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IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MONTANA  
BILLINGS DIVISION

RANCHERS CATTLEMEN ACTION LEGAL FUND  
UNITED STOCKGROWERS OF AMERICA,

Plaintiff,

vs.

UNITED STATES DEPARTMENT OF AGRICULTURE,  
ANIMAL AND PLANT HEALTH INSPECTION  
SERVICE, et al.,

Defendants.

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) Cause No. CV-05-06-BLG-RFC  
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**MEMORANDUM OF POINTS  
AND AUTHORITIES IN  
SUPPORT OF PLAINTIFF'S  
APPLICATION FOR  
PRELIMINARY INJUNCTION**

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## STATEMENT OF THE CASE

This action concerns a decision by the United States Department of Agriculture (“USDA”) Animal and Plant Health Inspection Service (“APHIS”) to lift a ban on the importation of live cattle and edible bovine products from Canada for human consumption. In a final rule published January 4, 2005 and titled “Bovine Spongiform Encephalopathy, Minimal-Risk Regions and Importation of Commodities; Final Rule and Notice,” 70 Fed. Reg. 460 (the “Final Rule”), USDA reversed a May 29, 2003, APHIS decision banning imports of cattle and edible bovine products from Canada, after a Canadian dairy cow was confirmed to have bovine spongiform encephalopathy (“BSE”), commonly known as “Mad Cow Disease.” The Final Rule is scheduled to go into effect on March 7, 2005, and Plaintiff seeks to enjoin it until the lawfulness of the Final Rule can be reviewed in full by this Court.

BSE is a degenerative, invariably fatal neurological disorder of cattle that results from infection by an unconventional transmissible agent. BSE was not known to exist in the United States until the discovery in late 2003 of an infected dairy cow in Washington State that had previously been imported from Canada. *See* 68 Fed. Reg. 62,386 (November 4, 2003) (included as Exhibit 1 to this Memorandum for the convenience of the Court). Eating meat products contaminated with the agent for BSE is believed to cause variant Creutzfeldt-Jakob Disease (“vCJD”) in humans, a degenerative, invariably fatal neurological disease for which there is no known cure. Both BSE and vCJD are generally thought to result from infection with a type of mis-formed protein called “prions.”

Eating contaminated bovine meat and other products is believed to have resulted in the death of over 100 people in the United Kingdom and at least one person in the United States, as well. Because of the incurable nature of this horrible, degenerative disease, fears about Mad

Cow Disease decimated the market for beef from the United Kingdom in the 1990s and had a substantial adverse effect on demand for beef in the United States. Moreover, fears that consumption of beef from the United States carries a risk of contracting vCJD because of Canadian cattle or beef products imported into the United States caused the largest foreign export customers of American beef, Japan and Korea, to cut off imports of beef from the United States. *See generally* Declaration of John J. VanSickle, Ph.D., Director of the International Agricultural Trade and Policy Center of the University of Florida, Exhibit 6 to this memorandum.

On May 29, 2003, USDA, acting “on an emergency basis to prevent the introduction of BSE into the United States,” issued regulations that include Canada on a list of regions where BSE is known to exist, based on a case of BSE in the Province of Alberta reported by the Canadian Food Inspection Agency (CFIA) on May 20, 2003. 68 Fed. Reg. 31,939, 31,940 (May 29, 2003) (Exhibit 2 to this Memorandum). The regulations prohibit importation of ruminants, as well as importation of meat, meat products, and certain other products and byproducts of ruminants, that have been in regions where BSE is known to exist. *Id.* The regulations provide that the Administrator of APHIS 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. *Id.*

The effect of the May 29, 2003 rule was that Canadian cattle and Canadian beef were banned from importation into the United States. Under intense pressure from the Canadian government and some U.S. meat packers, on August 8, 2003, Secretary of Agriculture Ann M. Veneman announced that USDA would grant 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* Attachment J to Exhibit 5 to this Memorandum.

On November 4, 2003, USDA commenced a rulemaking to amend these regulations regarding the importation of animals and animal products, to create a new category of regions that present “a minimal risk of introducing” BSE into the U.S. via live ruminants and ruminant products, and to place Canada in this new category. 68 Fed. Reg. 62,386 (the “Proposed Rule,” included as Exhibit 3). USDA proposed to allow the importation of certain live ruminants and ruminant products and byproducts from such regions under certain conditions. This included fresh meat from bovines less than 30 months of age, fresh bovine liver, and fresh bovine tongues. *Id.* at 62,394-95. Specific requirements for the slaughtering of cattle and processing the meat were included in the proposal. *Id.*

USDA re-opened the comment period on the proposed rule on March 8, 2004, in part to acknowledge the detection of BSE in a Canadian-origin cow in Washington State, which occurred after publication of the proposed rule and the USDA Risk Analysis for the proposed rule. 69 Fed. Reg. 10,633 (March 8, 2004) (Exhibit 4 to this Memorandum). Among other things, that notice stated: “We now believe it would not be necessary to require that beef imported from BSE minimal-risk regions be derived only from cattle less than 30 months of age, provided the equivalent measures are in place to ensure that SRMs [“specified risk materials” – skull, brain, vertebral column, spinal cord, and other neurological materials] are removed when the animals are slaughtered, and that such other measures as are necessary are in place. We believe such measures are already being taken in Canada. We invite comment from the public regarding this change to the provisions we proposed in November 2003 regarding the importation of beef.” *Id.* at 10,635. Plaintiff, Ranchers Cattlemen Action Legal Fund United Stockgrowers of America (“R-CALF USA”), and over 3000 others submitted written comments on the proposal. *See* Exhibit 5 Attachment E and 70 Fed. Reg. at 465.

