



Questions and Answers

Bovine Spongiform Encephalopathy (BSE) – Current USDA Actions and the Canadian Situation

Q. What is the latest USDA action regarding BSE in Canada?

A. The United States Department of Agriculture's Animal and Plant Health Inspection Service has issued a proposed rule to amend its bovine spongiform encephalopathy (BSE) regulations to establish a new category of regions that recognizes those that present a minimal risk of introducing BSE into the United States via the importation of certain low-risk live ruminants and ruminant products. The proposed rule would allow the importation of certain live ruminants and ruminant products and byproducts from minimal risk regions under specified conditions. Additionally, the proposed rule places Canada on a list of countries considered minimal risk for BSE, thus making Canada eligible to export specified live ruminants and ruminant products.

Q. What is a ruminant?

A. Ruminants are animals that have multiple stomachs, such as cattle, sheep, goats, bison, deer, elk, caribou, moose, camels, etc.

Q. What are the next steps in regard to this proposal?

A. This is a proposed rule, which means that it is open for public comment. All interested parties are encouraged to submit comments. The proposed rule has a 60-day comment period, so all comments received on or before January 5 will be considered. Once this period closes, USDA will evaluate and consider all comments received, and will then decide whether any changes need to be made to the proposed rule. The last step in the process will be to publish a final rule, reflecting any changes as decided.

Q. How do I comment on the proposal?

A. Comments may be submitted by postal mail, commercial delivery or by e-mail. Send an original and three copies of postal or commercial delivery comments to Docket No. 03-080-1, Regulatory Analysis and Development, PPD, APHIS, Station 3C71, 4700 River Road Unit 118, Riverdale, Md. 20737-1238. If you use e-mail, address your comments to regulations@aphis.usda.gov. Comments must be contained in the body of the message; do not send attached files. Please include your name and address in the message and use "Docket No. 03-080-1" on the subject line.

Q. What products would be eligible for entry under the proposed rule?

A. Under this proposal, ruminant and ruminant products eligible for entry into the United States from a BSE minimal risk region would include:

- 1) bovine animals less than 30 months of age for immediate slaughter;

- 2) bovine animals for feeding, moved to a designated feedlot and then to slaughter at less than 30 months of age;
- 3) sheep and goats less than 12 months of age for immediate slaughter;
- 4) sheep and goats for feeding, moved to a designated feedlot and then to slaughter at less than 12 months of age;
- 5) cervids for immediate slaughter;
- 6) fresh (chilled or frozen) meat from bovines less than 30 months of age;
- 7) fresh (chilled or frozen) whole or half carcasses of bovines less than 30 months of age;
- 8) fresh (chilled or frozen) bovine liver;
- 9) fresh (chilled or frozen) bovine tongues;
- 10) fresh (chilled and frozen) meat of sheep or goats less than 12 months of age;
- 11) fresh (chilled or frozen) carcasses of sheep or goats less than 12 months of age;
- 12) hunter harvested wild ruminant products;
- 13) fresh (chilled or frozen) meat of cervids either farm-raised or harvested on a game farm or similar facility;
- 14) fresh (chilled or frozen) meat from wild- harvested caribou, musk ox, or other cervids; and
- 15) certain types of gelatin, tallow and offal.

A full listing of the risk mitigation measures required to make these commodities eligible for entry into the United States can be found at <http://www.aphis.usda.gov/>.

Q. In the proposed rule, is an import permit required for the products eligible for entry?

A. No. The proposed rule does not require an import permit.

Q. Are all ruminant and ruminant products still banned from Canada? What is allowed entry while the rulemaking process is underway?

A. On August 8, USDA announced that it would allow certain ruminant products to enter the United States under permit. These same products can continue to enter under permit while the rulemaking process is moving forward.

Q. What is the legal authority for the permitting process? Is there a need for rulemaking?

A. The Department has regulatory authority to issue permits allowing ruminants and ruminant products to enter the United States from Canada, under prescribed conditions, if doing so will not endanger U.S. livestock or poultry (9 C.F.R. § 93.401(a)).

The Department has decided to make changes to the underlying regulation, and we are therefore following the regulatory process, including the opportunity for public comment. We believe there is a solid scientific justification for amending the regulations.

Q. Will USDA continue its BSE surveillance program?

A. Yes. Since 1990, USDA has had an aggressive BSE surveillance program in

place to ensure detection and swift response in the event that an introduction of BSE were to occur. Last year, USDA tripled testing levels and this year testing reached an all-time high of 20,526 head, or 47 times the level recommended by the OIE. Since the May 20, 2003 occurrence of a single case of BSE in Canada, APHIS is reviewing its current level of surveillance to continue to ensure a high confidence level.

