Questions and Answers for Minimal-Risk (Canada) Rule

Q. What does the final rule on bovine spongiform encephalopathy (BSE) and minimal-risk regions change?

A. The rule amends regulations regarding the importation of ruminants and ruminant products and byproducts. It establishes a set of conditions whereby a country can be recognized as presenting minimal risk of introducing BSE into the United States. The new rule will continue to protect the United States from the introduction of BSE, while removing unnecessary prohibitions on the importation of certain commodities from minimal-risk regions.

Q. What is a minimal-risk region?

A. A minimal-risk region must meet the standards described in the rule and includes

- A region in which BSE-infected animals have been diagnosed but sufficient regulatory measures have been put in place that would make the introduction of BSE into the United States unlikely; or
- A region that has taken effective regulatory measures to prevent BSE, has never detected the disease, but cannot be considered BSE-free.

A minimal-risk region must have had in place, prior to the detection of BSE, risk-mitigation measures—such as import restrictions, a ruminant-to-ruminant feed ban, and surveillance—adequate to prevent widespread establishment of the disease. The region also should conduct epidemiologic investigations and risk assessments when cases are identified and impose additional risk-mitigation measures as necessary.

Q. Has any country met the conditions and been listed as a minimal-risk region?

A. Canada has provided information for an evaluation and has been determined to meet the conditions of a minimal-risk region. The U.S. Department of Agriculture (USDA) conducted a thorough, scientific assessment to evaluate the risk of resuming the importation of Canadian ruminants and ruminant products in view of the two BSE cases of Canadian origin. This risk assessment included careful consideration of the risk-mitigation measures Canada has in place, the risk-mitigation measures in the United States, and also the risk-mitigation measures imposed in this final rule. The assessment confirms that allowing the importation of certain Canadian ruminants and ruminant products under the conditions imposed by the rule will continue to protect against introduction of BSE into the United States.

Q. What types of mitigation measures does Canada have in place to qualify as a minimal-risk region?

A. The minimal-risk standards that Canada has met include

- Import restrictions sufficient to minimize exposure to BSE: Since 1990, Canada has maintained stringent import restrictions, preventing the entry of live ruminants and ruminant products, including rendered protein products, from countries that have found BSE in native cattle or that are considered to be at significant risk for BSE.
- Surveillance for BSE at levels that meet or exceed international guidelines: Canada has conducted active surveillance for BSE since 1992 and exceeded the level recommended in international guidelines for at least the past 7 years.
- Ruminant-to-ruminant feed ban in place and effectively enforced: Canada has had a ban on the feeding of ruminant proteins to ruminants since August 1997, with compliance monitored through routine inspections.
- Appropriate epidemiologic investigations, risk assessments, and risk-mitigation measures imposed as necessary: Canada has conducted extensive investigations in response to any BSE finding and has taken additional mitigation measures in response. These risk-mitigation measures include, among others, prohibiting specified risk materials in human food.

Q. Why is Canada in a different category from other countries where BSE has been discovered?

A. USDA has determined through a scientific risk assessment that the risk presented by opening the borders to certain Canadian ruminants and ruminant products is minimal. We have used international recommendations—as defined by the World Organisation for Animal Health (OIE)—as a reference in developing these regulations. The OIE recom-

mendation, based on current scientific understanding, recognizes that there are different levels of risk in countries or regions, and provides guidelines for trade according to these levels of risk. Canada has had a stringent set of risk-mitigation measures in place for several years prior to the diagnosis of a case of BSE. Thus, the first case doesn't represent the front edge of a rapidly increasing outbreak situation. It represents a limited exposure that occurred years ago that has not continued to circulate or amplify. This creates a very different risk scenario as compared to a country that diagnoses the first case of BSE and then begins to institute risk-management measures. In this latter scenario, the disease would have continued to amplify, and the first case may have indicated the beginning of a significant outbreak curve.

Other countries may seek minimal-risk status if they meet the necessary conditions. USDA will determine the eligibility of future countries in the same manner it used with Canada-risk analysis and appropriate rulemaking procedures.

Q. What types of products will be eligible for importation from Canada?

A. The commodities that will be allowed to be imported from Canada under specified conditions under this final rule can be summarized as

- Bovines for feeding or immediate slaughter, as long as they are slaughtered at less than 30 months;
- Sheep and goats (ovines and caprines) for feeding or immediate slaughter, as long as they are slaughtered at less than 12 months of age;
- Meat from bovines, ovines, caprines, and cervids (deer, elk, caribou, moose, and reindeer); and
- Certain other products and byproducts, including bovine livers and tongues, gelatin, and tallow.

USDA is also specifying that there are no import restrictions due to BSE for live cervids or camelids (i.e., llamas, alpacas, guanacos, and vicunas) from a BSE minimal-risk region.

