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IN THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

NATIONAL MEAT ASSOCIATION, Plaintiff-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.	[illegible] **ANSWERING BRIEF OF RANCHERS CATTLEMEN ACTION LEGAL FUND UNITED STOCKGROWERS OF AMERICA**

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RULE 26.1 CORPORATE DISCLOSURE STATEMENT

Pursuant to Fed. R. App. P. 26.1 and Ninth Circuit Rule 26.1, Appellee Ranchers Cattlemen Action Legal Fund United Stockgrowers of America ("R-CALF USA") hereby states that it is a non-profit corporation organized under the laws of the State of Montana. R-CALF USA has no parent corporation, and no publicly traded company owns 10 percent or more of the stock of R-CALF USA.

Dated: March 28, 2005

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JURISDICTIONAL STATEMENT

Plaintiff-Appellee Ranchers Cattlemen Action Legal Fund United Stockgrowers of America ("R-CALF USA") agrees that this Court has jurisdiction over the National Meat Association's ("NMA's") appeal of the denial of its motion to intervene, under 28 U.S.C. § 1291. R-CALF USA does not agree that this Court has jurisdiction to review the District Court's grant of a preliminary injunction on an interlocutory basis under 28 U.S.C. § 1292(a)(1), because this Court has jurisdiction to hear an interlocutory appeal by a party, not by any interested entity. NMA has made no attempt to demonstrate, nor could it, that it presents exceptional circumstances that might justify an appeal by a non-party. Additionally, as discussed below, NMA lacks standing under Article III of the United States Constitution to challenge the District Court's omission of a requirement for R-CALF USA to post security for the preliminary injunction, because NMA alleges no injury that would be redressable by this Court requiring R-CALF USA to post security pursuant to Fed. R. Civ. P. 65(c). Accordingly, this Court lacks jurisdiction to consider, and should ignore, all of NMA's brief except for the portion that addresses the District Court's denial of NMA's motion to intervene in the proceedings below.

STATEMENT OF THE CASE

While R-CALF USA agrees with portions of the Statement of the Case in NMA's opening brief, it leaves out key aspects of the case that are necessary for understanding the District Court's action. NMA complains that there currently is an "unfair imbalance in the marketplace." It falsely asserts that this situation is the result of the preliminary injunction issued by the District Court on March 2, 2005 (the "Preliminary Injunction"). In fact, the situation NMA describes is the result of USDA's decision to create widespread exceptions to its general policy of prohibiting imports of cattle and beef from any country where bovine spongiform encephalopathy ("BSE") is known to exist, a policy it has had since 1989. *See* 70 Fed. Reg. at 462. That policy initially was applied to Canada on May 29, 2003, 68 Fed. Reg. 31,939, after the discovery of BSE in Canada. NMA challenged neither the May 29, 2003 rule nor the exceptions.

The USDA regulations provide that USDA may issue permits for ruminants or ruminant products to be brought into the United States in specific cases, where the Administrator determines in the specific case that the action will not endanger livestock or poultry in the United States. 68 Fed. Reg. at 39,140. Under intense pressure from the Canadian government

and some U.S.-based meat packers (who also operate packing plants in Canada), on August 8, 2003, then-Secretary of Agriculture Ann M. Veneman announced that USDA would grant blanket permits for the importation of a limited number of meat products from Canada, including boneless bovine meat from cattle under 30 months of age at the time of slaughter, boneless veal from calves under 36 weeks, and fresh or frozen bovine liver. *See* 70 Fed. Reg. 460, 536 (January 4, 2005) (the "Final Rule"); District Court's March 2, 2005 opinion supporting its preliminary injunction order ("Opinion") at 3, ER 158. In the spring of 2004, R-CALF USA learned that, although USDA had told the public that importation of other, higher-risk bovine products from Canada would have to await completion of the rulemaking USDA was undertaking, in fact USDA had, without notice and comment, authorized imports of those other higher-risk products.

R-CALF USA filed an action in Federal District Court in Montana, seeking to enjoin imports of these additional products until the rulemaking had been completed. On April 26, 2004, the District Court issued a Temporary Restraining Order, prohibiting importation from Canada of all edible bovine meat products beyond those authorized by USDA's action of August 8, 2003. *Ranchers Cattlemen Action Legal Fund United Stockgrowers of America v. United States Dept. of Agriculture, et. al.*, No.

CV-04-51-BLG-RFC, Supplemental Excerpts of Record ("SER") at 1-13. On May 5, 2004, with the stipulation of the parties, that Temporary Restraining Order was converted into a preliminary injunction, which expired after the Final Rule was issued. (R-CALF USA's arguments in that litigation that USDA had acted in response to pressure from meat packers and others to reopen trade with Canada without completing or, in some cases, ignoring its assessment of the risks of those imports was recently confirmed by a report of the USDA Inspector General, SER 14-22.)

Much later, NMA moved to intervene in that action, claiming that it needed to be a party to protect its interests against the possibility that that action could be used to enjoin the Final Rule once it was issued, resulting in financial harm to NMA's members because they would not be able to import Canadian cattle. The District Court rejected NMA's motion to intervene in that case, because there were no ongoing proceedings and R-CALF USA's claims in that case would become moot once the Final Rule was issued. D. Mont. No. CV-04-51-BLG-RFC, Order of December 1, 2004.

NMA's Statement of the Case also omits key aspects of the timing of the proceedings below: The Final Rule was scheduled to go into effect March 7, 2005 (70 Fed. Reg. at 460) and, as NMA's Brief indicates, its members and others were ready to begin importing Canadian cattle and meat

at that time. The scheduling order issued January 28, 2004, in response to a joint proposal, gave R-CALF USA just three days to file its application for preliminary injunction and supporting memorandum, and just three days to respond to USDA's brief in opposition due on February 22, 2005. Docket Entry 11. NMA filed a lengthy brief and supporting documents just three days before R-CALF had to respond to over 100 pages of briefing and declarations filed by USDA at the same time.

NMA's February 1, 200f Motion to Intervene opposed not only by R-CALF USA, but also by the defendants below ("USDA").

Prior to the March 2, 2005 hearing on R-CALF USA's application for a preliminary injunction, seven states, Connecticut, New Mexico, North Dakota, Montana, Nevada, South Dakota, and West Virginia filed an *amicus curiae* brief supporting the grant of a preliminary injunction.

The District Court has now a set schedule for briefing and hearing on the merits, consistent with a joint briefing proposal by the parties. A hearing on cross-motions for summary judgment is scheduled for July 27, 2005.

NMA also includes a description of the purported effect of the Preliminary Injunction that is argumentative and inaccurate. The Preliminary Injunction has not caused the situation that NMA complains

of—it has existed since the summer of 2003 as a result of USDA actions that NMA did not challenge.

STATEMENT OF FACTS

The Statement of Facts in NMA's opening brief omits numerous crucial facts.

In its description of the development of the BSE problem in Canada, NMA omits the fact that, once BSE was discovered in Canada, the United States' largest beef export trading partner, Japan, threatened to ban imports of US beef unless that beef was positively identified as not having come from Canadian-origin cattle. *See* 70 Fed. Reg. at 524. Then, after the December 2003 discovery of BSE in a Canadian-raised cow that had been imported to Washington State, Japan, Korea, Taiwan, and most of the other countries to which the U.S. exports beef banned imports of US beef because of fears that BSE had entered the United States from Canada. This had a devastating effect on U.S. exports of beef, reducing that market by billions of dollars per year. 70 Fed. Reg. at 521. Those markets remained largely closed to U.S. exports of beef even now. 70 Fed. Reg. at 524-25.

Remarkably, NMA neglects to mention that additional cases of BSE were found in Canada just before and just after publication of the Final Rule,

one of which was born after the Canadian ban on feeding ruminant protein to ruminants which supposedly created a "firewall" preventing the spread of BSE. Transcript at 25, SER 137. This prompted USDA's counsel to acknowledge in the preliminary injunction hearing that cattle in the Province of Alberta constitute a "high risk population" for BSE (Transcript at 57, SER 163). It also caused USDA to decide to reconsider that portion of the just-issued Final Rule that would have allowed imports of beef products from cattle that were slaughtered in Canada at 30 months of age or older, suspending that part of the Final Rule on March 11, 2005, 70 Fed. Reg. 12,112.

SUMMARY OF ARGUMENT

NMA has failed to demonstrate that it is entitled to intervene in the action below. NMA had the exact same objective in this litigation as USDA did: to ensure that USDA's new regulation, relaxing restrictions on importation of Canadian cattle and meat, would go into effect as planned on March 7, 2005. NMA offered no new defenses in its proposed complaint, nor did it make any new arguments (at least ones that have any relevance to this proceeding). NMA is not in as good a position as USDA to defend USDA's action based on the administrative record, and certainly it has not

presented arguments that would overcome the presumption that USDA can properly represent its interests in having the Final Rule upheld.

NMA's members believe that they have a legal entitlement to import "cheap Canadian cattle" (or, alternatively, to be protected from imports of cheap Canadian beef), without regard to the implications of those imports for the health of U.S. cattle and consumers. That is not a legally protected interest justifying intervention in this case, which concerns whether USDA's regulation relaxing BSE-related protections for Canadian cattle and beef was arbitrary and capricious or not in accordance with applicable statutes. NMA is in no different position than many other businesses and organizations that would benefit from USDA's decision to resume imports of Canadian cattle and increase imports of Canadian beef.

If NMA's undifferentiated financial interest in having USDA's Final Rule go into effect were sufficient to entitle NMA to intervene as of right, then just about any case concerning judicial review of just about any government regulation would present the opportunity for multiple interests to claim that they have a mandatory right to intervene in order to "help" the agency explain why its action was not arbitrary and capricious based on the administrative record. The District Court correctly decided that the interest

NMA described was insufficient to satisfy the criteria for intervention as of right.

NMA also failed to carry its heavy burden of demonstrating that the District Court abused its discretion when it concluded that it would be untimely to allow NMA to intervene and file a brief only days before the hearing on the preliminary injunction. NMA also failed to make any persuasive arguments showing that the District Court abused its discretion in refusing to grant NMA permissive intervention.

NMA lacks standing to challenge the District Court's March 2, 2005 Order granting the Preliminary Injunction. NMA makes no attempt to demonstrate that it presents the "exceptional circumstances" that this Court has said are required before a non-party may be allowed to appeal an action by the trial court. In fact, if NMA has the right to appeal the Preliminary Injunction, then any person that can claim it is suffering financial losses because an injunction was issued against someone else in a lawsuit to which that person was not a party would have the right to appeal that injunction. In light of NMA's lack of standing to challenge the Preliminary Injunction (which this Court *does* have jurisdiction to review in the pending appeal by USDA, No. 05-35264), this Court must dismiss NMA's appeal of the Preliminary Injunction and ignore its brief.

If the Court entertains NMA's appeal of the Preliminary Injunction, despite NMA's lack of standing, then the Court should reject NMA's attempt to turn another basic legal principle on its head: that of the limited appellate review of a district court's decision to grant a preliminary injunction. In an attempt to avoid that legal principle, NMA claims that the District Court applied the wrong legal standards, and therefore its decision should be reviewed by this Court *de novo*. In fact, however, the record shows that the District Court applied the correct legal standards and conducted a careful inquiry into the arguments for and against issuance of a preliminary injunction. NMA merely disagrees with the District Court's factual determinations of whether USDA's actions and conclusions were consistent with USDA's explanations and with other information in the administrative record.

Certainly NMA's disagreements with the District Court's conclusions are a far cry from a showing that the District Court abused its discretion. NMA's brief largely restates arguments that the District Court considered, questioned the parties about at the preliminary injunction hearing, and ultimately rejected. R-CALF USA demonstrated it had a substantial likelihood of showing that USDA's actions were inconsistent with the Administrative Procedure Act, the National Environmental Policy Act, and

the Regulatory Flexibility Act. NMA's incomplete quotations and partial explanations are an insufficient basis for this Court to substitute its judgment for the District Court's and conclude that R-CALF USA was unlikely to succeed on any of the claims that it set forth. In fact, NMA's deliberate use of inaccurate quotations and characterizations warrants ignoring NMA's arguments in total.

NMA also disagrees with the conclusions the District Court reached when it weighed the short-term financial disadvantage to NMA's members and others seeking access to cheap Canadian cattle and beef prior to the District Court's review of the USDA Final Rule, versus the threatened and anticipated risks to the health and financial well-being of the United States' cattle-producing industry and to U.S. consumers once the USDA Final Rule allowed imports of cattle and beef from a country known to have Mad Cow disease. The fact that NMA disagrees with the District Court's conclusion that preservation of the status quo best balances the harms, however, does not constitute a demonstration that there was an abuse of discretion by the District Court. (Under the limited review provided to grants of preliminary injunctions, even if this Court disagreed with the District Court's conclusions, that alone would not justify substituting this Court's assessment

of the facts for that of the District Court and overturning the preliminary injunction.)

NMA offers one other ground upon which it claims the Preliminary Injunction should be vacated: the fact that the Preliminary Injunction Order does not mention posting of security pursuant to Fed. R. Civ. P. 65(a). Since NMA was not a party and was not enjoined, it was not entitled to security, and NMA lacks standing to raise this issue. In any event, if this Court decides NMA's appeal of the Preliminary Injunction, that decision will moot NMA's claim concerning the lack of security.

ARGUMENT

I. NMA's Motion To Intervene Was Properly Denied.

The Ninth Circuit has set out four criteria that all must be met for an applicant to be entitled to intervene as of right: "(1) it has a significant 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 was timely; and (4) the existing parties may not adequately represent the applicant's interest." *United States v. Alisal Water Corp.*, 370

F.3d 915, 919 (9th Cir. 2004), *quoting United States v. City of Los Angeles*, 288 F.3d 391, 397 (9th Cir. 2002). NMA fails to demonstrate that it met each of those criteria, and therefore the District Court's denial of NMA's motion to intervene must be upheld.

A. The District Court did not abuse its discretion in finding NMA's intervention untimely.

The District Court's determination with respect to the timeliness of the motion to intervene is reviewed for abuse of discretion. *Southern Calif. Edison Co. v. Lynch*, 307 F.2d 794, 802 (9th Cir. 2002). If the district court in its discretion determines that the timeliness criterion has not been met, it need not consider the other criteria for intervention. *United States v. Oregon*, 745 F.2d 550, 558 (9th Cir. 1984). Timeliness is a flexible concept that depends upon the particular circumstances. *Dilks v. Aloha Airlines, Inc.*, 642 F.2d 1155, 1156 (9th Cir. 1981).

In this case, NMA was well aware of R-CALF USA's intentions and timing from at least January 10, 2005 when R-CALF USA filed a complaint seeking to enjoin the Final Rule and asking the District Court to expedite the proceedings so that its claims could be addressed before the Final Rule's March 7, 2005 effective date. *See* Verified Complaint at 34. NMA also was or should have been aware of the parties' January 25, 2005 request that the

Court establish a schedule requiring defendants' opposition to R-CALF USA's Application for Preliminary Injunction to be filed February 22, 2005, with R-CALF USA's reply due February 25, 2005 and a hearing on March 2, 2005, a schedule which the Court adopted in its January 28, 2005 scheduling order.

Nevertheless, NMA waited to move to intervene in the case until February 1, 2005, and it proposed that it file a brief in opposition to R-CALF USA's Application for Preliminary Injunction at the same time as USDA, on February 22, 2005, just three days before R-CALF USA's reply to both USDA's and NMA's briefs would be due. NMA's Motion to Intervene, etc., Docket entry 17, at 2.

In considering whether a motion to intervene meets the requirement of timeliness, courts look to three factors, *inter alia*, 1) the stage of the proceeding at which an applicant seeks to intervene; 2) the prejudice to other parties; and 3) the reason for and length of the delay. *Cal. Dep't of Toxic Substances Control v. Commercial Realty Projects, Inc.*, 309 F.3d 1113, 1119 (9th Cir. 2002).

NMA was represented by the same counsel that had moved to intervene in the preceding case filed by R-CALF USA, D. Mont. No. CV-04-51-BLG-RFC, a few months earlier, and in fact its motion to intervene in the

instant case was similar. It knew the implications of R-CALF USA's new complaint and the highly expedited schedule necessary and established for the preliminary injunction hearing. Under these circumstances, the District Court reasonably concluded that NMA did not meet the requirement that a party act "as soon as he knows *or has reason to know* that his interests might be adversely affected by the outcome of the litigation." *United States v. Oregon*, 745 F.2d at 559 (emphasis supplied).

The District Court properly concluded that it would have greatly prejudiced R-CALF USA to require it to respond not only to over 100 pages of briefs and argumentative statement of facts and declarations from USDA, but also to the 26 pages of briefing and declarations and attachments that NMA filed, all within three days. Certainly NMA has not carried the heavy burden of showing that the District Court abused its discretion when it determined that allowing NMA to intervene at that stage of the proceedings, which were moving very quickly in advance of the March 7, 2005 deadline, would have greatly prejudiced the parties, especially R-CALF USA. Additionally, NMA's interests did not create a strong need for intervention at the preliminary injunction state that would have justified granting NMA intervention to the detriment of the parties.

NMA's claim is that its members will benefit if imports of Canadian cattle, which have been banned almost two years, are allowed again. NMA Brief in Support of its Motion to Intervene at 2, 8-9, 10-11. R-CALF USA sought a preliminary injunction to maintain the status quo briefly, while the harms that NMA fears are more long-term: "outsourcing so that slaughter houses and slaughter jobs are moved to Canada" and Canada "taking over traditional US export markets for beef." *Id.* at 8. These alleged anticipated harms if the Final Rule does not go into effect are cumulative rather than precipitous. In contrast, R-CALF USA provided evidence in connection with its Application for Preliminary Injunction that, once the border is reopened and Canadian cattle and beef become intermingled with U.S. beef, the risk to U.S. cattle and consumers and the loss of domestic and foreign consumer confidence would be essentially immediate and irreparable.

B. NMA did not show a particular, legally protectable interest.

NMA claims an interest in assuring that the Final Rule goes into effect, because the Final Rule will allow its members to slaughter and process inexpensive Canadian cattle, cattle that have been banned since May 2003 because of the presence of BSE in Canada. NMA Brief at 8-11. But a mere interest in property that may be impacted by litigation is not a passport to participate in the litigation itself. *Alisal*, 370 F.3d at 920. "To hold

otherwise would create a slippery slope where anyone with an interest in the property of a party to a lawsuit could bootstrap that stake into an interest in the litigation itself." *Id.* NMA's interest is no different from that of many other entities (including other trade associations, such as the American Meat Institute) that would benefit from the final rule.

Allowing NMA to intervene based on the simple assertion that its members will be better off financially if the Final Rule goes into effect would open up this litigation to many other potential intervenors and start this case down the slippery slope the Ninth Circuit eschewed in *Alisal*. This is confirmed by the fact that at least five other organizations have contacted R-CALF USA's counsel in the last few days, seeking R-CALF USA's consent to either their filing an *amicus curiae* brief with this Court in support of NMA's appeal of the denial of its motion to intervene or their filing a motion to intervene in the ongoing case below. Certainly the District Court was justified in concluding that NMA had failed to show a differentiated, legally protectable interest that justified intervention.[1]

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[1] In its opposition to NMA's motion to intervene, USDA offered that it would not object if USDA expressed its concerns in an *amicus curiae* brief, but NMA chose not to follow that approach.

C. NMA failed to show USDA would not protect its interests.

1. NMA stated the same ultimate objective as USDA.

In its initial brief supporting its motion to intervene, NMA failed to explain *at all* why USDA could not protect its interests in having the Final Rule go forward, but only why USDA could not protect its interests (obviously) in NMA's cross-claim against USDA, a claim NMA has now dropped. NMA's Excerpts of Record ("ER" at 55-56). In its Supplement to Motion to Intervene, NMA merely stated that its interests are different, because its members will be harmed financially if the Final Rule does not go into effect, and that it can show that harm "in a manner not presented by USDA." Supplement to Motion To Intervene at 2. At that time, NMA restated that its purpose for seeking to participate as an intervenor is "to support the timely implementation of the remainder of USDA's Final Rule, particularly the resumption of imports of live cattle under 30 months of age from Canada, on the scheduled effective date of March 7, 2005." *Id.*

Obviously, USDA has the very same purpose in this litigation—to see that the Final Rule becomes effective and is implemented. In fact, Secretary Johanns on February 9 reaffirmed USDA's confidence in the remaining portions of the Final Rule. *See* SER 68.

"Under well-settled precedent in this circuit, where an applicant for intervention and an existing party have the same *ultimate objective*, a presumption of adequacy of representation arises." *League of United Latin American Citizens v. Wilson*, 131 F.3d 1297, 1305 (9th Cir. 1997) (internal quotations and citations omitted) (group that had sponsored California Proposition 187 and had the ultimate objective of ensuring that Proposition 187 was upheld as constitutional was adequately represented by California Governor and Attorney General). "If the applicant's interest is identical to that of one of the present parties, a compelling showing should be required to demonstrate inadequate representation." *Arakaki v. Cayetano*, 324 F.3d 1078, 1086 (9th Cir. 2003), *citing* 7C Wright, Miller & Kane, § 1909, at 318-19.

Just because NMA feels it can better describe the economic harm to its members if the Final Rule is enjoined does not change the fact that its objective is exactly the same as USDA's. "Where parties share the same ultimate objective, differences in litigation strategy do not normally justify intervention." *Id.*, *quoting United States v. City of Los Angeles*, 288 F.3d 391, 402 (9th Cir. 2002).

Both R-CALF USA and USDA opposed NMA's motion to intervene in part because NMA made no showing why its interests as an intervenor-

defendant would not be represented adequately by USDA. NMA wanted the Final Rule to go into effect on March 7, 2005, just as USDA did. As USDA argued in opposing NMA's intervention and the District Court agreed, NMA had no special advantage in demonstrating to the district court why USDA's action was supported by the administrative record than USDA had; to the contrary, USDA obviously was best able to argue why its actions were not arbitrary and capricious or contrary to law. *See* Feb. 24, 2005 Order denying NMA's motion to intervene, at 5. Moreover, in the upcoming hearing before the district court on R-CALF USA's application for a permanent injunction, NMA's claims that its members would be benefited economically by the Final Rule and are being adversely affected economically by the *status quo* are irrelevant to the question before the District Court: whether USDA's action was arbitrary and capricious or not according to law, based on the administrative record.

The fact that continuing the U.S. policy of banning imports from countries where BSE is known to exist will have adverse financial consequences for NMA's members would not justify a rule that otherwise is arbitrary and capricious and not according to law in any event. But to the extent that the economic benefits of the Final Rule for slaughter facilities and meat processors like NMA's members is relevant at all, USDA has

shown every intention to recognize those economic benefits, describing them extensively in an economic impact analysis accompanying the Final Rule and emphasizing these supposed benefits as part of the rationale for the Final Rule at 70 Fed. Reg. 536-43. Nothing here comes even close to the "compelling showing" that USDA will not adequately represent NMA's interests in having the Final Rule upheld and go into effect. *See Arakaki*, 324 F.3d at 1086.

2. NMA failed to overcome the presumption that USDA would represent its interests.

There is a presumption of adequacy when the United States government and the applicant for intervention are on the same side. *City of Los Angeles*, 288 F.3d at 401-02. *See also Arakaki*, 324 F.3d at 1086 ("In the absence of a 'very compelling showing to the contrary,' it will be presumed that a state adequately represents its citizens when the applicant shares the same interest." *quoting* 7C Wright, Miller & Kane, § 1909, at 332). That presumption is even stronger where the governmental body defending the rule is the body charged by law with representing the interests of the applicant, as in this case. *Forest Conservation Council v. U.S. Forest Serv.*, 66 F.3d 1489 (9th Cir. 1995). NMA's proposed complaint, in Paragraph 3,

responsible for implementing statutes enacted for the promotion of domestic agriculture...."

NMA simply has offered no arguments as to why that is not true in this case or why USDA therefore cannot be expected to defend vigorously NMA's interests in having USDA's Final Rule remain in effect. At the same time, NMA's proposed complaint offers no affirmative defenses at all, but rather just denies R-CALF USA's allegations that the Final Rule violates the Administrative Procedure Act, the National Environmental Policy Act ("NEPA"),[2] and the Regulatory Flexibility Act. USDA certainly can be expected to deny those allegations regardless of whether NMA is allowed to intervene.

3. In fact, USDA advocated NMA's interests in the preliminary injunction proceedings.

In this instance, the Court need not speculate about whether the presumption that USDA would represent NMA's interests is accurate. We already know that in the case below USDA has been advancing the financial concerns that NMA wrongly claims were not represented to nor considered

[2] Additionally, since only the federal government is a proper defendant in an action under NEPA, it would be improper to allow NMA to intervene as a defendant with respect to the NEPA claim. *See Kootenai Tribe of Idaho v. Veneman*, 313 F.3d 1094, 1108-09 (9th Cir. 2002); *Wetlands Action Network v. United States Army Corps of Engineers*, 222 F.3d 1105, 1114 (9th Cir. 2000).

by the District Court. USDA's economic impact analysis supporting the Final Rule projected substantial financial benefits to meat packers if imports of Canadian cattle were allowed (and export markets were unaffected by those imports). *See* 70 Fed. Reg. at 520. During the hearing on the preliminary injunction, counsel for USDA claimed that the Final Rule would protect economic interests other than those of the cattle producers represented by R-CALF USA, arguing: "Slaughter houses in this country are closing. Meat processing companies have laid off employees. They have suffered concrete, devastating harm compared to the plaintiffs, ..." Transcript at 89, SER 184.[3] This is precisely the type of argument that NMA asserts could only be considered if it had been allowed to intervene in the preliminary injunction proceeding.

NMA's stated concerns about job losses in the meat processing sector were specifically advocated by USDA, which asserted that R-CALF USA had "fail[ed] to factor in the employment gains from processing additional Canadian cattle at U.S. slaughter plants." USDA Opposition to Preliminary

[3] In fact, USDA even referenced NMA's (proposed) Opposition to R-CALF USA's Application for Preliminary Injunction in support of its assertion that: "The Act does not authorize animal regulation to maximize profits or erect trade barriers for any sector....The rule protects animal health and benefits not only private consumers, but also all sectors of the livestock and beef industry." USDA Opposition to R-CALF USA's Application for Preliminary Injunction at 32.

Injunction at 20. USDA declarant Frank Fillo elaborated even further, presenting the interests of one of NMA's most prominent members: "Also, Mr. VánSickle [Plaintiff's expert] did not take into consideration employment gains from processing the additional cattle in U.S. slaughter plants. Currently, a number of U.S. meat processing plants have excess capacity. For instance, Tyson [an NMA member] has suspended one or more shifts in five of its beef slaughtering plants due to lack of cattle to slaughter. We anticipate that the importation of Canadian cattle under this rule could help meet industry demand for additional cattle." Declaration of Frank Fillo at ¶ 9. This, of course, is precisely the point that NMA claims would not be represented adequately in the district court proceedings by USDA. *See* NMA Brief at 21, 27.

