

No. 05-35264

IN THE UNITED STATES COURT OF APPEALS FOR THE NINTH  
CIRCUIT

**RANCHERS CATTLEMEN ACTION  
LEGAL FUND UNITED  
STOCKGROWERS OF AMERICA**  
Plaintiff – Appellee,

v.

**UNITED STATES DEPARTMENT OF  
AGRICULTURE, Animal and Plant  
Health Inspection Service; et al.,**  
Defendants – Appellants.

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**MOTION FOR LEAVE TO FILE BRIEF OF *AMICI CURIAE*  
AMERICAN MEAT INSTITUTE, NORTH AMERICAN MEAT  
PROCESSORS, SOUTHWESTERN MEAT ASSOCIATION, EASTERN  
MEAT PACKERS ASSOCIATION, AMERICAN ASSOCIATION OF  
MEAT PROCESSORS, NATIONAL RESTAURANT ASSOCIATION, AND  
UNITED FOOD AND COMMERCIAL WORKERS**

Pursuant to Fed. R. App. P. 29, the American Meat Institute (“AMI”), North American Meat Processors (“NAMP”), Southwestern Meat Association (“SMA”), Eastern Meat Packers Association (“EMPA”), American Association of Meat Processors (“AAMP”), National Restaurant Association (“NRA”), and United Food and Commercial Workers (“UFCW”) hereby respectfully move this court for leave to file a brief as *amici curiae* in support of Appellants the United States

Department of Agriculture (“USDA”), Animal and Plant Health Inspection Service (“APHIS”), et al.

The above organizations represent virtually the entire spectrum of companies involved in packing, processing and selling of beef products in the United States as well as the workers employed by those companies and the major restaurant purchasers of beef products. Although all of these organizations and their members are significantly affected by the preliminary injunction issued by the court below, none of them was given an opportunity to participate in the proceedings before the district court, nor were their interests represented by the parties to those proceedings. In support of this motion, *amici* state as follows:

1: Interest of *Amici*

*Amicus* AMI is a non-profit, national trade association, whose members are the producers, packers, and processors of meat and poultry products marketed in the United States. AMI represents its members for purposes of furthering and protecting their interests, general welfare, and prosperity, and to foster improvements in the production of meat and allied products and to gather and disseminate practical and useful information, including scientific and economic information, relating to the meat industry. AMI member companies account for more than 75 percent of the United States output of beef products.

*Amicus* NAMP is a non-profit corporation, whose members are meat

processing companies and associates who share a continuing commitment to provide their customers with safe, reliable and consistent meat, poultry, seafood, game and other products.

*Amicus* SMA's members are meat processors, packers and purveyors, meat and meat product suppliers and service providers, livestock producers, financial institutions, and retail establishments. The primary focus of SMA's member companies is to produce products that meet or exceed consumer expectations with regard to product safety, nutrition and value. On behalf of its members, SMA initiates opportunities and resolves problems, thus helping to allow its member companies to earn a reasonable return on investment.

*Amicus* EMPA is a non-profit organization that has represented the interests of its members since 1927. Its membership consists primarily of small to medium-sized meat and poultry processing firms located in the northeastern United States. EMPA represents its members on a wide variety of public policy issues at the state and federal level and conducts various educational programs. Virtually all of its processing members utilize beef as a major ingredient in their processing operations.

*Amicus* AAMP is America's largest meat trade organization. AAMP's members include more than 1,700 medium-sized and smaller meat, poultry and food businesses: slaughterers, packers, processors, wholesalers, in-home food

service business, retailers, deli and catering operators, and industry suppliers.

*Amicus* NRA is a non-profit corporation and is the largest trade association representing restaurants in the United States. Membership in the Association includes over 325,000 establishments. The type of establishments include large chain restaurants, fine dining establishments and quick service restaurants.

*Amicus* UFCW is a union of working men and women from the United States and Canada who work in a wide range of industries including healthcare, meatpacking, poultry and food processing, manufacturing, distillery, winery, textile and chemical trades, and retail food. UFCW helps workers achieve better wages, better benefits, and safer working conditions.

In its appeal in this case, defendant-appellant USDA challenges a preliminary injunction granted by the district court, on motion of plaintiff-appellee Ranchers Cattleman Action Legal Fund United Stockgrowers of America (“R-Calf”), enjoining the implementation of a final rule that would have reopened the United States-Canadian border to importation of certain cattle and beef products from Canada after a nearly two-year suspension of such trade.

*Amici’s* member companies rely on beef supplied by producers, like R-Calf, for their businesses. Already, because of the border closure, the lack of competition from Canada has diminished the supply of cattle in the United States and raised domestic cattle prices. This has provided an economic windfall for R-

Calf and other cattle producers. Processors, packers, and restaurants, like *amici's* members, however, have been forced to purchase their beef supplies at these artificially inflated prices. Thus, *amici's* members' costs have been driven upward and their profit margins have been significantly decreased.

As a result, many of *amici's* members have found it necessary to reduce their businesses. Some have even contemplated closing facilities. Therefore, *amici's* members have a substantial economic interest in the reopening of the United States border to the importation of cattle and beef products from Canada.

Indeed, AMI's interest in the final rule is so substantial that AMI filed suit in a separate action in the United States District Court for the District of Columbia, asserting that it is scientifically unsupportable to distinguish, for importation purposes, between live animals 30 months of age or older and beef from those same animals or between animals 30 months of age or older and animals under 30 months of age. Therefore, AMI argued, the scientific evidence supports extending the final rule to permit importation of all cattle and cattle products from Canada, not just some.

Should this Court affirm the district court's injunction, the injury to *amici's* members and to the United States' beef processing, beef packaging, and restaurant industries will continue. Moreover, *amicus* AMI's ability to protect its interests by pursuing its claims in the District of Columbia will be severely impaired.

2. Why the proposed *amici* brief is desirable and why the matters asserted are relevant to the disposition of the case

*Amici* are uniquely positioned to present to the Court with complete evidence and argument in support of the final rule. Indeed, *amici* can present views in support of reopening the border to Canadian cattle and cattle products that the Government cannot, in light of the limited nature of the border reopening permitted by the final rule.

