Finding of No Significant Impact
for the Environmental Assessment Prepared for the Rulemaking,
Importation of Certain Commodities From BSE Minimal-risk Regions (Canada)

The U.S. Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS) prepared an environmental assessment that analyzes the potential effects on the human environment from the importation of live bovines born on or after March 1, 1999, bovine small intestines (with the exception of the distal ileum), and bovine blood and blood products from BSE minimal-risk regions into the United States. Currently, Canada is the only designated BSE minimal-risk region. The environmental assessment was prepared to comply with the National Environmental Policy Act of 1969 (NEPA), as amended,[1] the Council on Environmental Quality NEPA implementing regulations,[2] USDA NEPA regulations,[3] and APHIS NEPA implementing procedures.[4]

The environmental assessment entitled, "Importation of Certain Commodities From BSE Minimal-risk Regions (Canada)," is available on the Internet through the Web site at http://www.regulations.gov/. This Finding of No Significant Impact summarizes and incorporates by reference the final environmental assessment and concludes the environmental assessment process undertaken for the rulemaking.

Summary of the Environmental Assessment

The environmental assessment considered two alternatives: (1) "No Action," which would not change the current regulations and would continue to allow the importation of live bovines for feeding or immediate slaughter at less than 30 months of age and not allow the importation of live bovines other than those just described, bovine small intestines (with the exception of the distal ileum), and bovine blood and blood products from Canada and (2) the proposed rule alternative that would allow, under certain conditions, the importation of live bovines born on or after March 1, 1999, bovine small intestines (with the exception of the distal ileum), and bovine blood and blood products from Canada.

The environmental assessment addressed the potential impacts to the human environment from implementing the proposed rule, as summarized below.

A. Impacts on Public Health from BSE Exposure

Although protection of animal health from BSE exposure is the disease concern related to the scope of the rule and its associated risk assessment, the environmental assessment considers the potential for BSE exposure to humans because NEPA requires that Federal agencies consider impacts on public health from proposed actions.

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[1] 42 United States Code 4321 *et seq.*
[2] 40 Code of Federal Regulations (CFR) 1500-1508.
[3] 7 United States Code Part 1b.
[4] 7 CFR Part 372.

Live Bovines

The public health concern associated with the importation of live bovines and bovine products from a minimal-risk region is the potential for human exposure to BSE-infected materials. In the risk assessment supporting the proposed rule, APHIS evaluated risk factors related to biological pathways of BSE transmission that could influence the risk of BSE entering the United States. For each of the pathways identified, the risk assessment noted mitigating factors and mitigation measures that serve to reduce the risk of disease introduction, exposure, and establishment in the United States.

Additional requirements proposed for APHIS' regulations on this matter are designed to reduce the potential risk for introducing BSE-infected animals into the United States from Canada. Measures already in place in Canada and mitigation measures and requirements in APHIS regulations and related animal feed regulation under FDA and public health regulations under FDA and FSIS all work together to reduce the potential for significant impacts related to the risk of introducing BSE-infected bovine and certain bovine commodities and affecting animal health and/or public health in the United States.

The risk assessment prepared for the rulemaking to allow the importation of additional bovine commodities from Canada considered all safeguards in place to help prevent the spread of BSE, including those in the United States. The risk assessment concludes that the risk of BSE becoming established in the United States as a result of the proposed trade with Canada is negligible. Both qualitative and quantitative methods were used in the exposure assessment to evaluate the likelihood of exposing susceptible animals given the release of infectivity via imported animals. The most likely scenario—that the prevalence of BSE in Canada will decrease over the next 20 years—was evaluated qualitatively. The assessment considered less likely scenarios—an assumption that the prevalence of BSE in Canada will remain constant over the next 20 years—using a quantitative exposure model that also modeled the amount of infectivity that could potentially be available for human exposure. In the least likely scenario, using combined pessimistic assumptions, the exposure model estimated that the potential infectivity available for human exposure over the 20-year period could amount to 290 cattle oral infectious dose-50 (ID_{50}) units. [5] In extrapolating what this means, the environmental assessment compares these exposure model results to human exposure to BSE infectivity from cattle in the United Kingdom during the BSE epidemic there. The environmental assessment notes that the potential for human exposure to BSE in the United States, based upon the risk from implementing the rule, is estimated to be 1,200,000 times less in the United States than the human exposure to BSE that occurred in the United Kingdom during its BSE epidemic.

