



Explanatory Note

Risk Analysis: BSE Risk from Importation of Designated Ruminants and Ruminant Products from Canada into the United States

Animal and Plant Health Inspection Service

Veterinary Services

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Introduction and Objective

On November 4, 2003, the U.S. Department of Agriculture's (USDA) Animal and Plant Health Inspection Service (APHIS) published a risk analysis and proposed rule (Federal Register, Vol. 68, No. 213, pp. 62386-62405) which defined a new category of minimal risk regions for bovine spongiform encephalopathy (BSE), proposed to classify Canada as such a region and defined risk mitigations that it would apply to imports of ruminants and ruminant products from Canada. APHIS determined that this action was 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. At the time, BSE had never been detected in the United States, and only a single indigenous case had been reported in Canada.

On December 23, 2003, USDA announced a presumptive positive case of BSE in a Holstein cow that was slaughtered in the State of Washington. The epidemiological investigation revealed that the animal was born in Canada and most likely exposed to the BSE agent in that country. This imported case was detected after USDA published its risk analysis and proposed rule. The question has been raised as to whether the results of the risk analysis were altered by the finding of this infected animal.

This document explains why the detection of the BSE-infected cow in the United States does not affect the conclusions of the risk analysis. Although each component of the risk analysis will be addressed (release, exposure, consequence, and risk estimation), the detailed discussion presented in the original analysis will not be repeated. Rather, this note will explain the relevance of the new information to each component. It will also summarize control mechanisms in place at the time of the incident and new initiatives taken subsequently.

Background

The infected cow entered the United States on September 4, 2001, as part of a shipment of 81 animals from the source herd in Canada. The USDA has conducted an intensive epidemiological investigation, details of which are provided in the enclosure. The results indicated that the animal was born, and most likely became infected, in Alberta, Canada. Risk animals in the United States were traced and culled according to international standards; no additional cases were identified.

The epidemiological investigation revealed several points that are relevant to this explanatory note:

The cow was approximately 6 years and 8 months old at the time the disease was diagnosed. Its age indicated that it was born prior to the implementation of the feed ban in Canada. Therefore, it was most likely to have become infected prior to the implementation of the feed ban in that country.

The animal was imported in 2001 at approximately 4 1/2 years of age.

Release assessment

The risk analysis that was published in October 2003 evaluated the risk of importing BSEinfected animals and animal products from Canada under the restrictions described in the risk analysis and proposed in the rule. Included among these were restrictions that prohibited importation of animals older than 30 months of age and animals that had been fed ruminant protein.

The risk analysis addressed the likelihood that animals might have been infected prior to the implementation of the feed ban in Canada. It noted that the feed ban took effect in August 1997 and that compliance with the feed ban appeared to be good. In addition, the document cited evidence to indicate that the animals most likely to have infectious levels of the agent were 30 months of age or older.

Both of the BSE cases of Canadian origin occurred in cattle born before the feed ban was implemented. They were both older than 30 months of age when they were diagnosed as infected. Infection presumably occurred prior to or around the time the Canadian feed ban was enacted. The finding of an imported case in a cow greater than 30 months of age has little relevance to an analysis of risk under the proposed mitigation measures, beyond the implications for BSE prevalence in Canada. The proposed rule was not in effect in 2001 when the imported case, which was more than 4 years old at the time, entered the United States. Under the proposed conditions, the animal would not have been allowed entry into the United States. Therefore, we continue to consider the import controls in the proposed rule to be effective and the results of the analysis unchanged.

With regard to BSE prevalence in Canada, APHIS presented evidence in the original risk analysis that the prevalence was very low and that Canada had strong BSE controls in place. Although an additional animal of Canadian origin has been diagnosed with BSE since APHIS published its risk analysis and proposed rule, the total number of diagnosed cases attributed to that country remains low. Furthermore, Canada has implemented strong measures to prevent the establishment, propagation and spread of BSE among cattle; to detect infected animals through its surveillance program; and to protect the animal and human food supplies.

Consequently, it remains unlikely that BSE would be introduced from Canada under the conditions described in the proposed rule. Based on factors discussed in the original risk analysis and the existing and proposed risk mitigation measures, APHIS concludes that an additional BSE case of Canadian origin does not significantly alter the original risk estimate.