Q. What are the results of the second Harvard risk assessment?

A. The study found that even if infected animals or ruminant feed material entered the U.S. animal agriculture system from Canada, the risk of it spreading extensively within the U.S. herd was low, that any possible spread would have been reversed by controls put in place in the late 1990's, and that eventually, the disease would be eliminated from the United States. A complete copy of the second Harvard report can be obtained from USDA's official website at <http://www.usda.gov/>.

Q. Is the Harvard risk analysis in any way associated with the proposed rule?

A. No. The risk assessment was commissioned by USDA shortly after the discovery of a single case of BSE in Canada on May 20, 2003. The study evaluates the potential for BSE to spread if it were introduced from Canada prior to May 20, when USDA banned all ruminant and ruminant products from Canada because of the discovery of the single case of BSE. The assessment specifically examined scenarios for the likely introductions of BSE from Canada into the United States in prior years.

USDA Permitting Process

Q. Which ruminant products that were banned on May 20, 2003, can now be imported from Canada?

A. The following ruminant products from Canada are currently allowed to enter with a permit:

- Hunter-harvested wild ruminant products that are intended for personal use;
- Caribou and Musk ox meat from the Canadian province of Nunavut for commercial use;
- Veal (meat) from calves that were 36 weeks of age or younger at slaughter;
- Boneless meat from sheep or goats that were 12 months of age or younger at slaughter;
- Meat from farm-raised cervids (cervids include deer and elk);
- Boneless bovine meat from animals that were 30 months of age or younger at slaughter;
- Fresh or frozen bovine liver;
- Finished pet chews that are made from bone, ligaments, hides or hooves; and
- Calf milk replacer, pet food, and feed ingredients that contain only non-ruminant products when produced in facilities with dedicated manufacturing lines.

Q. What is meant by the term "dedicated"?

A. The term "dedicated" is used in the following context:

a. "Dedicated facility": an exporting facility that is under the oversight of the national animal health authorities and only receives, stores and processes ruminant material that is eligible for export to the United States

b. "Dedicated line" in a facility: an exporting facility having one or more processing lines dedicated to processing only ruminant material eligible for export to the United States. Such facility may process material that is not eligible for entry into the United States, but does so in separate processing lines, stores such material (both unprocessed and processed) separate and apart from export eligible product, and otherwise ensures that there is no commingling between eligible and ineligible product. Facilities that meet this definition need to be pre- approved by the National Center for Import and Export (NCIE) which will review the facility's CFIA approved HACCP plan which will have to address segregation as a critical control point. The approval process will be done thru the processing of an import permit application for eligible product from such a facility.

Q. What types of facilities in Canada may be used to process US origin meat and meat products for their return to the United States?

A. These facilities must be dedicated facilities or have dedicated lines – that is, the facility either only processes US origin meat and meat products and/or Canadian meat and meat products eligible for export (ie beef derived from cattle under 30 months of age), or the facility has one or more processing lines dedicated to process US origin meat and meat products and/or Canadian meat eligible for export to the United States.

Q. How can a hunter import wild ruminant meat?

A. In order to import hunter-harvested wild ruminant products, the hunter must obtain a "Veterinary Services Special Permit for the Importation of Hunter-Harvested Wild Ruminant Meat." Importers in the United States can download and print this document directly from APHIS' homepage at: <http://www.aphis.usda.gov/lpa/issues/bse/bse.html>. Importers can also contact APHIS' National Center for Import and Export by telephone at (301) 734-3277 to obtain the Special Permit or to ask questions.

Q. Can I re-enter the United States at any land border crossing with hunter-harvested meat?

A. No. Only certain ports can be utilized. Visit www.usda.aphis.gov for a list.

Q. Can I re-enter the United States by air with hunter-harvested meat or ship my hunter-harvested wild ruminant meat by air?

A. Yes. Any international airport may be utilized to either return with or ship hunter-harvested wild ruminant meat.

Q. What documentation must the hunter present to officials at the port of entry upon their return to the United States from their hunting expedition in Canada?

A. The hunter must have a "Veterinary Services Special Permit for the Importation of Hunter-Harvested Wild Ruminant Meat." The hunter must also have a valid hunting license or a photocopy of one. These documents must be presented at the U.S. port

of entry and will be reviewed and approved by an inspector with the Department of Homeland Security, Customs and Border Protection.

