Response to R-CALF

Claim 1: Regarding OIE guidelines for Minimal–Risk regions

To determine the risk category of a given country, the OIE recommends that a thorough risk assessment be conducted. This risk assessment should look at the criteria outlined in the OIE Code, such as number of years an effective feed ban has been in place, SRM removal, number of BSE cases, etc., and analyze the findings in their totality. The OIE guidelines are NOT specific international mandates, as misinterpreted by R–Calf, but rather are guidelines for countries to conduct risk assessments of potential trading partners. USDA's proposed rule, the final rule, and the risk analysis documents published for public comment contain an exhaustive analysis of all risk factors of the OIE guidelines for minimal–risk countries or zones and how Canada meets each individual criterion.

USDA's risk analysis looked at the OIE chapter in the manner it was intended to be used--that is, as a set of guidelines and recommendations, and not a prescriptive approach to regulation. Indeed, the preamble to the USDA rule states, "We stated in our proposal that we would use these standards (OIE Code) as a combined and integrated evaluation tool, basing a BSE minimal–risk classification on the overall effectiveness of control mechanisms in place (e.g., surveillance, import controls, and a ban on the feeding of ruminant protein to ruminants). We noted that this approach would differ from some of the numerical guidelines specified by OIE in its recommendations for a BSE minimal–risk country or zone..." For example, we have acknowledged that Canada's feed ban falls short of meeting the OIE feed ban criterion. **USDA's minimal–risk criteria are designed to consider an individual country's specific situation and to analyze risk based on the *overall* effectiveness of actions taken by the country to prevent the introduction and spread of BSE.** In regions where BSE has been diagnosed, USDA bases its evaluation on the overall effectiveness of all control measures in place, as well as all subsequent mitigation measures taken after the first BSE case has been detected.

It is also important to note that there is no reason to believe that ruminants were exposed to the non-ruminant feed that may have been derived from portions of the initial positive cow. Per the Canadian assessment: "The carcass of the index case was traced through the abattoir–renderer–feed mill–producer continuum to its direct allocation into pet food and poultry meal and its additional retail distribution across 1,800 farm sites. As earlier described, the associated cluster is typical of the pyramidal feed production and distribution relationship in Canada. Visits to the renderer and feed mills confirmed adherence to the MBM feed ban legislation on product receipt, segregation, labelling and distribution." Accordingly, there is no reason to believe that ruminants were exposed to this feed.

Claim 2: Regarding OIE recommendations for removal of specified risk materials

R–Calf has completely misunderstood the SRM removal recommendations of the OIE Code.

As a clarification, the OIE Article on SRM removal recommends, for countries of moderate and high BSE risk, the removal of tonsils and intestine at all ages and the removal of brains, eyes, spinal cord, skull and vertebral column from animals over 12 months of age. For countries determined to be of minimal–risk (like Canada), the OIE in fact recommends the removal of brains, eyes spinal cord, skull and vertebral column ONLY from animals that are 30 months of age and older at slaughter. Comparing systems in the UK, which has reported more than 185,000 cases and is classified as a high risk country, with Canada, which has had four indigenous BSE cases with an established surveillance system, is misleading. Given the low level of circulating BSE infectivity in minimal–risk countries such as Canada, USDA can safely allow trade in certain products with required mitigation steps to further ensure that BSE does not affect human or cattle health.

Claim 3: Regarding Canada's BSE surveillance testing

USDA cannot stress enough that BSE tests are not food safety tests – they are valid only for a statistically based surveillance system. (It is important to note that the removal of SRMs is the single most important action that can be taken to protect public health.) Europe and Japan have included testing healthy cattle at slaughter in their testing programs as a measure which they hope will restore consumer confidence. These countries do not conduct these tests for food safety purposes.