Exposure assessment

Actions being taken in the United States

Despite the fact that detection of the infected animal did not influence the original risk conclusions, it did raise consciousness of BSE challenges that might exist for the United States. As a result, the United States is redirecting resources toward planning, implementation, and enforcement of national policy measures to enhance BSE surveillance and protect human and animal health. Towards this end, an international panel of scientific experts appointed by the Secretary of Agriculture has provided a review of U.S. BSE response actions and made recommendations for enhancements of our national program. A copy of the report is available at http://www.aphis.usda.gov/lpa/issues/bse/bse.html.

The expert panel was complimentary of the scope, thoroughness and appropriateness of the epidemiological investigation and concluded that the investigation conformed to international standards. Key policy recommendations included (1) incorporation of multiple redundancies in production systems to prevent inclusion of specified risk materials (SRMs) in human food and animal feed, and to avoid cross-contamination; (2) additional measures to ensure continued access to nonambulatory cattle for surveillance purposes and to prevent them from entering into the food and feed chains; (3) enhanced targeted and passive BSE surveillance systems; (4) improved traceability through a comprehensive national animal identification system; and (5) reinforced educational efforts.

APHIS is evaluating these recommendations, many of which build on actions already taken in the United States, and considering policy options. However, APHIS believes that the recent detection and investigation of the single imported BSE case demonstrates the effective nature of the surveillance and response measures currently in place. Relevant to this, the expert panel did not expressly consider the measures implemented since 1985 to reduce the threat of BSE exposure or amplification within the United States. The U.S. Government has already taken significant actions that directly address many of the expert panel recommendations. Those actions are summarized in the following discussion.

The previous risk analysis identified the feed ban as the most effective risk mitigation measure for BSE. The United States implemented a feed ban prohibiting the use of most mammalian protein in feeds for ruminant animals which became effective on August 4, 1997. The rule establishing the feed ban was implemented by the U.S. Department of Health and Human Services' (HHS) Food and Drug Administration (FDA) and appears in Title 21, *Code of Federal Regulations*, Part 589.2000. Current estimates of compliance with the ban exceed 99 percent.

More recently, both USDA and FDA have initiated food and feed safety measures in response to the detection of the imported BSE case. General information and links to relevant documents are available at <u>http://www.fsis.usda.gov/oa/news/2004/bseregs.htm</u>.

For example, the feed ban, although comprehensive, currently allows nonruminant protein in ruminant feeds. FDA has announced the future publication of an interim final rule

designed to further minimize the risk that cattle will be purposefully or inadvertently fed prohibited protein. Details of this announcement are available on the HHS' Web site at. <u>http://www.hhs.gov/news/press/2004pres/20040126.html</u>.

The anticipated regulations will eliminate the exemption in the 1997 feed rule that allows mammalian blood and blood products to be fed to other ruminants. It will also ban the use of "poultry litter" and "plate waste" as feed ingredients for ruminants. The interim final rule will also minimize the possibility of cross-contamination of ruminant and nonruminant feed by requiring equipment, facilities, or production lines to be dedicated to nonruminant animal feeds if they use protein that is prohibited in ruminant feed.

To ensure continuing compliance with the new measures, in 2004, FDA has announced its intention to expand the scope of its inspections of feed mills and renderers. FDA will itself conduct 2,800 inspections and will continue to work with State agencies to fund 3,100 contract inspections of feed mills, renderers, and other firms that handle animal feed and feed ingredients. Through partnership with State agencies, FDA will also receive data on 700 additional inspections, which will account for 100 percent of all known renderers and feed mills that process products containing materials prohibited in ruminant feed.

In addition, FDA has begun a feed sampling program and is continuing to support the development and evaluation of diagnostic tests to identify prohibited materials. These tests would offer a quick and reliable method of testing animal feed for prohibited materials.

USDA has responded to the imported BSE case with significant risk mitigation measures as well. Perhaps most importantly, SRMs, the tissues that are most likely to contain the infectious agent, are banned from the human food supply. On January 12, 2004, USDA's Food Safety and Inspection Service (FSIS) published an interim final rule in the *Federal Register* (the official publication of U.S. Government regulations) that established as SRM the skull, brain, trigeminal ganglia, eyes, vertebral column, spinal cord, and dorsal root ganglia of cattle over 30 months of age, as well as the tonsils and small intestine of cattle of all ages. This regulation was effective immediately upon publication and prohibits the use of these materials in the human food supply.

Since identification of animal age is important to enforcement of this rule, FSIS has also developed procedures for verifying the age of cattle that are slaughtered in official establishments by examination of dentition. These measures are consistent with the actions taken by Canada after the discovery of BSE in that country in May 2003.