Counsel for R-CALF USA also discussed these issues at the hearing on the preliminary injunction, arguing that the net benefit to meat packers and others was small compared to the risks of further loss of export markets and adverse effects on the financial health of the cow/calf producing industry. Transcript at 19. Judge Cebull considered these arguments and concluded that the balance of hardships tips in favor of R-CALF USA, that the public interest is benefited by a preliminary injunction, and that neither Defendants nor anyone else would suffer significant harm by maintaining

the *status quo ante* until the hearing on the merits. Opinion at 26-27, ER 180-81. This Court must reject NMA's assertion that its interests were not represented and considered in the preliminary injunction proceeding.

NMA offers two other unusual arguments: that USDA does not represent its interests because USDA failed to request a bond under Fed. R. Civ. P. 65(a) and USDA has not "argued the border should be closed to Canadian boxed beef if Canadian cattle are kept out." NMA Brief at 26, 30. As to the former, first, as explained at pp. 64-66, *infra*, security under Rule 65(a) is available only to protect USDA's interests as the party enjoined, not to protect NMA's members. Secondly, USDA has not really had an opportunity yet to object to the absence of a requirement for R-CALF USA to post a bond in the District Court's March 2, 2005 Order.

As to the latter NMA argument, that USDA has not advocated banning imports of Canadian boneless beef if Canadian cattle are banned from importation, while that is true, that argument has nothing to do with the validity of the USDA rule being challenged here. R-CALF USA's Verified Complaint seeks a declaration that USDA should not have allowed imports of Canadian cattle *or* beef. It would be nonsensical for USDA (or anyone supporting USDA as an intervenor-defendant) to defend the case by arguing

that both cattle and boxed beef should be banned from importation.[4] Moreover, if NMA wanted to argue that USDA should not allow importation of boxed, boneless beef if it is at the same time prohibiting importation of Canadian cattle, then NMA should have challenged USDA's May 29, 2003, regulations, 68 Fed. Reg. 31,939, which banned imports of Canadian cattle and beef except for beef products allowed by permit, and USDA's August 8, 2003 decision to allowed imports by permit of Canadian boxed, boneless beef.

D. NMA fails completely to show why the District Court abused its discretion in denying it permissive intervention.

The District Court's denial of permissive intervention is reviewed for abuse of discretion. *Southern Calif. Edison*, 307 F.2d at 802. NMA has demonstrated no abuse of discretion, merely restating the arguments it made below. In fact, NMA failed to meet the criterion of timeliness, for the reasons discussed above. It also failed to present an independent ground of jurisdiction. Of the three statutory bases for jurisdiction offered in NMA's

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[4] This assertion also demonstrates that NMA's real purpose is to promote the narrow interests of its members, rather than any interests of the public. Its goal is to assure that USDA's BSE regulations, which are supposed to be aimed at protecting the health of U.S. cattle and U.S. consumers, will maximize NMA's members' competitive position. To NMA, a BSE policy that allows imports of all Canadian cattle and all Canadian beef is just as good as a policy that prohibits all imports of Canadian cattle and Canadian beef.

Brief (at 30), all of them would appear to apply only if NMA sought to intervene as a plaintiff against USDA, a position that NMA included in its original proposed complaint but later dropped in its Supplement to Motion. NMA has no independent grounds for jurisdiction, as it has no claim at all against R-CALF USA, or against USDA for that matter. *See, e.g. Blake v. Pallan*, 554 F.2d 947, 955-56 (9th Cir. 1977). Moreover, the fact that NMA's interests describe those of many other potential intervenors as well argues for the Court to exercise its discretion to deny NMA's motion.

Additionally, in considering whether to grant permissive intervention, a court may consider factors such as whether the intervenor-applicant's interests are adequately represented by other parties to the litigation and whether intervention will prolong or unduly delay the litigation. *Spangler v. Pasadena City Bd. of Educ.*, 552 F.2d 1326, 1329 (9th Cir. 1977). For the reasons described above, NMA's interests clearly were adequately represented by USDA, and allowing NMA to intervene just a few days before the preliminary injunction hearing would have prolonged or delayed that hearing.

II. NMA Lacks Standing to Challenge the District Court's Grant of a Preliminary Injunction.

NMA filed a Notice of Appeal and an Emergency Motion with respect to both the District Court's denial of its motion to intervene and the District Court's issuance of a preliminary injunction, preventing the Final Rule from going into effect on March 7, 2005. In a "Notice of Extension of Time to Respond to NMA's Motion," NMA later proposed briefing of the appeal of the Preliminary Injunction on a more extended schedule, which the Court declined to do. R-CALF USA opposed NMA's Emergency Motion in part on the grounds that NMA had failed to allege any basis for jurisdiction over an appeal by NMA of the Preliminary Injunction, since NMA was not a party to the case in which that injunction was issued.

It is not entirely clear whether the Court intends for the parties to brief NMA's challenge to the issuance of the Preliminary Injunction. In any event, the Court should dismiss that portion of NMA's appeal, because NMA lacks standing to challenge the Preliminary Injunction.

Despite the fact that R-CALF USA's opposition to NMA's Emergency Motion in this action pointed out that NMA lacks standing to challenge the Preliminary Injunction, NMA's Brief nevertheless provides no explanation for why this Court has jurisdiction over its challenge, save for NMA's

citation of 28 U.S.C. § 1292(a)(1), which authorizes the courts of appeals to hear interlocutory appeals such as from the grant of a preliminary injunction. NMA Brief at 2.

In responding to an individual's notice of appeal seeking review of both the district court's denial of its motion for intervention and the district court's granting of summary judgment in favor of the government, this Court rejected the individual's "erroneous assumption that he may challenge the district court's order granting summary judgment." *United States v. $129,374 in United States Currency*, 769 F.2d 583, 590 (1985). "The general rule is that one who was not a party of record before the trial court may not appeal that court's judgment unless extraordinary circumstances are present." *Id.* (quotation and citations omitted). *See also, e.g., Citibank International v. Collier-Traino, Inc.*, 809 F.2d 1438 (9th Cir. 1987); *Hendricks v. Bank of America, N.A.*, 2005 WL 433600 (9th Cir. Feb. 25, 2005) (*citing Marino v. Ortiz*, 484 U.S. 301, 304 (1988)); *Southern Calif. Edison Co. v. Lynch*, 307 F.2d 794, 804 (9th Cir. 2002).

NMA has not even argued that it presents "extraordinary circumstances" that would allow it to appeal the preliminary injunction, and indeed it could not. This Court has found extraordinary circumstances where, for example, the nonparty "had been haled into court over his

objections" and had been treated by the district court "throughout by accepting his briefs and giving him an opportunity to cross-examine witnesses." *Citibank*, 809 F.2d at 1441. In other cases, extraordinary circumstances have been found where the order being appealed was specifically directed to the nonparty seeking to appeal or was for the disclosure of testimony and materials that the nonparty had provided to a grand jury. *Brown v. Board of Bar Examiners of State of Nevada*, 623 F.2d 605, 608 (9th Cir. 1980); *Petrol Stops Northwest v. United States*, 571 F.2d 1127, 1128-29 (9th Cir. 1978), *rev'd on other grounds sub nom. Douglas Oil Co. v. Petrol Stops Northwest*, 441 US 211 (1979).

Nothing approaching those kinds of special circumstances exists in this case. In fact, if NMA's simple assertion of an economic interest in the proceeding below is sufficient to create exceptional circumstances, then almost any nonparty believing itself adversely affected by an order in a district court case could bring an appeal of that order in this Court.[5] This Court should emphatically reject that unsupported expansion of appellate jurisdiction.

[5] NMA's hyperbolic claims that the Preliminary Injunction, which has been in effect a few weeks and merely continues a situation that has existed almost two years, is devastating its members constitutes an ongoing financial interest shared by others, and not an "exceptional circumstance."

III. In any Event, the Preliminary Injunction Should Be Upheld.

A. The District Court's action should be reviewed for abuse of discretion, rather than *de novo*.

This Court's review of the issuance of a preliminary injunction "is limited and deferential." *Harris v. Board of Supervisors, Los Angeles County*, 366 F.3d 754, 760 (9th Cir. 2004) (quotations and citations omitted). NMA attempts to argue that, instead of the abuse of discretion standard which it acknowledges this Court "customarily" applies to the review of a district court's grant of a preliminary injunction, in this case this Court should review the District Court's decision on the preliminary injunction *de novo*. NMA Brief at 31-32. Its asserted basis for this is a bootstrap argument: since NMA disagrees with the District Court's conclusions about whether the Final Rule may not have been supported by the administrative record or may have been arbitrary and capricious, NMA asserts that the District Court applied the wrong standard of review and that its decision therefore should be reviewed *de novo*.

There is no basis, however, for NMA's assertion that the District Court applied the wrong standard of review either for granting a preliminary injunction or for judging whether R-CALF USA had a possibility of

succeeding on the merits.[6] In fact, the District Court stated the general standards for both in similar terms to NMA, even citing to some of the same cases.[7] *Cf.* Order at 6-8, ER 161-163 *with* NMA Brief at 19-20, 32-35. The District Court correctly stated the "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law" standard of review that would apply in judging R-CALF USA's likelihood of success on the merits, acknowledging that this standard is a narrow one and that the reviewing court may not merely substitute its judgment for that of the agency. Opinion at 7, ER 162. This is not a case where there was an "erroneous legal premise." *See Harris*, 366 F.3d at 760. Once this Court determines that "the district court 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 the litigation," its review is completed. *Id.*

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[6] As the District Court correctly noted, case law in the Ninth Circuit provides for the issuance of a preliminary injunction, where the potential for harm if the *status quo* is not preserved is great, even if there is less than a likelihood of success on the merits. Opinion at 6, ER 161.

[7] The District Court wisely did not cite to some of the cases cited by NMA, such as *United States v. Mead Corporation*, 533 U.S. 218 (2001), that deal with a court's review of an agency's interpretation of a statute that the agency implements, a question that was not raised in this case.

The fact that the District Court reached conclusions about USDA's rulemaking that NMA believes were not sufficiently deferential to USDA does not change NMA's critiques of the District Court's judgments into a question of law that requires or permits this Court's *de novo* review of those judgments.[8] The District Court's assessment of the probability of R-CALF USA's success on the merits must be reviewed for abuse of discretion, without getting into "the underlying merits of the case." *Harris* 366 F.3d at 760 (quotations and citations omitted); *Brown v. California Dept. of Transportation*, 321 F.3d 1217, 1221 (9th Cir. 2003).

B. The District Court applied the appropriate standards for granting a preliminary injunction.

As noted above, the District Court correctly stated (and applied) the criteria for issuance of a preliminary injunction under this Court's jurisprudence. Opinion at 6, 25-26, ER 161, 179-180. The District Court also correctly stated (and applied) the standard of review applicable to its determination of the probability of R-CALF USA's success on the merits of its claims under the Administrative Procedure Act, National Environmental Policy Act, and Regulatory Flexibility Act, which is one of the criteria for

[8] These conclusions were factual ones. *See, e.g.*, Opinion at 11, 12-13, SER 166-168.

granting a preliminary injunction. Opinion at 7-8, 13-14, 17, 18-19, 21, 22, ER 162-163,168-169, 172, 173-174, 175, 176.

NMA argues that the District Court was required to apply a highly deferential standard when reviewing USDA's judgments inherent in the Final Rule. But the District Court correctly pointed out that this still means that the reviewing court must "carefully review" the record and whether the agency decision reflects "a recent evaluation of the relevant factors." The deferential standard of review does not mean that a court should "rubber stamp" and agency decision, especially with respect to a decision that might result in increased risk to human health. Opinion at 7-8, ER 162-63.

An agency acts arbitrarily and capriciously when it does not articulate a "rational basis" for its conclusions. *NAHB v. Norton*, 340 F.3d 835, 841 (9th Cir. 2003). The reviewing court must determine whether USDA's investigatory procedures, compilation of data, and scientific analysis were reasonable, competent, informed, and properly applied to support the decision to resume of potentially harmful imports. *See Cactus Corners v. United States Dept. of Agriculture*, 346 F. Supp.2d 1075, 1095 (E.D. Cal. 2004).

R-CALF USA described to the District Court numerous statements in USDA's brief and supporting papers that simply did not make sense or were

contradicted by the facts. *See, e.g.,* R-CALF USA's Reply Memorandum in Support of its Application for Preliminary Injunction, at 6-9. In *Sierra Club v. EPA*, 346 F.3d 955 (9th Cir. 2003) this Court explained: "While our deference to the agency is significant, we may not defer to an agency decision that "is without substantial basis in fact." *Id.* at 961, *quoting Fed. Power Comm'n v. Florida Power & Light Co.*, 404 U.S. 453, 463 (1972). *See also, e.g., Ariz. Cattle Growers' Ass'n v. United States Fish & Wildlife Service*, 273 F.3d 1229, 1236 (9th Cir. 2001); *Blue Mountains Biodiversity Project v. Blackwood*, 161 F.3d 1208, 1211 (9th Cir. 1998) (court need not forgive a clear error of judgment); *Sierra Club v. EPA*, 346 F.3d 955, 961 (9th Cir. 2005) (Court did not defer to agency judgment where agency offered an explanation that ran counter to the evidence).

Judicial review begins with a presumption against the relaxation of safety standards. *See Motor Vehicle Mfrs. Ass'n v. State Farm Mutual,* 463 U.S. 29, 42 (1983) (reviewing proposed relaxation of passive restraint requirements in cars).[9] *Accord, Int'l Brotherhood of Teamsters v. United*

[9] NMA makes the disingenuous claim that the Final Rule is not a relaxation of safety standards, because the "current policy," by which NMA means the policy prior to USDA's May 29, 2003 regulations identifying Canada as a country where BSE is known to exist, 68 Fed. Reg. 31,939, was to allow importation of Canadian cattle. In fact, USDA policy has been to prohibit imports of live cattle from countries where BSE is known to exist since 1989. 70 Fed. Reg. at 462. The Final Rule relaxes that long-standing policy

States, 735 F.2d 1525, 1531 (D.C. Cir. 1984). Moreover, where, as here, an agency provides no data to support its assumptions and its conclusions, its decision is not entitled to deference. *Ober v. Whitman*, 243 F.3d 1190, 1195 (9th Cir. 2001). Where increased risk to human health is at issue, as it clearly is with respect to USDA's decisions concerning imports from a country known to have BSE, it is particularly critical that USDA be required to provide not only its conclusion that its action carries an acceptable risk to public health, but also the specific basis for that conclusion and the data on which each of the agency's critical assumptions is based. *See Harlan Land Co. v. U.S. Dept. of Agriculture*, 186 F. Supp. 2d 1076, 1094-95 (E.D. Calif. 2001).

USDA had a special obligation here to explain why it chose to abandon its prior decision to ban imports of cattle and bovine products from Canada once BSE was discovered in Canada, which reflected USDA policy since 1989 of excluding cattle from countries where BSE is known to exist (70 Fed. Reg. at 462), especially in light of the discovery of several more cases of BSE in Canadian cattle in the interim. *See Nat'l Conservative*

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with respect to Canadian cattle, a policy that USDA as recently as January 2003 identified to Congress as one of the three key strategies protecting the United States from BSE. *See* AR1510-11 and p. 5 of R-CALF's Reply Memorandum in Support of Its Application for Preliminary Injunction.

Political Action Comm. v. FEC, 626 F.2d 953, 959 (D.C. Cir. 1980); *Greater Boston Television Corp. v. FCC*, 444 F.2d 841, 852 (D.C. Cir. 1970), *cert denied* 403 U.S. 923 (1971).

In addition, the District Court had before it an audit report recently published by USDA's Office of Inspector General ("OIG"), "Animal and Plant Health Inspection Service Oversight of the Importation of Beef Products from Canada," ("Audit Report"), SER 69-118, describing the OIG's audit of USDA's oversight of the importation of beef products from Canada after the May 2003 detection of BSE in a native Canadian cow. *See* Audit Report at i, SER 71.[10] This Audit Report indicates numerous instances where USDA expanded imports from Canada based on a desire to respond to industry requests to expand trade, rather than on scientific principles that showed the products or Canadian establishments presented minimal risk. Based on the conclusions and recommendations in this Audit Report, it is clear that the presumption of deference to the agency has been overcome because the agency simply decided the borders should be reopened while providing little support for its decision.

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[10] The District Court could take judicial notice of this official document. *See, e.g., Blair v. City of Pamona*, 223 F.3d 1074 (2000) (taking judicial notice of Christopher Commission report on police misconduct in Los Angeles); *Barron v. Reich*, 13 F.3d 1370, 1377 (9th Cir. 1994) (report of an administrative body is clearly something court can take judicial notice of).

For instance, the Audit Report explains that in October 2003 USDA listed certain edible bovine products as part of a chart of eligible "low-risk" Canadian product, without explaining . USDA did not explain why these products were considered to be low-risk, especially when a TSE Working Group had concluded that one of the products, bovine tongues, was a "moderate risk" product. *See* Audit Report at 10, 11, SER 88-89.

The Audit Report indicate that USDA officials desired to satisfy "industry concerns," (i.e. the meat packers) and increase trade with Canada instead of using careful, reasoned scientific judgments to conclude that certain products presented minimal risks. *See id.* at 10, SER 88. USDA did not take the issue seriously even after the agency was admonished and subject to a temporary restraining order on April 26, 2004, continuing for months to authorize imports of prohibited products that had previously been classified as higher risk and issue or maintain permits that should have been cancelled. *See id.* at 10, 23, SER 88, 101.

The Audit Report found that from August 2003 through April 2004, USDA allowed the expansion of the types of Canadian beef products approved for import into the United Sates, which conflicted with public announcements by USDA, and, furthermore, failed to seek public comments on these changes. *See id.* at 6. It points out that many of the decisions to

continue to allow the expansion of the import of products "addressed industry concerns that permit policies were too restrictive for trade." *Id.* at 7 & 8. It is apparent from this report that USDA personnel were paying more attention to resumption of trade than any underlying risk issues relevant to their protection of human and animal health under the Animal Health Protection Act, 7 U.S.C. §§ 8301 *et seq*. *See id.* at 7.

This Audit Report, showing both improper procedures and apparent disregard for conclusions of risk assessment work groups, demonstrates that the presumption of deference to agency action need not be applied to USDA decisions concerning imports from Canada. *Gifford Pinchot Task Force v. U.S. Fish and Wildlife Service*, 378 F.3d 1059 (9th Cir. 2004) (improprieties in process overcame presumption that administrative record was complete); *Ariz. Cattle Growers' Ass'n*, 273 F.3d at 1236 (court need not rubber-stamp agency action inconsistent with statutory mandate and congressional policy).

C. The District Court's decision to grant the preliminary injunction must be upheld.

Far from demonstrating an abuse of discretion or clear error by the trial court in granting the Preliminary Injunction, NMA's brief for the most part simply restates arguments that USDA made to the District Court, without noting R-CALF USA's refutation of those arguments in its briefs

and at the preliminary injunction hearing. In fact, much of NMA's argument relies on the unsupported and unjustified assertion that the District Court was arbitrary and capricious and abused its discretion in issuing the Preliminary Injunction simply because its March 2, 2005 Opinion uses substantial portions of R-CALF USA's opening and reply briefs. Given that the hearing was held on Wednesday, March 2, 2005, just a few days after completion of briefing and just three business days before the Final Rule R-CALF USA sought to preliminarily enjoin was scheduled to go into effect on March 7, 2005, Judge Cebull should be praised, rather than ridiculed, for acting quickly to get an opinion out. Far from being a *per se* abuse of discretion, it is perfectly understandable that the District Court used language from portions of the successful party's briefs in putting together its Opinion so that it would be timely.[11]

NMA offers no authority for its assertion that the District Court's decision should be overturned because the Preliminary Injunction Order lifted passages from R-CALF USA's briefs. Indeed, *Wardley Int'l Bank, Inc.*

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[11] Judge Cebull also presumably was motivated to quickly issue a substantive opinion in anticipation that USDA might want to appeal a preliminary injunction before the Final Rule was scheduled to go into effect on March 7, 2005. He recognized this possibility in discussions with counsel in chambers prior to the hearing and mentioned a possible appeal near the conclusion of the hearing, as well. Transcript at 97-98.

v. Nasipit Bay Vessel, 841 F.2d 259 (9th Cir. 1988), squarely rejected the kind of inference that NMA argues for in this case:

> We will not vacate findings of fact unless they are clearly erroneous. Fed. R. Civ. P. 52(a). As long as findings are plausible in light of the record viewed in its entirety, a reviewing court may not reverse even if convinced it would have reached a different result. *Anderson v. Bessemer City, 470 U.S. 564, 574, 84 L. Ed. 2d 518, 105 S. Ct. 1504 (1985)*.... Although the parties agree that the appropriate standard of review is clearly erroneous, Wardley urges that we "closely scrutinize" the facts because they were prepared by the prevailing party after the court had rendered its decision. The Supreme Court, however, has rejected any stricter review. *Anderson, 470 U.S. at 571-73* ("Even when the trial judge adopts proposed findings verbatim, the findings are those of the court and may be reversed only if clearly erroneous.").

Id. at 261 n.1. *See also Unt v. Aerospace Corp*, 765 F.2d 1440, 1445 (9th Cir 1985) ("The verbatim adoption of findings suggested by a party is not automatically objectionable, ...so long as those findings are supported by the record.").

There certainly was support in the record for the District Court's conclusions that R-CALF USA was likely to succeed on the merits of its claims. R-CALF USA's claims were supported by extensive briefing, with reference to declarations of a number of experts, numerous articles from peer-reviewed scientific journals, and, to a great extent, statements in USDA's own documents. Judge Cebull admonished counsel, both before and during the hearing, that he had read every word of the briefs filed in the

case. Transcript at 4. The transcript of the hearing confirms that, far from accepting R-CALF USA's assertions uncritically, Judge Cebull probed the positions of both R-CALF USA and USDA carefully during the course of a hearing that lasted half a day. *See, e.g.,* excerpts of Transcript provided at SER 127-184. Under these circumstances, just because the District Court's findings were adopted in part from R-CALF USA's briefs "there is no reason to subject those findings to a more stringent appellate review than called for by the applicable rules." *Clady v. Cty. of Los Angeles*, 770 F.2d 1421, 1427 (9th Cir. 1985), citing *Anderson* at 1511. And there is **absolutely** no basis for NMA's disrespectful and wholly unsupported suggestion that the District Court's conduct of the preliminary injunction hearing "raises the question whether any future proceedings in this matter should be returned to this District Court." NMA Brief at 31.

NMA offers many criticisms of the District Court's Opinion. Many of NMA's arguments mis-state or incompletely state the facts in the arguments made below. In the space available here, and with the limited time for briefing provided in the expedited scheduled for this appeal, R-CALF USA cannot refute all of those allegations word-for-word. None of them, however, demonstrates an abuse of discretion by the District Court in assessing the probability of R-CALF USA's success on the merits. R-CALF

USA will respond to just a few of NMA's arguments here. Note that R-CALF USA need not demonstrate that every one of the District Court's conclusions was justified; so long as R-CALF USA was likely to succeed on any of its claims, it was entitled to a preliminary injunction in this case.

1. NMA mis-states the position of R-CALF USA and its expert on the risks associated with the Final Rule.

The centerpiece of NMA's challenge to the Preliminary Injunction is its claim that "the Plaintiff's own expert, Dr. Cox, admits...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.'" NMA brief at 17. That is an inaccurate quotation. What Dr. Cox said is: "While I do not consider a widespread health threat in the US to be a highly likely consequence of re-introducing Canadian imports as proposed, it is not sufficiently unlikely to be dismissed or ignored. Simple calculations suggest to me that the probability of catastrophic economic and animal health consequences -- with a smaller risk of human health consequences -- from relaxing standards for Canadian imports of cattle may be far too high to be acceptable if the risks were quantified, published, and publicly known." SER 58. Reviewing Dr. Cox's entire declaration, which NMA failed to include in its Excerpts of Record, as well as Dr. Cox's Supplemental Declaration, SER 119-126, it is clear that NMA not only misquoted Dr. Cox

but also mis-stated his conclusions. *See, e.g.,* NMA Brief at 3 ("... and Plaintiff's own expert concluded that the public would not be put at risk from such live cattle imports...").

These blatant misstatements by NMA justify this Court rejecting NMA's arguments altogether. R-CALF USA never argued that there was a great risk to human health from resumed imports of cattle and beef from Canada. Rather, R-CALF USA argued that USDA's failure to quantify that risk and to explain to the public why that risk is acceptable renders the Final Rule arbitrary and capricious. See, e.g., R-CALF USA's Memorandum in Support of its Application for Preliminary Injunction at 10, 16, 28. See also Transcript at 23, SER 135 ("...USDA can't tell us how great the risk is that someone will be infected from that. We do know what the risk is, if someone is infected, of dying. It's 100 percent.")

USDA admitted in the preamble to the Final Rule that it "has set no specific thresholds for an acceptable number of cases in humans or animals." 70 Fed. Reg. at 473. Consistent with applicable case law on review of agency action, the District Court properly concluded that: "Presented with the USDA's conclusions that the risks to U.S. cattle and consumers are "low" without any definition as to what that means and why the risks

presented by the Final Rule are acceptable, this Court has no way of assessing the merits of USDA's actions." Opinion at 9, ER 164.

During the hearing on the Preliminary Injunction, counsel for USDA acknowledged that the cattle population in Alberta Province "is a high-risk population," compared to other parts of Canada where she alleged "there is no BSE." Transcript at 57, SER 163. When Judge Cebull asked about the significance of the fact that two animals in Canada were discovered with BSE just before and just after the Final Rule was announced, USDA's counsel responded frankly: "These are a cluster. They have been investigated rigorously." Transcript at 85, SER 180.

In fact, as a result of those additional discoveries, USDA suspended a portion of the Final Rule. *See* SER 68 and 70 Fed. Reg. 12,112 (March 11, 2005), despite the fact that only weeks earlier USDA has announced confidence in its conclusion that Canadian cattle presented a "low" risk.[12]

These and other facts justify the District Court's conclusion that USDA failed adequately to assess the risks associated with importing Canadian cattle and beef products before it issued the Final Rule and failed

[12] NMA misrepresents what USDA has said about the risk associated with Canadian cattle and meat, as well. USDA has said (without adequate justification, as R-CALF USA and its experts have demonstrated) that the risk is a low, not that there is "no risk to human or animal health" as NMA falsely claims. NMA Brief at 15.

to explain to the public why those risks were acceptable. As R-CALF USA argued during the hearing on the Preliminary Injunction, by USDA's own estimates the Final Rule would only provide a net benefit of $11 million per year, hardly a rational basis for reversing 16-year-old protections against importation of BSE, and risking severe impacts on the U.S. cattle injury. Transcript at 19, SER 133; *see, e.g.*, Fox article, SER 31-36.