Q. How do I import the other ruminant products listed above?

A. The importer in the United States must apply for and receive a “United States Veterinary Permit for Importation and Transportation of Controlled Material.” There are three ways to apply:

1. You can apply on-line at the following address:

http://www.aphis.usda.gov/vs/import_export.htm. Click on “IMPORT AUTHORIZATION SYSTEM” and follow the directions to apply;

2. You can download and print an application (VS Form 16-3) at the following address <<www.aphis.usda.gov/vs/ncie>>; or

3. You can contact APHIS’ National Center for Import and Export by telephone at (301)734-3277 to have the application faxed or mailed to you.

Q. Where can low-risk ruminant-derived products from Canada, with the appropriate paperwork, enter the United States?

A. Ruminant products deemed low-risk may enter at any one of 18 U.S. ports of entry: Houlton, Maine; Derby Line and Highgate Springs, Vermont; Champlain, Alexandria Bay, and Buffalo (Lewiston Bridge, Peace Bridge, Rainbow Bridge), New York; Port Huron, Detroit (Ambassador Bridge), and Sault St. Marie, Michigan; International Falls, Minnesota; Pembina and Portal, North Dakota; Sweetgrass and Roosville, Montana; and Blaine (Peace Arch, Pacific Highway, Cargo Ops), Lynden, Sumas (Cargo), and Oroville, Washington.

Q. What is the definition of a “commercial importation?”

A. A commercial importation is an importation of a product that will be sold and/or further distributed.

Q. What is the definition of an importation that is for “personal use?”

A. Importations that are for personal use include meat and trophies from legally hunted wild ruminants that are imported strictly for the use of the hunter.

Q. Are there any products that do not require a United States Veterinary Import Permit?

A. No. All products on the list require either a “Veterinary Services Special Permit for Hunter-Harvested Wild Ruminant Meat” or a “Veterinary Services Import Permit.”

Q. How will I know what the Canadian Government Certificate needs to say?

A. Contact APHIS’ National Center for Import and Export at (301) 734-3277 for more information.

Q. What will happen if an importer does not have the required documentation?

A. The product will be refused entry into the United States.

Q. Can meat and cattle that originate in the United States be processed in Canada and then returned to the United States?

A. Yes, if certain requirements are met.

Q. What are the requirements to process U.S. origin meat in Canada and then return it to the United States?

A. The requirements will be based on whether the Canadian facility in which the U.S. origin meat is processed is dedicated or non-dedicated. Contact APHIS' National Center for Import and Export at (301) 734-3277 for specific requirements.

Q. What types of facilities in Canada may be used to process U.S. origin meat and meat products for their return to the U.S.?

A. These facilities must be dedicated facilities – i.e., they only process U.S. origin meat and meat products or Canadian meat eligible for export to the United States. A dedicated line, rather than a completely dedicated facility, may be used if all products coming into the facility qualify for export to the United States.

Q. Can any live ruminants be imported from Canada into the United States at this time?

A. No. The rulemaking process has begun for the importation of live ruminants and ruminant products and a proposed rule was issued Oct. 31, 2003.

Q. Are other countries besides Canada with BSE cases going to be allowed to import to the United States too?

A. If a country believes that they have the same status as Canada, it then can apply to export to the United States. Since Canada has requested that we open the border to low risk materials, the United States has reassessed the systems in place in Canada for reducing risk from BSE. Certain actions, including but not limited to the following, led us to conclude that Canada presents a minimal risk of BSE: A history of stringent import control measures, a strong surveillance system, a feed ban that has been in place for several years and appropriate additional mitigation actions taken as necessary. If another BSE-restricted country requested recognition of a similar status from the United States, we would assess the preventive systems in place in that country and evaluate the slaughter and processing systems to determine their equivalence with the United States system.

Trade Issues

Q. Will the import of certain products from Canada impact U.S. export markets?

A. We have been in close communication with our export partners regarding these actions. After failing to implement appropriate BSE preventative measures--- measures that have been in place in Canada and the United States since 1989--- Japan has had eight reported cases of BSE. The Japanese consumer received mixed messages about BSE and consumer confidence fell. Japan's government responded by requesting an identification process from all beef suppliers----and this was being discussed prior to BSE in Canada.

We do not feel that the Japanese government is justified in its decision to exclude Canadian beef from our beef and beef products exported to Japan. Although the

United States does not believe such steps are necessary, we are working to provide the industry a system that can be used to verify U.S. beef exports.

Q. Why is a certification process needed if Canadian beef is safe?

A. We do not feel that it is needed. Japan is basing its identification requirement on commercial marketing factors and not on science-based principles. However, in order to maintain an important export market for U.S. beef, we are working to provide a requested measure that meets Japan's current marketing expectations. Other foreign suppliers to Japan had already agreed to the Japanese demands.