Subsequently, and before completing the proposed rulemaking, USDA posted on the APHIS website a memorandum stating that, effective April 19, 2004, holders of existing beef import permits could import “all bovine meat products” from Canada simply by providing a statement that the meat was processed in “establishments that are certified to FSIS [USDA Food Safety and Inspection Service] as eligible for export to the United States.” That action was the subject of an earlier action by R-CALF USA in this Court that resulted in the issuance of a temporary restraining order against imports of that expanded list of products, *Ranchers Cattlemen Action Legal Fund United Stockgrowers of America v. U.S. Dept. of Agriculture, et al.*, No. CV-04-51-BLG-RFC. That temporary restraining order was converted to a preliminary injunction by stipulation of the parties. (The preliminary injunction expired January 5, 2005, and R-CALF USA has moved for voluntary dismissal of that action.)

On December 29, 2004, then-Secretary of Agriculture Veneman announced the issuance of a final rule creating a category of regions with minimal risk of BSE, setting conditions for importation of ruminants and of meat and other ruminant products from such regions, and naming Canada as the sole region with that classification. The final rule, “Bovine Spongiform Encephalopathy, Minimal-Risk Regions and Importation of Commodities; Final Rule and Notice,” was published on January 4, 2005, at 70 Fed. Reg. 460 (the “Final Rule”) (Exhibit 1).

Also on December 29, 2004, the CFIA announced publicly that yet another cow in Alberta had been tentatively identified as having BSE. That diagnosis was confirmed on January 2, 2005. On January 11, 2005, CFIA announced that a fourth cow from Alberta, this one only six years and nine months old, had been confirmed to have BSE. Bullard Declaration, Exhibit 5, at 7-8 and Attachments L-M. Neither the discovery of a BSE-infected Canadian-born cow in Washington State in December 2003 nor the discovery of additional BSE-infected cows in Canada at the end of 2004 and beginning of 2005 caused USDA to revise or seriously reconsider

its determination that opening the border to Canadian cattle and meat would present little risk to U.S. animals, human consumers, and the livestock industry. *Id.* The Final Rule is to become effective on March 7, 2005.

### **SUMMARY OF ARGUMENT**

USDA's Final Rule published January 4, 2005 will lift a ban on imports of live cattle less than 30 months of age and most kinds of bovine meat and other tissue from Canada for human consumption, effective March 7, 2005. USDA's action is an exception to the general policy of the United States (and many other nations) not to allow importation of cattle or beef from countries, such as Canada, known to have cattle infected with BSE, commonly known as "Mad Cow Disease." As a result of the Final Rule, plaintiff R-CALF USA and its members will be immediately and irreparably harmed. Imports of Canadian cattle will present a risk of infection of the U.S. herd, adversely affect prices for cattle in the U.S., cause domestic consumers of beef to question its safety, and may result in further constraints on exports of U.S. beef. In addition, R-CALF USA members and other members of the public will be exposed to greater risk of disease once Canadian cattle and beef enter the U.S. The seriousness of these concerns is underlined by the disclosure of two additional cases of BSE in Canada within the past few weeks.

R-CALF USA has a substantial likelihood of demonstrating that USDA's issuance of the Final Rule was arbitrary, capricious, and not in accordance with procedures required by the Administrative Procedure Act. USDA lacks a sound scientific basis for subjecting U.S. consumers to the risk of contracting variant Creutzfeldt-Jakob Disease, a fatal neurological disease for which there is no known cure, from Canadian bovine meat and meat products. It has

failed to assess in a meaningful way the human health risks of the Final Rule and to explain the criteria by which it determined those risks to be acceptable. In attempting to explain away the risks, USDA made critical assumptions that were inconsistent with scientific data before the agency and, in some cases, inconsistent with other USDA assumptions and conclusions. USDA failed to exercise the caution in protecting domestic animal and human health that its statutory mandates require, relaxing prior requirements and abandoning more-conservative positions without adequate justification. Key aspects of USDA's decision-making were not subjected to public comment, and key conclusions were not explained adequately or at all.

R-CALF USA also has a substantial likelihood of demonstrating that USDA has failed to comply with the National Environmental Policy Act and the Regulatory Policy Act. USDA totally ignored most of the environmental impacts of authorizing the shipment of millions of head of cattle into the U.S. It ignored the likely adverse effects of allowing imports from a country known to have BSE on domestic consumer demand for beef and on export markets that already have been devastated by the discovery of a Canadian-raised cow in the U.S. with BSE. It failed to consider the mitigation of adverse effects on small businesses that could be obtained through options such as requiring labeling of Canadian beef or allowing U.S. facilities to test the cattle they slaughter.

