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	FDA:	Docket No. 2004N-0264 (RIN 0910-AF46)

In the Matter of Federal Measures to Mitigate BSE Risks: Considerations for Further Action.

Dear Administrators:

Thank you for the opportunity to comment on the joint Advanced Notice of Proposed Rulemaking (ANPR) issued by the Animal and Plant Heath Inspection Service (APHIS), Food Safety and Inspection Services (FSIS), and the Food and Drug Administration (FDA), hereafter referred to collectively as the "Joint Agency," regarding Federal Measures to Mitigate BSE Risks: Considerations for Further Action.

The Ranchers Cattlemen Action Legal Fund - United Stockgrowers of America (R-CALF USA) is a non-profit association representing over 53,000 cattle producers, 10,900 of whom are voluntary, dues-paying R-CALF USA members, and over 43,000 are members of R-CALF USA's 60 affiliated ranch and cattle associations.

R-CALF USA represents U.S. cattle producers on issues concerning national and international trade and marketing and is dedicated to ensuring the continued profitability and viability of the U.S. cattle industry. R-CALF USA's membership consists primarily of cow-calf operators, cattle backgrounders, and independent feedlot owners. Various main street businesses are associate members of R-CALF USA.

I. General Comments: The Joint Agency ANPR Constitutes an Abrupt and Quiet Abandonment of the United States' Historically Successful and Publicly Noticed Disease Prevention Strategy, an Action that Endangers the Welfare of U.S. Consumers and U.S. Livestock.

## A. Without Any Scientific Basis, the Joint Agency ANPR Abruptly Abandons the United States' Primary Safeguard of Preventing the BSE Agent from Infecting the U.S. Cattle Herd.

R-CALF USA strongly supports strict and continued adherence to the United States' longstanding and successful BSE protection strategy, which is intrinsically based on a standard of avoidance and prevention. The Joint Agency publicly set forth this strategy in their 2003 Final Interagency Working Group Report on foot-and-mouth disease (FMD), bovine spongiform encephalopathy (BSE), and related diseases to Congress.<sup>1</sup> These agencies jointly and succinctly described the United States' BSE strategy as consisting of three primary goals:

- Prevent the agent of BSE from entering the United States and infecting U.S. cattle;
- Prevent the amplification of the agent of BSE throughout the U.S. cattle herd, were it to penetrate the primary safeguards at the U.S. borders and infect U.S. cattle; and
- Prevent the exposure of Americans to the agent of BSE via food and other products that are fully or partially of bovine derivation.<sup>2</sup>

The Joint Agency ANPR validates the scientific basis for the first two of these three goals by citing a conclusion of the Harvard Center for Risk Analysis study<sup>3</sup> (Harvard-Tuskegee Study), a conclusion which the Joint Agency ANPR characterizes as:

[T]he most effective measures for reducing potential introduction and spread of BSE are: (1) The ban placed by APHIS on the importation of live ruminants and

<sup>&</sup>lt;sup>1</sup> Federal Inter-agency Working Group, Final Report, January 2003, Animal Disease Risk Assessment, Prevention, and Control Act of 2001, (PL 107-9), January 2003.

 $<sup>^{2}</sup>$  *Id.* The Interagency Working Group introduced these three primary goals by stating, "To date, there is no evidence of BSE in the United States, and the U.S. Government has worked proactively to keep BSE out of this country," at 49.

<sup>&</sup>lt;sup>3</sup> Harvard Center for Risk Analysis, Harvard School of Public Health, and Center for Computational Epidemiology, College of Veterinary Medicine, Tuskegee University, "Evaluation of the Potential for Bovine Spongiform Encephalopathy in the United States," November 26, 2001.

http://www.aphis.usda.gov/Ipa/issues/bse/risk\_assessment/mainreporttext.pdf,2001.

ruminant meat-and-bone meal from the United Kingdom since 1989 and all of Europe since 1997; and (2) the feed ban instituted in 1997 by FDA to prevent recycling of potentially infectious cattle tissue.<sup>4</sup>

Obviously, the ban on the importation of live ruminants and ruminant meat-and-bone meal is a measure to prevent the agent of BSE from entering the United States and infecting U.S. cattle (the first of the three goals). And, the feed ban instituted in 1997 is a measure to prevent the amplification of the agent of BSE throughout the U.S. cattle herd (the second of the three goals).

The Joint Agency ANPR also validates the historical effectiveness of the first two of these three goals by acknowledging that not a single case of BSE has ever been detected in the native U.S. cattle herd, though the U.S. continues to exceed the World Organization for Animal Health (OIE) surveillance testing standard, an accomplishment the U.S. has achieved every fiscal year since 1993.<sup>5</sup>

Notwithstanding the Joint Agency ANPR validations of both the scientific and historical effectiveness of the United State's primary goal of preventing the agent of BSE from entering the United States and infecting U.S. cattle, the Joint Agency ANPR focuses exclusively on only the second and third goals for protecting the United States from BSE, i.e., preventing the amplification of BSE if it infects the U.S. cattle herd (feed ban discussion) and preventing the exposure of Americans to the BSE agent via food and other products (SRM discussion). The Joint Agency ANPR is wholly void of any discussion regarding measures to continue fulfilling the United States first line of defense, the primary goal of "preventing the agent of BSE from entering the United States and infecting U.S. cattle."

The Joint Agency ANPR, instead, infers that the current ban on the importation of live ruminants, ruminant products, and ruminant meat-and-bone meal, which presently applies to all countries where BSE is known to exist, is no longer necessary despite the Harvard-Tuskegee Study's validation that the ban remains one of the most effective measures in reducing the potential introduction and spread of BSE in the United States. The Joint Agency ANPR asserts it is taking a "leadership role" by proposing a new "minimal risk" BSE classification, which would effectively overturn the present ban by allowing the importation of live ruminants from Canada, and potentially from other countries where BSE is known to exist.<sup>6</sup>

B. The Abandonment of the United States' Primary Goal of Preventing the Agent of BSE from Entering the United States and Infecting U.S. Cattle Is an Abrupt Departure from U.S. Policy and Has Been Effected Quietly, Without Any Public Discussion.

The Joint Agency has publicly demonstrated both the importance of, and its previous commitment to, a specific science-based surveillance program needed to achieve the primary goal of preventing the BSE agent from infecting U.S. cattle via the co-mingling of cattle

<sup>&</sup>lt;sup>4</sup> Federal Measures to Mitigate BSE Risks: Considerations for Further Action, Proposed Rules, Federal Register, Vol. 69, No. 134, July 14, 2004, at 42290.

<sup>&</sup>lt;sup>5</sup> *Id.* at 42295.

<sup>&</sup>lt;sup>6</sup> *Id.* at 42294.

previously imported from countries where BSE was subsequently detected. These agencies firmly established the necessity of locating and monitoring all cattle within the U.S. cattle herd that originated in countries where BSE has been detected. These agencies reported to Congress in 2003:

Another part of the surveillance program is to locate and monitor all cattle imported from the United Kingdom during the 1980s, before the USDA ban. Any of these cattle found to be still alive were monitored, and APHIS offered to purchase them. Upon purchase, they were destroyed and tested for BSE. No evidence of BSE has been found in any of these imported animals. Currently, three of these UK imports are still alive and are regularly monitored by a Federal veterinarian for clinical signs compatible with BSE. In addition, APHIS traced all 46 cattle imported from continental Europe in 1996 and 1997. As with the United Kingdom imports, APHIS has offered to purchase these animals. As purchases occur, the cattle are destroyed and tested for BSE. No evidence of BSE has been found. Five of the 46 European imports are still alive as of October 2001, and Federal veterinarians are monitoring them. APHIS is also tracing cattle imported from Japan during the last decade.<sup>7</sup>

This United States' stated policy of locating and monitoring all cattle imported from countries where BSE was subsequently detected affords U.S. consumers and the U.S. cattle industry with significant protections, both economic and health related, should any of these imported cattle test positive for BSE. The World Health Organization provides an explanation for this fact by stating:

As BSE does not spread from one animal to another, there is no risk that an imported case will spark an outbreak within the herd. When a country reports BSE cases, the first question to ask is whether the case involves an imported animal or one born within the native herd. . . Far more alarming is a case born within the national herd, as additional cases, caused by the same exposure to contaminated feed, will nearly always be uncovered. For cases occurring in the native herd, the number of reported cases reflects the quality of the surveillance system and tells only part of the story. More important in terms of the degree of risk are the feeding practices allowed or followed in the country.<sup>8</sup>

Since May 2003, two confirmed cases of BSE have been detected in cattle originating from Canada, evincing that the BSE agent was and likely is circulating in the Canadian cattle herd. Yet, other than the epidemiological investigation involving the Canadian source herd of the BSE-infected cow, the U.S. has made no effort to either locate or monitor the remaining population of Canadian-origin cattle in the United States.<sup>9</sup> Failure to locate and monitor these Canadian-

<sup>&</sup>lt;sup>7</sup> Federal Inter-agency Working Group, Final Report, January 2003, Animal Disease Risk Assessment, Prevention, and Control Act of 2001, (PL 107-9), January 2003, at 57.

<sup>&</sup>lt;sup>8</sup> Understanding the BSE Threat, World Health Organization, Document WHO/CDS/CSR/EPH/2002.6, October 2002, at 18.