Disposal of SRMs has been identified as an issue that should be addressed. Through the interim final rule described above, FSIS further requires federally inspected establishments that slaughter cattle to develop, implement, and maintain procedures to remove, segregate, and dispose of these SRMs so that they cannot enter the food chain. Slaughter plants must also make that information readily available for review by FSIS inspection personnel. Plants inspected by State officials must have procedures in place that are equivalent to the new Federal requirements.

Since mechanically separated meat may be contaminated with SRMs during the separation process, the interim final rule on SRMs also prohibits the use of mechanically separated meat in human food.

FSIS has also taken actions that will effectively prohibit use of advanced meat recovery (AMR) in meat production from cattle that are 30 months of age or older.¹ In this regard, FSIS previously had regulations in place that prohibit spinal cord from being included in boneless meat. However, a new regulation, effective upon publication in the *Federal Register* on January 12, 2004, expands that prohibition to include dorsal root ganglia (clusters of nerve tissue connected to the spinal cord along the vertebral column), which could potentially be incorporated into boneless meat products through AMR. In addition, because the vertebral column and skull in cattle 30 months of age and older will be considered inedible, they cannot be used for AMR.

Air injected stunning, a process for humanely stunning cattle for slaughter, has been identified as a process that may result in contamination of carcasses with brain tissue. To ensure that portions of the brain are not dislocated into the tissue of the carcass as a result of the process, FSIS banned the practice of air-injection stunning with the publication of an interim final rule in the *Federal Register* published on January 12, 2004. Of note is the fact that industry had already voluntarily implemented a ban on air-injection stunning.

Screening for SRMs and verification of their absence in products has been identified as an issue that should be addressed. Therefore, in March 2003, FSIS began a routine regulatory sampling program for beef produced from AMR systems to ensure that spinal cord tissue is not present in the product. In the new interim rule, establishments must ensure process control through verification testing to ensure that neither spinal cord nor dorsal root ganglia is present in the product.

Before detection of the imported BSE-infected animal, certain downer cows were permitted to enter the human food supply. However, that will no longer be allowed. Effective on December 30, 2003, the USDA excluded all nonambulatory cattle from the human food chain. The specific details of this prohibition are established in the interim rule on SRM published in the *Federal Register* on January 12, 2004. All non-ambulatory animals, regardless of the reason for their nonambulatory status or the time at which they became nonambulatory, will be condemned at slaughter and prevented from entering the human food supply. In addition, FDA has extended that action and announced the future publication of an interim final rule that bans any material from nonambulatory (downer) or dead cattle, as well as SRM and mechanically separated beef, from FDA-regulated human food, including dietary supplements and cosmetics. To further control the incorporation of material from nonambulatory cattle in human food, an interpretive rule published in the *Federal Register* on January 12, 2004, mandated that FSIS inspectors not mark cattle tested

¹ AMR is an industrial technology that removes muscle tissues from the bone of beef carcasses under high pressure without incorporating bone material when operated properly. AMR enables processors to remove small amounts of meat from carcasses without breaking bones, but concerns have been raised regarding potential contamination of the meat with central nervous system tissue.

for BSE as "inspected and passed" until confirmation is received that the animals have, in fact, tested negative for BSE.

Surveillance activities are being enhanced beyond the active targeted surveillance program for BSE that has been in place in the United States since May 1990. Since inception of the program, the United States has targeted at-risk populations and has steadily increased the number of cattle tested. This approach is fully consistent with standards set out by the Office International des Epizooties (OIE).

USDA intends to maintain the focus of its surveillance efforts on nonambulatory cattle as it has in the past since this is a high risk target population. Concerns have been raised that access to nonambulatory animals as a target population for surveillance may be less than optimal if the animals are not sent to slaughter. Therefore, USDA is considering options to ensure continued access to nonambulatory animals. Relevant to this, even prior to the announcement on December 30, 2003, that a BSE-infected cow had been detected in the United States, not all nonambulatory cattle went to FSIS-inspected slaughter facilities. APHIS had already established efforts to sample this population at other salvage or rendering facilities and will continue to work closely with components of the animal disposal industry to ensure continued surveillance of these animals, as well as appropriate disposal. USDA will also increase efforts to obtain more samples from this high-risk group on the farm.