2. USDA's explanation of its assumption that Canada's feed ban minimizes the risk of BSE was internally inconsistent.

R-CALF USA explained, in its briefs and at the hearing, that USDA acted irrationally when it rejected international consensus that a feed ban should be at the in place at least eight years, and that USDA had provided inconsistent explanations of the "incubation time" for BSE and its implications for USDA's conclusions about the adequacy of Canada's feed ban. R-CALF USA Memorandum in Support at 15-16; Reply Memorandum at 13; Transcript at 29-31, SER 141-43. R-CALF USA pointed out that USDA's assumption that Canada's feed ban has been in place long enough to protect against a BSE was inconsistent with the fact that one of the cows found to have BSE in Alberta was born after the feed ban, and all of the native cattle found with BSE in Canada, if they were infected before the 1997 feed ban, first showed signs of BSE long after the 4.2 years that USDA

asserts is the average incubation period for BSE in Canada (which short incubation time supposedly excuses the fact that Canada's feed ban has not been in place for eight years). 70 Fed. Reg. at 470; Cox Declaration at 7, SER 53.

To get around this, USDA asserted that, despite what it had said previously, the incubation period in Canada is likely much longer than 4.2 years (7-8 years). USDA Opposition at 13; *cf.* R-CALF USA Memorandum in Support at 15-16, Reply Memorandum at 13, Transcript at 29-31, SER 141-43. That is precisely the kind of double-talk that renders an agency action arbitrary and capricious, and the District Court properly recognized that R-CALF USA had a substantial likelihood of prevailing on the merits.

3. R-CALF USA showed it was arbitrary and capricious for USDA to rely on the Canadian feed ban, since it does not ban bovine blood or poultry waste from cattle feed.

Both Canada and the United States allow bovine blood to be used in cattle feed. 70 Fed. Reg. at 491. USDA has acknowledged the possibility of transmission of BSE through blood and has refused to allow importation of blood products from Canada (*see e.g.*, 70 Fed. Reg. at 502), and there is growing recognition that BSE can be transmitted in humans and other animals through blood. *See* AR1560, SER 26. The Food and Drug

Administration (FDA) has recognized a need to upgrade current feed regulations to eliminate use of mammalian blood, but it has not yet taken that action. *See* 69 Fed. Reg. 42,288, 42,292-93 (July 14, 2004).

Similarly, USDA and FDA have acknowledged a need to keep poultry waste out of cattle feed, since rendered bovine protein is used in poultry feed, allowing a path for recycling contaminated bovine proteins into cattle feed. But USDA's response to comments that the feed ban is inadequate was simply to acknowledge that these gaps in the feed ban exist and that USDA and FDA are considering what improvements to the feed ban are needed. 70 Fed. Reg. at 466, 504. As the District Court correctly recognized, there is a substantial likelihood that R-CALF USA will succeed on its claim that it was arbitrary and capricious for USDA nevertheless to assume that the Canadian feed ban is effective and sufficient.[13]

4. R-CALF USA demonstrated a likelihood of success on its National Environmental Policy Act claim.

R-CALF USA demonstrated that USDA had failed entirely to consider significant adverse environmental impacts that would result from the Final

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[13] Similarly, the District Court correctly apprehended the irrationality of USDA's refusal to even consider prohibiting imports of or requiring testing of cattle under 30 months of age, in light of the facts that, *inter alia*, of the relatively few cattle found in Japan with BSE, at least two were substantially younger than 30 months and would not have been discovered but for testing. *See* AR1563, SER 29.

Rule in terms of increased truck traffic and increased environmental releases at feedlots. R-CALF USA showed that, even by USDA's estimation, the Final Rule would result in a flood of close to 2 million head of cattle from Canada into the U.S. in 2005, which would translate into about 35,000 truck round-trips between Canadian ranches and feedlots to feedlots and slaughter facilities in the U.S. [14] 70 Fed. Reg. at 540; Memorandum in Support of Application for Preliminary Injunction at 31 and Exhibit 5 pp. 8-9. R-CALF USA also pointed out that this Court recently concluded that allowing 34,000 Mexican trucks to cross the border would have a significant environmental impact. *Public Citizen v. United States Dep't Transp.*, 316 F.3d 1002, 1021 (9th Cir. 2003), *rev'd on other grounds, United States Dep't Transp. v. Public Citizen*, 124 S.Ct. 2204 (June 7, 2004). Consistent with the Ninth Circuit's decision on that issue, the impact of transporting 2 million head of cattle from farms in Canada to feedlots and slaughterhouse in the United States should have been assessed.

[14] There is no support for NMA's novel proposition that the environmental impact of USDA's issuance of the Final Rule should be judged not in comparison to the May 29, 2003 rule which it replaced, but rather by the situation before that. NMA Brief at 52 n.12. In any event, USDA predicts a large "backlog" of Canadian cattle will come streaming in to the United States once the import ban is lifted. 70 Fed. Reg. at 537-40.

In this instance, there is no question of deference to agency expertise, since USDA did not even claim to have considered these environmental impacts at all, much less to have taken the required "hard look" at the impacts. *See, e.g., The Lands Council v. Powell*, 379 F.3d 738, 744 (9th Cir. 2004); *Hells Canyon Alliance v. United States Forest Serv.*, 227 F.3d 1170, 1177 (9th Cir. 2000). In this case, because of that failure, the USDA decisionmakers did not have at their disposal all of the relevant information about the environmental impacts of the final rule. *Salmon River Concerned Citizens v. Robertson*, 32 F.3d 1346, 1356 (9th Cir. 1994). NMA has wholly failed to demonstrate that the District Court committed an abuse of discretion when it determined that USDA's failure to consider these significant environmental impacts was a violation of NEPA.[15]

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[15] R-CALF USA also demonstrated that USDA had failed to provide for public comment as required by NEPA and the Administrative Procedure Act. USDA revised its environmental assessment in December 2004, almost doubling its length, but offered it for public comment only after the Final Rule had been signed. 70 Fed. Reg. 554 (Jan. 4, 2005). After the Final Rule was published, USDA made even further revisions. 70 Fed. Reg. 3183 (Jan. 21, 2005). The (extended) deadline for comment on the revised Environmental Assessment was only 18 days before the Final Rule was to become effective, and this comment period clearly was a sham – not only was it after the rule had been signed, but the Secretary of Agriculture and other USDA officials made numerous public statements, before the comment period closed, that the rule would indeed go into effect on March 7, 2005. *See, e.g.,* SER 68. Just going through the motions to make it appear that it has provided adequate comment does not suffice. *Lanthan v. Brinegar*, 506

NMA also argues that R-CALF USA has failed to demonstrate that its injuries fall within the "zone of interests" that NEPA was designed to protect. NMA Brief at 49-50. Initially, it should be noted that NMA relies almost entirely on cases that predate *Bennett v. Spear*, 520 U.S. 154, 162-63 (1997), in which the Supreme Court restricted broad applications of the zone of interests test (holding that a group of ranchers could pursue Endangered Species Act claim that would be to their financial benefit). Additionally, the zone of interests argument is irrelevant because R-CALF USA has adequately alleged environmental harm in addition to economic harm. *See* Complaint at 3, ¶2 (clearly explaining that R-CALF USA members will suffer injury to human health and the environment). The fact that R-CALF USA members also suffer an economic injury does not preclude it from asserting a NEPA challenge. The types of injury that R-CALF USA members alleged, in the Complaint and the Bullard declaration, are the same types of injury that USDA discusses in the Final Environmental Assessment, AR8528.

Finally, NMA argues that an injunction was not automatically required even if USDA violated NEPA. NMA Brief at 52-53. This is hardly a

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F.2d 677, 693 (9th Cir. 1974) ("grudging, pro forma compliance will not do").

demonstration that the District Court abused its discretion in issuing an injunction. *See Idaho Sporting Congress Inc. v. Alexander*, 222 F.3d 562, 569 (9th Cir. 2000) (likelihood of environmental harm was sufficient to tip the balance in favor of injunctive relief).

5. The District Court properly determined that USDA failed to give serious consideration to regulatory options that would have lessened the impact of the Final Rule on small businesses.

The Regulatory Flexibility Act ("RFA") requires an agency to carefully consider the economic impact a rule will have on small entities by conducting a final regulatory flexibility analysis. 5 U.S.C. § 604(a). This analysis must address the steps the agency has taken to minimize the significant economic impact on small entities, and explain why it rejected significant alternatives that would reduce the impact on small businesses. 5 U.S.C. § 604(a)(5). Section 604 does not command an agency to take specific substantive measures, but, rather, only to give explicit consideration to less onerous options. *Associated Fisheries, Inc. v. Daley,* 127 F.3d 104, 114 (1st Cir. 1997). A court should determine whether an agency made "a reasonable, good-faith effort to canvass major options and weigh their probable effect." *Associated Fisheries, Inc.,* 127 F.3d at 114.

USDA admits that the Final Rule will primarily affect small businesses. 70 Fed. Reg. at 543. Many ranchers, including most R-CALF USA members, are small businesses within the meaning of the RFA, 5 U.S.C. §§ 601-612. *See* Bullard Declaration at 2, SER 15. USDA estimates that the Final Rule has a present value cost of close to $3 billion for U.S. cattle producers like R-CALF USA's members. 70 Fed. Reg. at 539.

USDA failed to comply with the requirements of the RFA because it did not consider significant alternatives that would have mitigated this severe impact on small businesses. USDA did not consider the mitigation of adverse effects of the Final Rule on small businesses that could have been achieved through a requirement that edible bovine products derived from Canadian cattle or imported from Canada be labeled so that consumers could choose not to purchase those products. 70 Fed. Reg. at 543. Nor did USDA's regulatory flexibility analysis assess the extent to which allowing slaughter facilities to voluntarily test cattle for BSE would mitigate the adverse effects on small businesses of diminished consumer confidence as a result of co-mingling of Canadian and U.S. meat supplies. Either of those options might have substantially mitigated the adverse economic effects of the Final Rule. VanSickle Declaration at 7-8, SER 66-67. USDA neglected to consider whether these alternatives, or possibly any other alternative,

would have less of an adverse impact on small entities. By offering only two alternatives, USDA did not make a good-faith effort to assess all significant alternatives.

Far from showing that the District Court abused its discretion in determining that USDA failed to comply with the RFA, NMA simply repeats USDA's non-responsive responses to R-CALF USA's arguments. NMA Brief at 54-55. USDA did not dispute that it had an obligation under the Regulatory Flexibility Act to consider alternatives to the Final Rule that would mitigate the economic impact of the Final Rule on small businesses, such as R-CALF USA's members. Instead, USDA offers illogical or unsupported reasons for not considering obvious mitigation measures, suggested to the agency in comments, as required by the Regulatory Flexibility Act.

USDA's basis for asserting that a requirement for labeling of Canadian-origin meat would not mitigate economic impacts of resuming Canadian imports is unsupported and illogical. USDA gives two responses to the obvious fact that labeling would allow consumers to assure themselves, if they chose, that they were not being exposed to meat products from a country where BSE is known to exist, thereby mitigating the adverse effect on domestic and foreign consumer demand for U.S. beef that even

USDA acknowledges is likely to result from resuming Canadian imports.[16] First, USDA says that it will be issuing a country-of-origin labeling program in September 2006, and USDA did not want to delay implementation of the Canadian BSE rule until then. Opposition at 19. USDA does not contest R-CALF USA's assertion that USDA has authority now to impose a country-of-origin labeling requirement with respect to Canadian beef, and so saying that it plans to do so two years in the future is hardly a reasoned consideration of alternatives as the Regulatory Flexibility Act requires.

Then USDA offers a curious rationale for not seriously considering the labeling option: it is not a food safety or an animal health measure, but rather a measure "to provide consumers with additional information on which to base their purchasing decisions." Fillo Declaration ¶12. That statement is no reason at all why USDA did not consider providing consumers with "additional information" on which to base their decision whether to purchase Canadian-origin meet in light of the discoveries of BSE in the Canadian herd, especially when doing so could blunt the impact of allowing imports from a country with BSE, especially if additional cases of

[16] It makes no difference, by the way, whether severe restrictions on foreign demand occur as a result of decisions by foreign governments or reflect some measure of consumer preferences. *Cf.* Fillo Declaration ¶11. The effect on U.S. producers is the same.

BSE are found in Canada or in Canadian cattle that have entered the United States.

With respect to the potential value of voluntary testing for BSE as a means to mitigate the adverse financial impacts of the Final Rule, USDA claims that the benefits are speculative. Opposition at 19. The notion that consumer demand will be adversely affected by imports from a country known to have BSE, and especially by the discovery of additional cases of BSE, which are likely in the Canadian herd, is not simply speculation on the part of Dr. VanSickle. There is no need to speculate: the discovery of a BSE-infected cow of Canadian origin in the United States caused dozens of countries to close their borders to U.S. meat and imposed many millions of dollars of losses on the U.S. livestock industry. VanSickle Declaration SER 61, 64; Bullard Declaration SER 16-17; Fox, *et al.*, "Risks and Implications of Bovine Spongiform Encephalopathy for the United States: Insights from other Countries," 29 *Food Policy* 45 (2004) (AR1565) ("A single case of BSE would have serious consequences for the US beef industry."). This is not speculation, but rather is based on experience in the United States and in other countries.[17]

[17] Most countries in Europe as well as Japan test virtually all of the cattle they slaughter for BSE. AR1508; AR1619.

USDA's adamant refusal to consider voluntary testing as an option under the Regulatory Flexibility Act that might reduce adverse impacts of the Final Rule on small businesses has not been justified in light of these facts. An agency decision that is not, at a minimum, based on "reasonable extrapolations from some available evidence" is arbitrary and capricious. *Natural Resources Defense Council v. Thomas*, 805 F.2d 410, 432 (D.C. Cir. 1986).

6. NMA lacks standing to challenge the lack of security for the preliminary injunction.

Even if NMA had standing to challenge the District Court's issuance of the Preliminary Injunction, it would not have standing under Article III of the Constitution to complain of the fact that the District Court's Order does not mention a requirement for R-CALF USA to post security under Fed. R. Civ. P. 65(c).

To satisfy requirements for Article III standing, a litigant must show that its alleged injuries are "redressable"; that is, that the Court could resolve the litigation in a way that would prevent the injury that the litigant alleges. *See e.g., Friends of the Earth v. Laidlaw Environmental Services*, 528 U.S. 167, 185-86 (2000); *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560-61, 571 (1992). In this case, even if the Court were to agree with NMA that the

District Court erred by failing to require R-CALF USA to post a bond pursuant to Fed. R. Civ. P. 65(c), that rule only allows the District Court to require security against potential injury from the preliminary injunction to the party enjoined or restrained, in this case, USDA.[18]

Fed. R. Civ. P. 65(c) states: "No restraining order or preliminary injunction shall issue except upon the giving of security by the applicant, in such sum as the court deems proper, for the payment of such costs and damages *as may be incurred or suffered by any party who is found to have been wrongfully enjoined or restrained.* (Emphasis supplied.) NMA makes no attempt to address the obvious fact that it is not a party and has not been enjoined by the Preliminary Injunction. Not surprisingly, R-CALF USA has found only one case that even considers a claim that someone not enjoined by a preliminary injunction is entitled to security under Rule 65(c). In the unpublished opinion *McGregor Printing Corp. v. Kemp*, 1992 U.S. Dist. LEXIS 6717; 38 Cont. Cas. Fed (CCH) P76 (D.D.C. 1992), Defendant National Industries for the Blind (NIB), a nonprofit representing six

[18] To state the obvious, NMA's claim that "NMA's members are suffering [damages] by being wrongfully restrained from importing healthy live cattle from Canada" (NMA Brief at 18) is simply false. NMA's members cannot import Canadian cattle because of current USDA regulations, and the Preliminary Injunction prevents USDA from modifying those regulations for the time-being. It is not directed to NMA or its members at all.

workshops for the blind, requested a security bond against plaintiff McGregor. The court denied the bond because while it had enjoined a codefendant, it had not enjoined NIB or the six workshops it represented. The court cited Wright & Miller's treatise *Federal Practice and Procedure* in agreeing that "someone not a party to the case or restrained or enjoined by order of the Court is without standing to demand security for possible damages incurred as a result of such restrainment or enjoinment." *McGregor* at 22, *citing* 11 Wright & Miller § 2954.[19]

The injury NMA claims -- that its members have no security against losses that its members may incur while the Final Rule is preliminarily enjoined -- thus would not be remedied in any way even if this Court agreed with NMA's claim that the District Court erred by not requiring security under Rule 65(c). Since neither this Court nor the District Court can order the bond to protect NMA's members against financial losses that NMA is seeking, NMA has failed to meet its burden of establishing its constitutional

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[19] See also Justice Stevens' concurring opinion in *Edgar v. Mite Corp.*, 457 U.S. 624, 629 (1982), noting that "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." *Id.* at 649 (emphasis added).

standing to seek review of the security aspect of the Preliminary Injunction Order. *See Lujan*, 504 U.S. at 561.

7. The fact that the District Court did not require R-CALF USA to post a bond was, at best, harmless error as to both USDA and NMA.

If the District Court had explicitly addressed provision of surety under Rule 65(c) in its Order or Opinion, the District Court would have been justified in imposing a minimal or no bond. Because R-CALF USA is a non-profit organization attempting to further the public interest and the goals of the Animal Health Protection Act, it would not be appropriate to impose other than a minimal bond requirement on R-CALF USA. Doing otherwise would effectively preclude review of USDA's actions and would not be in the public interest. *See, e.g., Friends of the Earth v. Brinegar*, 518 F.2d 322, 323 (9th Cir. 1975); *California ex rel. Van De Kamp v. Tahoe Reg'l Planning Agency*, 766 F.2d 1319, 1325-26 (9th Cir. 1985); *Davis v. Mineta*, 302 F.3d 1104, 1126 (10th Cir. 2002). Moreover, because the defendants are government authorities that were not at risk of financial harm as a result of the preliminary injunction, there is little or no need to provide for possible compensation of an incorrectly enjoined defendant, the purpose of Rule 65(c). *See Heather v. City of Mallard*, 887 F. Supp. 1249, 1268 (N.D. Iowa). Indeed, in R-CALF USA's related action last year, challenging USDA's

authorization of imports of various kinds of meat without completing the rulemaking on the Final Rule, the District Court required R-CALF USA to post only a $500 bond in connection with its order temporarily restraining those imports, and USDA did not object to that.

NMA's claim concerning the bond also arguably is moot. NMA notes that the purpose for such a bond is too protect the restrained party against losses occasioned by a preliminary injunction that was "wrongfully issued." NMA Brief at 59-60. Here, this Court, if it determines it has jurisdiction to review NMA's challenge to the Preliminary Injunction, will be deciding whether that the injunction was wrongfully issued. If not, there is no need to protect the enjoined party nor NMA from the may possibly wrongfully issued injunction. If so, this Court will dissolve the injunction, and there will be no need for a bond, either. *See Ikon Office Solutions, Inc. v. Dale*, 22 Fed. Appx. 647, 649, 2001 U.S. App. LEXIS 22855 (8th Cir. 2001) (unreported) (since court of appeals determined preliminary injunction was properly issued as to defendants, their claim that the district court required an insufficient bond under Rule 65(c) was moot).

CONCLUSION

For the reasons set forth above, R-CALF USA respectfully requests that this Court deny NMA's appeal of the District Court's decision not to allow NMA to intervene in the case below at the preliminary injunction stage. R-CALF USA also respectfully requests that this Court dismiss NMA's appeal of the District Court's issuance of the Preliminary Injunction for lack of jurisdiction.

Dated: March 29, 2005

Respectfully submitted,

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RANCHERS CATTLEMEN ACTION
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STOCKGROWERS OF AMERICA

CERTIFICATE OF COMPLIANCE PURSUANT TO FED. R. APP. P. 32(A)(7)(C) AND 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 _13,979_ 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).

DATED this 29th day of March 2005.

Respectfully Submitted,

Russell S. Frye

STATEMENT OF RELATED CASES

R-CALF USA is aware of one pending case that is related to the instant case: Ninth Circuit Docket No. 05-35264, which is USDA's interlocutory appeal of the District Court's March 2, 2005 issuance of a preliminary injunction in Ranchers Cattlemen Legal Action Fund United Stockgrowers of America v. U.S. Dept. of Agriculture, D. Mont. No. CV-05-06-BLG-RFC.

ADDENDUM OF 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

United States unless their importation is authorized by a permit, the provisions of § 93.404(a)(3) have been sufficient to prevent the entry of live ruminants from regions affected with BSE. However, the regulations in part 93 provide exemptions from the permit requirement for ruminants from several regions, including Canada, under certain circumstances. Given that the denial of a permit application may not serve in all cases to provide a regulatory basis for preventing the importation of ruminants from regions affected with BSE, we have amended the regulations in § 93.401, "General prohibitions; exceptions," to include an explicit prohibition on the importation of ruminants that have been in any region listed in § 94.18(a)(1) or (a)(2).

Emergency Action

This rulemaking is necessary on an emergency basis to prevent the introduction of BSE into the United States. Under these circumstances, the Administrator has determined that prior notice and opportunity for public comment are contrary to the public interest and that there is good cause under 5 U.S.C. 553 for making this rule effective less than 30 days after publication in the **Federal Register**.

We will consider comments we receive during the comment period for this interim rule (*see* **DATES** above). After the comment period closes, we will publish another document in the **Federal Register**. The document will include a discussion of any comments we receive and any amendments we are making to the rule.

Executive Order 12866 and Regulatory Flexibility Act

For this action, the Office of Management and Budget has waived its review under Executive Order 12866.

This emergency situation makes timely compliance with section 604 of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) impracticable. We are currently assessing the potential economic effects of this action on small entities. Based on that assessment, we will either certify that the rule will not have a significant economic impact on a substantial number of small entities or publish a final regulatory flexibility analysis.

Executive Order 12988

This rule has been reviewed under Executive Order 12988, Civil Justice Reform. This rule: (1) Preempts all State and local laws and regulations that are inconsistent with this rule; (2) has retroactive effective to May 20, 2003; and (3) does not require administrative proceedings before parties may file suit in court challenging this rule.

Paperwork Reduction Act

This interim rule contains no information collection or recordkeeping requirements under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

List of Subjects

9 CFR Part 93

Animal diseases, Imports, Livestock, Poultry and poultry products, Quarantine, Reporting and recordkeeping requirements.

9 CFR Part 94

Animal diseases, Imports, Livestock, Meat and meat products, Milk, Poultry and poultry products, Reporting and recordkeeping requirements.

■ Accordingly, we are amending 9 CFR parts 93 and 94 as follows:

PART 93—IMPORTATION OF CERTAIN ANIMALS, BIRDS, AND POULTRY, AND CERTAIN ANIMAL, BIRD, AND POULTRY PRODUCTS; REQUIREMENTS FOR MEANS OF CONVEYANCE AND SHIPPING CONTAINERS

■ 1. The authority citation for part 93 continues to read as follows:

Authority: 7 U.S.C. 1622 and 8301–8317; 21 U.S.C. 136 and 136a; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.4.

■ 2. In § 93.401, paragraph (a) is revised to read as follows:

§ 93.401 General prohibitions; exceptions.

(a) No ruminant or product subject to the provisions of this part shall be brought into the United States except in accordance with the regulations in this part and part 94 of this subchapter;[3] nor shall any such ruminant or product be handled or moved after physical entry into the United States before final release from quarantine or any other form of governmental detention except in compliance with such regulations. Notwithstanding any other provision of this subpart, the importation of any ruminant that has been in a region listed in § 94.18(a)(1) or (a)(2) of this subchapter is prohibited. *Provided, however,* the Administrator may upon request in specific cases permit ruminants or products to be brought into or through the United States under such conditions as he or she may prescribe, when he or she determines in the specific case that such action will not endanger the livestock or poultry of the United States.

* * * * *

[3] Importations of certain animals from various regions are absolutely prohibited under part 94 because of specified diseases.

PART 94—RINDERPEST, FOOT-AND-MOUTH DISEASE, FOWL PEST (FOWL PLAGUE), EXOTIC NEWCASTLE DISEASE, AFRICAN SWINE FEVER, CLASSICAL SWINE FEVER, AND BOVINE SPONGIFORM ENCEPHALOPATHY: PROHIBITED AND RESTRICTED IMPORTATIONS

■ 3. The authority citation for part 94 continues to read as follows:

Authority: 7 U.S.C. 450, 7701–7772, and 8301–8317; 21 U.S.C. 136 and 136a; 31 U.S.C. 9701; 42 U.S.C. 4331 and 4332; 7 CFR 2.22, 2.80, and 371.4.

§ 94.18 [Amended]

■ 4. In § 94.18, paragraph (a)(1) is amended by adding, in alphabetical order, the word "Canada,".

Done in Washington, DC, this 23rd day of May, 2003.

Bobby R. Acord,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 03–13440 Filed 5–28–03; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Part 94

[Docket No. 02–109–3]

Importation of Beef From Uruguay

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: We are amending the regulations governing the importation of certain animals, meat, and other animal products to allow, under certain conditions, the importation of fresh (chilled or frozen) beef from Uruguay. Based on the evidence presented in a recent risk assessment, we believe that fresh (chilled or frozen) beef can be safely imported from Uruguay provided certain conditions are met. This action will provide for the importation of beef from Uruguay into the United States while continuing to protect the United States against the introduction of foot-and-mouth disease.

EFFECTIVE DATE: May 29, 2003.

FOR FURTHER INFORMATION CONTACT: Dr. Hatim Gubara, Senior Staff Veterinarian, Regionalization Evaluation Services Staff, VS, APHIS, 4700 River Road Unit

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Parts 50, 51, 52, 53, 54, 55, 56, 57, 58, 59, 60, 61, 62, 63, 64, 65, 66, 67, 68, 69, 70, 71, 72, 73, 74, 75, 76, 77, 78, 79, 80, 81, 82, 83, 84, and 85

[Docket No. 04–047–1]

RIN 0579–AB86

Food Safety and Inspection Service

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

[Docket No. 04–021ANPR]

RIN 0583–AC88

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 589

[Docket No. 2004N–0264]

RIN 0910–AF46

Federal Measures To Mitigate BSE Risks: Considerations for Further Action

AGENCIES: Animal and Plant Health Inspection Service and Food Safety and Inspection Service, USDA; and Food and Drug Administration, HHS.

ACTION: Advance notice of proposed rulemaking; invitation to comment.

SUMMARY: Following detection of bovine spongiform encephalopathy (BSE) in an imported dairy cow in Washington State in December 2003, the Secretaries of the U.S. Departments of Agriculture and Health and Human Services announced a series of regulatory actions and policy changes to strengthen protections against the spread of BSE in U.S. cattle and against human exposure to the BSE agent. The Secretary of Agriculture also convened an international panel of experts on BSE to review the U.S. response to the Washington case and make recommendations that could provide meaningful additional public or animal health benefits. The purpose of this advance notice of proposed rulemaking is to inform the public about the panel's recommendations and to solicit comment on additional measures under consideration based on those recommendations and other considerations.

DATES: APHIS and FSIS will consider all comments received on or before September 13, 2004. FDA will consider all comments received on or before August 13, 2004.