First, *amici*, as representatives of companies and workers in the United States beef and restaurant industries, are uniquely positioned to provide the Court with information regarding the harms that will result if the ban on importation of Canadian cattle and beef products is continued. The Government simply does not have the same first-hand knowledge or access to resources relating to industry harm as *amici*.

Second, the nature and extent of the arguments that the Government can provide to support opening the border is constrained by APHIS' compromise position in the final rule, *i.e.*, that cattle under 30 months of age and beef from that same cattle may be imported into the United States, but that cattle 30 months of age or older and beef from cattle 30 months of age or older are prohibited from importation. Because of that position, the Government's hands are tied with regard to its ability to present this Court with all arguments in favor of opening the United States border to Canadian cattle imports. The Government must limit its

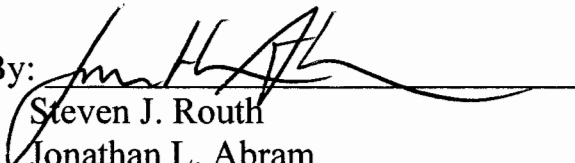
arguments so as to remain consistent in APHIS's decision to permit importation of *some but not all* cattle and beef products from Canada.

*Amici*, in contrast, face no such constraints. They can present all evidence and arguments supporting the reopening of the United States border for importation of Canadian cattle and beef products. Unlike APHIS, *amici* need not worry about revealing the illogic of distinguishing, for importation purposes, between cattle and beef from cattle 30 months of age or older and cattle and beef from cattle under 30 months of age. Indeed, *amici* will show that these distinctions are irrational and that the evidence and science require return to fully free trade.

Thus, *amici* respectfully submit that the evidence and arguments set forth in its brief will assist the Court in its consideration and disposition of this case. Given the importance of the issues to be decided in this case, the Court should have the benefit of *amici's* views.

Respectfully submitted,

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## **CORPORATE DISCLOSURE STATEMENT**

Pursuant to Fed. R. App. P. 26.1, American Meat Institute (“AMI”) states that it has no parent corporation and that no publicly held corporation owns 10% or more of AMI’s stock.; North American Meat Processors (“NAMP”) states that it has no parent corporation and that no publicly held corporation owns 10% or more of NAMP’s stock; Southwestern Meat Association (“SMA”) states that it has no parent corporation and that no publicly held corporation owns 10% or more of, SMA’s stock; Eastern Meat Packers Association (“EMPA”) states that it has no parent corporation and that no publicly held corporation owns 10% or more of EMPA’s stock; American Association of Meat Processors (“AAMP”) states that it has no parent corporation and that no publicly held corporation owns 10% or more of AAMP’s stock; National Restaurant Association (“NRA”) states that it has no parent corporation and that no publicly held corporation owns 10% or more of NRA’s stock; and United Food and Commercial Workers (“UFCW”) states that it has no parent corporation and that no publicly held corporation owns 10% or more of UFCW’s stock.

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## INTRODUCTION

After refusing even to hear from parties with significant interests at stake, including the American meat industry and the Government of Canada, the court below issued a nationwide preliminary injunction against implementation of a USDA rule that would have reopened the United States border to importation of certain Canadian cattle and beef products. The district court did so at the request of a narrow interest group – Appellee R-Calf, the membership of which is comprised of domestic cattle producers – seeking to protect against renewed competition from Canada. Because the district court refused to consider interests such as those of the American meat industry, it could not possibly have engaged in the balancing of interests required before issuing preliminary relief. When those interests are considered – along with the statutory presumption of an open border with Canada and the powerful scientific grounds compiled by USDA for reopening the border to cattle and beef products – it is clear that the district court’s injunction should be reversed. Indeed, while USDA may be faulted for not going far enough in reopening the border completely, there are no grounds for enjoining the limited resumption of trade authorized by the USDA rule.

*Amici* on this brief are representatives of the broader meat industry in the United States, the union that represents workers in that industry, and restaurants around the country seeking a safe and competitively priced meat supply. We will

first set forth reasons why the United States border should be reopened completely, and thus why, *a fortiori*, the district court erred in enjoining the partial reopening permitted by the USDA rule. The Appellants' brief ably defends the agency's decision to reopen the border to cattle under thirty months ("UTM") in age and meat from those cattle. But the Government is constrained in defending a reopened border by the Secretary's decision to leave the border closed to Canadian cattle over thirty months ("OTM") in age – a decision contradicted by scientific evidence and by international standards. Thus, before this Court, the Government has attempted to walk the fine line drawn by the USDA rule, arguing that the scientific evidence supports resumed importation of UTM cattle and beef products but not necessarily OTM cattle. Because we are not limited to defending the reopening of the border with one arm tied behind our backs, *Amici* here will summarize the scientific findings and evidence in the rule-making record that clearly support resumed trade in all Canadian cattle and beef products, UTM and OTM alike. Indeed, as discussed below, federal law requires resumption of trade in Canadian cattle and beef products, that the findings of the agency mandate it, and that the district court was manifestly wrong in enjoining the limited resumption of trade contemplated by the USDA rule.

This brief also will summarize the significant harm facing the American meat industry, its workers and customers, and ultimately the United States

consumer, because of the district court's ill-conceived preliminary injunction. To be sure, protection against competition from Canada has allowed some United States cattle producers, including R-Calf members, to increase prices, but when combined with the decreased supply of cattle from Canada, that has meant lost business for American meat processors, lost work for their employees, and higher beef prices for restaurants, consumers, and other buyers of beef products. While these effects will not be eliminated until the border is reopened to all Canadian cattle and beef imports, the final rule would have gone some distance toward ameliorating the adverse impacts of the original closure. Having heard from R-Calf alone, however, and believing inaccurately that continuing a closed border would be "largely harmless," the district court entered an injunction that, unless reversed, will perpetuate lost business and lost jobs in American plants that already have suffered for too long due to misperceptions concerning the risks posed by BSE in North America. Accordingly, the district court's order granting injunctive relief should be reversed.

