Docket No. 05-35214

IN THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

NATIONAL MEAT ASSOCIATION, Defendant-Intervenor – Appellant v. UNITED STATES DEPARTMENT OF AGRICULTURE, Animal And Plant Health Inspection Service, et al. Defendants - Appellees, And RANCHERS CATTLEMEN ACTION LEGAL FUND UNITED STOCKGROWERS OF AMERICA, Plaintiff – Appellee.	Appeal from D.C. No. CV-05-06-BLG-RFC, District of Montana, Billings **BRIEF OF APPELLANT NATIONAL MEAT ASSOCIATION**

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CORPORATE DISCLOSURE STATEMENT

Pursuant to Fed. R. App. P. 26.1, Appellant National Meat Association ("NMA") states that it has no parent corporation and that no publicly held corporation owns 10% or more of NMA's stock.

I. JURISDICTIONAL STATEMENT

A. Basis for District Court's Subject Matter Jurisdiction, With Citations To Applicable Statutory Provisions And Stating Relevant Facts Establishing Jurisdiction:

National Meat Association ("NMA") seeks to intervene in this action where Plaintiff Ranchers Cattlemen Action Legal Fund United Stockgrowers of America ("R-CALF") seeks a declaration that a Final Rule promulgated by U.S. Department of Agriculture ("USDA") and Animal and Plant Health Inspection Service ("APHIS") to allow importation of healthy live cattle and beef products from Canada is unlawful. R-CALF also seeks to enjoin implementation of the Final Rule. In its Complaint, R-CALF asserts jurisdiction under 28 U.S.C. § 1331 (federal question); 28 U.S.C. § 1346 (United States as a defendant); 5 U.S.C. § 701 *et seq.* (Administrative Procedure Act); 5 U.S.C. § 611(a) (Regulatory Flexibility Act), and 42 U.S.C. § 4821 *et. seq.* (National Environmental Policy Act).

B. Basis For Court Of Appeals' Jurisdiction, With Citations To Applicable Statutory Provisions And Stating Relevant Facts Establishing Jurisdiction:

The District Court denied NMA's motion to intervene as of right under FED. R. CIV. P. 24(a) and motion to intervene by permission under FED. R. CIV. P. 24(b). The denial of a motion to intervene is an appealable "final decision" under 28 U.S.C. § 1291. *United States v. City of L.A.*, 288 F.3d 391, 397 (9th

Cir. 2002); *Donnelly v. Glickman*, 159 F.3d 405, 409 (9th Cir. 1998).

The District Court granted R-CALF's motion for a preliminary injunction barring Defendants from implementing the Final Rule on March 7, 2005 as provided by the published notice of the Final Rule. The Court of Appeals has jurisdiction under 28 U.S.C. § 1292(a)(1) to review an interlocutory order granting a preliminary injunction.

C. The Filing Dates Establishing The Timeliness Of The Appeal:

The District Court entered its Order denying NMA's motion to intervene on February 24, 2005. The District Court entered its Order granting Plaintiff's motion for preliminary injunction on March 2, 2005. NMA's counsel delivered NMA's Notice of Appeal to the District Court Clerk for filing on March 9, 2005. The Court of Appeals entered its Order granting NMA's emergency motion to expedite appeal on March 11, 2005.

D. An Assertion That The Appeal Is From A Final Order Or Judgment That Disposes Of All Parties' Claims, Or Information Establishing The Court Of Appeals' Jurisdiction On Some Other Basis:

This appeal is from two orders of the District Court. The denial of intervention motion is an appealable "final decision" under 28 U.S.C. § 1291. *Donnelly,* 159 F.3d at 409; *City of L.A.*, 288 F.3d at 397. This Court has jurisdiction over the District Court's interlocutory order granting a preliminary injunction under 28 U.S.C. § 1292(a)(1).

II. STATEMENT OF THE ISSUES PRESENTED FOR REVIEW

A. Whether the District Court erred in denying NMA's motion to intervene under FED. R. CIV. P. 24(a) and (b) to protect the interests of its members in a suit challenging the importation of live cattle from Canada, where the Defendant USDA has determined on the basis of a well-reasoned and extensive rulemaking record that such imports do not pose a risk to the health of either U.S. citizens or U.S. livestock and where NMA's members have urgent economic interests that are not represented by either the Defendants or the Plaintiff.

B. Whether the District Court erred in denying NMA's motion to intervene and as a consequence of that error failed to require that the Plaintiff post bond to secure and indemnify NMA's members who slaughter cattle against irreparable injury which is already being caused by the Preliminary Injunction which has been sought and obtained by Plaintiff.

C. Whether the District Court erred in granting Plaintiff's motion for a preliminary injunction barring the importation of live cattle from Canada where both USDA, after an extensive rulemaking proceeding, and Plaintiff's own expert concluded that the public would not be put at risk from such live cattle imports and where the preliminary injunction causes immediate and irreparable injury to NMA's members who slaughter cattle in the U.S.

III. STATEMENT OF THE CASE

Bovine spongiform encephalopathy (BSE) was identified in a Canadian cow on May 20, 2003, and on May 29, 2003, APHIS, the internationally recognized USDA agency charged with protecting U.S. citizens and U.S. livestock from foreign and domestic animal disease, acted promptly to bar the importation of live cattle and bovine products from Canada. Change in Disease Status of Canada Because of BSE, 68 Fed. Reg. 31939 (May 29, 2003). USDA commenced a rulemaking to authorize resumption of live cattle imports from Canada on November 4, 2003. BSE Minimal Risk Regions and Importation of Commodities, 68 Fed. Reg. 62386 (proposed Nov. 4, 2003) (to be codified at 9 C.F.R. pt. 93-95). After a second Canadian born cow was identified as infected with BSE, this time in the State of Washington, USDA reopened its comment period and invited additional submissions to its rulemaking record.

On January 4, 2005, USDA published the BSE Minimal Risk Regions and Importation of Commodities Final Rule, 70 Fed. Reg. 460 (Jan. 4, 2005) (to be codified at 9 C.F.R. Parts 93-96) ("Final Rule") determining that the importation from Canada of live cattle under 30 months of age and beef products under conditions specified in the Final Rule would present no significant risk to the health of U.S. consumers or U.S. livestock. The Final

Rule was based on an extensive 12,650 page rulemaking record developed over a 14-month period to which more than 3,000 comments had been submitted.

Within a week following publication of the Final Rule, Plaintiff R-CALF filed suit in the U.S. District Court for the District of Montana, Billings Division, seeking to enjoin implementation of the Rule. R-CALF further sought a declaration that the Final Rule was unlawful. On February 1, 2005, R-CALF filed its Memorandum of Points and Authorities in Support of Plaintiff's Application for Preliminary Injunction ("PI Brief"). On that same day, February 1, 2005, NMA, pursuant to FED. R. CIV. P. 24, moved to intervene, primarily to oppose Plaintiff R-CALF's challenge to the Final Rule and its application for a preliminary injunction. The District Court denied NMA's motion to intervene on February 24, 2005.

The District Court granted R-CALF's application for a preliminary injunction on March 2, 2005 prohibiting the importation of live cattle from Canada, but allowing the continued import of Canadian beef products. The preliminary injunction's effect is to ban U.S. slaughterhouses from access to healthy, relatively inexpensive Canadian cattle while unfairly forcing them to compete with imported Canadian beef prepared from these same cattle. The preliminary injunction has created an unfair imbalance in the marketplace. Unless it is dissolved, U.S. jobs will be lost, U.S. businesses will close, and

meat-packing capacity will move from the U.S. to Canada. American consumers will pay artificially high prices for meat in the grocery store. This harm will be irreparable. The lost jobs will not reappear. The closed U.S. businesses will not reopen. No one will compensate the American consumer for the money that was wasted because of artificially high beef prices.

IV. STATEMENT OF FACTS

NMA is a non-profit industry organization with its principal office in Oakland, California. NMA has served the interests of the meat packing industry since 1946. The over 500 members of NMA include meat packers and processors, equipment manufacturers and suppliers throughout the U.S. NMA is a well-recognized voice on important issues of meat policy, processing and safety in the U.S. NMA provides regulatory assistance to its members, participates in the legislative process and administrative rulemakings, and represents member interests in judicial proceedings affecting the health and well-being of consumers and the meat industry. Excerpts of Record ("ER") 64.

BSE is a very serious disease that occurs in cattle. BSE was first identified in the United Kingdom in 1986, when a major epidemic is estimated to have infected more than one million cattle and to have caused more than 100 human deaths from variant Creutzfeld Jakob Disease ("vCJD"), which is caused by human consumption of highly infected cattle tissue. The federal, state and provincial meat inspection programs in both Canada and the U.S. require the exclusion from human food of Specified Risk Materials ("SRMs"), which are the tissues that have been shown to contain infectivity in an infected animal, 70 Fed. Reg. at 491, from the human food supply. There have been no

cases of vCJD attributable to consumption of Canadian or U.S. beef products. *Id.* at 503.

BSE spreads among cattle, when they are fed rations that contain meat and bone meal from infected cattle. *Id.* at 531. This is the only documented route of BSE transmission in cattle. *Id.* at 530. The feeding of ruminant protein to ruminant animals has been banned in the U.S. and Canada since August 1997. *Id.* at 512. Neither BSE nor vCJD is a conventional infectious disease like smallpox or AIDS, which are spread by personal contact. The only proven route of transmission for either disease is the consumption of highly infected tissue. *Id.* at 462, 531.

BSE was identified in a Canadian cow on May 20, 2003. On May 29, 2003, APHIS, the internationally recognized USDA agency charged with protecting U.S. citizens and U.S. livestock from foreign and domestic animal disease, barred the importation of live cattle and bovine products from Canada. 68 Fed. Reg. 31939. USDA commenced a rulemaking to authorize resumption of live cattle imports from Canada on November 4, 2003. 68 Fed. Reg. 62386. After a second Canadian born cow was identified as infected with BSE, this time in the State of Washington, USDA reopened its comment period and invited additional submissions to its rulemaking record. BSE Minimal Risk

Regions and Importation of Commodities Reopening of Comment Period. 69 Fed. Reg. 10633 (March 8, 2004).

On January 4, 2005, after an extensive and careful rulemaking, based on a 12,650 page administrative record and analysis by teams of experts, over a span of 14 months, of all relevant information and more than 3,000 public comments[1], USDA's APHIS promulgated the Final Rule, allowing live cattle and boxed beef to be imported from Canada beginning on March 7, 2005. 70 Fed. Reg. at 460. This new rule is based on the Secretary's careful determination that the importation of these live cattle and beef products would present essentially no risk to human health and that control measures in place in the U.S. and Canada would protect U.S. livestock from the introduction or spread of this disease.

While the 14-month-long rulemaking process had been triggered by the discovery in May 2003 of a cow infected with BSE in the Province of Alberta, the rulemaking record shows that USDA had been taking steps to protect both human health and animal health against this disease since the 1980s. The response of USDA to the discovery of a cow with BSE in Alberta in May 2003, had actually begun 14 years earlier in 1989, when APHIS closed the U.S.

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[1] *See* ER 128-147 for excerpts of the 94-page index of the USDA Administrative Record ("AR"). The full USDA AR has been provided to the Clerk of this Court on computer disks.

borders to imports of ruminants from the United Kingdom. *Id.* at 462.

APHIS's planning and preparation continued through the 1990s. In 1997 the U.S. and Canada engaged in coordinated action to implement their ruminant-to-ruminant feeding bans. *Id.* at 512.

In 1998, USDA commissioned a "quantitative analysis" from the Harvard School of Public Health and the Tuskegee University Center for Computational Epidemiology to evaluate the risk that BSE would spread in the U.S. livestock population in the event that one or more cases of BSE were to be discovered in the U.S. *Id.* at 464. That study was completed in 2001 and submitted to peer review, which was completed in 2002. *Id.* at 467. In 2003, after the discovery of the BSE case in Alberta, APHIS asked Doctors Cohen and Gray at Harvard to update their study, taking into account developments in Canada and U.S. *Id.*

During the ongoing rulemaking, Plaintiff and others submitted comments.[2] As part of its January 4, 2005, *Federal Register* notice and publication of the Final Rule, APHIS carefully addressed the substantive comments submitted and explained its expert judgment that it is now

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[2] APHIS specifically addressed comments raised by R-CALF and its expert in *The Analysis of Risk Update for the Final Rule: Bovine Spongiform Encephalopathy; Minimal Risk Regions and Importation of Commodities, December 2004* that APHIS issued with the Final Rule. The full 107-page Risk Assessment is included in the full AR of the Final Rule filed with the District Court (AR 11983) and is also available on the APHIS BSE website: http://www.usda.gov/lpa/issues/bse/bse.html.

appropriate to resume the importation of live cattle under 30 months of age from Canada. *Id.* 460.

At the time APHIS first banned importation of live cattle from Canada, the majority of Canadian cattle were exported to the U.S. for slaughter. These cattle were slaughtered in the U.S. by NMA members. The effect of the APHIS ban on the importation of live cattle from Canada has been to force NMA's members who slaughter cattle to rely exclusively on U.S. suppliers of livestock. As a result, the price of cattle in the U.S. has increased and the price of cattle in Canada has decreased. ER 77. Due to increased supplies, cattle prices in Canada presently are substantially lower than cattle prices in the U.S. *Id.* Since August 2003, USDA has allowed imports of Canadian boneless beef, but barred imports of Canadian live cattle, and Canadian beef exports to the U.S. are higher today than they were prior to the discovery of BSE in Canada in May 2003. ER 76A. This circumstance has created a gross inequity of allowing meat imports while prohibiting cattle imports and has caused U.S. packers to close plants, lay off U.S. workers, and cut shifts. ER 77. The inequity has caused meat-packing capacity to relocate to Canada and has caused U.S. consumers to pay artificially high prices for meat.

On January 10, 2005, R-CALF filed Cause No. CV-05-06-BLG-RFC, in the U.S. District Court for the District of Montana, Billings Division. ER

189, 3. Plaintiff R-CALF seeks to have the Final Rule declared unlawful and to stop all exports of live cattle and all beef products from Canada to the U.S. The Defendants USDA and APHIS seek to implement the Final Rule. Plaintiff R-CALF filed its application for a preliminary injunction and supporting memorandum on February 1, 2005. ER 3.

On that same day, February 1, 2005, NMA filed in the District Court a Motion to Intervene as Defendant and Cross-Claimant and for Expedited Briefing Schedule. ER 46, 191. In its motion, NMA, as a Defendant, sought to intervene under FED. R. CIV. P. 24(a) and 24(b), seeking to have R-CALF's Complaint dismissed and R-CALF's request for injunctive relief denied. ER 60-70. NMA, as a Plaintiff, challenged the provisions of USDA's Final Rule which would have newly authorized the importation of meat from Canadian cattle 30 months and older without authorizing the importation of this class of cattle.[3] ER 67. NMA also moved the Court to order an expedited briefing schedule on NMA's Motion to Intervene in order to allow the parties and the

[3] In its Motion to Intervene, NMA sought to both be an Intervenor/Defendant and a Cross Claimant for the purpose of opposing the entry of meat from Canadian cattle over 30 months of age, where Canadian cattle over 30 months of age were not permitted to enter the U.S. When the Secretary of Agriculture announced on February 9, 2005, that the agency was re-examining portions of the Final Rule dealing with over 30 month cattle and beef products therefrom, NMA filed a Supplement to its Motion to Intervene on the following day and subsequently only sought to intervene as an Intervenor/Defendant.

Court to proceed with the Court's January 28, 2005 scheduling order regarding R-CALF's Motion for Preliminary Injunction. ER 46.

The District Court denied NMA's Motion to Intervene in an Order issued February 24, 2005, finding that NMA did not have a significant protectable interest relating to the property or transaction that is the subject of the action or satisfy any of the other requirements for intervention as a matter of right under FED. R. CIV. P. 24(a) or for permissive intervention under FED. R. CIV. P. 24(b). ER 148-153.

The District Court held a hearing on R-CALF's Motion for Preliminary Injunction on March 2, 2005. ER 195. Since NMA's Motion to Intervene had been denied, NMA was not permitted to participate in the hearing. On March 2, 2005, the District Court announced from the bench its Order granting Plaintiff's Motion for Preliminary Injunction. ER 195. Later that day, the court issued its 28-page Opinion, more than 75 percent of which, including at least one typographical error, is taken in unedited form from R-CALF's PI Brief. ER 156-182.[4]

[4] NMA includes in its Excerpts of Record a version of the District Court's March 2, 2005 Order with those parts of the Order highlighted that repeat R-CALF's brief, verbatim. ER 156-182. A word count shows the text of the Order contains 8,246 words of which only 2040 are original.

V. SUMMARY OF THE ARGUMENT

NMA seeks expedited emergency relief in this proceeding because of the substantial, ongoing irreparable injury that is occurring to its members who slaughter cattle. The structure of the cattle slaughter industry in North America has been pushed to a fragile tipping point by the preliminary injunction which forces U.S. slaughter houses to compete with imported Canadian meat while being unable to obtain imported Canadian cattle.

Since 2003, U.S. beef processors have been faced with sharply reduced U.S. cattle supplies resulting from herd liquidation as cattlemen responded to drought and low returns. ER 89. This supply situation was further worsened when the Canadian border was closed to cattle previously imported to supplement U.S. supplies. ER 89. USDA indicates that cattlemen are now beginning to rebuild their herds, but this will not increase the available supply of slaughter cattle for at least two years. *Id.* Meanwhile the already reduced slaughter cattle supply situation is further exacerbated because cattlemen are now retaining more heifers and holding back cows in order to expand their breeding herds. *Id.* At the same time that U.S. cattle herds have shrunk significantly, the size of Canada's cattle herd has grown substantially and major packers in Canada are expanding their plant capacities. *Id.* Consequently,

while beef packers in the U.S. struggle to find cattle to fill their under-used capacity while experiencing negative returns, Canadian processors are expanding capacity and exporting their boneless beef to compete with the U.S. packers who are experiencing higher costs and lower volumes, thereby threatening the survival of these U.S. packing plants and the jobs in the rural communities that are dependent upon them. ER 89, 76A-77.

This financial pressure on NMA's members, which is an interest not represented by either USDA or R-CALF, is the primary reason that NMA filed its Motion to Intervene, and is also the primary reason why NMA seeks immediate, emergency and expedited relief from the District Court's Order, which prevents the entry of cattle from Canada, despite USDA's expert agency's rational and careful determination that such entry presents no risk to human health or animal health.

In NMA's absence, the District Court abused its discretion by entering a preliminary injunction that will keep out healthy live cattle, causing irreparable injury to NMA members.

NMA meets all of the requirements for intervention of right under FED. R. CIV. P. 24(a) and intervention by permission under FED. R. CIV. P. 24(b). NMA's members, who slaughter cattle and sell beef, are directly and significantly affected by either implementation or non-implementation of

APHIS's Final Rule. NMA's interests in purchasing Canadian cattle will be impaired by the outcome of R-CALF's case if R-CALF prevails.

The District Court abused its discretion by determining NMA's Motion to Intervene was untimely. NMA filed its motion just three weeks after R-CALF filed suit, on the same day that R-CALF filed its PI Brief, and prior to the time Defendants answered, and well before the District Court made any substantive rulings in the case. NMA immediately requested a briefing schedule that would not interfere with the schedule the District Court had set for determination of the merits of R-CALF's claims.

The District Court erred in determining that R-CALF would be prejudiced by allowing NMA to intervene. The Court waited from February 1 until February 24 to rule on NMA's Motion to Intervene. It then found that R-CALF would not have adequate time to respond to NMA's Memorandum in Opposition to R-CALF's motion for preliminary relief, which NMA had lodged with the District Court Clerk and served on R-CALF and the government, on February 21, the filing date set by the Court for filings by the Defendant. Last, neither R-CALF nor Defendants can or will adequately protect NMA's interests as shown by their collective failure to raise several critical arguments in connection with R-CALF's application for a preliminary injunction. The District Court erred in holding otherwise.

The District Court also erred in granting R-CALF's application for a preliminary injunction. The District Court's Opinion is arbitrary and capricious and an abuse of discretion in so far as it principally is a word-by-word duplication of the PI Brief Plaintiff submitted on February 1. ER 156-182. The Court's Opinion provides no reasoned discussion or consideration of the well-reasoned and careful analysis provided by APHIS in the *Federal Register* promulgation of the Final Rule. The District Court's failure to take into account the extensive discussion in the *Federal Register* supporting the Agency's conclusion that the risk to human health is effectively zero, is especially egregious — particularly where as here the Plaintiff's expert, Dr. Cox, admits in the same Declaration upon which the District Court relies that, **"I do not consider a widespread health threat in the U.S. to be a highly likely consequence of reintroducing Canadian imports as proposed."** (emphasis supplied). ER 45. In entering the preliminary injunction, the District Court abused its discretion and erred as a matter of law by failing to give APHIS the deference to which the Agency is entitled by law. That injunction should be dissolved.

The District Court also erred when it failed to require R-CALF to provide security for the preliminary injunction as required by FED. R. CIV.

P. 65(c) to provide security for the damages NMA's members are suffering by being wrongfully restrained from importing healthy live cattle from Canada.

VI. ARGUMENT

A. The District Court Erred In Denying NMA's Motion To Intervene Under FED. R. CIV. P. 24(a) And (b) To Protect The Economic Interests Of Its Members In A Suit Challenging The Importation Of Live Cattle And Beef From Canada, After USDA Had Determined These Imports Did not Pose A Risk To The Health Of U.S. Citizens Or Livestock.

1. The District Court erred in denying NMA's Motion to Intervene as a matter of right under Rule 24(a).

In the U.S. Court of Appeals for the Ninth Circuit, an applicant for intervention as of right must demonstrate that (1) it has a "significantly protectable interest relating to the property or transaction that is the subject of the action"; (2) the disposition of the action may, as a practical matter, impair or impede the applicant's ability to protect its interest; (3) the application is timely; and (4) the existing parties may not adequately protect the applicant's interest. *Southwest Ctr. for Biological Diversity v. Berg*, 268 F.3d 810, 817-18 (9th Cir. 2001) (citations and internal quotations omitted). On appeal of denial of Rule 24(a) intervention of right, review is *de novo*. *Id.* The timeliness determination is subject to an abuse of discretion standard. *Id.*

When considering whether the requirements for intervention as of right are met, the court is guided by practical and equitable considerations. *City of L.A.*, 288 F.3d at 397; *Southwest Ctr.*, 268 F.3rd at 818. Further, courts generally construe the Rule broadly in favor of intervention. *City of L.A.*, 288

F.3d at 397; *Southwest Ctr.*, 268 F.3d at 818. The court must accept as true, non-conclusory allegations in support of an intervention motion. *Id.*

In this case, NMA satisfies all four requirements to intervene as of right under Rule 24(a).

a. NMA has significant protectable interests.

Whether an intervenor has a significant protectable interest is a practical, threshold inquiry; there is no specific legal or equitable interest that must be established. *Southwest Ctr.,* 268 F.3d at 818; *Forest Conservation Council v. United States Forest Serv.*, 66 F.3d 1489, 1493 (9th Cir. 1995). The proposed intervenor's interest must be related to the underlying subject matter of the litigation. *State of Cal. v. Tahoe Reg'l Planning Agency*, 792 F.2d 779, 781-82 (9th Cir. 1986). The intervening party must assert an interest that is protected under some law and show that there is a relationship between the legally protected interest and the Plaintiff's claims. *Forest Conservation Council*, 66 F.3d at 1494; *Donnelly,* 159 F.3d at 409.

"[W]hen, as here, the injunctive relief sought by Plaintiffs will have direct, immediate, and harmful effects upon a third party's legally protectable interests, that party satisfies the 'interest' test of FED. R. CIV. P. 24 (a) (2); he has a significantly protectable interest that relates to the property or transaction that is the subject of the action." *Forest Conservation Council*, 66 F.3d at

1494. A non-speculative economic interest may be sufficient to support a right of intervention. *United States v. Alisal Water Corp.*, 370 F.3d 915, 919 (9th Cir. 2004). "To trigger a right to intervene, however, an economic interest must be concrete and related to the underlying subject matter of the action." *Id.*

NMA's members who slaughter cattle have a substantial economic interest in the Final Rule. These members have traditionally slaughtered cattle sourced from both the U.S. and from Canada. ER 89. Since August 8, 2003, USDA has allowed the imports of beef from Canadian cattle less than 30 months of age to resume, while the import of live cattle from Canada has not been allowed. This has had the effect of moving the work of slaughtering Canadian cattle under 30 months to Canada with the result that there has been a 22% increase in the Canadian cattle slaughter capacity during the last 12 months. ER 93. This means that jobs and eventually cattle production are being outsourced to Canada by the operation of USDA regulations. The Final Rule would have allowed the importation of healthy live cattle under 30 months of age and beef obtained from this class of cattle, and would have rectified this imbalance — hopefully preventing further outsourcing of U.S. jobs and cattle production. ER 77, 89. These are the principal reasons why NMA opposes Plaintiff's petition to delay implementation of the Final Rule.

The District Court erred when it suggested that NMA's members had only "a mere interest in property that may be impacted by litigation" and held that "NMA's interest is no different than that of many entities that would benefit from the final rule." ER 150.

NMA and its members who operate slaughter plants only in the U.S. have more than "a mere interest in property that may be impacted by litigation." They have already suffered irreparable injury because their very large competitors, some of whom operate slaughter plants both in Canada and the U.S., have been allowed to bring in increased quantities of boneless beef of Canadian origin since August 8, 2003, while the U.S. slaughter plants have had to compete using higher-cost U.S. cattle. ER 77. When healthy Canadian cattle are again allowed to enter the U.S., cattle prices will equalize and fair competition will be restored.

The fact that neither Plaintiff nor Defendants have spoken out against this continuing irreparable injury confirms that NMA and its members indeed have a significant, unrepresented interest in the underlying litigation. The District Court's rulings are having an anticompetitive effect, to the detriment of NMA's members and the ultimate detriment of U.S. beef consumers.

The District Court's cursory analysis of NMA's interests ignored the facts. While the Court cited to *Alisal Water Corp.*, 370 F.3d at 915; ER 149,

that case is distinguishable. In *Alisal*, a creditor sought to intervene and its interest was properly deemed speculative because it was not a party with a direct relationship to the case. The creditor's interest was solely to collect a debt and was "several degrees removed from the overriding public health and environmental policies that are the backbone of this litigation." *Alisal*, 370 F.3d at 920. Here, NMA's members are directly affected by the outcome of R-CALF's suit and its requested injunction constitutes a direct, significant, legally protectable interest under Rule 24(a). *See, e.g., Cascade Natural Gas Corp. v. El Paso Natural Gas Corp.*, 386 U.S. 129, 132-36 (1967); *Southwest Ctr.*, 268 F.3d at 820-22.

NMA satisfies the interest element described in the other case the District Court cited, *Arakaki v. Cayetano*, 324 F.3d 1078 (9th Cir. 2003). "An applicant satisfies the 'relationship' requirement only if the resolution of the Plaintiff's claims actually will affect the applicant." *Id.* at 1084 (quoting *Donnelly*, 159 F.3d. at 410). There is no question that resolution of R-CALF's claims will have a direct bearing on NMA's members since the suit deals with their ability to import healthy live cattle.

b. NMA's interests may be impaired.

In considering whether disposition of the action may, as a practical matter, impair or impede the applicant's interest relating to the property or

transaction that is the subject of the action, the Ninth Circuit follows the guidance of Rule 24 advisory committee notes that state, "If an absentee would be substantially affected in a practical sense by the determination made in an action, he should, as a general rule, be permitted to intervene." *Southwest Ctr.*, 268 F.3d at 822. NMA's members purchased live cattle from Canada prior to the closing of the Canadian border. NMA's members desire to purchase healthy live cattle from Canada and were preparing to resume their purchases of healthy Canadian cattle when R-CALF filed this suit. The relief R-CALF seeks would prevent NMA's members from purchasing those cattle.

c. NMA's Motion to Intervene was timely.

The Ninth Circuit considers three criteria in determining whether a motion to intervene is timely: (1) the stage of the proceedings; (2) whether the parties would be prejudiced; and (3) the reason for any delay. *Northwest Forest Res. Council v. Glickman*, 82 F.3d 825, 836-37 (9th Cir. 1996).

The District Court abused its discretion in finding the motion was untimely. NMA filed its motion to intervene just 21 days after R-CALF filed its suit. ER 191. No substantive rulings had been made. See ER 187-197. USDA had not filed its answer. R-CALF's PI Brief was filed on the same day as NMA's motion to intervene. ER 191. NMA did not wait for the District Court to rule on its intervention motion, but complied with the expedited

schedule established and offered a substantive brief opposing the Plaintiff's motion for preliminary injunction on February 21, 2005, the day set by the Court for the Defendant's filing of its opposition pleading. ER 2, 71, 88. Thus, R-CALF would have had ample opportunity to formulate its reply.

In *Northwest Forest Res. Council*, 82 F.3d at 836-37, this Court deemed a motion to intervene to be timely where it was filed before defendant filed an answer and the motion to intervene did "not appear to have prejudiced either party in the lawsuit, since the motion was filed before the district court made any substantive rulings." *Id.* at 837. Likewise, there is no prejudice in this case since NMA's motion was filed before the District Court made any substantive rulings.

There was no substantial delay here. *See, e.g., Blake v. Pallan*, 554 F.2d 947 (9th Cir. 1977) (timely intervention granted after 11 months); *United States v. State of Or.*, 745 F.2d 550, 552 (9th Cir. 1984) (timely intervention granted after 15 years); *Arakaki*, 324 F.3d at 1084 (timely intervention granted after 3 weeks). This Court has held a motion to intervene to be untimely when the motion was filed within 21 days of the initial complaint.

While timeliness is a flexible concept (*see Dilks v. Aloha Airlines, Inc.*, 642 F.2d 1155, 1156 (9th Cir. 1981)), prejudice to the parties is the most important consideration in deciding whether a motion for intervention is

untimely. *State of Or.*, 745 F.2d at 552 (intervention motion filed 15 years after suit filed was not untimely without showing of prejudice). There simply is no prejudice here.

The District Court simply abused its discretion in determining that NMA's motion was untimely.

d. No party will adequately represent NMA's interests.

The burden of showing inadequacy of representation is "minimal" and the applicant need only show that representation of its interests by existing parties "may be" inadequate. *Trbovich v. United Mine Workers*, 404 U.S. 528, 538 n.10 (1972); *Southwest Ctr.*, 268 F.3d at 823. In assessing this requirement, this Court considers (1) whether the interest of a party is such that it will undoubtedly make all the intervenor's arguments; (2) whether the present party is capable and willing to make such arguments; and (3) whether the would-be intervenor would offer any necessary elements to the proceedings that the other parties would not. *City of L.A.*, 288 F.3d at 398.

In this case, APHIS will not adequately protect NMA's interests because no one argued the border should be closed to Canadian boxed beef if Canadian cattle are kept out. USDA seeks to open the Canadian border to under 30 month cattle and boxed beef. R-CALF asked in its complaint for the border to be closed to both cattle and beef, but R-CALF's preliminary injunction request

was vague, and both R-CALF and USDA are acquiescing in an outcome where the border is closed to live cattle but open to boxed beef from Canadian cattle. This result is apparently acceptable to Plaintiff and Defendant, while causing irreparable injury to NMA's members.