No significant adverse impacts on public health are expected from the importation of live bovines from Canada based upon implementation of the rule.

[5] A cattle oral ID_{50} is defined as the amount of infectivity required to cause infection in 50 percent of an exposed cattle population.

Small Intestines, with the Exception of the Distal Ileum

Infectious levels of the BSE agent have not been found in bovine intestinal tissue, excluding the distal ileum. Removal of the distal ileum is required under FDA and FSIS regulations. An authorized veterinary official of the Government of Canada will be required to certify that any product containing bovine small intestine does not include the distal ileum.

The importation of bovine small intestines from Canada will not result in the transmission of the BSE agent to humans provided that establishments comply with FSIS and FDA regulatory requirements for slaughter and processing. These requirements include that the distal ileum is effectively removed from cattle that have been inspected and passed in an official U.S. establishment or in a certified establishment listed by FSIS as eligible to export meat products to the United States. The risk assessment prepared for the rule concludes that the likelihood of introducing BSE infectivity in bovine small intestine other than distal ileum imported from Canada is negligible. No significant adverse impacts on the human environment are expected from the importation of bovine small intestines from Canada based upon implementation of the rule.

Bovine Blood and Blood Products

BSE infectivity has not been detected in bovine blood and, therefore, bovine blood is not considered to be a specific risk material (SRM). However, cross-contamination of blood with SRMs during the slaughter and blood collection process could be a concern for blood and blood products for animal health uses and human health uses, such as in the manufacture of vaccines. The rule would require implementation of mitigation measures intended to prevent cross-contamination of blood with SRMs. The related risk assessment concludes that the likelihood of BSE release and subsequent exposure of bovines to infectivity from blood and blood products is negligible. No significant adverse impacts on animal health are expected from the importation of bovine blood and blood products from Canada based upon implementation of requirements in the rule.

FDA regulates bovine blood and blood products used for human medical products and oversees the safety of vaccines and drugs for consumers. FDA reviews drugs and vaccines on a product by product basis, ensuring that risks are evaluated and appropriate mitigations are in place for safe human use. As presented in the environmental assessment, FDA has concluded that control measures in place, including the ruminant-to-ruminant feed ban and others that are similar in the United States and Canada, assure the safety of bovine-derived materials originating from these countries for use in the manufacture of vaccines.

B. Impacts on the Physical Environment

The environmental assessment considered impacts on the physical environment from the transport of bovines from Canada, the holding of bovines in feedlots, and the generation of specified risk materials (SRMs) that would be removed from imported live bovines.

Allowing importation of bovines for any use born on or after March 1, 1999, will reestablish imports of cattle to projected levels of 130,000 to 446,000 bovines per year over a 20-year period, resuming between 2,600 to 8,920 truck transports through 20 possible ports of entry at the Canada-U.S. border over a 20-year period. Truck transports through the 20 ports of entry for cattle have averaged about 5.6 million annually. The proportion of truck transports for the additional live bovine imports would comprise about 0.05-0.16 percent of the overall baseline of truck transports through the 20 U.S.-Canadian border ports of entry. In considering the baseline of truck transports, resuming truck transports for bovines born on or after March 1, 1999, will not result in a significant increase in truck transports and, therefore, is not expected to contribute significantly to adverse impacts on the human environment.