Q. When will cattle start crossing the border from Canada?

A. The rule is effective immediately–July 15, 2005–due to the order from the Circuit Court, and the live animals and products addressed in the rule are eligible for importation as of that date. However, to ensure appropriate certification procedures and policies are in place, USDA does not expect any movement to occur until Monday, July 18, 2005.

Q. Under the new rule, can live ruminants from Canada enter the United States through any port?

A. The final rule requires that live ruminants from Canada enter the United States through specified ports-of-entry. These 20 entry points have the facilities available to ensure the requirements of the final rule are being met: Eastport, ID; Houlton, and Jackman, ME; Detroit, Port Huron, and Sault Ste. Marie, MI; Baudette, MN; Opheim, Raymond, and Sweetgrass, MT; Alexandria Bay, Buffalo, and Champlain, NY; Dunseith, Pembina, and Portal, ND; Derby Line and Highgate Springs, VT; Oroville and Sumas, WA.

Q. Can ruminant products come through the same entry ports as live ruminants?

A. No, all ruminant products entering the United States from Canada must, if arriving at a land border port, arrive at one of the following ports: Eastport, ID; Calais and Houlton, ME; Detroit (Ambassador Bridge), Port Huron, and Sault St. Marie, MI; International Falls, MN; Raymond, Roosville, and Sweetgrass, MT; Alexandria Bay, Buffalo (Lewiston Bridge and Peace Bridge), and Champlain, NY; Pembina and Portal, ND; Derby Line and Highgate Springs, VT; and Blaine (Pacific Highway and Cargo Ops), Lynden, Oroville, and Sumas (Cargo), WA.

Q. Will feeder cattle and feeder sheep and goats imported from minimal-risk regions require identification before they cross the border?

A. Yes. 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 must be branded with "C/\N" and feeder sheep and goats from Canada will be branded with "C."

In addition, all feeder cattle and feeder sheep and goats imported from minimal-risk regions must be individually identified by an official eartag of the country of origin. The eartag must be applied before the animal's arrival at the port-of-entry into the United States, meet U.S. eartag standards, and be traceable to the animal's premises of origin. No person may alter, deface, remove, or otherwise tamper with the individual identification while the animal is in the United States or moving through the United States.

Q. Will Canadian products be labeled with their country of origin?

A. All Canadian ruminant products and byproducts will need to have the proper import documentation when they cross the border into the United States. However, these products won't be labeled with their country of origin when they reach the consumer.

It is important to remember that imported meat products are subject to the same stringent food safety standards as domestic products. Foreign countries must undergo a stringent review process before they become eligible to export meat, poultry, or egg products to the United States.

The 2002 Farm Bill provided for country-of-origin labeling for beef, lamb, pork, fish, perishable agricultural commodities, and peanuts. However, Public Law 108–199 (the FY 2004 Consolidated Appropriations Act) delayed the implementation of mandatory country of origin labeling (COOL) for all covered commodities, except wild and farm-raised fish and shellfish, until September 30, 2006. When mandatory COOL goes into effect for beef, it will apply to all appropriate Canadian ruminant products and byproducts.

Q. What safeguarding measures does the rule require for the importation of live Canadian cattle for immediate slaughter?
A. Canadian cattle imported for immediate slaughter must be less than 30 months of age when imported. They must be accompanied by a health certificate, attesting to their age and relating to animal identification, origin, destination, and responsible parties.

Cattle for immediate slaughter must move directly as a group from the port of entry to a recognized slaughtering establishment in sealed containers. They must be slaughtered as a group, and all appropriate specified risk materials as defined by USDA's Food Safety and Inspection Service (FSIS) must be removed.

Q. What happens if a bovine animal over 30 months of age enters the United States from Canada?
A. USDA thinks such a scenario is very unlikely due to the fact that each animal presented at slaughter comes in under sealed containers and with a veterinary health certificate attesting to the age and health condition of the animal. If the animal is determined to be over 30 months of age, it will be properly disposed of and will not enter the human or animal food chains.

As noted in the March 2004 notice reopening the comment period on the proposed minimal-risk region rule, APHIS is currently evaluating the appropriate approach regarding live cattle 30 months of age and older and intends to address that issue in a separate rulemaking proceeding in the *Federal Register.*

Q. Will Canadian cattle be tested for BSE in the United States?
A. BSE testing in the United States is conducted for animal health surveillance purposes. The current enhanced surveillance program focuses on obtaining samples from the targeted population of cattle where the disease is most likely to be found—in adult animals that have some type of clinical abnormality that could be consistent with BSE. Because of the nature of the disease and limitations of current BSE testing technology, testing clinically normal animals does not provide any significantly meaningful information for surveillance purposes. In addition, the BSE test cannot be considered a food safety test.