NMA's interests differ from APHIS. While NMA shares APHIS's objective to protect both human health and animal health, NMA has economic interests, too. NMA's members perform commercial services for profit and employee U.S. citizens. APHIS's interests are not dependent upon operating efficiency or protecting the asset base or property of NMA members.

It is well-established in this Circuit that under these circumstances, NMA may not look to the government to protect the parochial, personal interests that its members have in implementation of the Final Rule. For example, in *Forest Conservation Council*, 66 F.3d at 1499, this Court permitted the State of Arizona and Apache County to intervene in a suit brought against the U.S. Forest Service that sought an order requiring the Forest Service to comply with the procedural requirements of certain environmental laws. The Court permitted intervention because the intervenors' personal interests were narrower than the broader public interest the Forest Service was charged with

protecting. *Id.* ("The Forest Service is required to represent a broader view than the more narrow, parochial interests of the State of Arizona and Apache County").[5]

Similarly, in *Southwest Ctr.*, 268 F.3d at 823, this Court held that the City of San Diego and the U.S. Fish and Wildlife Service "cannot be expected under the circumstances presented to protect [the] private interests" of the intervening developers and builders in an underlying environmental suit challenging the measures the government entities had taken to preserve wetlands. Intervention was appropriate because the "priorities of the defending government agencies are not simply to confirm the Applicants' interests" and the "interests of government and the private sector may diverge." *Id.* at 823.

Private parties affected by an injunction of government action are responsible for protecting their own personal interests and this Circuit allows them to intervene to do so.

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[5] *See also Dimond v. District of Columbia*, 792 F.2d 179, 192 (D.C. Cir. 1986) ("application for intervention thus falls squarely within the relatively large class of cases in this circuit recognizing the inadequacy of governmental representation of the interests of private parties" with "financial stake in the outcome" of the government action). *Accord Trbovich*, 404 U.S. at 539 ("the Secretary has an obligation to protect the vital public interest . . . that transcends the narrower interest of the complaining" intervenor).

Additionally USDA made no request that R-CALF be required to provide security for its preliminary injunction as required by FED. R. CIV. P. 65(c), again confirming that USDA will not adequately protect NMA's interests.

NMA satisfies all four requirements to intervene as a matter or right under FED. R. CIV. P. 24(a). The District Court erred in holding otherwise.

2. The District Court abused its discretion in denying NMA's Motion to Intervene by permission under Rule 24(b).

A court may exercise its discretion to grant permissive intervention under FED. R. CIV. P. 24(b) when: (1) The motion to intervene is timely; (2) The applicant's claim or defense and the main action share a common question of law or fact; and (3) The court has an independent ground of jurisdiction over the applicant's claims. *Greene v. United States,* 996 F.2d 973, 978 (9th Cir.1993); *see also Donnelly*, 159 F.3d at 411-12. The Ninth Circuit applies an abuse of discretion standard when reviewing a district court's denial of a Rule 24(b) motion to intervene by permission. *Northwest Forest Res. Council*, 82 F.3d at 836.

In this case, the District Court abused its discretion because NMA satisfied each of the elements for permissive intervention. As noted above, NMA's motion was timely, since it was filed on the same day that R-CALF filed its PI Brief and before any substantive rulings were made by the District

Court. Second, the claims NMA presented in its proposed Complaint lodged with the District Court share common questions of fact and law with the claims of R-CALF since both depend upon a determination of the legality of the Final Rule. Finally, the District Court erred in determining that NMA had no independent grounds for jurisdiction, since NMA's Complaint alleged jurisdiction under 28 U.S.C. § 1331 (federal question jurisdiction); § 1346 (United States as a Defendant); 5 U.S.C. §§ 702-704 (Administrative Procedure Act).

B. In Granting A Preliminary Injunction, The District Court Failed To Defer To USDA's Well-reasoned And Careful Rulemaking, But Instead Gave Overwhelming Deference To The Plaintiff By Importing Extensive Portions Of Plaintiff's Preliminary Injunction Brief Filed On February 1, 2005 Without Significant Critical Analysis.

In this case, the *Federal Register* publication of the Final Rule occupies 92 pages and the rulemaking record contains more than 12,500 pages. Nonetheless, the District Court uncritically based its decision almost entirely on the Plaintiff's February 1, 2005 Preliminary Injunction ("PI") Brief, relying even on the least documented, most speculative arguments of the Plaintiff and using the Plaintiff's exact words, phrases, and paragraphs in the bulk of what is put forward as the Court's own Opinion. This cloning of the Plaintiff's PI Brief even extends to replicating at least one typographical error. The Plaintiff's PI Brief (ER30) uses the phrase "calves **born by** imported Canadian cattle"

(emphasis supplied), where it apparently means "born to" or "born of." The Court's Opinion uncritically repeats this typographical error at ER 171.[6] *Compare* ER 156-182 (District Court's Opinion) *and* ER 3-45 (Plaintiff's PI Brief). In this case, where the Court was required by law to give great deference to the judgment and expertise of the agency, it has done the exact opposite and shown an arbitrary and capricious deference to the Plaintiff, which compromises its preliminary injunction and indeed raises the question whether any future proceedings in this matter should be returned to this District Court.

1. The District Court's deference to R-CALF rather than to APHIS' scientific expertise is an error of law reviewed de novo.

In this case, the District Court adopted R-CALF's opinion that APHIS erred in its scientific conclusion that importation of live cattle from Canada posed no risk to human and animal health. The District Court then enjoined the Final Rule.

This Court customarily reviews a District Court's grant of a preliminary injunction under the abuse of discretion standard. *Harris v. Bd. of Supervisors, L.A. County*, 366 F.3d 754, 760 (9th Cir. 2004). While that review is deferential, the reviewing court will look to whether "the district court

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[6] *See* ER 156-182 which is a highlighted version of the Court's Opinion showing the portions thereof which are copied directly from the Plaintiff's February 1, 2005 PI Brief.

employed the appropriate legal standards which govern the issuance of a preliminary injunction, and correctly apprehended the law with respect to the underlying issues in litigation." *Id.* (internal quotations and citations omitted). To the extent the District Court's issuance of a preliminary injunction hinges on a question of law, this Court's review is *de novo*. *Brown v. Cal. Dept. of Transp.*, 321 F.3d 1217, 1221 (9th Cir. 2003).

In this case, the District Court made clear errors of law that are reviewable *de novo* because, in enjoining the Final Rule on "health and safety" grounds, the District Court substituted the opinions of Plaintiff R-CALF for the considered scientific determinations of the expert agency APHIS. Under the Administrative Procedure Act (APA), the District Court should have only set aside the Agency's Final Rule as ". . . arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law," 5 U.S.C. § 706(2)(A),[7] after giving full consideration to the scientific determinations of the Agency, which the Court did not do here. Under this highly deferential standard, the District Court's review of the Final Rule should have been narrowly circumscribed:

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[7] *See also, Public Utility Dist. No. 1 of Snohomish County, v. FEMA*, 371 F.3d 701, 706 (9th Cir. 2004); *Safari Aviation Inc. v. Garvey*, 300 F.3d 1144, 1150 (9th Cir. 2002), *cert. denied*, 123 S. Ct. 1635 (2003).

> [T]he court must consider whether the decision was based on a consideration of the relevant factors and whether there has been a clear error of judgment. Although this inquiry into the facts is to be searching and careful, the ultimate standard of review is a narrow one. The court is not empowered to substitute its judgment for that of the agency.

Citizens to Preserve Overton Park, Inc. v. Volpe, 401 U.S. 402, 416 (1971) (citations omitted). *See also Cent. Ariz. Water Conservation Dist. v. E.P.A.*, 990 F.2d 1531, 1539-40 (9th Cir. 1993) (the "reviewing court must generally be at its most deferential when the agency is making predictions within its area of special expertise...").

A highly deferential review is appropriate where, as here, the agency has engaged in notice-and-comment rulemaking. *United States v. Mead Corp.*, 533 U.S. 218, 235 (2001); *Chevron U.S.A., Inc. v. Natural Res. Defense Council*, 467 U.S. 837 (1984).[8] An agency's decision is presumed valid. *See, e.g., Irvine Med. Ctr. v. Thompson*, 275 F.3d 823, 831 (9th Cir. 2002); *Ethyl Corp. v. E.P.A.*, 541 F.2d 1, 34 (D.C. Cir.) (en banc), *cert. denied*, 426 U.S. 941 (1976).[9]

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[8] *See also The Wilderness Society v. United States Fish & Wildlife Serv.*, 353 F.3d 1051, 1059 (9th Cir. 2003).

[9] The District Court misapprehends the proposition of a presumption against agency changes in "current" policy. ER 163. The current policy, as of May 2003, had been to allow importation of live cattle from Canada – a policy that changed temporarily with the discovery of a BSE-positive cow in Alberta, Canada. APHIS evaluated the science and determined after exhaustive review that it was safe to reopen the border. To the extent there is a change of policy, APHIS' 12,560-page administrative record amply demonstrates that there was no "important aspect of the problem" APHIS failed to consider. *Cf. Motor Vehicle*

APHIS is entitled to substantial deference in matters such as these that rest upon the Agency's scientific and specialized expertise. *See Marsh v. Or. Natural Res. Council*, 490 U.S. 360, 376 (1989).[10] Even where the evidence is susceptible to more than one interpretation, a reviewing court may not substitute its judgment for that of the expert agency. *Id.*, at 378; *Safari Aviation*, 300 F.3d at 1150. A reviewing court must be at its most deferential when, as here, the agency is "making predictions, within its area of special expertise, at the frontiers of science." *Cen. Ariz. Water Conversation* Dist., 990 F.2d at 1539 (*quoting Balt. Gas & Elec. Co. v. NRDC, Inc.*, 462 U.S. 87, 103 (1983)). As this Court has stated:

> Courts are extremely deferential to administrative agencies in cases involving technical rulemaking decisions. We are particularly deferential when reviewing agency actions involving policy decisions based on uncertain technical information. As long as Congress delegates power to an agency to regulate on the borders of the unknown, courts cannot interfere with reasonable interpretations of equivocal evidence.

Mfrs. Ass'n. of United States, Inc. v. State Farm Mutual Auto. Ins. Co., 463 U.S. 29, 43 (1983). Moreover this Court and the U.S. Supreme Court have "rejected the notion that an agency's interpretation is not entitled to deference because it represents a sharp break with prior interpretations of the statute in question;" "[a]n agency is not required to establish rules of conduct to last forever." *Irvine Med. Ctr.*, 275 F.3d at 831 n. 6 (quoting *Rust v. Sullivan*, 500 U.S. 173, 186-87 (1991)).

[10] *Safari Aviation Inc.* 300 F.3d at 1150; *Cent. Ariz. Water Conversation Dist.*, 990 F.2d at 1539

Cent. Ariz. Water Conservation Dist., 990 F.2d at 1539-40 (internal citations omitted).

Here, it is plain that the District Court did not defer at all to APHIS's expertise, choosing instead to defer to the Plaintiff's allegations and open-ended questions over the well-reasoned and careful conclusions of APHIS's expert agency and ultimately adopting, almost verbatim, the Memorandum of the Plaintiff/Appellee's PI Brief as its own Opinion.

2. The District Court erred in finding that Plaintiff was likely to prevail on the merits, because the Court failed to address or consider USDA's exposition of the measures which protect human health so that imports of live cattle from Canada effectively pose no risk to the health of consumers.

The Court accepts and reiterates the allegation of the Plaintiff that "neither the Harvard Risk Assessment nor the USDA Risk Analysis contain an assessment of the risks of consumers contracting vCJD from consuming Canadian beef, other than subjective conclusions that the risk will be "low" or "very low." ER 15, 164.

The "Harvard Risk Assessment" is a major study commissioned by APHIS in 1998 from the Harvard School of Public Health's Center for Risk Analysis and the Tuskegee University Center for Computational Epidemiology to evaluate potential risk if BSE were to be discovered in the U.S. 70 Fed. Reg. at 466-67. The study concluded that even if there are a small number of

undetected BSE cases in the U.S., they will not "amplify," but will be extinguished over time by the firewalls presently in effect. *Id.* at 507. The Harvard-Tuskegee study was completed in 2001, and then put out for peer review, which was completed in 2002. *Id.* at 467. The study uses a measurement of minimum risk characterized as a "coefficient of reproducibility" [R_0]. When R_0 is less than 1, the disease will not amplify, and Cohen and Gray the principal authors of the H-T report conclude that $R_0 < 1$. *Id.* at 508. They tested their methodology against the statistics generated by the outbreak of BSE in Switzerland and found that the Swiss statistics coincide with and validate their algorithm. *Id.* at 509.

In 2003, after the first BSE case was detected in Canada, Cohen and Gray were asked by APHIS to review their conclusions in light of new data, and they found that using new FDA generated data about feed ban compliance, R_0 is even smaller than they had previously calculated. *Id.* at 508. The one area where they did not have good statistical data was for on-farm misuse, where a farmer might feed a chicken or swine ration containing ruminant meat and bone meal to cattle, and they assigned a fairly generous, arbitrary allowance for this misuse factor. *Id.* The new conclusions of Cohen and Gray were put on the public record by APHIS in mid-2004. *Id.* at 467; 545. *See also* footnote 1, *supra*; ER 84A-86.

In 2004, Cohen and Gray were asked by APHIS to review the comments of R-CALF's expert, Dr. Cox, which were critical of their work, and that third Harvard report, which carefully analyzes Dr. Cox's comments was relied on in promulgating the Final Rule and is part of the administrative record. *See* footnote 1, *supra*. Thus three Harvard studies confirm that even if there is a small number of undetected cases of BSE in either Canada or the U.S., because of the firewall, which APHIS has put in place, the coefficient of reproducibility [R_0] is so low that there is no significant risk that the disease will amplify, but instead it will be self-extinguishing. 70 Fed. Reg. at 508. Thus, APHIS uses the coefficient of reproducibility [R_0] developed and refined through the Harvard Risk Assessment and this is a reasonable measure of minimal and acceptable risk.

APHIS's own evaluation of the risk of humans contracting vCJD is described in the *Federal Register* notice in a well-reasoned and careful manner as follows:

> As the Harvard-Tuskegee Study noted, the information necessary to quantitatively assess the risk of humans contracting vCJD as a result of consuming BSE-contaminated food products is not available (Ref 33). Thus, the Harvard-Tuskegee Study quantified potential human exposure, but did not estimate how many people might contract vCJD from such exposure. That does not mean, however, that there is insufficient information about the potential impacts of the rule on human health. The Harvard-Tuskegee Study concluded that only a small

> amount of potentially infective tissues would likely reach the human food supply and be available for human consumption. As explained above, that amount was based on conditions as they existed in 2001, before safeguards implemented recently by FSIS and FDA.... These newly implemented safeguards, as well as additional information that indicates that compliance with feed restrictions in the United States is better than had been estimated, makes it far less likely that even small amounts of infective tissue would reach the human food supply and be available for human consumption. Further, we know that, despite estimates that more than 1 million cattle may have been infected with BSE during the course of the epidemic in the United Kingdom, which could have introduced a significant amount of infectivity into the human food supply, only 150 probable and confirmed cases of vCJD have been identified worldwide. This data suggests a substantial species barrier that may protect humans from widespread illness due to ingesting BSE-contaminated meat. This barrier suggests that it is unlikely that there would be any measurable effects on human health from small amounts of infectivity entering the food chain. We believe that this information allows an appropriate assessment of the effects of this rulemaking on human health.

Id. at 505.

The APHIS analysis proceeds to conclude that it would be extremely unlikely for cattle or beef imports from Canada to either "infect U.S. cattle or to result in human exposure to the BSE agent" stating:

> Based on the hazard identification, hazard characterization (referred to in our risk analysis using the OIE terminology, "release assessment"), and exposure assessment, APHIS' risk analysis then estimated the adverse effects likely to occur--that is, we characterized the risk. The hazard

> identification, release assessment, and exposure assessment clearly indicated that it is unlikely that infectious levels of BSE would be introduced into the United States from Canada with any of the commodities included in the assessment, and that, even if the BSE agent were introduced into the United States, it would be extremely unlikely to enter commercial animal feed and thereby infect U.S. cattle or to result in human exposure to the BSE agent.

Id. at 505.

In the *Federal Register* publication of the Final Rule, APHIS reports that the Harvard/Tuskegee Study identified three practices that could create a pathway for human exposure to the BSE agent or the spread of BSE should it be introduced into the U.S.: (1) Non-Compliance with FDA's regulations prohibiting the use of certain proteins in feed for cattle and other ruminants; (2) Rendering of animals that die on the farm and use (through illegal diversion or cross contamination) of the rendered product in ruminant feed; and (3) the inclusion of high-risk tissues from cattle, such as brain and spinal cord, in products for human consumption. *Id.* at 467.

USDA describes the steps that have been taken in Canada to eliminate each of these practices that could create a pathway for human exposure. *Id.* In the U.S., the inclusion of high-risk tissues from cattle, the so-called SRMs, has been banned from foods for human consumption since January 12, 2004. Prohibition of the Use of Specified Risk Materials for Human Food and

Requirements for the Disposition of Non-ambulatory Disabled Cattle, 69 Fed. Reg. 1862 (Jan. 12, 2004). The rendering of animals that die other than by slaughter at a federal or state inspected facility (so-called downer animals and 4-D animals) has also been prohibited since this time. FDA surveys have determined that there is a very high level of compliance with that agency's regulations prohibiting the feeding of ruminant protein to ruminant animals. 70 Fed. Reg. at 466.

Bovine muscle tissue does not carry the BSE infectivity. This is the case even in cattle that may carry the BSE agent. APHIS addressed this in the Proposed Rule, stating "even cattle carrying the infectious agent are unlikely to carry that agent in tissues that have not demonstrated infectivity (e.g., muscle, liver, skin, hide, milk, embryos) or products derived from these tissues." 68 Fed. Reg. at 62391. Moreover, even in tissues that have demonstrated infectivity (brain, tonsil, spinal cord, eyes, trigeminal ganglia, dorsal root ganglia), in all but the distral ileum and tonsils[11], "[i]nfectivity was not detected in most tissues in cattle until at least 32 months post-exposure." 70 Fed. Reg. at 483.

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[11] "The exception to this is the distal ileum (a part of the intestines), where infectivity was confirmed in the *experimentally* infected cattle as early as 6 months post-exposure, and the tonsils, where infectivity was confirmed at 10 months post-exposure." 70 Fed. Reg. at 483 (emphasis added).

The Court's uncritical adoption of the Plaintiff's suggestion that a consumer is at risk of contracting vCJD by consuming Canadian beef is contradicted by the conclusions APHIS describes and supports in the Final Rule and by the Harvard Risk Assessment. Nonetheless, the Court uncritically accepts Plaintiff's speculative suggestion that USDA's risk evaluation was inadequate and that the agency was thereby arbitrary and capricious not to have performed additional statistical risk assessment. In this regard, the Court itself was arbitrary and capricious, and the Court clearly erred in failing to defer to the sound analysis provided by USDA.

3. The Court erred in rejecting USDA's assessment of the incidence of BSE in Canada, where testing for BSE has been as or more intensive than in the U.S.

As the Court's Opinion and the Plaintiff's PI Brief agree, Canada has tested approximately 40,000 head of cattle in the past decade, almost exclusively cattle with outward signs of possible BSE, while the U.S. has tested over 200,000 cattle believed to be at risk for BSE. ER 16-17, 165. When one compares the total cattle population of 95 million in the U.S. and 15 million in Canada (ER 89), Canada's testing on its face has been as or more intensive than that in the U.S. Both countries have far exceeded the level of testing recommended by the OIE Terrestrial Animal Health Code Appendix 3.8.4 for the past seven years. 70 Fed. Reg. at 531.

The District Court and R-CALF erred in opining that Canada's BSE prevalence rate is 5.5 cases per million. This estimate is based on a flawed analysis by Plaintiff's expert, Dr. Cox, who improperly extrapolates data from one geographic area in Canada to the whole country, and who fails to calculate incidence rates over a single given year. ER 112. Dr. Cox's estimated incidence rate of 5.5 cases per million is counter-intuitive and conflicts with the incidence rate of 0.33 cases per million for 2003 calculated by the OIE (ER 111), and with the incidence rate for the last twelve-month period of 0.36 cases per million. ER 112.

The Court states that "evidence strongly indicates that if the testing so far has been representative," there will be an unusually high prevalence of BSE, but does not provide either its own calculations of incidence or some other explanation for this counter-intuitive conclusion. ER 15-16. Once again the Court has abused its discretion and given total deference to the Plaintiff's assertions, ignoring APHIS's carefully explained and supported scientific conclusions. Plaintiff's PI Brief, ER 17, ER 165-166.

4. The Court erred in characterizing USDA's reliance on Canada's ruminant-to-ruminant feeding ban as arbitrary and capricious.

The U.S. and Canada adopted their ruminant-to-ruminant feeding bans in August 1997. 70 Fed. Reg. at 512. The simultaneous adoption of these

regulations is indicative of the long-standing, close coordination and cooperation that has existed between the animal health programs of the two countries.

The Court's Opinion accepts the proposition put forward by the Plaintiff that "the most important means of preventing the spread of BSE in cattle is limitations on cattle feed, so that healthy animals are not exposed to BSE prions through feed that contains protein from animals infected with BSE." PI Brief, ER 19; District Court Opinion, ER 167. NMA emphatically agrees with this proposition.

The Court and R-CALF err when they speculate on other unproven routes of transmission. Oral ingestion of feed contaminated with BSE is the only scientifically documented route for transmission of the disease in cattle. *Id.* at 486. The Court and R-CALF rely upon studies showing blood carries infectivity, but the administrative record is very clear that there is no scientific evidence that BSE will enter the food chain through bovine blood. 70 Fed. Reg. at 502; ER 102-103.

The administrative record also shows USDA considered the length that Canada's feed ban was in effect and determined that 7.5 years was adequate within the context of the many other control measures Canada had in place at the time of diagnosis. 70 Fed. Reg. at 470. Seven years also represents the 95th

percentile of the incubation period distribution. *Id.* Cattle born and hypothetically exposed to feed produced prior to the August 1997 feed ban are now at least 7 years old and cannot be imported into the U.S. under this rule. *Id.* at 515.

The Court and R-CALF also err in their interpretation of the OIE guidelines. ER 124-127. The OIE only examines a member country's claim as being BSE free or provisionally free. *Id.* Assessment of any other BSE status (such as "minimal risk") is a matter between the respective importing and exporting countries. The OIE would consider it inappropriate for the importing country to apply each criterion as an item on a checklist and to conclude that the exporting country fails to qualify for a particular risk status merely because it does not meet a listed criterion. *Id.* at 463; ER 126-127.

The Court and R-CALF also mistakenly conclude that because the mean incubation period for BSE is 4.2 years, all four Canadian-origin cows infected with BSE could have contracted the disease after the 1997 implementation of Canada's feeding ban. Plaintiff's assumptions in applying the mean rate of incubation to determine the date of exposure to BSE in the four Canadian cattle are incorrect and scientifically unsound. ER 115-117. Animals affected by BSE typically contract the disease within the first year of life. *Id.* The incubation period of BSE (*i.e.*, the time it takes for the animal to exhibit clinical

signs of infection) depends upon the dose of the infectious agent that the animal consumes. *Id.*; 70 Fed. Reg. at 483. This incubation period is generally 2 to 8 years. ER 116. In the United Kingdom, the mean incubation period was 4.2 years. ER 116; 70 Fed. Reg. at 470. The fact that Canadian cattle found positive for BSE were all older indicates low initial exposure, so that their incubation period does not indicate that they were infected relatively recently. It probably has been longer. *Id.* at 483; ER 116. Accordingly, the Canadian cows most likely contracted BSE before, and in the case of the latest discovered cow, shortly after the implementation of the feed ban.

Uncontroverted science says beef fat creates a risk of BSE transmission only if it is contaminated with protein. 70 Fed. Reg. at 501. APHIS regulations at 9 C.F.R. § 95.4 authorize the importation only of tallow that is free of animal protein. *Id.* The Court accepts the Plaintiff's speculative argument that "scientific understanding of transmissibility of BSE is still evolving" (ER 19, 167) and the unproven hypotheses that BSE may be spread through ingestion of blood and tallow. These are unproven hypotheses.

USDA's track record shows that where a risk factor is confirmed, APHIS has moved quickly to limit and eliminate that risk. Imports of cattle from the United Kingdom were not allowed after 1989. 70 Fed. Reg. at 462. The ruminant-to-ruminant feeding ban was instituted in 1997 as soon as scientific

information documented the feeding of ruminant protein as the vector for transmission of BSE. *Id.* at 512. Apparently the District Court believes that it is impermissible to reinstitute the importation of Canadian cattle until every hypothesis of the most remote risk has been investigated and resolved to the satisfaction of the Plaintiff. This is an extraordinary deference to the Plaintiff, which, if applied as a general regulatory principle either within the U.S. or in respect to the international trade of the U.S., could bring economic activity to a halt.

5. The Court provides no support for its conclusion that SRM removal is not an effective protection of public health, and therefore this conclusion is arbitrary and capricious.

The Court's fourth area of conclusion and criticism of the Final Rule is based on the exact language of the fourth area of discussion in the Plaintiff's PI Brief. In its discussion, the Court recites that, "plaintiff contends that the USDA failed to respond adequately to comments..." and that "plaintiff submitted extensive comments in numerous reports..." and finally that, "USDA's failure to explain clearly why these concerns do not undercut its reliance on SRM removal ... again underscores Plaintiff's likelihood of success on the merits." ER 20. These conclusory statements are not supported by citations or footnotes in either the Court's Opinion or in the Plaintiff's PI Brief.

The District Court and R-CALF erred. The broad scientific consensus is that infectivity is contained in SRMs, and their removal is the single most effective step to minimizing the risk of BSE transmission to humans. 70 Fed. Reg. at 467; ER 96-97; ER 107-08. USDA's experts were familiar with the research R-CALF offered, carefully considered, and ultimately rejected it for sound scientific reasons. ER 98. The scientific studies on which R-CALF and the District Court rely involve sheep, but there is no evidence that findings in sheep can be extrapolated to cattle. ER 102; ER 118-120. The broadly held scientific view based on epidemiological studies and reports is that BSE cannot be transmitted among cattle through saliva. ER 103.

The Court simply accepts the Plaintiff's allegations that APHIS's response to Plaintiff's concerns has been inadequate without examining the specifics of either the concerns or the response, and therefore determines that R-CALF is likely to succeed on the merits. This turns the whole concept of deference to agency knowledge and expertise on its head. Under the Court's approach, an agency could never prevail unless the Plaintiff conceded that it should.

6. The Court erred in its conclusion that APHIS failed to give careful consideration to the benefits and costs of mandatory testing of cattle for BSE.

The District Court and R-CALF concluded that APHIS failed to give adequate consideration to the possibility of mandatory testing.

Actually, APHIS considered this issue and came to a conclusion consistent with that of the international scientific community – the testing of every animal is not scientifically justified, and in fact, mandatory testing is the control method least likely to produce meaningful results. 70 Fed. Reg. at 475; ER 113-115. Current testing methods can detect a positive case of BSE at the earliest 2 to 3 months before the animal begins to demonstrate clinical signs, and the average incubation period is generally very long, about 4-5 years. 70 Fed. Reg. at 475. Thus, testing an infected animal that has not demonstrated clinical signs of the disease would incorrectly produce negative results. *Id. See also* ER 113-116. There is no scientific evidence or opinion that testing of all cattle is an effective surveillance measure. Testing healthy cattle is unlikely to yield positive test results for BSE. In the U.S., APHIS has tested more than 250,000 at-risk cattle during the past nine months, without finding a single BSE positive. In the event that BSE is present but goes undetected, firewalls and mitigation measures, such as the ruminant-to-ruminant feeding ban and the removal of SRMs, will prevent both human exposure and the spread of the disease in cattle. 70 Fed. Reg. at 475.

7. The District Court Erred In Adopting R-CALF's NEPA Analysis

a. The District Court erred in holding that R-CALF had standing to assert a NEPA claim.

The District Court's analysis of Plaintiff's National Environmental Policy Act (NEPA) challenge is flawed. Plaintiff has not satisfied the standing requirements necessary to establish an actual case or controversy. The Supreme Court has stated that a Plaintiff must, at an "irreducible minimum," show that: (1) he has suffered a "concrete and particularized" injury which is "actual and imminent" rather than "conjectural or hypothetical;" (2) the injury was caused by or is "fairly traceable to" the action of the defendants; and (3) a favorable decision by the court is likely to redress the injury. *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560-61 (1992). The District Court failed to perform a complete standing analysis. Rather, the Court merely reiterated the standing elements required by the Supreme Court and concluded: "this Court finds that Defendant has standing to make a NEPA challenge." ER 173.

Plaintiff's alleged economic injury falls outside the "zone of interests" that NEPA is designed to protect. In a NEPA case, the "concrete interest" requires a "geographic nexus" between the individual asserting the claim and the location suffering an environmental impact." *Cantrell v. City of Long Beach,* 241 F.3d 674, 679 (9th Cir. 2001) (*citing Douglas County v. Babbitt*, 48

F.3d 1495, 1500 n.5 (9th Cir. 1995)). Plaintiff has not asserted a claim establishing an environmental impact to which it bears a "geographic nexus;" therefore, Plaintiff has failed to demonstrate the requisite injury-in-fact. *Lujan*, 504 U.S. at 562-63 (the party seeking review must be among the injured).

Moreover, a Plaintiff who asserts purely economic injuries does not have standing to challenge an agency action under NEPA. *Nev. Land Action Ass'n v. U.S. Forest Serv.*, 8 F.3d 713, 716 (9th Cir. 1993); *see also Cal. Forestry Ass'n v. Thomas*, 936 F. Supp. 13, 20-22 (D.D.C. 1996). Here, the only injury Plaintiff has alleged is an economic injury that may result from import of ruminant products from Canada. *See* ER 37. Plaintiff has failed to establish a "concrete and particularized" injury within NEPA's "zone of interest"; hence, the District Court did not have jurisdiction to hear Plaintiff's NEPA challenge.

b. The District Court Erred in Ruling that APHIS's Decision to Issue an EA Instead of an EIS Violated Its Duties under NEPA

Even if this Court finds that Plaintiff established standing, the District Court's decision to stay the Final Rule must fail because APHIS's environmental assessment (EA) complies with NEPA. The statute requires that an agency take a "hard look" at the environmental consequences of its actions; however, it does not bind an agency's ultimate determination. *See Robertson v.*

Methow Valley Citizens Council, 490 U.S. 332, 350-51 (1989); *Morongo Band of Mission Indians v. FAA*, 161 F.3d 1062, 1067 (9th Cir. 2002).

During the rulemaking process, APHIS complied with the procedural requirements of NEPA. Contrary to the District Court's opinion, APHIS did involve and inform the public during its preparation of its Final EA, and the public was afforded more than 100 days to comment on the EA. While the public should be involved or informed to some extent regarding preparation of an EA and Finding of No Significant Impact (FONSI), *Citizens for Public Forestry v. USDA*, 341 F.3d 961, 970 (9th Cir. 2003), no particular public comment period is required. In its *Federal Register* notices APHIS explicitly states that it "will consider all comments" received by the deadline. BSE; Minimal Risk Regions and Importation of Commodities; Availability of an Envtl. Assessment, 70 Fed. Reg. 554 (Jan. 4. 2005); BSE; Minimal Risk Regions and Importation of Commodities; Availability of an Envtl. Assessment with Corrections and Extension of Comment Period, 70 Fed. Reg. 3183 (Jan. 21, 2005). Hence, the District Court's allegation that APHIS took action before its Final EA was made available to the public is in error.