The substantial, irreparable injury R-CALF USA members will suffer from the Final Rule is almost self-evident. USDA projects that producers such as R-CALF USA members will suffer losses of \$2.5 to 3 billion due to competition from Canadian cattle, which will be sold at low prices because other countries will not buy Canadian cattle or beef due to its BSE problem. Additionally, experience shows that once meat derived from Canadian cattle has been co-mingled with U.S.-produced beef, BSE fears will diminish domestic and consumer confidence in the U.S. beef supply.

The potential damage to human health, the health of U.S. cattle, and the economic well-being of the domestic cattle industry are very serious. R-CALF USA is raising substantial questions about the procedural and substantive legitimacy of the Final Rule, and the balance of hardships clearly favors maintaining the status quo.

### ARGUMENT

The traditional criteria for granting preliminary injunctive relief are: 1) a substantial likelihood of success on the merits; 2) the possibility of irreparable injury to the plaintiff if injunctive relief is not granted; 3) a balance of hardships favoring the plaintiff; and 4) advancement of the public interest. *Los Angeles Mem'l Coliseum Comm'n v. Nat'l Football League*, 634 F.2d 1197, 1201 (9<sup>th</sup> Cir. 1980); *Textile Unlimited, Inc. v. A..BMH and Co., Inc.*, 240 F.3d 781, 786 (9<sup>th</sup> Cir. 2001). However, in the Ninth Circuit, the moving party may meet its burden by demonstrating either: (1) a combination of probable success on the merits and the possibility of irreparable injury, or (2) that the plaintiff's papers raise "serious questions" on the merits and the balance of hardships tips sharply in its favor. *Los Angeles Mem'l Coliseum Comm'n*, 634 F.2d at 1201; *Stuhlberg Int'l Sales Co., Inc. v. John D. Brush and Co., Inc.*, 240 F.3d 832, 840-41 (9<sup>th</sup> Cir. 2001). These two schemes represent a sliding scale where the required degree of irreparable harm increases as the probability of success decreases. *Friends of the Clearwater v. McAllister*, 214 F. Supp. 2d 1083, 1086 (D. Mont. 2002). Furthermore, the plaintiff must show that there is a significant threat of irreparable injury. *Id.* A preliminary injunction is not a preliminary adjudication on the merits but rather "a device for preserving status quo and preventing irreparable loss of rights before judgment." *Textile Unlimited*, 240 F.3d at 786. In this case, all factors favor the issuance of a preliminary injunction.

**I. PLAINTIFF IS SUBSTANTIALLY LIKELY TO PREVAIL ON THE MERITS.**

**A. Arbitrary and Capricious Action under the Administrative Procedure Act**

When reviewing an agency action such as the Final Rule under the Administrative Procedure Act (“APA”), the Court must “hold unlawful and set aside agency actions, findings, and conclusions found to be – (A) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law....” 5 U.S.C. § 706(2). An agency acts in a way that is arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law when it fails to apply criteria for its action contained in relevant statutes, applies criteria for its decision not authorized by its statutory authority, fails to consider relevant information, fails adequately to explain the basis for its action or to respond to important public comments, acts inconsistent with the purpose and intent of the statutes granting it authority, or offers an explanation for its action that runs counter to the evidence before it. *See, e.g., Motor Vehicle Mfrs. Ass’n v. State Farm Mutual*, 463 U.S. 29, 43 (1983).

In considering whether an agency acted in an arbitrary and capricious manner, a court must “carefully review the record to ‘ensure that agency decisions are founded on a reasoned evaluation of the relevant factors,’” *Ariz. Cattle Growers’ Ass’n v. United States Fish & Wildlife Service*, 273 F.3d 1229, 1236 (9th Cir. 2001) (quoting *Marsh v. Or. Natural Res. Council*, 490 U.S. 360, 378 (1989)). Courts should not “‘rubber-stamp . . . administrative decisions that they deem inconsistent with a statutory mandate or that frustrate the congressional policy underlying a statute,’” *id.* (quoting *NLRB v. Brown*, 380 U.S. 278, 291-92 (1965)).

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). *Accord, Int’l Brotherhood of Teamsters v.*

*United 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 (9<sup>th</sup> 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).

The following sections provide a few examples of the ways in which R-CALF USA intends to present facts that, applying the legal criteria set forth above, make it likely that R-CALF USA will prevail on the merits of the claims presented in its complaint.

**1. USDA failed adequately to assess the impact of its action on human health.**

The Animal Health Protection Act directs the Secretary of USDA to protect the health and welfare of the people of the United States. 7 U.S.C. § 8301(5)(B)(iii); *see also* 7 U.S.C. § 8301(1)(B). USDA's action in issuing the Final Rule provides no assurance that the risk to human health is minimized, and USDA has not explained the criteria and basis for its conclusion that the increased risk presented by imports of Canadian cattle and beef is acceptable. USDA's failure to do so renders its action arbitrary and capricious. *See Harlan Land Co. v. USDA*, 186 F. Supp. 2d at 1085-87 (APHIS failed to define "negligible risk" in Argentine citrus decision).