### **INTEREST OF *AMICI***

The several *amici* represent a wide array of organizations concerned about the district court's unnecessary and unjustified closing of the border. Joining in this submission are organizations that represent the vast majority of U.S. meat processors and packers, which buy cattle and beef and sell beef products,

restaurants that purchase huge amounts of beef products, and workers in the meat industry concerned for their jobs. The American Meat Institute and the National Association of Meat Processors are the two largest association of meat processors in the United States. The American Association of Meat Processors represents small meat packing and processing operations, both here and in Canada. The Southwestern Meat Association represents processors and others in the meat industry in the southwestern part of the United States. The Eastern Meat Packers Association represents small to medium-sized meat and poultry processing firms located in the northeastern part of the United States. The United Food and Commercial Workers represents meat industry and other commercial workers throughout North America. The National Restaurant Association is the nation's the largest association of restaurant operators, representing over 325,000 restaurant establishments here in the United States in an industry that employs over 12 million people, making it the largest private sector employer in the country. Each has a strong interest in assuring a safe meat supply, protecting both the American consumer and the American cattle herd from BSE and BSE-related infection, and assuring that the United States market is not closed to imported meat supply unnecessarily.

## **BACKGROUND**

Prior to May 20, 2003, the United States and Canadian cattle and beef industries operated largely as a single integrated North American industry with both live cattle and processed beef flowing freely between the two countries. That not only was consistent with the history of free trade with Canada but also was required by U.S. law and an international trade agreement, which provide that trade across the border must remain free unless a restriction is shown to be necessary to prevent the introduction into the United States of a livestock disease, and even then the restriction may remain in place only as long as the necessity does. Thus, prior to 2003, Canadian cattle and beef products were routinely imported and sold in the United States, and decisions whether to process cattle in Canada and ship their meat to the United States or, alternatively, to ship cattle into the United States for slaughter and processing in this country were driven by free market forces.

On May 20, 2003, a single cow in Canada was diagnosed with BSE, commonly known as “mad cow disease.” BSE is a “progressive neurological disorder that results from infection by an unconventional transmissible agent” and is spread when cattle consume feed infected with BSE-infected animal proteins. 70 Fed. Reg. 460, 486 (USDA Jan. 4, 2005). BSE is not transmitted by cattle-to-cattle contact like some bacterial or viral diseases. Therefore, the mere presence of a BSE-infected animal does not present a risk of contamination to other animals in

a herd. Id.

In response to the discovery of the BSE-infected cow in Canada, APHIS exercised its emergency rulemaking authority and issued the Initial Border Closing Order, which suspended importation from Canada of ruminants and ruminant products. 68 Fed. Reg. 31939, 40 (USDA May, 29, 2003). For its part, Canada immediately conducted an extensive investigation of the May 2003 BSE occurrence and took action to guard against spread of the disease, including the quarantining and depopulation of herds and animals that might have been at risk for BSE. 68 Fed. Reg. 62386, 62387 (USDA Nov. 4, 2003). Those actions supplemented earlier actions taken by Canada to address BSE, including a 1990 ban of imports into Canada from the United Kingdom and Ireland and a 1997 implementation of a “feed ban,” equivalent to the United States’ own 1997 feed ban, which prohibits the feeding of ruminant proteins to ruminants.

Following completion of its investigation and thorough safeguarding against any spread of BSE from the infected cow, Canada requested that the United States reopen its borders to restore the free trade in ruminants and ruminant products that the two countries had enjoyed prior to May 20, 2003. 68 Fed. Reg. at 62387.<sup>1/</sup>

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<sup>1/</sup> In August 2003, the United States began to allow importation of a restricted set of boneless beef products from Canada. Those products continue to be imported into the United States. 70 Fed. Reg. at 536.

## **November 4, 2003 Proposed Rule**

In response to Canada's efforts, APHIS published a proposed rule on November 4, 2003, 68 Fed. Reg. 62386, under which the United States would recognize what APHIS termed "minimal-risk regions" with regard to BSE and allow the importation of ruminants and ruminant products from these regions. Id. at 62387. In doing so, APHIS relied in significant part on standards promulgated by the Organization for International Epizootics ("OIE"), a world animal health organization. Id. at 62389.

APHIS further concluded that Canada qualified as a minimal-risk region. Id. In reaching this conclusion, APHIS reasoned that (1) Canada has maintained stringent import restrictions on live ruminants and ruminant products since 1990; (2) Canada has conducted surveillance for BSE in accordance with OIE guidelines since 1992; (3) Canada implemented a "feed ban" in 1997 that prohibits the feeding of most mammalian protein to ruminants – essentially the same as the feed ban in place in the United States; and (4) Canada has conducted an extensive and thorough investigation and eradication program after the discovery of the BSE infected cow in May 2003. APHIS also noted that the infected cow was born prior to the time Canada implemented its feed ban in 1997. Id. at 62389-90; see also 21 C.F.R. § 589.2000 (United States Food and Drug Administration "feed ban"). The November 2003 Proposed Rule was limited, however, in that it would have

allowed importation from Canada only of animals under 30 months of age and meat from animals that were slaughtered when under 30 months of age. 68 Fed. Reg. at 62391.

### **December 23, 2003 BSE Diagnosis in the United States**

On December 23, 2003, a cow in the United States was found to be infected with BSE. 69 Fed. Reg. 10633, 10634 (USDA Mar. 8, 2004). This cow had been imported from Canada at approximately 4 years (or 48 months) of age and was not diagnosed with BSE until it was approximately 6 years and 8 months (80 months) old. Id. Significantly, the cow was born prior to the date in 1997 when Canada implemented its “feed ban,” which has been recognized as the principle means of preventing ruminant-to-ruminant spread of BSE infectivity. 70 Fed. Reg. at 467.