 <sup>&</sup>lt;sup>9</sup> Federal Measures to Mitigate BSE Risks: Considerations for Further Action, Proposed Rules, Federal Register, Vol. 69, No. 134, July 14, 2004, at 42291. The Joint Agency ANPR reports that a total of 255 cattle linked to the

origin cattle renders them undifferentiated from U.S. cattle, effectively forcing the U.S. cattle industry to assimilate these higher-risk, Canadian-origin cattle into the U.S. cattle herd.

Should a BSE-positive test be detected in a Canadian-origin cow that is undifferentiated from a U.S.-origin cow within the borders of the U.S., it would effectively become the first native case of BSE in the U.S. cattle herd, and U.S. cattle producers will be economically harmed. The value to the U.S. cattle industry of knowing which cattle in the United States are of Canadian origin at the time of testing for BSE is quantified in the attached study, "Optimal Tracking and Testing of U.S. and Canadian Herds for BSE: A Value-of-Information (VOI) Approach," completed by Louis Anthony Cox, Jr., Ph.D., et al, a nationally recognized expert on risk analysis. The study demonstrates that if a Canadian animal is found in the future to have BSE, and the animal is identifiable as to its Canadian origin, the U.S. cattle industry will be benefited by more than \$80 million annually.<sup>10</sup>

By abandoning the United States' longstanding BSE surveillance program of locating and monitoring cattle imported from countries where BSE has been documented, i.e., Canada, the U.S. is now ignoring the international science-based recommendations set forth by the OIE, which specifically advises nations to consider targeting their BSE surveillance programs to test cattle imported from countries not free from BSE.<sup>11</sup>

Notwithstanding the Joint Agency's recent assurance to Congress that its surveillance efforts included a program to locate and monitor cattle in the U.S. that originated from countries with documented cases of BSE, along with the scientific validation by the OIE for implementing such a surveillance program, the United States has taken no action to locate and monitor cattle of Canadian origin, other than the narrow epidemiological investigation conducted from December 2003 through February 2004. Furthermore, the Joint Agency ANPR is ominously void of any discussion regarding the need to locate and monitor Canadian cattle that were imported into the United States prior to the May 20, 2003, discovery of BSE in the Canadian cattle herd.

# C. The Unfolding Disease Strategy of the Joint Agency ANPR, Marked by an Abandonment of the Primary Goal to Prevent the Agent of BSE from Entering the United States and Infecting U.S. Cattle, Endangers the Welfare of U.S. Consumers and U.S. livestock.

In the wake of Canada's two confirmed cases of BSE in its native cow herd, the agencies participating in the Joint Agency ANPR are rushing pell-mell to alleviate the resulting trade impact between the U.S. and Canada. In doing so, these joint agencies are unnecessarily compromising the welfare of U.S. consumers and the U.S. cattle herd by not taking into account the importance of maintaining a universally applied disease prevention strategy, which provides a robust framework for protecting against both present and future diseases. Dismantling the

Canadian source herd were located at the time the United States concluded its active investigation and culling activities.

<sup>&</sup>lt;sup>10</sup> Louis Anthony Cox, Jr., Ph.D., et al, Optimal Tracking and Testing of U.S. and Canadian Herd for BSE: A Value-of-information (VOI) Approach ("Cox VOI Study"). A copy of Dr. Cox's study is attached to these comments as Appendix A the study's spreadsheet is available by contacting R-CALF USA (406-252-2516)

comments as Appendix A, the study's spreadsheet is available by contacting R-CALF USA (406-252-2516). <sup>11</sup> Terrestrial Animal Health Code, 11<sup>th</sup> edition – 2003, Appendix 3.8.4. Surveillance and Monitoring Systems for Bovine Spongiform Encephalopathy, at Article 3.8.4.4.

United States' underlying disease-protection framework, as the U.S. is attempting to do to achieve BSE-specific exceptions for Canada, will result not only in the weakening of the United States' ability to prevent BSE from infecting U.S. cattle, but also in the weakening of its long-term ability to protect itself from current and future diseases.

The agencies participating in the Joint Agency ANPR must remain cognizant of the fact that BSE is only one of the numerous new diseases that have emerged in recent years. According to the World Health Organization:

[N]ew diseases are emerging at an unprecedented rate. In the last decade of the 20<sup>th</sup> Century, more than 30 new diseases – including HIV/AIDS and Ebola haemorrhagic fever – were detected for the first time in history. Bovine spongiform encephalopathy (BSE), or "mad cow disease," is one of these newly emerging diseases. Its related human form, variant Creutzfeldt-Jakob disease (vCJD), is another.<sup>12</sup>

Thus the Joint Agency ANPR, while posing an immediate risk to the welfare of U.S. livestock by knowingly allowing Canadian cattle from a BSE infected country to be assimilated in the U.S. cow herd, also poses a highly probable future risk by not maintaining an adequate disease protection framework that would, for example, enable the U.S. to immediately locate and monitor Canadian cattle already in the U.S. should a future case of BSE, or some other emerging disease outbreak occur in that country.

The dismantling of the current disease protection framework represents a monumental paradigm shift, significantly changing the United States' approach to new diseases like BSE. Such a departure from the historically successful, science-based disease prevention strategy may not be consistent with the Joint Agencies' mandate under the Animal Health Protection Act.<sup>13</sup> Under the new paradigm recommended by the Joint Agency ANPR, the U.S. will no longer emphasize avoidance and prevention of Foreign Animal Diseases like BSE, but rather, will focus exclusively on the management of such diseases, regardless of whether the disease is preventable or even prevalent. The effect of this new policy will be to cause greater risk exposure to U.S. consumers and the U.S. cattle industry to Foreign Animal Diseases while simultaneously forcing the U.S. cattle industry to incur the added expense associated with specific disease mitigations, again, regardless of whether the disease was preventable or even prevalent. In essence, this new policy will burden the U.S. cattle industry with the disease-related risks and costs of its foreign competitors, a patently unfair and unconscionable policy.

While participants of the Joint Agency ANPR continue to provide public assurances that the U.S. is continuing to maintain adequate safeguards to prevent BSE from entering the United States and infecting U.S. cattle, principally by continuously describing the current U.S. ban on live ruminants, ruminant products and ruminant meat-and-bone meal from countries where BSE is known to exist, the United States is simultaneously lobbying the OIE to adopt its proposal to dismantle its current disease protection framework. The U.S. is clearly attempting to change

<sup>&</sup>lt;sup>12</sup> Understanding the BSE Threat, World Health Organization, Document WHO/CDS/CSR/EPH/2002.6, October 2002, p. 1.

<sup>&</sup>lt;sup>13</sup> Animal Health Protection Act, 7 U.S.C. Section 8301 *et seq*.

current animal disease control policy from one of disease avoidance and prevention to a lesser standard based on controlled risk and acceptable risk (disease management). In comments submitted to the World Organization for Animal Health (OIE) the United States stated its policy as follows:

[T]he United States continues to believe that the risk status of a country or region be based on the results of a risk assessment which identifies key risk factors and determines the "overall effectiveness" of control and risk mitigation measures in place (i.e., surveillance, import controls, specified risk material removal and feed ban). Thus, the risk status of a given country/region should be based on the effective implementation of mitigation measures against known risk factors for BSE. It is a risk-based approach classification rather than a prevalence-based approach.<sup>14</sup>

The economic risks to the U.S. cattle industry resulting from the United States' unwillingness to locate and monitor imported Canadian cattle, a circumstance demonstrable of the United States' abandonment of its primary disease prevention goal, can now be quantified by the attached Cox VOI Study which introduces a formal decision-analytic value-of-information (VOI) framework to quantify and compare the economic costs to the U.S. of implementing a tracking program for imported Canadian cattle to the costs of not doing so. The study shows:

[T]he value of tracking information is great enough to justify locating and beginning to track Canadian cattle already in the US when this can be done for a reasonable cost, e.g., less than \$35 per head, even under the pessimistic assumption that the US has already permanently lost many of its export markets due to the Washington State BSE case discovered in a Canadian-origin cow in December, 2003. If aggressive tracking and testing can win back lost exports, then the VOI of a tracking program may increase by an order of magnitude, to over half a billion dollars per year.<sup>15</sup>

D. The Agencies Participating in the Joint Agency ANPR Should Immediately Reaffirm their Commitment to the United States Primary Line of Defense Against BSE: Preventing the Agent of BSE from Entering the United States and infecting U.S. Cattle by First Affirmatively Preventing the Agent of BSE from Entering the United States Via the Assimilation of Canadian-origin Cattle into the U.S. Cattle herd.

As a prerequisite to issuing proposed rules that would attempt to codify the United States' abrupt departure from its science-based and historically successful strategy of preventing the BSE agent from entering the United States and infecting U.S. cattle, such as via the assimilation of cattle

<sup>&</sup>lt;sup>14</sup> Comments from the United States on the OIE's proposed changes to the Code Chapter on Bovine Spongiform Encephalopathy December 2003 Report of the Terrestrial Animal Health Standards Commission Comments, March 12, 2004, at 4.