R-CALF USA participated in the public comment period on the proposed rule and thoroughly reviewed the documents USDA relied upon for the proposed rule. None of those documents contained an adequate assessment of the impact on human health of importation of

Canadian beef. *See* Declaration of Louis Anthony Cox, Jr., Exhibit 7 to this Memorandum, at 3-4; Exhibit 5 Attachment E Exh. B. The same is true of the documents on which USDA says it relied in promulgating the Final Rule. Cox Declaration, Exhibit 7, at 4-5, 7-12.

Rather than perform a quantitative assessment of the risks of various options, USDA made assumptions and qualitative judgments. USDA's risk assessment assumed that the prevalence of BSE in the Canadian herd is "very low," without any apparent support in the administrative record. *See, e.g.*, Cox Declaration, Exhibit 7 at 5-6. It relied on numerous assumptions for which it failed to demonstrate justification. *Id.* at 7-8. Neither the Harvard risk assessment nor the USDA Risk Analysis contained an assessment of the risk of consumers contracting vCJD from consuming Canadian beef, other than subjective conclusions that the risk will be "low" or "very low." *Id.* at 4, 7-12. Indeed, APHIS stated 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.

Presented with USDA's conclusions that the risks to U.S. cattle and consumers are "low," without any definition of what that means and why the risks presented by the Final Rule are acceptable, members of the public, as well as this Court, have no way of assessing the merits of USDA's action. Would the Final Rule be reasonable if it resulted in one additional case of BSE in an animal in the United States? Ten additional cases? Would the perceived benefits of the Final Rule outweigh a probability of causing one more death from vCJD in this country? Ten more deaths?

APHIS' action in this case is remarkably similar to its action in another reported case, *Harlan Land Co. v. USDA*, 186 F. Supp. 2d 1076. There, the United States District Court for the Eastern District of California concluded that APHIS' failure to define "negligible risk" rendered its risk assessment inadequate and its decision unsupported by the administrative record. *Id.* at

1087. There, APHIS persisted in applying an undefined standard of “negligible risk,” despite public comments that this concept was undefined and impossible to determine—similar to comments that R-CALF USA made on the Proposed Rule and the March 8, 2004 notice. *Cf. id.* at 1085-86 *with* Exhibit 5 Attachment E. The only difference is that in the *Harlan Land* case, APHIS was assessing the risks to domestic plants from possible pests associated with the importation of citrus from Argentina. *Id.* Here, APHIS applied the same arbitrary approach to a decision that subjects the entire U.S. beef industry to potentially catastrophic damage and that presents a real, although unquantified, risk of death for U.S. consumers.

Clearly, USDA’s failure to conduct a proper risk assessment, and its failure to articulate any standards by which it has judged the risks of these potentially terrible outcomes to be acceptable, renders its action arbitrary and capricious and unsupported by the record. *Id.* at 1084, 1094-95. Here, where increased risk to human health is at issue, 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 id.* In light of the paucity of information indicating that USDA has fulfilled its statutory mandate to protect the health and welfare of the people of the United States, R-CALF USA has a substantial likelihood of prevailing on the merits and demonstrating that the Final Rule violated the Administrative Procedure Act.

**2. USDA’s assumption that the BSE incidence in Canada is very low was unsupported and is demonstrably wrong.**

USDA variously characterizes the incidence of BSE in the Canadian herd as “minimal,” “low,” or “very low.” Unfortunately, this is little more than wishful thinking. Canada has not conducted sufficient testing for BSE to assess accurately the rate of BSE infection in Canada. Cox Declaration, Exhibit 7 at 6-7. To date, Canada has tested on the order of 40,000 head of

cattle in the past decade, and almost exclusively cattle with outward signs of possible BSE. *See* 70 Fed. Reg. at 476. In the past year and a half, four cases of BSE have been identified in cattle born and raised in Canada. Disease Information, Office International des Epizooties (OIE), Vol. 18 – No. 3, 21 January, 2005, available at [http://www.oie.int/eng/info/hebdo/AIS\\_09.HTM#Sec0](http://www.oie.int/eng/info/hebdo/AIS_09.HTM#Sec0). *See also* Disease Information, Office International des Epizooties (OIE), Vol. 17 – No. 2, 9 January, 2004, available at [http://www.oie.int/eng/info/hebdo/AIS\\_63.HTM#Sec0](http://www.oie.int/eng/info/hebdo/AIS_63.HTM#Sec0). In contrast, the U.S. has tested over 200,000 native cattle believed to be at risk of BSE and has never found a single case. *See* 70 Fed. Reg. at 476-77.

The discovery, in a relatively short time, of four animals raised in Alberta province stricken with BSE is inconsistent with USDA's assertion that the BSE incidence rate in Canada is "very low" or "minimal." Exhibit 7 at 5-6. If the testing so far has been representative of the Canadian herd, a BSE prevalence greater than 5.5 cases per million head of cattle, which would put Canada on a par with a number of European countries with a BSE problem. *Id.* If, once the ban on Canadian cattle imports is lifted by the Final Rule, Canada ships about 1.7 million head of cattle a year to the U.S., as it did in 2002 before the discovery of BSE in Canada, it is a virtual certainty that Canadian cattle infected with BSE will be imported into the U.S. *Id.* at 6.