ADDRESSES:

You may submit comments to APHIS by any of the following methods:

- Postal Mail/Commercial Delivery: Please send four copies of your comment (an original and three copies) to Docket No. 04–047–1, 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. 04–047–1.
- 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. 04–047–1" on the subject line.
- Agency Web Site: Go to *http://www.aphis.usda.gov/ppd/rad/cominst.html* for a form you can use to submit an e-mail comment through the APHIS web site.
- Federal eRulemaking Portal: Go to *http://www.regulations.gov* and follow the instructions for locating this docket and submitting comments.

Reading Room: 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.

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*.

You may submit comments to FSIS by any of the following methods:

- Mail, including floppy disks or CD–ROM's, and hand-or courier-delivered items: Send to Docket Clerk, U.S. Department of Agriculture, Food Safety and Inspection Service, 300 12th Street, SW., Room 102 Cotton Annex, Washington, DC 20250.
- Federal eRulemaking Portal: Go to *http://www.regulations.gov*. Follow the online instructions at that site for submitting comments.

Instructions: All submissions received must include the Agency name and Docket No. 04–021ANPR.

Other information: All comments submitted in response to this advance notice of proposed rulemaking, as well as research and background information used by FSIS in developing this document, will be available for public inspection in the FSIS Docket Room at the address listed above between 8:30 a.m. and 4:30 p.m., Monday through Friday. The comments also will be posted on the Agency's Web site at *http://www.fsis.usda.gov/OPPDE/rdad/FRDockets.htm*.

You may submit comments to FDA by any of the following methods:

- Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the instructions for submitting comments.
- Agency web site: *http://www.fda.gov/dockets/comments*. Follow the instructions for submitting comments.
- E-mail: *fdadockets@oc.fda.gov*. Include Docket No. 2004N–0264 or Regulatory Identification No. (RIN) 0910–AF46 in the subject line of your e-mail message.
- Fax: (301) 827–6870.
- Mail/hand delivery/courier (for paper, disc, or CD–ROM submissions): Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions must include the Agency name and Docket No. 2004N–0264 or Regulatory Identification No. (RIN) 0910–AF46.

Other information: All comments received, including any personal information provided, will be posted without change to *http://www.fda.gov/dockets/ecomments*, For access to the docket to read background documents or comments received, go to *http://www.fda.gov/dockets/ecomments* or the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT:

APHIS: Dr. Anne Goodman, Supervisory Staff Officer, Regionalization Evaluation Services, National Center for Import and Export, VS, APHIS, 4700 River Road Unit 38, Riverdale, MD 20737–1231; (301) 734–4356.

FSIS: Daniel L. Engeljohn, Ph.D., Deputy Assistant Administrator, Office of Policy, Program, and Education Development, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250–3700, Telephone (202) 205–0495, Fax (202) 401–1760. Copies of references cited in this document are available in the FSIS Docket Clerk's Office (see **ADDRESSES**).

FDA: Burt Pritchett, D.V.M., Center for Veterinary Medicine (HFV–220), Food and Drug Administration, 7500

spread through animal feed, the broader measures recommended by the IRT, if implemented, could make some of the previously announced measures unnecessary. Either approach would require a significant change in current feed manufacturing practices. Therefore, FDA believes that additional information is needed to determine the best course of action in light of the IRT recommendations and has decided not to issue an interim final rule with the changes to the feed ban described in the January 26 announcement. Instead, FDA is requesting additional information through this ANPRM on the recommendations of the IRT, as well as on other measures under consideration to protect the animal feed supply.

The Federal Government has also taken additional significant nonregulatory actions in response to the detection of BSE in North America. These actions include enhancing surveillance for BSE; implementing a national animal identification system; enhancing laboratory diagnosis; and obtaining and providing guidance and strategies for the future.

Animal Surveillance

On March 15, 2004, Secretary of Agriculture Ann Veneman announced a one-time enhanced BSE surveillance plan, targeting cattle from populations considered at highest risk for BSE, as well as a sampling of animals from the clinically normal, aged cattle population (over 30 months as evidenced by the eruption of at least one of the second set of permanent incisors). The plan, implemented on June 1, 2004, incorporates recommendations from the IRT and the Harvard Center for Risk Analysis. Notably, the IRT has reviewed the surveillance plan and indicated that it is comprehensive and science-based, and that it addresses the important issues with regard to BSE surveillance in cattle.

Over a period of 12–18 months, APHIS will test as many cattle as possible in the targeted high-risk population. Data obtained in this effort will help determine the probable prevalence of BSE in the United States and whether risk management policies need to be adjusted. If at least 268,500 targeted high-risk animals are sampled, we will be able to detect BSE even if as few as 5 animals in this targeted population are positive. 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.

In addition, FSIS public health veterinarians have begun assisting in APHIS' BSE animal surveillance efforts by collecting brain samples from all cattle condemned during ante-mortem inspection at federally inspected establishments. This allows APHIS to focus on sample collection at locations other than federally inspected establishments, such as rendering operations and farms.

APHIS ensured access to slaughterhouses and rendering plants for sample collection via a final rule published March 4, 2004 (APHIS Docket No. 99–017–3, 69 FR 10137, "Blood and Tissue Collection at Slaughtering and Rendering Establishments"). Samples may also be collected on the farm, at veterinary diagnostic laboratories, at public health laboratories, at veterinary clinics, sale barns, livestock auctions, etc.

Strengthening of the passive surveillance system for BSE through outreach and education is an integral part of the USDA surveillance plan. In this regard, APHIS has developed plans to enhance existing educational materials and processes in conjunction with other Federal and State agencies. These outreach efforts will inform veterinarians, producers, and affiliated industries of the USDA surveillance goals and the sometimes subtle clinical signs of BSE, and will encourage reporting of suspect or targeted cattle on farm and elsewhere. One of the tools for reporting high-risk cattle, announced on June 8, 2004, is a toll-free number (1–866–536–7593).

To help cover additional costs incurred by industries participating in the surveillance plan, and to help encourage reporting and collection of targeted samples, USDA may provide payments for certain transportation, disposal, cold storage, and other costs.

For a complete discussion of the enhanced BSE surveillance plan that will be carried out over the next 12–18 months, refer to APHIS' Bovine Spongiform Encephalopathy (BSE) Surveillance Plan of March 15, 2004 (available at *http://www.aphis.usda.gov/lpa/issues/bse/BSE_Surveil_Plan03–15–04.pdf).*

Laboratory Diagnosis

Testing of BSE surveillance samples is conducted at APHIS' National Veterinary Services Laboratories (NVSL) and at a participating network of State and Federal veterinary diagnostic laboratories throughout the continental United States. USDA has approved 12 geographically dispersed laboratories to assist with BSE surveillance.

USDA has also approved five rapid screening test kits and has provided funding for high-throughput laboratory equipment as necessary. The rapid screening test kits are commercially produced diagnostic test kits, intended for use in surveillance programs such as these. These kits are best used as screening tests—*i.e.*, they are very sensitive and are intended to identify anything that might possibly be positive. Each of the laboratories will use one or more of the rapid screening tests with the goal of having initial results available within 24 to 72 hours after the sample is collected.

NVSL remains the national reference laboratory for BSE. If any sample reacts on the initial screening test, the tissues will be immediately forwarded to NVSL for confirmatory testing. Samples with this type of initial reaction will be reported as inconclusives. Samples will only be determined to be negative or positive by NVSL using immunohistochemistry and/or western blot confirmatory testing. NVSL will also conduct quality assurance check testing and test a certain number of routine samples to ensure proficiency in conducting all approved rapid screening tests.

USDA will make public the number of tests conducted and the results on a periodic basis. Updates are available at *http://www.aphis.usda.gov/lpa/issues/bse-enhan_surv/bse_test_results.html.*

The United States Government encourages and supports the development of new diagnostic tests for BSE and other TSEs. USDA researchers regularly discuss advancements in this area with their counterparts throughout the world and will evaluate all scientific data submitted as part of an application for USDA approval of a diagnostic test.

Animal Identification (Traceability)

Animal disease outbreaks around the globe over the past decade and the detection of a BSE-positive cow in the United States in December 2003 have intensified public interest in developing a national animal identification program for the purpose of protecting animal health.

Having a system that can identify individual animals or groups, the premises where they are located, and the date of entry to each premises is fundamental to controlling any disease threat, foreign or domestic, to U.S. animal resources. Further, we must be able to retrieve this information in a timely manner after confirmation of disease outbreak in order to implement successful intervention strategies.

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

mitigation requirements would be able to be considered BSE minimal-risk regions.

Response: We agree that countries that were among the first to diagnose BSE will, under the standards in this rule, not qualify as BSE minimal-risk regions. Because of the lengthy incubation period of the disease, by the time BSE was diagnosed in such countries and control measures were implemented, the chances that the disease had significantly spread were great. However, individual regions may apply to APHIS to be able to export to the United States specific products under conditions that could differ from those in our current regulations. Such applications should be submitted in accordance with 9 CFR part 92 and will be considered when received by APHIS.

Measures to Prevent Widespread Exposure or Establishment

Issue: In our proposed definition of *BSE minimal-risk region* in § 94.0, we provided that such a region must maintain, and, in the case of regions where BSE was detected, must have had in place prior to the detection of BSE, risk mitigation measures adequate to prevent widespread exposure and/or establishment of the disease. One commenter asked the following questions: (1) What exactly are the risks to be addressed and mitigated by the country seeking minimal-risk status; (2) what risk mitigation measures are deemed adequate; and (3) what are the standards to be used to judge whether the measures are adequate?

Response: As discussed in the preamble to our proposed rule, in evaluating whether a country had in a place risk mitigation measures adequate to prevent widespread exposure or establishment of BSE, we would consider whether the country had in place:

- 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 OIE recommendations 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 infectious agent, with no evidence of significant noncompliance with the ban.

We provided, further, that, in regions where BSE was detected, a minimal-risk region must have 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 must continue to take such measures. Additionally, the region must have taken additional risk mitigation measures, as necessary, following the BSE outbreak based on risk analysis of the outbreak, and continue to take such measures.

We did not specify numeric thresholds for each of the above criteria. As discussed above, 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. Further, in some cases, holding a country to a rigid criterion without consideration of compensatory risk reduction measures may not be scientifically justified and may unfairly discriminate against regions where the overall conditions indicate 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 numeric criteria but, nonetheless, present, in our view, an undue risk of BSE introduction. Therefore, 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.

Issue: As noted above, one of the proposed standards for a BSE minimal-risk region was that, in regions where BSE was detected, the region "had in place prior to the detection of BSE, risk mitigation measures adequate to prevent widespread exposure and/or establishment of the disease." One commenter asked for clarification of the meaning of "widespread exposure or establishment," of whether moderate exposure or establishment is acceptable, and of how many cases are acceptable in both humans and animals. Another commenter stated that the wording in the definition could create disagreements with regions applying for BSE minimal-risk status as to whether the disease is widespread in a particular region.

Response: APHIS has set no specific thresholds for an acceptable number of cases in humans or animals. Rather, the Agency will conduct an evaluation of the BSE situation in a region according to the factors in that region and define mitigations appropriate for the conditions. APHIS would consider in its evaluations OIE recommendations regarding the recommended maximum number of BSE cases per million at different BSE risk levels.

As an example, APHIS considers the situation that existed in the United Kingdom and certain other European countries in the 1990s to be clearly an example of widespread exposure or establishment, and also one that would clearly contribute to a high-risk categorization under OIE guidelines (Ref 1). Widespread BSE exposure in the United Kingdom was at its peak in the early 1990's, as reflected by the finding of more than 30,000 cases per year in 1992–1993. The situation has improved dramatically with the stringent control measures that have been imposed in the United Kingdom. This has also been the case in other European countries that have had what we consider "widespread exposure." It is important to note that, in each of these situations, BSE was detected and control measures were then instituted, resulting in some delay until the effects of the control measures could become apparent. These situations were very different, for example, from the situation in Canada, where: (1) Control measures were in place before the detection of the disease; (2) only two animals of Canadian origin have been confirmed with BSE; (3) both were born before implementation of Canada's feed ban; and (4) Canada has maintained other protective measures (including import restrictions) that would help preclude a significant level of infectivity from being transmitted to the cattle population.

Surveillance

Issue: One commenter stated that the premise in the proposed rule that prevalence of BSE will be lower in regions with adequate prevention and control measures does not take into account that the level of determined prevalence is dependent on the quality and level of surveillance in each region. The commenter expressed concern that, although a country may say it has low prevalence, its surveillance may be inadequate to accurately measure the prevalence.

Response: We agree with the commenter concerning the importance of a valid and effective surveillance program. One of the first evaluations we make regarding a country or other region seeking a particular animal health status is the effectiveness and

for feeder and fed cattle, given a resumption of imports from Canada. As a group, U.S. entities in competition with firms exporting the Canadian cattle can be expected to experience reduced earnings. They will sell fewer cattle at lower average prices. Entities buying feeder and fed cattle at lower average prices due to the increased supply from Canada can be expected to experience increased earnings. Quantities of cattle assumed to be imported from Canada are based on the backlog that has built up because of current restrictions and on historic import levels. Once the backlog has cleared in 2005, prices for feeder and fed cattle in Canada relative to prices in the United States will influence the number of Canadian cattle sold in the United States and, therefore, the ultimate price effects as well.

Issue: With the December 2003 BSE discovery in Washington State, we have a very clear example of negative price impact from losing our export markets. The only export market currently closed that we estimate would remain open under the least favorable reaction to the APHIS proposal is Mexico. The January Live Cattle contract fell from $90.80 per cwt to $73.50 per cwt, or approximately 19 percent. This negative price impact has not only deflated fed-cattle prices, but is also discounting feeder cattle and calf prices. Every animal slaughtered will take discounts each time it is sold, resulting in heavy cumulative discounts. The APHIS proposal shows potential losses from a 32 percent reduction in beef exports (approximately Japan's portion) to range from $1.65 to $1.93 per cwt on a live weight basis. Another very clear example of the significance of Japan as an export market is demonstrated by the loss of 44 percent of the volume of beef and beef variety meat exports to Japan in 2001–2002 due to the discovery of BSE in Japan. Industry economists estimated the sharp decline in exports to Japan negatively impacts fed cattle prices in the United States by $2.50 per cwt to as much as $4.00 per cwt. Nor was the impact confined to the beef industry—shockwaves rippled through the grain and oilseed sectors, as well as the shipping industry. It is important to realize that this impact was felt from only a 44 percent loss of the Japan market * * *[I]t took nine months to make significant progress and full recovery had not occurred in the trade sector after one year. Determining the actual price impact of lost export markets appears much more amplified than the APHIS proposal suggests.

Response: Although prices for cattle did decline sharply immediately following the Washington State BSE discovery in December 2003, they quickly rebounded. Forecasted annual 2005 prices for feeder cattle, as of October 2004, are $94 to $100 per cwt. This is one of the baseline price ranges used in the analysis for this final rule. Beef prices are also forecasted to remain high despite export restrictions. A wholesale light Choice boxed beef price for 2005 of $141 to $147 per cwt is used in the analysis. In the discussion of possible effects of this rule on U.S. exports, we acknowledge the premium earnings foregone due to closed foreign markets.

Issue: The economic analysis assumes a scenario where U.S. markets are unaffected with BSE—a scenario that is no longer true. In addition, it accepts as justification, in part, for the economic risks, the high prices received by cattle producers and feeders in recent months. However, if you adjust dollars for inflation, producers received less for cattle than they did 40 years earlier.

Response: The analysis for this final rule takes into consideration existing conditions for the U.S. cattle and beef markets. Today's cattle prices, adjusted for inflation, may well be lower than 40 years ago, but this fact is not pertinent in considering expected benefits and costs of the rule.

Issue: Annual imports of beef into the United States rose from 3.6 billion pounds in 1995 to 5.5 billion pounds in 2000. In addition, other factors, such as the declining share of the retail dollar passed on to U.S. producers, have already injured the U.S. cattle industry. To open the border will accentuate this problem. Opening the border to live cattle imports combined with Canadian beef imports will result in supplies being increased by 9 percent and will result in an 18 to 20 percent decline in prices. When the Canadian border was opened to beef imports into the United States, our cattle prices declined 20 percent.

Response: The economic analysis performed for the proposed rule did not indicate the cattle and beef increases suggested by the commenter. The analysis showed that with resumption of imports from Canada, the number of fed cattle may increase by about 3 percent, the number of feeder cattle by less than 2 percent, and beef supplies by less than 1 percent (given ongoing boneless beef imports). We expect a decline in prices due to these increased supplies, but not an 18 percent to 20 percent decline. With the resumption of beef imports from Canada in 2003, there was an increase in cattle prices (choice steers, Nebraska, 1100–1300 lbs) from $78.49 per cwt in the second quarter, to $83.07 per cwt in the third quarter, to $99.38 per cwt in the fourth quarter (USDA World Agricultural Supply and Demand Estimates). The analysis for this final rule indicates a decline in cattle prices for 2005 of roughly between 0.63 percent and 3.2 percent due to reestablishment of imports from Canada, depending on the category of cattle frame and underlying import assumptions.

Issue: The beef analysis for the proposed rule used two different baseline prices for beef, $3.00 and $3.50 per pound. It should be noted that these values for beef may be low. USDA's Economic Research Service (ERS) quotes beef prices at $4.32 per pound in November 2003, a record high.

Response: In the economic analysis for the proposed rule, we noted that $3.00 and $3.50 per pound were used as baseline prices to take into consideration affected beef products lower in value than choice cuts. In the analysis for this final rule, we use a wholesale beef price range of $141 to $147 per cwt (light Choice boxed beef), a forecasted annual 2005 price provided by USDA Economic Research Service.

3. Social Welfare Changes

Issue: Despite APHIS' assertions that price decreases associated with the renewal of trade of feeder and slaughter cattle with Canada would not significantly affect buyers or sellers of slaughter cattle, APHIS must recognize that these costs would be borne entirely by relatively few small businesses, whereas the consumer surplus (in the form of reduced beef prices) would be spread out among millions of consumers.

Response: We acknowledge that consumers who benefit from the expected price decreases will outnumber U.S. livestock producers and other entities harmed by the same price decreases. The economic analysis indicates that the net change in welfare due to these impacts within the United States will be positive.

Issue: Three scenarios in the analysis for the proposed rule are used to evaluate reestablished cattle and beef imports from Canada, assuming (1) no loss, (2) 32 percent loss, and (3) 64 percent of U.S. beef export markets. Based on the APHIS analysis, producers and feeders lose under all three scenarios. Packers gain only if export markets are maintained while live cattle imports resume. Benefits to retailers/consumers are positive under each assumption. The only net benefit scenario for all sectors occurs if live cattle imports resume and export markets are maintained.

In this final rule, we specify that sheep and goats not for immediate slaughter will be required to be moved to designated feedlots. Criteria for designated feedlots include a written agreement between the feedlot's representative and APHIS that the feedlot will not remove eartags from animals unless medically necessary and cross-reference with the original eartag any eartag that must be replaced on an animal, will create and maintain acquisition and disposition records for at least 5 years, will maintain copies of APHIS movement permits, will allow Federal and State health officials to inspect the premises and animals upon request, and will designate either the entire feedlot or designated pens within the feedlot as terminal for sheep and goats to be moved only directly to slaughter at less than 12 months of age.

Issue: The record high prices for cattle that farmers and ranchers received during the summer and fall of 2003 have given way to limit[ed] down drops in live and future cattle prices. In addition, the market analysis done for the proposed rule ignores recent changes in Americans' diets and cattle herd culling due to extended drought conditions throughout the United States. The economic analysis also ignores that Canadian cattle were captive supplies for cattle that may have been used to manipulate United States cattle markets. These factors were not considered by APHIS in weighing the costs and benefits of the proposed rule.

Response: Record high prices for cattle during the summer and fall of 2003 primarily resulted from tight cattle supplies due to weather conditions and the ban on imports from Canada. With resumption of imports from Canada and improved forage conditions, there will be an increase in the cattle supply, causing downward pressure on prices received by domestic producers. APHIS, of course, does not have authority under statutory mandate to regulate marketing practices such as packer ownership of captive cattle, and any issues presented by packer ownership of cattle supplies is outside the scope of this rule. The economic analysis does not consider captive cattle supplies in examining the costs and benefits of this regulation.

6. U.S. Beef Exports

Issue: The economic analysis does not estimate the impact on the U.S. beef cattle industry as a result of trading partner discomfort with the lessening of restrictions on the importation of ruminants and their products from Canada. APHIS must rework the economic analysis to take this significant impact into consideration.

Response: In the economic analysis for the proposed rule, we addressed possible impacts of the rule on U.S. cattle and beef exports. Consideration was given to the possibility that importing countries may not agree with the United States' categorization of Canada as a region of minimal risk. That part of the analysis, regarding possible restrictions on cattle and beef imports from the United States by other countries because of the rule, addressed possible impacts due to "trading partner discomfort." The analysis for this final rule takes into consideration current restrictions on U.S. beef exports and addresses the question of how the rule may affect these restrictions.

Issue: The negative trade scenarios outlined in the cost-benefit analysis of the proposed rule are based upon there continuing to be very few countries in the world that fully adopt or embrace the recommendations of the OIE regarding imports from BSE-affected countries. Such an underlying assumption is rapidly changing. The possibility that the United States would face lasting negative trade effects as a result of implementation of the proposed rule seems increasingly remote.

Response: In the economic analysis for the proposed rule, we did not assume there would be lasting negative trade effects. However, neither could we assume that negative trade reactions might not result if importing countries did not accept the U.S. categorization of Canada as a BSE minimal-risk region. We now have a different situation, with beef imports from the United States prohibited by a number of countries. It is possible that, because of the rule, these countries may either delay lifting current restrictions on cattle and beef imports from the United States or become more open to reestablishment of the imports. The analysis for this final rule addresses these possible impacts for U.S. beef exports.

Issue: In its cost-benefit analysis, APHIS does not appear to have considered the recent U.S. experience with the cost of segregating U.S. origin meat from Canadian meat to meet Japan's demand that we ship to that country only U.S. born and slaughtered meat. To the extent there are data or estimates available regarding the cost to the U.S. industry to meet Japanese demands, this should be considered in APHIS' analysis.

Response: We believe that the commenter is referring to the voluntary BEV program. Under the BEV program, USDA's Agricultural Marketing Service certifies through compliance audits that beef and other products exported by an eligible supplier are derived from cattle slaughtered in the United States. The BEV program, while ongoing for Canada and Mexico, has been terminated for Japan pending resumption of U.S. beef exports to that country. The BEV program will not be affected by this rule.

Issue: Even if BEV-compliant slaughter facilities do not import Canadian live cattle, they will have to comply and certify they are not receiving Canadian-origin cattle from feedlots and adopt new BEV regulations.

Response: As noted above, the BEV is a program, not a regulation, and is not covered by this rule. Slaughter facilities, if necessary, will be able to identify Canadian-origin cattle by the animal identification requirements included in the rule.

Issue: The proposed analysis calculated the price effect from lost export markets by using elasticities and price information. A large factor that was not analyzed was the loss in premiums that the U.S. beef industry gains by "upgrading" cuts with a low value in the United States by sending them to markets that pay a much higher price for them. Japan is the main premium market for U.S. beef and beef variety meats. Based on 2000 research conducted by the United States Meat Export Federation, the extra value achieved by U.S. beef exports is $1.2 billion per year (Ref 46). The loss of export markets will directly pass those markets' portions of this loss of value back to the U.S. beef industry. These losses are in addition to the losses caused by an increased supply of beef on the U.S. market. The extent to which export premiums support prices of domestic beef should be further analyzed.

Response: In the economic analysis accompanying the proposed rule, we stated that we were unsure how other countries would react to a resumption of ruminants and ruminant products from Canada. Because of the Washington State BSE discovery, most U.S. beef exports are now restricted. The question has become how the rule might affect current restrictions. In addressing this issue, we acknowledge the premium earnings foregone due to closed foreign markets.

Issue: The proposed rule fails to take into account the value of the entire animal to the industry. The rule appears to look at muscle cuts, but ignores the "drop value" of products such as variety meats, rendered products and goods that utilize such items as a base ingredient (*i.e.*, pet foods). No analysis was done for the potential loss of variety meat exports, both in terms of increased

supply in the United States and lost premiums. Beef variety meat (BVM) exports to Japan averaged 149,388 metric tons from 2000–2002 and averaged $309 million in value. Japan is the number two market for BVM, while Korea is number four with an average of 22,949 metric tons valued at an average $36.5 million from 2000–2002. The Livestock Marketing Information Center states "The byproduct value can have a considerable impact on current slaughter cattle prices." In mid-November, the byproduct (drop credit) value surpassed $10 per cwt on a live weight basis. This is a significant proportion (ten percent) of the entire animal value. What are the costs of losing these variety meat markets?

Response: In response to the single case of BSE in Washington State, many export markets placed bans on imports from the United States. As the commenter states, Japan was the second largest market for U.S. BVM. Exports of BVM to Japan, January to March for 2003 and 2004, illustrate the significance of lost sales. During these three months in 2003, 18,988 metric tons of BVM valued at over $41 million were exported to Japan. During the same months in 2004, only 154 metric tons of BVM with a value of $1.4 million were exported. A question addressed in the analysis for the final rule is whether the rule, in itself, can be expected to affect the restrictions on U.S. beef exports and therefore the continued loss of premium earnings on beef variety meat.

Issue: It is assumed, although not stated in the proposed rule, that beef and variety meats would be segregated through processing beyond slaughter. If this is not done, all economic advantages of prior animal segregation are lost, while the associated costs of segregation are incurred by the industry with no benefit accruing to the domestic or international consumer.

Response: This final rule does not impose any requirements vis-a-vis labeling, segregation, or preservation of identity of the product of Canadian feeder or slaughter cattle. Once imported Canadian cattle are moved to slaughter, the application of FSIS rules for the removal and disposal of SRMs will prevent adverse consequences related to BSE.

Issue: Costs of plant segregation lines were not included in the analysis. Assuming that the proposed rule allows the reestablishment of Canadian beef and cattle imports, and our export markets, mainly Japan and Korea, require that no Canadian beef be exported to them, the costs of animal and beef segregation would become a direct cost to the U.S. beef industry.

Response: APHIS agrees that there could be operational and recordkeeping costs associated with exporting U.S. beef to Asian markets once they reopen, if the importing countries require that the products be derived from cattle of U.S. origin. However, if such requirements were placed on U.S. exports, the effects would be attributable to the policies of the importing countries, not to this rule.

Issue: The APHIS analysis fails to address the likelihood that U.S. beef export customers would reject the proposed actions.

Response: In the economic analysis for the proposed rule, APHIS addressed possible effects of the rule on U.S. cattle and beef exports. Consideration was given to the possibility that importing countries might not agree with the U.S. categorization of Canada as a region of minimal risk. In the analysis for this final rule, we consider whether the rule may influence other countries' decisions with regard to lifting of current restrictions on U.S. beef.