<sup>&</sup>lt;sup>15</sup> Louis Anthony Cox, Jr., Ph.D., et al, Optimal Tracking and Testing of U.S. and Canadian Herd for BSE: A Value-of-information (VOI) Approach ("Cox VOI Study"). A copy of Dr. Cox's study is attached to these comments as Appendix A.

imported from countries where BSE exists into the U.S. cattle herd, R-CALF USA urges the agencies participating in the Joint Agency ANPR to immediately:

- Identify all Canadian-born cattle that have been imported into the United States and that may still reside in the United States approximately 450,000 animals<sup>16</sup> and track those animals so they are tested for BSE before they enter the food supply; and
- Convene and chair a series of public hearings around the United States to solicit the views of individual consumers and experts in public and animal health on this topic; and
- Insist that Canada, in particular, aggressively expand its BSE testing program to establish on a scientific basis the actual prevalence of BSE in the entire Canadian cattle herd; and
- Join with the Department of Health and Human Services to commission a study by the Institute of Medicine of the National Academy of Sciences to fully assess the risks (including both the risks to human and animal health) of importing cattle and beef from Canada and other countries infected with BSE into the United States.

### II. Specific Comments: Addressing the Specific Questions and Recommendations Made Within the Joint Agency ANPR.

### A. Comments to Part III, The Case in Washington State and U.S. Actions in Response, of the Joint Agency ANPR.

*Animal Surveillance:* R-CALF USA strongly encourages the permitting of private meatpackers to voluntarily test for BSE. Voluntary testing by private meatpackers will further assist the United States in establishing the prevalence of BSE in the U.S. by expanding the testing population beyond the resource limitations of the federal government. In addition, the United States' refusal to allow private meatpackers to test for BSE has contributed to the protracted closure of important Asian beef markets. In a recent letter to USDA Secretary Ann Veneman, a coalition representing all segments of the U.S. beef industry wrote:

USDA's outright refusal to allow private businesses to voluntarily provide BSE testing to meet the purchase requirements of their customers has harmed cattle producers, packers, wholesale and retail businesses that sell beef, particularly those businesses that export beef to Asia. USDA has failed to reopen most

<sup>&</sup>lt;sup>16</sup> Estimate based on United States Department of Agriculture Foreign Agricultural Service (USDA-FAS) HS 10-Digit Import data indicating total numbers of cattle imported from Canada from 1997 – 2003. This data shows a total of 8.1 million head were imported during this period, 6.1 million were imported directly for slaughter, and 1.5 million were feeder cattle, which, like cattle imported directly for slaughter, would likely be purged from the system. This leaves approximately 382,000 breeding-type dairy cattle and 55,000 breeding-type beef cattle from Canada that could still be alive in the U.S., for a total estimate of less than 450,000 cattle. Based on the relatively short average production-life of dairy cattle, which according to the USDA Animal Improvement Programs Laboratory (AIPL) is three-four years, the number of Canadian-origin cattle remaining in the U.S. may be significantly less than 450,000 because of the high likelihood that many of the imported dairy cattle have been culled from the herd.

export markets, despite over six months of negotiations. Rather than opposing Creekstone and Gateway, USDA should be working with beef processors to help them establish standards for voluntary BSE-testing that respond to the demands of its customers.<sup>17</sup>

### **B.** Comments to Part V, Recommendations of the IRT and Additional Measures for Consideration.

*Animal Feed Restrictions:* R-CALF USA strongly supports the strengthening of the U.S. feed ban by prohibiting blood, tallow, and poultry and hog litter from cattle feed; and by strengthening feed import bans to include the testing of all imported feed for mammalian products.

Several news articles from the United Kingdom (UK) suggest that the human form of BSE can be spread through blood transfusions. Such articles include:

- According to a September 10, 2004, news article from the United Kingdom's (UK's) Mirror.co.uk, the Department of Health in that country is notifying patients who have had blood transfusions that they could be infected with the human form of BSE.<sup>18</sup>
- According to the August 5, 2004, Associated Press article written in London, Human Mad Cow May be More Widespread," Dr. Kumanan Wilson, a blood safety expert at Toronto General Hospital in Canada, indicated that new evidence suggests that the human form of BSE can be spread through blood transfusions.<sup>19</sup>
- According to the May 21, 2004, Reuters news article, Sir Leszek Borysiewicz of Imperial College in London indicated that the findings of a recent report published in the Journal of Pathology and authored by David Hilton, of Derriford Hospital in Plymouth, reinforce the safety measures to reduce the spread of vCJD through blood transfusions or surgical equipment.<sup>20</sup>

These articles, representing a growing body of scientific knowledge regarding the role blood may play in the spread of the human form of BSE, reinforce the need to ban blood from animal feed until science can definitively dismiss animal blood as a contaminant source of BSE.

<sup>&</sup>lt;sup>17</sup> Letter from Creekstone Farms Premium Beef, Gateway Beef Cooperative, and R-CALF USA addressed to USDA Secretary Ann Veneman, July 27, 2004.

<sup>&</sup>lt;sup>18</sup> Alert on Mad Cow Infection, Mirror.co.uk, September 10, 2004.

<sup>&</sup>lt;sup>19</sup> Human Mad Cow May Be More Widespread, Emma Ross, AP Medical Writer, Associate Press, August 5, 2004.

<sup>&</sup>lt;sup>20</sup> More Human Mad Cow Disease Cases Possible, Reuters, London, May 21, 2004.

*Animal Identification (Tracebility):* In response to questions 24 and 25, R-CALF USA provides below excerpts from its July 27, 2004, testimony to Congress regarding its position on animal identification.<sup>21</sup>

Our objectives [for animal identification] are straightforward:

- 1. To clarify the intended purpose and need of a national animal identification (ID) program and to implement effective measures to prevent the misuse and abuse of proprietary information.
- 2. To evaluate both the costs and the benefits of implementing a national animal ID plan, which can only be done following the completion of a comprehensive, science-based cost/benefit analysis.
- 3. To evaluate the effectiveness of current state and regional animal identification methods that may already meet the intended purpose of a national animal ID program, or that may be easily assimilated into a nationwide plan at little to no cost.
- 4. To ensure that if the overall cost of implementing a national animal ID plan is considerable, which according to the United States Animal Identification Plan (USAIP) plan is the case, then a means other than allocating those costs to the U.S. live cattle industry must be found.
- 5. To ensure that if a network infrastructure is needed to enable a national animal ID program, then that infrastructure is designed to accommodate many other needed services in Rural America, rather than simply maintaining information about livestock. Such a system may allow for the sharing of infrastructure-related costs among many industries and service providers, such as rural health care providers;
- 6. To ensure that the current rush to implement a national animal ID program does not distract the United States from its far more immediate and important responsibility, which is to protect the United States cattle herd from the introduction of Foreign Animal Diseases that may enter the U.S. through inadequate border controls.
- 7. To maintain, as this nation's highest priority, the highest standards of health and safety for our cattle industry and to not compromise our resolve to continue avoiding and preventing the introduction or spread of animal diseases by substituting our strategy of "disease prevention" with a new strategy of "disease management."
- 8. To ensure that the United States implements and enforces the measures already in place and readily available with which to meet the objective of preventing the introduction of Foreign Animal Diseases, differentiating cattle as to origin, and tracing beef and cattle as to their origins. It is disconcerting to the U.S. cattle industry that while mandatory country-of-origin labeling has been passed by Congress and is now available to both immediately determine the country-of-origin of cattle and to trace the origins of beef, at least with respect to foreign cattle and foreign meat, Congress itself has postponed its implementation. It is

<sup>&</sup>lt;sup>21</sup> Testimony of Kenny Fox on behalf of R-CALF USA before the U.S. House of Representative Committee on Agriculture on the Development of a U.S. Animal Identification Plan, August 17, 2004, attached to these comments as Appendix B.

equally disconcerting that while our current regulations provide the U.S. cattle industry with the most complete protection against the introduction of Foreign Animal Diseases from countries where such diseases are known to exist, the USDA is working aggressively to relax and weaken these regulations.

### II. R-CALF USA's Opinion on How an Animal ID Program Would be Funded

The Committee has also asked our opinion on how the program would be paid for. In general, there are three major components for which animal ID costs will be assigned. They include costs associated with premise identification; costs associated with collecting, transferring, and accessing traceability information; and costs associated with building, connecting, and maintaining a ubiquitous network infrastructure system that allows all existing and new networks to communicate with each other from all regions of the U.S., however remote those regions may be.

In essence, the Committee is asking how much independent cattle producers are willing to pay to implement a program which is expressly designed to control and eradicate Foreign Animal Diseases like Foot and Mouth Disease (FMD) that has not been diagnosed in the U.S. for decades, or BSE that has never been diagnosed in the U.S. But, which diseases may be introduced into the U.S. because longstanding disease prevention policies, that is, our import and border control policies, are either scheduled to be relaxed or their current effectiveness is being questioned.

Independent cattle producers strongly support the current high standards of healthy production practices and disease prevention practices. However, we are confounded by the government's resistance to both implement and enforce our primary line of defense for both preventing the introduction of diseases into the United States and for quickly identifying foreign meat and foreign cattle that are, by definition, the primary means of transmitting Foreign Animal Diseases. R-CALF USA has called on Congress and the USDA to implement and enforce the following measures that provide our industry and our consumers with the first line of defense against both the introduction of foreign animal diseases and the potential spread of a Foreign Animal Disease:

- 1. Mark all imported cattle with a permanent mark of origin.
- 2. Identify all imported cattle already in the United States with a permanent mark of origin.
- 3. Implement country-of-origin labeling so that in the event of a disease outbreak in a foreign herd, all foreign cattle and foreign meat can be immediately identified and quarantined.
- 4. Maintain current regulations that prohibit the importation of cattle or beef from any country where BSE and FMD are known to exist.