When a second Canadian-raised cow was found with BSE in Washington State, APHIS claimed that this discovery would not affect its risk analysis. 69 Fed. Reg. at 10,636; Exhibit 5 Attachment B at 1. Dr. Cox, an expert in statistics and risk analysis, tells us what would for most people be intuitive: saying that a second observed event in a relatively short period of time doesn't affect the risk analysis violates principles of sound statistics and risk assessment. Exhibit 5 Attachment E Exh. B at 12. Now, there have been two additional cases of BSE found in

Canadian cattle, and USDA announced that those discoveries do not affect its risk assessment literally within hours of the Canadian government's announcement of the positive test results. See Exhibit 5 Attachments L-M. In other words, APHIS will not abandon its assumption that the incidence of BSE in the Canadian herd is minimal, regardless of what testing shows. Again, Dr. Cox tells us what should be obvious: USDA's assumption that the incidence of BSE in Canada is minimal or very low is inconsistent with the discovery of BSE in four animals from Alberta in a relatively short time, and "[i]t is not credible that the magnitude of the risk does not depend on how large a portion of Canadian cattle are discovered to have BSE." Exhibit 7 at 7-8.

USDA's claim, without sufficient data, that the incidence of BSE in Canada is very low, that accepting cattle and meat from Canada therefore carries essentially no incremental risk, and that additional cases of BSE do not affect its assessment of the BSE risks associated with resuming imports of cattle and beef products from Canada is simply inconsistent with the facts. For that reason, R-CALF USA is likely to succeed on its claim that the Final Rule is arbitrary and capricious. See, e.g., *Ariz. Cattle*, 273 F.3d at 1236 (court should not credit agency "conclusions that do not have a basis in fact"); *Blue Mountains Biodiversity Project v. Blackwood*, 161 F.3d 1208, 1211 (9th Cir. 1998) (court need not forgive a clear error of judgment).

### **3. USDA's reliance on the Canadian feed ban was unjustified.**

Transmission of BSE can occur when cattle consume feed or supplements that contain bovine protein, typically meat and bone meal. While this is believed to have been the primary route of BSE transmission in the past, there is no conclusive scientific proof that it is the only route, and it is unknown what other routes of transmission may be available. See, e.g., Cox Declaration, Exhibit 7 at 8.

Experts do agree that the most important means of preventing the spread of BSE in cattle is limitations on cattle feed, so that healthy animals are not exposed to BSE prions through feed that contains protein from animals infected with BSE. The U.S. adopted a ban on certain animal proteins in cattle feed in 1997, and Canada adopted a similar restriction in August of 1997 (the “Canadian feed ban”). USDA relies on the Canadian feed ban for its conclusion that BSE is unlikely to be spreading in the Canadian herd, and it relies on the similar feed ban in the U.S. for its conclusion that, if BSE-infected cattle are imported from Canada, there is virtually no risk that those cattle will transmit BSE to domestic cattle.

These assumptions are subject to substantial uncertainty, although USDA does not acknowledge that uncertainty in explaining the basis for the Final Rule. Recent scientific data suggests that BSE prions may be transmitted by blood and perhaps by saliva. See Exhibit 5 Attachment F at 7, 10 and Attachment G at 2-4. In truth, scientific understanding of the transmission and transmissibility of BSE is still evolving. Even if one could say that BSE is only transmitted through contaminated feed, however, USDA’s assumptions that the Canadian and American feed bans provide a complete defense against the BSE infection known to exist in the Canadian herd would be unwarranted.

The O.I.E. specifies that, to be considered a region with minimal risk of BSE, a country must have had in place and been enforcing a ban on feeding of ruminant protein to ruminants for at least eight years. 70 Fed. Reg. at 470. USDA rejected those international guidelines because the 8-year time period “may be conservative,” asserting that the incubation period for BSE infection in cattle is generally less than 7 years. *Id.* USDA then concluded that, since Canada’s feed ban has been in place for a little over 7 years, it provides assurance that BSE is not spreading in the Canadian herd. *Id.* USDA attempted to convince O.I.E. to adopt its view of the appropriate duration of an effective feed ban in order to be considered a minimal risk country,

but the O.I.E. was not convinced. USDA's rejection of international standards because they "may be conservative," and its substitution of a criterion that the feed ban must have been in place for approximately the same length of time as the maximum expected incubation of BSE (i.e., virtually no safety factor) is itself arbitrary and capricious and inconsistent with USDA's responsibility to protect American cattle and consumers.

Beyond that, though, USDA's suggestion that the Canadian feed ban has actually been *effective* for over seven years is inconsistent with the facts. In attempting to explain away the discovery of an additional case of BSE in Canada in a cow born after the Canadian feed ban was in place, USDA claimed that this event did not undercut its confidence in the effectiveness in the Canadian feed ban, because the cow probably was exposed to feed that had been manufactured prior to the Canadian feed ban, which did not require that stocks of such feed be disposed of. Thus, by USDA's own admission, Canada has had an *effective* feed ban for substantially less than even seven years. USDA's assertion that the Canadian feed ban is effective and has been in place for a sufficient length of time, when in fact Canadian cattle apparently could have been fed ruminant protein much more recently than the seven years that the USDA is necessary, renders USDA's conclusion, that the risk presented by the Final Rule is acceptable, arbitrary and capricious. *Motor Vehicle Mfrs. Ass'n*, 463 U.S. at 43. In fact, as recently as 2003 a Canadian cow with BSE made its way into cattle feed to which over 1800 Canadian cattle may have been exposed. Bullard Declaration, Exhibit 5 at 7.