Current testing methodology can detect a positive case of BSE approximately 3 months before the animal begins to demonstrate clinical signs. The incubation period for BSE – the time between initial infection and the manifestation of clinical signs – is generally very long, on average about 4 years. Accordingly, there is a long period during which testing an infected animal with the current methodology would, wrongly, produce negative results. This is especially likely if the animal is clinically normal at the time samples are obtained for testing. One estimate is that current test methodology would have a false negative test rate of 92% for clinically normal adult cattle (i.e., if 100 BSE-infected adult cattle were tested while clinically normal, 92% of them would test negative even though they were, in fact, infected). If, however, the animal is exhibiting some type of clinical signs that could be consistent with BSE, then the test is much more meaningful and is not likely to produce false negative results. Since current tests only determine the presence of BSE shortly before the likely onset of symptoms, testing apparently normal animals presented for slaughter is not an effective use of the tests, and again, provides no assurance of food safety.

The OIE is very clear in stating that the likelihood of detecting BSE in cattle varies immensely among cattle sub–populations, and testing healthy cattle at slaughter is the least likely to produce results. For example, based on European data, it is estimated that finding BSE in cattle displaying clinical signs compatible with BSE is 100 times more likely than finding it in downers or dead on farms; and 5,000 to 10,000 times more likely than finding it in healthy, 30 month old cattle at slaughter.

Claim 4: Regarding international trade relations

The Minimal–Risk Rule (and identifying Canada as a minimal–risk region for BSE purposes) is designed to apply appropriate public and animal health mitigations to ensure protection of public and animal health while providing a standard for risk–based trade practices. **Unless USDA takes the lead to establish the concept of Minimal–Risk Regions, based on risk analysis, for animal pests and diseases—especially for BSE—the United States (which has multiple effective mitigation measures in place) will be vulnerable to having its exports treated no differently than those of countries with rampant levels of pests and diseases.** In implementing this rule, the United States is clearly seeking to ensure that ALL countries adopt scientifically sound, risk–based import and export standards and apply them equivalently. The United States cannot protest unjustified measures applied to our products if we similarly apply the same virtually impossible measures to others.

Furthermore, the OIE Code has never recommended banning the trade of cattle or their products even from countries with high BSE risk. Even under the current OIE guidelines, the United States could detect 50 or 60 BSE cases and not pose a threat of spreading the disease to other countries via exports because of the overall effectiveness of control mechanisms in place (e.g., surveillance, SRM removal, import controls, and a ban on the feeding of ruminant protein to ruminants). However, the United States' one detection (even though it was of a non–U.S. origin cow) has given other countries the excuse to ban our exports. Hence, there is a need to establish science-based regulations. By any measure, the United States presents a minimal risk of transmitting BSE. Likewise, we are convinced that Canada poses a minimal–risk to trading partners.

Resumption of imports from Canada may be seen by other countries as reflecting the United States' conviction as to the safety of U.S. and Canadian beef products, since the same or equivalent sanitary measures for BSE prevention are enforced by both countries, and since Canada and the United States are viewed by most countries as having a similar BSE risk. As clearly outlined in the Minimal-Risk final rule, USDA is confident that the animal and public health measures that Canada has in place to prevent BSE, combined with existing U.S. domestic safeguards and additional safeguards provided in the final rule provide the utmost protections to U.S. consumers and livestock. Consequently, USDA is optimistic that the rule and the assurances and protections it affords will ultimately alleviate certain restrictions on U.S. beef imports imposed by several of our trading partners.

Claim 5: Regarding feed ban protections in the United States

While APHIS is confident in both the U.S. and Canadian feed ban, it is vital to remember that the MBM feed ban is one important mitigation in a series of interlocking, overlapping, and sequential barriers to the introduction and establishment of BSE. The total effect of these mitigations reflects the combined results – in fact, the risk assessment examined the following five barriers that must be compromised before BSE could be transmitted to a U.S. cow from a Canadian animal: (1) U.S. import restrictions; (2) slaughter controls; (3) rendering inactivation; (4) feed manufacturing controls; (5) dose limitations.

Furthermore, we fully agree that any feed ban may not have perfect compliance – including in the United States and Canada – but based on scientific risk analyses in both countries we believe there is a

negligible risk that the BSE agent would amplify within the system. When concluding this risk to be extremely low, the Harvard study included the assumption of a "leaky" feed ban. Additionally, FDA data suggests that compliance with the feed ban in the United States has improved substantially over time. Even if an infected animal were to be imported into the United States from Canada, each of the remaining barriers outlined above reduces the level of infectivity in the system. APHIS remains confident that slaughter, rendering, and feed manufacturing controls should remove all of the residual risk in sequence.

