

Proposed Rules

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This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Parts 93, 94, and 95

[Docket No. 03–080–1]

RIN 0579–AB73

Bovine Spongiform Encephalopathy; Minimal Risk Regions and Importation of Commodities

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Proposed rule.

SUMMARY: We are proposing 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 are proposing to add Canada to this category. We are also proposing to allow the importation of certain live ruminants and ruminant products and byproducts from such regions under certain conditions. We believe this action is warranted because it would continue to protect against the introduction of BSE into the United States while removing unnecessary prohibitions on certain commodities from Canada and other regions that qualify as BSE minimal-risk regions.

DATES: We will consider all comments that we receive on or before January 5, 2004.

ADDRESSES: You may submit comments by postal mail/commercial delivery or by e-mail. If you use postal mail/commercial delivery, please send four copies of your comment (an original and three copies) to: Docket No. 03–080–1, Regulatory Analysis and Development, PPD, APHIS, Station 3C71, 4700 River Road Unit 118, Riverdale, MD 20737–1238. Please state that your comment refers to Docket No. 03–080–1. If you use e-mail, address your comment to regulations@aphis.usda.gov. Your

comment must be contained in the body of your message; do not send attached files. Please include your name and address in your message and “Docket No. 03–080–1” on the subject line.

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

APHIS documents published in the **Federal Register**, and related information, including the names of organizations and individuals who have commented on APHIS dockets, are available on the Internet at <http://www.aphis.usda.gov/ppd/rad/webrepor.html>.

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

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

BSE is a progressive neurological disorder of cattle that results from infection by an unconventional transmissible agent and is not known to exist in the United States. The disease has been difficult to define experimentally with precision, although risk factors that are independent of the causative agent have been identified and

can be mitigated. Much of the available data originated from epidemiological observations and not from controlled studies. Controlled studies are often difficult to conduct because of limitations in experimental models and the length of time necessary to conduct the studies, which may require years. Currently, the most accepted theory is that the agent is a modified form of a normal cell surface component known as prion protein, although other types of agents have been implicated, including virinos. The pathogenic form of the protein is both less soluble and more resistant to degradation than the normal form. The BSE agent is extremely resistant to heat and to normal sterilization processes. It does not evoke any demonstrated immune response or inflammatory reaction in host animals.

Despite the difficulty in defining BSE experimentally with precision, risk factors for BSE that can be mitigated have been identified. These factors are based on technical knowledge and disease epidemiology and do not require definition of the nature of the agent. We believe that risk mitigation measures that address the risk factors for BSE will be effective regardless of the precise nature of the BSE agent.

It appears that BSE is spread primarily through the use of ruminant feed containing protein and other products from ruminants infected with BSE. Ruminants in the United States could be exposed to the disease if materials carrying the BSE agent—such as certain meat, animal products, or animal byproducts from ruminants—were imported into the United States and were fed to ruminants in this country. BSE could also be introduced into the United States if ruminants with BSE were imported into the United States.

Because of these risks, the regulations prohibit the importation of live ruminants and certain ruminant products and byproducts from two categories of regions: (1) Those regions in which BSE is known to exist, which are listed in § 94.18(a)(1) of the regulations; and (2) those regions that present an undue risk of introducing BSE into the United States because their import requirements are less restrictive than those that would be acceptable for import into the United States and/or because the regions have inadequate surveillance. These regions of “undue