Holding of cattle in feedlots from implementation of the rule is not expected to contribute to a significant impact on the environment. The additional live bovine imports most likely would not be held in feedlots because they would be imported either for slaughter or for integration into U.S. cattle herds. The cattle that are imported for slaughter may be held at slaughter facilities for conditioning for several days but would not contribute significantly to adverse impacts on the environment.

The proportion of SRMs that would be generated from imported Canadian cattle under the rule, based on recent import projections, is expected to be about 5% of the annual amount of SRMs that would be generated from U.S. commercial cattle slaughter.

No significant adverse impacts on the physical environment are reasonably foreseeable from implementation of the rule.

C. Highly Uncertain or Unique or Unknown Risks

While the science is not complete with regard to the BSE agent, including the amount of exposure to the BSE agent that would infect humans, there is strong scientific consensus about the BSE agent, the mechanisms for its spread, and the tissues that are most likely to harbor the infective agent. Based on the current knowledge, safeguards and mitigation measures that are in place to prevent animal and human exposure to the infective agent and the additional requirements that would be implemented by the rule, no significant adverse impacts to the human environment are expected with regard to uncertain or unknown risks.

D. Other Environmental Reviews Considered

APHIS considered the potential effects of the proposed rule on federally listed endangered or threatened species and designated critical habitat. Six endangered ruminant species were considered as potentially at risk of the possibility of ingesting contaminated ruminant feed. However, based on prohibitions of ruminant materials in ruminant feed, it would be unlikely that the listed ruminants would be exposed to BSE-contaminated bovine or bovine materials. The environmental assessment concludes that the rule will have no effect on federally listed endangered or threatened species or critical habitat.

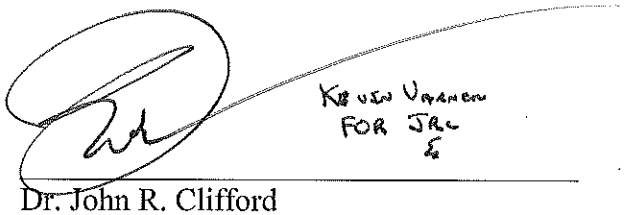
E. Cumulative Impacts

Based on consideration of cumulative impacts from the importation of live bovines born on or after March 1, 1999, no significant adverse impacts to public health or the physical environment are expected from implementation of the rule. The multiple mitigation measures prescribed by the rule and ongoing requirements through FSIS and FDA regulations that minimize human exposure to materials that could contain the BSE agent thereby protecting both animal health and public health, protect the quality of the human environment. The resumption of 0.05-0.16 percent of annual U.S.-Canada truck crossings for the projected available cattle imports from Canada is not expected to significantly contribute to adverse impacts on the environment. Also, cattle imported under the rule would result in a proportion of about 5% of the SRMs generated from annual U.S. cattle slaughter; this amount of SRMs should not create an excessive burden on the ability of U.S. slaughter facilities to properly dispose of the material and is not expected to significantly contribute to adverse impacts on the environment.

Finding

In reviewing the final environmental assessment (dated September 2007) prepared for the rulemaking and comments received on the October 27, 2006, environmental assessment, I have determined that implementation of the proposed rule should not have significant adverse impacts on the human environment. Accordingly, I have determined that this Finding of No Significant Impact is the appropriate decision to make in reference to the environmental assessment for the proposed action to allow the importation of live bovines for any use born on or after March 1, 1999, bovine small intestines except for the distal ileum, and bovine blood and blood products from Canada into the United States. Because this Finding of No Significant Impact has been made, the preparation of an environmental impact statement will not be necessary before implementing the proposed rule as a final rule.

Implementation of the proposed rule alternative to allow, under certain conditions, the importation of live bovines born on or after March 1, 1999, bovine small intestines except for the distal ileum, and bovine blood and blood products from Canada will continue to protect animal health and human health in the United States while removing unnecessary prohibitions on certain low risk products in accordance with international guidelines on BSE. This alternative also will not present any significant adverse impacts on the human environment.



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Date