7. Effects on Small Entities

Issue: With regard to potential effects of the rule on small entities, economies of scale dictate that larger entities will be better able to absorb increased fixed costs on a per-unit basis. Segregation costs in packing and processing sectors will have a larger impact on smaller entities. It is believed that larger entities are better situated to absorb market volatility than smaller firms. The history of production agriculture has shown that smaller producers have higher costs of production and face higher risks associated with lower market prices. The economic analysis as proposed by USDA would have harsher consequences on smaller enterprises.

Response: APHIS agrees that larger entities will be better able to absorb costs associated with the rule than smaller entities, such as costs of segregating sheep and goats less than 12 months of age at designated feedlots. We expect entities that envisage a profit by doing so to make the capital investments and plan for the operating outlays that may be required to import such ruminants from Canada.

Issue: The claim that the impacts on small business cannot be estimated due to lack of data is not correct. There is considerable data available from USDA's National Agricultural Statistics Service (NASS) on livestock inventories by operation size. There is clearly adequate data to define small business impact. APHIS should complete a more thorough economic analysis of these impacts, particularly in light of the events of December 2003. Such an analysis should be made available for public comment before consideration of adoption of the proposed rule.

Response: APHIS showed in table 19 of the economic analysis for the proposed rule that the great majority of entities in industries expected to be directly affected by the rule are small, based on NASS data and Economic Census data. It is understood that effects of the rule will differ among entities, depending on specific business circumstances. APHIS does not have data that would allow a comprehensive analysis of potential economic effects for small entities beyond the price declines and welfare gains and losses that are described generally. We are unaware of NASS data or additional data available from the producer segment of the livestock industry that can be used to more finely examine these variations in impact. However, we do provide as an example possible effects of the rule on earnings by small beef cow operations.

Issue: Any resumption of Canadian live cattle imports should be carefully studied to ensure there is no negative impact on the U.S. cattle market. Such analysis should focus on specific geographic areas, especially Idaho and the Pacific Northwest.

Response: The various price and welfare effects described in the analysis are for the nation as a whole, because reestablished imports from Canada will not be restricted by region. However, it is recognized that regions of the United States that historically have been more closely associated with cattle imports from Canada can be expected to be more heavily affected by the rule. An example of possible effects on northern U.S. packing plants is referred to in the analysis of impacts of small entities.

8. Other

Issue: Costs of removing intestines are not included in the analysis. This would be a requirement of cattle imported from Canada and associated costs should be outlined. Associated costs include the costs of removal as well as the loss of the intestine as a product as opposed to removal of only the distal ileum. The intestines are a significant product for international markets.

Response: The FSIS SRM rule requires removal of the small intestine from all cattle slaughtered in the United States. For illustrative purposes, the FSIS Regulatory Impact Analysis estimates small intestine disposal costs to be $0.22 per animal, the value of the small intestine (casings and trepas) to be $12.21 per animal, and the value of alternative industrial uses of small intestine to be $0.33 per animal.

are a making a nonsubstantive change to § 93.400 to define *flock* as "a group of one or more sheep maintained on common ground; or two or more groups of sheep under common ownership or supervision on two or more premises that are geographically separated, but among with there is an interchange or movement of animals." This definition is the same as the existing definition of *herd* in § 93.400, except that the revised definition of *flock* refers specifically to sheep.

Wording Clarification

We are also amending § 94.18(a)(1) to make it clear that imports of ruminants and ruminant products from Canada are not subject to the restrictions of that paragraph.

Executive Order 12866 and Regulatory Flexibility Act

This rule has been reviewed under Executive Order 12866. The rule has been determined to be economically significant for the purposes of Executive Order 12866 and, therefore, has been reviewed by the Office of Management and Budget.

Under the Animal Health Protection Act of 2002 (7 U.S.C. 8301 *et seq.*) the Secretary of Agriculture is authorized to promulgate regulations to prevent the introduction into the United States or dissemination of any pest or disease of livestock.

The regulations in 9 CFR parts 93 to 96 include provisions that prohibit the importation of ruminants and most ruminant products (meat and certain other products and byproducts) from (1) regions where BSE exists and (2) regions that present an undue risk of introducing BSE into the United States because of import requirements less restrictive than those that would be acceptable for import into the United States or because of inadequate surveillance.

In this rule, APHIS is establishing an additional category of regions that present a minimal risk of introducing BSE into the United States. This category will include (1) those regions in which a BSE-infected animal has been diagnosed but in which measures have been taken that reduce the risk of BSE being introduced into the United States, and (2) those regions in which BSE has not been detected, but that cannot be considered BSE-free. In this rule, APHIS (1) sets forth the standards the Agency will consider before listing a region as one of minimal risk for BSE, (2) lists Canada as the only BSE minimal-risk region at this time, and (3) establishes measures to mitigate any risk that BSE would be introduced into the United States through the importation of ruminants and ruminant products from a BSE minimal-risk region. Future requests received from other regions to be considered BSE minimal-risk regions will be evaluated.

On May 20, 2003, CFIA reported a case of BSE in a beef cow in northern Alberta. To prevent the introduction of this disease into the United States, APHIS issued an interim rule that listed Canada as a region where BSE exists, thereby prohibiting the importation of ruminants and most ruminant products from Canada, effective May 20, 2003.

Following the discovery of the BSE-infected cow, Canada conducted an epidemiological investigation of the BSE occurrence, and took action to guard against any spread of the disease, including the quarantining and depopulation of herds and animals determined to be possibly at risk for BSE. Subsequently, Canada asked APHIS to consider resumption of ruminant and ruminant product imports into the United States, based on information regarding the following: Canada's veterinary infrastructure; disease history; practices for preventing widespread introduction, exposure, and/or establishment of BSE; and measures taken following detection of the disease.

The prohibition was modified on August 8, 2003, to allow the importation of certain ruminant-derived products from Canada under APHIS Veterinary Services permit. The most important commodity that can enter by permit is boneless bovine meat from cattle less than 30 months of age.

This study analyzes ruminant and ruminant product imports from Canada that will be allowed to resume because of this rule. Expected benefits and costs are examined in accordance with requirements of the Office of Management and Budget for benefit-cost analysis as described in Circular A–4, "Regulatory Analysis," which provides guidance for agencies on the analysis of economically significant rulemakings as defined by Executive Order 12866. Effects on small entities are also considered, as required by the Regulatory Flexibility Act.

Although not addressed in the analysis, Canadian producers and suppliers of ruminants and ruminant products will clearly benefit from the resumption of exports to the United States. In 2002, about 90 percent of Canadian beef exports and virtually all (99.6 percent) of Canada's cattle exports were shipped to the United States. Canada's cattle producers reportedly had one million more head of cattle on their farms on July 1, 2004, than they did one year earlier. This increase is largely due to the collapse of Canadian cattle exports.

Below is a summary of our economic analysis. A copy of the full economic analysis is available by contacting the individual listed under **FOR FURTHER INFORMATION CONTACT.** You may also view the economic analysis on the Internet by accessing the APHIS Web site at *http://www.aphis.usda.gov/lpa/issues/bse/bse.html.* Click on the listing for "Economic Analysis, Final Rule, Bovine Spongiform Encephalopathy: Minimal-Risk Regions and Importation of Commodities (APHIS Docket No. 03–080–3.)"

The commodities that will be allowed to be imported from Canada under specified conditions under this final rule can be summarized as:

- Bovines, as long as they are slaughtered at less than 30 months of age, and as long as those bovines not imported for immediate slaughter are moved to a single feedlot before slaughter;
- Sheep and goats (ovines and caprines), as long as they are slaughtered at less than 12 months of age, and provided sheep and goats not imported for immediate slaughter are moved to a single designated feedlot before slaughter;
- Cervids of any age;
- Camelids (*i.e.*, llamas, alpacas, guanacos, and vicunas);
- Meat from bovines, ovines, and caprines; and
- Certain other products and byproducts, including bovine livers and tongues, gelatin, and tallow.

Model and Assumptions

Cattle and beef imports comprise 99 percent of the value of commodities that will be allowed entry from Canada because of this rulemaking, and they are therefore the focus of the analysis. The model used is a net trade partial equilibrium welfare model. Net trade is defined as the absolute value of the difference between exports and imports. Individual country trade with the United States is not modeled. Non-spatial means that price and quantity effects resulting from geographic differences in market locations are not included. Therefore, price and quantity effects obtained from the model are assumed to be the average of effects across geographically separated markets. Partial equilibrium means that the model results are based on maintaining a commodity-price equilibrium in a limited portion of the overall economy.

Economic sectors not explicitly included in the model are assumed to have a negligible effect on the model

results. Welfare refers to benefits or losses to society, as measured by changes in consumers' willingness to pay for commodities beyond their actual price (a measure of utility known as consumer surplus) and changes in producers' revenue beyond their variable costs (a measure of returns to fixed investment known as producer surplus).

This quantitative economic modeling approach is appropriate because the rule changes are specific to the U.S. cattle and beef sectors, are focused in extent, and have only limited extensions into non-agricultural sectors of the economy. A disadvantage of the model is the lack of linkages between the cattle production and beef processing sectors. This disadvantage is addressed through the presentation of results from an agricultural multi-sector model that recognizes such linkages.

We estimate effects of additional supplies to the United States of fed cattle and feeder cattle, due to resumption of imports from Canada. The additional quantities of cattle, all things equal, will cause prices to fall. The model indicates the expected price decline and the increase in quantity demanded and decrease in domestic production/supply that will occur in response to the fall in price. Summing welfare gains for consumers/buyers and losses for producers/ suppliers (changes in consumer and producer surplus) yields estimated net benefits for the United States. For beef, we expect a small decline in imports from Canada with the rule due to the replacement of beef produced from fed cattle by beef produced from cows, as explained below. Estimated effects for beef are in the opposite direction from those for cattle, with losses for U.S. consumers/ buyers outweighing gains for U.S. producers/suppliers. The effects for beef are much smaller than the effects for cattle.

Cattle imports from Canada. There are three components to the number of cattle under 30 months of age that are expected to be imported from Canada: A quantity that would be imported normally, a quantity that would have entered if cattle imports from Canada were not prohibited (termed the backlog); and a quantity of fed cattle that would be expected to be displaced from slaughter in Canada by increased cow slaughter for the export of processing beef to the United States.

For the first component, the quantities of fed and feeder cattle that would enter normally are based on average imports for 2001 and 2002: About 652,400 fed cattle and about 311,400 feeder cattle in 2005, with somewhat lesser quantities in years 2006–2009 because of assumed expanded slaughter capacity in Canada.

The backlog is the additional Canadian cattle that may have accumulated due to the closing of the border to live ruminant imports in May 2003. Importation of the backlog or some fraction of it would begin as soon as the rule is in effect, with most of these fed and feeder cattle expected to enter in 3 to 6 months.

Calculation of the size of the backlog is based on the change in Canada's cattle inventory from July 2003 to July 2004. The backlog may include about 394,500 fed cattle under 30 months of age and about 204,000 feeder cattle. The backlog of cattle over 30 months of age (not eligible for importation under the rule) numbers about 462,500 head.

The third component of expected cattle imports, an additional supply of fed cattle derives from another change included in the rule-namely, removal of the requirement that beef imported from Canada come from cattle slaughtered at less than 30 months of age. We expect this change to result in a large increase in cow slaughter in Canada for the export of processing beef to the United States. We discuss these expected effects here in greater detail.

Our assumptions regarding (1) the shift in Canada from slaughter of fed cattle under 30 months of age to slaughter of cattle (principally cows) over 30 months of age, for the export of processing beef to the United States, and (2) the shipment to the United States of the fed cattle under 30 months of age not-slaughtering in Canada, are based on relative prices and margins in the two countries for fed cattle, cows, fed beef, and processing beef. As of mid-November 2004, a Canadian packer could buy a cow for about US$17 per cwt and sell the processing-grade beef for about US$123 per cwt. The packer also could buy a fed steer or heifer at about US$67 per cwt and sell the beef for about US$132 per cwt. In the United States, the cow would cost a packer about $55 per cwt and the beef would sell for about $125 per cwt; a fed steer or heifer would cost about $85 per cwt and the beef would sell for about $135 per cwt.

Although differences in weights and dressing percentages do not permit the direct comparison of live animals to dressed meat, the difference between the relative purchase prices to sales prices indicate that the margin buying cows and selling processing beef is much larger for a Canadian packer than it is for a U.S. packer. Canadian packers are prevented from taking greater advantage of this large margin by Canada's relatively small market for cow beef. Canadian production of processing beef has already displaced much of Canada's imported product. Without a larger demand, increased production would cause the Canadian price of processing beef to decline sharply.

The United States is already providing Canada with additional demand for beef from fed cattle, through the importation of boneless beef under permit from cattle slaughtered at less than 30 months of age. The United States, in a sense, is currently importing Canada's surplus production of fed beef. Allowing the United States to import Canadian beef from cattle slaughtered at more than 30 months of age would enable Canada to produce and sell much larger quantities of processing beef without fearing the significant price collapse that would likely occur if the entire additional product were only for the Canadian market.

This is not to say that the price of processing beef or cow prices in the United States would not decline from their current levels due to the supply from Canada, but we would not expect a sharp decline. Two facts concerning the U.S. supply of processing beef underlie this reasoning. First, U.S. cow slaughter is forecast to decline in 2005, as producers begin to rebuild herds that have been characterized by diminishing cow inventories for several years. Second, cow retention for herd rebuilding is also expected to take place in Australia and New Zealand, major sources of processing beef for the United States. Their beef exports are forecast to remain largely unchanged in 2005. As long as principal Asian markets continue to prohibit entry of U.S. beef, any increase in imports of beef from Australia and New Zealand by these markets may limit the supply of beef from Australia and New Zealand into the United States.

With the rule, entry of Canadian steers and heifers is expected to result in steer and heifer prices in the two countries becoming more similar. For example, in 2002, fed steer prices in Alberta averaged about US$63 per cwt, while in the United States, the Nebraska Direct Choice steer price averaged about $67 per cwt. Given the difference in mid-November 2004 prices for fed cattle, $67 per cwt in Canada and $85 per cwt in the United States, shipment of fed cattle to the United States will be an attractive alternative for Canadian producers, at least until Canadian prices rise to the level of U.S. prices (adjusted for grade differentials and minus transportation and transaction costs).

Prices for slaughter cows in the two countries are expected to continue to differ because Canadian cattle more

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The backlog is the additional Canadian cattle that may have accumulated due to the closing of the border to live ruminant imports in May 2003. Importation of the backlog or some fraction of it would begin as soon as the rule is in effect, with most of these fed and feeder cattle expected to enter in 3 to 6 months.

Calculation of the size of the backlog is based on the change in Canada's cattle inventory from July 2003 to July 2004. The backlog may include about 394,500 fed cattle under 30 months of age and about 204,000 feeder cattle. The backlog of cattle over 30 months of age (not eligible for importation under the rule) numbers about 462,500 head.

The third component of expected cattle imports, an additional supply of fed cattle derives from another change included in the rule-namely, removal of the requirement that beef imported from Canada come from cattle slaughtered at less than 30 months of age. We expect this change to result in a large increase in cow slaughter in Canada for the export of processing beef to the United States. We discuss these expected effects here in greater detail.

Our assumptions regarding (1) the shift in Canada from slaughter of fed cattle under 30 months of age to slaughter of cattle (principally cows) over 30 months of age, for the export of processing beef to the United States, and (2) the shipment to the United States of the fed cattle under 30 months of age not slaughtering in Canada, are based on relative prices and margins in the two countries for fed cattle, cows, fed beef, and processing beef. As of mid-November 2004, a Canadian packer could buy a cow for about US$17 per cwt and sell the processing-grade beef for about US$123 per cwt. The packer also could buy a fed steer or heifer at about US$67 per cwt and sell the beef for about US$132 per cwt. In the United States, the cow would cost a packer about $55 per cwt and the beef would sell for about $125 per cwt; a fed steer or heifer would cost about $85 per cwt and the beef would sell for about $135 per cwt.

Although differences in weights and dressing percentages do not permit the direct comparison of live animals to dressed meat, the difference between the relative purchase prices to sales prices indicate that the margin buying cows and selling processing beef is much larger for a Canadian packer than it is for a U.S. packer. Canadian packers are prevented from taking greater advantage of this large margin by Canada's relatively small market for cow beef. Canadian production of processing beef has already displaced much of Canada's imported product. Without a larger demand, increased production would cause the Canadian price of processing beef to decline sharply.

The United States is already providing Canada with additional demand for beef from fed cattle, through the importation of boneless beef under permit from cattle slaughtered at less than 30 months of age. The United States, in a sense, is currently importing Canada's surplus production of fed beef. Allowing the United States to import Canadian beef from cattle slaughtered at more than 30 months of age would enable Canada to produce and sell much larger quantities of processing beef without fearing the significant price collapse that would likely occur if the entire additional product were only for the Canadian market.

This is not to say that the price of processing beef or cow prices in the United States would not decline from their current levels due to the supply from Canada, but we would not expect a sharp decline. Two facts concerning the U.S. supply of processing beef underlie this reasoning. First, U.S. cow slaughter is forecast to decline in 2005, as producers begin to rebuild herds that have been characterized by diminishing cow inventories for several years. Second, cow retention for herd rebuilding is also expected to take place in Australia and New Zealand, major sources of processing beef for the United States. Their beef exports are forecast to remain largely unchanged in 2005. As long as principal Asian markets continue to prohibit entry of U.S. beef, any increase in imports of beef from Australia and New Zealand by these markets may limit the supply of beef from Australia and New Zealand into the United States.

With the rule, entry of Canadian steers and heifers is expected to result in steer and heifer prices in the two countries becoming more similar. For example, in 2002, fed steer prices in Alberta averaged about US$63 per cwt, while in the United States, the Nebraska Direct Choice steer price averaged about $67 per cwt. Given the difference in mid-November 2004 prices for fed cattle, $67 per cwt in Canada and $85 per cwt in the United States, shipment of fed cattle to the United States will be an attractive alternative for Canadian producers, at least until Canadian prices rise to the level of U.S. prices (adjusted for grade differentials and minus transportation and transaction costs).

Prices for slaughter cows in the two countries are expected to continue to differ because Canadian cattle more

than 30 months of age will not be allowed entry by the rule, despite a ready market for them at slaughter facilities located in the Northern United States. Thus, in the absence of trade in those cattle, the backlog of cattle over 30 months of age will remain until increased cow slaughter in Canada reduces their inventory. We would expect the price of cows in Canada to increase as slaughter increases in response to opportunities to export beef from cattle more than 30 months of age to the United States. However, the margin earned from slaughtering cows in Canada and exporting the processing beef to the United States is likely to remain favorable (though decreasingly so as Canada's backlog of cattle more than 30 months of age is reduced).

It is assumed that the Canadian slaughter sector is operating at full capacity. Key to assumptions underlying this analysis is the willingness of Canadian slaughter facilities to add cow slaughter shifts or days to their operations at the expense of steer and heifer slaughter. We believe they would want to do so, given the price differentials in Canada and the United States and the opportunity for Canadian beef exports to the United States from cattle slaughtered at more than 30 months of age. With the rule, beef imported from Canada would no longer be required to come from a slaughter facility that either slaughters only cattle less than 30 months of age or complies with an approved segregation process, which may permit increased flexibility in scheduling cow slaughter.

In 2005, APHIS expects this shift by Canada to exports of processing beef and additional fed cattle to the United States to take place throughout the year, not during one or two quarters as assumed for the backlog of steers and heifers under 30 months of age. Beyond 2005, additions to Canadian slaughter capacity are expected to allow increased slaughter of cattle of all ages. Canada has been able to increase its slaughter numbers during the past year, but the opening of new plants and major expansion of current processing facilities to accommodate increased cow slaughter will likely take some years. The lack of excess slaughter capacity in Canada and the described price differentials are the basis for the assumed shift to increased cow slaughter in Canada for the production of processing beef for export to the United States, and the assumed additional imports of Canadian fed cattle.

In 2005, the maximum number of imported fed cattle displaced from Canadian slaughter may equal the backlog of cattle over 30 months of age (assumed to be slaughtered for the export of processing beef to the United States), about 460,000 head. For years 2006–2009, we assume the number of fed cattle displaced from slaughter in Canada and exported to the United States to decline, as Canada's slaughter capacity increases and Canada's cow prices trend upward. However, all things equal, as long as live cattle imports from Canada are limited to animals less than 30 months of age and the U.S. demand for processing beef is high, beef imports from Canadian cow slaughter may be favored.

Uncertainty surrounds both the assumed backlog quantities and the quantity of fed cattle expected to be displaced by cows slaughtered in Canada and exported to the United States. We acknowledge these uncertainties by also conducting the analysis using one-half of the assumed backlog and one-half of the assumed number of displaced fed cattle.

After the backlog of cattle has been imported, imports of cattle under 30 months of age from Canada are expected to continue at historic levels elevated by the importation of the fed cattle displaced from Canadian slaughter by the slaughter of cows. We therefore expect the largest impact of the rule to occur during the first 3 to 6 months that the rule is in effect. In order to assess these very near-term price impacts, we estimate effects of the rule for the first and second quarters of 2005, in addition to the five-year analysis of welfare effects. As in the analysis of welfare impacts, we acknowledge uncertainty about the quantity of cattle what will enter from Canada by conducting a sensitivity analysis of near-term price effects using one-half of the assumed backlog and one-half of the assumed number of displaced fed cattle.

Beef imports from Canada. Boneless beef entering from Canada under permit represents a large share of historic beef imports from Canada. Before the Alberta BSE discovery, Canada's share of U.S. beef imports was about 41 percent (90 percent of fresh/chilled beef imports and 4 percent of frozen beef imports). Currently, Canada's share of U.S. beef imports is about 32 percent (fresh/chilled beef, 85 percent; frozen, 3 percent). For this reason alone, the effect of the rule for beef imports will be much smaller than the effect for cattle imports. Canadian beef entering the United States by permit is included in the baseline for the analysis.

As described, we expect Canadian cows to be slaughtered in place of fed cattle for the export of processing beef to the United States, given Canada's limited capability to increase its slaughter capacity in the short term. A cow that is slaughtered produces less meat than a fed steer or heifer due to a lighter weight and lower dressing percentage. Recent statistics from Canada indicate an average difference in beef produced from one steer/heifer and one cow of 150 pounds. In 2005, assuming Canada is fully utilizing all available slaughter capacity, the decrease in beef production would total about 69 million pounds if the backlog of about 460,000 cattle over 30 months of age is slaughtered in place of steers and heifers. To take into consideration possible declines in Canada's domestic consumption of beef as beef prices rise slightly relative to other meats, and therefore movement of beef from the domestic to export markets, we reduce the decline of 69 million pounds by one-third, to 46 million pounds.

The forecast for Canada's beef exports worldwide in 2005 is 570,000 metric tons. U.S. imports of beef from Canada are forecast to equal about 86 percent of Canada's total beef exports, or about 490,200 metric tons. The 490,200 metric tons is equivalent to 1,081 million pounds. In other words, Canada's beef exports to the United States, compared to what would have been exported without this rule, can be expected to decline in 2005 by 4.3 percent (46 million pounds divided by 1,080 million pounds) because of the displacement of steer/heifer slaughter by cow slaughter in Canada. The decrease in Canadian beef exports to the United States because of this displacement is assumed to diminish in years 2006–2009, as Canada's slaughter capacity expands.

Processing-grade beef is not perfectly substitutable for fed beef. The two commodities compete in different but closely related markets. This distinction is not included in the analysis because the model is based on aggregate beef price ranges and elasticities. Increased supplies of processing beef are expected to compete with fed beef in the same fashion as other close substitutes. Thus, allowing imports of beef from cattle slaughtered at over 30 months of age, together with fed cattle imports augmented by the cattle displaced from Canadian slaughter, is expected to result in lower prices for U.S. steers and heifers.

As with the assumed backlog and displaced fed cattle imports, there is uncertainty as to the amount of beef from Canadian cow slaughter that will be imported by the United States. Accordingly, we include in the sensitivity analysis a reduction by one-

half of the assumed change in beef imports from Canada. In 2005, for example, this reduced amount would represent a decrease in beef imports from Canada of 2.1 percent from what would have been imported without the rule.

Welfare and Near-term Price Effects of the Rule for Cattle and Beef

Welfare effects. Welfare effects of the rule for cattle and beef are summarized in Table 1. Present values and annualized values of welfare gains and losses over the five-year period 2005–2009, are determined using 3 percent and 7 percent discount rates, in both 2005 and 2001 dollars.

TABLE 1.—PRESENT AND ANNUALIZED VALUE ESTIMATIONS OF EFFECTS OF THE RULE FOR FED CATTLE, FEEDER CATTLE, AND BEEF, DISCOUNTED AT 3 PERCENT AND 7 PERCENT, IN 2005 AND 2001 DOLLARS, 2005–2009

Value	Discount rate (percent)	Changes in welfare (per thousand dollars)		
		Consumer	Producer	Net
Present, 2005 dollars	3	$2,982,088	−$2,907,462	$74,626
	7	2,592,201	−2,525,852	66,349
Present, 2001 dollars	3	2,810,618	−2,740,283	70,335
	7	2,443,150	−2,380,616	62,534
Annualized, 2005 dollars	3	651,153	−634,858	16,295
	7	632,214	−616,032	16,182
Annualized, 2001 dollars	3	613,711	−598,353	15,358
	7	595,861	−580,610	15,251

Note: The present and annualized values are taken from Appendix H, based on assumed import of the backlog, import of fed cattle displaced from slaughter in Canada by increased cow slaughter for the export of processing beef to the United States, and beef imports from cows slaughtered in place of fed cattle.

The present value of the net benefit of the rule for cattle and beef is estimated to range in 2005 dollars between $66.3 million and $74.6 million, depending on the discount rate used. Over the five-year period, the annualized value of the net benefit in 2005 dollars, depending on the discount rate, ranges between $16.2 million and $16.3 million.

The largest effects for cattle are expected to occur in 2005, when the backlog would be imported and the displacement of fed cattle slaughter by cow slaughter would be largest. The impact for fed cattle would be greater than for feeder cattle because of the larger number of fed cattle expected to be imported. For fed cattle, the annual price declines may range from an average of 3.2 percent in 2005 to 1.3 percent in 2009. For feeder cattle, the price declines range from an average of 1.3 percent in 2005 to 0.6 percent in 2009.

Estimated net benefits in 2005 for fed cattle are estimated to range from $25.0 million to $26.9 million, and for feeder cattle, from $10.4 million to $11.0 million. In each successive year, the net benefits are expected to become smaller, such that by 2009 they may range for fed cattle from $3.8 million to $4.3 million, and for feeder cattle, from $4.3 million to $4.8 million.

Effects of the rule for beef attributable to the change in beef imports from Canada are expected to be much smaller than those for cattle. For example, the expected 2005 net welfare loss (because of the decline in imports due to cow slaughter replacing fed cattle slaughter) in 2005 dollars is estimated to range between $94,000 and $98,000. Average percentage increases in price may range from 0.09 percent in 2005 to 0.01 percent in 2009, suggesting nearly negligible impacts. If the beef-equivalent of the fed and feeder cattle imported from Canada is considered, the supply of beef in the United States increases and the price of beef decreases by 1 to 2 percent from 2005 baseline levels. Smaller decreases from baseline projections would occur after 2005 because the volume of imported animals declines.