USDA is working to enhance its BSE testing capacity. Currently, all of the testing conducted as part of the U.S. surveillance program for BSE is currently performed by APHIS at the National Veterinary Services Laboratories (NVSL) in Ames, Iowa. NVSL personnel are evaluating more rapid assays, and APHIS is accepting data submissions to support licensing these tests. One of the ELISA tests (BioRad) has recently been put in use at NVSL.

To enhance its ability to trace animals, the USDA has assigned top priority to implementation of a verifiable system of national animal identification. Development of this system in cattle has been underway for over a year and a half. Under the auspices of APHIS, a partnership of industry, State, and Federal officials was formed in 2002 to uniformly coordinate the national animal identification plan. A draft plan was presented at the annual U.S. Animal Health Association meeting in October 2003. This draft plan would provide for implementation in three phases: (1) premises identification, (2) individual or group/lot identification for interstate and intrastate commerce, and (3) retrofitting remaining processing plants, markets, and other industry segments with appropriate technology to enhance tracking of animals throughout the marketing and slaughter chain. Further details of the draft plan are available on the U.S. Animal Identification Plan Web site at <u>http://www.usaip.info/</u>.

USDA continues to expand its educational activities. It has developed and distributed extensive educational and training materials in the past, and new materials are being developed to reflect the recent regulatory changes. USDA has collaborated extensively with academic, professional, trade and consumer organizations in this effort.

In addition, since BSE became a reportable disease in the United States in 1986, USDA has conducted an active and effective Awareness Program on BSE for veterinarians, farmers, and other personnel involved in the transportation, marketing, and slaughter of cattle for more than a decade. Specifically, in May 1990, USDA began educational outreach to veterinarians, cattle producers, and laboratory diagnosticians regarding the clinical signs and diagnosis of BSE. These activities have been broadened both in terms or scope and targeted audiences in recent years, and USDA continues to educate U.S. cattle producers, veterinarians, industry groups, and the general public on BSE through frequent briefings and press conferences. In addition to press releases and fact sheets, a videotape on BSE and an information packet have been distributed to all APHIS field offices, State veterinarians, extension veterinarians, colleges of veterinary medicine, and industry groups. USDA also maintains an extensive BSE Web site at http://www.aphis.usda.gov/.

The actions taken before December 30, 2003, and the actions taken since diagnosis of BSE in Washington State demonstrate that, although rigorous measures were already in place to safeguard human and animal health in the United States, the United States is continually working to improve its national program. APHIS concludes that the additional measures in place since the original risk analysis further limit the potential for exposure of animals or humans in the United States to BSE.

Actions being taken in Canada

CFIA reported that the latest finding of a BSE-infected cow with BSE did not change its assessment of the situation in North America with respect to the safety of the food supply. The finding of a small number of additional cases has never been excluded and is consistent with the report of the International Panel of BSE experts who reviewed and commended Canada's program.

However, in response to the detection of the infected animal of Canadian origin in Washington State, CFIA initiated an epidemiological investigation. This investigation was concurrent and cooperative with the United States investigation of animals from the same herd of origin. CFIA initially identified 12 animals of interest from the herd and is considering additional tracing efforts. In addition, CFIA continues an extensive epidemiological investigation into the feed sources of the herd of origin.

As part of its on-going policy considerations, CFIA made enhancements to the measures that it had strengthened in response to the diagnosis of the BSE-infected animal in Canada. Relevant to this, CFIA plans to test a minimum of 8,000 animals over the next 12 months, and will continue to increase that number progressively. The ultimate number of animals tested will reflect international standards existing at the time. These are expected to be revised over the next one to two years.

Testing will focus on those animals most at risk for BSE. These include animals demonstrating clinical signs consistent with BSE, so-called downer animals (those unable to stand or move without assistance), as well as animals that have died on the farm, are

diseased, or must be destroyed because of serious illness. A sample of healthy older animals will also be tested. Provincial government officials will play a significant role in the surveillance activities.

As in the United States, an international team of animal and human health experts reviewed the situation in Canada. A summary report is posted on the CFIA Web site at <u>http://www.inspection.gc.ca/english/anima/heasan/disemala/bseesb/evalsume.shtml</u>.

Enhancements recommended by the international team of experts are being introduced to strengthen Canada's cattle identification program. The identification program provided invaluable information about the BSE-infected cow's background during the investigation last May. Enforcement of the program will be increased, as will research into new technologies to detect disease. CFIA will also foster linkages and integration with provinces, territories, industry and trading partners, to expand its resources.