In response to this discovery, the United States and Canada worked together to enhance their BSE risk-mitigation measures. As a result, the two countries have equivalent BSE risk-mitigation measures in place. 69 Fed. Reg. at 10635. In addition to the measures discussed above, aimed at preventing any spread of BSE among cattle, both countries adopted “belt and suspenders” rules aimed at assuring that no infected tissue can enter the human food supply. Those rules distinguish between UTM and OTM animals because, if an animal were to have BSE, infectivity could find its way to more tissues over time. Thus, the rules require removal of the small intestine and tonsil in UTM cattle but all Specified Risk

Materials (“SRMs”) in OTM cattle. 70 Fed Reg. at 465. <sup>2/</sup> Additionally, as indicated above, both countries have had equivalent feed bans prohibiting feeding ruminant products to other ruminants in place since 1997 and other BSE risk-mitigation measures. 70 Fed. Reg. at 467.

### **January 4, 2005 Final Rule**

After issuing a second proposed rule and receiving extensive public comment, APHIS published a final rule on January 4, 2005, that eliminated the requirement that beef imported from BSE minimal-risk regions be derived only from cattle less than 30 months of age, as long as appropriate safety measures are in place in the exporting region. 70 Fed. Reg. 460. The final rule maintained the distinction between cattle 30 months of age or older and cattle under 30 months of age for purposes of importation of live animals from Canada. *Id.* at 461. Thus, the final rule left the interim rule’s ban on importation of OTM cattle in place, but permitted importation of meat from those same animals – essentially assuring Canadian processors a significant advantage in processing OTM cattle. The final rule was scheduled to go into effect on March 7, 2005.

### **AMI’s Challenge to the Final Rule**

The continued prohibition against importation of OTM cattle threatened to

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<sup>2/</sup> SRMs include the tonsil, small intestine, brain, spinal cord, and eyes. 70 Fed. Reg. at 466. The U.S. requires removal of the tonsil from UTM cattle; Canada has that same requirement for UTM cattle exported to the U.S. *Id.* at 497.

perpetuate the injury faced by the American meat industry. Many members of *amici* are processors and packers of beef, and some process only “cows” and “bulls,” which are older cattle – generally over 30 months of age. To be sure, the final rule ameliorated some of the adverse impact of the Initial Border Closing Order by allowing import of UTM animals. But by prohibiting the importation of live OTM cattle into the United States for processing at United States plants while allowing Canadian plants to process the very same animals and then sell their meat into the United States market, the final rule failed to completely eliminate import restrictions and made matters worse by causing some of *amici’s* members and other United States processors to lose substantial business to their Canadian counterparts who remained free to process OTM animals from Canada.

For that reason, AMI filed suit in the District of Columbia challenging the Secretary’s decision to continue the agency’s ban on importation of OTM cattle, a ban that was completely unsupported by any scientific evidence that importation of such animals posed a threat to the American cattle herd, meat industry, or consumer. AMI v. DeHaven, No. 1:04CV02262 (D.D.C., filed Dec. 30, 2004). AMI presented compelling evidence that no rational basis remains for excluding OTM animals from Canada. AMI demonstrated that international standards on which USDA purported to rely actually require fully open borders in the situation presented here in North America. And AMI showed that the remaining ban on

OTM cattle imports was inconsistent with the agency's own decisions to allow import of UTM animals and of beef from cattle of any age. AMI showed that the 30-months age limitation has nothing to do with the likelihood that a particular animal is infected with BSE, especially since both the United States and Canada closed off the only known transmission vector for BSE some seven years ago by banning the use of animal protein in cattle feed. And AMI showed it made no sense for the agency to allow imports of beef from OTM animals processed in Canada – meat that the agency found was safe for import -- and not allow imports of OTM animals for processing in the United States. Presumably seeing that his rule was indeed nonsensical on this point, the Secretary promptly changed it. Without making any findings that meat from OTM animals is unsafe for consumption or that Canadian plants are any better than those here in this country, the Secretary decided that he would continue to ban import of meat from OTM animals anyway. 70 Fed. Reg. 12112, 12113 (USDA Mar. 11, 2005).

### **R-Calf's Suit to Keep the Border Closed**

Shortly after AMI filed suit to restore an open United States-Canada border, R-Calf filed its suit to keep the border closed. R-Calf is an organization representing a narrow segment of the United States beef industry, certain producers of cattle in the United States, who have a strong interest in keeping the border closed to cattle from competing Canadian producers. It sued in Montana, where it

had litigated related issues before.

Representatives of the American meat industry sought to intervene, but the Montana District Court denied their motion. Incredibly, the District Court also refused to allow the Government of Canada to present its views, even as *amicus curiae*. Having excluded those critical voices, District Judge Richard Cebull then granted R-Calf's motion to preliminarily enjoin enforcement of USDA's rule, effectively banning importation of cattle that would compete with those produced by R-Calf's members without hearing from other segments of the American beef industry. Shortly after receiving Judge Cebull's preliminary injunction order, the District Court in the District of Columbia announced that it would not issue the injunction sought by AMI for restoration of a fully open border.

Major segments of the American beef industry are now engaged in a fight for economic survival, due in significant measure to economic dislocations caused by the Canadian border closing. Undeniably, producers of cattle, including R-Calf's members, have an economic interest in keeping the border closed so that their cattle will command a higher price free of competition with Canadian cattle. But that is contrary to the interests of those who buy and process cattle and beef, those who earn their livelihood in the meat industry, and those who operate restaurants and other purchasers of beef products, all of whom share a critical interest in assuring that the North American market operates efficiently, without

unnecessary import restrictions unsupported by sound science. Judge Cebull's order prevents a return to the open border that is legally required now that it is clear no scientific basis remains for keeping it closed.