Effects may be even smaller for U.S. producers than these percentages indicate, given that nearly all U.S. beef imports from countries other than Canada consist of processing beef. Demand for imported processing beef has increased drastically as ground beef sales continue at a robust pace. At the same time, U.S. production of processing beef has fallen to record lows because of the cyclical decline in cow slaughter.

Table 2 shows the results of the sensitivity analysis, assuming importation of one-half of the backlog, one-half of the fed cattle expected to be displaced from slaughter in Canada, and one-half of the expected replacement of fed cattle beef imports derived from fed cattle by beef imports derived from cows. The present value of the net benefit for cattle and beef in this case is estimated to range in 2005 dollars between $48.9 million and $56.1 million, depending on the discount rate used. Over the five-year period, the annualized value of the net benefit in 2005 dollars, depending on the discount rate, may range between $11.9 million and $12.3 million—that is, about three-fourths of the expected annualized net benefit with the rule.

TABLE 2.—SENSITIVITY ANALYSIS BASED ON REDUCED IMPORT QUANTITIES: PRESENT AND ANNUALIZED VALUE ESTIMATIONS OF EFFECTS OF THE RULE FOR FED CATTLE, FEEDER CATTLE, AND BEEF, DISCOUNTED AT 3 PERCENT AND 7 PERCENT, IN 2005 AND 2001 DOLLARS, 2005–2009

Value	Discount rate (percent)	Changes in welfare (per thousand dollars)		
		Consumer	Producer	Net
Present, 2005 dollars	3	$2,571,323	−$2,515,180	$56,144
	7	2,211,115	−2,162,168	48,947
Present, 2001 dollars	3	2,423,472	−2,370,557	52,915
	7	2,083,976	−2,037,844	46,132

TABLE 2.—SENSITIVITY ANALYSIS BASED ON REDUCED IMPORT QUANTITIES: PRESENT AND ANNUALIZED VALUE ESTIMATIONS OF EFFECTS OF THE RULE FOR FED CATTLE, FEEDER CATTLE, AND BEEF, DISCOUNTED AT 3 PERCENT AND 7 PERCENT, IN 2005 AND 2001 DOLLARS, 2005–2009—Continued

Value	Discount rate (percent)	Changes in welfare (per thousand dollars)		
		Consumer	Producer	Net
Annualized, 2005 dollars	3	561,460	−549,201	12,259
	7	539,270	−527,333	11,938
Annualized, 2001 dollars	3	529,176	−517,622	11,554
	7	508,262	−497,011	11,251

Note: The present and annualized values are midpoints taken from Appendix I, based on assumed imports of one-half of the backlog, one-half of the fed cattle numbers, and one half of the replacement of fed cattle beef imports by cow beef imports.

In this scenario, the impact in 2005, in particular, would be smaller because of the fewer cattle imported. For fed cattle, the annual price declines may range from 2.3 percent in 2005 to 1.2 percent in 2009. For feeder cattle, the price declines over the five-year period may average 0.7 percent. Estimated net benefits in 2005 for fed cattle may range from $12.9 million to $13.9 million, and for feeder cattle, from $8.0 million to $8.5 million. In each successive year, the net benefits are expected to become smaller, such that by 2009 they may range for fed cattle from $3.5 million to $3.9 million, and for feeder cattle from $4.3 million to $4.8 million.

The estimated percentage decrease in the price of fed cattle, if one-half of the backlog and one-half of the fed cattle expected to be displaced from slaughter in Canada were imported, would be about 1 percent less than when we assume importation of the full backlog and full quantity of displaced fed cattle (2.3 percent decrease compared to a 3.2 percent decrease). For feeder cattle, the difference in the effect is smaller in absolute terms, but larger in relative terms (0.6 percent decrease compared to a 1.3 percent decrease). In both cases the effects are expected to diminish over the five-year period.

Near-term price effects. As expected, price effects are larger when the backlog is assumed to enter in one quarter rather than two quarters, and are larger for fed cattle than for feeder cattle, given the larger number of fed cattle expected to be imported. For example, for fed cattle, the decrease in price when the backlog is assumed to enter entirely within one quarter is estimated to be 5.4 percent, assuming a price elasticity of supply of 0.61 and a price elasticity of demand of −0.76. When the backlog of fed cattle is assumed to enter over two quarters using the same price elasticities, the decline in price is estimated to be 3.8 percent. Entry of the backlog of feeder cattle over the two quarters could result in price declines of 1.9 percent, for the same elasticities, compared to a possible price drop of 3.3 percent when the enter entirely within one quarter.

The less elastic the price elasticities (the less responsive sellers and buyers are to price changes), the larger the expected percentage changes in price. When the supply and demand elasticities are halved (supply elasticity of 0.30 and demand elasticity of −0.38), for example, and fed cattle are assumed to enter within two quarters, the decrease in price could be 4.8 percent, compared to a price decrease of 3.8 percent when a supply elasticity of 0.61 and demand elasticity of −0.76 are used.

When the assumed backlog and assumed number of imported fed cattle displaced from Canadian slaughter are halved as a sensitivity analysis, the near-term price effects are found to be smaller overall, with the smaller elasticities again yielding larger price decreases. For example, the percentage decrease in price for fed cattle entering over two quarters is estimated to be 2.5 percent for a supply elasticity of 0.61 and a demand elasticity of −0.76 (compared to a 3.8 percent price decline when the full backlog and number of displaced fed cattle are imported). If the supply elasticity were 0.30 and the demand elasticity were −0.38, the price decline is estimated to be 3.2 percent (compared to 4.8 percent for the full cattle import numbers). Similarly, smaller percentage price declines are observed for feeder cattle when in the sensitivity analysis the backlog and the number of imported fed cattle displaced from Canadian slaughter are halved.

Other Impacts of the Rule

We consider other effects of the rule besides those estimated for cattle and beef, including: The results of an agricultural multi-sector analysis; costs that may be incurred in monitoring the movement of imported Canadian feeder ruminants; effects for ruminant products other than cattle and beef; and possible effects of the rule on U.S. exports.

Multi-sector analysis. Some commenters on the analysis for the proposed rule emphasized the integrated structure of the cattle and beef processing industries, and noted potential effects of the rule on other sectors of the economy. APHIS agrees that a multi-sector analysis can capture industry interactions that are missing from single-sector analyses. We therefore report the results of an analysis based on a model that includes the animal feed, animal production, and animal product processing sectors.

While the major vertically linked marketing channels are included in this model, effects of the rule farther downstream in the economy are not modeled. For example, economic benefits to surrounding communities of increased employment in slaughter plants receiving greater supplies of cattle due to reopening of the Canadian border are not captured by the model, nor are similar economic losses resulting from reduced spending in communities by cattle producers due to reductions in their returns. These effects are believed to be very small on a national basis, but may show some geographic concentration.

The multi-sector analysis simulates percentage changes in prices and gross revenues (price multiplied by the quantity sold) using the assumed 2005 range of imported Canadian cattle (roughly 1.5 million to 2 million head, fed and feeder cattle combined). The results of the analysis show for the combined livestock, feed, and grain sectors, a possible decline in gross revenues of 1.4 percent to 1.7 percent. For the beef and cattle sectors, the gross revenue declines may range from 1.3 percent to 1.6 percent, and from 3.9 percent to 4.8 percent, respectively.

With respect to the change in the price of cattle in 2005, the multi-sector analysis indicates a possible decline of between 3.3 percent and 4.1 percent, compared to 2005 price declines estimated in the single-sector analyses of between 0.6 percent and 1.3 percent

for feeder cattle, and between 2.3 percent and 3.2 percent for fed cattle. To the extent that sector interactions result in expanded effects as indicated by these relative price declines, welfare gains and losses will be larger than are indicated in Table 1. The multi-sector model simulates price and revenue changes, but does not yield measures of welfare change. However, this model does indicate a decline in consumer expenditures by about 1 percent, a finding that supports the estimated consumer welfare gains attributable to the rule.

The multi-sector analysis also examines possible effects if beef consumption in the United States were to decline by 2 percent because of consumers' perception of increased risk of BSE with the rule. Compared to the assumption of no consumer response, this scenario shows that there would be a decline in beef and cattle prices by an additional 0.2 percent to 0.4 percent, causing gross revenues for the beef and cattle sectors to fall by an additional 0.2 percent to 0.5 percent.

A third scenario considered in the multi-sector analysis is partial restoration of beef exports to Japan, such that U.S. beef exports in 2005 would double, from an expected 0.3 million metric tons to 0.6 million metric tons. In this instance, gross revenue for the cattle sector (assuming 1.5 million head of Canadian cattle are imported) could decline by 1.7 percent, compared to a possible decrease of 3.9 percent assuming no change in U.S. beef exports. For the beef sector, gross revenue losses of 1.3 percent may become gains of 2.2 percent because of the exports to Japan. For both sectors, increased U.S. exports could moderate by at least one-half the price declines due to resumption of cattle imports from Canada.

Monitoring the movement of feeder cattle. Movement within the United States of feeder cattle (and feeder lambs and goats) imported from a BSE minimal-risk region such as Canada—from the U.S. port of entry to a feedlot and from the feedlot to slaughter—will require that certain inspection and record keeping safeguards be satisfied. The increased cost of these requirements is considered a cost to this rulemaking. These include certification of each animal's identification (by eartag and branding), age, and feeding history. Feeder cattle will be listed on the APHIS Form VS 17–130 that accompanies the animals from the port of entry and on the APHIS Form VS 1–27 that accompanies the animals to slaughter.

Costs of the process can be approximated by considering the time Federal or State officials or their designees would spend monitoring the movement of these cattle. We approximate the cost of performing the inspections and related tasks to be $10 per animal, based on direct salary, personnel benefits, administrative support costs, agency overhead, and departmental charges, and using a simplified example developed by APHIS Veterinary Services. Given the number of feeder cattle that may enter because of the rule, the overall cost in 2005 would be between $4.1 million and $5.2 million

Commodities other than cattle and beef. Other, less major commodities that will be allowed entry under the rule and for which we have data are sheep, goats, and farmed cervids; meat from these ruminants; and bovine tongues and livers. In all cases, reestablished imports from Canada will have small effects on the U.S. supply of these commodities and the welfare of U.S. entities. Feeder lambs and goats will be required to be moved to designated feedlots. As with feeder cattle from Canada, movement of feeder lambs and goats from the port of entry to feedlot and from feedlot to slaughter will be monitored, which will lead to a small cost.

U.S. exports. The rule, of course, will have no immediate effect for U.S. exports to countries that currently prohibit beef imports from the United States. It could influence these countries' future decisions regarding resumption of beef imports from the United States. A country may consider the rule to lend justification to a decision to continue to prohibit entry of U.S. beef because of concern about BSE risks posed by Canadian cattle, even though there would be no scientific basis. In such a case, there would be continued premium losses over and above the domestic value of the products, especially for beef variety meats. On the other hand, resumption of U.S. imports from Canada may help convince other countries of the sanitary safety of both U.S. and Canadian beef. Any effects the rule may have for future U.S. beef exports may vary from one trading partner to another.

Alternatives to the Rule

Alternatives to the rule would be to leave the regulations unchanged—that is, continue to prohibit entry of ruminants and most ruminant products from regions of minimal BSE risk (other than products allowed entry under permit), or modify the commodities and/or import requirements specified in the rule. By maintaining current import restrictions, the net benefits of reestablishing imports from Canada of fed and feeder cattle, and beef not by permit, and other affected commodities would not be realized. Two possible modifications would be to (i) require that imported beef come from cattle slaughtered at less than 30 months of age, or (ii) continue to prohibit the entry of live ruminants.

Beef only from cattle less than 30 months of age. The proposed rule would have required beef imports from Canada to come from cattle slaughtered at less than 30 months of age. In a notice that reopened the comment period for the proposed rule, APHIS stated that it no longer believed that it would be necessary to require that beef imported from BSE minimal-risk regions be derived only from cattle less than 30 months of age, provided measures are in place to ensure that SRMs are removed when the animals are slaughtered, and that such other measures as are necessary are in place. Canada is removing SRMs at slaughter and fulfilling other required measures.

Requiring that beef come only from cattle slaughtered at less than 30 months of age would continue the prohibition on Canadian cows and bulls as source animals, and eliminate effects of the rule for beef. Continuing to limit imports from Canada to veal from calves and beef from steers and heifers would cause Canada's cow and bull inventories to continue to grow and exert downward pressure on Canada's cow prices, which are already well below U.S. price levels. Canadian suppliers would be prevented from participating in the current high-demand market in the United States for processing beef, and U.S. processors would not benefit from the additional source of supply during a time when U.S. cow slaughter is cyclically low.

This alternative would maintain the status quo in terms of beef imports, other than removing permit requirements and broadening the commodities allowed to be imported beyond boneless beef. In terms of the quantity of beef imported, we expect that these changes would have a very small effect, given the large share of Canada's historic exports that enter currently.

This alternative would affect cattle imports from Canada by removing the incentive for Canadian cows to be slaughtered in place of fed cattle, since the processing beef would not be allowed to be imported by the United States; there would not be the displaced fed cattle assumed to be available for import under the rule. The number of fed cattle imports would be fewer than

with the rule, especially in 2005, and price and welfare impacts, including net benefits, would be smaller.

Welfare effects of this alternative for cattle and beef are summarized in Table 3. Present values and annualized values of welfare gains and losses over the five-year period 2005–2009 are determined using 3 percent and 7 percent discount rates in both 2005 and 2001 dollars.

TABLE 3.—ALTERNATIVE OF CANADIAN BEEF IMPORTS ONLY FROM CATTLE LESS THAN 30 MONTHS OF AGE: PRESENT AND ANNUALIZED VALUE ESTIMATIONS OF THE EFFECTS OF THE RULE FOR FED CATTLE, FEEDER CATTLE, AND BEEF, DISCOUNTED AT 3 PERCENT AND 7 PERCENT, IN 2005 AND 2001 DOLLARS 2005–2009

Value	Discount rate (percent)	Changes in welfare (per thousand dollars)		
		Consumer	Producer	Net
Present, 2005 dollars	3	$2,399,299	−$2,345,160	$54,139
	7	2,064,181	−2,016,794	47,387
Present, 2001 dollars	3	2,261,339	−2,210,314	51,026
	7	1,945,490	−1,900,828	44,662
Annualized, 2005 dollars	3	523,898	−512,076	11,821
	7	503,434	−491,877	11,557
Annualized, 2001 dollars	3	493,774	−482,632	11,142
	7	474,487	−463,594	10,893

Note: The present and annualized values are midpoints taken from Appendix U, based on the assumed backlog imports.

The present value of the net benefit of the alternative for cattle and beef is estimated to range in 2005 dollars between $47.4 million and $54.1 million, depending on the discount rate used (with the rule: Between $66.3 million and $74.6 million). Over the five-year period, the annualized value of the net benefit in 2005 dollars, depending on the discount rate, may range between $11.6 million and $11.8 million (with the rule: Between $16.2 million and $16.3 million).

The largest effects for cattle are expected to occur in 2005, when the backlog is imported. Since allowing Canadian beef imports only from cattle slaughtered at less than 30 months of age would not affect the number of feeder cattle expected to be imported, effects for feeder cattle would be the same as with the rule.

Possible effects of this alternative for future U.S. exports would differ from possible effects with the rule only if other countries perceived BSE-risks associated with Canadian beef produced from cattle slaughtered at less than 30 months of age as different from those associated with Canadian beef produced from cattle slaughtered at more than 30 months of age.

There would be no known reduction in risk of BSE introduction under this alternative. Removal of SRMs at slaughter and other required risk-mitigating measures of the rule will ensure that beef entering from Canada satisfies animal health criteria the same as or equivalent to those required in the United States.

Near-term price effects of this alternative would be similar to those of this rule. For example, for fed cattle the decrease in price when the backlog is assumed to enter entirely within one quarter is estimated to be 4.4 percent (with the rule: 5.4 percent), assuming a price elasticity of supply of 0.61 and a price elasticity of demand of −0.76. When the backlog of fed cattle is assumed to enter over two quarters using the same price elasticities, the decline in price is estimated to be 2.8 percent (with the rule: 3.8 percent). Entry of the backlog of feeder cattle over the two quarters could result in a price decline of 1.9 percent under this alternative and using the same elasticities, compared to a possible price drop of 3.3 percent when the backlog is assumed to enter entirely within one quarter. The expected effects are the same for feeder cattle under this alternative and with the rule because their number is assumed to be unaffected by whether Canadian beef imports are restricted to being derived from cattle less than 30 months of age. When the supply and demand elasticities are halved (supply elasticity of 0.30, and demand elasticity of −0.38, for example, and fed cattle are assumed to enter within two quarters, the decrease in price is estimated to be 3.6 percent (with the rule, 4.8 percent), compared to a decrease of 2.8 percent (with the rule, 3.8 percent) when a supply elasticity of 0.61 and demand elasticity of −0.76 are used.

No live ruminants. Direct effects of this alternative would be equivalent to expected effects of the rule only for ruminant products. We would expect the same effect for beef as with the rule; imports of beef from cows would replace imports of beef from fed cattle, yielding, for the five-year period 2005–2009, present value losses for consumers of between $73.9 million and $78.8 million, gains for producers of between $73.7 million and $78.5 million, and net welfare losses of between $264,000 and $283,000, compared to the baseline (3 percent discount rate, 2005 dollars). There would also be net benefits forgone by the continued prohibition on the importation of sheep and goats. Possible effects of this alternative on future U.S. exports would likely be small, since it would maintain the current prohibition on imports of live ruminants from Canada.

In sum, the rule is preferable in terms of expected net benefits to the status quo (continuing to prohibit the entry of Canadian ruminants, and the entry of Canadian ruminant products other than those allowed by permit), and to the two alternatives discussed: Limiting beef imports to cattle slaughtered at less than 30 months of age or allowing entry of ruminant products but not live ruminants. Risks of BSE introduction would not be reduced to any known degree by selecting one of the alternatives in place of the rule. We believe that listing Canada as a minimal-risk region subject to the required risk-mitigating measures is a balanced response, based on scientific evidence, to Canada's request that certain ruminant and ruminant product imports by the United States be allowed to resume.

Final Regulatory Flexibility Analysis

As a part of the rulemaking process, APHIS evaluates whether regulations are likely to have a significant economic impact on a substantial number of small entities. The resumption of ruminant and ruminant product imports from Canada will most importantly affect the cattle industry, reducing prices and increasing supplies. Entry of fed cattle

(and fed sheep and goats) will benefit U.S. slaughtering establishments, and entry of feeder cattle (and feeder sheep and goats) will benefit feedlots. Also, entry of beef from cattle slaughtered at over 30 months of age will benefit some U.S. meat and meat product wholesalers and packers by providing an additional source of processing beef. At the same time, these imports will increase the competition for U.S. and foreign suppliers of these commodities.

The main industries expected to be affected by the rule are composed predominantly of small entities, as indicated by the 1997 Economic Census, the 2002 Census of Agriculture, and USDA's "Cattle on Feed" (February 20, 2004). The small entities number in the hundreds of thousands, with cattle producers comprising the largest number. For beef cattle ranching and farming, the 2002 Census of Agriculture indicates a total of about 657,000 operations, of which nearly 656,000 are considered small entities. For cattle feedlots, more than 91,000 of the approximately 93,200 total operations are small entities. For sheep and goat farming, 44,000 out of about 44,200 operations are considered small entities. Small entities similarly dominate, in terms of percentage operations, other affected industries, including animal slaughtering, meat and meat byproduct processing, and meat and meat product wholesaling.

Notwithstanding the prevalence of small entities, the concentrated structure of affected industries is well-documented. In the U.S. meatpacking industry, for example, four firms handle nearly 80 percent of all steer and heifer slaughter. The cattle feedlot industry is also highly concentrated. Data from 2003 show that only 2 percent of feedlots have capacities greater than 1,000 head, and yet these larger feedlots market 85 percent of fed cattle.

Imports from Canada that will be allowed to resume are expected to have a larger effect on the fed cattle market than on the feeder cattle market. Prices and welfare of producers and suppliers will decline because of the additional supply and the welfare of consumers and buyers will increase. Net benefits of the rule will be positive.

The analysis provides an estimation of possible price effects for small-entity and other producers and processors during the first 3 to 6 months that the rule is in effect, when impacts may be greatest due to the expected importation of the backlog. Depending on the assumed elasticities of supply and demand and the period over which the backlog enters, the estimated price declines could range from 1.9 percent to 4.4 percent for feeder cattle and from 3.8 percent to 6.9 percent for fed cattle. For the year 2005, the model indicates a possible decline in feeder cattle prices of 1.3 percent and a possible decline in fed cattle prices of 3.2 percent.

To give these average percentage price decline some perspective, we consider as an example their effect on earnings by small U.S. beef cow herds. Based on data from the 2002 Census of Agriculture, the average value of sales of cattle and calves by small-entity beef cow operations was about $26,700. Given the forecast feeder cattle baseline price for 2005 of between $94 and $100 per cwt, the 2005 estimated price decline of 1.3 percent would be equivalent to a decrease of between $1.22 to $1.30 per cwt, or a decrease in annual revenue of between $326 and $347, assuming no reduction in the number of cattle marketed. This example abstracts from the wide range in size for small beef cow herds, but gives an indication of a possible average price effect of the rule for these operators in 2005. It should be recognized that while the decline in price would be a loss for producers, it would represent a gain for small-entity feedlot operators.

Beyond the net welfare gains as summarized in Table 1, there will likely be regional impacts not captured in the analysis. Among comments received on the proposed rule were ones that pointed out the historical reliance of some northern U.S. meat processing plants (and the communities they support) on cattle imports from Canada to maintain necessary throughput volumes. Historical dependence of these processing facilities on cattle imports from Canada exemplifies economic ties with Canadian entities that existed prior to the prohibition on ruminant imports. Resumption of imports will enable trade relationships involving small-entity operations to be reestablished.

Alternatives to the rule, whether leaving the regulations unchanged or modifying the commodities and/or import requirements specified in the rule, would benefit certain categories of small entities while harming others. For example, a continued prohibition on the importation of Canadian feeder cattle would benefit small-entity suppliers of feeder cattle, but at the expense of small-entity feedlot operators. Estimated price declines, particularly in the near term, will cause economic losses for some entities and at the same time benefit other entities. Overall, the analysis indicates the rule will have a net positive effect for the United States.

Small Business Regulatory Enforcement Fairness Act of 1996

This rule has been designated by the Administrator, Office of Information and Regulatory Affairs, Office of Management and Budget, as a major rule under the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801–808). Accordingly, the effective date of this rule has been delayed the required 60 days pending congressional review.

Executive Order 12988

This final rule has been reviewed under Executive Order 12988, Civil Justice Reform. This rule: (1) Preempts all State and local laws and regulations that are inconsistent with this rule; (2) has no retroactive effect; and (3) does not require administrative proceedings before parties may file suit in court challenging this rule.

National Environmental Policy Act

In October 2003, APHIS prepared an environmental assessment to consider potential impacts to the human environment from implementation of the proposed rulemaking. During the comment period for the proposed rulemaking, comments were received from the public regarding the environmental assessment. As a result of those comments, APHIS revised the environmental assessment to discuss in more detail the potential impacts of concern for the human environment.

The environmental assessment was 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).

APHIS sent copies of the revised environmental assessment to those who commented on the October 2003 environmental assessment, in accordance with 7 CFR 372.9(a)(3). In a separate notice in today's issue of the **Federal Register**, APHIS is announcing the availability of the revised assessment and is requesting comments on the revised assessment for 30 days.

Paperwork Reduction Act

This final rule includes certain regulatory provisions that differ from those included in the November 2003 proposed rule. Some of those provisions involve changes from the information collection requirements set out in the proposed rule. These changes include

the following regarding ruminants from Canada:

- Bovines, sheep, and goats moved from a U.S. port of entry to a feedlot before being moved to slaughter must be accompanied by an APHIS Form VS 17–130, rather than an APHIS Form VS 1–27 as proposed.
- Those animals moved to a feedlot before being moved to slaughter must be permanently identified in Canada as being of Canadian origin with a distinct and legible mark, properly and humanely applied with a freeze brand, hot iron, or other method. This is a change from the proposed requirement that permanent identification be done by tattooing the animal.
- Those animals moved to a feedlot must be individually identified in Canada by an official Canadian eartag. This requirement was not in the proposed rule.
- The owners of feedlots wishing to be considered designated feedlots must sign an agreement with APHIS. This requirement was not in the proposed rule.

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the information collection or recordkeeping requirements included in this rule have been approved by the Office of Management and Budget (OMB) under OMB control number 0579–0234.

Government Paperwork Elimination Act Compliance

The Animal and Plant Health Inspection Service is committed to compliance with the Government Paperwork Elimination Act (GPEA), which requires Government agencies in general to provide the public the option of submitting information or transacting business electronically to the maximum extent possible. For information pertinent to GPEA compliance related to this rule, please contact Mrs. Celeste Sickles, APHIS' Information Collection Coordinator, at 301–734–7477.

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List of Subjects

9 CFR Part 93

Animal diseases, Imports, Livestock, Poultry and poultry products, Quarantine, Reporting and recordkeeping requirements.

9 CFR Part 94

Animal diseases, Imports, Livestock, Meat and meat products, Milk, Poultry and poultry products, Reporting and recordkeeping requirements.

9 CFR Part 95

Animal feeds, Hay, Imports, Livestock, Reporting and recordkeeping requirements, Straw, Transportation.

9 CFR Part 96

Imports, Livestock, Reporting and recordkeeping requirements.

■ Accordingly, we are amending 9 CFR parts 93, 94, 95, and 96 as follows:

PART 93—IMPORTATION OF CERTAIN ANIMALS, BIRDS, AND POULTRY, AND CERTAIN ANIMAL, BIRD, AND POULTRY PRODUCTS; REQUIREMENTS FOR MEANS OF CONVEYANCE AND SHIPPING CONTAINERS

■ 1. The authority citation for part 93 continues to read as follows:

Authority: 7 U.S.C. 1622 and 8301–8317; 21 U.S.C. 136 and 136a; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.4.

■ 2. Section 93.400 is amended by revising the definitions of *flock* and *inspector* and adding definitions of *as a group, bovine, bovine spongiform encephalopathy (BSE) minimal risk region, camelid, cervid, designated feedlot, positive for a transmissible spongiform encephalopathy, premises of origin, State representative, suspect for a transmissible spongiform encephalopathy,* and *USDA representative,* in alphabetical order, to read as follows:

§ 93.400 Definitions.

* * * * *

As a group. Collectively, in such a manner that the identity of the animals as a unique group is maintained.

Bovine. Bos taurus, Bos indicus, and *Bison bison.*

Bovine spongiform encephalopathy (BSE) minimal risk region. A region listed in § 94.18(a)(3) of this subchapter.

* * * * *

Camelid. All species of the family *Camelidae,* including camels, llamas, alpacas, and vicunas.