In fact, if USDA is correct that the mean incubation period for BSE infection in Canada is 4.2 years, then each of the four Canadian-origin cattle confirmed to have BSE certainly could have contracted the BSE infection after the effective date of the Canadian feed ban, since in each case more than 4.2 years had elapsed since implementation of the feed ban at the time the animal exhibited signs of and was tested to have BSE. See Cox Declaration, Exhibit 7 at 7. USDA's

assertion that the Canadian feed ban is effective and has been in place long enough to make the risk of additional cases of BSE insignificant is at odds with the facts and therefore arbitrary and capricious. *See, e.g., Ariz. Cattle Growers*, 273 F.3d at 1236.

USDA's reliance on both the U.S. and the Canadian feed bans to protect against the spread of BSE is also misplaced because those feed bans are incomplete. Both allow bovine blood to be used in cattle feed. 70 Fed. Reg. at 491. USDA has acknowledged the possible transmission of BSE through blood (*see, e.g., 70 Fed. Reg. at 502*), and there is growing information that the human form, vCJD, can be transmitted through blood, as well. *See Exhibit 5 Attachment F at 8*. The Food and Drug Administration has recognized a need to upgrade current feed regulations to eliminate use of mammalian blood, but it has not yet done so. *See 69 Fed. Reg. 42,288, 42,292-93 (July 14, 2004)*. Yet USDA treats the feed bans as an absolute "firewall" for BSE transmission even though cattle feed can include blood (potentially, from a BSE-infected animal).

Similarly, unlike the European countries, the U.S. and Canada allow rendered animal fat in cattle feed. APHIS has acknowledged that: "Based on scientific evidence currently available, it is not possible to dismiss the possibility that ingestion of tallow infected with BSE creates a risk of the transmission of BSE." 70 Fed. Reg. at 501. APHIS' claim that, nonetheless, importing Canadian cattle with their known potential for BSE infection creates minimal or no risk because of the U.S. feed ban is inconsistent with that pronouncement. When an agency acts inconsistent with its factual determinations, its action must be remanded under the APA. *See Burlington Truck Lines Inc. v. United States*, 371 U.S. 156, 167 (1962).

Another important loophole in the feed bans concerns poultry feed. Bovine protein can be used for poultry feed, and poultry waste in turn is used in animal feed, including potentially cattle feed. *See Exhibit 5 Appendix F at 7-8*. The Food and Drug Administration has recognized

the need for new rulemaking to eliminate the exemption for mammalian blood and poultry wastes, but has not yet done so. See Exhibit 5 Attachment B at 3-4; 70 Fed. Reg. at 466, 504.

USDA did not assert that there is no risk of BSE transmissions from these loopholes in the U.S. feed ban, but instead pointed out that FDA, APHIS, and FSIS are considering what improvements are needed to the U.S. feed ban. 70 Fed. Reg. at 466, 504. USDA's decision to move ahead with allowing importation of Canadian cattle, without first having addressed this important potential route for the spread of BSE within the United States under the Final Rule, renders the Final Rule arbitrary, capricious, and an abuse of discretion.

USDA had before it numerous other indications that the feed bans represent an incomplete "firewall." These include, inter alia, Canadian investigations that indicate almost 2000 head of Canadian cattle may have been exposed to BSE-contaminated feed because of the rendering of the BSE-infected animal discovered in Canada in May 2003 (*see* Exhibit 5 Attachment F at 4-5 and Attachment K); a U.S. Government Accounting Office study in 2002 showing inadequate enforcement and significant noncompliance among U.S. feed producers with a similar feed ban in the United States (GAO-02-183, January 2002); and the conclusion of USDA's own International Review Team responding to the discovery of the BSE-infected cow in Washington State that "...the partial ruminant to ruminant feed ban that is currently in place [in the U.S.] is insufficient to prevent exposure of cattle to the BSE agent" (*see* Exhibit 5 Attachment F at 7-8).

USDA's claims that there is minimal risk of transmission of BSE within the United States, and that Canadian cattle under 30 months of age should be BSE-free, based on the assumed high effectiveness of the Canadian and U.S. feed bans, are inconsistent with the facts available to USDA. Since USDA based the Final Rule largely on this assumed effectiveness of the feed bans, and failed to justify this assumption in light of all of the contrary evidence

described above, R-CALF USA is likely to be able to demonstrate that the Final Rule is arbitrary and capricious under the APA.