#### C. Comments to Part VI, Other Considerations

*Equivalence:* In response to questions 34, 35, and 36: The United States should not relax its current BSE import restrictions applicable to countries where BSE is known to exist. For countries considered BSE-free or BSE provisionally free under OIE guidelines, under no circumstances should the United States accept any cattle, beef or beef products from such countries if they do not maintain identical or more stringent safeguard measures than is presently required or presently proposed in the United states and which measures have been enforced for at least as long as those in the United States.

In addition, R-CALF USA strongly supports the recommendation the agencies participating in the Joint Agency ANPR made to Congress in 2003 regarding the requirement that all imported products be declared with country-of-origin documentation. The specific recommendation states:

As BSE cases are confirmed in other countries, USDA and DHHS need to update risk assessments, import regulations, and guidance on enforcing regulations at ports-of-entry. . . To require that all imported products containing either mammalian or mammalian-sourced ingredients be declared with country-of-origin documentation of all such ingredients on import manifests<sup>22</sup>

R-CALF USA would encourage the immediate adoption of this country-of-origin requirement for all cattle and beef products, with the additional requirement that such country-of-origin declarations be permanently marked on the cattle, attached to the product, or maintained on the product package until removed by the consumer that ultimately ingests the product.

R-CALF USA appreciates the opportunity to submit these comments.

Sincerely,

Bill Bullard CEO R-CALF USA

<sup>&</sup>lt;sup>22</sup> Federal Inter-agency Working Group, Final Report, January 2003, Animal Disease Risk Assessment, Prevention, and Control Act of 2001, (PL 107-9), January 2003, at 44-45.

#### APPENDIX A

### OPTIMAL TRACKING AND TESTING OF US AND CANADIAN HERDS FOR BSE: A VALUE-OF-INFORMATION (VOI) APPROACH

#### ABSTRACT

The USDA currently tests a subset of cattle slaughtered in the US for BSE. If the origin of the cattle (US versus Canada) were known at the time of testing, improved testing or surveillance policies could be devised for the future, based on the origin of any cattle testing positive. For example, if a Canadian origin cow tests positive for BSE, while no US origin cattle test positive, the US could decide that cattle of Canadian origin should be subject to more stringent testing than US origin cattle. To implement a "tracking decision", any imported cattle already in or entering the US would require some sort of permanent marking and incur implementation costs. This paper introduces a formal decision-analytic value-of-information (VOI) framework to quantify and compare the economic costs to the US of implementing such a tracking program to the costs of not doing so. The economic value of information from a tracking program is estimated to exceed its costs by a factor of over 5 even under conservative assumptions, since such information can potentially be used to avoid or mitigate future losses in export and domestic markets and to reduce costs of future testing required to reassure or win back customers. Sensitivity analyses indicate that the conclusion that implementing a tracking program for any Canadian cattle imported into the US is highly worthwhile appears to be robust to many technical, scientific, and market uncertainties, including the current prevalence of BSE in the US and/or Canada and the likely reactions of consumers to possible future discoveries of BSE in the US and/or Canada. Indeed, the value of tracking information is great enough to justify locating and beginning to track Canadian cattle already in the US when this can be done for a reasonable cost, e.g., less than \$35 per head, even under the pessimistic assumption that the US has already permanently lost many of its export markets due to the Washington State BSE case discovered in a Canadian-origin cow in December, 2003. If aggressive tracking and testing can win back lost exports, then the VOI of a tracking program may increase by an order of magnitude, to over half a billion dollars per year.

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#### INTRODUCTION: A RISK MANAGEMENT DILEMMA

For the past several years, Canada has tested thousands of cattle per year for BSE – for example, 3377 animals in 2002. To date, this testing has found only one cow with BSE (Canadian Food Inspection Agency, 2004). In the province of Alberta, "The brains of 2769 targeted cattle were tested from October 1996 to March 31, 2004. One cow, condemned at slaughter (did not enter the human food chain), was confirmed positive for BSE in May 2003... Brain tissue samples from the remaining 2768 cattle had no evidence of BSE" (Government of Alberta, 2004). It is assumed that this prevalence level is representative of and consistent with current Canadian practices with regards to minimizing BSE in the Canadian herd. Targeted Canadian cattle included animals with neurological signs and/or emaciation, submitted through provincial slaughter facilities and by field veterinarians, as well as samples from cattle submitted to provincial diagnostic laboratories for post-mortem examination. If, based on European experience, targeted animals are about 60 times more likely to have BSE than non-targeted animals as a base case, then a prevalence rate of BSE among non-targeted cattle of (1/2768)\*(1/60) = 6.0E-6 might be estimated from this case.

In December, 2003, a second dairy cow from Alberta, imported into the US to the state of Washington, was also diagnosed with BSE. Following a prompt, thorough investigation by The United States Department of Agriculture (USDA) and the Canadian Food Inspection Agency (CFIA), USDA's APHIS Veterinary Services (VS) issued an "Explanatory Note" in February, 2004, concluding that its previous risk analysis of the risks from Canadian cattle and beef products imported into the US remained unchanged by the new case, and that the risks remained low. As stated in the note:

"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." (USDA, 2004)

From a statistical perspective, the detection of two BSE cases from Alberta in less than eight months raises the question of what the true prevalence of BSE in Canadian cattle may be at

present. The statistical inference problem is complicated by the fact that the cow in Washington State was not detected as part of Canada's routine sampling program, and the probability that such cattle will be detected once they have been imported into the US is not known. From a risk management perspective, the key question is what actions, if any, the US should take now in light of uncertainty about the true prevalence rate of BSE among Canadian cattle now and in the future. This decision problem is made more challenging by scientific uncertainties regarding BSE sources, reservoirs, and dynamics. Examples of uncertainties include:

- Roles of horizontal and vertical transmission (if any) within herds
- Existing and potential BSE reservoirs in Canada and the US and how these are affected by respective ongoing imports
- Transmission dynamics within and between different reservoirs
- Differences in susceptibility among individual cattle of the same age
- The shape of the age versus infectivity curve for cattle
- Distribution of infectivity and differences in virulence among new BSE cases
- Latency period until clinical expression; possibility of subclinical cases (<u>Thackray et al.</u>, <u>2003</u>; <u>Hill and Collinge</u>, <u>2003</u>;); common definition of clinical BSE expression
- Potential for clustering of rare events within geographic areas, processing plants, affected populations etc.
- Error and compliance rates (such as mislabeling, etc.) in Canada and the US
- Possible heterogeneity of the basic reproductive rate R<sub>0</sub> for BSE in different geographic areas or for different strains of BSE, different types of cattle, etc.
- Detection probabilities per case, given the target and sampling schemes used
- Uncertainty of inferred cattle age measurements (e.g., from dentition, etc)
- Variability and accuracy in testing methods for BSE detection

With so many unknowns, predictive modeling can be highly uncertain. Real-world data on observed cases of BSE can therefore potentially be especially valuable for improving estimates of true BSE prevalence. However, the two BSE cases from Alberta detected in 2003 support alternative interpretations, ranging from (a) the first beginnings of a wave of BSE cases to; (b) the last remnants of a problem from the 1980s and 1990s that has already been fixed and that, by chance, escaped detection until 2003 and (c) possibly scenarios in between. The data do not reveal a unique correct interpretation.

This creates a dilemma for both health and economic risk management. On the one hand, experience since 2003 has shown that discovery of BSE cases in the US can dramatically reduce US beef exports, even if the infected animals originated in Canada. If the true prevalence of BSE in Canadian cattle shipped to the US were known to be as high as 6.0E-6, then continued prevention of cattle imports from Canada might be expected. On the other hand, if the prevalence of BSE in Canadian cattle were known to be much smaller or zero, then the advantages of resumed trade could be gained by allowing unrestricted imports, without incurring a substantial risk of additional BSE cases. Given the high economic stakes and the uncertainties about the prevalence of BSE in Canadian cattle (and, for that matter, US cattle), it has been difficult to determine what policies would best promote US and international interests - what policies would be optimal based on a solid analytic foundation. Options range from maintaining the status quo (e.g., preserving current import restrictions and testing programs) to tightening or loosening current import policies to gathering more information first – for example, by tracking all imported cattle and testing all Canadian cattle in the US – and then using this information and the results of future sampling to decide when and whether to change import restrictions. To discover which of these (or other) options is most desirable, it is necessary to compare their conditional probability distributions of gains and losses.

This paper applies constructive decision-analytic techniques, including value-ofinformation (VOI) calculations (<u>Yokota and Thompson, 2004</u>), to quantify and compare the economic values of different risk management and information-seeking options available to the US for managing the uncertain risks of BSE originating in Canada. The analysis focuses mainly on a near-term decision – whether to require Canadian cattle in the US to be identified, permanently marked, and tracked to provide information about their origins in case future BSE cases are found – and on the economic consequences of different potential futures whose probabilities can be affected by these near-term decisions. This focus reflects the facts that economic consequences will probably dominate near-term policy decisions, are easier to estimate reliably from available information than possible human health risks, and provide an analytic framework that can later be extended to include health risk considerations. By explicitly representing key uncertainties and assessing the probable consequences of alternative current decisions, the decision-analytic framework presented here may prove useful to policy analysts

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and decision-makers in considering how best to assess and manage the highly uncertain risks of BSE in the US from imported cattle.