## ARGUMENT

### **I. The District Court Abused Its Discretion By Mandating Continued Closure Of The Border to Canadian Cattle and Beef Products.**

#### **A. United States and International Law Require Open Borders Unless Closure is Necessary to Prevent Introduction of a Disease of Livestock.**

The Animal Health Protection Act establishes a presumption that the Secretary will not restrict international trade and permits the Secretary to prohibit or restrict importation only if he determines – rationally and consistent with law – “that the prohibition or restriction is necessary to prevent the introduction into or dissemination within the United States of any pest or disease of livestock.” 7 U.S.C. § 8303(a)(1). That requirement is fully in keeping with U.S. obligations under the North American Free Trade Agreement (“NAFTA”) and the General Agreement on Tariffs and Trade 1994 (“GATT 94”).<sup>3/</sup> NAFTA states that one of its primary objectives is to “eliminate barriers to trade in, and facilitate the cross-border movement of, goods and services between the territories of the Parties[.]” NAFTA, art. 102(1)(a). To that end, NAFTA requires each signatory country to

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<sup>3/</sup> Congress enacted NAFTA into law when it passed the North American Free Trade Agreement Implementation Act, Pub.L. No. 103-82, 107 Stat.2057 (1993). Congress similarly implemented GATT 1994 by passing the Uruguay Round Agreements Act of 1994, Pub.L. 103-465, 108 Stat. 4809 (1994).

“ensure that any sanitary or phytosanitary measure that it adopts, maintains or applies is applied only to the extent necessary to achieve its appropriate level of protection, taking into account technical and economic feasibility.” NAFTA, art. 712(5). To the extent a phytosanitary measure is necessary, it must be based, *inter alia*, on “scientific principles” and “not maintained where there is no longer a scientific basis for it[.]” NAFTA, art. 712(3). <sup>4/</sup>

**B. The Scientific Evidence Makes Clear that Continued Closure of the Border is Unnecessary and Therefore Violates U.S. and International Law.**

In their opening brief, Appellants have summarized the compelling scientific evidence that supports USDA’s decision to reopen the border to UTM cattle and beef products derived from them. Gov’t Br. at 22-43. As the Government has explained, Canada has long banned importation of live cattle and beef products, virtually insulating itself from the serious BSE outbreak that has resulted in over 187,000 confirmed cases of BSE in cattle worldwide, 95% in the United Kingdom. The Government has shown that the infinitesimal incidence of BSE in North America is unsurprising because of the many overlapping risk-mitigation measures implemented in Canada and the United States. It has ably catalogued the

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<sup>4/</sup> Similarly, the General Agreement on Tariffs and Trade 1994, Agreement On The Application Of Sanitary And Phytosanitary Measures requires that “Members shall ensure that their sanitary and phytosanitary measures do not arbitrarily or unjustifiably discriminate between Members where identical or similar conditions prevail, including between their own territory and that of other Members.” GAAT 94, art. 2 ¶3 (emphasis added).

“equivalent” measures taken by our two countries over the past two decades, including feed bans implemented by both countries on the very same day over seven years ago, blocking the only known transmission vector for BSE by prohibiting the use of ruminant protein or products in feed. It has described Canada’s BSE-tracking system, every bit as comprehensive as that here in the United States, and it has described Canada’s program of BSE testing, which far exceeds international standards and equates proportionally to that in the United States. As the Secretary found after exhaustive analysis, the science demonstrates that these measures will prevent the establishment or spread of BSE in Canada, just as they have and will in the United States.

The Government also has described the many overlapping measures taken in Canada and here to prevent transmission of BSE to humans. First among these is the requirement that SRMs be removed when cattle are slaughtered – whether here or in Canada -- to assure that tissues susceptible to BSE infectivity are nowhere to be found in the human food chain.

In all of this, the Government is undeniably correct. The American meat industry, its workers, and buyers of meat products all share a strong interest in assuring the safety of the American meat supply and in maintaining consumer confidence in that supply. We fully support USDA’s decision to reopen the border to UTM cattle and beef because doing so is demonstrably safe, both to the

American consumer and to the American herd. In fact, if the agency can be faulted, it is because it did not go far enough. Although its own findings support full reopening of the border, the agency needlessly left the border closed to OTM animals, asserting that it had more work to do and another rulemaking to conduct before deciding to reopen the borders completely. The same science that supports reopening the border to UTM cattle and beef products also supports reopening the border to OTM animals and products as well. That is so for two reasons.

- 1. The Secretary's Determination that Importing UTM Cattle and Beef Products is Safe Also Establishes that Importing OTM Cattle and Beef Is Safe.**

The Secretary's decision to limit imports to UTM animals and beef was cautious to a fault, because continued ban on imports of OTM animals and beef is demonstrably unnecessary. That is because there is no rational basis for using 30 months of age as a measure in assessing the risk that an animal may be infected with BSE in either Canada or the United States. There is nothing that happened thirty months ago – and there is nothing about a 30-month-old cow – that has any bearing whatsoever on that risk assessment.

Instead, as explained above and acknowledged by USDA in issuing the final rule, the UTM/OTM distinction was developed for, and is relevant to, the SRM-removal requirement. As an infected animal ages, the BSE agent can spread from the small intestine or tonsil to certain additional tissues like the spinal cord.

Because there is scientific evidence that links the spread of infectivity beyond small intestine and tonsil to time frames that at least roughly correspond to 30 months, it is rational to require removal of a greater number of SRMs from OTM cattle than from UTM cattle at the time of slaughter. No one disputes that. And both Canada and the United States agree, for they both have implemented SRM-removal requirements calling for removal of more types of tissue from OTM animals than from UTM animals.

But there is no basis in science or logic to distinguish between UTM and OTM cattle for purposes of deciding whether to allow importation. That decision depends on the risk that an animal may be BSE-infected in the first place; it has nothing to do with the tissues likely to harbor the disease, since in all cases, whether UTM or OTM, those tissues will be removed at slaughter.