The District Court's determination that the Final EA is arbitrary and capricious (because of the Agency's risk assessment) has been addressed previously. *See* pages 35-42 *supra*. APHIS did provide an adequate risk

assessment for public comment. APHIS complied with the procedural requirements of NEPA.

In addition, the District Court's determination that APHIS failed to comply with its obligations under NEPA because it failed to assess the environmental impact of increased truck traffic is in error. ER 174A-175. The Court neglects to demonstrate any "substantial question" as to how increased truck traffic will have a significant impact on the environment. *See Anderson v. Evans*, 371 F.3d 475, 488 (9th Cir. 2004). Moreover, prior to May 29, 2003, the U.S.-Canadian border was open to truck traffic transporting Canadian cattle into the U.S. There is no "substantial question" as to the environmental impact of truck traffic attributable to the Final Rule because the Final Rule would merely reinstate the *status quo* regarding truck traffic from Canada.[12]

c. The District Court erred in staying the Final Rule on the basis of its flawed NEPA analysis.

The District Court held that because USDA failed to conduct the required analysis of the environmental impacts of its proposed action, NEPA requires a stay of the agency action until the required analysis can be completed. ER 175. Again, the District Court's Opinion is in error. Even if APHIS had violated

[12] Implementation of the Final Rule merely lifts the moratorium on importation. It makes little sense for APHIS to assess the environmental impact of increased truck traffic using the moratorium period as its baseline because the decrease in truck traffic from Canada was a byproduct of APHIS's decision to prohibit the importation of Canadian beef. Rather,

NEPA (which it has not), an injunction does not automatically issue for a NEPA violation. *Amoco Prod. Co. v. Village of Gambell*, 480 U.S. 531, 542 (1987). Plaintiff's asserted injuries are economic in nature; NEPA is intended to protect environmental interests. Thus, a permanent injunction is not proper with regard to Plaintiff's NEPA challenge.

8. The District Court Erred In Adopting R-CALF's RFA Analysis

USDA's Final Rule complies with the provisions of the Regulatory Flexibility Act (RFA), requiring that agencies conduct an analysis of the economic impact a rule will have on small entities and an explanation for rejection of each significant alternative considered by the agency. *See* 5 U.S.C. § 604(a). The District Court erred in holding otherwise.

The District Court held that APHIS failed to consider two alternatives that would impact small businesses. First, the District Court stated that APHIS failed to consider whether requiring Canadian edible bovine products to bear a country of origin label would mitigate the adverse effects of the Final Rule on small businesses. ER 176-77. Second, the District Court states that APHIS failed to consider whether allowing slaughter facilities to privately test cattle for BSE would mitigate the adverse effects of the Final Rule on small

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the appropriate baseline for assessing the impact of truck traffic is the period immediately prior to APHIS' May 29, 2003 Interim Rule.

businesses. ER 177. However, both alternatives cited by the Court were considered by APHIS during the rulemaking process and rejected. 70 Fed. Reg. at 533, 34.

The Court's Opinion misapprehends the scope of the RFA. The RFA does not require that agencies adopt alternative rules put forward by small business commenters. Rather, the RFA is procedural in nature and mandates that agencies consider the alternatives put forward by small businesses during the rulemaking process and " an administrative agency remains free to regulate as it sees fit." *Envtl. Defense Ctr., Inc. v. EPA*, 344 F.3d 832, 879 (9th Cir. 2003), *cert. denied*, 124 S. Ct. 2811 (2004); *see also Nat'l Coalition for Marine Conservation v. Evans*, 231 F. Supp.2d 119, 143 (D.D.C. 2002); *Cement Kiln Recycling Coalition v. E.P.A.*, 255 F.3d 855, 868 (D.C. Cir. 2001). The RFA is not intended to be determinative of an agency's ultimate substantive decision. *See Nat'l Coalition for Marine Conservation*, 231 F. Supp. 2d at 143.

APHIS has met its burden. In its Final Rule, APHIS responded to comments requesting that USDA postpone implementation of the Rule until the country of origin labeling program (COOL) takes effect in September 2006. 70 Fed. Reg. at 533. APHIS considered the comments on this topic and determined that delaying implementation of the Final Rule was not necessary because the intent of COOL is not to address food safety or animal health

concerns; rather, it is intended to "provide consumers with additional information on which to base their purchasing decisions." *Id.* In addition, USDA "considered carefully" the comment requesting private testing for BSE and concluded that such testing is "inconsistent with USDA's mandate to ensure effective, scientifically sound testing for significant animal diseases and to maintain domestic and international confidence in U.S. cattle and beef products." *Id.* at 534.

Thus, the District Court erred in ruling that USDA failed to comply with the RFA.

C. The District Court Erred In Granting A Preliminary Injunction

1. Standards

For entry of a preliminary injunction, R-CALF was required to demonstrate the following: 1) a substantial likelihood of success on the merits; 2) the possibility of irreparable injury to the Plaintiff/appellee if injunctive relief is not granted; 3) the balance of hardships favoring the Plaintiff/appellee; and 4) advancement of the public interest. *Textile Unlimited, Inc. v. A.BMH & Co., Inc.*, 240 F.3d 781, 786 (9th Cir. 2001); *L.A. Mem'l Coliseum Comm'n v. Nat'l Football League*, 634 F.2d 1197, 1200-01 (9th Cir. 1980). This Court requires that the moving party meet its burden by demonstrating either: (1) a combination of probable success on the merits and the possibility of irreparable

injury, or (2) that the Plaintiff's papers raise "serious questions" on the merits and "the balance of hardships tips sharply in [its] favor." *Stuhlbarg Int'l Sales Co., Inc. v. John D. Brush & Co., Inc.*, 240 F.3d 832.

This Court customarily reviews a District Court's grant of a preliminary injunction under the abuse of discretion standard. *Harris*, 366 F.3d at 760. To the extent the District Court's decision hinges on a question of law, this Court's review is *de novo*. *Brown,* 321 F.3d at 1221.

2. The District Court abused its discretion in enjoining USDA's Final Rule because R-CALF was not likely to succeed on the merits and its request did not raise serious questions.

As discussed above, pages 30-55 *supra*, the District Court erred as a matter of law in relying so entirely upon R-CALF's PI brief, in refusing to defer to APHIS's expertise, and in ignoring the agency's carefully arrived at conclusion that Canadian cattle do not pose a risk to human or animal health. The District Court further erred in denying NMA's Motion to Intervene and even dismissing the *amicus curiae* brief offered by the Government of Canada (ER 193), each of which would have provided information that would have been useful for the Court's decision process. If the District Court had applied the proper standard of deference to the decision of the Agency and just conducted a review of the record to assure its decision was properly supported, it would have been readily apparent that R-CALF had *no* chance of succeeding

on the merits, much less a probability of success. Thus, even applying this Circuit's sliding standard that allows a District Court to enter a preliminary injunction by relaxing the showing of probability of success on the merits where the threat of harm is great, no preliminary injunction should have been entered in this case. There must be some merit to a Plaintiff's claim before the actions of a federal agency, taken for the good of the country, after a thorough and scientific investigation, are halted by a Court.

3. The District Court abused its discretion in accepting R-CALF's assertions of irreparable injury.

In order to support to the issuance of a preliminary injunction, the court needed to find "the possibility of irreparable injury to the plaintiffs if injunctive relief is not granted," *Textile Unlimited, Inc.*, 240 F.3d at 786. The District Court's primary findings of irreparable injury reference "the possibility of quintessential irreparable harm to the citizens of the United States" and the conclusion that "alleged environmental injury is sufficiently likely and the balance of harms weighs in favor of protection of the environment." ER 178-179. Even assuming that these characterizations are correct, these harms are not attributable to R-CALF. Irreparable injury to the moving party is a necessary prerequisite to entry of preliminary injunction. *Beacon Theatres, Inc. v. Westover,* 359 U.S. 500, 506-07 & n. 8 (1959).

The District Court goes on to state that resumption of imports of cattle from Canada will create the perception "that the U.S. meat supply is not free of BSE agents' and will thereby be damaging to ranchers in the U.S, and to the U.S. economy. ER 179. This of course is a risk that is highly speculative and does not constitute the kind of irreparable injury to the Plaintiff that would justify the issuance of a preliminary injunction during the pendency of the present litigation. *See Caribbean Marine Services Co, Inc. v. Baldrige*, 844 F.2d 668, 674 (9th Cir. 1988); *Goldie's Bookstore v. Superior Ct.*, 739 F.2d 466, 472 (9th Cir. 1984) ("Speculative injury does not constitute irreparable injury").

In fact, neither the Plaintiff nor the Court makes a convincing demonstration that irreparable injury is likely to occur to R-CALF's members during the pendency of this litigation. The clearest and most irreparable injury in this case is that which is caused by entry of the preliminary injunction to NMA's members who are dependent upon a supply of healthy Canadian cattle. The balance of harm in this case does not tip in R-Calf's favor, but rather, is borne principally by NMA's members.

4. **The District Court abused its discretion in accepting only the public interest R-CALF claimed and failing to consider the harm to other parties.**

The District Court abused its discretion in failing to consider the harm to other parties and the public interest, specifically, as detailed above, the extensive injury to NMA's members – a harm the District Court refused to consider. *See* pages 19-29 *supra*. Moreover, the District Court failed to weigh the interests of American consumers in having safe, lower cost Canadian beef available to them.

D. The District Court Erred As A Matter Of Law By Failing To Address The Posting Of A Security Bond

As a direct result of the Preliminary Injunction, NMA members were deprived of their much-needed supply of Canadian cattle. As noted above, NMA provided the District Court with substantial evidence of the harm that would befall its members should an injunction be entered.

The District Court erred in failing to address the posting of a security bond by R-CALF. Rule 65(c) states, in mandatory terms, that:

> No restraining order or preliminary injunction shall issue except upon the giving of security by the applicant ....

FED. R. CIV. P. 65(c).

The primary purpose of the rule is to enable a restrained party to secure indemnification for the costs "and pecuniary injury that may accrue during the period in which a wrongfully issued equitable order remains in effect." 11A C.

Wright, A. Miller, M. Kane, Federal Practice and Procedure, § 2954 at 287 (1995).

> Since a preliminary injunction may be granted on a mere probability of success on the merits, generally the moving party must demonstrate confidence in his legal position by posting bond in an amount sufficient to protect his adversary from loss in the event that future proceedings prove that the injunction issued wrongfully.

Edgar v. Mite Corp., 457 U.S. 624, 649 (1982) (Stevens, J., concurring) (footnote omitted).

In this case, the District Court failed to require the posting of a bond or even mention the issue in its ruling. All courts have treated such a failure as serious, some holding that the failure to require a bond warrants dismissal, or is reversible error if the District Court has failed to consider the question of requiring a bond. 11A C. Wright, A. Miller, M. Kane, Federal Practice and Procedure, § 2954 at 288-290. (and cases cited therein).

VII. CONCLUSION

The members of the National Meat Association who slaughter live cattle are seriously and irreparably injured by the Preliminary Injunction the District Court issued, which bars them from purchasing healthy live cattle from Canada. The District Court erred when it denied NMA's Motion to Intervene, holding that NMA does not have a significant protectable interest in this litigation and that NMA Motion to Intervene was not timely. Both conclusions are without merit.

Because NMA's Motion to Intervene was denied, NMA was unable to participate in the District Court's hearing on March 2, 2005, at which time the Court failed to provide any reasoned consideration of the rulemaking record, but instead issued a Preliminary Injunction that causes irreparable injury to NMA's members. At the same time the District Court failed to require the Plaintiff to post a bond to secure NMA's members against their mounting and irreparable losses. This court should overturn the District Court's denial of NMA's Motion to Intervene, and should move on an expedited and emergency basis to vacate the Preliminary Injunction at the earliest possible date.

DATED this 21th day of March 2005.

Respectfully submitted,

BROWN LAW FIRM, P.C.

By _____
John W. Ross

OLSSON, FRANK AND WEEDA, P.C.

By _____
Philip C. Olsson

Attorneys for National Meat Association

VIII. STATEMENT OF RELATED CASES

NMA understands that USDA and APHIS have filed a Notice of Appeal of the District Court's March 2, 2005 Order with the Court.

IX. CERTIFICATE OF COMPLIANCE REQUIRED BY FED. R. APP. P. 32(A)(7)(C) AND NINTH CIRCUIT RULE 32-1

I certify that:

_X_ 1. Pursuant to FED. R. APP. P. 32(a)(7)(C) and Ninth Circuit Rule 32-1, the attached opening/answering/reply/cross-appeal brief is

X Proportionately spaced, has a typeface of 14 points or more and contains 13,058 words (opening, answering, and the second and third briefs filed in cross-appeals must not exceed 14,000 words; reply briefs must not exceed 7,000 words).

Or is

☐ Monospaced, has 10.5 or fewer characters per inch and contains ____ words or _____ lines of text (opening, answering, and the second and third briefs filed in cross-appeals must not exceed 14,000 words or 1,300 lines of text; reply briefs must not exceed 7,000 words or 650 lines of text).

___ 2. The attached brief is **not** subject to the type-volume limitations of FED. R. APP. P. 32(a)(7)(B) because

☐ This brief complies with FED. R. APP. P. 32(a)(1)-(7) and is a principal brief of no more than 30 pages or a reply brief of no more than 15 pages.

☐ This brief complies with a page or size-volume limitation established by separate court order dated _____ and is

☐ Proportionately spaced, has a typeface of 14 points or more and contains ____ words,

Or is

☐ Monospaced, has 10.5 or fewer characters per inch and contains ___ pages or _____ words or _____ lines of text.

___ 3. *Briefs in Capital Cases*

☐ This brief is being filed in a capital case pursuant to the type-volume limitations set forth at Circuit Rule 32-4 **and is**

☐ Proportionately spaced, has a typeface of 14 points or more and contains ____ words (opening, answering, and the second and third briefs filed in cross-appeals must not exceed 21,000 words; reply briefs must not exceed 9,800 words).

Or is

☐ Monospaced, has 10.5 or fewer characters per inch and contains ____ words or _____ lines of text (opening, answering,

and the second and third briefs filed in cross-appeals must not exceed 75 pages or 1,950 lines of text; reply briefs must not exceed 35 pages or 910 lines of text).

___ 4. *Amicus Briefs*

☐ Pursuant to FED. R. APP. P. 29(d) and 9th Cir. 32-1, the attached amicus brief is proportionally spaced, ahs a typeface of 14 points or more and contains 7,000 words or less.

Or is

☐ Monospaced, has 10.5 or fewer characters per inch and contains not more than either 7,000 words or 650 lines of text.

Or is

☐ **Not** subject to the type-volume limitations because it is an amicus brief of no more than 15 pages and complies with FED. R. APP. P. 32(a)(1(5).

DATED this 21th day of March 2005.

Respectfully submitted,

OLSSON, FRANK AND WEEDA, P.C.

By _____
Philip C. Olsson

X. ADDENDUM CONTAINING REGULATIONS

Rules and Regulations

Federal Register
Vol. 68, No. 103
Thursday, May 29, 2003

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Parts 93 and 94

[Docket No. 03–058–1]

Change in Disease Status of Canada Because of BSE

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Interim rule and request for comments.

SUMMARY: We are amending the regulations by adding Canada to the list of regions where bovine spongiform encephalopathy exists because the disease has been detected in an animal in that region. This action prohibits or restricts the importation of ruminants that have been in Canada and meat, meat products, and certain other products and byproducts of ruminants that have been in Canada. This action is necessary to help prevent the introduction of bovine spongiform encephalopathy into the United States.

DATES: This rule is effective retroactively to May 20, 2003. We will consider all comments that we receive on or before July 28, 2003.

ADDRESSES: You may submit comments by postal mail/commercial delivery or by e-mail. If you use postal mail/commercial delivery, please send four copies of your comment (an original and three copies) to: Docket No. 03–058–1, Regulatory Analysis and Development, PPD, APHIS, Station 3C71, 4700 River Road Unit 118, Riverdale, MD 20737–1238. Please state that your comment refers to Docket No. 03–058–1. If you use e-mail, address your comment to *regulations@aphis.usda.gov*. Your comment must be contained in the body of your message; do not send attached files. Please include your name and address in your message and "Docket No. 03–058–1" on the subject line.

You may read any comments that we receive on this docket in our reading room. The reading room is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue, SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 690–2817 before coming.

APHIS documents published in the **Federal Register**, and related information, including the names of organizations and individuals who have commented on APHIS dockets, are available on the Internet at *http://www.aphis.usda.gov/ppd/rad/webrepor.html*.

FOR FURTHER INFORMATION CONTACT: Dr. Gary Colgrove, Director, Sanitary Trade Issues Team, National Center for Import and Export, VS, APHIS, 4700 River Road Unit 38, Riverdale, MD 20737–1231; (301) 734–4356.

SUPPLEMENTARY INFORMATION:

Background

The regulations in 9 CFR parts 93, 94, 95, and 96 (referred to below as the regulations) govern the importation of certain animals, birds, poultry, meat, other animal products and byproducts, hay, and straw into the United States in order to prevent the introduction of various animal diseases, including bovine spongiform encephalopathy (BSE).

BSE is a neurological disease of cattle and is not known to exist in the United States. It appears that BSE is primarily spread through the use of ruminant feed containing protein and other products from ruminants infected with BSE. Therefore, BSE could become established in the United States if materials carrying the BSE agent, such as certain meat, animal products, and animal byproducts from ruminants, are imported into the United States and are fed to ruminants in the United States. BSE could also become established in the United States if ruminants with BSE are imported into the United States.

Sections 94.18, 95.4, and 96.2 of the regulations prohibit or restrict the importation of certain meat and other animal products and byproducts from ruminants that have been in regions in which BSE exists or in which there is an undue risk of introducing BSE into the United States. Paragraph (a)(1) of § 94.18 lists the regions in which BSE exists. Paragraph (a)(2) lists the regions that present an undue risk of introducing BSE into the United States because their import requirements are less restrictive than those that would be acceptable for import into the United States and/or because the regions have inadequate surveillance. Paragraph (b) of § 94.18 prohibits the importation of fresh, frozen, and chilled meat, meat products, and most other edible products of ruminants that have been in any region listed in paragraphs (a)(1) or (a)(2). Paragraph (c) of § 94.18 restricts the importation of gelatin derived from ruminants that have been in any of these regions. Section 95.4 prohibits or restricts the importation of certain byproducts from ruminants that have been in any of those regions, and § 96.2 prohibits the importation of casings, except stomach casings, from ruminants that have been in any of these regions. Additionally, the regulations in part 93 pertaining to the importation of live animals provide that the Animal and Plant Health Inspection Service (APHIS) may deny an application for a permit for the importation of ruminants from regions where a communicable disease such as BSE exists and from regions that present risks of introducing communicable diseases into the United States (*see* § 93.404(a)(3)).

On May 20, 2003, the Canadian Food Inspection Agency reported a case of BSE in a beef cow in northern Alberta. Therefore, in order to prevent the introduction of BSE into the United States, we are amending § 94.18(a)(1) by adding Canada to the list of regions where BSE is known to exist. This action prohibits or restricts the importation of ruminants that have been in Canada and the importation of meat, meat products, and certain other products and byproducts of ruminants that have been in Canada. We are making this amendment effective retroactively to May 20, 2003, which is the date that Canada reported the BSE case.

As noted previously, the regulations in § 93.404(a)(3) provide the basis for APHIS to deny an application for a permit for the importation of ruminants from regions listed in § 94.18(a)(1) or (a)(2). Because, with certain exceptions, ruminants may not be imported into the

Proposed Rules

Federal Register
Vol. 68, No. 213
Tuesday, November 4, 2003

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Parts 93, 94, and 95

[Docket No. 03–080–1]

RIN 0579–AB73

Bovine Spongiform Encephalopathy; Minimal Risk Regions and Importation of Commodities

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Proposed rule.

SUMMARY: We are proposing to amend the regulations regarding the importation of animals and animal products to recognize a category of regions that present a minimal risk of introducing bovine spongiform encephalopathy (BSE) into the United States via live ruminants and ruminant products, and are proposing to add Canada to this category. We are also proposing to allow the importation of certain live ruminants and ruminant products and byproducts from such regions under certain conditions. We believe this action is warranted because it would continue to protect against the introduction of BSE into the United States while removing unnecessary prohibitions on certain commodities from Canada and other regions that qualify as BSE minimal-risk regions.

DATES: We will consider all comments that we receive on or before January 5, 2004.

ADDRESSES: You may submit comments by postal mail/commercial delivery or by e-mail. If you use postal mail/commercial delivery, please send four copies of your comment (an original and three copies) to: Docket No. 03–080–1, Regulatory Analysis and Development, PPD, APHIS, Station 3C71, 4700 River Road Unit 118, Riverdale, MD 20737–1238. Please state that your comment refers to Docket No. 03–080–1. If you use e-mail, address your comment to *regulations@aphis.usda.gov*. Your comment must be contained in the body of your message; do not send attached files. Please include your name and address in your message and "Docket No. 03–080–1" on the subject line.

You may read the risk assessment, environmental assessment, economic analysis, and any comments that we receive on this docket in our reading room. The reading room is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue, SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 690–2817 before coming.

APHIS documents published in the **Federal Register**, and related information, including the names of organizations and individuals who have commented on APHIS dockets, are available on the Internet at *http://www.aphis.usda.gov/ppd/rad/webrepor.html*.

FOR FURTHER INFORMATION CONTACT: Dr. Karen James-Preston, Director, Technical Trade Services, National Center for Import and Export, VS, APHIS, 4700 River Road Unit 38, Riverdale, MD 20737–1231; (301) 734–4356.

SUPPLEMENTARY INFORMATION:

Background

The Animal and Plant Health Inspection Service (APHIS) of the United States Department of Agriculture (USDA or the Department) regulates the importation of animals and animal products into the United States to guard against the introduction of animal diseases. The regulations in 9 CFR parts 93, 94, 95, and 96 (referred to below as the regulations) govern the importation of certain animals, birds, poultry, meat, other animal products and byproducts, hay, and straw into the United States in order to prevent the introduction of various animal diseases, including bovine spongiform encephalopathy (BSE).

BSE is a progressive neurological disorder of cattle that results from infection by an unconventional transmissible agent and is not known to exist in the United States. The disease has been difficult to define experimentally with precision, although risk factors that are independent of the causative agent have been identified and can be mitigated. Much of the available data originated from epidemiological observations and not from controlled studies. Controlled studies are often difficult to conduct because of limitations in experimental models and the length of time necessary to conduct the studies, which may require years. Currently, the most accepted theory is that the agent is a modified form of a normal cell surface component known as prion protein, although other types of agents have been implicated, including virinos. The pathogenic form of the protein is both less soluble and more resistant to degradation than the normal form. The BSE agent is extremely resistant to heat and to normal sterilization processes. It does not evoke any demonstrated immune response or inflammatory reaction in host animals.

Despite the difficulty in defining BSE experimentally with precision, risk factors for BSE that can be mitigated have been identified. These factors are based on technical knowledge and disease epidemiology and do not require definition of the nature of the agent. We believe that risk mitigation measures that address the risk factors for BSE will be effective regardless of the precise nature of the BSE agent.

It appears that BSE is spread primarily through the use of ruminant feed containing protein and other products from ruminants infected with BSE. Ruminants in the United States could be exposed to the disease if materials carrying the BSE agent—such as certain meat, animal products, or animal byproducts from ruminants—were imported into the United States and were fed to ruminants in this country. BSE could also be introduced into the United States if ruminants with BSE were imported into the United States.

Because of these risks, the regulations prohibit the importation of live ruminants and certain ruminant products and byproducts from two categories of regions: (1) Those regions in which BSE is known to exist, which are listed in § 94.18(a)(1) of the regulations; and (2) those regions that present an undue risk of introducing BSE into the United States because their import requirements are less restrictive than those that would be acceptable for import into the United States and/or because the regions have inadequate surveillance. These regions of "undue

confirmed from the experimentally infected cattle as early as 6 months post-exposure. In this proposed rule, we take these findings into account when establishing measures to mitigate the risk of infectious levels of the BSE agent being present in animals and animal products imported from a BSE minimal-risk region. For example, with regard to bovines, because BSE infectivity has not been found in most bovine tissues until at least 32 months post-exposure, we believe that by requiring that bovines imported into the United States from BSE minimal-risk regions be less than 30 months of age, the risk of the BSE agent being present at infectious levels in most tissues in the animal is minimized. The 30-month age limit is accepted internationally in BSE standards set by various countries and is consistent with OIE recommendations. Similarly, the proposed regulations would require that imported meat from bovines be derived from animals less than 30 months of age when slaughtered. However, because of evidence that the BSE agent may be present at infectious levels in the distal ileum of infected bovines as early as 6 months post-exposure, we would require that the intestines of bovines imported into the United States be removed at slaughter, and that meat imported from bovines from BSE minimal-risk regions be derived from animals from which the intestines were removed at slaughter.

Although the risks associated with age can be mitigated by accepting for import only animals or commodities derived from animals of an age where even high risk tissues (discussed below) are unlikely to have infectious levels of the BSE agent, restrictions applicable to age alone may not always be possible or sufficient. For instance, in the case of wild cervids, because it is not always possible to determine the age of the cervids, we believe that alternative risk measures, discussed below, are necessary.

Research demonstrates that the incubation period for BSE is apparently linked to the infectious dose received—*i.e.*, the larger the infectious dose received, the shorter the incubation period (EU SSC 2002). While some cases of BSE have been found in animals less than 30 months of age, these are relatively few and have occurred primarily in countries with significant levels of circulating infectivity (*i.e.*, where infected ruminants are used for feed for other ruminants, which in turn become infected). The conditions, discussed above, for qualifying for a BSE minimal-risk region guard against such circulating infectivity.

Similar observations regarding the importance of the size of the infectious dose were made in sheep and goats (EU SSC 2002). In these animals, infectivity could not be demonstrated in most tissues until at least 16 months post-exposure to the agent.

In summary, infected cattle over 30 months of age or sheep and goats over 16 months of age may have levels of the abnormal prion in affected tissues that are sufficient to infect other animals fed protein derived from these tissues. Infected animals less than 30 months of age or sheep and goats less than 16 months of age are unlikely to have infectious levels of the prion protein (EU SSC 2002; Wells, *et al.*; 1994; Wells, *et al.*; 1998).

Animals that were born before the feed ban but were not fed risk material, such as wild ruminants or domestic livestock in the minimal-risk region that were fed solely materials that are extremely unlikely to contain the infectious agent, are unlikely to contain infectious levels of BSE.

Tissue Localization

Some bovine tissues have demonstrated infectivity, whereas others have not. Tissues that have demonstrated infectivity, and thus are likely to contain the infectious agent in infected cattle, are brain, tonsil, spinal cord, eyes, trigeminal ganglia, dorsal root ganglia, and distal ileum. (Please note that, as discussed above, the age of an animal is a key factor in whether the animal is likely or unlikely to be infected. Cattle less than 30 months of age unlikely to be infected with BSE, and, therefore, even the tissues listed above, except for the distal ileum, from such animals are unlikely to contain the infectious agent.) Affiliated tissues or structures such as skull or vertebral column are considered risk materials because of the difficulty in separating out small tissues such as dorsal root ganglia from the vertebral column. Possibilities for cross contamination from risk materials must be considered also. However, even cattle carrying the infectious agent are unlikely to carry that agent in tissues that have not demonstrated infectivity (*e.g.*, muscle, liver, skin, hide, milk, embryos) or products derived from these tissues [5] (also, Wells, *et al.*; 1994; Wells, *et al.*; 1998).

The risks associated with tissue localization can be mitigated by accepting only tissues that are unlikely to have infectious levels of the agent, due to the nature of the tissue or the age of the animal (in cattle under 30 months of age, only the distal ileum is such a risk material), or commodities derived from those tissues.

Source Species

Tissue distribution of the agent varies with species. Results from experimental infections of sheep have shown that the BSE prion is distributed more widely in sheep tissues than in cattle.[6] This distribution is similar to the distribution of scrapie (a transmissible spongiform encephalopathy present in the United States) infections in sheep. In these infections, the agent may be found in the lymphoreticular system and in peripheral nerves (Foster *et al.*; 1996; Foster *et al.*; 2001).

However, no natural infections with BSE have yet been confirmed in sheep, although testing is ongoing in Europe. Similarly, no natural infections have been confirmed in goats, although actual experiments have not been conducted in the species. In the absence of actual data, distribution of the agent in goat tissues has been assumed to be similar to distribution of the agent in sheep tissues, based on the fact that scrapie acts very similarly in sheep and goats.

Similarly, natural infection of cervids (deer and elk species) with BSE has not been documented, and no challenge studies on cervid susceptibility to BSE have been conducted. In the absence of actual data, it is assumed that distribution of any BSE agent in cervid tissues would be similar to the distribution of the chronic wasting disease agent in cervid tissues, which is a naturally occurring transmissible spongiform encephalopathy.

Prevalence of BSE

The possible prevalence of disease in the region of origin will influence the risk. Prevalence of the disease will be lower in a country with adequate prevention and control measures; thus, animals from such a region will be at lower risk of being exposed to infection. The risks associated with prevalence can be mitigated by accepting commodities only from a country with low prevalence that can be classified as minimal or low risk.

[5] Wrathall, A.E., *et al.*; 2002; Studies of embryo transfer from cattle clinically affected by bovine spongiform encephalopathy (BSE); Veterinary Record; 150; pg 365–378.

[6] Foster, J.D., *et al.*; 1996; Detection of BSE infectivity in brain and spleen of experimentally infected sheep; Veterinary Record; 139; pg 912–915.

Foster, J.D., *et al.*; 2001; Distribution of the prion protein in sheep terminally affected with BSE following experimental oral transmission; J. Gen Virol.; 82; pg 2319–2326.

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Parts 309, 310, 311, 318, and 319

[Docket No. 03–025IF]

Prohibition of the Use of Specified Risk Materials for Human Food and Requirements for the Disposition of Non-Ambulatory Disabled Cattle

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Interim final rule and request for comments.

SUMMARY: The Food Safety and Inspection Service (FSIS) is amending the Federal meat inspection regulations to designate the brain, skull, eyes, trigeminal ganglia, spinal cord, vertebral column (excluding the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae, and the wings of the sacrum), and dorsal root ganglia (DRG) of cattle 30 months of age and older, and the tonsils and distal ileum of the small intestine of all cattle, as "specified risk materials" (SRMs). The Agency is declaring that SRMs are inedible and prohibiting their use for human food. In addition, FSIS is requiring that all non-ambulatory disabled cattle presented for slaughter be condemned. The Agency is requiring that federally-inspected establishments that slaughter cattle and federally-inspected establishments that process the carcasses or parts of cattle develop, implement, and maintain written procedures for the removal, segregation, and disposition of SRMs. Establishments must incorporate these procedures into their HACCP plans or in their Sanitation SOPs or other prerequisite program. FSIS is taking this action in response to the diagnosis on December 23, 2003, by the U.S. Department of Agriculture of a positive case of bovine spongiform encephalopathy (BSE) in an adult Holstein cow in the State of Washington. This action will minimize human exposure to materials that scientific studies have demonstrated as containing the BSE agent in cattle infected with the disease. Infectivity has never been demonstrated in the muscle tissue of cattle experimentally or naturally infected with BSE at any stage of the disease.