* * * * *

Cervid. All members of the family *Cervidae* and hybrids, including deer, elk, moose, caribou, reindeer, and related species.

* * * * *

Designated feedlot. A feedlot that has been designated by the Administrator as one that is eligible to receive sheep and goats imported from a BSE minimal-risk region and whose owner or legally responsible representative has signed an agreement in accordance with § 93.419(d)(8) of this subpart to adhere to, and is in compliance with, the requirements for a designated feedlot.

* * * * *

Flock. Any group of one or more sheep maintained on common ground; or two or more groups of sheep under common ownership or supervision on two or more premises that are geographically separated, but among which there is an interchange or movement of animals.

* * * * *

Inspector. Any individual authorized by the Administrator of APHIS or the Commissioner of Customs and Border Protection, Department of Homeland Security, to enforce the regulations in this subpart.

* * * * *

Positive for a transmissible spongiform encephalopathy. A sheep or goat for which a diagnosis of a transmissible spongiform encephalopathy has been made.

Premises of origin. Except as otherwise used in § 93.423 of this subpart, the premises where the animal was born.

* * * * *

State representative. A veterinarian or other person employed in livestock sanitary work by a State or political subdivision of a State who is authorized by such State or political subdivision of a State to perform the function involved under a memorandum of understanding with APHIS.

Suspect for a transmissible spongiform encephalopathy. (1) A sheep or goat that has tested positive for a transmissible spongiform encephalopathy or for the proteinase resistant protein associated with a transmissible spongiform encephalopathy, unless the animal is designated as positive for a transmissible spongiform encephalopathy; or

(2) A sheep or goat that exhibits any of the following signs and that has been determined to be suspicious for a transmissible spongiform encephalopathy by a veterinarian: Weight loss despite retention of appetite; behavior abnormalities; pruritus (itching); wool pulling; biting at legs or side; lip smacking; motor

abnormalities such as incoordination, high stepping gait of forelimbs, bunny hop movement of rear legs, or swaying of back end; increased sensitivity to noise and sudden movement; tremor, "star gazing," head pressing, recumbency, or other signs of neurological disease or chronic wasting.

* * * * *

USDA representative. A veterinarian or other individual employed by the United States Department of Agriculture who is authorized to perform the services required by this part.

* * * * *

■ 3. Section 93.405 is amended as follows:

■ a. A new paragraph (a)(4) is added to read as set forth below.

■ b. In paragraphs (b)(2) introductory text, (c)(2), and (c)(3) the phrase "Australia, Canada, and New Zealand" is removed and the phrase "Australia and New Zealand" is inserted in its place.

■ c. In paragraph (c)(3), the phrase "Australia, Canada, New Zealand, or the United States" is removed and the phrase "Australia, New Zealand, or the United States" is added in its place.

■ d. The Office of Management and Budget citation at the end of the section is revised to read as set forth below.

§ 93.405 Certificate for ruminants.

(a) * * *

(4) If the ruminants are bovines, sheep, or goats from regions listed as BSE minimal-risk regions in § 94.18(a)(3) of this subchapter, the certificate must also include the name and address of the importer; the species, breed, and number or quantity of ruminants to be imported; the purpose of the importation; individual ruminant identification, which includes the eartag required under § 93.419(d)(2) or § 93.436(b)(4) of this subchapter, and any other identification present on the animal, including registration number, if any; a description of the ruminant, including name, age, color, and markings, if any; region of origin; the address of or other means of identifying the premises of origin and any other premises where the ruminants resided immediately prior to export, including the State or its equivalent, the municipality or nearest city, or an equivalent method, approved by the Administrator, of identifying the location of the premises, and the specific physical location of the feedlot where the ruminants are to be moved after importation; the name and address of the exporter; the port of embarkation in the foreign region; and the mode of transportation, route of travel, and port of entry in the United States.

* * * * *

(Approved by the Office of Management and Budget under control numbers 0579–0040, 0579–0165, and 0579–0234)

■ 4. In § 93.419, new paragraphs (c) and (d) are added to read as follows:

§ 93.419 Sheep and goats from Canada.

* * * * *

(c) Any sheep or goats imported from Canada must be less than 12 months of age when imported into the United States and when slaughtered, and must be from a flock or herd subject to a ruminant feed ban equivalent to the requirements established by the U.S. Food and Drug Administration at 21 CFR 589.2000. The animals must be accompanied by a certificate issued or endorsed by a salaried veterinarian of the Canadian Government that states that the conditions of this paragraph have been met. Additionally, for sheep and goats imported for other than immediate slaughter, the certificate must state that the conditions of paragraphs (d)(1) and (d)(2) of this section have been met. For sheep and goats imported for immediate slaughter, the certificate must also state that:

(1) The animals have not tested positive for and are not suspect for a transmissible spongiform encephalopathy.

(2) The animals have not resided in a flock or herd that has been diagnosed with BSE; and

(3) The animals' movement is not restricted within Canada as a result of exposure to a transmissible spongiform encephalopathy.

(d) *Imported for feeding.* Any sheep or goats imported from Canada for feeding at a feedlot must be imported only through a port of entry listed in § 93.403(b) or as provided for in § 93.403(f) in a means of conveyance sealed in the region of origin with seals of the national government of the region of origin, must be moved directly as a group from the port of entry to a designated feedlot, must not be commingled with any sheep or goats that are not being moved directly to slaughter from the designated feedlot at less than 12 months of age, and must meet the following conditions:

(1) The sheep and goats must be permanently and humanely identified before arrival at the port of entry with a distinct and legible "C" mark, properly applied with a freeze brand, hot iron, or other method, and easily visible on the live animal and on the carcass before skinning. The mark must be not less than 1 inch or more than 1¼ inches high. Other means of permanent identification may be used upon request if deemed adequate by the Administrator to humanely identify the animal in a distinct and legible way as having been imported from Canada;

(2) Each sheep and goat must be individually identified by an official Canadian Food Inspection Agency eartag, applied before the animal's arrival at the port of entry into the United States, that is determined by the Administrator to meet standards equivalent to those for official eartags in the United States as defined in § 71.1 of this chapter and to be traceable to the premises of origin of the animal. No person may alter, deface, remove, or otherwise tamper with the individual identification while the animal is in the United States or moving into or through the United States, except that the identification may be removed at the time of slaughter;

(3) The animals may be moved from the port of entry only to a feedlot designated in accordance with paragraph (d)(8) of this section and must be accompanied from the port of entry to the designated feedlot by APHIS Form VS 17–130 or other movement documentation deemed acceptable by the Administrator, which must identify the physical location of the feedlot, the individual responsible for the movement of the animals, and the individual identification of each animal, which includes the eartag required under paragraph (d)(2) of this section and any other identification present on the animal, including registration number, if any;

(4) The seals of the national government of Canada must be broken only at the port of entry by the APHIS port veterinarian or at the designated feedlot by an accredited veterinarian or a State or USDA representative or his or her designee. If the seals are broken by the APHIS port veterinarian at the port of entry, the means of conveyance must be resealed with seals of the U.S. Government before being moved to the designated feedlot;

(5) The animals must remain at the designated feedlot until transported to a recognized slaughtering establishment. The animals must be moved directly to the recognized slaughtering establishment in a means of conveyance sealed with seals of the U.S. Government by an accredited veterinarian or a State or USDA representative. The seals must be broken only at the recognized slaughtering establishment by a USDA representative;

(6) The animals must be accompanied to the recognized slaughtering establishment by APHIS Form VS 1–27 or other documentation deemed acceptable by the Administrator, which must identify the physical location of the recognized slaughtering establishment, the individual responsible for the movement of the animals, and the individual identification of each animal, which includes the eartag required under paragraph (d)(2) of this section and any other identification present on the animal, including registration number, if any;

(7) The animals must be less than 12 months of age when slaughtered;

(8) To be approved to receive sheep or goats imported for feeding, a feedlot must have signed a written agreement with the Administrator stating that the feedlot:

(i) Will not remove eartags from animals unless medically necessary, in which case another eartag or other form of official identification, as defined in § 79.1 of this chapter, will be applied and cross referenced in the records;

(ii) Will monitor all incoming imported feeder animals to ensure that they have the required "C" brand;

(iii) Will maintain records of the acquisition and disposition of all imported sheep and goats entering the feedlot, including the Canadian Food Inspection Agency tag number and all other identifying information, the age of each animal, the date each animal was acquired and the date each animal was shipped to slaughter, and the name and location of the plant where each animal was slaughtered. For Canadian animals that die in the feedlot, the feedlot will remove its eartag and place it in a file along with a record of the disposition of the carcass;

(iv) Will maintain copies of the APHIS Forms VS 17–130 and VS 1–27 or other movement documentation deemed acceptable by the Administrator that have been issued for incoming animals and for animals moved to slaughter and that list the official identification of each animal;

(v) Will allow State and Federal animal health officials access to inspect its premises and animals and to review inventory records and other required files upon request;

(vi) Will keep required records for at least 5 years;

(vii) Will designate either the entire feedlot or pens within the feedlot as terminal for sheep and goats to be moved only directly to slaughter at less than 12 months of age, and

(viii) Agrees that if inventory cannot be reconciled or if animals are not moved to slaughter as required the approval of the feedlot will be immediately withdrawn.

(Approved by the Office of Management and Budget under control numbers 0579–0040 and 0579–0234)

■ 5. Section 93.420 is revised to read as follows:

§ 93.420 Ruminants from Canada for immediate slaughter.

(a) Ruminants imported from Canada for immediate slaughter must be imported only through a port of entry listed in § 93.403(b) or as provided for in § 93.403(f) in a means of conveyance sealed in Canada with seals of the Canadian Government, and must be moved directly as a group from the port of entry to a recognized slaughtering establishment for slaughter as a group. The seals must be broken only at the port of entry by the APHIS port veterinarian or at the recognized slaughtering establishment by an accredited veterinarian or a State or USDA representative or his or her designee. If the seals are broken by the APHIS port veterinarian at the port of entry, the means of conveyance must be resealed with seals of the U.S. Government before being moved to the recognized slaughtering establishment. The shipment must be accompanied from the port of entry to the recognized slaughtering establishment by APHIS Form VS 17–33, which shall include the location of the recognized slaughtering establishment. Such ruminants shall be inspected at the port of entry and otherwise handled in accordance with § 93.408.

(b) In addition to meeting the requirements of paragraph (a) of this section, sheep and goats imported from Canada for immediate slaughter must meet the requirements of § 93.419(c) as well as the following conditions:

(1) The animals have not tested positive for and are not suspect for a transmissible spongiform encephalopathy;

(2) The animals have not resided in a flock or herd that has been diagnosed with BSE; and

(3) The animals' movement is not restricted within Canada as a result of exposure to a transmissible spongiform encephalopathy.

■ 6. An undesignated center heading "Additional General Provisions" is added preceding reserved § 93.430.

■ 6a. A new § 93.436 is added to subpart D to read as follows:

§ 93.436 Ruminants from regions of minimal risk for BSE.

The importation of ruminants from regions listed in § 94.18(a)(3) of this subchapter is prohibited, unless the conditions of this section and any other applicable conditions of this part are met. Once the ruminants are imported, if they do not meet the conditions of this section, they must be disposed of as the Administrator may direct.

(a) *Bovines for immediate slaughter.* Bovines from a region listed in § 94.18(a)(3) of this subchapter may be imported for immediate slaughter under the following conditions:

(1) The bovines must be less than 30 months of age when imported into the United States and when slaughtered;

(2) The bovines must have been subject to a ruminant feed ban equivalent to the requirements established by the U.S. Food and Drug Administration at 21 CFR 589.2000;

(3) The bovines must be accompanied by a certificate issued by a full-time salaried veterinary officer of the national government of the region of origin, or issued by a veterinarian designated or accredited by the national government of the region of origin and endorsed by a full-time salaried veterinary officer of the national government of the region of origin, representing that the veterinarian issuing the certificate was authorized to do so, and the certificate states that the conditions of paragraphs (a)(1) and (a)(2) of this section have been met;

(4) The bovines must be imported only through a port of entry listed in § 93.403(b) or as provided for in § 93.403(f) in a means of conveyance sealed in the region of origin with seals of the national government of the region of origin, and must be moved directly as a group from the port of entry to a recognized slaughtering establishment. The seals must be broken only at the port of entry by the APHIS port veterinarian or at the recognized slaughtering establishment by a USDA representative. If the seals are broken by the APHIS port veterinarian at the port of entry, the means of conveyance must be resealed with seals of the U.S. Government before being moved to the recognized slaughtering establishment;

(5) The bovines must be accompanied from the port of entry to the recognized slaughtering establishment by APHIS Form VS 17–33; and

(6) At the recognized slaughtering establishment, the bovines must be slaughtered as a group.

(b) *Bovines for feeding.* Bovines from a region listed in § 94.18(a)(3) of this subchapter may be imported for movement to a feedlot and then to slaughter under the following conditions:

(1) The bovines must be less than 30 months of age when imported into the United States;

(2) The bovines must have been subject to a ruminant feed ban equivalent to the requirements established by the U.S. Food and Drug Administration at 21 CFR 589.2000;

(3) The bovines must be permanently and humanely identified before arrival at the port of entry with a distinct and legible mark identifying the exporting country, properly applied with a freeze brand, hot iron, or other method, and easily visible on the live animal and on the carcass before skinning. The mark must be not less than 2 inches nor more than 3 inches high, and must be applied to each animal's right hip, high on the tail-head (over the junction of the sacral and first cocygeal vertebrae). Other means of permanent identification may be used upon request if deemed adequate by the Administrator to humanely identify the animal in a distinct and legible way as having been imported from the BSE minimal-risk exporting region. Bovines exported from Canada must be so marked with "CAN;"

(4) Each bovine must be individually identified by an official eartag of the country of origin, applied before the animal's arrival at the port of entry into the United States, that is determined by the Administrator to meet standards equivalent to those for official eartags in the United States as defined in § 71.1 of this chapter and to be traceable to the premises of origin of the animal. No person may alter, deface, remove, or otherwise tamper with the individual identification while the animal is in the United States or moving into or through the United States, except that the identification may be removed at the time of slaughter;

(5) The bovines must be accompanied by a certificate issued in accordance with § 93.405 that states, in addition to the statements required by § 93.405, that the conditions of paragraphs (b)(1) through (b)(4) of this section have been met;

(6) The bovines must be imported only through a port of entry listed in § 93.403(b) or as provided for in § 93.403(f) in a means of conveyance sealed in the region of origin with seals of the national government of the region of origin, and must be moved directly from the port of entry as a group to the feedlot identified on the APHIS VS Form 17–130 or other movement documentation required under paragraph (b)(8) of this section;

(7) The seals of the national government of the region of origin must be broken only at the port of entry by the APHIS port veterinarian or at the feedlot by an accredited veterinarian or a State or USDA representative or his or her designee. If the seals are broken by the APHIS port veterinarian at the port of entry, the means of conveyance must be resealed with seals of the U.S. Government before being moved to the feedlot;

(8) The bovines must be accompanied from the port of entry to the feedlot by APHIS Form VS 17–130 or other movement documentation deemed acceptable by the Administrator, which must identify the physical location of the feedlot, the individual responsible for the movement of the animals, and the individual identification of each animal, which includes the eartag required under paragraph (b)(4) of this section and any other identification present on the animal, including registration number, if any;

(9) The bovines must remain at the feedlot until transported from the feedlot to a recognized slaughtering establishment for slaughter;

(10) The bovines must be moved directly from the feedlot identified on APHIS Form VS 17–130 to a recognized slaughtering establishment in conveyances that must be sealed at the feedlot with seals of the U.S. Government by an accredited veterinarian or a State or USDA representative. The seals may be broken only at the recognized slaughtering establishment by a USDA representative.

(11) The bovines must be accompanied from the feedlot to the recognized slaughtering establishment by APHIS Form VS 1–27 or other movement documentation deemed acceptable by the Administrator, which must identify the physical location of the recognized slaughtering establishment, the individual responsible for the movement of the animals, and the individual identification of each animal, which includes the eartag required under paragraph (b)(4) of this section and any other identification present on the animal, including registration number, if any; and

(12) The bovines must be less than 30 months of age when slaughtered.

(c) *Sheep and goats for immediate slaughter.* Sheep and goats from a region listed in § 94.18(a)(3) of this subchapter may be imported for immediate slaughter under the conditions set forth in this subpart for such sheep and goats. The conditions for the importation of sheep and goats from Canada for immediate slaughter are set forth in §§ 93.419(c) and 93.420.

(d) *Sheep and goats for feeding.* Sheep and goats from a region listed in § 94.18(a)(3) of this subchapter may be imported for other than immediate slaughter under the conditions set forth in this subpart for such sheep and goats. The conditions for the importation of sheep and goats from Canada for other than immediate slaughter are set forth in §§ 93.405 and 93.419.

(e) *Cervids.* There are no BSE-related restrictions on the importation of cervids from a region listed in § 94.18(a)(3) of this subchapter.

(f) *Camelids.* There are no BSE-related restrictions on the importation of camelids from a region listed in § 94.18(a)(3) of this subchapter.

(Approved by the Office of Management and Budget under control number 0579–0234)

PART 94—RINDERPEST, FOOT-AND-MOUTH DISEASE, FOWL PEST (FOWL PLAGUE), EXOTIC NEWCASTLE DISEASE, AFRICAN SWINE FEVER, CLASSICAL SWINE FEVER, AND BOVINE SPONGIFORM ENCEPHALOPATHY: PROHIBITED AND RESTRICTED IMPORTATIONS

■ 7. The authority citation for part 94 continues to read as follows:

Authority: 7 U.S.C. 450, 7701–7772, and 8301–8317; 21 U.S.C. 136 and 136a; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.4.

■ 8. Section 94.0 is amended by revising the definitions of *authorized inspector* and *cervid* and adding new definitions of *bovine, bovine spongiform encephalopathy (BSE) minimal-risk region, Food Safety and Inspection Service, personal use, positive for a transmissible spongiform encephalopathy, specified risk materials (SRMs),* and *suspect for a transmissible spongiform encephalopathy,* in alphabetical order, to read as follows:

§ 94.0 Definitions.

* * * * *

Authorized inspector. Any individual authorized by the Administrator of APHIS or the Commissioner of Customs and Border Protection, Department of Homeland Security, to enforce the regulations in this part.

* * * * *

Bovine. Bos taurus, Bos indicus, and *Bison bison.*

Bovine spongiform encephalopathy (BSE) minimal-risk region. A region that:

(1) Maintains, and, in the case of regions where BSE was detected, had in place prior to the detection of BSE in an indigenous ruminant, risk mitigation measures adequate to prevent widespread exposure and/or establishment of the disease. Such measures include the following:

(i) 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;

(ii) Surveillance for BSE at levels that meet or exceed recommendations of the World Organization for Animal Health (Office International des Epizooties) for surveillance for BSE; and

(iii) A ruminant-to-ruminant feed ban that is in place and is effectively enforced.

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

Cervid. All members of the family *Cervidae* and hybrids, including deer, elk, moose, caribou, reindeer, and related species.

* * * * *

Food Safety and Inspection Service. The Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture.

* * * * *

Personal use. Only for personal consumption or display and not distributed further or sold.

* * * * *

Positive for a transmissible spongiform encephalopathy. A sheep or goat for which a diagnosis of a transmissible spongiform encephalopathy has been made.

* * * * *

Specified risk materials (SRMs). Those bovine parts considered to be at particular risk of containing the bovine spongiform encephalopathy (BSE) agent in infected animals, as listed in the FSIS regulations at 9 CFR 310.22(a).

Suspect for a transmissible spongiform encephalopathy. (1) A sheep or goat that has tested positive for a transmissible spongiform encephalopathy or for the proteinase resistant protein associated with a transmissible spongiform encephalopathy, unless the animal is designated as positive for a transmissible spongiform encephalopathy; or

(2) A sheep or goat that exhibits any of the following signs and that has been determined to be suspicious for a transmissible spongiform encephalopathy by a veterinarian: Weight loss despite retention of appetite; behavior abnormalities; pruritus (itching); wool pulling; biting at legs or side; lip smacking; motor abnormalities such as incoordination, high stepping gait of forelimbs, bunny hop movement of rear legs, or swaying of back end; increased sensitivity to noise and sudden movement; tremor, "star gazing," head pressing, recumbency, or other signs of neurological disease or chronic wasting.

* * * * *

§ 94.1 [Amended]

■ 9. In § 94.1, paragraph (b)(4) and the introductory text to paragraph (d) are amended by removing the reference to "§ 94.21" each time it appears and adding in its place a reference to "§ 94.22".

■ 10. Section 94.18 is amended as follows:

■ a. In paragraph (a)(1), the word "Canada," is removed.

■ b. Paragraph (a)(3) is redesignated as paragraph (a)(4) and newly redesignated paragraph (a)(4) is revised to read as set forth below.

■ c. A new paragraph (a)(3) is added, and paragraph (b) and the introductory text of paragraph (c) are revised, to read as set forth below.

■ d. In paragraph (d), the introductory text and paragraph (d)(3) are revised and a new paragraph (d)(5) is added to read as set forth below.

§ 94.18 Restrictions on importation of meat and edible products from ruminants due to bovine spongiform encephalopathy.

(a) * * *

(3) The following are minimal-risk regions with regard to bovine spongiform encephalopathy: Canada.

(4) A region may request at any time that the Administrator consider its removal from a list in paragraphs (a)(1) or (a)(2) of this section, or its addition to or removal from the list in paragraph (a)(3) of this section, by following the procedures in part 92 of this subchapter.

(b) Except as provided in paragraph (d) of this section or in § 94.19, the importation of meat, meat products, and edible products other than meat (except for gelatin as provided in paragraph (c) of this section, milk, and milk products) from ruminants that have been in any of the regions listed in paragraph (a) of this section is prohibited.

(c) *Gelatin.* The importation of gelatin derived from ruminants that have been in any region listed in paragraph (a) of this section is prohibited unless the following conditions or the conditions of § 94.19(f) have been met:

* * * * *

(d) *Transit shipment of articles.* Meat, meat products, and edible products other than meat that are prohibited importation into the United States in accordance with this section may transit air and ocean ports in the United States for immediate export if the conditions of paragraph (d)(1) through (d)(4) of this section are met. If such commodities are derived from bovines, sheep, or goats from a region listed in paragraph (a)(3) of this section, they are eligible to transit the United States by overland transportation if the requirements of paragraphs (d)(1) through (d)(5) of this section are met:

* * * * *

(3) The person moving the articles must notify, in writing, the inspector at both the place in the United States where the articles will arrive and the port of export before such transit. The notification must include the:

* * * * *

(5) The commodities must be eligible to enter the United States in accordance with § 94.19 and must be accompanied by the certification required by that section. Additionally, the following conditions must be met:

(i) The shipment must be exported from the United States within 7 days of its entry;

(ii) The commodities must not be transloaded while in the United States;

(iii) A copy of the import permit required under paragraph (d)(1) of this section must be presented to the inspector at the port of arrival and the port of export in the United States.

* * * * *

§§ 94.19 through 94.25 [Redesignated as §§ 94.20 through 94.26]

■ 11. Sections 94.19 through 94.24 are redesignated as §§ 94.20 through 94.26, respectively.

■ 12. A new § 94.19 is added to read as follows:

§ 94.19 Restrictions on importation from BSE minimal-risk regions of meat and edible products from ruminants.

Except as provided in § 94.18 and this section, the importation of meat, meat products, and edible products other than meat (excluding gelatin that meets the conditions of § 94.18(c), milk, and milk products), from bovines, sheep, or goats that have been in any of the regions listed in § 94.18(a)(3) is prohibited. The commodities listed in paragraphs (a) through (f) of this section may be imported from a region listed in

§ 94.18(a)(3) if the conditions of this section are met; if (except for commodities described in paragraph (e) of this section) the commodities are accompanied by an original certificate of such compliance issued by a full-time salaried veterinary officer of the national government of the region of origin, or issued by a veterinarian designated or accredited by the national government of the region of origin and endorsed by a full-time salaried veterinary officer of the national government of the region of origin, representing that the veterinarian issuing the certificate was authorized to do so; and if all other applicable requirements of this part are met.

(a) *Meat, meat byproducts, and meat food products from bovines.* The meat, meat byproduct, or meat food product, as defined by FSIS in 9 CFR 301.2—that those terms as applied to bison shall have a meaning comparable to those provided in 9 CFR 301.2 with respect to cattle, sheep, and goats—is derived from bovines that have been subject to a ruminant feed ban equivalent to the requirements established by the U.S. Food and Drug Administration at 21 CFR 589.2000 and meets the following conditions:

(1) The meat, meat byproduct, or meat food product is derived from bovines for which an air-injected stunning process was not used at slaughter; and

(2) The SRMs and small intestine of the bovines were removed at slaughter.

(b) *Whole or half carcasses of bovines.* The carcasses are derived from bovines for which an air-injected stunning process was not used at slaughter and that meet the following conditions:

(1) The bovines are subject to a ruminant feed ban equivalent to the requirements established by the U.S. Food and Drug Administration at 21 CFR 589.2000; and

(2) The SRMs and small intestine of the bovines were removed at slaughter.

(c) *Meat, meat byproducts, and meat food products from sheep or goats or other ovines or caprines.* The meat, meat byproduct, or meat food product, as defined by FSIS in 9 CFR 301.2, is derived from ovines or caprines that are from a flock or herd subject to a ruminant feed ban equivalent to the requirements established by the U.S. Food and Drug Administration at 21 CFR 589.2000, that were less than 12 months of age when slaughtered, and that meet the following conditions:

(1) The animals were slaughtered at a facility that either slaughters only sheep and/or goats or other ovines and caprines less than 12 months of age or complies with a segregation process approved by the national veterinary authority of the region of origin and the Administrator as adequate to prevent contamination or commingling of the meat with products not eligible for importation into the United States;

(2) The animals did not test positive for and were not suspect for a transmissible spongiform encephalopathy;

(3) The animals have not resided in a flock or herd that has been diagnosed with BSE; and

(4) The animals' movement is not restricted within Canada as a result of exposure to a transmissible spongiform encephalopathy.

(d) *Carcasses of ovines and caprines.* The carcasses are derived from ovines or caprines that are from a flock or herd subject to a ruminant feed ban equivalent to the requirements established by the U.S. Food and Drug Administration at 21 CFR 589.2000, that were less than 12 months of age when slaughtered, and that meet the following conditions:

(1) The animals were slaughtered at a facility that either slaughters only sheep and/or goats or other ovines and caprines less than 12 months of age or complies with a segregation process approved by the national veterinary authority of the region of origin and the Administrator as adequate to prevent contamination or commingling of the meat with products not eligible for importation into the United States;

(2) The animals did not test positive for and were not suspect for a transmissible spongiform encephalopathy;

(3) The animals have not resided in a flock or herd that has been diagnosed with BSE; and

(4) The animals' movement is not restricted within Canada as a result of exposure to a transmissible spongiform encephalopathy.