In its brief, the Government relies on its OTM ban as another barrier to importation of BSE-infected cattle. In explaining why that is so, the Government says that “the 30-month rule also ensures that all cattle imported will have been born long after Canada imposed its feed ban in 1997.” Gov’t Br. at 27. But while the 30-month rule is certainly a barrier, the same could be said of a 5-month rule, or a 70-month rule; either would assure that imported cattle were born after Canada’s feed ban was imposed some 92 months ago, in August 1997. Indeed, the Secretary accounted for the possibility that BSE might be found in additional

animals born “at or near the time the feed ban was implemented.” Gov’t Br. At 29, citing 70 Fed. Reg. at 514. Accordingly, there simply is no reason to believe that animals present any greater risk of carrying BSE regardless of whether they are over or under ten months, twenty months, thirty months, forty months, fifty months, sixty months, or seventy months. 5/

That is confirmed under internationally accepted OIE standards, on which the Secretary relied in the rule. 70 Fed. Reg. at 463; Gov’t Br. at 8-9. Under OIE’s standards, live cattle of all ages could be imported from Canada into the United States, as long as the cattle have identification markers (as Canadian cattle do) and as long as they were born after the implementation of the region’s feed ban. OIE Terrestrial Animal Health Code, 12 edition, 2004 Article 2.3.13.11. As stated above, Canada implemented a feed ban at the same time we did, in 1997. Thus, under the OIE Code, Canadian cattle born after the implementation of Canada’s feed ban in 1997 could be imported into the United States. See Attachment A, (Declaration of Alex Thiermann) (“Thiermann Decl.”) ¶ 3 & Ex. 1.

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5/ Although cattle born before the U.S. and Canada fully implemented their mirror-image feed bans in 1998 may present a somewhat higher risk of BSE infectivity, that increased risk necessarily is associated only with animals well over 80 months in age at present. And that age cut-off will increase as more time passes since the feed ban was fully implemented.

**2. The Secretary's Determination that Importing Beef From OTM Animals is Safe Also Establishes that Importing OTM Cattle is Safe As Well.**

The Secretary's decision to continue to ban imports of OTM animals is demonstrably unnecessary for the additional reason that the final rule specifically allowed for importation into the United States of beef and beef products from Canadian cattle regardless of whether the cattle were UTM or OTM. 70 Fed. Reg. 460, 461. As recently as February 2, 2005, APHIS explained that it was confident that the final rule, including provisions authorizing importation of meat from OTM cattle, "provide the utmost protections to U.S. consumers and livestock." Attachment B, (APHIS's February 2, 2005 "Factsheet," issued after the most recent discovery of a BSE-infected animal in Canada) (emphasis added).

In its own lawsuit, AMI showed that it made no sense to exclude OTM cattle from Canada while permitting importation of meat from those same cattle. Beef from OTM animals is no safer if the cow is slaughtered and the beef produced in Canada than if the same is done here in the United States. As noted, the same SRM-removal requirements apply north and south of the border, and the Secretary has never even intimated, much less found, that Canadian plants are more reliable than United States processing plants in removing SRMs. See 70 Fed. Reg. at 466 and Gov't Br. At 23 (FDA inspections reveal high level of compliance with U.S. feed ban).

Recognizing – indeed, effectively conceding – the strength of that argument, the Secretary on February 9, 2005 reversed USDA’s position on meat from OTM cattle. He issued a statement announcing that he felt “it is prudent to delay the effective date for allowing imports of meat from animals 30 months and over,” without citing any scientific evidence that such meat is unsafe or offering any other rationale for reversing the considered position that had been set forth in the final rule a month earlier and confirmed by APHIS only days before.

The Secretary was right the first time, and his February 9, 2005, Statement provides no basis for disregarding or altering any of the findings or scientific evidence included in the final rule issued only a month earlier. Although the February 9 statement makes reference to “recent finds of BSE in Canada in animals over 30 months,” three of the four BSE-infected animals discovered in Canada were known to USDA before January 5, 2005, and yet it published the final rule opening the border to meat from OTM cattle because it had considered the possibility of future BSE cases in Canada. The February 9 Statement provides no basis, moreover, for concluding that the one BSE-infected cow discovered in Canada after January 5, 2005 supports reversal of USDA’s position of only a month earlier or that opening the border to meat from OTM cattle would present an unacceptable risk to any health or safety interests in the United States. That is particularly true in light of the fact that all BSE-infected cattle discovered in

Canada were more than 80 months old, born before the feed ban was fully implemented. Thus, the only reasoned agency findings are those set forth by USDA in issuing the final rule, and those findings all support the decision in the final rule to permit importation of meat from Canada from UTM and OTM cattle.

Thus, far from being the imprudent action R-Calf claims, the Secretary's decision to reopen the border was cautious, sound, and erred only in not going far enough. The historically open border with Canada was closed in May 2003 upon discovery of a single BSE-positive animal in Alberta. Now, after almost two years of study, the Secretary correctly determined in the final rule that the science supports restoring an open border for UTM cattle and beef products. That same science supports – and federal and international law therefore mandate – a return to the fully open border that we have historically enjoyed with Canada. At a minimum, the Secretary should be freed to implement the agency's well-supported decision with respect to UTM animals and beef.

## **II. The Lower Court's Injunction Will Perpetuate Significant Injury To The American Meat Industry and Beef Consumers Due To The Closing Of The Border To Canadian Cattle And Beef Products.**

Judge Cebull issued his injunction after refusing to allow representatives of the American meat industry to be heard. Instead, he heard from the one segment of that industry with an economic interest in keeping the borders closed to Canadian cattle – select producers of cattle here in the United States. As a result, the

balancing of hardships required by this Circuit could not be and was not done. Instead, the District Court simply assumed that delaying implementation of the rule would be “largely harmless.” Opinion at 27, R-Calf v. USDA, et al., CV-05-06-BLG-RFC (D. Mont. Mar. 2, 2005). Nothing could be further from the truth.

The border was closed as an emergency measure in May 2003. Since then, huge market distortions have arisen. Cattle that would otherwise have been imported for slaughter and processing in the United States have accumulated in Canada. Freed from competition with Canadian cattle producers, producers here in the United States have raised the price of their cattle dramatically. The result has been a boon for R-Calf members. But it has been a disaster for most of the American beef industry, which relies on competitively priced cattle. The many companies to whom access to Canadian cattle is of special importance have been hurt particularly severely by nearly two years of effective embargo. Now, with the lower court’s injunction, that will continue, with resulting job losses and other economic dislocation, and with no end in sight.