DATES: This interim final rule is effective January 12, 2004. Comments on this interim final rule must be received by April 12, 2004.

ADDRESSES: Submit written comments to: FSIS Docket Clerk, Docket #03–025IF, Room 102, Cotton Annex, 300 12th and C Street, SW., Washington, DC 20250–3700. Reference materials cited in this document and any comments received will be available for public inspection in the FSIS Docket Room from 8:30 a.m. to 4:30 p.m., Monday through Friday. Reference materials that are not copyrighted will also be available on the FSIS Web site at *http://www.fsis.usda.gov*.

FOR FURTHER INFORMATION CONTACT: Daniel L. Engeljohn, Ph.D., Executive Associate, Policy Analysis and Formulation, Office of Policy and Program Development, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250–3700; (202)205–0495.

SUPPLEMENTARY INFORMATION:

Background

Under the Federal Meat Inspection Act (FMIA) (21 U.S.C. 601 *et seq.*), FSIS issues regulations governing the production of meat and meat food products prepared for distribution in commerce. The regulations, along with FSIS inspection programs, are designed to ensure that meat and meat food products are safe, wholesome, unadulterated, and properly marked, labeled, and packaged. The FMIA prohibits anyone from selling, transporting, offering for sale or transportation, or receiving for transportation in commerce, any adulterated or misbranded meat or meat food product (21 U.S.C. 610).

Under the FMIA, a meat food product is adulterated if, among other circumstances, it bears or contains any poisonous or deleterious substance that may render it injurious to health (21 U.S.C. 601(m)(1)) or if it is for any reason unsound, unhealthful, unwholesome, or unfit for human food (21 U.S.C. 601(m)(3)). The FMIA requires that FSIS inspect the carcasses, parts of carcasses, and meat food products of all cattle, sheep, swine, goats, horses, mules, or other equines that are capable for use as human food to ensure that such articles are not adulterated (21 U.S.C. 604, 606). If the carcasses, parts of carcasses, and meat food products are found, upon inspection, to be not adulterated, FSIS marks them as "Inspected and passed" (21 U.S.C. 604, 606, 607). The FMIA gives FSIS broad authority to promulgate such rules and regulations as are necessary to carry out the provisions of the Act (21 U.S.C. 621).

As discussed in greater detail below, infectivity has been confirmed in the brain, trigeminal ganglia, tonsils, spinal cord, DRG, and distal ileum of the small intestine of cattle experimentally infected with BSE, and in the brain, spinal cord, and eyes of cattle infected with BSE under field conditions. Data on the age distribution of clinical cases of BSE in the field reported in the United Kingdom indicate that clinical BSE disease has rarely been reported in cattle younger than 30 months of age.

In cattle experimentally infected with BSE, infectivity has been confirmed in the distal ileum at various stages of the disease process and as early as 6 months after oral exposure to the BSE agent. The tonsils of experimentally infected cattle have demonstrated apparently weak infectivity as early as 10 months after oral exposure to the BSE agent. The other tissues in which BSE infectivity has been confirmed have demonstrated infectivity at the end stages of disease, which, in experimentally infected cattle, was 32 months after exposure to the BSE agent and later. The brain, trigeminal ganglia, tonsils, DRG, and distal ileum are materials of experimentally infected cattle in which infectivity has been confirmed before the onset of clinical disease.

Based on these findings, FSIS has concluded that the brain, skull, eyes, trigeminal ganglia, spinal cord, vertebral column (excluding the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae, and the wings of the sacrum), and DRG of cattle 30 months of age and older, and the tonsils and distal ileum of the small intestine of all cattle are unfit for human food under section 1(m)(3) of the FMIA (21 U.S.C 601(m)(3)). Therefore, FSIS is designating these materials as SRMs, declaring that they are inedible and, pursuant to its authority to promulgate regulations necessary to carry out the provisions of the FMIA, prohibiting their use for human food.

Because there are currently no restrictions on the incorporation of spinal cord and DRG into MS(Beef) meat food product, such product may contain concentrated amounts of these high-risk tissues. Therefore FSIS has concluded that, like the SRMs described above, MS(Beef) is unfit for human food under section 1(m)(3) of the FMIA (21 U.S.C. 601(m)(3)).

As discussed in detail below, surveillance data from European countries in which BSE has been detected indicate that non-ambulatory cattle are among the animals that have a greater incidence of BSE than other cattle. Surveillance data also indicate that clinical signs of BSE cannot always be observed in non-ambulatory cattle. Furthermore, due to limitations in the testing methods for BSE that are available today, certain tissues of cattle

country pursuant to a bilateral or multilateral agreement, only with respect to aliens whom DHS has chosen to place in removal proceedings under section 240 of the Act, as provided in 8 CFR 1240.11(g). For DHS regulations relating to determinations by asylum officers on this subject, see 8 CFR 208.30(e)(6).

* * * * *

5. Section 1208.30 is amended by:

a. Revising paragraphs (a) and (e); and by

b. Removing and reserving paragraphs (c), (d), (f) and (g)(1).

The revisions read as follows:

§ 1208.30 Credible fear determinations involving stowaways and applicants for admission found inadmissible pursuant to section 212(a)(6)(C) or 212(a)(7) of the Act.

(a) Jurisdiction. The provisions of this subpart apply to aliens subject to sections 235(a)(2) and 235(b)(1) of the Act. Pursuant to section 235(b)(1)(B), asylum officers have exclusive jurisdiction to make credible fear determinations, and the immigration judges have exclusive jurisdiction to review such determinations.

* * * * *

(e) Determination. For the standards and procedures for asylum officers in conducting credible fear interviews and in making positive and negative credible fear determinations, see 8 CFR 208.30(b), (c), (d), (e), (f), and (g)(1). The immigration judges will review such determinations as provided in paragraph (g)(2) of this section and 8 CFR 1003.42.

* * * * *

PART 1212—DOCUMENTARY REQUIREMENTS; NONIMMIGRANTS; WAIVERS; ADMISSION OF CERTAIN INADMISSIBLE ALIENS; PAROLE

6. The authority citation for part 1212 is revised to read as follows:

Authority: 8 U.S.C. 1101 and note, 1103.

7. Section 1212.5 is revised to read as follows:

§ 1212.5 Parole of aliens into the United States.

Procedures and standards for the granting of parole by the Department of Homeland Security can be found at 8 CFR 212.5.

PART 1240—PROCEEDINGS TO DETERMINE REMOVABILITY OF ALIENS IN THE UNITED STATES

8. The authority citation for part 1240 is revised to read as follows:

Authority: 8 U.S.C. 1103, 1182, 1186a, 1224, 1225, 1226, 1227, 1251, 1252 note, 1252a, 1252b, 1362; secs. 202 and 203, Pub. L. 105–100, 111 Stat. 2160, 2193; sec. 902, Pub. L. 105–277, 112 Stat. 2681; sec. 1101, Pub. L. 107–269, 116 Stat. 2135.

9. Section 1240.11 is amended by adding a new paragraph (g), to read as follows:

§ 1240.11 Ancillary matters, applications.

* * * * *

(g) Safe third country agreement. (1) The immigration judge has authority to apply section 208(a)(2)(A) of the Act, relating to a determination that an alien may be removed to a safe third country pursuant to a bilateral or multilateral agreement, in the case of an alien who is subject to the terms of the agreement and is placed in proceedings pursuant to section 240 of the Act without being processed under section 235 of the Act. In an appropriate case, the immigration judge shall determine whether under the Agreement the alien should be returned to the safe third country, or whether the alien should be permitted to pursue asylum or other protection claims in the United States.

(2) An alien described in paragraph (g)(1) of this section is ineligible to apply for asylum, pursuant to section 208(a)(2)(A) of the Act, unless the immigration judge determines, by preponderance of the evidence, that:

(i) The agreement does not apply to the alien or does not preclude the alien from applying for asylum in the United States; or

(ii) The alien qualifies for an exception to the agreement as set forth in paragraph (g)(3) of this section.

(3) The immigration judge shall apply the applicable regulations in deciding whether the alien qualifies for any exception under the agreement that would permit the United States to exercise authority over the alien's asylum claim. The exceptions under the agreement are codified at 8 CFR 208.30(e)(6)(iii). The immigration judge shall not review, consider, or decide any issues pertaining to any discretionary determination on whether the alien should be permitted to pursue an asylum claim in the United States notwithstanding the general terms of the agreement, as such discretionary public interest determinations are reserved to the Department of Homeland Security. However, an alien in removal proceedings who is otherwise ineligible to apply for asylum under the agreement may apply for asylum if the Department of Homeland Security files a written notice in the proceedings before the immigration judge that it has decided in the public interest to allow the alien to pursue claims for asylum or withholding of removal in the United States.

(4) An alien who is found to be ineligible to apply for asylum under section 208(a)(2)(A) of the Act is ineligible to apply for withholding of removal pursuant to section 241(b)(3) of the Act and the Convention against Torture. However, the alien may apply for any other relief from removal for which the alien may be eligible. If an alien who is subject to section 208(a)(2)(A) of the Act is ordered removed, the alien shall be ordered removed to the safe third country in which the alien will be able to pursue his or her claims for asylum or protection under the laws of that country.

Dated: March 1, 2004.

John Ashcroft,

Attorney General.

[FR Doc. 04–5065 Filed 3–5–04; 8:45 am]

BILLING CODE 4410–30–P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Parts 93, 94, and 95

[Docket No. 03–080–2]

RIN 0579–AB73

Bovine Spongiform Encephalopathy; Minimal Risk Regions and Importation of Commodities

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Proposed rule; reopening of comment period.

SUMMARY: We are reopening the comment period for our proposed rule that would amend the regulations regarding the importation of animals and animal products to recognize, and add Canada to, a category of regions that present a minimal risk of introducing bovine spongiform encephalopathy into the United States via live ruminants and ruminant products. The proposed rule also set out conditions under which we would allow the importation of certain live ruminants and ruminant products and byproducts from such regions. This action will allow interested persons additional time to prepare and submit comments.

DATES: We will consider all comments that we receive on or before April 7, 2004.

ADDRESSES: You may submit comments by any of the following methods:

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Parts 93, 94, 95, and 96

[Docket No. 03–080–3]

RIN 0579–AB73

Bovine Spongiform Encephalopathy; Minimal-Risk Regions and Importation of Commodities

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: We are amending the regulations regarding the importation of animals and animal products to establish a category of regions that present a minimal risk of introducing bovine spongiform encephalopathy (BSE) into the United States via live ruminants and ruminant products and byproducts, and we are adding Canada to this category. We are also establishing conditions for the importation of certain live ruminants and ruminant products and byproducts from such regions. These actions will continue to protect against the introduction of BSE into the United States while removing unnecessary prohibitions on the importation of certain commodities from minimal-risk regions for BSE, currently only Canada.

EFFECTIVE DATE: March 7, 2005.

FOR FURTHER INFORMATION CONTACT: For information concerning ruminant products, contact Dr. Karen James-Preston, Director, Technical Trade Services, National Center for Import and Export, VS, APHIS, 4700 River Road Unit 38, Riverdale, MD 20737–1231; (301) 734–4356.

For information concerning live ruminants, contact Lee Ann Thomas, Director, Technical Trade Services, Animals, Organisms and Vectors, and Select Agents, National Center for Import and Export, VS, APHIS, 4700 River Road Unit 38, Riverdale, MD 20737–1231; (301) 734–4356.

For other information concerning this rule, contact Dr. Gary Colgrove, Director, Sanitary Trade Issues Team, National Center for Import and Export, VS, APHIS, 4700 River Road Unit 38, Riverdale, MD 20737–1231; (301) 734–4356.

SUPPLEMENTARY INFORMATION:

I. Purpose

This document makes final, with changes, a proposed rule that the Animal and Plant Health Inspection Service (APHIS) of the U.S. Department of Agriculture (USDA or the Department) published in the **Federal Register** on November 4, 2003 (68 FR 62386–62405, Docket No. 03–080–1). In that document, we proposed to establish a category of regions that present a minimal risk of introducing bovine spongiform encephalopathy (BSE) into the United States via live ruminants and ruminant products and byproducts, and to add Canada to this category. The proposal also set forth conditions for the importation of certain live ruminants and ruminant products and byproducts from BSE minimal-risk regions. We solicited public comment on the proposed rule and its underlying risk analysis and other supporting analyses for 60 days ending on January 5, 2004. At the time the proposed rule was published, BSE had never been detected in a native animal in the United States and only a single case in a native animal had been reported in Canada (in Alberta in May 2003). In December 2003, BSE was detected in an imported dairy cow in Washington State. This document describes the course of this rulemaking before and after the detection in Washington State, including how the rulemaking was affected by additional BSE-related safeguards imposed by USDA's Food Safety and Inspection Service (FSIS) in January 2004. It also responds to public comments received on the proposed rule and its underlying risk analysis and other supporting analyses, both before the original closing date on January 5, 2004, and during an extended comment period that closed on April 7, 2004, and explains the changes we are making in this final rule.

II. Summary of Changes Made in This Final Rule

Based on our continued analysis of the issues and on information provided by commenters, we have made certain changes in this final rule from the provisions we proposed in November 2003, as supplemented by our March 2003 notice of the extension of the comment period. Those changes, summarized in the list below, are discussed in detail in our responses to comments.

1. For bovines imported from a BSE minimal-risk region for feeding and then slaughter (referred to as feeder cattle), we are making the following changes:

- We are requiring that feeder cattle be permanently marked before entry as to country of origin with a brand or other means of identification approved by the Administrator, rather than by an ear tattoo as proposed. Feeder cattle imported from Canada must be marked with "C∧N."
- We are requiring that feeder cattle be individually identified before entry by an eartag that allows the animal to be traced back to the premises of origin and are specifying that the eartag may not be removed until the animal is slaughtered.
- We are requiring that the animal health certification currently required under existing § 93.405 for certain live animals imported into the United States include, for feeder cattle imported from a BSE minimal-risk region, additional information relating to animal identification, origin, destination, and responsible parties.
- We are requiring that feeder cattle be moved from the port of entry to a feedlot in a sealed means of conveyance and then from the feedlot to a recognized slaughtering establishment in a sealed means of conveyance. The cattle may not be moved to more than one feedlot.
- When referring to the destination of feeder cattle imported into the United States, we are using the terminology "the feedlot identified on the APHIS Form VS 17–130" rather than "designated feedlot."
- We are specifying that the physical location of the feedlot of destination and the person responsible for movement of the cattle be identified on the documentation required for movement from the port of entry to the feedlot.

2. For sheep and goats imported from a BSE minimal-risk region for feeding and then slaughter (referred to as "feeder sheep and goats") we are making the following changes:

- As with cattle, we are requiring that feeder sheep and goats be permanently marked before entry as to country of origin (with the requirements for marking modified as appropriate for sheep and goats). Feeder sheep and goats imported from Canada must be marked with "C."
- As with cattle, we are requiring that feeder sheep and goats be individually identified before entry by an eartag that allows the animal to be traced back to the premises of origin and are specifying that the eartag may not be removed until the animal is slaughtered.
- We are continuing to refer to the feedlot of destination for feeder sheep and goats as a "designated feedlot" and are adding criteria for such feedlots. The sheep and goats may not be moved to more than one designated feedlot.
- We are requiring the same additional information on the health certification required under § 93.405 as described above for feeder cattle.
- We are requiring that feeder sheep and goats be moved from the port of entry to a designated feedlot as a group in a sealed means of conveyance, not be

has been confirmed in native-born cattle in 20 European countries in addition to the United Kingdom, and in some non-European countries, including Japan, Israel, and Canada. Over 95 percent of all BSE cases have occurred in the United Kingdom, where the epidemic peaked in 1992/1993. Agricultural officials in the United Kingdom have taken a series of actions to mitigate BSE, including making it a reportable disease, banning mammalian meat-and-bone meal in feed for all food-producing animals, prohibiting the inclusion of animals more than 30 months of age in the animal and human food chains, and destroying all animals showing signs of BSE and other potentially exposed animals at high risk of developing the disease. As a result of these actions, most notably the feed bans, the annual incidence of BSE in the United Kingdom has fallen dramatically. The figure below illustrates the downward trend in BSE cases among cattle born after implementation of the feed ban.

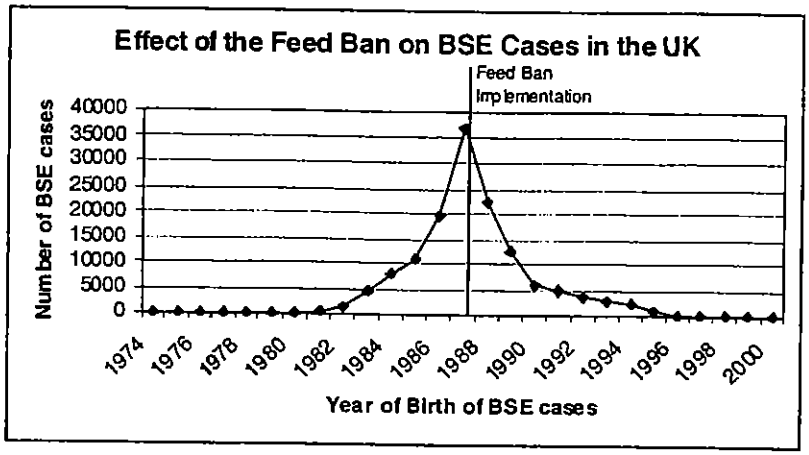

Figure 1.–Confirmed cases in UK cattle born after feed ban implementation. [Note: The first feed ban was implemented in the summer of 1988 (before fall calving).]

Variant Creutzfeld-Jakob disease (vCJD), a chronic and fatal neurodegenerative disease of humans, has been linked via scientific and epidemiological studies to exposure to the BSE agent, most likely through consumption of cattle products contaminated with the BSE agent. To date, since vCJD was first identified in 1996, approximately 150 probable and confirmed cases of vCJD have been identified. The majority of these cases have either been identified in the United Kingdom or were linked to exposure that occurred in the United Kingdom, and all cases have been linked to exposure in countries with native cases of BSE. Some studies estimate that more than 1 million cattle may have been infected with BSE throughout the epidemic in the United Kingdom. This number of infected cattle could have introduced a significant amount of infectivity into the human food supply. Yet, the number of cases of vCJD identified to date suggest a substantial species barrier that may protect humans from widespread illness due to BSE.

B. APHIS' Regulatory Approach to BSE: Past and Present

Since 1989 APHIS has prohibited the importation of live cattle and other ruminants and certain ruminant products, including most rendered protein products, into the United States from countries where BSE is known to exist. In 1997, due to concerns about widespread risk factors and inadequate surveillance for BSE in many European countries, APHIS added an additional classification of countries as regions of undue risk for BSE and extended importation restrictions on ruminants and ruminant products to all of the countries in Europe. In December 2000, APHIS expanded its prohibitions on imports of rendered ruminant protein products from BSE-restricted regions to include rendered protein products of any animal species, due to concern that cattle feed supposedly free of ruminant protein may have been cross-contaminated with the BSE agent. The same importation restrictions apply to regions where BSE has been confirmed in a native animal and regions that present an undue risk of BSE because of import requirements less restrictive than those that would be acceptable for import into the United States and/or because of inadequate surveillance (9 CFR 94.18).

In effect then, until implementation of this final rule, countries have fallen into one of three categories with regard to BSE:

- Regions in which BSE is known to exist;
- Regions that present an undue risk of BSE because of import requirements less restrictive than those that would be acceptable for import into the United States and/or because of inadequate surveillance; and
- Regions that do not fall into either of the above two categories.

This regulatory framework recognized only two risk situations—those regions considered free of BSE and those regions considered to present a BSE risk—and prohibited the importation of live ruminants and most ruminant products from those regions considered to present a BSE risk.

In our November 2003 proposed rule, we explained that we believed it was appropriate to establish an additional category of regions with regard to BSE—the BSE minimal-risk region. We stated that regions that could be eligible for a minimal-risk classification would be (1) those regions in which a BSE-infected animal has been diagnosed, but in which measures have been taken that make it unlikely that BSE would be introduced from that region into the United States, and (2) those regions that cannot be considered BSE-free even though BSE has not been detected, but that have taken sufficient measures to be

considered minimal risk. We proposed to add Canada to the new BSE minimal-risk category and also proposed conditions for the importation of certain live ruminants and ruminant products and byproducts from BSE minimal-risk regions.

Our proposed definition of BSE minimal-risk regions included the standards we would use to evaluate the BSE risk from a region and to classify a region as one of minimal risk for BSE. To qualify as a BSE minimal-risk region, we proposed that a region be one that meets the following standards:

1. The region maintains and, in the case of regions where BSE was detected, had in place prior to the detection of BSE, risk mitigation measures adequate to prevent widespread exposure and/or establishment of the disease. Such measures include the following:

- Restrictions on the importation of animals sufficient to minimize the possibility of infected ruminants being imported into the region, and on the importation of animal products and animal feed containing ruminant protein sufficient to minimize the possibility of ruminants in the region being exposed to BSE;
- Surveillance for BSE at levels that meet or exceed recommendations of the Office International des Epizooties (OIE, also now referred to as the World Organisation for Animal Health) for surveillance for BSE; and
- A ban on the feeding of ruminant protein to ruminants that appears to be an effective barrier to the dissemination of the BSE agent, with no evidence of significant noncompliance with the ban.

2. In regions where BSE was detected, the region conducted an epidemiological investigation following detection of BSE sufficient to confirm the adequacy of measures to prevent the further introduction or spread of BSE, and continues to take such measures.

3. In regions where BSE was detected, the region took additional risk mitigation measures, as necessary, following the BSE outbreak based on risk analysis of the outbreak, and continues to take such measures.

We stated in our proposal that we would use these standards 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 (discussed below).

Basis for Focused Regulatory Restrictions

Our proposed rule was based on a number of considerations. A significant amount of research has been conducted on BSE since the disease was initially identified and since we first established our regulatory framework to protect against the introduction of BSE. (Please note: In this final rule, we use the term "importation" to mean the movement of animals or products into the United States or another country and the term "introduction" to mean the movement of a disease agent into the United States or another country.)

While there are many unanswered questions, both research studies and field epidemiological experience have demonstrated effective control measures to prevent spread of this disease. Ongoing studies have identified specific tissues where the majority of infectivity appears to reside, so that these tissues can be removed from the food chain. Early epidemiological work identified contaminated feed as the primary method of spread of the disease between animals. Continued monitoring and surveillance in Europe—where the exposure is assumed to be the highest—have demonstrated the effectiveness of control measures that have been enacted, such as feed bans that prevent the recycling of the agent. This increased body of knowledge provides a sound and compelling scientific basis for more focused regulatory restrictions with regard to BSE than those we have been operating under.

A more focused approach is also supported by the international community, as evidenced by the evolution of BSE guidelines adopted by the OIE (Ref 1). The OIE is recognized by the World Trade Organization (WTO) as the international organization responsible for development and periodic review of standards, guidelines, and recommendations with respect to animal health and zoonoses (diseases that are transmissible from animals to humans). The OIE guidelines for trade in terrestrial animals (mammals, birds, and bees) are detailed in the Terrestrial Animal Health Code (Ref 2). The OIE guidelines on BSE, contained in Chapter 2.3.13 of the Terrestrial Animal Health Code, and supplemented by Appendix 3.8.4 of the Code, currently provide for five possible BSE classifications for regions. For each classification, the guidelines recommend different export conditions for live animals and products, based on the risk presented by the region. This framework not only recognizes different levels of risk among regions, but provides for trade in live animals and products under certain conditions even from regions considered high-risk under the OIE guidelines.

As a member of the OIE, the United States, represented by APHIS, has been actively involved in the development of OIE guidelines and fully supports the OIE position that gradations in BSE risk among regions should be recognized and that trade should be commensurate with risk. Although APHIS did not incorporate the text of OIE's BSE guidelines into its proposed rule, the agency based its standards on these guidelines. The standards contain the same basic factors for assessing a region's BSE status as the OIE guidelines (e.g., import requirements, incidence, surveillance, feed restrictions, etc.). APHIS also considered the OIE guidelines, in conjunction with other relevant factors and available information, when evaluating Canada as a BSE minimal-risk region, and will do so in the future in evaluating other countries that may apply for minimal-risk status under our regulations. It is in this context that APHIS' standards and the OIE guidelines should be viewed.

We believe it is important to explain the relationship of our standards to the OIE guidelines because a number of commenters questioned why we did not adopt the OIE guidelines outright and/or assumed that differences in text meant that APHIS had rejected the OIE guidelines. While there are differences between the APHIS standards and the OIE guidelines, these differences reflect the different purposes and uses of the OIE guidelines and our standards.

The OIE guidelines are designed to provide a science-based reference document for international trade in animals and animal products. To this end, the OIE Terrestrial Animal Health Standards Commission draws upon the expertise of internationally renowned specialists to draft new and revised articles of the Terrestrial Code in light of advances in veterinary science. Draft texts are circulated to member countries for review and comment and, as a general rule, are adopted based on consensus of the OIE membership. Articles adopted by the membership provide guidance for use by veterinary authorities, import/export services, epidemiologists and all those involved in international trade. OIE guidelines are not intended to be prescriptive; each member nation may determine its own appropriate level of protection and, therefore, establish its own import requirements. (In accordance with Article 5 of the WTO "Agreement on the Application of Sanitary and

Phytosanitary Measures" (WTO–SPS Agreement), WTO members are obligated to base their import requirements on an assessment of risk, taking into account the standards, guidelines, and recommendations, and the risk assessment techniques developed by the relevant international organizations.)

Regulations, which may be based on the OIE guidelines, are prescriptive, as they are intended to be enforced as written and are not designed to be a point of reference. Furthermore, because rulemaking may take considerable time, the most successful regulations must also be flexible enough to allow a country to consider individual circumstances among its trading partners, as well as changes in science, without undergoing constant revisions. One reason that APHIS has decided not to simply adopt the OIE guidelines as regulations is that they are constantly evolving and subject to change. Some chapters, in fact, such as the one on BSE, are continually being updated as new information becomes available. For example, the OIE is currently considering proposing a three-tier country classification system for BSE as an alternative to the existing five-tier system. In 2004, the OIE changed the recommended reported incidence rate for minimal-risk regions from less than 1 case per million during each of the last four consecutive 12-month periods within the cattle population over 24 months of age to less than 2 cases per million during that time period within that cattle population. This example of a numeric threshold points to another reason that APHIS chose not to adopt the OIE guidelines as regulations. In some cases, holding a country to a rigid criterion without consideration of compensatory risk reduction measures may not be scientifically justified and unfairly discriminate against regions where the overall conditions indicate equivalence with minimal BSE risk. In other cases, rigidly applying a numeric criterion without a thorough consideration and evaluation of relevant factors (e.g., the quality of a country's surveillance program and the supporting veterinary infrastructure) could result in trade with a region that may meet OIE guidelines but, nonetheless, present, in our view, an undue risk of BSE introduction. Therefore, rather than incorporate the text of the OIE guidelines into our regulations, APHIS chose to base its evaluation on OIE guidelines in a way that allows us 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.

As stated above, APHIS considered the OIE guidelines in evaluating whether Canada met our proposed standards, and we plan to consider them in assessing whether other countries that may apply for minimal-risk classification meet our standards. To illustrate how we would use the OIE guidelines for minimal-risk regions in applying our own standards, we can look to our evaluation of the incidence of BSE with respect to Canada. Although APHIS' standards do not include a numerical threshold for incidence, our standards provide that a region must have in place risk mitigation measures adequate to prevent widespread exposure and/or establishment of the disease. In concluding that measures taken in Canada had prevented widespread exposure and/or establishment, we compared Canada's incidence rate of two infected cattle in 2003 out of a population of 5.5 million cattle over 24 months of age with OIE's recommendation of less than two infected cattle per million during each of the last four consecutive 12-month periods within the cattle population over 24 months of age. Canada's incidence rate (0.4 per million head of adult cattle) is well below the current OIE recommendation regarding incidence in minimal-risk regions. We also considered that the reported rate of disease cannot be considered independently from either the level and quality of disease surveillance or from the position on the epidemic curve. In this regard, we note that Canada exceeds the OIE recommended level of testing. We also consider Canada's surveillance program for BSE in cattle to be of high quality because it includes active surveillance for BSE in cattle that is appropriately targeted based on known risk factors. Also, because Canada implemented import restrictions and a feed ban before detection of BSE in any indigenous animals, it is more likely that the incidence of BSE in Canada is decreasing (on the down slope of the epidemic curve), rather than increasing (on the up slope).

The November 2003 Proposed Rule

As explained above, our proposed standards for minimal-risk regions were based on the OIE guidelines for BSE minimal-risk regions, using those guidelines as a reference. We based our proposed classification of Canada as a minimal-risk region, as well as our proposed mitigation measures for live ruminants and ruminant products and byproducts from Canada, on an analysis of risk APHIS prepared entitled, "Risk Analysis: BSE Risk from Importation of Designated Ruminants and Ruminant Products from Canada into the United States." The analysis drew on a number of sources of information, including scientific literature, results of epidemiological investigations, data provided by the Canadian Government, a quantitative analysis (i.e., uses numerical values) of the risk of BSE in Canada prepared by the Canadian Food Inspection Agency (CFIA), and quantitative analyses of the consequences of BSE being introduced into the United States prepared by the Harvard Center for Risk Analysis at Harvard University (HCRA) and the Center for Computational Epidemiology at Tuskegee University (Ref 3) (discussed in more detail below under the heading "Harvard-Tuskegee Investigation of BSE Risk in the United States"). This analysis was made available to the public when the proposed rule was published in November 2003.

We solicited public comment on the proposed rule and its underlying risk analysis and other supporting analyses for 60 days ending on January 5, 2004. As noted, at the time the proposed rule was published, BSE had never been detected in a native animal in the United States, and only a single case in a native animal had been reported in Canada (in Alberta in May 2003).

The Reopening of the Comment Period and Explanatory Note

On December 23, 2003, less than 2 weeks before the close of the comment period for our proposed rule, USDA announced a presumptive positive case of BSE in a dairy cow in Washington State. Samples had been taken from the cow on December 9 as part of USDA's BSE surveillance program. The BSE diagnosis was made on December 22 and 23 by histopathology and immunohistochemical testing at the National Veterinary Services Laboratories in Ames, IA, and was verified on December 25 by the international reference laboratory, the Veterinary Laboratories Agency in Weybridge, England.

Upon detection of the BSE-positive cow in Washington State, USDA, FDA, and other Federal and State agencies, along with CFIA, immediately began working together to perform an epidemiological investigation (Ref 4), trace any potentially infected cattle, trace potentially contaminated rendered product, increase BSE surveillance, and take additional measures to address human and animal health.

devices containing bovine material. These agencies collaborate, issuing regulations under their respective authorities, to implement a coordinated U.S. response to BSE.

APHIS is promulgating this final rule under the authority of the Animal Health Protection Act, which gives the Secretary broad discretion to regulate the importation of animals and animal products when he or she determines it to be necessary. As discussed below, FSIS and FDA have recently published regulations regarding BSE to protect human health. Because of the specific focus of each of these three agencies, provisions for similar products may sometimes differ slightly in the agencies' respective regulations as appropriate based on the intended consumer.