If any Canadian cattle fit our targeted population as described, they will be subject to sampling under the enhanced BSE surveillance program. This would include any cattle condemned by FSIS at antemortem examination.

Q. If Canada discovers additional cases of BSE, will the border be closed again?
A. Should another case of BSE be discovered, any actions taken by USDA will depend on the facts and circumstances of the situation, an analysis of these facts and circumstances, and Canada's subsequent response to the detection.

Q. How will the amended regulations affect transshipment of domestic ruminants and ruminant products through Canada to Alaska?
A. This regulation will not affect the transshipment of domestic ruminants and ruminant products through Canada to Alaska. Earlier this year, the Canadian Food Inspection Agency (CFIA) began allowing the temporary entry of live cattle under conditions that included the USDA's assurance that the animals would return to the United States. Accordingly, all BSE-based restrictions that prohibited the transshipment of ruminant livestock from the lower 48 States to Alaska via Canada were lifted. However, CFIA's regulations pertaining to the humane transport of livestock continue to preclude the transshipment of livestock by land via Canada.

Q. What process did USDA use to amend these regulations?
A. USDA amended the regulations through the Federal rulemaking process. USDA first proposed changes to its regulations regarding establishing minimal-risk regions and conditions for safely importing certain live ruminants and ruminant products from such regions on November 4, 2003, and the comment period was still under way when the United States announced its first case of BSE on December 23, 2003, in a cow imported from Canada. To allow additional time for commenters to evaluate the proposal in the context of the first U.S. finding of the disease, USDA reopened the comment period and accepted comments until April 7, 2004.

Q. Is USDA confident that the final rule will continue to safeguard U.S. public and animal health?
A. USDA conducted a thorough, scientific assessment of the risk of certain types of Canadian ruminants and ruminant products introducing BSE into

the United States. This risk assessment included consideration of the risk-mitigation measures Canada has in place, the risk-mitigation measures in the United States, and also the risk-mitigation measures imposed in this final rule. USDA determined that allowing the importation of Canadian ruminants and ruminant products under the conditions imposed by the rule will continue to protect against the introduction of BSE into the United States and protect human and animal health.

Q. Is USDA working with any other agencies to implement these regulations? How will USDA implement this rule?

A. USDA's Animal and Plant Health Inspection Service (APHIS) is finalizing preparations to implement the rule and will have these in place by Monday, July 18, 2005.

APHIS and FSIS have worked closely together throughout the rulemaking process and have agreed on certification language for ruminant products and prepared importer information. These will be posted to the APHIS Web site on July 15, 2005. Stakeholders can find out more about importing animal products by going to <http://www.aphis.usda.gov/lpa/issues/bse/trade/Dear_Product_importer.pdf>.

USDA has also coordinated these regulations with the U.S. Department of Health and Human Services' (HHS) Food and Drug Administration. In addition, APHIS will be working closely with the U.S. Department of Homeland Security's Customs and Border Protection to ensure that the regulations and policies are clear to those performing inspections at the border.

Q. Will other countries be categorized as minimal-risk regions in the future?

A. Other countries that meet the conditions necessary to be recognized as a minimal-risk region will be considered in the future. The designation of any future countries as minimal risk will be accomplished in the same manner as Canada—through risk analysis and appropriate rulemaking.

Q. What is the risk of allowing cattle to enter from Canada?

A. The risk of BSE being introduced and spread through cattle imported under the provisions of this rule is absolutely minimal. The risk analysis conducted demonstrates that Canada has taken appropriate risk mitigation measures and that the possible prevalence of BSE circulating in Canada is extremely low. The risk of introduction is further lessened by the specific import restrictions imposed on animals and animal products imported under this rule. In addition to these measures, there are measures in place in the United States, such as the ruminant-to-ruminant feed ban, that prevent the disease from spreading into the U.S. domestic cattle population in the highly unlikely even that it is introduced.

The risk is further mitigated by five interlocking, overlapping, and sequential risk barriers applied at critical control points. For an infected Canadian animal to transmit infection to a U.S. cow, five barriers must be crossed: (1) U.S. import restrictions; (2) slaughter controls; (3) rendering inactivation; (4) feed manufacturing controls; and (5) dose limitations. Since the risk of infectivity circulating in Canada is already minimal, each of these barriers will further reduce that risk, leading to a very small residual risk.

Q. Where can the public view a copy of the final rule?

A. The final rule is available online at <http://www.aphis.usda.gov/lpa/issues/bse/bse.html>.

Q. Where can the public view a copy of the risk assessment?

A. The risk assessment is available online at <http://www.aphis.usda.gov/lpa/issues/bse/bse.html>.

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