#### 2. METHODS AND DATA

The decision-analytic approach to risk management developed in this paper proceeds through the following steps:

- Identify a set of *alternative decision rules* or options to be compared. A decision rule specifies the actions to be taken at each time, given the information available at that time. It may be thought of as a plan that specifies what to do under different contingencies.
- 2. Identify the *consequences* of concern, which the actions may affect.
- 3. Identify the *probabilities* of different consequences, for each decision rule. This typically requires considering different *scenarios* or assumption sets describing alternative ways in which current uncertainties might be resolved. These are also called "*states of nature*". Often, there is no objective, uniquely correct way to determine the prior probabilities of alternative scenarios. Then, conservative assumptions (tending to favor the *status quo*) and sensitivity analyses (in which various prior probabilities of scenarios are assumed) may be used to determine how robust the conclusions and decision recommendations from the analysis are to variations in scenario probabilities.
- 4. Identify the *optimal decision rule,* defined as the one with the most desirable probability distribution of consequences, given current information and assuming that future actions will be made optimally given future information.
- 5. Identify and recommend the *optimal current action*, as determined by the optimal decision rule.

This framework is explained in detail in Raiffa, 1968 and Clemen, 1996.

#### Formulation of the Risk Management Decision Problem as a Decision Tree

The decision rules compared in this paper are structured as follows (see Figure 1). First, an initial ("Stage 1") decision must be made either to track Canadian cattle in the US ("Track CA imports") or not to track them ("Do not track CA imports"). The main purpose of the decision analysis is to compare the probable consequences to the US of these two alternative initial actions. Following this Stage 1 decision, additional information will be obtained from ongoing sampling programs in the US and Canada that perform tests for BSE on both symptomatic (e.g., "downer" cattle) and randomly selected healthy-appearing cattle at slaughter. If the Stage 1 decision was "Track CA imports", then any of the following informative events may be observed over a specified following time period (e.g., 1 year):

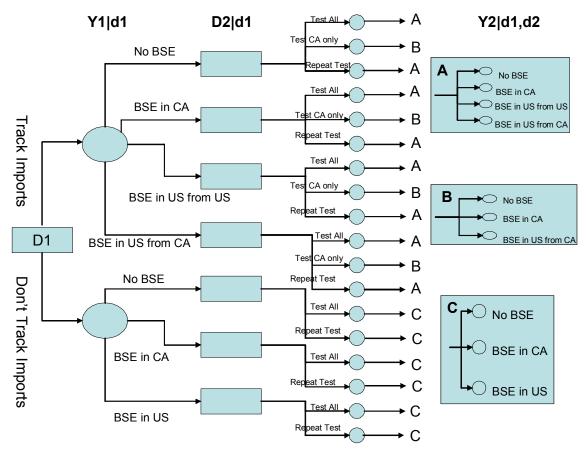
- No new BSE cases detected
- BSE case of Canadian origin detected in US
- BSE case of US origin detected in US
- BSE case of Canadian origin detected in Canada

(If several of the last three events occur in a year, we focus on the first to occur as the event of interest.) The probabilities of these events depend on both the unknown true prevalence rates of BSE in the US and Canadian herds (i.e., on which scenario or state of nature is correct) and also on the sampling plans and tests used to examine the herds. If the Stage 1 decision is "Don't track CA imports", then the four possible observations for the next period are aggregated to only the following three:

- No new BSE cases detected
- New BSE case detected in Canada
- New BSE case detected in US

In reality, as in the case of the Washington state cow, forensic efforts might successfully identify the origin of a BSE case even without new tracking measures. The effect of a Stage 1 decision to track imports is then to increase the probability that the origin of a new case can be determined. The formal analysis treats the Track *vs.* Do not track decisions as providing *vs.* failing to provide, respectively, the information needed to identify the origin (Canadian or not) of any new BSE case, while recognizing that partial tracking via ear tags, brands, and tattoos may already be available. (Indeed, the tracking issue is confined to Canadian cattle because Mexican cattle in the US are already well identified.)

After the Stage 1 decision, and given updated information about any new BSE cases, a subsequent ("Stage 2") decision must be made about whether to sell and process healthy-appearing cattle without first requiring them to be tested for BSE ("No required test") *vs.* requiring all US cattle to be tested for BSE before being sold or processed ("Test all") *vs.* requiring only all Canadian cattle in the US to be tested for BSE before being sold or processed ("Require testing for CA cattle only".) The latter option is available only if the Stage 1 decision was "Track CA imports". In addition to any required testing, some cattle will continue to be sampled and tested according to a USDA test program, and this is not affected by the Stage 1 and Stage 2 decisions. The Stage 2 decision presumably will be made to obtain the most desirable outcome possible, given the information available then. For example, if a new BSE case is detected in the US and its origin cannot be ascertained, then the Stage 2 decision might be "Test all" US cattle at slaughter, to reduce export and domestic consumption losses (if the economic benefits outweigh the costs of testing); while if the origin of the case is known to be Canadian and the Stage 1 decision was to "Track CA imports", then the best Stage 2 decision might be "Require testing for CA cattle only".



Notation for decision problem components

- D1 = Stage 1 choice set = {Track Imports, Do Not Track Imports}
- $\{Y1 \mid d1\}$  = information sets of possible outcomes based upon the Stage 1 decision d1  $\varepsilon$  D1
- $\{D2 \mid d1\} =$ Stage 2 choice set, given the Stage 1 decision d1  $\varepsilon$  D1
- {Y2 | d1,d2} = information sets of possible outcomes after decisions d1  $\varepsilon$  D1 and d2  $\varepsilon$  {D2 | d1}

#### Figure 1. Decision Tree for BSE Testing Policy

After Stage 1 and Stage 2 decisions have been made and the future information has been obtained, it becomes possible to evaluate how much beef consumption, if any, has been lost in export and domestic markets due to BSE cases and risk management responses, and how much the Stage 1 and Stage 2 decisions cost to implement. A goal for rational risk management decision-making *today* is to anticipate how current decisions change probable *future* total costs (i.e., the sum of implementation costs and costs from lost domestic and export sales) as they will eventually be assessed in hindsight. Each Stage 1 decision, in conjunction with optimized Stage 2 decisions given future information, determines a probability distribution for total cost.

Rational risk management requires making the choice today that induces the most desirable probability distribution for total costs, as they eventually will be evaluated in the future.

Figure 1 presents a decision tree model summarizing the logical structure of the decision problem. In this tree, a *decision rule* specifies which outgoing branch to follow at each decision node (represented by a rectangular node in Figure 1.) "Repeat test" refers to the action of doing nothing other than to continue the routine BSE sampling and testing programs. The notation for Stage 1 and Stage 2 decisions ("choice sets") and observed outcome events ("information sets") listed at the bottom of Figure 1 allows the same framework to be expanded to include additional decisions, scenarios, and information events if so desired to increase the resolution of the problem description. However, the relatively simple, aggregate descriptions of possible decisions and futures in Figure 1 suffice to carry out the decision analysis calculations; analogous calculations can be performed for more detailed descriptions.

#### **Estimated Economic Consequences of Detecting Additional BSE Cases**

To finish describing the decision problem, it is necessary to estimate the economic costs associated with each terminal node (i.e., "leaf" node) at the tips of Figure 1. Only the direct costs of implementing the different Stage 1 decisions and of reduced beef sales in case of detection of new BSE cases will be considered, as a first approximation to the full societal costs. (A refined analysis could estimate economic multiplier effects and reductions in consumer surplus from reduced domestic sales, which would increase their impacts further. However, sensitivity analysis suggests that the main conclusions, which are dominated by loss-of-export-related impacts, would not be changed by these refinements.) The decision model incorporates the following three types of cost: Tracking Costs, Testing Costs, and Market Costs. Tracking labor and materials. Testing costs represent the costs per BSE test, including kits, labor, shipping, holding, laboratory facilities, and expenses. Market costs represent market losses (or gains) associated with each second stage outcome as a function of all that occurred up to that point. Baseline values for each of these costs are estimated next. These are then varied to obtain sensitivity analyses.

#### Market Impacts

The main economic impacts on the US of discovering a new BSE case are assumed to be as follows for the baseline scenario.

- If a new BSE case of *unknown origin* is discovered in the US, then both domestic demand and remaining exports of US beef will immediately decline. Following the discovery of the BSE-positive cow in Washington State in 2003, US exports declined by approximately 50%. For the baseline scenario, we assume that discovery of a new BSE case of unknown origin in the US will result in a further loss of -12.27B dollars per year in cattle sales, corresponding to a 25% assumed reduction in consumer demand. The situation where full testing identifies a BSE case of known US origin in the US provides a similar loss.
- If a new BSE case is found in the US that is not specifically known to be of Canadian origin, but subsequent full testing does not find a similar case, a smaller loss of -6.14B dollars per year will occur.
- If a new BSE case is discovered *in Canada*, then US exports may increase to replace decreased Canadian exports. The magnitude of this effect is estimated as a gain of +1.382B dollars per year in the base case.
- If a new BSE case known to be of Canadian origin is discovered in the US, and if Canadian cattle are then removed from US exports and from the food supply, the net impact on the US is a loss of -2.683B dollars per year in the base case, primarily from additional lost exports. (The US domestic markets responded only relatively slightly to the Canadian BSE cases discovered in 2003, suggesting that the main economic impacts come from the closing of export markets to US beef.)