Measures Implemented by FSIS

FSIS, in a series of three interim final rules that were published and made effective on January 12, 2004, took additional measures to prevent the BSE agent from entering the human food supply. In its interim final rule titled, "Prohibition on the Use of Specified Risk Materials for Human Food and Requirements for the Disposition of Non-Ambulatory Disabled Cattle" (FSIS Docket No. 03–025IF; 69 FR 1861), and referred to below as the SRM rule, FSIS designated certain cattle tissues as SRMs and prohibited their use in human food. As noted earlier, FSIS designated as SRMs the brain, skull, eyes, trigeminal ganglia, spinal cord, vertebral column (excluding the vertebrae of the tail, the transverse process of the thoracic and lumbar vertebrae, and the wings of the sacrum), and dorsal root ganglia of cattle 30 months of age and older, and the tonsils and distal ileum of the small intestine of all cattle as SRMs. FSIS also required removal of the entire small intestine and disposal of it as inedible to ensure effective removal of the distal ileum.

To facilitate enforcement of the SRM rule, FSIS has developed procedures to verify the approximate age of cattle that are slaughtered in official establishments. Such procedures, based on records or examination of teeth, are intended to ensure that SRMs from cattle 30 months of age and older are effectively segregated from edible materials (Ref 5).

As provided by the SRM rule, materials designated as SRMs if they are from cattle 30 months of age and older will be deemed to be SRMs unless the establishment can demonstrate that they are from an animal that was younger than 30 months of age at the time of slaughter.

Further, FSIS developed procedures to verify that cross-contamination of edible tissue with SRMs is reduced to the maximum extent practical in facilities that slaughter cattle or process carcasses or parts of carcasses of cattle, for cattle both younger than 30 months of age and 30 months of age and older (Ref 5).

The SRM rule also declared mechanically separated beef (MS(beef)) to be inedible and prohibited its use for human food. Additionally, the SRM rule prohibited all non-ambulatory disabled cattle for use as human food.

The second interim final rule, titled "Meat Produced by Advanced Meat/Bone Separation Machinery and Meat Recovery (AMR) Systems" (FSIS Docket No. 03–038IF; 69 FR 1874–1885), prohibited products produced by advanced meat recovery (AMR) systems from being labeled as "meat" if, among other things, they contain central nervous system (CNS) tissue. AMR is a technology that enables processors to remove the attached skeletal muscle tissue from livestock bones without incorporating significant amounts of bone and bone products into the final meat product. FSIS had previously established and enforced regulations that prohibited spinal cord from being included in products labeled "meat." The interim final rule expanded that prohibition to include dorsal root ganglia (DRG)—clusters of CNS tissue connected to the spinal cord along the vertebral column. In addition, because the vertebral column and skull of cattle 30 months of age and older have been designated as SRMs, they cannot be used for AMR. Because they are not SRMs, the skull and vertebral column from cattle younger than 30 months of age are allowed to be used in AMR systems. However, establishments that use skulls and vertebral columns in the production of beef AMR product must be able to demonstrate that such materials are from cattle younger than 30 months of age.

The third interim final rule, titled "Prohibition on the Use of Certain Stunning Devices Used to Immobilize Cattle During Slaughter" (FSIS Docket No. 01–0331IF; 69 FR 1885–1891), prohibited the use of penetrative captive bolt stunning devices that deliberately inject air into the cranial cavity of cattle, because the use of such devices may force large fragments of CNS tissue into the circulatory system of stunned cattle where the fragments may become lodged in edible tissues.

Also on January 12, 2004, FSIS published a notice, "Bovine Spongiform Encephalopathy Surveillance Program," announcing it would no longer pass and apply the mark of inspection to carcasses and parts of cattle selected for BSE testing by APHIS until the sample testing has been completed, and the result is negative (FSIS Docket No. 03–048N; 69 FR 1892).

Measures Implemented by FDA

FDA, like FSIS, has taken additional measures to prevent the BSE agent from entering the human food supply. In an interim final rule published in the **Federal Register** on July 14, 2004, "Use of Materials Derived from Cattle in Human Food and Cosmetics," FDA prohibited SRMs (the same as defined by FSIS), the small intestine of all cattle, material from non-ambulatory disabled cattle, material from cattle not inspected and passed for human consumption, and MS(beef) from use in FDA-regulated human food, including dietary supplements, and cosmetics (69 FR 42255; FDA Docket No. 2004N–0081).

In an advance notice of proposed rulemaking issued jointly by FDA, FSIS, and APHIS on July 14, 2004, "Federal Measures to Mitigate BSE Risks: Considerations for Further Action" (69 FR 42288–42300, FDA Docket No. 2004N–0264, FSIS Docket No. 04–021ANPR, APHIS Docket No. 04–047–1), FDA requested additional information to help it determine the best course of action to reduce the already small risk of BSE spread through animal feed. (We refer to the advance notice of proposed rulemaking below as the "USDA/FDA joint notice.")

FDA continues to conduct inspections to monitor compliance of domestic feed mills, renderers, and protein blenders with regulations it put in place in 1997 to prevent recycling of potentially infectious cattle tissue through ruminant feed. (FDA regulations at 21 CFR 589.2000 prohibit the feeding of most mammalian protein to ruminants in the United States.) FDA also has expanded the scope of its inspections to include other segments of animal feed production and use, such as transportation firms, farms that raise cattle, and animal feed salvage operations. Compliance with the feed ban by U.S. feed mills, renderers, and protein blenders is currently very high. As of July 2004, conditions or practices warranting regulatory sanctions had been found in less than 1 percent of inspected facilities (Ref 6).

Harvard-Tuskegee Investigation of BSE Risk in the United States

In April 1998, USDA commissioned the HCRA at Harvard University and the Center for Computational Epidemiology at Tuskegee University to conduct a comprehensive investigation of BSE risk

in the United States. The report was completed in 2001 and released by the USDA. Following a peer review of the Harvard-Tuskegee Study in 2002 (Ref 7), the authors responded to the peer review comments (Ref 8) and released a revised risk assessment in 2003 (Ref 3). The report, widely referred to as the Harvard Risk Assessment or the Harvard Study, is referred to in this document as the Harvard-Tuskegee Study.

The Harvard-Tuskegee Study reviewed available scientific information related to BSE and other TSEs, assessed pathways by which BSE could potentially occur in the United States, and identified measures that could be taken to protect human and animal health in the United States. The assessment concluded that the United States is highly resistant to any amplification of BSE or similar disease and that measures taken by the U.S. Government and industry make the United States robust against the spread of BSE to animals or humans should it be introduced into this country.

The Harvard-Tuskegee Study concluded that the most effective measures for preventing the potential spread of BSE are: (1) The ban placed by APHIS on the importation of live ruminants and 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. The Harvard-Tuskegee Study further indicated that, if introduction of BSE had occurred via importation of live animals from the United Kingdom before 1989, mitigation measures in place in the United States at the time the Study was conducted would have minimized exposure and worked to eliminate the disease from the U.S. cattle population.

The Harvard-Tuskegee Study also identified three practices that could create a pathway for human exposure to the BSE agent or the spread of BSE should it be introduced into the United States: (1) Non-compliance with FDA's regulations prohibiting the use of certain proteins in feed for cattle and other ruminants; (2) rendering of animals that die on the farm and use (through illegal diversion or cross-contamination) of the rendered product in ruminant feed; and (3) the inclusion of high-risk tissues from cattle, such as brain and spinal cord, in products for human consumption.

The Harvard-Tuskegee Study's independent evaluation of the potential risk mitigation measures predicts that a prohibition against rendering of animals that die on the farm would reduce the number of potential cases of BSE in cattle following hypothetical exposure by 82 percent as compared to the base case scenario, and that a ban on SRMs (which included, according to the evaluation, the brain, spinal cord and vertebral column, "gut," and eyes) from inclusion in human and animal food would reduce potential BSE cases in cattle by 88 percent and potential human exposure to BSE by 95 percent as compared to the base case scenario (Ref 9).

In 2003, following the identification of BSE in a native-born cow in Canada, USDA, working with HCRA, evaluated the implications of a then-hypothetical introduction of BSE into the United States from Canada, using the same simulation model developed for the initial Harvard-Tuskegee Study. This assessment, titled "Evaluation of the Potential Spread of BSE in Cattle and Possible Human Exposure Following Introduction of Infectivity into the United States from Canada" (Ref 10), confirmed the conclusions of the earlier Harvard-Tuskegee Study—namely, that a very low risk exists of BSE becoming established or spreading should it be introduced into the United States.

Cohen and Gray Memorandum

Following receipt of comments from the public on its November 2003 proposed rule, APHIS requested the HCRA to respond to comments that pertained to the Harvard-Tuskegee Study. The HCRA's response to the comments, authored by Joshua Cohen and George Gray, was reported to APHIS in a June 18, 2004, memorandum, referred to below as "the Cohen and Gray memorandum." The memorandum also updates the model used in the Harvard-Tuskegee Study with new data from the FDA addressing two critical model parameters—mislabeling of products containing prohibited ruminant protein and contamination of nonprohibited protein with prohibited protein. You may view the memorandum on the Internet by accessing the APHIS Web site at *http://www.aphis.usda.gov/lpa/issues/bse/bse.html*. Click on the document titled "Analysis of Risk—Update for the Final Rule: Bovine Spongiform Encephalopathy; Minimal Risk Regions and Importation of Commodities, December 2004."

Measures Taken in Canada in Response to BSE Risk Prior to May 2003

Import restrictions. Canada imposed import restrictions to guard against the introduction of BSE, starting in 1990. In that year, Canada prohibited the importation of live cattle from the United Kingdom and the Republic of Ireland. In 1994, an import ban was imposed on all countries where BSE had been detected in native cattle. In 1996, Canada made this policy even more restrictive and prohibited the importation of live ruminants from any country that had not been recognized as free of BSE following a comprehensive risk assessment. Some animals were imported into Canada from high-risk countries prior to the imposition of these import restrictions. A total of 182 cattle were imported into Canada from the United Kingdom between 1982 and 1990. Similar to actions taken in the United States, efforts were made in Canada to trace these animals. In late 1993, after Canada identified a case of BSE in one of the imported bovines, all cattle imported from the United Kingdom or the Republic of Ireland that remained alive at that time were killed.

Canada has also restricted the importation of ruminant products, including meat-and-bone meal, since 1978. In general, Canada has prohibited the importation of most meat-and-bone meal from countries other than the United States, Australia, and New Zealand. Limited amounts of specialty products of porcine or poultry origin have been allowed to be imported into Canada under permit for use in aquaculture feed products. No meat-and-bone meal for livestock feed-associated uses has been imported, except from the United States, Australia, and New Zealand.

Feed ban. A crucial element in preventing the spread and establishment of BSE in a country is the implementation of a ruminant-to-ruminant feed ban. Canada implemented a feed ban in 1997 that prohibits the feeding of most mammalian protein to ruminants. Under the ban in Canada, mammalian protein may not be fed to ruminants, with certain exceptions. These exceptions include pure porcine or equine protein, blood, milk, and gelatin. The feed ban is equivalent to the feed ban in place in the United States, with the addition that Canada prohibits the feeding of plate waste and poultry litter to ruminants.

Canada has provided information, including statistics on compliance, demonstrating that an effective feed ban is in place in the rendering, feed manufacturing, and livestock raising industries. Few cattle born before implementation of the Canadian feed ban are alive today, given that most male cattle are slaughtered before 24 months of age and given the normal cull rates for beef and dairy cows. It is estimated that 39.4 percent of the beef cattle born in 1996 are alive today. It is estimated that 5.8 percent of the dairy cattle born in 1996 are alive today.

OIE guidelines for BSE minimal-risk regions or questioned APHIS' basis for doing so. One of these commenters stated that OIE guidelines have highly detailed and specific criteria that allow the identification of minimal-risk regions and said that APHIS did not provide sufficient analysis in the proposed rule to support the creation of a new minimal-risk category. Some others said that APHIS did not adequately describe the scientific basis for deviating from the OIE guidelines, particularly with respect to time during which ruminant feed restrictions have been in place.

Response: We are making no changes based on these comments. We consider the definition of *BSE minimal-risk region* in this rule to be clear. We have explained our reasoning in detail for adopting performance standards for the critical factors, and discussed at some length our conclusion that some regulatory flexibility is essential. We noted the that the OIE guidelines are fluid, and discussed above in section III. B., under the heading "APHIS' Regulatory Approach to BSE: Past and Present," that OIE may revise its BSE classifications in the near future.

As discussed above in section III. B. under the heading "More Focused Regulatory Restrictions," although APHIS did not incorporate the text of OIE's BSE guidelines into its proposed rule, the agency based its standards on those guidelines, and the APHIS standards contain the same essential factors for assessing a region's BSE status as the OIE guidelines (*e.g.*, import requirements, incidence, surveillance, feed restrictions, etc.). The proposed rule and associated risk analysis explain where APHIS' proposed standards for minimal-risk regions departed from OIE guidelines. The preamble to the proposed rule discussed how we would use those standards to evaluate the BSE risk of a region. We said we would use the standards as a combined and integrated evaluation tool in evaluating a region, focusing on the overall effectiveness of all control mechanisms in place (*e.g.*, surveillance, import controls, and a ban on the feeding of ruminant protein to ruminants). We further explained that, in regions where BSE had been diagnosed, we would base our evaluation on the overall effectiveness of all control mechanisms in place at the time BSE was diagnosed in the region, and on actions taken after the diagnosis (*e.g.*, the epidemiological investigation of the occurrence). We agree that this approach differs from the OIE's in that it does not adhere to specific numerical recommendations specified in some of the OIE guidelines, but, as discussed earlier, the OIE guidelines are in flux and are meant to be a reference document. Further, disqualification of a region for failure to precisely meet one OIE recommendation would not account for a region's potential to present an overall minimal risk for BSE by exceeding other OIE recommendations or other relevant factors bearing on a risk to animal health.

We discussed in the proposed rule's preamble how we applied our standards for minimal risk to an evaluation of Canada's BSE risk. For example, we stated that, although Canada has had a feed ban in place for only 7 years (1 year less than provided for by OIE), this time period may be conservative because of the variability in the incubation period for BSE. Based on an analysis of data collected in the United Kingdom, the Harvard-Tuskegee Study (Ref 17) estimates that the variability distribution for the BSE incubation period in cattle has a median (50th percentile) of approximately 4 years and a 95th percentile of approximately 7 years. Based on the best-fit parameter values provided in the Harvard-Tuskegee Study (Ref 18), the mean (expected value) of the incubation period distribution is estimated at 4.2 years, and 7.5 years (August 1997 through January 2005) represents the estimated 97.5th percentile of the incubation period. We determined that the duration of the feed ban in Canada adequately addresses the expected BSE incubation period, taking into consideration all of the actions Canada has taken to prevent the introduction and control the spread of BSE (*e.g.*, import controls, level and quality of surveillance, effectiveness of feed ban, epidemiological investigation of detected cases, and depopulation of herds possibly exposed to suspected feed sources). We, therefore, concluded that a feed ban of less than 8 years' duration was appropriate for Canada. Canada, in fact, meets all OIE guidelines for a minimal-risk region, except for the duration of its feed ban.

We also note that OIE's guidelines for BSE include not just guidelines for classifying regions according to risk, but corresponding guidelines for trade in cattle, meat, and meat products from regions, according to the region's BSE risk classification. Our rule is consistent with this two-part OIE approach of considering a region's overall BSE risk status in combination with appropriate import restrictions for specific commodities.

Issue: A few commenters said that adopting criteria less stringent than OIE guidelines could result in other countries' perceiving the United States as having a greater BSE risk status and, therefore, prohibiting or restricting imports of cattle and beef from the United States. One commenter observed that OIE has five risk classifications for regions and said that, while some countries may choose to trade with high-risk regions, the United States should trade only with countries determined to be free of BSE.

Response: We are working diligently on an international level to ensure that BSE-related trade restrictions are based on sound science and a realistic understanding of the risks presented by the commodities we are proposing for trade. We do not believe it is appropriate to limit trade in cattle, meat, and meat products only to regions determined to be free of BSE if there are measures that can be applied to mitigate the risk of those commodities introducing BSE into the United States. There are such mitigation measures, consistent with those we have proposed. In fact, OIE guidelines provide for trade in cattle of any age, as well as beef and many other cattle products, even from countries that are considered high risk for BSE.

Issue: One commenter said that he was not opposed to APHIS' adopting criteria for minimal-risk regions that differ from OIE guidelines, but that APHIS' criteria put too much emphasis on import controls and epidemiological investigations and not enough on risk management measures in a country under consideration. The commenter mentioned a variety of risk mitigation measures in place in the European Union, including removal of SRMs; a ban on the feeding of mammalian meat-and-bone meal (MBM) to cattle, sheep, and goats; a suspension on the use of processed animal protein in feeds for any animals farmed for the production of food since January 2001, with the exception of fish meal for pigs and poultry; high processing standards for the treatment of ruminant animal waste; surveillance measures in accordance with the OIE Code; an ongoing awareness program for veterinarians; compulsory notification of all cattle showing clinical signs of BSE; testing of risk animals (fallen stock, emergency slaughtered animals, and animals with clinical signs at post-mortem inspection) over 24 months of age and healthy slaughtered animals over 30 months of age; culling policy for animals with a high probability of receiving the same potentially infected feed as a BSE case and offspring of female BSE cases; approval of rapid tests with the same sensitivity as the confirmatory methods.

we provide several more examples of additional mitigation measures we are considering, e.g., an ongoing awareness program for veterinarians, farmers, and workers involved in transportation, marketing, and slaughter of cattle; compulsory notification and investigation of all suspected cases of BSE; and examination in an approved laboratory of brain and other tissues collected within the framework of the surveillance and monitoring system. As we stated in the preamble of our proposal, measures will be required that are appropriate depending on the conclusions of the risk analysis that is required following a BSE diagnosis.

Human Health Risks

Issue: Several commenters recommended that the definition of *BSE minimal-risk region* specifically list actions taken to minimize human health risks, which the commenter said should be equal to or more stringent than those in the United States. The commenters stated that the definition should require, for example, that minimal-risk regions do the following: (1) Ban use of non-ambulatory cattle; (2) hold product/carcass until negative results are obtained; (3) prohibit air-injected stunning; (4) remove high-risk tissues; and (5) prevent the inclusion of central nervous system tissue in "meat" products.

Response: The issues raised by the commenters relate to the equivalency of standards for the production of meat in countries that export to the United States. The FSIS regulations in 9 CFR 327.2 provide that, to be eligible to export meat and meat products to the United States, a foreign country must be able to certify that it applies to its own meat processing establishments requirements equivalent to those in the United States. Under those regulations, exporting countries are required to provide documentation supporting how their meat inspection system is equivalent to that of the United States. FSIS determines whether the systems are equivalent. The FSIS procedures for evaluating such equivalency are discussed below in more detail, under the heading "Verification of Compliance in the Exporting Region." Each of the requirements recommended by the commenter are currently required of meat processing establishments in the United States and, therefore, are applicable to establishments in foreign countries that wish to export meat and meat products to the United States.

Tracking and Labeling

Issue: One commenter recommended that requirements for a minimal-risk region include existence of a national animal identification and tracking program, adequate and active testing and monitoring programs for all OIE List A animal diseases, and product labeling to enable tracking of the product.

Response: Although the standards for a BSE minimal-risk region in this rule do not specifically require a national animal identification and tracking program, they do include a requirement for an effective epidemiological investigation and the ability of authorities in the region to conduct traceback and trace-forward of animal feed or rendered material. An evaluation of these capabilities will include consideration of animal identification. Although we acknowledge the importance of adequate testing and monitoring for OIE List A diseases with regard to whether and under what conditions animals and animal products should be allowed importation from a particular region, those diseases are already addressed individually in the regulations in 9 CFR 92, 93, 94, 95, 96, and 98. Further, we do not consider List A diseases to fall under the scope of this rulemaking. List A diseases are defined by OIE as transmissible diseases that: (1) Have the potential for very serious and rapid spread, irrespective of national borders; (2) are of serious socioeconomic and/or public health consequences; and (3) are of major importance in the international trade of animals and animal products. BSE is not included as an OIE List A disease but, instead, is categorized as a List B disease. List B diseases are considered to be (1) of socioeconomic and/or public health importance within countries and (2) significant in the international trade of animals and animal products.

With regard to product labeling in the exporting region, it is not clear to us from the comment what type of labeling the commenter is referring to.

Testing of Ruminants

Issue: One commenter stated that, if BSE is diagnosed in a country, the United States should not accept ruminants and ruminant products from that country until the country tests all cattle over 20 months of age at slaughter. Other comments recommended that we require that all cattle slaughtered in such a country be tested for BSE. Some commenters recommended that such testing be carried out by USDA representatives in Canada.

Response: We understand the interest expressed by some commenters in testing certain cattle for slaughter. However, no live animal tests exist for BSE and the currently available postmortem tests, although useful for disease surveillance (i.e., in determining the rate of disease in the cattle population), are not appropriate as food safety indicators. We know that the earliest point at which current testing methods can detect a positive case of BSE is 2 to 3 months before the animal begins to demonstrate clinical signs. We also know that the incubation period for this disease—the time between initial infection and the manifestation of clinical signs—is generally very long, on the average of about 5 years. Accordingly, we know there is a long period during which, using the current methodology, testing an infected animal that has not demonstrated clinical signs of the disease would, incorrectly, produce negative results. If, however, the infected animal is already exhibiting some type of clinical signs that could be consistent with BSE, then the test is not likely to produce false negative results.

Development of reliable food safety indicators will require improved understanding of the pathogenesis of the disease and improved laboratory methods. However, if BSE is present in a country's cattle population, various mitigation measures, such as feed bans and removal of SRMs, are available to prevent the spread of BSE in cattle and to prevent human exposure to the BSE agent. The United States and Canada have already implemented such measures. The results of an enhanced animal surveillance program for BSE, announced by the Secretary on March 15, 2004 (Ref 20), and currently underway, which will help determine the prevalence of BSE in the United States, should the disease exist, and will provide information that will indicate whether these measures should be adjusted. But measures such as SRM removal and the prohibition of the use of non-ambulatory cattle in human food will ensure a safe meat supply. Testing of individual animals, especially if it is performed on clinically normal animals at slaughter, is not in itself an effective risk mitigation measure for protecting public health. The purpose of a surveillance program is to gauge the level of BSE prevalence. This can be achieved through targeted sampling, as is being carried out in the United States and Canada.

For these reasons, we do not consider the testing at slaughter of every bovine over 20 months of age, or the testing of every bovine at slaughter, to be scientifically justified or meaningful in the context of either human or animal health. Making this a criterion for minimal-risk regions would not contribute to human or animal health protection beyond the protection

the feedlot identified on the APHIS movement permit and other accompanying documentation to help ensure they are slaughtered in a timely manner.

Maximum Age of Cattle, Sheep, and Goats Imported From a BSE Minimal-Risk Region

Issue: APHIS proposed to limit live cattle imported from a BSE minimal-risk region to those that would be less than 30 months of age at slaughter. A number of commenters expressed concerns regarding that maximum age. The commenters stated that, because there have been multiple detections of BSE in cattle less than 30 months of age in Europe and Japan, APHIS should decrease the maximum age for imports. Recommended maximums ranged from 18 to 28 months of age. Several commenters requested that APHIS more comprehensively state and validate the scientific basis for determining that cattle in the 20 to 30 month age range do not present a risk of BSE. Another commenter cited evidence from Britain that the commenter said indicates some cattle may be fast incubators of the disease and, therefore, have the potential to introduce detectable levels of BSE into the food chain. One commenter expressed concern that, because bulls are routinely slaughtered at 19 to 22 months old, they may be too young to test positive for the disease, even though those animals may be infected with BSE. One commenter stated that with prion diseases, the incubation time tends to become shorter the longer a specific prion has been circulating within a species.

Response: As discussed in our proposal, pathogenesis studies—where tissues obtained from orally infected calves were assayed for infectivity—have illustrated that levels of infectious BSE agent in certain tissues vary with the age of an animal. Infectivity was not detected in most tissues in cattle until at least 32 months post-exposure. The exception to this is the distal ileum (a part of the intestines), where infectivity was confirmed in the experimentally infected cattle as early as 6 months post-exposure, and the tonsils, where infectivity was confirmed at 10 months post-exposure.

Research demonstrates that the incubation period for BSE in cattle is linked to the infectious dose received—*i.e.*, the larger the infectious dose received, the shorter the incubation period. While some cases of BSE have been found in cattle less than 30 months of age, these are relatively few and have occurred in countries with significant levels of circulating infectivity (*i.e.*, where infected ruminants are used for feed for other ruminants, which in turn become infected).

In our proposal, we set out a list of standards we will use to evaluate the BSE risk from a region and determine whether it is appropriate to classify that region as a region of minimal-risk for BSE. We stated that we would use these standards 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). Given the low level of circulating infectivity in minimal-risk regions, we proposed a 30-month age limit for cattle and proposed that the intestines be removed from those imported cattle. As discussed already, following the detection of a BSE-positive cow in Washington State in December 2003, FSIS implemented additional measures to protect the human food supply in the United States—including a requirement that SRMs be removed from all cattle—and prohibited the use of SRMs in human food.

Under these circumstances, we continue to consider 30 months of age to be the appropriate age threshold for removal of most SRMs. We are evaluating whether cattle over 30 months of age could be safely imported into the United States from a BSE minimal-risk region under the same conditions as younger cattle, since SRM removal is now standard operating procedure for all cattle 30 months of age and older that go to slaughter in the United States. However, we are not making a change with regard to live cattle over 30 months of age in this final rule, because, as stated in our March 8, 2004, notice, we are currently evaluating the appropriate approach regarding live cattle other than those specified in our proposal and intend to address that issue in a supplemental rulemaking proposal in the **Federal Register.**

Issue: Several commenters asked why we proposed that live sheep and goats 12 months of age and older would not be allowed importation into the United States. One commenter noted that we said in our proposal that we would allow cattle less than 30 months of age to be imported from BSE minimal-risk regions because BSE infectivity was not detected in most tissues in cattle until at least 32-months post-exposure to the agent. In contrast, said the commenter, although we stated BSE infectivity has not been demonstrated in most tissues in sheep and goats until 16 months post-exposure, we proposed to prohibit the importation of live sheep and goats 12 months of age or older from a BSE minimal-risk region. The commenter noted that APHIS was establishing a safety margin of 2 months for cattle (6.25 percent) (32 months/30 months), but 4 months (25 percent) for sheep and goats. The commenter requested that APHIS provide the scientific basis for determining whether this distinction is significant.

Response: As noted above, research has indicated that the levels of infectious agent in certain tissues vary with the age of an animal. Infectivity in cattle was not detected in most tissues until the animal was at least 32 months post-exposure. In sheep and goats, infectivity has not been demonstrated in most tissues until 16 months of age post-exposure. The 30-month age limit for cattle imported from minimal-risk regions is accepted internationally in BSE standards set by various countries and is consistent with OIE guidelines and target surveillance (Ref 23). We proposed a 12-month age limit for sheep and goats based on the research regarding infectivity in such animals and, practically speaking, because 12 months is consistent with the age at which lambs are generally sent to slaughter.

Issue: Several commenters recommended that, rather than using the age of an animal as a risk mitigation measure, APHIS should follow OIE guidelines that allow the movement of cattle born after an effective feed ban was implemented, provided appropriate risk mitigation measures are applied during slaughter and processing.

Response: The import conditions proposed by APHIS for importation of bovines for immediate slaughter from BSE minimal-risk regions included several restrictions, including both age of the animal and the requirement that the animal not be known to have been fed ruminant protein. Those conditions were analyzed together in our risk analysis, which did not differentiate among the efficacy of the alternative risk mitigation options. Based on that analysis of risk, we are including both conditions in this final rule.

Issue: One commenter asked if, since the May 2003 diagnosis of a BSE infected cow, CFIA has tested a statistically "responsible" number of brains of cattle less than 30 months of age in order to state with confidence that the region does not have younger animals that would test positive, as has happened in the United Kingdom and Japan.

Response: APHIS published a risk assessment in November 2003 that discussed the risks and identified

effective and will protect against the introduction of BSE into the United States. In our proposal, we set out a list of standards we would use to evaluate the BSE risk from a region and determine whether it is appropriate to classify that region as a region of minimal-risk for BSE. We stated that we would use these standards 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).

In addition, we proposed individual risk mitigation measures for specific commodities, including live animals intended for importation from BSE minimal-risk regions, to further protect against the introduction and transmission of BSE in the United States. For live animals, such measures include: Maximum age requirements, movement restrictions and use within the United States, identification requirements, and removal of SRMs. As noted, our proposed rule specified removal of the intestines. However, FSIS has since issued regulations regarding SRM removal in all cattle slaughtered in the United States, including the removal of the tonsils and distal ileum in cattle of any age.

Canada has implemented strong measures to guard against the introduction, establishment, and spread of BSE among cattle in that country, to detect infected animals through surveillance, and to protect the Canadian animal and human food supplies. Among other things, Canada has taken the following actions: Maintenance of stringent import restrictions since 1990; prohibition of the importation of live ruminants and most ruminant products from countries that have not been recognized as free of BSE; surveillance for BSE since 1992; implementation of a feed ban in 1997 that prohibits the feeding of most mammalian protein to ruminants; and extensive epidemiological investigations after the case of BSE in May 2003 and the Canadian origin case in Washington State in December 2003. Given these and other measures taken by Canada (*e.g.*, requirements for removal of SRMs), and the conditions in this rule for the importation of ruminants and ruminant products from BSE minimal-risk regions, it is highly unlikely BSE would be introduced through the importation of live cattle for immediate slaughter or for feeding and slaughter under this rule.

Issue: One commenter stated that, because every infected cow in North America has been a Holstein cow from Canada, APHIS should specifically prohibit the importation of dairy (in general, Holstein) cows. Another commenter stated that the differences between the risk profiles of dairy and beef cattle should be taken into account; that the feeding practices of dairies are more risky than those used by beef producers. The commenter requested that APHIS increase BSE testing for dairy cattle.

Response: We are making no changes based on these comments. (It should be noted that, contrary to the commenter's statement, the cow that was diagnosed as BSE-infected in Alberta Canada in May 2003 was a beef cow and not a Holstein cow.) BSE is spread primarily through the use of ruminant feed containing protein and other products from ruminants infected with BSE. In cattle, oral ingestion of feed contaminated with the BSE is the only documented route of field transmission of the disease (Ref 24). Although there is no evidence to indicate that the breed of cattle is a risk factor for BSE, there is some evidence that the use of BSE-contaminated ruminant protein results in an increased risk of BSE in dairy cattle compared to beef cattle. However, this is most likely due to the differences in feeding practices between dairy and beef producers, because dairy cattle routinely receive high-protein feeds during milk production. In regions with an effective feed ban on ruminant protein, the differences in feeding practices should not significantly increase the level of risk, given that no ruminant protein is fed to either beef or dairy cattle.

Issue: One commenter stated that APHIS should prohibit the importation for slaughter of any foreign animal born before the feed ban that is intended for human consumption or rendering. Another commenter stated the cattle born in Canada in a high-risk area before implementation of that country's feed ban should be prohibited importation.

Response: From the context of the first comment, it appears the commenter is referring only to the importation of bovines. Practically speaking, the guidelines of both commenters will be met by the combination of the required feed ban and the provision limiting the importation of bovines to those less than 30 months of age.

Importation of Cattle for Subsequent Export of Meat

Issue: One commenter stated that we should allow the importation of live cattle for slaughter through eastern U.S./Canadian border ports and allow the meat to be exported to Canada for use at fast food outlets.