During modern times, the border with Canada justifiably has been one of the most open in the world. In 2002, Canada exported nearly a million head of cattle for slaughter and processing in the United States. In May 2003, when the border was closed, the United States was importing some 16,000 head of “fed” or younger cattle and around 4,000 head of “non-fed” older animals (referred to as “cows” and

“bulls) per week. America’s meat industry, restaurants, and consumers all relied on that supply of cattle to serve the very substantial demand for beef here in this country and to enable exports of beef around the world, including some 20 million pounds a month back to Canada.

That supply of Canadian cattle disappeared with the border closing. With reduced supply of cattle, many American processing plants were forced to close or reduce their labor force, resulting in painful layoffs, with resulting job and earnings losses to the typically small, rural communities hosting the plants. Because of reductions in force at one company alone, Long Prairie, Minnesota suffered job losses resulting in payroll reductions of almost \$2.5 million and overall lost household earnings of over \$11 million in 2004, with similar losses at the company’s other plants in Gibbons, Nebraska, South St. Paul, Minnesota, and Yankton, South Dakota. Losses like these faced companies throughout the meat packing industry, which historically has accounted for one of every 16 rural manufacturing jobs in this country.

The lack of competition from Canada allowed U.S. cattle producers like R-Calf’s members to increase prices dramatically. The Canadian market for exports from the U.S. declined as the supply of Canadian cattle ballooned and the prices of cattle and beef dropped north of the border. In August 2003, USDA began to allow imports of boneless beef from Canada to resume, at least from animals under

thirty months of age at slaughter. 70 Fed. Reg. 460, 536. Canadian processors shifted to younger animals whose beef could be exported to the United States. But this meant that U.S. processors suffered while their counterparts in Canada enjoyed a captive supply of cattle and access to the United States market for their boneless beef products. Cattle slaughter dropped nearly 8% in the United States compared to the year before, while slaughter operations in Canada increased 24% in 2004.

Like all market distortions, the border closing had winners and losers. Canadian consumers enjoyed lower prices at the expense of Canadian cattle producers, due to the pent up supply north of the border. And, freed from Canadian competition, U.S. cattle producers including R-Calf's members were able to raise their prices. But American slaughter houses and meat packers saw their business drop off for lack of Canadian supply, American workers lost jobs, and American consumers, restaurants, and other buyers of beef products paid significantly higher prices.

The impact on American slaughter and packing operations will only get worse as long as the injunction remains in effect, as Canada ramps up capacity to take advantage of artificially low prices of Canadian animals and the available American market for boneless products. As noted, Canadian firms increased slaughter capacity some 24% in 2004 alone.

Obviously, the agency's decision to leave the import ban in place with

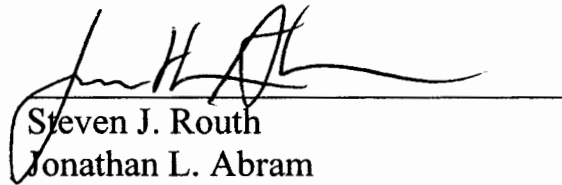
respect to OTM animals means that some of the market disruption will remain even without the injunction. In issuing its final rule, the agency noted that because of the continued prohibition against importing OTM animals, Canada's backlog of cattle 30 months months of age and older will remain until the expected increase in Canada's cow slaughter reduces that inventory. Final Rule, Economic Analysis at 15, 70 Fed. Reg. at 537. But with the injunction in place, that will be true of UTM animals as well. Effectively, the slaughter and processing business would continue to shift north to Canada as the supply of animals remains captive north of the border while available markets for boneless products are open here in the States.

While these effects will not be eliminated until the border is reopened to all Canadian imports, the final rule would have gone some distance toward ameliorating the adverse impacts of the original closure. And as USDA found, it would do so with no significant risk of BSE, either to the American herd or to the American consumer. Instead, having heard from R-Calf and believing that continuing the ban would be "largely harmless," the district court has perpetuated losses and business impacts that have already gone on far too long. Its order granting injunctive relief should be reversed.

## CONCLUSION

For these reasons, *amici* respectfully support Appellants' request that the order of the District Court be reversed and the preliminary injunction vacated.

Respectfully submitted,



Steven J. Routh  
Jonathan L. Abram

Lisa Cylus  
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202-637-5681

Counsel to Amici American Meat  
Institute, North American Meat  
Processors, Southwestern Meat  
Association, Eastern Meat Packers  
Association, American Association of  
Meat Processors, National Restaurant  
Association, and United Food and  
Commercial Workers

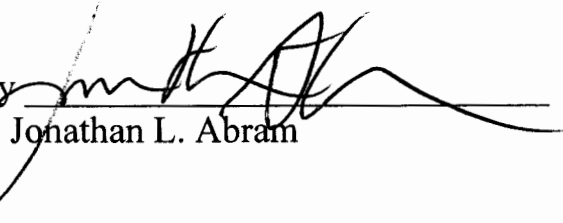
**CERTIFICATE OF COMPLIANCE WITH FED. R. APP. P. 32 (a) (7) (B)  
AND NINTH CIRCUIT RULE 32-1**

Pursuant to Federal Rule of Civil Procedure 32 (a) (7) (B) and (C) and Ninth Circuit Rule 32-1, I certify that the attached Brief of *Amici Curiae* American Meat Institute, North American Meat Processors, Southwestern Meat Association, Eastern Meat Packers Association, American Association of Meat Processors, National Restaurant Association, and United Food and Commercial Workers is proportionately spaced, has a typeface of 14 points or more and contains 6181 words.

Respectfully submitted,

HOGAN & HARTSON, L.L.P.

By

A handwritten signature in black ink, appearing to read 'Jonathan L. Abram', is written over a horizontal line. The signature is stylized and cursive.