<u>Table 1</u> summarizes the baseline economic impacts for each of the possible futures (i.e., branches through the decision tree to a leaf node) in <u>Figure 1</u>. Appendix A provides the supporting rationale and data for the estimated market impacts.

Sta	ge 1	Sta	ge 2	Economic Impacts				
	Outcom			Market	Tracking	Testing	<b>Total Economic</b>	
Decision	e	Decision	Outcome	Impacts	Costs	Costs	Impact	
					-	-		
Track					30,774,30	1,099,200,0		
Imports	No BSE	Test All	No BSE	0	0	00	-1,129,974,300	
-			BSE in	1,382,000,000	-	-	252,025,700	

#### **TABLE 1:** Economic Impact Estimates

		CA		30,774,30 0	1,099,200,0 00	
		BSE in US from US	12,270,000,00	30,774,30 0		-13,399,974,300
			2,863,000,000	30,774,30 0	1,099,200,0 00	-3,992,974,300
	Test CA Only	No BSE	0	30,774,30 0	-47,361,450	-78,135,750
		BSE in CA	1,382,000,000	30,774,30 0	-47,361,450	1,303,864,250
				30,774,30 0	-47,361,450	-2,941,135,750
	Repeat Test	No BSE	0	30,774,30 0	-2,400,000	-33,174,300
		BSE in CA	1,382,000,000	30,774,30 0	-2,400,000	1,348,825,700
		BSE in US from US	12,270,000,00 0	30,774,30 0	-2,400,000	-12,303,174,300
				30,774,30 0	-2,400,000	-2,896,174,300
BSE in CA	Test All	No BSE	1,382,000,000	30,774,30 0	1,099,200,0 00	252,025,700
		BSE in CA	1,382,000,000	30,774,30 0	1,099,200,0 00	252,025,700
		BSE in US from US	12,270,000,00 0	30,774,30 0		-13,399,974,300
		BSE in US from CA	2,863,000,000	30,774,30 0	1,099,200,0 00	-3,992,974,300
	Test CA Only	No BSE BSE in	1,382,000,000	30,774,30 0	-47,361,450	1,303,864,250
		CA	1,382,000,000	30,774,30	-47,361,450	1,303,864,250

				0		
		BSE in US from CA	2,863,000,000	30,774,30 0	-47,361,450	-2,941,135,750
	Repeat Test	No BSE	1,382,000,000	30,774,30 0	-2,400,000	1,348,825,700
		BSE in CA	1,382,000,000	30,774,30 0	-2,400,000	1,348,825,700
		BSE in US from US	12,270,000,00 0	30,774,30 0	-2,400,000	-12,303,174,300
BSE in		BSE in US from CA	2,863,000,000	30,774,30 0	-2,400,000	-2,896,174,300
US from US		No BSE	6,140,000,000	30,774,30 0	1,099,200,0 00	-7,269,974,300
		BSE in CA	- 6,140,000,000	30,774,30 0	1,099,200,0 00	-7,269,974,300
		BSE in US from US	12,270,000,00 0	30,774,30 0		-13,399,974,300
		BSE in US from CA	- 6,140,000,000	30,774,30 0	1,099,200,0 00	-7,269,974,300
	Test CA Only	No BSE	12,270,000,00		-47,361,450	-12,348,135,750
		BSE in CA	12,270,000,00 0		-47,361,450	-12,348,135,750
		BSE in US from CA	12,270,000,00 0		-47,361,450	-12,348,135,750
	Repeat Test	No BSE	- 6,140,000,000	30,774,30 0	-2,400,000	-6,173,174,300
		BSE in CA	6,140,000,000	30,774,30 0	-2,400,000	-6,173,174,300
		BSE in US from US	12,270,000,00 0	30,774,30 0	-2,400,000	-12,303,174,300

1					-		1
	BSE in		BSE in US from CA	- 6,140,000,000	30,774,30 0	-2,400,000	-6,173,174,300
	US from CA	Test All	No BSE	0	30,774,30 0	1,099,200,0 00	-1,129,974,300
			BSE in CA	0	30,774,30 0	1,099,200,0 00	-1,129,974,300
			BSE in US from US	12,270,000,00 0	- 30,774,30 0	1,099,200,0 00	-13,399,974,300
			BSE in US from CA	2,863,000,000	30,774,30 0	- 1,099,200,0 00	-3,992,974,300
		Test CA Only	No BSE	0	30,774,30 0	-47,361,450	-78,135,750
			BSE in CA	0	30,774,30 0	-47,361,450	-78,135,750
			BSE in US from CA	- 2,863,000,000	30,774,30 0	-47,361,450	-2,941,135,750
		Repeat Test	No BSE	0	30,774,30 0	-2,400,000	-33,174,300
			BSE in CA	0	30,774,30 0	-2,400,000	-33,174,300
			BSE in US from US	- 12,270,000,00 0	30,774,30 0	-2,400,000	-12,303,174,300
			BSE in US from CA	2,863,000,000	30,774,30 0	-2,400,000	-2,896,174,300
Don't Track	No BSE	Test All	No BSE	0	0	- 1,099,200,0 00	-1,099,200,000
			BSE in CA	0	0	- 1,099,200,0 00	-1,099,200,000
		Repeat	BSE in US No BSE	- 12,270,000,00 0 0	0 0	- 1,099,200,0 00 -2,400,000	-13,369,200,000 -2,400,000

		Test					
			BSE in CA	0	0	-2,400,000	-2,400,000
			BSE in US	12,270,000,00 0	0	-2,400,000	-12,272,400,000
	BSE in CA	Test All	No BSE	0	0	- 1,099,200,0 00	-1,099,200,000
						-	,,
			BSE in CA	0	0	1,099,200,0 00	-1,099,200,000
				12,270,000,00		- 1,099,200,0	
		Demost	BSE in US	0	0	00	-13,369,200,000
		Repeat Test	No BSE BSE in	0	0	-2,400,000	-2,400,000
			CA	0	0	-2,400,000	-2,400,000
				- 12,270,000,00			
			BSE in US	0	0	-2,400,000	-12,272,400,000
	BSE in US	Test All	No DSE	-	0	- 1,099,200,0	7 220 200 000
l	03	Test All	No BSE	6,140,000,000	0	00	-7,239,200,000
			BSE in CA	- 6,140,000,000	0	1,099,200,0 00	-7,239,200,000
			BSE in US	- 12,270,000,00 0	0	- 1,099,200,0 00	-13,369,200,000
		Repeat Test	No BSE	6,140,000,000	0	-2,400,000	-6,142,400,000
			BSE in CA	- 6,140,000,000	0	-2,400,000	-6,142,400,000
				- 12,270,000,00			
			BSE in US	0	0	-2,400,000	-12,272,400,000

#### Tracking Costs

<u>Table 1</u> also shows the estimated costs of tracking and testing cattle that are included in the model. Annual cattle-tracking costs are calculated by multiplying an estimated unit cost-peranimal by the number of live cattle imported annually into the US from Canada. In 2002, prior

BSE detections. this number 1.538,715 cattle to any was (http://cattle.guelph.on.ca/statistics/livetrade-withus.html). The annual cost of tracking any newly imported cattle is estimated as \$10 to cover tags, labor, and compliance checks. The baseline total annual tracking costs for such cattle, assuming a return to 2002 levels of imports, are thus  $1,538,715 \ge 15,538,715$ . (Part of this cost may initially be borne by Canadian producers, but it is included in the model as the cost results directly from a Track Imports policy and may ultimately be passed on to US consumers.) The costs of locating and then tracking Canadian cattle already in the US are more difficult to estimate; they are addressed in the Sensitivity Analysis and Discussion sections.

#### **Testing Costs**

The Stage 1 testing costs in the US are obtained by multiplying a unit test cost-per-animal by the size of the assumed Stage 1 sample size. In FY2004, the USDA tested 20,543 cattle (http://www.usda.gov/Newsroom/0105.04.html). In the wake of the December, 2003 finding of a BSE-positive cow, the annual number of cattle sampled will probably be at least doubled, to around 40,000, in addition to one-time. much larger sampling efforts (http://usda.mannlib.cornell.edu/reports/nassr/livestock/pct-bb/catl0104.pdf). The per-animal unit has recently been estimated approximately \$30 test cost as (http://www.meatnews.com/index.cfm?fuseaction=article&artNum=7345). The Stage 1 annual testing costs in the US are therefore estimated as  $30 \times 40,000 = 1,200,000$ .

Approximately 36.6 million cattle were slaughtered in the US in 2003 (USDA, 2004). If each animal is tested at slaughter for a unit cost of \$30, then the baseline total annual US testing cost in Stage 2 for "Test All" is approximately \$30 per animal x 36.6M animals per year = \$1,098,000,000 per year. The corresponding cost for the "Test Canadian-origin cattle only" is estimated by assuming that the Canadian-origin portion of the US herd is approximately in steady state, that is, the number of Canadian origin cattle slaughtered annually is equal to the number imported. Thus, testing costs are 1,538,715 animals per year x \$30 per animal tested = \$45,161,450 per year.