**4. USDA arbitrarily assumed that SRM removal eliminates all risks despite scientific evidence to the contrary.**

Central to USDA's rationale for relaxing the ban on imports of Canadian cattle and beef is its assumption that removal from the carcass of certain materials where most of the BSE infectivity is believed to reside (SRMs) will effectively shield consumers from exposure to BSE. USDA has failed to respond adequately to comments demonstrating that current scientific knowledge calls that assumption into question. USDA's decision to rely on this questionable assumption, rather than take the cautious approach of assuming that there might still be exposure to the BSE infectious agent even if there are regulations requiring SRM removal, was inconsistent with the congressional intent evidenced in the Animal Health Protection Act, 7 U.S.C. §§ 8301 *et seq.* and the Meat Inspection Act, 21 U.S.C. §§ 601 *et seq.*

R-CALF USA submitted extensive comments, including copies of numerous reports on the latest scientific research on the occurrence and transmission of BSE and related prions, which indicate that it is no longer reasonable to presume that there is no risk of exposure to BSE infectious agents once an SRM removal requirement is in place. Exhibit 5 Attachments E, F, and G. Some of those studies are summarized succinctly in Dr. Cox's Declaration, Exhibit 7 at 8-9. USDA's failure to explain clearly why these concerns do not undercut its almost-exclusive reliance on SRM removal requirements for the protection of public health from Canadian imports violated the Administrative Procedure Act.

**5. USDA's decision to allow imports of beef from older Canadian cattle was arbitrary and capricious.**

The Final Rule allows importation of edible bovine products from Canada, regardless of the age of the Canadian cattle at the time of slaughter, but restricts imports of live cattle to only those less than 30 months of age. *Cf.* 70 Fed. Reg. at 484 *with* 70 Fed. Reg. at 494. This represents a reversal of prior USDA policy decisions that restricted imports to those derived from animals that were under 30 months age at the time of slaughter (the "30-month restriction"). This policy decision was contained in USDA's August 8, 2003 announcement that it would grant permits to import certain meat products from cattle under 30 months of age at the time of slaughter. The 30-month restriction was based on USDA's assessment that products from these younger cattle would have the lowest risk of exposing consumers to BSE. See Exhibit 5 Attachment F p. 5 of 10. This assessment of risk was also reflected in the Proposed Rule, which proposed to continue the age restriction (although applied to a greater number of edible products). *See* 68 Fed. Reg. at 62,390-91.

The 30-month restriction was based on the assumption that younger animals, born after Canada enacted its feed ban, would not have been exposed to potentially contaminated feed and on the assumption that, since recognizable symptoms of BSE generally occur in cattle older than 30 months, levels of BSE contamination would be low even in infected cattle if the cattle were slaughtered at under 30 months of age. *See, e.g.,* 68 Fed. Reg. at 62,390-91; 70 Fed. Reg. at 513, 514; APHIS October 2003 Risk Analysis (Exhibit 5 Attachment A) at 16-18. USDA considered the 30-month restriction so important that, prior to the Final Rule, USDA only permitted importation of boneless beef from Canada if it came from cattle not only less than 30 months of age but also slaughtered at a facility or line dedicated to such younger animals (*see* 70 Fed. Reg.

at 494), a restriction it proposed to continue in the November 4, 2003 Proposed Rule. *See* 68 Fed. Reg. at 62,404.

In the Final Rule, USDA does not repudiate its prior assertion that older cattle in Canada have a higher risk of BSE infection and a higher risk that BSE prions will be sufficiently concentrated to make transmission of the disease possible. In fact, USDA prohibits the importation of live cattle 30 months of age or older and requires that any Canadian cattle be slaughtered in the U.S. before they reach 30 months of age, noting that this is consistent with O.I.E. guidelines. *See, e.g.*, 70 Fed. Reg. at 483, 513-14. But USDA asserts that the requirements the Final Rule imposes on the slaughter of cattle in Canada for products destined for the U.S. will eliminate any risk associated with consuming those products, even from older animals with a higher risk (of a higher level) of BSE infection. On that basis, USDA lifted the 30-month restriction it had advocated since August 2003.

In the Proposed Rule, imports of Canadian beef from animals under 30 months of age would have been allowed only if they were not known to have been fed ruminant protein during their lifetime and the intestines were removed at the time of slaughter. 68 Fed. Reg. at 62,404. These are similar to the requirements under the Final Rule for cattle less than 30 months of age slaughtered in Canada (only the small intestine and tonsils must be removed at time of slaughter). 70 Fed. Reg. at 551. For older animals, had USDA not considered the 30-month restriction to be an important safeguard, it simply could have included in the Proposed Rule a requirement that older bovines slaughtered for products destined for the U.S. have the brain, eyes, spinal cord, etc. removed along with the intestines.

USDA has a special obligation here to explain why it chose to abandon its prior decision only to allow importation of boneless meat cuts from cattle less than 30 months of age, especially in light of the discovery of several more cases of BSE in Canadian cattle in the