Response: We are making no changes based on the comment. We consider it necessary to apply the same risk mitigation measures regarding the importation of cattle from Canada for slaughter regardless of the intended destination of the meat derived from the animals. With regard to exportation of beef to Canada, this rule does not place any restrictions on the export to Canada of meat from cattle slaughtered in the United States. Those meat commodities that can be exported to Canada from the United States can be found at *http://www.inspection.gc.ca.*

Cattle Importations From Any Region

Issue: One commenter stated that all beef cows imported into the United States from any country should be processed as a group.

Response: Our proposal concerned the importation of live ruminants and ruminant products from regions that present a minimal risk of introducing BSE into the United States. Requirements regarding the importation of beef cows from elsewhere in the world are beyond the scope of this rulemaking.

Importation of Veal Calves

Issue: Several commenters recommended that veal calves not be subject to the ban on the importation of live ruminants from Canada that the United States established in May 2003, because veal calves are a low-risk commodity due to their diet and their age at slaughter.

Response: Veal calves are eligible for importation into the United States under this rule.

Basis for Restrictions on Sheep and Goats

Issue: In § 93.436(b) and (c) of our proposed rule, we proposed to allow the importation of sheep and goats from a BSE minimal-risk region for either immediate slaughter or for feeding and then slaughter, provided specified conditions were met. These conditions included, among others, the requirements that the sheep or goats be less then 12 months of age when slaughtered and not have been known to have been fed ruminant protein, other than milk protein, during their lifetime. Additionally, we proposed to require that sheep and goats imported for feeding and then slaughter be moved directly from the port of entry to a designated feedlot and then to slaughter.

A number of commenters recommended that, because the OIE guidelines do not specifically address

population and, if so, help provide estimates of the level of the disease. This data will also help determine whether risk management policies need to be adjusted. The key to surveillance is to look at the population of animals where the disease is likely to occur. Thus, if BSE is present in the U.S. cattle population, there is a significantly better chance of finding the BSE within this targeted high-risk cattle population than within the general cattle population.

Non-Ambulatory Disabled (Downer) Animals

Issue: Many commenters stated that no beef derived from non-ambulatory ("downer") animals should be allowed either to enter the United States or enter the U.S. food supply. Other commenters stated that meat from any downer animal should be held until the animal is tested for BSE, and should be allowed into the food supply only if the animal tests negative. Some commenters stated that downer animals should be allowed to go to custom slaughtering for the owner's personal use.

Response: The issues raised by the commenters concern the safety for human consumption of beef slaughtered in the United States, which USDA addresses through its food safety agency, FSIS. As discussed above under the heading "Measures Implemented by FSIS," that agency has determined that the carcasses of non-ambulatory disabled cattle are unfit for human food under section 1(m)(3) of the Federal Meat Inspection Act (FMIA), and that all non-ambulatory disabled cattle that are presented for slaughter will be condemned (*i.e.*, not passed for human consumption). With regard to Canada specifically, that country is not allowing non-ambulatory animals to be slaughtered for export.

Issue: One commenter expressed concern that Canada has not adopted the same BSE risk mitigation measures adopted by the United States, such as not prohibiting downer animals from entering the human food chain.

Response: As noted above, Canada is not allowing non-ambulatory animals to be slaughtered for export. All of the FSIS requirements imposed on the U.S. domestic beef supply as a consequence of that agency's January 12, 2004, rulemakings also apply to foreign countries that are eligible to export beef to the United States. The foreign country's inspection program must be deemed by FSIS to be equivalent to the U.S. inspection program before the country can ship beef to the United States. This means that SRMs must have been properly removed in the exporting country consistent with the U.S. requirements, and that non-ambulatory disabled cattle be prohibited for human food purposes. FSIS has an on-going verification system to assess the effectiveness of the equivalency determination made for each foreign country deemed eligible to export meat to the United States, as discussed below under the heading "Verification of Compliance in the Exporting Region."

Issue: Several commenters expressed concern that if non-ambulatory animals are excluded from slaughter in the United States, the current targeted surveillance systems will miss the chance to test these animals.

Response: We disagree with the commenter that non-ambulatory animals will not be tested under the U.S. targeted surveillance system. Even before the FSIS determination that all non-ambulatory disabled cattle that are presented for slaughter will be condemned, these types of animals have often moved through channels other than for human consumption. A comparison of testing records before and after the FSIS determination indicates that this category of animals was being tested before that determination and continues to be tested.

Use of Blood in Ruminant Feed

Issue: Several commenters stated that we should continue to prohibit the importation of live cattle from Canada because, according to the commenters, that country allows the feeding of blood and certain other ruminant products to cattle that are banned in the United States. Another commenter expressed concern that the proposal did not contain adequate verification that cattle imported from Canada are not fed animal blood.

Response: The CFIA feed ban was implemented in 1997 to prevent BSE from entering the food chain. The CFIA's feed ban, equivalent to the FDA prohibition on the feeding of most mammalian protein to ruminants, prohibits materials that are comprised of protein, including meat-and-bone meal, derived from mammals such as cattle, sheep and other ruminants, as well as salvaged pet food, plate waste and poultry litter. Products exempt from CFIA's feed ban include pure porcine and equine proteins, poultry and fish proteins, milk, blood, and gelatin, and non-protein animal products such as rendered animal fats (*e.g.*, beef tallow, lard, poultry fat). These are products that are also exempt from the FDA prohibition. (Please note, however, that as discussed above in section III. C. under the heading "Measures Implemented by FDA," in an advance notice of proposed rulemaking issued jointly by FDA, FSIS, and APHIS on July 14, 2004, FDA requested additional information to help it determine the best course of action regarding the feed ban.)

In 2001, the EU Scientific Steering Committee (SSC), a scientific advisory committee for the EU, considered the amount and distribution of BSE infectivity in a typical case of BSE and estimated that, in an animal with clinical disease, the brain contains 64.1 percent of the total infectivity in the animal and the spinal cord contains 25.6 percent. Thus, the brain and spinal cord of cattle with clinical BSE are estimated to contain nearly 90 percent of the total infectivity in the animal. According to the EU SSC, the remaining proportion of infectivity in a typical animal with clinical BSE is found in the distal ileum (3.3 percent), the dorsal root ganglia (2.6 percent), the spleen (0.3 percent), and the eyes (0.04 percent). Similar conclusions on the relative infectivity of specific tissues from an infected cow have been reached by Comer and Huntley in their evaluation of the available literature (Ref 27).

We have noted that recent scientific studies have indicated that blood may carry some infectivity for BSE; however, those studies have concerned blood transfusions in animals. Additional research is necessary to determine which animals may become infected with BSE via blood, as well as the amount of infectivity contained in blood. We continue to consider it appropriate to recognize Canada as a minimal-risk region because that country has taken a number of measures that would make it unlikely that BSE would be introduced from that country into the United States. The measures include a feed ban equivalent to that in effect in the United States.

In addition to CFIA's feed ban on ruminant protein, Canada has taken additional measures to protect against the importation and possible spread of BSE. Such measures include: Import restrictions on live ruminants and ruminant products from countries that have not been recognized as free of BSE, surveillance and monitoring for BSE, and epidemiological investigation following the detection of BSE sufficient to confirm the adequacy of measures to prevent the further introduction and spread of the disease. Because of the mitigation measures taken by Canada to guard against the introduction and spread of BSE, we consider there to be minimal risk of infected blood entering the food chain from that region. However, to ensure the adequacy of feed restrictions for ruminants imported from Canada and other regions that may be

conducted by Dr. D.M. Taylor, *et al.*, of the Animal Health Institute, Edinburgh Scotland, failed to find an association between the occurrence of BSE and the consumption of tallow by cattle, and that in studies using BSE-spiked tallow, no infectivity was found in crude, unfiltered tallow extracted from rendered meat-and-bone meal. The commenter stated that the study was validated by injecting spiked BSE tallow intracerebrally into experimental mice without resulting demonstrated changes associated with TSEs. The commenter stated further that, in 1991, the World Health Organization (WHO) assembled consultants who determined tallow not to be a risk to animal or human health. Additionally, stated the commenter, the Harvard-Tuskegee Study refers to the safety of tallow.

Response: The research referenced by the commenter documents the results of mouse assays. We are unaware of any studies that have been performed using cattle experimentally fed tallow infected with BSE with resulting absence of infectivity. Based on the scientific evidence currently available, it is not possible to dismiss the possibility that ingestion of tallow infected with BSE creates a risk of the transmission of BSE. This conclusion is consistent with the OIE Code, Article 2.3.13.1., which recommends that one of the conditions for the importation of tallow from any country, regardless of its BSE status, be that the tallow is protein-free (*i.e.*, have a maximum level of insoluble impurities of 0.15 percent in weight).

While WHO concluded that because of the proteinaceous nature of TSE agents, they will tend to remain with the cellular residues of meat-and-bone meal during the extraction process rather than being extracted with the lipids of tallow, the EU SSC considers that possible TSE risks associated with tallow will result from protein impurities that may be present in the end product, because it is expected that TSE agents, if present in the product, would be associated with those impurities (Ref 28).

Issue: One commenter specifically supported the proposed provisions regarding edible tallow. Another commenter supported the proposed conditions except for the requirement that the intestines of the bovine had been removed at slaughter and the requirement that the bovine not have been fed ruminant protein other than milk protein. Instead, said the commenter, the requirement regarding feeding should refer instead to adherence to the CFIA and FDA feed bans. Another commenter stated that importation of all tallow should be prohibited. Several commenters stated that tallow should be accepted from BSE minimal-risk regions only if all SRMs were removed from the bovines from which the tallow was derived, segregation of the tallow from potentially risky materials is carried out in the region of origin, and the tallow is accompanied by certification by the owner of the animal from which the animal was derived that the animal was not fed ruminant protein. Other commenters recommended that there be no restrictions on the importation of tallow from BSE minimal-risk regions. One commenter stated that it was not scientifically defensible to require that tallow not be derived from an animal that died otherwise than by slaughter. Several commenters stated that, under the OIE Code, tallow is considered protein-free if it contains no more than 0.15 percent impurities, and that protein-free tallow should be allowed importation without further restriction. Several commenters said such tallow should be allowed importation no matter what the BSE status of the region of origin. The commenters stated further that, even if tallow intended for food, feed, fertilizers, cosmetics, pharmaceuticals including biologicals, or medical devices is not protein-free, it should be allowed importation if (1) it came from bovines that were subject to ante-mortem inspection with favorable results, and (2) had not been prepared using SRMs. One commenter also recommended that derivatives of non-protein-free tallow intended for the uses listed above be allowed importation without restriction.

Response: In this rule, we are making some changes to the requirements we proposed regarding the importation of tallow from BSE minimal-risk regions. We agree that protein-free tallow will not pose a risk of introducing BSE into the United States. As noted above, this conclusion is consistent with the recommendation in the OIE Code that protein-free tallow (maximum level of insoluble impurities of 0.15 percent in weight) be considered a commodity that may be imported without restriction, regardless of the BSE status of the exporting country. Therefore, we are removing the restrictions we proposed for the importation of protein-free tallow from BSE minimal-risk regions that could be used in animal feed, except for the requirements that the tallow be accompanied by certification that it is protein-free and, if arriving at a land border port, that it arrive at a port listed § 94.19(g). Additionally, with the commenter who recommended segregation of the tallow from any other risky products for BSE. We are also adding language to § 95.4(f) to indicate that the listed importation requirements for tallow are for tallow imported into the United States from BSE minimal-risk regions as listed in § 94.18(a)(3).

Therefore, in this final rule, § 95.4(f) authorizes the importation of tallow from BSE minimal-risk regions that could be used in animal feed, provided the tallow is accompanied by official documentation certifying that: (1) The tallow is protein-free tallow (maximum level of insoluble impurities of 0.15 percent in weight); and (2) after processing, the tallow was not exposed to or commingled with any other animal origin material. The requirements of our proposal pertaining to the port of arrival of the shipment and the requirement that each shipment be accompanied by an original certificate will remain. We intend to address the importation of tallow from regions other than BSE minimal-risk regions in future rulemaking.

Under the existing regulations in § 95.4, tallow derivatives are allowed importation from regions listed in § 94.18(a) as regions affected with BSE or that pose an undue risk of BSE. Likewise, under this rule, tallow derivatives from BSE minimal-risk regions will be eligible for importation into the United States.

Tallow and Offal Testing and Inspection

Issue: One commenter requested that our rule include the methods that will be used to test or inspect at the border any tallow or offal intended for importation into the United States from a BSE minimal-risk region to ensure that BSE-contaminated tallow or offal does not enter this country.

Response: For tallow or offal subject to the FMIA to enter the United States, it must originate from a country where the inspection system has been determined by FSIS to be equivalent to the U.S. meat inspection system. As part of its equivalence determination, FSIS requires that certified establishments in foreign countries eligible to export meat product to the United States develop, implement, and maintain written procedures for the removal, segregation, and disposition of materials identified by FSIS as SRMs, to ensure that such materials are not used for human food. Thus, the use of SRMs in the production of edible tallow and offal imported into the United States is prohibited. When shipments reach the U.S. border, they are subject to reinspection by FSIS. Such reinspection can include review of documentation, product examination, and laboratory testing. If the product is not covered under the FMIA, FDA

enforces its import restrictions applicable to those products.

Issue: One commenter recommended that the importation of any organ meat into the United States from a BSE minimal-risk region be prohibited.

Response: We are making no changes based on this comment. Some bovine tissues have demonstrated infectivity, whereas others have not. Tissues that have demonstrated infectivity are designated as SRMs and must be removed and disposed of as inedible. The small intestine of all cattle must also be removed and disposed of as inedible to ensure effective removal of the distal ileum. There is no BSE basis for prohibiting the importation of other tissue, including other tissue that is organ meat.

Sheep Casings

Issue: As discussed above, in this rule we are adding the category of BSE minimal-risk regions to the existing categories in § 94.18(a) of regions where BSE exists or that present an undue risk of BSE. Several commenters stated that, although our proposed rule would allow the importation of live sheep from BSE minimal-risk regions under certain conditions, there was no mention of amending part 96, which, among other things, prohibits the importation of casings (bovine or other ruminant casings) from any region listed in § 94.18(a). Because BSE minimal-risk regions will be listed in § 94.18(a), said the commenters, this will preclude the importation of sheep casings from BSE minimal-risk regions. The commenters stated that APHIS should address this inconsistency by amending § 96.2(b) to allow the importation of casings from BSE minimal-risk regions such as Canada.

Response: The commenters are correct that we did not address the importation of sheep casings from BSE minimal-risk regions in the proposed rule. We agree that sheep casings imported from a BSE minimal-risk region that are derived from sheep that were less than 12 months of age when slaughtered and that were from a flock subject to a ruminant feed ban equivalent to the requirements of FDA pose no more of a BSE risk than live sheep that meet the same conditions imported from such a region. Therefore, we are providing in § 96.2(b) that sheep casings from a BSE minimal-risk region that are derived from animals less than 12 months of age when slaughtered and that were from a flock subject to a feed ban equivalent to FDA's may be imported into the United States from a BSE minimal-risk region, provided the casings are accompanied by an original certificate stating those conditions have been met. The certificate must be written in English. The certificate must be issued by an individual authorized to issue such a certificate under the provisions of current § 96.3, which contains provisions for the issuance of certificates of animal casings from any foreign region. Upon arrival of the sheep casings in the United States, the certificate must be presented to an authorized inspector at the port of arrival. We are also adding a new paragraph (d) to § 96.3 to provide that the required certification for sheep casing imported from BSE minimal-risk regions must be included on the certification required by that section.

Bile

Issue: One commenter expressed concern that our proposed rule did not include provisions for the importation of bile from BSE minimal-risk regions. The commenter stated that bile is synthesized in the liver and recycled from the intestines back to the liver before being stored in the gall bladder. In addition, said the commenter, bile has very low protein content, has never been found to contain any BSE agent, and has been classified by the EU in the same low-risk category as milk and liver. The commenter stated that if APHIS will allow the importation of bovine liver without regard to the age of the animal from which it was derived, then the importation of bile should also be allowed, because the process of collecting bile includes removing the gall bladder from the liver before emptying it.

Response: The opinion of the European Union Scientific Steering Committee (Ref 29) includes bile in category IV—no detectible infectivity in a BSE-infected animal. However, because we did not address the importation of bile from a BSE minimal-risk region in our risk analysis for the proposed rule, we are not including bile in this final rule as a product eligible for importation from a BSE minimal-risk region. However, we intend to address the importation of ruminant bile from such regions in separate rulemaking.

Blood Products

Issue: One commenter recommended that APHIS allow the importation of blood products, including serum and products derived from serum, from a BSE minimal-risk region, provided the product is accompanied by certification by the exporting country that the blood was collected at the time of slaughter in a hygienic manner from either (1) a fetus or an animal that is less than 30 months of age; or (2) an animal older than 30 months of age that was either a live animal or stunned with a non-penetrating stunning device. The commenter noted that APHIS stated in its proposed rule that infectivity has not been detected in bovine tissues apart from the distal ileum until at least 32 months post-exposure. As a result, said the commenter, the probability that blood collected from animals less than 30 months of age at slaughter might be contaminated with BSE is negligible. The commenter stated that, for animals older than 30 months, the potential that blood might be contaminated with BSE infectivity following stunning can be effectively mitigated by ensuring that blood is collected either from animals slaughtered with a non-penetrating stunning device or from live animals.

Response: We did not address the importation of blood and blood products from BSE minimal-risk regions in the risk analysis we conducted for this rulemaking. Currently, conclusive science is lacking regarding the risk of BSE transmission by blood and blood products. Scientific studies researching TSE infectivity and blood have to date been limited to mouse bioassay. In those studies, infectivity in mice was not demonstrated (Ref 30). However, in studies with sheep, TSE infectivity in blood was demonstrated. To date, there are no known cattle studies researching TSE/BSE infectivity and blood.

Fetal Bovine Serum

Issue: A number of commenters recommended that APHIS allow the importation of fetal bovine serum (FBS) from BSE minimal-risk regions. Commenters stated that FBS is collected from fetuses, which, if allowed to develop into calves, would meet the under-30-months-of-age criterion of our proposal. Further, it is collected under a controlled system that ensures that it is not exposed to SRMs. One commenter stated that there have been no documented cases of transmission of BSE from cow to fetus during pregnancy.

Response: We are making no changes based on the comments. There is no conclusive data to indicate whether BSE is transmitted by blood or blood products such as FBS. The commenters did not identify the uses to which FBS would be applied. Were serum to contain infectious levels of the BSE agent, it might pose a risk for livestock if used in certain applications such as bovine vaccine production or bovine embryo transfer, or for other products brought into direct exposure with ruminants. Unless and until there is conclusive data to demonstrate that BSE is not transmitted by blood and would

not be a contaminant of FBS, we consider it necessary to prohibit the importation of FBS from BSE minimal-risk regions. However, we realize that more information is necessary on this subject, and we are working with FDA to assess the risk from FBS and related materials and their various uses.

Issue: One commenter recommended that, because of the need for FBS and the potential serious consequences of BSE in FBS, APHIS should pursue rulemaking to allow the importation of FBS under certain conditions from countries affected with foot-and-mouth-disease.

Response: We have taken the commenter's guideline under consideration, but consider it outside the scope of this rulemaking, and are making no changes based on the comment in this final rule.

Gelatin and Collagen

Issue: In § 94.19(j) of our proposal, we proposed to allow the importation of gelatin from BSE minimal-risk regions, provided the gelatin was derived from the bones of bovines that were less than 30 months of age when slaughtered and that were not known to have been fed ruminant protein other than milk protein during their lifetime. One commenter stated that those restrictions on the importation of gelatin were unnecessary and that the only requirement for the importation of gelatin from a BSE minimal-risk region should be that the bones used in the production of gelatin did not include the skull or vertebral columns from animals older than 30 months of age.

Response: Consistent with the changes we discuss above under the heading "Age of Animals from which Meat is Derived" regarding the effectiveness of the removal of SRMs in mitigating BSE risk, we are removing the proposed requirement that the gelatin be derived from the bones of bovines less than 30 months of age when slaughtered and are requiring instead that the gelatin be derived from the bones of bovines from which the SRMs were removed. Also, consistent with the changes we discuss above under the heading "Certification of Feed Ban Compliance," we are revising our provisions regarding gelatin from BSE minimal-risk regions to require that the bovines from which the gelatin was derived were subject to a ruminant feed ban equivalent to that established by FDA.

We are also adding language to the regulations to clarify how the provisions regarding gelatin in § 94.19(f) of this final rule differ from the existing provisions regarding gelatin in § 94.18. The existing provisions in § 94.18 have allowed the importation of gelatin under import permit from regions in which BSE exists or that pose an undue risk of BSE. APHIS issues such a permit only after determining that the gelatin will be imported only for use in human food, human pharmaceutical products, photography, or some other use that will not result in the gelatin coming in contact with ruminants in the United States. We are making no changes to those provisions. The provisions in § 94.19(f) of this final rule regarding gelatin from BSE minimal-risk regions allow for the importation of certain gelatin over and above that eligible for importation under § 94.18(c)—*i.e.*, if the gelatin from a BSE minimal-risk region meets the conditions of § 94.19(f), it will not be limited to uses that will not result in the gelatin coming in contact with ruminants in the United States. To clarify this, we are identifying the gelatin addressed in this final rule in § 94.19(f) as gelatin not allowed importation under § 94.18(c). Additionally, we are making a nonsubstantive wording change to § 94.18(b) to clarify that the only gelatin derived from ruminants from regions listed in § 94.18(a)(1) or (a)(2) as regions in which BSE exists or that pose an undue risk of BSE that is eligible for importation is gelatin that meets the requirements of § 94.18(c).

Issue: One commenter recommended that collagen also be addressed in the regulations and be allowed importation from a BSE minimal-risk region under the same conditions as gelatin.

Response: Collagen derived from hides is not considered a risk (hides are exempt from most restrictions). However, collagen can be derived from bones. In addition, collagen is not subjected to the same extreme conditions of processing as is gelatin. We believe there is a need for more research regarding the risk from bone-derived products that have the potential for direct exposure to ruminants and are making no changes based on the comment.

Issue: One commenter requested that this final rule confirm there will be no restrictions on the importation of gelatin and collagen from hides or skins.

Response: According to the OIE guidelines, hide-derived products should be allowed unrestricted entry because they do not pose a BSE risk. At this time, we allow the importation of hide-derived gelatin and collagen under permit.

Issue: One commenter stated that all gelatin derived from the bones of bovines should be prohibited importation into the United States because there have been instances of people contracting vCJD from gardening with bone meal.

Response: We are making no changes based on this comment. We assume the commenter linked gelatin and bone meal because both products are derived from bones.

In this rule, we are allowing the importation of gelatin from a BSE minimal-risk region only if the gelatin is derived from bovines from which SRMs have been removed in the exporting region, and, further, that the bovines from which the gelatin was derived were subject to a ruminant feed ban equivalent to the requirements established by the U.S. Food and Drug Administration.

To date, there is no known link between bone-derived gelatin and vCJD and we are unaware of any evidence that shows that handling bone meal can cause vCJD. Additionally, on January 9, 2004, the Centers for Disease Control issued a *Morbidity and Mortality Weekly Report* (Ref 31) that confirms that since 1996, surveillance efforts have not detected any cases of indigenous vCJD in the United States.

Importation of Animal Feed From Canada

Issue: Several commenters stated that the importation of feed that contains animal byproducts from Canada should be prohibited. Another commenter addressed the requirements in part 95 of the regulations regarding certification for the importation of products used in animal feed into the United States. The commenter stated that, because obtaining original certifications for each load of feed can be time-consuming and expensive for feed mills not located close to government veterinary certification services, the Canadian regulations allow faxed copies of veterinary certificates to accompany loads of feed, with the understanding that the feed mill will keep a copy of the original on file once it arrives at the mill. The commenter requested that APHIS honor this form of certification for feed containing animal protein, or, at a minimum, for feeds containing only vitamins and minerals as the only animal source of ingredients in the feed.

Response: We are making no changes based on these comments. We did not propose any changes to the provisions in 9 CFR part 95 regarding the importation of meat meal and bone meal for animal feed and consider the comments to be outside the scope of the proposal.

Issue: One commenter recommended a prohibition on the importation of feed and feed byproducts from either of the

information, including the Harvard-Tuskegee Study's quantitative analysis of the risk of BSE spreading if introduced into the United States (Ref 3), provided the information necessary to make informed, scientifically sound, well-reasoned decisions for our action with respect to Canada.

Issue: The same commenter maintained that APHIS' risk analysis fails to answer questions about the impacts of the proposed rule on human health, including: What is the probable change to human health risk (*i.e.*, frequency and severity) that would be caused by each alternative risk management option considered (*e.g.*, reopening the border to less restricted imports, importing under different types of restrictions, keeping the status quo), and how certain is the change in health risk caused by each proposed action? Specifically, the commenter stated that the risk analysis does not provide "any quantitative or substantive qualitative estimation of the frequency and severity of adverse health effects from the different decision alternatives, beyond undefined adjectives such as 'low,' offered without any clear explicit interpretation or any explicit verifiable derivation from data."

The commenter stated that these questions, and analogous questions for animal health, are usually considered essential components of a health risk assessment. For example, said the commenter, a Joint United Nations Food and Agricultural Organization/World Health Organization Expert Consultation "defines risk characterization (corresponding approximately to what USDA terms 'risk estimation') as the 'integration of hazard identification, hazard characterization [*i.e.*, dose-response or exposure-response relation] and exposure assessment into an estimation of the adverse effects likely to occur in a given population, including attendant uncertainties.'" The commenter also pointed to a similar definition used by the Codex Alimentarius Commission: "The qualitative and/or quantitative estimation, including attendant uncertainties, of the probability of occurrence and severity of known or potential adverse health effects in a given population based on hazard identification, hazard characterization, and exposure assessment." The commenter asserted that "qualitative reassurances do not constitute an adequate risk analysis."

The commenter also stated that the Harvard-Tuskegee Study found "available information inadequate" to assess the risk of U.S. consumers developing vCJD from cows or meat. The commenter said that when maintaining the status quo will have no adverse impact on public health, and a proposed change could have a negative impact on public health, sound public policy dictates that the change not be made until all information needed to adequately assess the public health risk is available.

Response: The commenter suggested that the risk analysis for the rulemaking answer very specific questions about the precise impacts of the rule on human health. As the Harvard-Tuskegee Study noted, the information necessary to quantitatively assess the risk of humans contracting vCJD as a result of consuming BSE-contaminated food products is not available (Ref 33). Thus, the Harvard-Tuskegee Study quantified potential human exposure, but did not estimate how many people might contract vCJD from such exposure. That does not mean, however, that there is insufficient information about the potential impacts of the rule on human health. The Harvard-Tuskegee Study concluded that only a small amount of potentially infective tissues would likely reach the human food supply and be available for human consumption. As explained above, that amount was based on conditions as they existed in 2001, before safeguards implemented recently by FSIS and FDA, including prohibitions on the use of air injection stunning devices at slaughter and prohibitions on the use of nonambulatory cattle and SRMs in human food. These newly implemented safeguards, as well as additional information that indicates that compliance with feed restrictions in the United States is better than had been estimated, makes it far less likely that even small amounts of infective tissue would reach the human food supply and be available for human consumption. Further, we know that, despite estimates that more than 1 million cattle may have been infected with BSE during the course of the epidemic in the United Kingdom, which could have introduced a significant amount of infectivity into the human food supply, only 150 probable and confirmed cases of vCJD have been identified worldwide. This data suggests a substantial species barrier that may protect humans from widespread illness due to ingesting BSE-contaminated meat. This barrier suggests that it is unlikely that there would be any measurable effects on human health from small amounts of infectivity entering the food chain. We believe that this information allows an appropriate assessment of the effects of this rulemaking on human health.

Regarding the commenter's assertion that our risk analysis lacked essential components and provides only qualitative assurances, we disagree. As explained earlier, APHIS analyzed the risk of BSE being introduced into the United States through the importation of live ruminants and ruminant products and byproducts from Canada under the proposed rule. In doing so, we drew on a number of sources of information, including the Harvard-Tuskegee Study, which, as noted, specifically and quantitatively assessed the consequences of an introduction of BSE.

APHIS' risk analysis began with identifying the hazard as "the BSE risk that might be posed by importation of designated commodities and animals into the United States from Canada." Carefully scrutinizing both qualitative and quantitative information, we characterized the hazards to animal health, public health, the environment, and trade and evaluated the likelihood that U.S. livestock would be exposed to infectious levels of BSE from any of the commodities that would be allowed into the United States under the proposed rule.

Based on the hazard identification, hazard characterization (referred to in our risk analysis using the OIE terminology, "release assessment"), and exposure assessment, APHIS' risk analysis then estimated the adverse effects likely to occur—that is, we characterized the risk. The hazard identification, release assessment, and exposure assessment clearly indicated that it is unlikely that infectious levels of BSE would be introduced into the United States from Canada with any of the commodities included in the assessment, and that, even if the BSE agent were introduced into the United States, it would be extremely unlikely to enter commercial animal feed and thereby infect U.S. cattle or to result in human exposure to the BSE agent.

This conclusion was based on multiple factors, each of which reduces risk. These factors include the low number of infected animals or products that might conceivably be imported into the United States from Canada even without the mitigations applied by this rule, given the import and feed restrictions in place in Canada; the low reported incidence rate in that country coupled with Canada's active surveillance program—both of which satisfy and exceed the OIE guideline for a minimal BSE risk country or zone; the further reduction in risk associated with imports as a result of the mitigation measures imposed by this rule; the very

ID_{50}s. A cattle oral ID_{50} is the amount of infectious tissue that would be expected to cause 50 percent of exposed cattle to develop BSE. By tracking cattle oral ID_{50}s in the tissues of cattle through slaughter, processing, rendering, animal feeding, and human consumption, the model can evaluate the human exposures and animal health consequences of introducing BSE in imported animals or meat.

The Harvard-Tuskegee Study concluded that, based on conditions as they existed in 2001, the three practices that could contribute most to either human exposure or the spread of BSE, should it be introduced into the United States, were noncompliance with FDA's feed restrictions, rendering of animals that die on the farm and illegal diversion or cross-contamination of the rendered product in ruminant food, and inclusion of high-risk tissue, such as brain and spinal cord, in human food. As noted earlier in section III. C. in the discussion of Federal actions since December 2003, FSIS and FDA have implemented comprehensive safeguards that both agencies have concluded provide exceptionally effective protection to both human and animal health, and a higher level of protection than contemplated in 2001.

Even without these additional safeguards, however, the Harvard-Tuskegee Study concluded that, based on conditions as they existed in 2001, if 10 infected cows were introduced into the United States, only five new cases of BSE in cattle would be expected. In fact, the Harvard-Tuskegee Study predicted that there was at least a 50 percent chance that there would be no new cases at all. The extreme case (95th percentile of distribution) predicted 16 new cases of BSE in cattle and 180 cattle oral ID_{50}s available for potential human exposure over 20 years. Even the highest of these predictions indicate a small number of cases of BSE and extremely small potential for human exposure. With the additional safeguards implemented in the United States in 2004 (*i.e.*, the FSIS requirement that SRMs be removed from all cattle at slaughter and the condemnation of non-ambulatory disabled cattle presented for slaughter), this already small potential is reduced even further. This outcome is dramatically different from the experience in the United Kingdom, where it is estimated that there were nearly 1 million infected animals and millions of cattle oral ID_{50}s were available for potential human exposure (Ref 36).