Health Canada (the agency responsible for human health in Canada) is also enhancing its capacity to identify and trace the presence of bovine-derived material in the products it regulates.

The Canadian Government has worked in close consultation with provincial, territorial, industry and U.S. representatives during the development of these measures. This collaboration will continue in order to ensure that enhancements are effectively and efficiently implemented.

Furthermore, CFIA has taken actions in response to United States policy changes. After the United States prohibited the slaughter of non-ambulatory animals for human consumption, it imposed a similar requirement on countries that export meat to the United States. In response to this requirement, on January 13, 2004, CFIA announced that all downers are banned from slaughter in Canadian registered establishments eligible for export to the United States.

For additional information, see the news release dated January 9, 2004, located at the CFIA Web site: <u>http://www.inspection.gc.ca/</u>

Exposure assessment conclusions

In the original analysis of Canada, APHIS' Veterinary Services (VS) considered the sum total of the control mechanisms (e.g., effectiveness of surveillance, import controls, and feed ban) in place at the time of the diagnosis and the actions taken after it (e.g., epidemiological investigations, depopulation) to be adequate, as long as the mitigations described in the analysis and the proposed rule were applied. APHIS' analysis indicated that the mitigations should be effective in addressing the risk of importing BSE from Canada. However, not only have we made the enhancements described above to our own system, but also we are in regular contact with Canadian officials about BSE policy development in Canada. U.S. policy changes, such as removal of SRMs from human food and increased surveillance, are in accord with similar approaches being taken in Canada.

We are holding ongoing discussions in anticipation of developing a North American strategy.

However, even without the institution of the additional measures, the animal would not have been imported into the United States under the conditions of the proposed rule. Therefore, the conclusions of the original exposure assessment remain unchanged. In summary, the fact that only two indigenous cases of BSE have been identified as Canadian in origin, the existence of strong BSE controls in Canada, and the importation restrictions VS would impose before allowing these imports make it unlikely that BSE would be introduced from Canada under the conditions described in the proposed rule. With regard to assessing exposure, the Harvard study suggested that the measures taken by the U.S. Government and industry give the United States an effective program to preclude the spread of BSE to animals should it be introduced into this country. These measures, which have been enhanced significantly since the original analysis, will further ensure that these risks remain low.

Consequence assessment

As a practical matter, the diagnosis of BSE in the cow had significant consequences in the United States in terms of human and financial resources and lost trade in ruminants and ruminant products. However, the infected animal would not have been imported under the conditions assessed in the analysis and defined in the proposed rule. Therefore, VS maintains that the consequences with regard to animal health, human health, and the environment continue to be minimal or low under the conditions described in the risk analysis and proposed rule.

Risk Estimate

In summary, we reiterate the conclusion reached in the original risk estimate. Under the conditions described in the analysis and proposed rule, VS considered the risk of BSE infected animals or animal products entering the United States from Canada under the conditions described in the analysis and proposed rule and exposing US livestock through feeding of infected materials to susceptible animals to be low.

Comment

As noted above, the USDA has responded to the detection of the case of BSE in an imported BSE-infected cow with significant BSE risk mitigation measures in this country. Perhaps most importantly, parts of slaughtered animals that are considered at particular risk of containing the BSE agent in an infected animal (SRMs) have been banned from the human food supply. Specifically, FSIS has established the skull, brain, trigeminal ganglia, eyes, vertebral column, spinal cord, and dorsal root ganglia of cattle over 30 months of age, as well as the tonsils and small intestine of cattle of all ages, as SRMs. Furthermore, FSIS prohibits such SRMs from the human food supply. The Canadian Government established similar safeguards in Canada.

The measures taken by FSIS do not restrict the slaughter of cattle in the United States based on the age of the animals. In this regard, meat from cattle 30 months of age or older will continue to be allowed into the human food supply. However, measures are in place to ensure that SRMs from such cattle do not enter the food supply. We now believe it would not be necessary to require that beef imported from BSE minimal-risk regions be derived only from cattle less than 30 months of age, provided equivalent measures are in place to ensure that SRMs are removed when the animals are slaughtered and that such other measures as necessary are in place. We believe such measures are already being taken in Canada.

