef to the United States. We acknowledged that there was a good deal of uncertainty in projecting the number of cattle that would be imported from Canada and that changes in production, feeding, slaughter and trade patterns and circumstances could well affect the result. In recognition of these uncertainties, we also conducted the analysis using one-half of the assumed backlog and one-half of the assumed number of imported fed cattle displaced from slaughter in Canada.

Using the 2 million number, R–CALF estimated that the resumption of limited trade in live cattle would result in 35,000 truck round-trips between Canada and the United States. Assuming these would represent an actual increase in trips involving live cattle and meat, the truck traffic represented by this estimation is wholly insignificant. For 2003, the incoming truck crossings from Canada into the United States totaled 13.3 million crossings, which included 6.7 million truck crossings, 5.7 million loaded truck container crossings, and 0.9 million unloaded truck container crossings. (*See http://www.bts.gov/programs/international/border_crossing_entry_data/.*) For 2002, the total incoming truck crossings from Canada into the United States were 13.7 million crossings, which included 6.9 million truck crossings, 5.8 million loaded truck container crossings and 1.0 million unloaded truck container crossings. (*Id.*) For 2001, the total incoming truck crossings from Canada into the United States were 13.4 million crossings, which included 6.8 million truck crossings, 5.6 million loaded truck container crossings, and 1.0 million unloaded truck container crossings. (*Id.*)

There is little variation in the annual volume of truck traffic entering the United States from Canada over this 3-year period, and, in addition, an increase of 35,000 truck crossings would be well within the variation shown by the data. Even with an increase of 35,000 truck round-trips between Canada and the United States, the total increase would amount to approximately 1/4 of one percent increase in truck traffic, an amount that is *de minimus* by any measure. An examination of truck traffic through the 20 ports of entry through which importations of live ruminants and ruminant products from Canada are authorized under the MRR rule yields similar conclusions. The 2003 truck crossings at the 20 ports of entry were approximately 11.1 million. (*Id.*) Therefore, an increase of 35,000 truck crossings spread over just these 20 ports of entry would result in less than 1/3 of a one percent increase. It is also important to note that truck traffic between the United States and Canada is merely a subset of all vehicular traffic between the two countries. When considering the total volume of all vehicular traffic traveling across the border with Canada, the environmental impacts associated with an increase of 35,000 truck round-trips are even less significant. Accordingly, R–CALF's claim that increased truck traffic would result in environmental damage is without merit.

R–CALF also alleges that there will be significant environmental effects attendant to the importation of live animals for feeding and for slaughter. R–CALF asserts that these live cattle would be required to be moved to a limited number of feedlots and slaughter facilities in the United States. However, the final regulation contains no limitation on the number of feedlots or slaughter facilities. The MRR rule is merely restoring, for live cattle under 30 months, longstanding trade with Canada, trade that has persisted for years and was only temporarily halted in May 2003 due to the finding of BSE in Canada. There is no reason to believe that these cattle would be destined for a different set of feedlots or slaughter facilities than cattle imported from Canada prior to 2003.

Whatever the potential environmental effects that theoretically might be associated with the importation of live cattle for feeding or for slaughter, there would be a significant difference in the magnitude of such potential effects depending on whether the cattle were being transported directly to slaughter facilities or were destined for feedlots, where they may be fed for some period of time prior to moving to slaughter. The potential environmental effects, while inconsequential, would be significantly less for cattle moved immediately to slaughter facilities. Based on historical data for cattle imports from Canada, between 65 percent and 75 percent of imported cattle have gone directly to slaughter and the remainder (other than the very small number historically imported for breeding) have been transported to feedlots and then to slaughter facilities. Based on the projection in the final economic analysis of 2 million cattle imported, approximately 1.4 million would be moved immediately to slaughter and 600,000 feeder cattle would be moved to feedlots.

Subsequent to the estimates in the final economic analysis and publication of the MRR rule, on February 9, 2005, the Secretary announced that implementation of the part of the MRR rule that would allow for importation of beef from cattle 30 months of age or older would be delayed. Therefore, there was no longer a basis for assuming the displacement from slaughter in Canada of cattle under 30 months of age by cattle 30 months of age or older. The estimate of the number of cattle that would be imported from Canada was revised downward. We further modified the estimate downward to reflect an increase in Canadian slaughter capacity over the past year. Therefore, based on these factors, we estimated that as many as 1.4 million cattle could be imported from Canada in the first year after the effective date of the MRR rule. Of this number, we estimate that 900,000 fed cattle would be moved directly to slaughter facilities and that 500,000 feeder cattle would be sent to feedlots and then to slaughter, further reducing any potential impacts.