In all cases, even the most extreme, the Harvard-Tuskegee Study concluded that the United States is highly resistant to the spread of BSE or a similar disease and that BSE is extremely unlikely to become established in the United States (where establishment is defined as continued occurrence after 20 years). Thus, APHIS' statement that the Harvard-Tuskegee Study found that, even if BSE were to enter the United States, it would be unlikely to spread, is an accurate representation of the Study's findings. Again, it must be emphasized that the Harvard-Tuskegee Study did not factor in the additional safeguards in place in the United States today.

As mentioned earlier in connection with our revised risk analysis, the HCRA recently updated its model using updated estimates for some of the model parameters, based on new data about compliance with feed restrictions. The results are even lower estimates of risk than previously predicted. This recent revision is discussed in more detail in the response to the next comment.

Issue: The same commenter maintained that APHIS' risk analysis represented the Harvard-Tuskegee Study as being more definitive and reassuring than it really is by stating that the Study found, even if BSE were to enter the United States, that it would be unlikely to spread. The commenter said that APHIS gave inadequate consideration to worst case scenarios, which the commenter referred to as "low-frequency, potentially high health consequence events," and to the sensitivity analysis in the Harvard-Tuskegee Study.

The commenter stated that the Harvard-Tuskegee Study reports that its sensitivity analysis indicates that the predicted number of additional cattle infected is particularly sensitive to the assumed proportion of ruminant meat-and-bone meal (MBM) that is mislabeled and the assumed proportion of properly labeled MBM that is incorrectly fed to cattle. The commenter stated that the predicted human exposure is likewise sensitive to these parameters. The commenter stated that assigning worst case values to even two of the three sets of parameters (demographic assumptions and MBM production; feed production; and feed practice) is sufficient to shift the conclusion based on the base case scenario that "imported BSE cases will probably die out" to "imported cases will probably start an epidemic." The commenter further stated that, even if a subset of the key drivers were assigned values within its allowed uncertainty range, spread of BSE is highly likely, which suggests the need for a much more thorough risk analysis. The commenter stated that the findings of the Harvard-Tuskegee Study should have driven USDA to commission additional refined data gathering, development of more refined models, and consequent refined risk analysis.

Response: APHIS is confident that it appropriately represented the Harvard-Tuskegee Study as demonstrating that BSE would be unlikely to spread even if it were to be introduced into the United States.

Sensitivity analysis evaluates the degree to which changes in the data used in a model affect the model's results. The Harvard-Tuskegee Study used a sensitivity analysis to mathematically evaluate the extent to which variations in input data affected the modeled results, including the likelihood that BSE would spread if introduced, rather than die out. The Harvard-Tuskegee Study evaluated the effects of changes when one model parameter was assigned a worst case value but other model parameters were held at values assigned in the base case, as well as the effects of assigning worst case values to multiple model parameters at the same time. (The base case values represent the Harvard-Tuskegee Study's, and USDA's, best estimates of what is likely to be representative of conditions in the United States. Extreme case scenarios are those in which some or all model parameters are given worst case values; in the worst of the extreme case scenarios, all model parameters are simultaneously assigned worst case values.)

We evaluated the Harvard-Tuskegee Study's sensitivity analysis and extreme case scenarios and used the results as a key factor in reaching our conclusion that the risk from importing Canadian animals and products is very low.

According to the Harvard-Tuskegee Study, changing the value assigned to most model parameters had only a limited influence on results. That is, even when they were assigned their worst case values, the results were not substantially different from what was predicted when all model parameters were assigned their base case values.

The model parameters that had the most significant effects on the Harvard-Tuskegee model results were: (1) The misfeeding rate (proportion of correctly labeled prohibited feed that is incorrectly administered to cattle); (2) the feed mislabeling rate (proportion of prohibited feed incorrectly labeled as nonprohibited); and (3) the render reduction factor (amount by which the rendering treatment reduces the amount of BSE infectivity).

When Harvard-Tuskegee conducted its original analysis in 2001,

establishing realistic bounds for the values of some of these model parameters was complicated by the limited amount of available information. For example, data on feed ban compliance indicated the fraction of facilities out of compliance with the feed ban regulations, but not the fraction of all prohibited material passing through noncompliant facilities. Second, the data did not differentiate between technical violations (*e.g.*, incorrect paperwork) and substantive violations. Harvard-Tuskegee therefore estimated the frequency of violations indirectly (Ref 36).

Simultaneously assigning estimated worst case values to the model's demographic model parameters (*i.e.*, proportion of animals that die on farm that are rendered, relative susceptibility vs. age for BSE in cattle, and the incubation period for BSE in cattle) and all MBM production, feed production, and feed administration model parameters at the same time resulted in a 75 percent chance that BSE would not become established in the United States. The "upper tail of the distribution" (*i.e.*, the 25 percent chance that BSE would spread in the worst of the worst case scenarios) is what concerned the commenter.

To reduce uncertainty about the importance of extreme case scenarios, we requested, as the commenter suggested, additional data gathering and refinement of the analysis. Specifically, we asked Joshua Cohen and George Gray at the HCRA in 2004 to refine its risk analysis to incorporate additional, more recent data on the mislabeling of products containing prohibited ruminant protein and the contamination of nonprohibited feeds with ruminant protein. Cohen and Gray ran the model using updated worst case values for model parameters related to ruminant MBM production and feed production. No new information on the rate of misfeeding was available, so Cohen and Gray continued to use the same value for misfeeding as had been used previously. However, because the misfeeding rate has the greatest influence on the predicted number of infected cattle following the introduction of BSE into the United States, Cohen and Gray ran multiple sets of simulations to determine how its value influenced the predicted results. Values tested included the original worst case value of 15 percent, as well as a range of values below that, from 0 percent to 12.5 percent.

Cohen and Gray used the most recent FDA data to estimate probabilities for mislabeling and contamination in MBM production (rendering) facilities and feed production facilities. Mislabeling occurs when a producer fails to label a product with prohibited material (*e.g.*, ruminant material) as "Do not feed to cattle or other ruminants." Contamination may occur when a prohibited product is incorporated into a nonprohibited product, or when prohibited and nonprohibited products are handled by the same facility without proper segregation or cleaning and disinfection.

Since the publication of the 2001 Harvard-Tuskegee Study, FDA has collected and distributed additional information on compliance with its feed restrictions that quantifies the number of facilities out of compliance and provides information on the nature of violations discovered. With respect to the number of noncompliant facilities, FDA's databases do not report the size of the facilities (*i.e.*, amount of material produced), so Cohen and Gray conservatively estimated that noncompliant facilities were the same size on average as compliant facilities. With respect to data on the nature of violations discovered, Cohen and Gray relied on data collected by FDA before September 2003, because it provides better detail on the nature of violations than data collected afterward. Data collected before September 2003 is reported as the total number of firms with at least one violation and designates each violation as a case in which (1) products were not labeled as required; (2) the facility did not have adequate systems to prevent commingling, or (3) the facility did not adequately follow recordkeeping regulations. More recent data do not provide this level of detail.

Cohen and Gray reported their results in a June 18, 2004, memorandum to the Agency (Ref 37). The following table (Table 2 in the analysis) shows the original and revised assumptions for rates of contamination and mislabeling at MBM production (rendering) facilities and feed production facilities.

ASSUMPTIONS FOR MISLABELING AND CONTAMINATION

Parameter	MBM production			Feed production		
	Base case 2003[a] (percent)	Worst case 2003[a] (percent)	Revised worst case[b] (percent)	Base case 2003[a] (percent)	Worst case 2003[a] (percent)	Revised worst case[b] (percent)
Probability of contamination	14	25	1.8	16	16	1.9
Proportion of prohibited material transferred to nonprohibited material per contamination event	0.1	1	1	0.1	1	1
Mislabeling probability	5	10	2.3	5	33	4

[a] Values from Cohen *et al.* (2003)
[b] Values developed for the 2004 assessment.

This table shows that, not only are the revised worst case estimates for certain of the model parameters much lower than the original worst case estimates, they are also lower than the base case estimates.

The predicted results based on the revised estimates show, with 95 percent confidence, that BSE will not spread if the misfeeding rate is 7.5 percent or less. Even when higher misfeeding rates are assumed, however, the results indicate that BSE spread would be very slow.

Using the terminology of the model, the value of R_0 determines whether the number of BSE infected cattle will increase or decrease over time and how rapidly. R_0 is calculated based on information put into the model, including information on the number of infected animals slaughtered, the amount of infectivity remaining after rendering, and the quantity of ruminant MBM that is consumed by cattle. Values of R_0 greater than 1 indicate an outcome where the number of infected animals will increase; values less than 1 indicate an outcome where the disease will decrease and eventually disappear. The degree to which R_0 is greater than or less than 1 is a measure of the rapidity with

which the disease will increase or decrease.

Using even the highest estimated misfeeding rate of 15 percent, Cohen and Gray found that the value of R_0 is 1.23, only slightly higher than 1, which indicates a very slow rate of spread in the worst case. HCRA noted in its 2004 analysis that data to characterize the misfeed rate would be very useful and might make it possible to judge whether a misfeed rate of more than 7.5 percent is even plausible. Regardless, the risk of BSE spreading at even a very slow rate when the highest estimated misfeeding rate is used assumes that no further mitigation measures are taken that could prevent the disease from spreading in the cattle population. As mentioned previously, FDA continues to conduct inspections to monitor compliance of feed mills, renderers, and protein blenders with the 1997 feed ban rule and has expanded the scope of its inspections to monitor compliance with the 1997 feed ban rule.

Issue: The same commenter stated further that the Harvard-Tuskegee Study noted that a "true validation of the simulation model * * * is not possible" due to lack of direct, real world experience with importing BSE-infected cattle.

Response: Although the Harvard-Tuskegee model is not amenable to formal validation through controlled experiments that monitor and measure the consequences of introducing BSE into a country, Harvard-Tuskegee did test its model using a real world situation. As a test of the model's plausibility, Harvard-Tuskegee modeled the small BSE outbreak identified in Switzerland following the introduction of BSE infectivity from the United Kingdom. Working with experts in Switzerland, the authors identified appropriate values for model parameters necessary to appropriately characterize that country's practices and procedures and then simulated the introduction of BSE infectivity. The simulation took into account risk management actions, such as feed bans instituted by the Swiss. HCRA found that the model's predictions were "reasonably close to empirical observations (Ref 38)," providing confidence in the model's structure and approach.

Issue: The same commenter stated that the need for more refined quantitative risk analysis is further increased by the fact that the Harvard-Tuskegee Study did not thoroughly model spatial (or other) heterogeneity of BSE risks. In other words, the Study did not, in the commenter's words, consider the extent to which some herds are particularly susceptible, or if other rare conjunctions of unfavorable conditions occur in a small fraction (e.g., less than 1 percent of cases) of a large number of replicates (e.g., farms, processing runs, etc.) each year in the United States, then, by chance, combinations of worst case conditions may occur several times per year at random locations, leading to sporadic adverse animal and human health events. The commenter further stated that the Harvard-Tuskegee Study authors noted something similar, stating, "Many of the simulation results are 'right skewed, meaning that the average value often exceeds the median (50th percentile) and can sometimes exceed even the 95th percentile.'" The commenter stated that while the average case is reassuring, the extreme cases are not, and said that extreme cases need to be better quantified. Such analysis of low frequency, potentially high health consequence events from removing current restrictions on Canadian beef imports appears to have been omitted entirely from any of USDA's risk analyses, and is not fully addressed by the Harvard-Tuskegee Study, which indicates the possibility of such events but does not address them specifically for the Canadian situation, which was not the focus of that study.

In summary, the commenter stated, it is not concern about the average case or base case alone that should inform the risk analysis component of decision making in this case, but concern about the less likely but high consequence events and the upper tail of the risk distribution that should be the focus of substantive analysis. Unless some credible information is provided about how frequently adverse events are expected to occur with and without the proposed changes, it is impossible to make an informed judgment about whether the economic benefits outweigh the human and animal health risks.

Response: We disagree that the Harvard-Tuskegee Study did not model the heterogeneity of BSE risks sufficiently to allow it to provide meaningful information for decisions about this rulemaking. We believe that our risk analysis does provide sufficient information about the potential for adverse events.

Specifically, the Harvard-Tuskegee Study considered differential susceptibility of cattle with respect to age, as well as differential infectivity by duration of infection and differential exposure by usage type and age. In their June 18, 2004, memorandum Cohen and Gray conclude "There is no evidence that susceptibility differs substantially among animals of the same age * * * [E]ven if susceptibility does vary * * *, there is no reason to believe the Harvard-Tuskegee model would substantially * * * underestimate the degree to which the disease would spread * * *" (Ref 37).

The Harvard-Tuskegee Study did not consider heterogeneity in virulence of BSE strains, clustering of rare events within geographic areas or affected populations, or varying susceptibility between breeds of cattle. The commenter did not provide any evidence or data to show that such heterogeneities exist, and we are unaware of any such data or evidence that would allow the modeling suggested by the commenter. To our knowledge, there is nothing in the scientific literature that concludes that one herd or breed is more susceptible to BSE than another. Cohen and Gray concur (Ref 37). We also note that, while samples from a few cattle in Japan and Italy have recently demonstrated some unusual patterns on Western blot tests, which suggests a possibility that different strains of BSE may exist, the evidence is far from conclusive and could be explained by other factors (Ref 39). Thus, there is no information at this point about the existence of different strains, much less about differences in virulence among strains, that could be modeled. In the absence of such data or evidence, any consideration of the potential impacts of these heterogeneities would be purely hypothetical and speculative, and would not provide an appropriate basis for making regulatory decisions. However, we continue to monitor the latest scientific research, and will certainly consider any significant information that becomes available.

APHIS' risk analysis evaluated known BSE risks and provided a rational, scientific basis for our classification of Canada as a BSE minimal-risk region and for determination that the application of specified mitigation measures would allow for the safe importation of certain animals and products from Canada. Further, our assessment of actions taken by the Canadian Government lead us to place Canada on the list of BSE minimal-risk regions.

Data and Uncertainties

Issue: The same commenter asserted that USDA's recent re-analysis (the Explanatory Note) was not adequately sensitive to data and did not attempt to address uncertainties and that its conclusions are, therefore, unsupportable.

Specifically, the commenter said that APHIS' conclusion and supporting reasoning that the second case does not alter the risk estimate "violates

commodities, is necessary to prevent the introduction of BSE from Canada.

APHIS carries out an array of animal and plant health regulatory programs, governing both domestic and imported commodities. In none of these programs, many of which have been in place for years, is it possible to assure that there is zero risk. Indeed, were we to make trade dependent on zero risk, foreign, as well as interstate, trade in animals and animal products would cease to exist.

Issue: The same commenter quoted APHIS as stating that, "[a]lthough the BSE-infected cow in Washington State was more than 30 months of age when diagnosed, it was obviously not imported under the conditions of the yet-to-be-implemented proposed rule and would not have been allowed to be imported under the proposed rule." The commenter said that USDA has not shown it is impossible for BSE to occur in some cattle less than 30 months of age or that some cattle older than 30 months of age might be inadvertently imported.

Response: As discussed above, the epidemiological investigation conducted by APHIS and others following the detection of BSE in a cow in Washington State in December 2003 indicated that the cow was born in Canada early in 1997 before Canada initiated a feed ban. This animal and all others born before Canada's feed ban would now be at least 7 years old. Because the rule requires that all cattle imported into the United States from Canada be less than 30 months old, no animals born before Canada's feed ban will be allowed to enter the United States under this rule. Furthermore, the rule also requires that cattle imported from Canada be slaughtered before they are 30 months of age. In actual practice, because cattle imported into the United States from Canada will be coming in for slaughter or for feeding and slaughter, the large majority will be less than 24 months of age (most male cattle are slaughtered before 24 months of age). FSIS has established procedures for checking an animal's age at slaughter through records and/or dentition. These procedures apply to both domestic and imported cattle and we are confident they are effective in determining age. The appropriate SRMs based on age will be removed from any cattle that are determined to be 30 months of age or older based on those procedures, and APHIS will take enforcement action as necessary.

With regard to the possibility that BSE could occur in cattle younger than 30 months of age, research demonstrates that the shorter incubation period (*i.e.*, infection developing in less than 30 months) is apparently linked to younger animals receiving a relatively large infectious dose (Ref 40). The younger cases have occurred primarily in countries with significant levels of circulating infectivity. Specifically, BSE was found in animals less than 30 months of age in the United Kingdom in the late 1980's to early 1990's, when the incidence of BSE was extremely high. This research also suggests that a calf must receive an oral dose of 100 grams of infected brain material containing high levels of the infectious agent to produce disease within a minimum of approximately 30 months (Ref 40). All available evidence leads to the conclusion that the level of infectivity in the Canadian cattle population is low and that compliance with the feed ban is high. Further, infectivity in animals younger than 30 months has in most cases been confined to tonsils and distal ileum, both of which would be removed at slaughter in the United States.

Prevalence of BSE in Canada

Issue: The same commenter specifically argued that APHIS should present quantitative evidence of the true prevalence of BSE in Canada and that the risk analysis for the rule should take this into account. The commenter said that the risk analysis only discusses the prevalence of BSE in Canada in vague, subjective terms such as "very low" and "unlikely" to generate cases in the United States, but that recent history now suggests that figure is 100 percent. The commenter asserted that more quantitative information is needed on the likely prevalence of BSE infections in Canadian ruminants and ruminant products that would be imported under the proposed rule (true prevalence, not just detected or qualitatively perceived). How likely is it, asked the commenter, that BSE prevalence in Canada could be 0.01 percent or 0.1 percent, or 1 percent, given current and prior testing? The commenter stated the belief that available data could help provide useful upper bounds.

Response: We disagree with the comment. Precise measurement of true prevalence of BSE is difficult to achieve, given the constraints of current testing methods available. It should be noted that no country in the world is attempting to officially define the true prevalence of BSE in its entire cattle population. Reports of incidence rates are indications of detectable levels of disease. Current testing methodology can only detect BSE, at the earliest, a few months before an animal exhibits clinical signs and, therefore, limits the ability to measure true prevalence in the entire cattle population. Data obtained through targeted surveillance can be extrapolated to make inferences about prevalence in broader populations as necessary. However, a specific calculation of true prevalence of BSE is not necessary to determine whether risk management policies or control policies are appropriate or need to be changed, and the importance of determining an exact prevalence rate should not be overstated.

We also disagree with the commenter's assertion that APHIS needs to establish a more precise estimate of the true prevalence of BSE in Canada for this rulemaking. Our risk analysis presented compelling evidence that the prevalence of BSE in Canada is low. The absence of a precise numeric measurement of prevalence of BSE in the Canadian cattle population is not an absence of information to inform estimates. As we have stated, we will use a combined and integrated approach that examines the overall effectiveness of control mechanisms in place when evaluating a country for BSE minimal risk. We believe that such an evaluation will provide a better indication of a country's BSE risk than simply a numeric threshold for BSE incidence or prevalence.

The threshold for incidence set by OIE for BSE minimal-risk regions is less than 2 cases per million cattle over 24 months of age during each of the last four consecutive 12-month periods. There have been two cases of BSE in Canadian-origin cattle since May 2003 out of an adult (over 24 months of age) cattle population of 5.5 million (0.4 per million) and no cases before May 2003. While we recognize that the number of detected cases does not, by itself, allow for a determination of prevalence, the number may be taken as a strong indication in countries with active surveillance that the mitigation measures in place to prevent the introduction and spread of BSE are working, thus prevalence is likely to be low. As we have discussed elsewhere, this is the case in Canada, which has had strict import controls in place since 1978 and instituted its feed ban, equivalent to that of the United States, on the same date as the United States in August 1997. Canada has also conducted surveillance for BSE since 1992 and has met or exceeded OIE guidelines for surveillance since 1995. It should be noted that OIE guidelines refer to the reported incidence of BSE infection or levels of detectable disease.

The commenter is incorrect in asserting that recent history suggests that Canadian imports are 100 percent likely to generate cases of BSE in the United States. While our risk analysis

infection was most likely a bovine imported from the United Kingdom in the 1980's.

We agree it is possible there may be other asymptomatic BSE-infected animals in Canada. However, because the two BSE-infected animals were born before the feed ban, there is no evidence to suggest that the feed ban is ineffective. The feed mills identified as having provided possibly infected feed most likely distributed that feed before the ban was implemented. The feed mills complied with CFIA feed ban regulations after they were implemented and have a good compliance record based on CFIA inspections. CFIA indicates that with respect to the inedible rendering sector, full compliance with the feed ban requirements has been consistently achieved, and that with respect to the Canadian commercial feed industry, non-compliance of "immediate concern" has been identified in fewer than two percent of feed mills inspected during the period April 1, 2003, to March 31, 2004. Those instances of noncompliance of "immediate concern" are dealt with when identified (Ref 11). According to CFIA, non-compliance of immediate concern includes situations where direct contamination of ruminant feed with prohibited materials has occurred, as identified through inspections of production documents or visual observation, and where a lack of appropriate written procedures, records, or product labeling by feed manufacturers may expose ruminants to prohibited animal proteins.

An effective feed ban is an important part of the mitigation measures proposed for the importation of ruminants and ruminant products from a BSE minimal-risk region. However, the feed ban is not the sole mitigation in this rule. In addition to the risk-mitigating effect of the feed ban, importations of cattle and cattle products will also be subject to the import restrictions described in this rule. Those restrictions are based on the scientifically demonstrated likelihood of the BSE agent residing selectively in various tissues of animals of specified species and ages. Based on our analysis of the risk of such importations, it is highly unlikely that the BSE agent will be transmitted to the cattle population of the United States or into the U.S. human food supply through ruminants or ruminant products or byproducts imported into the United States under this rule.

Additionally, the rule prohibits the importation of any cattle 30 months of age or older, which includes cattle born before Canada implemented its feed ban. This age restriction was not in place when the cow that was detected as positive for BSE in December 2003 was imported into the United States.

Issue: One commenter expressed concern that some cattle under 30 months of age and, therefore, eligible for importation from Canada under the proposed rule, might be offspring of cattle born before the feed ban (and thus offspring of potentially infected cattle). The commenter noted that Canadian officials indicated that 68 British cattle that died or were slaughtered in Canada more than 10 years ago are the probable source of the original BSE infection in Canada. The commenter stated that current OIE guidelines do not recommend the immediate culling of offspring in the case of index or cohort animals, provided they are excluded from food and feed chains at the end of their lives. The commenter stated that until all animals born in Canada before the feed ban have been properly identified, as well as their offspring, the risk of importing one of these animals into the United States remains a risk that USDA has not adequately recognized. Other commenters also stated that there are likely additional undetected cases of BSE in Canada resulting from exposure to contaminated feed and that we should not relieve import restrictions at this time. One commenter stated that there are still breeding cattle alive in Canada that may have been exposed to the similar infectious material as the two BSE-positive cows identified in Alberta, Canada, and Washington State.

Response: We disagree that the possible presence of additional animals in Canada, infected before implementation of the Canadian feed ban, present risks that have not been addressed for this rulemaking. As stated in responses to several other comments, it is possible that cattle born before Canada initiated its feed ban in August of 1997 may still exist in Canada. Because these cattle are now 7 years old or older, this rule will not allow them to be imported into the United States. Offspring of such cattle, which may be eligible for importation, are not likely to be infected with BSE. Although some evidence suggesting maternal transmission exists, such transmission has not been proven and, if it occurs at all, it occurs at very low levels not sufficient to sustain an epidemic (Ref 41). Canada has conducted extensive investigations of both of the two known BSE-infected animals in Canada and culled all of those animals' herdmates and offspring, all of which tested negative for BSE. Based on the low prevalence of BSE in Canadian cattle combined with the unlikely occurrence of maternal transmission, we concluded that cattle eligible for importation from Canada under this rule are highly unlikely to have BSE. Breeding cattle of any age may not be imported into the United States from Canada under this rule.

Issue: One commenter stated that Canada has offered no scientific proof that it has either contained or eradicated BSE from its cattle herd, and that the two BSE-infected cattle detected were discovered despite a very limited testing program in effect in both the United States and Canada at the time.

Response: We disagree. We believe Canada has established through import restrictions, a rigorous feed ban and ongoing surveillance that BSE is contained and that the necessary mitigation measures are in place to detect and prevent the dissemination of BSE infected material and eradicate the disease. Our rule is not predicated on eradication of BSE from a region. Canada meets our requirements for a minimal-risk region in part because the country has had an active, targeted surveillance program since 1992, and has exceeded OIE guidelines for BSE surveillance for more than the past 7 years. Additionally, as discussed above, Canada has significantly broadened that surveillance program.

Issue: One commenter stated that, because BSE has a long latency period, it is not possible to know at present the exact disease status of Canada.

Response: We concur that at present it is not possible to know with certainty whether any additional cows in Canada are infected with BSE. However, as documented in our risk analysis, we have concluded that the surveillance, prevention, and control measures implemented by Canada, in combination with the import restrictions imposed by this rule, will comprehensively mitigate the risk of introducing BSE into the United States through imported Canadian-origin animals and animal products.

Whether Existing Regulations Should be Maintained

Issue: One commenter stated that APHIS has not demonstrated that the current regulations applicable to regions where BSE exists are not necessary in all cases. According to the commenter, the Harvard-Tuskegee Study said import restrictions and the feed ban in the United States were the two most important reasons the United States was unlikely to have BSE. The commenter maintained that these regulations are essential now that BSE has "crossed the Atlantic" and pointed out that most

above under the heading "Reopening of the Comment Period and Explanatory Note," the epidemiological investigation of the imported BSE-positive cow slaughtered in Washington State shows that the infected cow was not indigenous to the United States and most likely became infected in Canada before that country's implementation of a feed ban, and, therefore does not reflect current risk conditions. Furthermore, all cattle identified in the United States as possibly having been from the Canadian source herd of the infected cow were euthanized and tested for BSE, and all of the animals tested negative. Because there is a small probability that BSE can be transmitted maternally, the two live offspring of the infected cow were also euthanized. A third had died at birth in October 2001. All carcasses were properly disposed of in accordance with Federal, State, and local regulations. Also, in conjunction with USDA's investigation, FDA conducted an extensive feed investigation. By December 27, 2003, FDA had located all potentially infectious product rendered from the BSE-positive cow in Washington State. The product was disposed of in a landfill in accordance with Federal, State, and local regulations. This rule by its terms requires that any cattle imported into the United States from Canada were born after the implementation of that country's feed ban.

Enforcement of Current Regulations

Issue: One commenter suggested that USDA focus its limited resources on effectively enforcing current BSE regulations, rather than subjecting the U.S. industry and consumers to what the commenter viewed as an increased BSE risk. The commenter stated that import data obtained through reports from the Economic Research Service (ERS) in 2001 and the Foreign Agricultural Service (FAS) show that several BSE-affected countries have exported beef to the United States. Also, the commenter said Japan should have been listed as an "undue risk" country because it did not implement internationally recommended feed import restrictions and because its import requirements were less restrictive than those acceptable for import by the United States.

Response: APHIS has examined U.S. import statistics reported by ERS and FAS that the commenter stated indicated the importation of products from countries with cases of BSE in violation of current APHIS import rules. In many cases, these reports have turned out to be erroneous. In the import databases, several commodities—including those that are restricted from importation and those that are not—may be included in a given category of imports, so the data are subject to misinterpretation. In addition, we have identified certain errors in the reports, such as the miscoding of imports that actually came from Australia as having originated in Austria. Further, import codes are based on tariff needs rather than on animal health needs, which makes it difficult to use the reports to determine compliance with animal health based trade restrictions. We are satisfied that our current import requirements are being properly enforced.

With regard to imports from Japan, following the finding of the first case of BSE in Japan in 2001, APHIS immediately banned the importation of live ruminants and ruminant products and byproducts from that country, and codified that ban by publishing an interim rule in the **Federal Register** on October 16, 2001 (66 FR 52483–52484, Docket No. 01–094–1), that added Japan to the list in § 94.18(a) of regions in which BSE exists. Before detection of BSE in Japan, that country was not listed as a region that posed an undue risk of BSE. At the time the "undue risk" category was developed, the focus was on trading practices among Member States of the European Union, because the European Union was where BSE was first detected and its Member States largely follow uniform trade practices. It is not clear to us from the comment what import practices in Japan are being referred to. The lack of a feed ban was not specifically part of the rationale for establishing the "undue risk" category.

Follow-Up to Washington State Detection

Issue: Following detection of BSE in an imported cow in Washington State in December 2003, one commenter recommended that a group of USDA stakeholders be assembled to work with the Secretary of Agriculture's BSE advisory group to address all issues arising out of the epidemiological investigation, emergency response, and mitigating measures announced by the Secretary on December 30, 2003.

Response: Following detection of BSE in December 2003 in an imported dairy cow in Washington State, USDA and other Federal and State agencies worked together closely to perform an epidemiological investigation, trace any potentially infected cattle, trace potentially contaminated rendered product, increase BSE surveillance, and take additional measures to protect human and animal health. USDA worked in collaboration with the CFIA in conducting the investigations. Additionally, an international team of scientific experts (the IRT) convened by the Secretary of Agriculture as a subcommittee of the Secretary's Advisory Committee on Foreign Animal and Poultry Diseases (SACFADP) reviewed the U.S. response and recommended actions that could provide additional meaningful human or animal health benefits in light of the North American experience. Both the IRT and the full SACFADP include governmental and nongovernmental representatives who made recommendations for enhancements of the national BSE response program in the United States (Ref 34 and 35).

Imports From Canada Before May 2003

Issue: Several commenters recommended that BSE surveillance in the United States be targeted at cattle imported from Canada into the United States before May 2003.

Response: This recommendation does not directly apply to this rulemaking but, rather, to our animal surveillance program for BSE. Nevertheless, to address the potential risk posed by these earlier imports, USDA and the U.S. Department of Health and Human Services have opted to focus resources on activities that offer the most direct protection of animal and public health. These included applying SRM removal requirements, enforcing the feed ban, and very aggressively increasing overall surveillance in the United States. The Departments have determined that focusing on these measures will be very effective and will do far more to lessen the possibility of BSE-infected material affecting animal health or reaching the public than devoting resources to the exceptionally difficult task of tracing Canadian-origin animals and conducting a surveillance program focused on such Canadian-origin animals.

Possible Causes of BSE Infection

Issue: One commenter asked whether it is known conclusively that cattle can become infected with BSE through eating contaminated materials.

Response: Oral ingestion of feed contaminated with the abnormal BSE prion protein is the only documented route of field transmission of BSE (Ref 49) although other routes have been considered. Thus, the primary source of BSE infection appears to be commercial feed contaminated with the infectious agent. The scientific evidence shows that feed contamination results from the incorporation of ingredients that contain ruminant protein derived from infected

animals. Standard rendering processes do not completely inactivate the BSE agent. Therefore, rendered protein such as meat-and-bone meal derived from infected animals may contain the infectious agent and can result in the infection of other animals that consume the material.

Canadian Prohibition of Imports

Issue: One commenter noted that in 1996 Canada prohibited imports of live ruminants from any country not recognized as free of BSE, and asked why, now that BSE has been detected in cattle indigenous to Canada, the United States would take a different approach than Canada did and allow imports from that country.