Enclosure

A Case of Bovine Spongiform Encephalopathy (BSE) in the United States As of February 4, 2004

Executive Summary

On December 23, 2003, the U.S. Department of Agriculture (USDA) announced a presumptive positive case of BSE in a Holstein cow slaughtered in the State of Washington. The infected cow entered the United States on September 4, 2001, as part of a shipment of 81 animals from the source herd in Canada. Of these 81 animals, 25 were considered to be higher risk as defined by the Office International des Epizooties (OIE): animals born on a known source premises within 12 months of an affected animal, either before or after.

Counting the index animal, USDA has definitively accounted for 14 of the 25 animals considered to be higher risk. In total, USDA has accounted for 29 of the 81 cattle in the initial shipment, plus 7 additional animals also dispersed from the birth herd. The number of animals found is consistent with the number expected after analysis of regional culling rates. The epidemiological investigation is currently yielding little additional information. USDA is therefore concluding active investigation and culling activities at this time.

A total of 255 cattle have been depopulated from 10 premises on which one or more source herd animals were found. This number includes the 35 animals definitively identified as originating from the source herd (aside from the index cow), as well as any other cattle on those 10 premises that could possibly be from the Canadian source herd. Out of an abundance of caution, all 255 animals were depopulated and tested for BSE; all of the animals tested negative. Because there is a small probability that BSE can be transmitted maternally, the two live offspring of the infected cow were also euthanized. A third had died at birth in October 2001. All carcasses were properly disposed of in accordance with Federal, State, and local regulations.

Emergence of a Single Case of BSE

The index cow had difficulty giving birth to a bull calf on November 29, 2003, and was subsequently sent to slaughter. On December 9, 2003, the animal was observed to be nonambulatory (a "downer" animal). Accordingly, as part of USDA's targeted BSE surveillance program, brain samples were taken from the animal and sent to USDA's National Veterinary Services Laboratories (NVSL) in Ames, Iowa, for testing. After NVSL's presumptive positive finding, samples were hand-carried to the OIE reference laboratory in Weybridge, England, for final confirmatory testing according to international animal health requirements. On the morning of December 25, 2003, the OIE reference laboratory confirmed USDA's diagnosis of BSE.

Even before the confirmation from Weybridge, the presumptive positive result at NVSL triggered an epidemiological investigation by Federal and State officials. Immediately, USDA's Animal and Plant Health Inspection Service (APHIS) activated its Emergency

Operations Center (EOC) in Riverdale, Maryland; and representatives from APHIS' Transmissible Spongiform Encephalopathy Working Group as well as emergency response leaders were mobilized to begin an aggressive investigation.

The positive cow was traced from the slaughter plant back to a 4,000 cow dairy herd near Mabton, Washington. This herd (the index premises) was placed under quarantine on December 23, 2003, to prevent further complications to traceback and traceforward investigations. In Washington State, USDA and State officials mobilized an Area Command office in Olympia and an Incident Command Post in Yakima. Both offices worked in close contact with the APHIS National Coordinating Group at the EOC.

Investigative Details Regarding the BSE-Positive Cow

The cow, known to be approximately 6 years and 8 months old at slaughter, was purchased into the Mabton herd in October 2001. The cow was culled from the herd due to paralysis resulting from calving complications. She had given birth to two live offspring in the United States. A bull calf born November 29, 2003, was sold to a calf-raising facility in Sunnyside, Washington, and the other calf, a yearling heifer, was known to be present in the Mabton herd.

Tracing Back the BSE-Positive Cow

On January 6, 2003, Dr. Ron DeHaven, USDA's Chief Veterinary Officer, and Dr. Brian Evans, Canada's Chief Veterinary Officer, held a joint press conference to announce that DNA evidence indicated—with a high degree of certainty—that the BSE-positive cow found in Washington State originated from a dairy farm in Calmar, Alberta, Canada. The DNA evidence is based on comparative testing of DNA from the brain of the positive cow with DNA from semen of her sire and with blood from the heifer calf born from the BSE-positive cow on the index farm. The test results were independently confirmed by both U.S. and Canadian animal health laboratories. Breeding records for the heifer calf confirmed that the animal was born from the cow bearing the tag number found on the BSE-positive cow at slaughter and found in the records on the farm in Alberta. This DNA information, coupled with information obtained from the owner of the index farm in Mabton, Canadian officials, and import records, adds certainty to the accuracy of the traceback to Alberta.

Other elements of this investigation continued in both the United States and Canada and provided additional information. U.S and Canadian officials are actively communicating as they continue a feed investigation. While it is clear that the BSE-positive cow originated in Canada, U.S. and Canadian officials are cooperating fully to address the issue.