In Canada, until recently, fewer than 4,000 cattle per year have been tested for BSE nation-wide. In 2002, for example, Canada tested a total of 3377 animals (http://www.inspection.gc.ca/english/anima/heasan/disemala/bseesb/bsefaqe.shtml). In 2003, 5500 tested, with 8000 2004 about cattle were plans for cattle in (http://www.cbc.ca/stories/2004/01/08/madcow 040108). Canadian testing costs are not included in our US policy model, but the numbers of animals tested are included since they affect the probability of detecting new BSE cases.

#### **Scenario Probabilities**

The probable consequences of current decisions, specifically, whether to Track Canadian cattle imports, depend on whether and where BSE is detected next. The probabilities of the different economic consequences in <u>Table 1</u>, i.e., of different rows, given the choices of Stage 1 and Stage 2 decisions, are modeled via the variables and formulas in <u>Table 2</u>.

Varia bles	Meaning	Formulas and Baseline Values
PI	proportion of US cattle tested that were imported from CA	1,538,715/36.6M = 4.0%
рса	probability a Canadian animal test is positive for BSE	See scenarios in <u>Table 3</u>
n <sub>CA</sub>	number of Canadian tests performed	See scenarios in <u>Table 3</u>
p <sub>US</sub>	probability a US animal test is positive for BSE	$p_{\text{USUS}}*(1 - P_{\text{I}}) + p_{\text{USCA}}*P_{\text{I}}$
n <sub>US</sub>	number of US tests performed	$n_{\rm USUS} + n_{\rm USCA}$
pusu s	probability US testing of an animal of US origin is positive	See scenarios in <u>Table 3</u>
pusc A	probability US testing of an animal of CA origin is positive	See scenarios in <u>Table 3</u>

**TABLE 2:** Probability Model and Notation for Scenario Outcomes

n <sub>USU</sub> s	number of US tests of animals of US origin	38,400 per year
n <sub>USC</sub> A	number of US tests of animals of CA origin	1,600 per year
	Pr{no new BSE cases}	$(1 - p_{CA})^{n_{CA}} (1 - p_{US})^{n_{US}}$
	Pr{case in CA}	$\approx (1 - (1 - p_{CA})^{n_{CA}})$
	Pr{case in US}	$\approx (1 - (1 - p_{US})^{n_{US}})$
	Pr{case is of US origin   US case}	$\approx 1 - (1 - p_{USUS})^{n_{USUS}}$
	Pr {case in US of Canadian origin   a US case}	$\approx 1 - (1 - p_{USCA})^{n_{USCA}}$
	Pr {case in US of US origin}	$\approx (1 - (1 - p_{US})^{n_{US}}) * \frac{1 - (1 - p_{USUS})^{n_{USUS}}}{1 - (1 - p_{USUS})^{n_{USUS}} + 1 - (1 - p_{USCA})^{n_{USCA}}}$
	Pr {case in US of CA origin}	$\approx (1 - (1 - p_{US})^{n_{US}}) * \frac{1 - (1 - p_{USUS})^{n_{USUS}}}{1 - (1 - p_{USUS})^{n_{USUS}} + 1 - (1 - p_{USCA})^{n_{USC}}}$

These formulas are based on a simple, approximate binomial model, in which only the average probability of detecting BSE per animal tested is used (for each of Canada and the US separately) and details of inter-animal variability are ignored. (In practice, the outcome probabilities in the table are renormalized to sum to 1, since ignoring the possibility of multiple BSE discoveries in the same year may lead to slight departures from 1.)

The probabilities  $p_{USUS}$ ,  $p_{USCA}$ ,  $p_{CA}$  are estimates of the probabilities of finding one or more BSE positive cattle among each batch of 1000 tested. (Probability per 1000 is more convenient than probability per animal, given the small probabilities involved, but either could be used.) Uncertainty about the correct values of these probabilities is modeled by using five possible scenarios or "states of nature", shown in <u>Table 3</u>. Columns 2-4 show the values of  $p_{USUS}$ ,  $p_{USCA}$ , and  $p_{CA}$  for each of the five scenarios.

#### TABLE 3. Scenario Definitions and BSE Detection Rates (per 1000 animals tested)

States of Nature	PUSUS	PUSCA	PCA	Prior Estimate
1	0	0	0	0.2
2	0	1.00E-04	1.00E-04	0.2
3	0	1.00E-06	1.00E-06	0.2
4	1.00E-06	1.00E-04	1.00E-04	0.2
5	1.00E-06	1.00E-06	1.00E-06	0.2

The values in <u>Table 3</u> for each scenario are averages for the entire US and Canadian herds. The rationale for these values is as follows. Past testing suggests that the BSE rate in cattle of US origin is likely very low or zero, since no confirmed cases have been discovered to date. The BSE rate in cattle of Canadian origin may be zero (if there are no new cases to be discovered), very low, or relatively high, with zero being perhaps somewhat less likely than the others, given the two BSE cases detected in 2003. The value corresponding to "relatively high" (1E-4 per 1000) is consistent with the rate provided by the World Organization for Animal Health (http://www.oie.int/eng/info/en\_esb.htm), which shows a 2003 incidence rate for Canada of .33 per million. The "very low" rate (1E-6 per 1000 animals) is a plausible high end estimate for the US that considers the large number of cattle slaughtered annually (~36.6M) without any cases detected thus far. We combined these considerations into the five scenarios shown. (Each scenario may also be viewed as the centroid of a cluster representing all possible scenarios that are closer to it than to any of the other four, in which case the discretization of all possible scenarios into only these five represents the relatively low degree of resolution permitted by current data.)

The selection of scenario prior probabilities is potentially controversial. We adopt the following bounding approach to avoid needless controversy. If the main conclusion from the analysis is that the *status quo* is justified (i.e., tracking of Canadian cattle imports is not recommended because the incremental costs exceed the value of the information provided), then little justification may be needed. By contrast, if the analysis shows that a change from the *status quo* to "Track Canadian imports" is recommended (because the value of the tracking information exceeds the costs of acquiring it), then more justification may be needed to persuade stakeholders to adopt the conclusion. Therefore, we will pick values of highly uncertain inputs (such as the scenario probabilities) to favor the *status quo*, so that if the analysis still recommends a change, the result will be relatively strongly supported despite uncertainties in the model inputs. (This intentional bias toward the *status quo* is not strictly rational, but recognizes

the reality that any recommended changes from the *status quo* may require an additional burden of robustness.) Given that the limited available evidence favors the hypothesis that Canadian BSE prevalence is higher than US BSE prevalence (as in scenarios 2 and 4), and that these scenarios imply relatively high information values for tracking Canadian cattle, we will use a *uniform distribution* of scenario probabilities as a conservative (i.e., *status quo* favoring) prior distribution, thereby giving more relative weight to scenarios 1 and 5 (no difference between US and Canadian cattle) than the available data might suggest. The uniform prior also represents a maximum-entropy prior, and in this sense imposes as few assumptions as possible.

In the current situation of limited BSE testing, animals that are considered most likely to have BSE are targeted. Testing data from Europe suggests that the BSE rate among this subpopulation is 60 times greater than that of the general cattle population. This factor is applied to the probabilities in <u>Table 3</u> to obtain the probabilities of positive test results among sampled cattle in Stage 1 with limited testing. The sampling factor will be subject to sensitivity analysis.

Let  $s_i \in S$  represent state of nature, *i* with initial probability  $ps_i$ . Then

- $P(y1|d1,s_i) = Probability of event y1 occurring, given that the first stage decision was d1 and the state of nature is <math>s_i$ , and
- $P(y1|d1) = \sum_{i=1}^{5} P(Y1|d1,s_i) ps_i$  = unconditional probability for event y1 given decision d1.

#### Second Stage Probabilities via Bayes Rule

The states of nature provide a basis for computing second stage probabilities via Bayesian updating. The first stage outcomes  $\{Y1 | d1\}$  provide information regarding the likelihood of the states of nature, allowing us to revise the estimates, ps<sub>i</sub>. Specifically,

$$ps'_{i} = \frac{P(Y1 \mid d1, s_{i})ps_{i}}{\sum_{j=1}^{5} P(Y1 \mid d1, s_{j})ps_{j}}$$

Then similar to the first stage:

$$P(y2|d1,d2) = \sum_{i=1}^{5} P(Y2|d1,d2,s_i) ps_i$$

The conditional probabilities  $P(y2 | d1, d2, s_i)$  are computed using the binomial formulas from stage one, but with the test quantities  $n_{USUS}$ ,  $n_{USCA}$ , and  $n_{CA}$  revised. In particular, if d2 indicates full testing (of all cattle or all cattle from Canada)  $n_{USUS}$ ,  $n_{USCA}$ , will be greatly increased to reflect full *vs.* partial testing. Second, the probabilities  $p_{USUS}$ ,  $p_{USCA}$ ,  $p_{CA}$  may be quite different than those in stage 1. In stage 1, the testing regime is targets "downer" cattle and others considered most likely to have BSE. In stage 2, under full testing, the probabilities of a positive batch are diluted by less likely animals and therefore may be much (e.g., 60-fold) lower.