Response: The BSE situation addressed by Canada in 1996 was significantly different from the BSE situation in that country today. Actions taken now can be based on scientific research and information that was not available in 1996. In 1996, BSE concerns were focused on the United Kingdom and other countries with a high incidence of the disease. In addition, significant concern existed regarding the risks of possible human exposure to the BSE agent if the importation of live cattle from those regions were allowed. At that time, the apparent link between BSE and vCJD had just been announced, and predictions were being made of huge numbers of cases of vCJD. Since 1996, understanding of the disease has increased significantly, as has our knowledge of and experience with measures that can be taken to mitigate the risk. In addition, the predictions related to numbers of human cases have been scaled down dramatically, reflecting a better understanding of the true exposure that might have occurred. Today, effective import conditions can be designed to address specific risk issues.

U.S. Approach to BSE as Compared to Other Diseases

Issue: Several commenters expressed concern that APHIS' import policy with regard to BSE seems to differ from its general policy with regard to other foreign animal diseases. One commenter stated that, with most diseases, APHIS does not allow importation until adequate surveillance has been done to prove freedom from the disease. However, with regard to BSE, stated the commenter, APHIS allows imports from a region until a case of BSE is identified in that region. The commenter stated that APHIS should define standards for all levels of trade with various countries concerning BSE. Another commenter said that a country should be classified into one of the BSE established categories before trade in ruminant and ruminant products can be established.

Response: With regard to trade from BSE-affected countries, in § 94.18(a)(1) APHIS currently maintains a list of regions where BSE is known to exist. Additionally, § 94.18(a)(2) lists regions that present an undue risk of BSE because their import requirements are less restrictive than those that would be acceptable for import into the United States and/or because the regions have inadequate surveillance for BSE. APHIS prohibits the importation of live ruminants and certain ruminant products and byproducts both from regions where BSE is known to exist (and that are not considered BSE minimal-risk regions) and from regions of undue risk, even though BSE has not been diagnosed in a native animal in the latter regions.

As a newly discovered disease, BSE was limited in its geographic distribution to the United Kingdom and certain other countries in Europe. There was no evidence to suggest the disease existed elsewhere in the world. This situation lent itself to the policy of adding regions to lists of BSE-affected regions or regions that present an undue risk of BSE based on evidence of the disease's existence in those regions or on evidence that there was an undue risk of the disease existing in those regions, rather than assuming that BSE exists in every country of the world unless proven otherwise. This is consistent with our approach to other diseases, such as African horse sickness, which has never been shown to exist in countries other than in Africa and some countries on the Arabian Peninsula. Also, in contrast to infectious diseases that can be diagnosed relatively quickly, BSE has an extremely long incubation period.

If the commenter who discussed the need to conduct adequate surveillance to prove freedom from a disease before allowing importations was referring to the proposed provisions that would allow the importation of ruminants and ruminant products from Canada, it should be noted that we did not propose to consider Canada as a region free of BSE. Rather, in this rule we are creating a new category of regions that present a minimal risk of introducing BSE into the United States via imported ruminants and ruminant products and byproducts. This category is in addition to the categories of regions where BSE exists and regions that present an undue risk for BSE. We are adding conditions to allow the importation of certain live ruminants and ruminant products and byproducts from BSE minimal-risk regions (at this time, only Canada). As discussed in our proposed rule and in this **SUPPLEMENTARY INFORMATION** section, we will evaluate other regions as potential BSE minimal-risk regions upon their request and submission of the necessary information.

We described in the proposed rule and the risk analysis conducted for this rulemaking that Canada has conducted BSE surveillance since 1992. For the past 7 years, Canada has tested more than the minimum number of samples recommended by OIE. Additionally, we consider Canada to have exceeded the OIE guideline for surveillance by conducting active targeted surveillance, as has been done in the United States. We concluded that Canada's level of surveillance is adequate for that country to be recognized as a BSE minimal-risk region.

Change in BSE Status

Issue: One commenter stated that this rule should include criteria for determining when the BSE minimal-risk status of a region will be changed to a status of higher or lower risk, and should include how criteria for such a change in classification will be reviewed and evaluated.

Response: We acknowledge that there may be situations where the BSE minimal-risk status of a region should be changed to a status of higher or lower risk. As proposed, however, this rulemaking was intended to establish and address standards for recognizing a region as a BSE minimal-risk region, along with mitigation measures for the importation of susceptible animals and animal products from such regions. We have taken the commenter's recommendation under review, and, if we determine that standards for movement to a higher or lower risk status should be promulgated, we will propose those standards in a separate rulemaking. The provisions in § 92.2(g) recognize the need to conduct ongoing monitoring of a region's animal health status and provide that a region that has been granted animal health status under the APHIS regulations may be required to submit additional information pertaining to animal health status or allow APHIS to conduct additional information collection activities in order for that region to maintain its status.

WHO Guidelines

Issue: One commenter stated that the WHO does not recognize "minimal-risk BSE countries" and that WHO policy is not to allow imports of beef or cattle from BSE countries. Therefore, said the commenter, the import of beef and cattle from Canada should not be allowed.

mammalian protein (other than that from horses and pigs) to ruminants, and is developing a proposed rule to further strengthen the feed ban.

Uniform Standards

Issue: Several commenters requested that this rule not be implemented until a uniform set of BSE standards has been agreed upon among the United States, Canada, and Mexico. The commenters stated that particular relevance should be placed on a ban on the inclusion of blood meal in ruminant feed and on the segregation of lines in feed mills, as FDA announced it was planning to propose.

Response: The United States has been discussing a North American approach to the BSE issue for a number of years. Officials from the United States hold annual meetings with Canadian and Mexican technical experts from counterpart agencies that cover animal health, public health, diagnostics, and research. These meetings have contributed to greater understanding and harmonization of BSE control and prevention policies among the three countries. In fact, the United States, Canada, and Mexico have an agreement to recognize BSE region evaluations conducted by any of the three countries, using the same standards.

Currently, the United States is working with Canada and Mexico to develop a joint North American BSE strategy that promotes international guidelines protecting public and animal health, while encouraging the use of science- and risk-based trade measures in order to maintain sound disease surveillance and transparent reporting. Some of the preliminary results from those discussions are reflected in this final rule, such as the changes from our proposed provisions regarding the importation of live cervids into the United States (discussed above under the heading "*Cervids*").

Issue: One commenter recommended that implementation of this rule be delayed until there is a clear consensus among trading partners as to what constitutes SRMs.

Response: As noted above, the United States is working with Canada and Mexico to develop a joint North American BSE strategy and those three countries agree on what constitutes SRMs. APHIS is also interested in maintaining consistency with OIE guidelines regarding SRMs, although in certain cases the USDA considers it prudent to exceed the guidelines currently recommended by OIE.

Country-of-Origin Labeling

Issue: A number of commenters recommended that country-of-origin labeling be required in the United States so that beef imported from Canada would be so labeled. Some commenters suggested APHIS postpone implementation of this rule until such labeling is in place in this country. Several commenters raised concerns about how the United States would be able to certify U.S.-produced material as free of Canadian-sourced material.

Response: Under the Farm and Security and Rural Investment Act of 2002 and the 2002 Supplemental Appropriations Act, USDA is required to implement a mandatory country of origin labeling program (COOL) (Ref 50). USDA's Agricultural Marketing Service (AMS) published a proposed rule on the COOL program on October 30, 2003 (68 FR 61944–61985, Docket No. LS–03–04). Under the proposal, retailers would be required to notify their customers of the country of origin of all beef (including veal), lamb, pork, fish, and selected other perishable commodities being marketed in their stores. In addition, the AMS proposal identified criteria that these commodities must meet to be considered of U.S. origin. In January 2004, President Bush signed Public Law 108–199, which includes a provision to delay until September 2006 the implementation of mandatory COOL for all covered commodities except wild and farm-raised fish and shellfish. The COOL program, when implemented, will address the labeling concerns raised by commenters with regard to APHIS" proposed rule. APHIS does not consider it necessary to delay implementation of this rule until those labeling provisions are implemented. In its October 30, 2004 proposal, AMS noted, in discussing Section 10816 of Public Law 107–171 (7 U.S.C. 1638–1638d) regarding COOL that the "intent of the law is to provide consumers with additional information on which to base their purchasing decisions. It is not a food safety or animal health measure. COOL is a retail labeling program and as such does not address food safety or animal health concerns."

Jurisdiction

Issue: One commenter expressed the need for elimination of what the commenter termed conflicts of jurisdiction between the agencies of the Federal Government that oversee public health and safety. As an example, stated the commenter, the November 2003 APHIS proposed rule gives APHIS precedence over FSIS in determining whether an animal or its food products are safe to import, even though APHIS does not have authority to regulate food derived from the animal. One commenter stated that this rulemaking should be under the control of a human health agency because USDA has no expertise in the subject area. Another commenter suggested as a possible solution to what the commenter viewed as overlapping agency authorities the development of a single food agency in the United States to oversee all aspects of the food product safety system.

Response: We disagree with the commenters' assessments. The issues of protecting human and animal health from the risks of BSE are sufficiently diverse to require involvement of multiple agencies acting under their respective authorities. This work is carried out primarily through the USDA agencies of APHIS for animal health and FSIS for food safety, along with FDA. USDA has the statutory authority to protect both animal agriculture (AHPA) and public health (the Federal Meat Inspection Act, the Poultry Products Inspection Act of 1968, and the Egg Products Inspection Act).

APHIS regulates the importation of animals and animal products into the United States to guard against the introduction of animal diseases, including BSE. FSIS is responsible for ensuring the nation's commercial supply of meat, poultry, and egg products is safe, wholesome, and correctly labeled and packaged, whether produced domestically or imported. To ensure the safety of imported products, FSIS maintains a comprehensive system of import inspection and controls, which includes audits of a region's foreign inspection system, port-of-entry reinspection, and annual review of inspection systems of foreign countries eligible to export meat and poultry to the United States. These two USDA agencies, under their respective authorities, act together in the prevention, monitoring, and control of BSE in the U.S. livestock and meat and meat products food supply.

USDA agencies coordinate their responsibilities with FDA's Center for Veterinary Medicine regarding safety of animal feed. Likewise, such coordination is carried out with the FDA's Center for Food Safety and Applied Nutrition regarding the safety of all foods other than meat, poultry, and egg products, and with other FDA Centers having responsibility for drugs, biologics, and devices containing bovine material. These agencies collaborate, issuing regulations under their respective, to implement a coordinated U.S. response to BSE.

Private Testing for BSE

Issue: Several commenters recommended that private companies be provided the opportunity to do their own testing for BSE.

Response: APHIS has considered carefully the possibility of allowing private companies to conduct their own BSE testing, and remains convinced that allowing such testing for private marketing programs is inconsistent with USDA's mandate to ensure effective, scientifically sound testing for significant animal diseases and to maintain domestic and international confidence in U.S. cattle and beef products. As we continue to deal with the complexities of BSE, we consider it important to maintain clarity with regard to the purpose of USDA's BSE testing and the results such testing yields. As explained previously, currently available post-mortem tests, although useful for disease surveillance, are not appropriate as food safety indicators.

User Fees

Issue: One commenter stated that the $94.00 fee for a permit to import animals and products into the United States is unfair to private individuals and that there should be a minimal or no fee for permits.

Response: The issue raised by the commenter pertains to general import procedures and is not within the scope of this rulemaking. However, with regard to the general issue of user fees, under APHIS' regulations, user fees are charged for the services APHIS provides related to the importation, entry, or exportation of animals and animal products. As provided in 9 CFR part 130, APHIS charges all individuals a $94.00 fee for processing an application for a permit to import live animals, animal products or byproducts, organisms, vectors, or germplasm (embryos or semen) or to transport organisms or vectors. These charges are necessary for APHIS to recover the costs of providing these services. APHIS does not receive funds appropriated by Congress for these activities, and Congress has directed APHIS to charge user fees to recover its costs. The $94.00 cost for APHIS" processing of applications for permits to import products was set in August 2001 (66 FR 39628–39632, Docket No. 99–060–2) based on the average of the actual volumes of each type of application processed in fiscal years 1998 and 1999. The user fee amount includes cost components for the salaries of employees involved in the processing applications, along with costs of billings and collections, rent, equipment (such as computer technologies), Agency overhead, and departmental charges.

Flexibility and BSE Research Advances

Issue: One commenter recommended that this rule explicitly provide administrative flexibility to the Administrator, with the understanding that the flexibility granted to the Administrator would be applied on the basis of risk assessment and sound science. The commenter stated that such an approach would provide for transparent and predictable application of the rule, while accommodating the evolution of scientific knowledge and risk mitigation processes, new product development, market demand, and revisions to OIE standards or WHO guidance. Another commenter requested that USDA review the provisions in this final rule 2 years after publication to see if technology and research advances warrant changes in the regulations. Another commenter requested that APHIS reassess the rule in 5 or 10 years.

Response: We are making no changes based on these comments. In developing this rule, we considered the best current BSE research available to us and designed the standards for minimal-risk regions to provide for some flexibility. We continually evaluate our regulations to consider advancement in knowledge and science.

Zero Risk

Issue: Several commenters disagreed that importations of ruminants and ruminant products should be allowed under certain conditions from regions that APHIS considers minimal risk for BSE. Some commenters said that countries exporting such commodities to the United States should present a "zero risk" of BSE, not a minimal risk. Even with a zero risk standard, said one of these commenters, it would be incorrect to say any region is BSE free and that the most that can be said is testing has not been conducted for BSE in that region.

Response: Zero risk is virtually, if not completely, impossible to achieve. As noted above, if we were to make trade dependent on zero risk, foreign, as well as interstate, trade in animals and animal products would cease to exist. APHIS agrees with the conclusion expressed in international trade agreements, such as the WTO-SPS Agreement and NAFTA, that trade should be commensurate with risk. Under these agreements, participating nations, including the United States and U.S. trading partners, have agreed to base conditions for importations on risk assessment and international standards. Regarding the risk associated with regions that have no or inadequate surveillance for BSE, we do not currently accept live ruminants or ruminant products from these regions, either because they are listed in § 94.18 as a BSE-restricted region or because they have not applied for status necessary to trade in ruminants or ruminant products with the United States, which would involve an evaluation by APHIS of the region for other diseases, such as foot-and-mouth disease and rinderpest, as well as for BSE.

The Harvard-Tuskegee Study

Issue: One commenter asked why USDA requested Harvard to conduct a risk analysis to evaluate the effectiveness of the U.S. system with the presence of Canadian products in U.S. channels, instead of requesting that Canada conduct a similar risk assessment of its system.

Response: As discussed above under the heading "Harvard-Tuskegee Investigation of BSE Risk in the United States," in April 1998, USDA commissioned Harvard and Tuskegee Universities to conduct a comprehensive investigation of BSE risk in the United States. The purpose of the Harvard-Tuskegee Study was to assess the effectiveness of the U.S. domestic system with regard to BSE. The initial study did not specifically address the risk of BSE being introduced into the United States from Canada. The study was completed in 2001 and released by the USDA. Following a peer review of the Harvard-Tuskegee Study in 2002, the authors responded to the peer review comments and released a revised risk assessment in 2003 (Ref 2).

In 2003, using the same simulation model developed for the initial study, the HCRA evaluated the implications of a then-hypothetical introduction of BSE into the United States from Canada (Ref 10). Again, this was an assessment of the internal system in the United States, rather than an assessment of the risk of BSE in Canada. This assessment confirmed the conclusions of the earlier study-namely, that a very low risk exists of BSE becoming established or spreading should it be introduced into the United States. In December 2002, the CFIA, Science Branch, issued a risk assessment that evaluated the risk for BSE in Canada. (Ref 12).

J-List

Issue: One commenter stated that, when the border is opened, we should remove Canadian cattle from the "J-list."

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DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. 03–080–4]

RIN 0579–AB73

Bovine Spongiform Encephalopathy; Minimal Risk Regions and Importation of Commodities; Availability of an Environmental Assessment

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice of availability and request for comments.

SUMMARY: We are advising the public that the Animal and Plant Health Inspection Service has prepared an environmental assessment relative to a final rule published in today's issue of the **Federal Register** to amend the regulations regarding the importation of animals and animal products to recognize, and add Canada to, a category of regions that present a minimal risk of introducing bovine spongiform encephalopathy into the United States via live ruminants and ruminant products. The rule also sets out conditions under which certain live ruminants and ruminant products and byproducts may be imported from such regions. We are making the environmental assessment available to the public for review and comment.

DATES: We will consider all comments that we receive on or before February 3, 2005.

ADDRESSES: You may submit comments by any of the following methods:

- EDOCKET: Go to *http://www.epa.gov/feddocket* to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Once you have entered EDOCKET, click on the "View Open APHIS Dockets" link to locate this document.
- Postal Mail/Commercial Delivery: Please send four copies of your comment (an original and three copies) to Docket No. 03–080–4, Regulatory Analysis and Development, PPD, APHIS, Station 3C71, 4700 River Road Unit 118, Riverdale, MD 20737–1238. Please state that your comment refers to Docket No. 03–080–4.
- E-mail: Address your comment to *regulations@aphis.usda.gov*. Your comment must be contained in the body of your message; do not send attached files. Please include your name and address in your message and "Docket No. 03–080–4" on the subject line.

Reading Room: You may read any comments that we receive on the environmental assessment in our reading room. The reading room is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue, SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 690–2817 before coming.

Other Information: You may view APHIS documents published in the **Federal Register** and related information, including the names of groups and individuals who have commented on APHIS dockets, on the Internet at *http://www.aphis.usda.gov/ppd/rad/webrepor.html.*

FOR FURTHER INFORMATION CONTACT: Dr. Karen James-Preston, Director, Technical Trade Services, National Center for Import and Export, VS, APHIS, 4700 River Road Unit 38, Riverdale, MD 20737–1231; (301) 734–4356.

SUPPLEMENTARY INFORMATION:

Background

On November 4, 2003, the Animal and Plant Health Inspection Service (APHIS) published in the **Federal Register** (68 FR 62386–62405, Docket No. 03–080–1) a proposal to amend the regulations regarding the importation of animals and animal products to recognize a category of regions that present a minimal risk of introducing bovine spongiform encephalopathy (BSE) into the United States via live ruminants and ruminant products, and proposed to add Canada to this category. We also proposed to allow the importation of certain live ruminants and ruminant products and byproducts from such regions under certain conditions.

In that proposed rule, we informed the public that we had prepared an environmental assessment (EA) regarding the potential impact on the quality of the human environment due to the importation of ruminants and ruminant products and byproducts from Canada under the conditions specified in the proposed rule. APHIS' review and analysis of the potential environmental impacts associated with those proposed importations were documented in the EA, titled "Proposed Rulemaking to Establish Criteria for the Importation of Designated Ruminants and Ruminant Products from Canada into the United States, Environmental Assessment (October 2003)." We made that EA available to the public for review and comment during the proposed rule's comment period, which originally closed on January 5, 2004, but was subsequently extended to April 7, 2004, by a notice published in the **Federal Register** on March 8, 2004 (69 FR 10633–10636, Docket No. 03–080–2).

During the comment period for the proposed rule, comments were received from the public regarding the EA. As a result of those comments, and in light of new circumstances that have arisen since the October 2003 EA was prepared (most notably the detection of BSE in a Holstein cow in Washington State in December 2003), APHIS has revised the October 2003 EA to discuss in more detail the potential impacts of concern for the human environment. We are making this revised EA, titled "Rulemaking to Establish Criteria for the Importation of Designated Ruminants and Ruminant Products From Canada into the United States, Final Environmental Assessment (December 2004)," available to the public for review and comment. We will consider all comments that we receive on or before the date listed under the heading **DATES** at the beginning of this notice.

The EA may be viewed on the EDOCKET Web site (*see* **ADDRESSES** above for instructions for accessing EDOCKET) or on the APHIS Web site at *http://www.aphis.usda.gov/lpa/issues/bse/bse.html.* You may request paper copies of the EA by calling or writing to the person listed under **FOR FURTHER INFORMATION CONTACT.** Please refer to the title of the EA when requesting copies. The EA is also available for review in our reading room (information on the location and hours of the reading room is provided under the heading **ADDRESSES** at the beginning of this notice).

The EA has been prepared in accordance with: (1) The National Environmental Policy Act of 1969 (NEPA), as amended (42 U.S.C. 4321 *et seq.*), (2) regulations of the Council on Environmental Quality for implementing the procedural provisions of NEPA (40 CFR parts 1500–1508), (3) USDA regulations implementing NEPA (7 CFR part 1), and (4) APHIS' NEPA Implementing Procedures (7 CFR part 372).

Done in Washington, DC, this 27th day of December 2004.

Kevin Shea,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 04–28594 Filed 12–29–04; 3:00 pm]

BILLING CODE 3410–34–P

where a borrower received an excessive write down or write-off of their debt. The information collected under the provisions of this regulation is provided on a voluntary basis by the borrower, although failure to cooperate to correct loan accounts may result in liquidation of the account.

Need and Use of the Information: The information to be collected by FSA will primarily be financial data such as amount of income, farm operating expenses, crop yields, etc. The borrower will provide written records or other information to refute FSA's findings when it is determined through audit or by other means that a borrower has received unauthorized financial assistance. If the borrower is unsuccessful in having the FSA change its determination of unauthorized assistance, the borrower may appeal the FSA decision. Otherwise, the unauthorized loan recipient may pay the loan in full, apply for a loan under a different program, convey the loan security to the government, enter into an accelerated repayment agreement, or sell the security in lieu of forced liquidation.

Description of Respondents: Farms; individuals or household; business or other for-profit.

Number of Respondents: 200.

Frequency of Responses: Reporting; on occasion; annually.

Total Burden Hours: 800.

Ruth Brown,

Departmental Information Collection Clearance Officer.

[FR Doc. 05–1080 Filed 1–19–05; 8:45 am]

BILLING CODE 3410–05–M

DEPARTMENT OF AGRICULTURE

Submission for OMB Review; Comment Request

January 13, 2005.

The Department of Agriculture has submitted the following information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13. Comments regarding (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of burden including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology should be addressed to: Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB),*Pamela_Beverly_OIRA_Submission@OMB.EOP.GOV* or fax (202) 395–5806 and to Departmental Clearance Office, USDA, OCIO, Mail Stop 7602, Washington, DC 20250–7602. Comments regarding these information collections are best assured of having their full effect if received within 30 days of this notification. Copies of the submission(s) may be obtained by calling (202) 720–8681.

An agency may not conduct or sponsor a collection of information unless the collection of information displays a currently valid OMB control number and the agency informs potential persons who are to respond to the collection of information that such persons are not required to respond to the collection of information unless it displays a currently valid OMB control number.

Food and Nutrition Service

Title: Food Stamp Nutrition Education Systems Review.

OMB Control Number: 0584–NEW.

Summary of Collections: The Food Stamp Act of 1977 (Pub. L. 88–525, as amended; 7 U.S.C. 2011) authorized the Food Stamp Act. Under implementing Food Stamp Program (FSP) Regulations (7 CFR 272.2) state FSP agencies have the option to include nutrition education for program participants as part of their administrative operations. The states must submit an annual nutrition education plan to the Food and Nutrition Service (FNS) for approval; FNS then reimburses states 50 percent of the allowable expenses for nutrition education.

Need and Use of the Information: The Food and Nutrition Service will conduct a descriptive study to develop a more in-depth understanding of the Food Stamp Nutrition Education (FSNE) infrastructure, policy choices, operations, and decision-making. The last descriptive study of FSNE operations was conducted in fiscal year 1997. Since that time, several factors have converged making it critical for FNS to obtain more current information. First the scale of FSNE has grown rapidly. Second there is growing Agency and public interest in improving the diets and reducing the prevalence of overweight and obesity. Finally, FNS has limited information on the states use of new approaches to nutrition education.

Description of Respondents: State, Local, or Tribal Government; business or other for-profit; not-for-profit institutions.

Number of Respondents: 1,110.

Frequency of Responses: Reporting; other (one time).

Total Burden Hours: 1,730.

Ruth Brown,

Departmental Information Collection Clearance Officer.

[FR Doc. 05–1081 Filed 1–19–05; 8:45 am]

BILLING CODE 3410–30–M

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. 03–080–5]

RIN 0579–AB73

Bovine Spongiform Encephalopathy; Minimal Risk Regions and Importation of Commodities; Availability of an Environmental Assessment With Corrections and Extension of Comment Period

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice of availability and extension of comment period.

SUMMARY: We are advising the public that the Animal and Plant Health Inspection Service is making available a corrected version of an environmental assessment relative to a final rule that was published in the January 4, 2005, issue of the **Federal Register**. We are making the corrected version of the environmental assessment available to the public for review and comment through February 17, 2005.

DATES: We will consider all comments that we receive on or before February 17, 2005.

ADDRESSES: You may submit comments by any of the following methods:

- EDOCKET: Go to *http://www.epa.gov/feddocket* to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Once you have entered EDOCKET, click on the "View Open APHIS Dockets" link to locate this document.
- Postal Mail/Commercial Delivery: Please send four copies of your comment (an original and three copies) to Docket No. 03–080–5, Regulatory Analysis and Development, PPD,

Infected animals typically exhibit clinical signs of BSE 4 to 6 years after infection, and 95 percent of infected cattle exhibit clinical signs in less than 7 years. Since cattle born before the feed ban would now be 7 years of age or older, any remaining infected cattle, if present, would likely be showing clinical signs of BSE that would allow their detection through Canada's BSE surveillance system.

Canadian Government authorities inspect rendering facilities, feed manufacturers, and feed retailers to ensure compliance with the feed ban. Rendering facilities are regulated under an annual permit system, and compliance with the regulations is verified through at least one inspection each year. Feed manufacturers or mills, feed retailers, and farms have been inspected on a routine basis. These inspections have shown a high level of compliance. CFIA indicates that, with respect to the inedible rendering sector, full compliance with the feed ban requirements has been consistently achieved, and that, with respect to the Canadian commercial feed industry, CFIA has identified noncompliance of "immediate concern" in fewer than 2 percent of feed mills inspected during 2003–2004. Those instances of noncompliance of "immediate concern" are dealt with when identified. According to CFIA, noncompliance of immediate concern includes situations where direct contamination of ruminant feed with prohibited materials has occurred, as identified through inspections of production documents or visual observation, and where a lack of appropriate written procedures, records, or product labeling by feed manufacturers may expose ruminants to prohibited animal proteins (Ref 11).

Surveillance. Canada has an adult cattle population of approximately 5.5 million cattle older than 24 months of age. The current OIE Code, Appendix 3.8.4, references adult cattle populations as those greater than 30 months and recommends examining at least 300 samples per year from high-risk animals in a country with an adult cattle population of 5 million, or 336 samples per year in a country with an adult cattle population of 7 million. Even though the adult cattle population in Canada is defined as greater than 24 months of age and OIE defines it as greater than 30 months of age, Canada has met or exceeded this level of surveillance for the past 7 years, thus exceeding the OIE guidelines. Active targeted surveillance was begun in Canada in 1992, with numbers of annual samples ranging from 225 in 1992 to current levels of over 15,800 per year. This surveillance has continued to be targeted surveillance, with samples obtained from adult animals exhibiting some type of clinical signs or considered high risk for other reasons that could be considered consistent with BSE. During the time Canada has been conducting surveillance for BSE, BSE has been detected in only two cattle indigenous to Canada—the cows diagnosed with BSE in May and December 2003.

Canadian 2002 BSE Risk Assessment

In December 2002, CFIA issued an assessment of the risk of BSE in Canada. The assessment evaluated BSE risk factors and correlating risk mitigation measures being taken in Canada, as well as surveillance being conducted in that country to detect any BSE-infected animals. The risk assessment analyzed the possibility that BSE infectivity was introduced into Canada through 665 cattle imported into Canada from Europe between 1979 and 1997, when Canada implemented its feed ban. The analysis indicated a low potential for cumulative introduction of infectivity into Canada via these cattle and further suggested that the likelihood of the spread and establishment of BSE in Canada, both before and after the 1997 feed ban, was negligible (Ref 12).

Epidemiological Investigation and a Report by an International Review Team

On May 20, 2003, CFIA reported a case of BSE in a beef cow in northern Alberta. Following the detection of the BSE-infected cow, Canada conducted an epidemiological investigation of the BSE occurrence, working with, among others, APHIS representatives. The epidemiological investigation showed that the animal was born before implementation of the feed ban in 1997, and that exposure likely occurred prior to or near the time of the imposition of the feed regulations. Although a specific source of infection was not identified, the most likely source of exposure was feed that contained protein from an infected animal imported from the United Kingdom between 1982 to 1989.

Additionally, the epidemiological investigation focused on rendered material or feed that could have been derived from the carcass of the infected cow. As part of that investigation, a survey was conducted of approximately 1,800 sites that were at some risk of having received such rendered material or feed. The survey suggested that 99 percent of the sites surveyed experienced either no exposure of cattle to the feed (96 percent of the sites) or only incidental exposure (3 percent of the sites). The remaining 1 percent represented limited exposures, such as cattle breaking into feed piles, sheep reaching through a fence to access feed, and a goat with possible access to a feed bag. Depopulation of Canadian herds possibly exposed to the feed in question was carried out by the Canadian Government. Canadian officials conducted a wide-ranging investigation of possible exposure to the feed in question and carried out depopulation of Canadian herds possibly exposed to the feed. On each of those farms where the investigation could not rule out the possibility of exposure to feed that may have contained rendered protein from the infected animal, the herds were slaughtered and tested. All of those animals tested negative for BSE and their carcasses were disposed of in ways, such as disposal in landfills, to ensure that they did not go into the animal food chain (Ref 13).

In June 2003, an international review team (IRT) of animal disease experts assessed the CFIA's investigation of the May 2003 case of BSE and Canada's overall protective measures. The IRT noted the quality of the Canadian investigation and the effectiveness of protective measures in place in Canada. The IRT recommended a number of actions to further enhance the safety of human and animal health, including putting in place a national requirement that SRMs be removed from products destined for consumption; a review of animal feed restrictions; strengthened tracking and tracing systems; improved disease testing and surveillance; and additional efforts to improve disease awareness among producers, veterinarians, and the public (Ref 14).

Additional Measures Taken in Canada

Response to the IRT Report. Subsequent to the IRT report, in July 2003 Canada implemented the requirement that SRMs be removed from cattle at slaughter (Ref 15). Additionally, Canada implemented enhanced measures for identification and for tracking and tracing, as well as for increased BSE surveillance and testing. We discuss the increased surveillance and testing in greater detail below. (Ref 16).

Epidemiological Investigation of the Case in Washington State. As noted above, in December 2003, BSE was detected in a Canadian-origin cow in Washington State. Canada, along with the United States, conducted a rigorous epidemiological investigation. As with the May 2003 case, the epidemiological investigation showed that the animal was born in Canada before implementation of the feed ban in 1997 and, in all likelihood, was exposed to

CERTIFICATE OF SERVICE

I hereby certify that, on the 21st day of March 2005, I have caused a true and accurate copy of the Appellant's Brief and Excerpts of Record to be served by hand upon:

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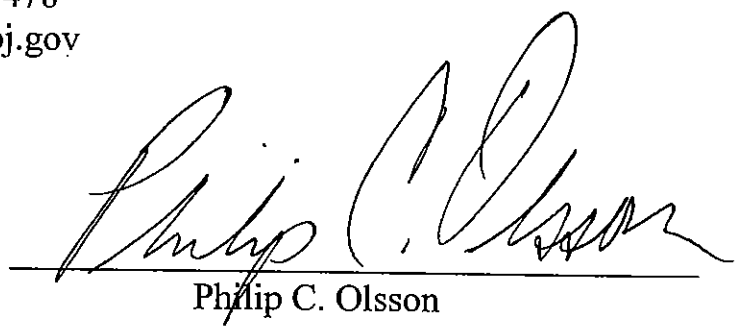

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