Details Regarding Cohorts

On December 31, 2003, USDA determined that a Canadian health certificate, signed on August 30, 2001, listed 82 eartag numbers from cattle that were part of the source herd dispersal in Calmar, Alberta, Canada. One of those eartag numbers matched the number on the BSE-positive cow. It has been confirmed that 81 of those 82 animals crossed the border

into the United States on September 4, 2001, through the port of Oroville, Washington. Of these 81 animals, 25 were considered to be higher risk as defined by the OIE: animals born on a known source premises within 12 months of an affected animal, either before or after.

Through February 4, 2004, task force members performed 185 herd investigations, including 52 complete herd inventories totaling over 75,000 cattle, in an effort to find any cattle that may have entered the United States from the source herd in Alberta. Counting the index animal, USDA has now definitively accounted for 14 of the 25 animals considered to be higher risk. In total, USDA has accounted for 29 of the 81 cattle that entered on September 4, 2001: 1 was the index cow from Mabton; 9 were on the index premises near Mabton; 3 were located on a nearby premises in Mattawa, Washington; 1 was on a premises in Quincy, Washington; 3 were on a dairy in Tenino, Washington; 6 were on a dairy in Othello, Washington; 3 were on a dairy in Burley, Idaho; and 1 was on a second dairy (not the index premises) in Mabton, Washington.

In addition to those 81 cattle, another 17 heifers were sold at the source herd dispersal in Calmar, Alberta. Although the total number of those 17 that entered the United States is not known, 7 have now been located: 3 were on a dairy in Quincy, Washington; 1 was on a dairy in Boardman, Oregon; 1 was on a dairy in Othello, Washington; 1 was on a dairy in Burley, Idaho; and 1 was on a second dairy (not the index premises) in Mabton, Washington. The animal on the second Mabton premises was actually an earlier offspring of the index cow born in December 2000 in Alberta. A chart diagramming the source herd animal movements can be found at the end of this document.

A total of 255 cattle have been depopulated from 10 premises where 1 or more source herd animals were found. This total includes the 35 animals definitively identified as originating from the source herd (aside from the index cow), as well as any other cattle on those 10 premises that could possibly be from the Canadian source herd. None of the 255 cattle tested positive for BSE. The carcasses of the euthanized animals were held until the test results were returned; after receiving the negative results, the carcasses were disposed of in a landfill in accordance with all Federal, State, and local regulations.

Actions Taken on the U.S. Offspring of the BSE-Positive Cow

After it was determined that the bull calf delivered by the positive cow in late November 2003 was sold to a calf-raising facility in Sunnyside, Washington, State officials immediately quarantined that premises. Identification of animals was incomplete, so APHIS determined that, out of an abundance of caution, all animals on the premises should be euthanized. On January 6, 2004, APHIS personnel gathered the animals from the Sunnyside premises and transferred them to a slaughter facility in Wilbur, Washington. All 449 animals were humanely euthanized. The remains of those animals were delivered to a landfill on January 8, 2004. The yearling heifer in the Mabton herd that was definitively identified to be the offspring of the BSE-positive cow, along with 130 other cattle from the Mabton herd with known or potential risk for having been infected with the BSE agent in Canada, have been euthanized.

Collaboration with the Food and Drug Administration (FDA) Feed Investigation

On December 27, 2003, FDA announced that its investigators and inspectors from the States of Washington and Oregon had located all potentially infectious product rendered from the BSE-positive cow in Washington. The rendering plants that processed all the nonedible material from the BSE cow have placed a voluntary hold on all potentially infectious products. The rendering firms, located in Washington and Oregon, have assisted and cooperated fully with FDA's investigation. This product is being disposed of in a landfill in accordance with Federal, State, and local regulations. FDA also reported that the feeding and feed mixing practices related to the Mabton index premises were in full compliance with all mammalian protein restrictions and other regulations.

Conclusion

This investigation demonstrates that the affected animal was not indigenous (not born in the United States) and that her exposure to the causative agent of BSE occurred in Canada. As provided in the OIE Code (Article 2.3.13.4), her progeny born in the previous 2 years (the heifer calf in 2002 and bull calf in 2003) were identified and destroyed.

Explanatory Note - Risk analysis: BSE Risk from Importation of Designated Ruminants and Ruminant Products from Canada Into the United States APHIS, February 2004