#### **Solution Algorithms**

The decision tree in <u>Figure 1</u>, together with the quantitative data in Tables 1-3 which populate it, specify the base case risk management decision problem to be solved. A standard dynamic programming algorithm (<u>Raiffa, 1968</u>) provides the solution and allows variations of the problem with different input values to be solved to yield sensitivity analyses and to characterize the robustness of model recommendations to uncertainties in the input values. We used the TreePlan<sup>TM</sup> decision tree software package for Excel<sup>TM</sup> to solve the decision optimization problem for the base case and for sensitivity runs.

#### 3. RESULTS

#### Optimal Decision Rule for the Base Case

Under the baseline assumptions in Tables 1-3, the expected net cost of Track Imports is \$10,385,294 per year while the expected cost of Do Not Track Imports is \$90,045,020 per year. Thus, the expected net economic value of the information provided by tracking is \$79,658,726 per year, reflecting the much higher probability of large market losses when imports are not tracked, as BSE cases of Canadian origin in the US then are not distinguished from, and so have the same economic impact as, BSE cases of US origin. The optimal decision rule for the base case is as follows: *Track Canadian cattle imports, then continue limited sampling in Stage 2 no* 

*matter what occurs.* In other words, the benefit from tracking in this case does *not* come from avoiding the cost of 100% testing of US cattle, since this is too expensive to undertake. Rather, it comes from the reduced loss of US beef sales if the country of origin of a BSE case detected in the US is Canada and this can be ascertained and announced.

#### Sensitivity Analysis Results

The base case is of limited interest by itself, since it is not clear how robust the optimal current decision (Track Canadian imports) is to plausible variations in the inputs. However, the following sensitivity analysis results indicate that this recommended initial decision is very robust to key input uncertainties:

- Robustness to market benefit estimates. Suppose that the positive market impacts (of 1,382,000,000) for the US of another BSE discovery in Canada in some rows of <u>Table 2</u> may have been estimated incorrectly. What degree of error would change the optimal decision from "Track Canadian imports" to "Don't track Canadian imports"? The answer is that the optimal base case decision (Track CA imports) remains optimal when all positive market outcomes (those with a value of 1,382,000,000 in <u>Table 2</u>) are multiplied by *any* positive number, whether less than 1 (scaled down benefit estimate) or greater than 1 (scaled up benefit estimate). Indeed, the VOI for tracking remains positive for any benefit multiplier > -.58.
- Robustness to market loss estimates. Similarly, if all outcomes with a negative Market Impact in <u>Table 2</u> are multiplied by any positive factor (and, indeed, any factor > -1.57), the optimal Stage 1 decision remains Track Canadian imports. (The optimal second stage decision changes as a function of the scaling factor, with full testing of Canadian-only or all-US cattle becoming optimal for some values, but the VOI increases linearly for all positive values of the loss multiplier.)
- *Robustness to targeting efficiency*. Define the *targeting efficiency factor* as the ratio of the probability of a positive BSE test in a targeted animal *vs*. a purely randomly sampled animal. Its baseline value is 60. The VOI for tracking Canadian imports increases linearly as this

factor is increased, but becomes negative (expected cost > expected benefit) only for values less than 17.

- *Robustness to consumer loss of confidence.* Suppose that baseline negative consequences are multiplied by a "fear factor" when the Repeat Test decision is chosen at the second stage and the market impact is negative, to reflect greater-than-estimated consumer fear and adverse reaction (loss of confidence in beef safety) that could occur if BSE is found in the second stage, but only limited sampling (the "Repeat Test" decision in Figure 1) is used. The VOI for tracking Canadian imports increases as this factor is increased, by over 50% when the "fear factor" is 2 (i.e., if the loss of beef sales due to consumer fear is twice as great as estimated in the base case.) The optimal Stage 1 decision remains Track Canadian imports for *all* positive values of the "fear factor", indicating considerable robustness to uncertainty about how customers would react to further BSE cases. (Interestingly, the optimal Stage 2 decision shifts from *Repeat Test* to *Test All* if the first stage detects BSE in the US, and the fear factor is greater than about 1.20, as seems quite plausible.)
- Robustness to tracking costs. The base case assumes a tracking cost per animal per year of \$10. This cost could be as high as \$35.00 while leaving the VOI from tracking greater than zero. Therefore, for locating and tracking Canadian cattle already in the US appears to be worthwhile when the cost is less than \$35.00/head.
- *Robustness to scenario probabilities.* Figure 2 shows the results of varying the probability of each of the individual scenarios in <u>Table 3</u> from 0 to 1, while leaving the remaining probability spread evenly among the other four scenarios. The VOI (= desirability index for tracking imports) increases with the probabilities of scenarios 2 and 4 and decreases with the probabilities of scenarios 1, 3, and 5. Scenarios 2 and 4 are those with a high probability for BSE in CA and low (or zero) probability for BSE in the US. Scenarios 1, 3, and 5 each have a zero or very low probability of BSE in the US or CA. They have the potential for a negative VOI, but only at high values (exceeding approximately 0.78). All available data are most consistent with scenarios 2 and 4, which imply a positive VOI for tracking Canadian cattle.

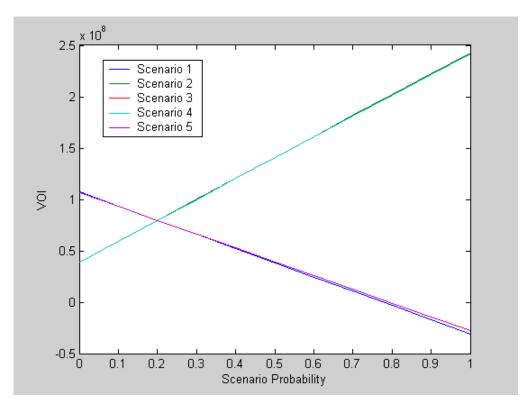


FIGURE 2: Sensitivity Analysis Plot for Scenario Probabilities

In summary, the optimal decision for the base case, Track Canadian imports, appears to be very robust to a wide range of plausible variations in the input data, as well as to combinations of variations (not shown). Thus, the model's recommendation to begin tracking appears to be well justified, even if conservative assumptions are made that tend to discount the value of tracking information. The economic value of tracking information in some sensitivity analyses comes primarily from limited export losses if the next case of BSE detected in the US can be shown to be of Canadian origin; while in others, it comes primarily from avoiding the need to test all US cattle, as opposed to just those of Canadian origin, to win back customers. Although the second-stage decisions that benefit from a first-stage decision to track Canadian cattle imports vary across sensitivity analysis cases, most of the sensitivity analyses agree that this is the optimal current decision, even while differing in their precise (Stage 2 planning) reasons.

#### Impacts of Possible Win-Back of Export Markets

The base case analysis and the assumptions in <u>Table 1</u> are perhaps pessimistic, in that they assume that the losses of US cattle and beef export markets following the discovery of a Canadian-origin BSE case in December 2003 are persistent and irreversible. Depending on the evolution of international risk perceptions and harmonization of risk management standards and

plans, it is possible that aggressive tracking and testing policies in the US might result in recovery of some lost export markets. If so, the economic impacts from tracking and testing could dwarf those calculated for the base case. For example, under an assumption that aggressive testing would allow the US to regain its lost exports (as long as no confirmed BSE case of US origin is discovered), the optimal strategy becomes to immediately start tracking all Canadian cattle and, if a confirmed BSE case of Canadian origin is found, to test all Canadian-origin cattle in the US prior to export. In this case, the expected net economic value of the information provided by tracking increases to \$771,570,514 per year, i.e., by close to an order of magnitude.

#### 4. DISCUSSION AND CONCLUSIONS

This paper has developed and applied a decision-analytic value-of-information (VOI) framework to identify robustly optimal decision recommendations for whether to track Canadian cattle imported into the US. The major conclusion is that the economic value of such information to the US greatly exceeds its costs for cattle that may be imported in future (by a ratio of 79,658,726 to 15,538,715  $\approx$  5 in the base case, and more in many sensitivity analyses). For "legacy" Canadian cattle that have already entered the US, moving quickly to locate and start tracking them before any additional BSE cases are detected appears to be well justified for almost any plausible set of input assumptions, provided that the cost per head is kept within bounds (e.g., up to \$35 per head, based on the sensitivity analyses for the base case). If the costs per head are too great to justify locating all legacy animals, then location and tracking efforts should focus on the oldest animals – those with the greatest risk of becoming new BSE cases.

The analysis in this paper has focused on potential economic consequences and risk management options for possibly mitigating them if another BSE case is discovered in the US. The possibility that some BSE cases might pose health risks of vCJD to humans reinforces the conclusions from this economic analysis, insofar as they make it even more important to be able to identify the origin of any new BSE cases quickly to enable effective targeting of interventions to reduce possible human health risks as soon and as fully as possible.

That tracking and testing may be imperfect has sometimes been advanced as a qualitative argument for restricting or rejecting them. The quantitative comparisons carried out in our sensitivity analyses suggest that this reasoning is usually not justified: measures that help to identify the origins and prevalence of BSE cases have high information value for improving future risk management decisions and creating additional risk management options, even if they are less than perfect.

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