A process verification system for beef exports to Japan is voluntary. It is a proven marketing tool that is currently used by many different sectors of the U.S. beef industry at all levels of marketing, but it has nothing to do with food safety.

We will continue to work to convince Japan to remove this unnecessary requirement.

Safety

Q. How does the permitting process change the risk of BSE occurring in the United States?

A. Our experts have thoroughly reviewed the scientific evidence and determined that the risk to animal and public health is extremely low. We feel that the Canadian system of beef production and processing has been and continues to be based on a strong foundation of preventive measures to keep BSE from spreading. Canada has also taken numerous actions, including an effective feed ban in the 1990's, an aggressive surveillance program, and a heightened awareness at ante-mortem inspection for central nervous system disorders to minimize the risk of BSE.

In addition, the U. S. has had a strong system of preventive measures in place since 1997. We have had a feed ban in place since 1997 that, according to a Harvard Risk Assessment, has been our most effective means of BSE prevention. The United States has continued to expand the BSE surveillance program as well as strengthen efforts on feed ban compliance. We are currently evaluating all of our safeguards to ensure that they reflect the most recent science.

Other countries such as Japan that have found recurring cases of BSE did not have effective preventive programs in place until after a case of BSE was found.

Q. Should the United States take any additional preventive actions?

A Canada announced additional steps that are appropriate for a country that has had a case of BSE. The United States has already taken aggressive action to provide multiple firewalls against BSE, including prohibiting certain specified risk material in ground beef products and has an active surveillance program in place to ensure risk material is not present. Although we feel confident that safeguards currently in place provide ample safety, we will continue to reassess our safeguard measures using science based principles.

Q. Can you explain the justification for allowing such products as boneless beef in from Canada, as well as the proposal for certain live ruminants and ruminant products?

A. The USDA Transmissible Spongiform Encephalopathy (TSE) Working Group continues to reassess the information that they had been working on for some time prior to the Canadian case regarding the identification of products that present low risk for carrying the BSE-infectious agent. Based on peer-reviewed research, muscle meat does not appear to transmit infection. Additional information and details about the scientific justification behind the proposed rule can be found in the APHIS risk analysis, at <http://www.aphis.usda.gov/>.

We are taking a measured approach to allowing low risk materials from Canada into the United States. We believe that Canada, like the United States, has had an effective prevention system in place for many years in order to reduce the likelihood that the BSE-infective agent was present. We believe that the Canadian system of beef production and processing has been and continues to be based on a strong foundation of BSE prevention measures. The combination of an effective feed ban in the 1990's, an aggressive surveillance program, and a heightened awareness at ante-mortem inspection for CNS disorders has been effective in reducing the risk of BSE in Canada.

In addition, Canada has had a regulatory system for beef slaughter and processing that has been deemed equivalent to the U.S. system. Since the identification of the BSE case in Canada, the U. S. government has sent delegations of scientists to Canada to further improve the preventive and compliance measures employed by Canada to ensure that the on-going systems are sound and effective.

Q. Are you confident that the single Canadian cow is an isolated case?

A. Canada conducted an extensive investigation into the case of BSE including the trace back and trace forward of the suspected animals of origin. Canada depopulated over 2700 animals that could have been associated with the case animal and tested them for BSE. No other cases were found. In addition, Canada had an international expert panel review their investigation and found it to be scientifically valid.

Canada had strong mitigation steps in place, including a ruminant feed ban, to prevent the spread of BSE should a case been found--mitigation steps not present in other BSE countries such as Japan. As noted in the 2001 Harvard Risk Assessment, this type of ban is an important measure to prevent the spread of the animal disease. Canada has implemented additional measures as necessary in response to the finding of the case of BSE.

Q. Is bison meat acceptable for import?

A. Yes, bison meat is considered bovine meat. Boneless bison meat from animals less than 30 months of age will be allowed to enter with a permit.

Q. Is beef trim allowed to enter with a permit?

A. Yes, certain types of beef trim or lean trimmings will be allowed to enter with a

permit. Trim must be derived from boneless skeletal muscle with normal associated tissue. It cannot be ground meat, cannot be derived from a mechanical separation process (including advanced meat recovery), nor can it be derived from the vertebral column. In addition to these points, it must meet the same criteria as otherwise outlined for boneless meat imports (i.e., from animals less than 30 months of age at slaughter, etc.)

Q. Are veal carcasses allowed to enter with a permit?

A. Yes, veal carcasses will be allowed to enter with a permit. They must be from animals less than 36 weeks of age at slaughter and meet the criteria as otherwise specified.