(e) *Meat or dressed carcasses of hunter-harvested wild sheep, goats, or other ruminants other than cervids.* The meat or dressed carcass (eviscerated and the head is removed) is derived from a wild sheep, goat, or other ruminant other than a cervid and meets the following conditions:

(1) The meat or dressed carcass is derived from an animal that has been legally harvested in the wild, as verified by proof such as a hunting license, tag, or the equivalent that the hunter must show to the United States Customs and Border Protection official; and

(2) The animal from which the meat is derived was harvested within a jurisdiction specified by the Administrator for which the game and wildlife service of the jurisdiction has informed the Administrator either that the jurisdiction conducts no type of game feeding program, or has complied with, and continues to comply with, a ruminant feed ban equivalent to the requirements established by the U.S. Food and Drug Administration at 21 CFR 589.2000.

(f) *Gelatin other than that allowed importation under § 94.18(c).* The gelatin is derived from the bones of bovines subject to a ruminant feed ban equivalent to the requirements established by the U.S. Food and Drug Administration at 21 CFR 589.2000 and from which SRMs and small intestine were removed.

(g) *Ports.* All products to be brought into the United States under this section must, if arriving at a land border port, arrive at one of the following ports: Eastport, ID; Houlton, ME; Detroit (Ambassador Bridge), Port Huron, and Sault St. Marie, MI; International Falls, MN; Sweetgrass, MT; Alexandria Bay, Buffalo (Lewiston Bridge and Peace Bridge), and Champlain, NY; Pembina and Portal, ND; Derby Line and Highgate Springs, VT; and Blaine (Pacific Highway and Cargo Ops), Lynden, Oroville, and Sumas (Cargo), WA.

PART 95—SANITARY CONTROL OF ANIMAL BYPRODUCTS (EXCEPT CASINGS), AND HAY AND STRAW, OFFERED FOR ENTRY INTO THE UNITED STATES

■ 13. The authority citation for part 95 continues to read as follows:

Authority: 7 U.S.C. 8301–8317; 21 U.S.C. 136 and 136a; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.4.

■ 14. Section 95.1 is amended by revising the definition of *inspector* and adding new definitions of *bovine, bovine spongiform encephalopathy (BSE) minimal-risk region, offal, positive for a transmissible spongiform encephalopathy, specified risk materials (SRMs), and suspect for a transmissible spongiform encephalopathy,* in alphabetical order, to read as follows:

§ 95.1 Definitions.

* * * * *

Bovine. Bos taurus, Bos indicus, and *Bison bison.*

Bovine spongiform encephalopathy (BSE) minimal-risk region. A region listed in § 94.18(a)(3) of this subchapter.

* * * * *

Inspector. Any individual authorized by the Administrator of APHIS or the Commissioner of Customs and Border Protection, Department of Homeland

Security, to enforce the regulations in this part.

* * * * *

Offal. The inedible parts of a butchered animal that are removed in dressing, consisting largely of the viscera and the trimmings, which may include, but are not limited to, brains, thymus, pancreas, liver, heart, kidney.

Positive for a transmissible spongiform encephalopathy. A sheep or goat for which a diagnosis of a transmissible spongiform encephalopathy has been made.

* * * * *

Specified risk materials (SRMs). Those bovine parts considered to be at particular risk of containing the bovine spongiform encephalopathy (BSE) agent in infected animals, as listed in the FSIS regulations at 9 CFR 310.22(a).

Suspect for a transmissible spongiform encephalopathy. (1) A sheep or goat that has tested positive for a transmissible spongiform encephalopathy or for the proteinase resistant protein associated with a transmissible spongiform encephalopathy, unless the animal is designated as positive for a transmissible spongiform encephalopathy; or

(2) A sheep or goat that exhibits any of the following signs and that has been determined to be suspicious for a transmissible spongiform encephalopathy by a veterinarian: Weight loss despite retention of appetite; behavior abnormalities; pruritus (itching); wool pulling; biting at legs or side; lip smacking; motor abnormalities such as incoordination, high stepping gait of forelimbs, bunny hop movement of rear legs, or swaying of back end; increased sensitivity to noise and sudden movement; tremor, "star gazing," head pressing, recumbency, or other signs of neurological disease or chronic wasting.

* * * * *

■ 15. Section 95.4 is amended as follows:

■ a. In paragraph (a) introductory text, the words "paragraphs (c) through (f)" are removed and the words "paragraphs (c) through (h)" are added in their place.

■ b. In paragraph (b), the words "paragraphs (d) and (f)" are removed and the words "paragraphs (d) and (h)" are added in their place.

■ c. In paragraph (c)(4), the first sentence is revised and a new sentence is added after the final sentence to read as set forth below.

■ d. Paragraph (c)(6) is revised to read as set forth below.

■ e. Paragraph (f) is redesignated as paragraph (h).

■ f. New paragraphs (f) and (g) are added to read as set forth below.

■ g. In newly redesignated paragraph (h), the introductory text, paragraph (h)(3) introductory text, and paragraph (h)(4) are revised to read as set forth below.

§ 95.4 Restrictions on the importation of processed animal protein, offal, tankage, fat, glands, certain tallow other than tallow derivatives, and serum due to bovine spongiform encephalopathy.

* * * * *

(c) * * *

(4) Except for facilities in regions listed in § 94.18(a)(3) of this subchapter, if the facility processes or handles any material derived from mammals, the facility has entered into a cooperative service agreement executed by the operator of the facility and APHIS. * * * In facilities in regions listed in § 94.18(a)(3) of this subchapter, the inspections that would otherwise be conducted by APHIS must be conducted at least annually by a representative of the government agency responsible for animal health in the region.

* * * * *

(6) Each shipment to the United States is accompanied by an original certificate signed by a full-time, salaried veterinarian of the government agency responsible for animal health in the region of origin certifying that the conditions of paragraph (c)(1) through (c)(3) of this section have been met, except that, for shipments of animal feed from a region listed in § 94.18(a)(3) of this subchapter, the certificate may be signed by a person authorized to issue such certificates by the veterinary services of the national government of the region of origin.

* * * * *

(f) Tallow otherwise prohibited importation under paragraph (a)(1) of this section may be imported into the United States if it meets the following conditions:

(1) The tallow is derived from bovines that have not been in a region listed in § 94.18(a)(1) or (a)(2) of this subchapter;

(2) The tallow is composed of less than 0.15 percent insoluble impurities;

(3) After processing, the tallow was not exposed to or commingled with any other animal origin material; and

(4) Each shipment to the United States is accompanied by an original certificate signed by a full-time salaried veterinary officer of the national government of the region of origin, or issued by a veterinarian designated by or accredited by the national government of the region of origin and endorsed by a full-time salaried veterinary officer of the national government of the region of origin, representing that the veterinarian issuing the certificate was authorized to do so. The certificate must state that the requirements of paragraphs (f)(1) through (f)(3) of this section have been met; and

(5) The shipment, if arriving at a U.S. land border port, arrives at a port listed in § 94.19(g) of this subchapter.

(g) Offal that is otherwise prohibited importation under paragraph (a)(1) of this section may be imported if the offal is derived from cervids or the offal is derived from bovines, ovines, or caprines from a region listed in § 94.18(a)(3) of this subchapter that have not been in a region listed in § 94.18(a)(1) or (a)(2) of this subchapter, and the following conditions are met:

(1) If the offal is derived from bovines, the offal:

(i) Contains no SRMs and is derived from bovines from which the SRMs and small intestine were removed;

(ii) Is derived from bovines for which an air-injected stunning process was not used at slaughter; and

(iii) Is derived from bovines that are subject to a ruminant feed ban equivalent to the requirements established by the U.S. Food and Drug Administration at 21 CFR 589.2000;

(2) If the offal is derived from ovines or caprines, the offal:

(i) Is derived from ovines or caprines that were less than 12 months of age when slaughtered and that are from a flock or herd subject to a ruminant feed ban equivalent to the requirements established by the U.S. Food and Drug Administration at 21 CFR 589.2000;

(ii) Is not derived from ovines or caprines that have tested positive for or are suspect for a transmissible spongiform encephalopathy;

(iii) Is not derived from animals that have resided in a flock or herd that has been diagnosed with BSE; and

(iv) Is derived from ovines or caprines whose movement was not restricted in the BSE minimal-risk region as a result of exposure to a transmissible spongiform encephalopathy.

(3) Each shipment to the United States is accompanied by an original certificate signed by a full-time salaried veterinary officer of the national government of the region of origin, or issued by a veterinarian designated by or accredited by the national government of the region of origin and endorsed by a full-time salaried veterinary officer of the national government of the region of origin, representing that the veterinarian issuing the certificate was authorized to do so. The certificate must state that the requirements of paragraph (g)(1) or (g)(2) of this section have been met; and

(4) The shipment, if arriving at a U.S. land border port, arrives at a port listed in § 94.19(g) of this subchapter.

(h) *Transit shipment of articles.* Articles that are prohibited importation into the United States in accordance with this section may transit air and ocean ports in the United States for immediate export if the conditions of paragraphs (h)(1) through (h)(3) of this section are met. If such commodities are derived from bovines, sheep, or goats from a region listed in § 94.18(a)(3) of this subchapter, they are eligible to transit the United States by overland transportation if the requirements of paragraphs (h)(1) through (h)(4) of this section are met:

* * * * *

(3) The person moving the articles notifies, in writing, the inspector at both the place in the United States where the articles will arrive and the port of export before such transit. The notification includes the following:

* * * * *

(4) The articles are eligible to enter the United States in accordance with this section and are accompanied by the certification required by this section. Additionally, the following conditions must be met:

(i) The shipment is exported from the United States within 7 days of its entry;

(ii) The commodities are not transloaded while in the United States;

(iii) A copy of the import permit required under paragraph (h)(2) of this section is presented to the inspector at the port of arrival and the port of export in the United States.

* * * * *

PART 96—RESTRICTION OF IMPORTATIONS OF FOREIGN ANIMAL CASINGS OFFERED FOR ENTRY INTO THE UNITED STATES

■ 16. The authority citation for part 96 continues to read as follows:

Authority: 7 U.S.C. 8301–8317; 21 U.S.C. 136 and 136a; 7 CFR 2.22, 2.80, and 371.4.

■ 17. In § 96.1, a definition of *authorized inspector* is added in alphabetical order to read as follows:

§ 96.1 Definitions.

* * * * *

Authorized inspector. Any individual authorized by the Administrator of APHIS or the Commissioner of Customs and Border Protection, Department of Homeland Security, to enforce the regulations in this subpart.

* * * * *

■ 18. In § 96.2, paragraph (b) is revised to read as follows:

§ 96.2 Prohibition of casings due to African swine fever and bovine spongiform encephalopathy.

* * * * *

(b) *Bovine or other ruminant casings.* The importation of casings, except stomachs, from bovines and other ruminants that originated in or were processed in any region listed in § 94.18(a) this subchapter is prohibited, except that casings derived from sheep that were slaughtered in a region listed in § 94.18(a)(3) of this subchapter at less than 12 months of age and that were from a flock subject to a ruminant feed ban equivalent to the requirements established by the U.S. Food and Drug Administration at 21 CFR 589.2000 may be imported, provided the casings are accompanied by a certificate that states that the casings were derived from sheep that met the conditions of this paragraph and that meets the following conditions:

(1) The certificate is written in English;

(2) The certificate is signed by an individual eligible to issue the certificate required under § 96.3; and

(3) The certificate is presented to an authorized inspector at the port of arrival.

* * * * *

■ 19. In § 96.3, a new paragraph (d) is added to read as follows:

§ 96.3 Certificate for Animal Casings.

* * * * *

(d) In addition to meeting the other requirements of this section, the certificate accompanying sheep casings from a region listed in § 94.18(a)(3) of this subchapter must state that the sheep from which the casings were derived were less than 12 months of age when slaughtered and were subject to a ruminant feed ban equivalent to the requirements established by the U.S. Food and Drug Administration at 21 CFR 589.2000.

* * * * *

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

Bill Hawks,

Under Secretary for Marketing and Regulatory Programs.

[FR Doc. 04–28593 Filed 12–29–04; 3:00 pm]

BILLING CODE 3410–34–P

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,

APHIS, Station 3C71, 4700 River Road Unit 118, Riverdale, MD 20737–1238. Please state that your comment refers to Docket No. 03–080–5.

• 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. 03–080–5" 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 January 4, 2005, the Animal and Plant Health Inspection Service (APHIS) published in the **Federal Register** (70 FR 460–553, Docket No. 03–080–3) a final rule 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 to add Canada to this category. The final rule also provides for the importation of certain live ruminants and ruminant products and byproducts from such regions under certain conditions.

Also in the January 4, 2005, issue of the **Federal Register**, we published a notice (70 FR 554, Docket No. 03–080–4) announcing the availability of, and requesting comments on, a final 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 final rule. APHIS' review and analysis of the potential environmental impacts associated with those importations were documented in the 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)." We announced that the EA would be available to the public for review and comment until February 3, 2005.

We have become aware, however, that the version of the EA that was made available on January 4, 2005, contained some transcription errors that resulted in the omission of several references to an updated APHIS risk analysis regarding the final rule, as well as the incorrect formatting of several source citations. We have corrected those errors.

We are giving notice that the corrected version of the EA is available to the public for review and comment, and we are extending the comment period on the EA until February 17, 2005.

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 18th day of January 2005.

W. Ron DeHaven,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 05–1202 Filed 1–19–05; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Foreign Agricultural Service

Trade Adjustment Assistance for Farmers

AGENCY: Foreign Agricultural Service, USDA.

ACTION: Notice.

The Administrator, Foreign Agricultural Service (FAS), today accepted a petition filed by the Olive Growers Council, Visalia, California 93291, for trade adjustment assistance for olive producers in the state of California. The Administrator will determine within 40 days whether or not increasing imports of processed olives in a saline solution contributed importantly to a decline in domestic producer prices of 20 percent or more during the marketing period beginning August 2003 and ending July 2004. If the determination is positive, all producers who market their olives in California will be eligible to apply to the Farm Service Agency for technical assistance at no cost and for adjustment assistance payments.

FOR FURTHER INFORMATION CONTACT: Jean-Louis Pajot, Coordinator, Trade Adjustment Assistance for Farmers, FAS, USDA, (202) 720–2916, e-mail: *trade.adjustment@fas.usda.gov*.

Dated: January 6, 2005.

A. Ellen Terpstra,

Administrator, Foreign Agricultural Service.

[FR Doc. 05–1083 Filed 1–19–05; 8:45 am]

BILLING CODE 3410–10–P

DEPARTMENT OF AGRICULTURE

Foreign Agricultural Service

Trade Adjustment Assistance for Farmers

AGENCY: Foreign Agricultural Service, USDA.

ACTION: Notice.

The Administrator, Foreign Agricultural Service (FAS), today accepted a petition filed by the Spokane Hutterian Brethren, Reardan, Washington 99029, for trade adjustment assistance for seed potato producers in the state of Washington. The Administrator will determine within 40 days whether or not increasing seed potato imports contributed importantly to a decline in domestic producer prices of 20 percent or more during the marketing period beginning February 2004 and ending May 2004. If the determination is positive, all producers who market their seed potatoes in

Regulatory Flexibility Act

As Acting Director of the Office of Government Ethics, I certify under the Regulatory Flexibility Act (5 U.S.C. chapter 6) that this rulemaking will not have a significant economic impact on a substantial number of small entities because it primarily affects Federal employees.

Paperwork Reduction Act

The Paperwork Reduction Act (44 U.S.C. chapter 35) does not apply because this amendatory rulemaking does not contain information collection requirements that require the approval of the Office of Management and Budget.

Unfunded Mandates Reform Act

For purposes of the Unfunded Mandates Reform Act of 1995 (2 U.S.C. chapter 25, subchapter II), the final rule will not significantly or uniquely affect small governments and will not result in increased expenditures by State, local and tribal governments, in the aggregate, or by the private sector, of $100 million or more (as adjusted for inflation) in any one year.

Congressional Review Act

The Office of Government Ethics has determined that this amendatory rulemaking is a nonmajor rule under the Congressional Review Act (5 U.S.C. chapter 8) and will submit a report thereon to the U.S. Senate, House of Representatives and General Accounting Office in accordance with that law at the same time this rulemaking document is sent to the Office of the Federal Register for publication in the **Federal Register**.

Executive Order 12866

In promulgating these technical amendments, OGE has adhered to the regulatory philosophy and the applicable principles of regulation set forth in section 1 of Executive Order 12866, Regulatory Planning and Review. These amendments have not been reviewed by the Office of Management and Budget under that Executive order, since they are not deemed "significant" thereunder.

Executive Order 12988

As Acting Director of the Office of Government Ethics, I have reviewed this final amendatory regulation in light of section 3 of Executive Order 12988, Civil Justice Reform, and certify that it meets the applicable standards provided therein.

List of Subjects

5 CFR Part 2634

Certificates of divestiture, Conflict of interests, Financial disclosure, Government employees, Penalties, Privacy, Reporting and recordkeeping requirements, Trusts and trustees.

5 CFR Part 2635

Conflict of interests, Executive branch standards of ethical conduct, Government employees.

Approved: March 4, 2005.

Marilyn L. Glynn,

Acting Director, Office of Government Ethics.

■ For the reasons set forth in the preamble, the Office of Government Ethics is amending 5 CFR parts 2634 and 2635 as follows:

PART 2634—EXECUTIVE BRANCH FINANCIAL DISCLOSURE, QUALIFIED TRUSTS, AND CERTIFICATES OF DIVESTITURE

■ 1. The authority citation for part 2634 continues to read as follows:

Authority: 5 U.S.C. App. (Ethics in Government Act of 1978); 26 U.S.C. 1043; Pub. L. 101–410, 104 Stat. 890, 28 U.S.C. 2461 note (Federal Civil Penalties Inflation Adjustment Act of 1990), as amended by Sec. 31001, Pub. L. 104–134, 110 Stat. 1321 (Debt Collection Improvement Act of 1996); E.O. 12674, 54 FR 15159, 3 CFR, 1989 Comp., p. 215, as modified by E.O. 12731, 55 FR 42547, 3 CFR, 1990 Comp., p. 306.

§ 2634.304 [Amended]

■ 2. Section 2634.304 is amended by:
■ a. Removing the dollar amount "$285" in paragraphs (a) and (b) and in example 1 following paragraph (d) and adding in its place in each instance the dollar amount "$305";
■ b. Removing the dollar amount "$114" in paragraph (d) and in examples 1 and 2 following paragraph (d) and adding in its place in each instance the dollar amount "$122"; and
■ c. Removing the dollar amount "$285" in examples 3 and 4 following paragraph (d) and adding in its place in each instance the dollar amount "$305".

PART 2635—STANDARDS OF ETHICAL CONDUCT FOR EMPLOYEES OF THE EXECUTIVE BRANCH

■ 3. The authority citation for part 2635 continues to read as follows:

Authority: 5 U.S.C. 7301, 7351, 7353; 5 U.S.C. App. (Ethics in Government Act of 1978); E.O. 12674, 54 FR 15159, 3 CFR, 1989 Comp., p. 215, as modified by E.O. 12731, 55 FR 42547, 3 CFR, 1990 Comp., p. 306.

§ 2635.204 [Amended]

■ 4. Section 2635.204 is amended by:
■ a. Removing the dollar amount "$285" in paragraph (g)(2) and in examples 1 and 2 (in the latter of which it appears twice) following paragraph (g)(6) and adding in its place in each instance the dollar amount "$305"; and
■ b. Removing the dollar amount "$570" in example 2 following paragraph (g)(6) and adding in its place the dollar amount "$610".

[FR Doc. 05–4879 Filed 3–10–05; 8:45 am]
BILLING CODE 6345–02–P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Parts 94 and 95

[Docket No. 03–080–6]

RIN 0579–AB73

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

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Final rule; partial delay of applicability.

SUMMARY: The amendments in this final rule delay until further notice the applicability of certain provisions of the rule entitled "Bovine Spongiform Encephalopathy; Minimal-Risk Regions and Importation of Commodities," published in the **Federal Register** on January 4, 2005, 70 FR 460–553. That rule was scheduled to amend the regulations in 9 CFR parts 93, 94, 95, and 96, effective March 7, 2005, to establish a category of regions that present a minimal risk of introducing bovine spongiform encephalopathy into the United States via live ruminants and ruminant products and byproducts and to add Canada to this category. That rule included conditions for the importation of certain live ruminants and ruminant products from such regions.

DATES: Effective March 7, 2005.

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: On January 4, 2005, we published a final rule in the **Federal Register** (70 FR 460–553, Docket No. 03–080–3) that establishes a category of regions that present a minimal risk of introducing

bovine spongiform encephalopathy into the United States via live ruminants and ruminant products and byproducts and that adds Canada to this category. The rule also establishes conditions for the importation of certain live ruminants and ruminant products from such regions. The rule was scheduled to become effective on March 7, 2005.[1]

Pursuant to an announcement by the Secretary of Agriculture on February 9, 2005, this document delays the applicability of the provisions in that rule as they apply to the importation from Canada of the following commodities when derived from bovines 30 months of age or older when slaughtered: (1) Meat, meat food products, and meat byproducts other than liver;[2] (2) whole or half carcasses; (3) offal; (4) tallow composed of less than 0.15 percent insoluble impurities that is not otherwise eligible for importation under 9 CFR 95.4(a)(1)(i); and (5) gelatin derived from bones of bovines that is not otherwise eligible for importation under 9 CFR 94.18(c).

If the courts allow the January 4, 2005, rule to go into effect while this delay of applicability is in effect, the commodities listed above that are derived from bovines less than 30 months of age when slaughtered must be accompanied to the United States by certification that (1) the age requirement has been met and (2) the commodity was processed in an establishment inspected by the Canadian Food Inspection Agency (CFIA) that operates in compliance with an approved CFIA program to prevent commingling of ruminant products eligible for export to the United States with ruminant products ineligible for export to the United States. Such certification must be made by a full-time salaried veterinary officer of Canada, or by a veterinarian designated and accredited by the Canadian Government, provided the certification is endorsed by a full-time salaried veterinary officer of Canada who represents that the veterinarian issuing the certification was authorized to do so.

To the extent that 5 U.S.C. 553 applies to this action, it is exempt from notice and comment because it constitutes a rule of procedure under 5 U.S.C. 553(b)(A). Alternatively, the Department's implementation of this action without opportunity for public comment is based on the good cause exceptions in 5 U.S.C. 553(b)(B) and 553(d)(3). Seeking public comment is impracticable, unnecessary, and contrary to the public interest. The delay of applicability is necessary to give Department officials the opportunity for further review and consideration of the specified provisions. Given the scheduled effective date of those provisions, seeking prior public comment on this delay would have been impractical, as well as contrary to the public interest, in the orderly promulgation and implementation of regulations.

[1] On March 2, 2005, Judge Richard F. Cebull of the U.S. District Court for the District of Montana ordered that the implementation of APHIS' January 4, 2005, final rule is preliminarily enjoined.

[2] In accordance with an August 8, 2003, announcement by the Secretary of Agriculture, since August 2003 APHIS has issued permits for the importation into the United States from Canada of certain fresh or frozen liver from bovines of any age.

List of Subjects

9 CFR Part 94

Animal diseases, Imports, Livestock, Meat and meat products, Milk, Poultry and poultry products, Reporting and recordkeeping requirements.

9 CFR Part 95

Animal feeds, Hay, Imports, Livestock, Reporting and recordkeeping requirements, Straw, Transportation.

■ Accordingly, we are amending 9 CFR parts 94 and 95 as follows:

PART 94—RINDERPEST, FOOT-AND-MOUTH DISEASE, FOWL PEST (FOWL PLAGUE), EXOTIC NEWCASTLE DISEASE, AFRICAN SWINE FEVER, CLASSICAL SWINE-FEVER, AND BOVINE SPONGIFORM ENCEPHALOPATHY: PROHIBITED AND RESTRICTED IMPORTATIONS

■ 1. The authority citation for part 94 continues to read as follows:

Authority: 7 U.S.C. 450, 7701–7772, and 8301–8317; 21 U.S.C. 136 and 136a; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.4.

■ 2. Section 94.19 is amended by adding notes at the end of paragraphs (a), (b), and (f) to read as follows:

§ 94.19 Restrictions on importation from BSE minimal-risk regions of meat and edible products from ruminants.

* * * * *

(a) * * *

Note to paragraph (a): The applicability of paragraph (a) to meat, meat byproducts other than liver, and meat food products when such commodities are derived from bovines that were 30 months of age or older when slaughtered is delayed indefinitely.

(b) * * *

Note to paragraph (b): The applicability of paragraph (b) to whole or half carcasses derived from bovines that were 30 months of age or older when slaughtered is delayed indefinitely.

* * * * *

(f) * * *

Note to paragraph (f): The applicability of paragraph (f) to gelatin derived from the bones of bovines that were 30 months of age or older when slaughtered is delayed indefinitely.

* * * * *

PART 95—SANITARY CONTROL OF ANIMAL BYPRODUCTS (EXCEPT CASINGS), AND HAY AND STRAW, OFFERED FOR ENTRY INTO THE UNITED STATES

■ 3. The authority citation for part 95 continues to read as follows:

Authority: 7 U.S.C. 8301–8317; 21 U.S.C. 136 and 136a; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.4.

■ 4. Section 95.4 is amended by adding notes at the end of paragraphs (f) and (g) to read as follows:

§ 95.4 Restrictions on the importation of processed animal protein, offal, tankage, fat, glands, certain tallow other than tallow derivatives, and serum due to bovine spongiform encephalopathy.

* * * * *

(f) * * *

Note to paragraph (f): The applicability of paragraph (f) to tallow derived from bovines that were 30 months of age or older when slaughtered is delayed indefinitely.

(g) * * *

Note to paragraph (g): The applicability of paragraph (g) to offal derived from bovines that were 30 months of age or older when slaughtered is delayed indefinitely.

* * * * *

Done in Washington, DC, this 8th day of March 2005.

Bill Hawks,

Under Secretary for Marketing and Regulatory Programs.

[FR Doc. 05–4917 Filed 3–10–05; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2004–19470; Directorate Identifier 2003–NM–268–AD; Amendment 39–13997; AD 2005–05–08]

RIN 2120–AA64

Airworthiness Directives; Boeing Model 747–100B SUD, –300, –400, and –400D Series Airplanes

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Final rule.

CERTIFICATE OF SERVICE

I hereby certify that, on the 29th day of March 2005, I have caused two copies of the Answering Brief of Ranchers Cattlemen Action Legal Fund United Stockgrowers of America and one copy of its Supplemental Excerpts of Record, along with its Motion for a One-Day Enlargement of Time, to be served by hand delivery or Federal Express upon:

Joshua Waldman, Esq.
Appellate Litigation Counsel
U.S. Department of Justice
950 Pennsylvania Avenue, N.W.
Room 7232
Washington, D.C. 20530
(202) 514-0236
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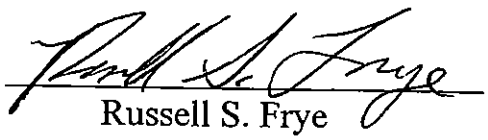

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