On January 6, 2005, the National Cattlemen's Beef Association (NCBA) sent a delegation of U.S. cattle producers to Canada on a fact-finding mission regarding BSE and the MRR rule. One task assigned to the NCBA delegation was to identify Canadian cattle that would qualify for export under the MRR rule and determine the impact on U.S. producers. The NCBA delegation report, dated February 2, 2005 (*http://www.beefusa.org/uDocs/acf985911.pdf*) stated, based on Can-Fax data gathered over a 20-month period of time, that there were approximately 900,000 head of cattle available for export. This consisted of approximately 600,000–700,000 head of fed cattle and approximately 200,000–300,000 feeder cattle. The NCBA report suggested that the import quantities assumed in APHIS' economic analysis were too high. The NCBA report suggests that the APHIS estimate did not fully account for the 22 percent increase in Canadian slaughter capacity between 2003 and 2004. The NCBA report concluded that the delegation agreed with Can-Fax and other private sector estimates and put the likely imports of feeder cattle in the range of 200,000–300,000 during calendar year 2005 and assumed that the MRR rule would be implemented on March 7, 2005.

Under either of APHIS' two estimates, any environmental effects would not be significant. The average annual number of fed cattle slaughtered for the years 2002 and 2003 in the United States was 29 million. Total cattle slaughter, which includes fed cattle, cows and bulls, averaged 35.6 million head annually for the same period. Thus, the estimated maximum imports of cattle for immediate slaughter would amount to approximately 4.8 percent of the total fed cattle slaughter and 3.9 percent of total cattle slaughter spread over a 12-month period. For the years 2003 and 2004, an average of 26.9 million cattle were marketed by U.S. feedlots annually. The estimated number of feeder cattle that may be imported from Canada in the first year (500,000–600,000 head) would represent between 1.8 and 2.2 percent of fed cattle marketed annually in the United States. Even assuming that Canadian feeder cattle actually imported after implementation of the MRR rule represented an actual increase in the number of cattle on feed in the United States, the potential effects would not be significant. The transitory nature of even this volume of imports from Canada is discussed in the final EA, where estimates that imports would decline over the years 2006–2009 are discussed and displayed.

Furthermore, any potential impacts on air and water quality associated with the importation of cattle from Canada are addressed under an array of existing statutes and regulations in the United States. These regulations include the National Pollutant Discharge Elimination System Permit regulations and Effluent Limitation Guidelines and Standards for Concentrated Animal Feeding Operations (CAFO) under the Clean Water Act, as well as State environmental regulations for proper management of manure and wastewater from animal feedlot operations. In addition to state laws and regulations for air emissions, there are a variety of provisions under the Clear Air Act that could address air emissions relating to this activity. The U.S. Environmental Protection Agency has also established requirements for CAFOs under the

Clean Water Act and regarding nitrate contamination of underground sources of drinking water under the Safe Drinking Water Act. The United States' Clean Air Act and Canadian environmental protection laws have vehicle emissions requirements that are designed to prevent harmful air emissions from vehicles, including transport trucks. These activities have a very low potential to negatively affect human health and safety since each is subject to comprehensive environmental regulation in this country and in Canada. Compliance with these requirements by transporters, feedlot operators, and slaughterhouses assures that the quality of the human environment will be safeguarded in all respects. Our border ports are adequately staffed and capable of handling movement of cattle into this country, which will not concentrate at a single border port. Historically, Canadian cattle imported into the United States for slaughter have been shipped to numerous States throughout the United States. Because cattle are not required to be shipped to specific feedlots or slaughter facilities, it is expected that trucks will utilize all available border crossings and highway routes. There is no evidence or data to suggest that our roadways, feedlots, and slaughterhouses, as currently operated, cannot accommodate the resumption of Canadian cattle imports in a manner that fully protects all potentially impacted environmental quality values.

I have determined that the final BSE MRR rule will not have a significant effect on the human environment and accordingly I have decided that it is appropriate to issue a finding of no significant impact for the final MRR rule. Thus, having fully considered the two environmental assessments prepared for the MRR rule, as well as all of the comments submitted on them, along with the reports and analyses referenced in the EA and in the MRR rule, I conclude that the MRR rule will protect animal and human health and the environment. Accordingly, I find that adoption of the MRR final rule and the recognition of Canada as a BSE minimal-risk region will not significantly affect the quality of the human environment.

The finding of no significant impact was signed by Dr. W. Ron DeHaven, Administrator, Animal and Plant Health Inspection Service, on April 5, 2005.

Done in Washington, DC, this 5th day of April 2005.

Bill Hawks,

Under Secretary for Marketing and Regulatory Programs.

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