Jonathan L. Abram

Date: April 21, 2005

## CERTIFICATE OF SERVICE

I hereby certify that on the 21st day of April 2005, I have caused two true and accurate copies of the Motion for Leave to File and Brief of Amici Curiae American Meat Institute, North American Meat Processors, Southwestern Meat Association, Eastern Meat Packers Association, American Association of Meat Processors, The National Restaurant Association and United Food and Commercial Workers and the Motions for Admission of Steven J. Routh and Jonathan L. Abram to be served by first class mail, postage pre-paid to:

Mark B. Stern  
Michael S. Raab  
Joshua Waldman  
Eric D. Miller  
U.S. Department of Justice  
Civil Division, Room 7256  
950 Pennsylvania Avenue, N.W.  
Washington, DC 20530-0001

A. Clifford Edwards  
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William L. Miller  
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Fourth Floor  
Washington, DC 20007

I also certify, that on the 21<sup>st</sup> day of April, 2005, I filed the original and 15 copies of the foregoing brief by causing them to be sent by Federal Express overnight delivery to:

Ms. Cathy Catterson  
Clerk, United States Court of Appeals for the Ninth Circuit  
95 Seventh Street  
San Francisco, CA 94103-1526

  
\_\_\_\_\_  
Robert Gruwell



IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF COLUMBIA

AMERICAN MEAT INSTITUTE,

Plaintiff,

v.

W. RON DEHAVEN,  
in his official capacity as  
ADMINISTRATOR,  
ANIMAL AND PLANT HEALTH  
INSPECTION SERVICE

and

ANN M. VENEMAN,  
in her official capacity as  
SECRETARY,  
UNITED STATES DEPARTMENT  
OF AGRICULTURE

Defendants.

Civil Action No. 1:04CV02262

DECLARATION OF ALEX THIERMANN

I, Alex Thiermann, declare and state the following:

1. I am the President of the Terrestrial Animal Health Standards Commission of the World Organization for Animal Health ("OIE").
2. OIE is an internationally recognized authority on animal health issues and currently has 167 member countries, including the United States and Canada.

3. Attached as Exhibit 1 to this declaration is a letter from David Wilson, Head of OIE's International Trade Department, to Jonathan Abram of the law firm Hogan & Hartson, L.L.P., which accurately reflects OIE's objectives with regard to developing international health standards for trade in animals and animal products, as well as OIE's standards and guidelines for prevention of Bovine Spongiform Encephalopathy, or "BSE."

I declare under penalty of perjury that the foregoing is true and correct.

Executed on January 26, 2005

  
\_\_\_\_\_  
Alex Thiermann

**EXHIBIT 1**

**TO**

**DECLARATION OF ALEX THIERMANN**

**(January 18, 2005 Letter from David Wilson to Jonathan Abram)**



Organisation Mondiale de la Santé Animale  
World Organization for Animal Health  
Organización Mundial de Sanidad Animal

18 January 2005

Jonathan Abram  
Hogan & Hartson  
555 13th Street, N.W.  
Washington, D.C. 20004  
202-637-5681  
202-365-2200 (cell)

Dear Mr Abram

I would like to pass on the following information to you in response to the questions you posed to Dr. Alex Thierman, President of the Terrestrial Animal Health Standards Commission, regarding the OIE *Terrestrial Animal Health Code* chapter on BSE.

The OIE develops and publishes two international health standards for trade in animals and animal products, the *Terrestrial Animal Health Code (Terrestrial Code)* and the *Aquatic Animal Health Code (Aquatic Code)*. It also develops and publishes two equivalent *Manuals*. These standards are developed by elected Specialist Commissions, using the latest scientific information, and adopted by OIE Member Countries during the OIE General Session each May, by consensus.

The aim of the two *Codes* is to facilitate the safe international trade of animals and animal products. This is achieved through the detailing of health measures for the diseases listed by the OIE to be used by the veterinary authorities or other competent authorities of importing and exporting countries to establish health regulations for the safe importation of animals and animal products. Thus they aim to avoid the transfer of agents pathogenic for animals or humans, without the imposition of unjustified trade restrictions.

In general, each chapter in Part 2 of the *Terrestrial Code* addresses a single disease and is designed to prevent the disease in question being introduced into the importing country. The measures recommended by the Member Countries of the OIE for BSE are found in Chapter 2.3.13 of that *Code*.

This chapter starts (Article 2.3.13.1) with a list of commodities which are considered not to require any disease-specific measures (irrespective of the BSE status of the exporting country) and a list of commodities which are considered to require the measures described in the chapter relevant to the BSE status of the cattle population of the exporting country. Implicit in this statement is an inference that such commodities should require no additional measures. The second list includes cattle, and fresh meat and meat products.

The chapter then describes (Article 2.3.13.2) how to determine the BSE status of the cattle population of an exporting country, including the factors which should be taken into account in conducting a risk assessment, and other relevant criteria (such as surveillance systems and farmer awareness programmes).

Articles 2.3.13.3 to 2.3.13.7 describe the conditions which must be met in order for the cattle population of a country or zone to be considered to have a certain status for BSE eg provisionally free, minimal risk.

The subsequent articles in the chapter contain the recommended health measures to be applied to commonly traded commodities, taking into account the likelihood of the pathogen being transmitted through that commodity and the BSE status of the exporting country or zone. Commodities addressed include live cattle, certain types of bovine embryos, fresh meat and meat products, gelatin and tallow. These articles are designed to be applied by importing countries after they have determined the BSE status of the cattle population of a trading partner through a risk assessment and an examination of the other criteria listed in Article 2.3.13.2. The surveillance programmes in place and the number and distribution of cases found in the exporting country would form part of that determination.

The particular article applied to trade, for example in live cattle, would depend on the assessed status of the exporting country. As the OIE has not determined the BSE status of either Canada or the USA, this assessment is a matter between the respective importing and exporting countries. If the importing country has assessed the exporting country as presenting a minimal BSE risk, Article 2.3.13.10 applies to the importation of live cattle. If the assessment is that a moderate BSE risk is presented, Article 2.3.13.11 applies and, for a high BSE risk exporting country, Article 2.3.13.12 applies. You will note that it is not recommended that a ban be placed on the import of live cattle, even if the BSE status of the exporting country is determined to be high.

I hope that this information has assisted you.

Yours sincerely

A handwritten signature in black ink, appearing to read 'David Wilson', with a long horizontal flourish extending to the right.

David Wilson  
Head  
International Trade Department  
OIE



## 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 evidence 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 minimal risk 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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