And, R–Calf has again mis–stated OIE's recommendation of SRM removal for young cattle from a minimal–risk country such as Canada (addressed in response to Claim #2).

Claim 6: Regarding the likely age of BSE exposure

R–Calf's assumptions in applying the mean rate of incubation to determine the time of exposure to the BSE agent in the older cattle in Canada that have tested positive for BSE are incorrect and are scientifically unsound.

Susceptibility to BSE infection in cattle declines with age, and animals are most susceptible at a young age. In addition to this difference in susceptibility, the incubation period for BSE (i.e., the time it takes for the animal to exhibit clinical signs of the disease) is contingent on the dose of the infectious agent that an animal consumes. The combination of both of these factors - age at exposure and dose received - contribute to the incubation period. The incubation period can vary widely, but is generally 3-8 years. As noted in the APHIS risk assessment, an analysis of the data collected in the UK outbreak estimates the mean incubation period in that outbreak at 4.2 years, with 7.5 years estimated as the higher end of the incubation period. This assessment also noted that the UK epidemic represented the most intense exposure to BSE that has occurred, and that the same level of exposure is not likely to occur in Canada. The expected incubation period would be expected to be shorter in the UK, given the higher exposure, than in Canada.

The estimate of when an animal became infected is not calculated simply by subtracting an assumed mean incubation period from the date of its death. A wider range of factors that are generally identified in the epidemiological investigation must be considered. These include an identification of feeding history, among other factors. Unless there is significant evidence to the contrary, it is generally assumed that the time of infection is when the animal was most susceptible - i.e., within the first year of its life. Since Canadian cattle found positive for BSE have all been older, this indicates a low initial exposure (low exposure giving a longer incubation period). Only the most recent positive animal was born after the implementation date of the Canadian feed ban, but evi dence obtained in the epidemiological investigation have indicated the presence of feed obtained prior to the feed ban going into effect. Similar to the situation in the United States and elsewhere, a significant change in feed regulations can not immediately go into effect with 100% compliance instantly.

The final rule does use modeling assumptions to predict some infectivity rates, but it explains any assumptions and the final decision does not rely entirely on any individual assumption. The combination of all factors considered in Canada, including the fact that the feed ban was implemented prior to identifying the first case, led to the determination that the duration of the feed ban was adequate. Again, it is vital to view the feed ban as important, but one of several interlocking, redundant mitigation measures to prevent BSE transmission to U.S. animals from Canada.

Claim 7: Regarding BSE risk to consumers

While there are uncertainties about BSE, USDA and the international scientific community have learned from Europe the primary pathways of spread of this disease and put measures in place to prevent its dispersion. Based on internationally accepted scientific principles, and using guidelines recommended by the OIE, the United States has published a final rule (following extensive notice and comment rulemaking) to allow trade in certain products from countries that present a minimal risk. A thorough review of Canada has shown it to be in the minimalrisk category.

The final rule does seek to prevent U.S. exposure to BSE. In fact, USDA considered the following facts in its analysis:

- Import restrictions sufficient to minimize exposure to BSE: Since 1990, Canada has maintained stringent import restrictions, preventing the entry of live ruminants and ruminant products, including rendered protein products, from countries that have found BSE in native cattle or that are considered to be at significant risk for BSE.
- Surveillance for BSE at levels that meet or exceed international guidelines: Canada has conducted active surveillance for BSE since 1992 and exceeded the level recommended in international guidelines for at least the past 7 years.

- Ruminant–to–ruminant feed ban in place and effectively enforced: Canada has had a ban on the feeding of ruminant proteins to ruminants since August 1997, with compliance monitored through routine inspections.
- Appropriate epidemiological investigations, risk assessments and risk mitigation measures imposed as necessary: Canada has conducted extensive investigations in response to any BSE finding and has taken additional mitigation measures in response. These risk mitigation measures include, among others, prohibiting specified risk materials in human food.

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