interim. See *Nat'l Conservative 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 this case, nothing has changed since APHIS' August 8, 2003 announcement nor since the November 4, 2003 Proposed Rule to make cattle in Canada over 30 months of age less of a risk of BSE transmission. To the contrary, the discovery of three more cases of BSE in Canada since the Proposed Rule suggests that USDA should be adopting *more* protections against the possibility of contaminated meat being imported into the U.S., not fewer. APHIS provided no scientific basis for the assertion that removal of SRMs and "such other measures that are necessary" make meat from Canadian cattle over 30 months of age no more likely to carry BSE contamination than meat from younger cattle. Nor is there any scientific basis for concluding that meat from Canadian cattle from which SRMs have been removed is no more likely to carry BSE than meat from U.S. cattle from which SRMs have been removed, considering that BSE is known to exist in the Canadian herd that has not been found after testing over 220,000 head of cattle in the U.S. USDA's assertion that there would be no reduction in risk from eliminating the 30-month restriction because SRM removal and other measures "ensure that beef entering from Canada satisfies animal health criteria the same as or equivalent to those required in the United States," 70 Fed. Reg. at 542, thus is nonsensical for two reasons: It conflates animal health protection measures with human health protection—limits on imports of beef such as the 30-month restriction are directed at protecting human health, not domestic animal health—and it implies, despite manifest evidence to the contrary, that the underlying risk that the animal whose SRMs are removed is infected with BSE is the same in Canada as in the United States. When an agency's rationale for its actions is clearly inconsistent with the facts, the action is arbitrary and capricious. *Motor Vehicle Mfrs. Ass'n*, 463 U.S. at 43 (1983).

While APHIS explains that the risk of exposure to BSE from Canadian meat is reduced by SRM removal and “other measures,” it does not, and cannot, explain how great that reduced risk is or why it is acceptable. Under those circumstances, removing an admitted substantial safeguard (the 30-month restriction) is arbitrary and capricious.<sup>1</sup> USDA’s relaxation of the 30-month restriction in the face of evidence that BSE is more widespread in the Canadian herd than previously thought is especially perplexing, given that the Canadian government believes it prudent to restrict imports into Canada of U.S. beef products to those derived from cattle slaughtered at less than 30 months of age. *See* Exhibit 6 at 5-6 and Attachments C and D. USDA’s decision to allow imports of beef from cattle of all ages from a country where BSE clearly exists stands in stark contrast to Canada’s restriction on imports of beef from the U.S., where BSE has not been found despite extensive testing. R-CALF USA is likely to prevail on its claim that USDA’s decision to allow imports of Canadian beef products from Canada of all ages is arbitrary and capricious.

**6. USDA’s actions concerning Canadian bred heifers and fetal blood serum are inconsistent.**

The preamble to the Final Rule purports to prohibit breeding stock from entering the United States. However, the regulation does not expressly prohibit cattle of breeding age from being bred either before or after entering the U.S., either intentionally or otherwise. This

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<sup>1</sup> USDA does explain that allowing imports of beef from cattle slaughtered at more than 30 months of age will “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 products were only for the Canadian market.” 70 Fed. Reg. at 537. Moreover, if the 30-month restriction were continued, “Canadian suppliers would be prevented from participating in the current high-demand market in the U.S. for processing beef, and U.S. processors would not benefit from the additional source of supply....” *Id.* at 541. These benefits for Canadian suppliers are hardly a sufficient justification under the relevant statutes for relaxing measures designed to protect U.S. consumers from a human health risk.

loophole creates a number of potential pathways through which BSE could enter the United States.

While it is clear in the preamble that USDA did not intend to allow breeding cattle into the United States (70 Fed. Reg. at 484, 485), the Final Rule does not include any precautionary measures to prevent bred cattle from entering the U.S. or to prevent cattle from being bred upon arrival in the United States. The Final Rule does not require the spaying of heifers or castration of bulls, nor does it require heifers to be pregnancy checked as a condition of entry into the U.S.

USDA estimates that approximately two million Canadian cattle will be imported into the U.S. in 2005. Approximately 500,000 of these cattle are expected to be feeder cattle. Bullard Declaration, Exhibit 5 at 8. Given the lack of measures to guard against pregnancy in imported heifers, it is highly likely that a percentage of both heifers imported for direct slaughter and heifers imported for further feeding will be pregnant. Because the Final Rule ignores this likelihood, it is void of any provisions specifying the proper disposition of fetuses at slaughtering facilities or calves in feedlots.

The Final Rule, consistent with the OIE, recognizes that there is a small probability that BSE can be transmitted maternally, which is why USDA euthanized the two offspring of the Canadian-origin BSE-infected cow discovered in Washington State. 70 Fed. Reg. at 530. However, because USDA does not require any calves born by imported Canadian cattle to be euthanized, such calves could become a vector for BSE infection in the United States.

USDA was quite emphatic in the Final Rule when it stated it would not accept the uncertain risk associated with the importation of Fetal Blood Serum (FBS), which is used in bovine vaccine production and bovine embryo transfer. 70 Fed. Reg. at 502. USDA stated,

“Unless and until there is conclusive data to demonstrate that BSE is not transmitted by blood and would not be a contaminant of FBS, we consider it necessary to prohibit the importation of FBS from BSE minimal risk regions.” *Id.* But the lack of prescriptive measures for the disposal of bovine fetuses discovered in imported cattle at slaughter effectively nullifies USDA’s import prohibition against Fetal Blood Serum. By failing to issue regulations consistent with the intent expressed in the preamble, and by leaving this loophole open in spite of its conclusion that fetal blood may transmit BSE, USDA has acted arbitrarily and capriciously. *See, e.g., Burlington Truck Lines Inc. v. United States*, 371 U.S. 156, 167 (1962).

**7. USDA failed to respond adequately to comments suggesting mandatory BSE testing of Canadian Cattle.**

R-CALF USA and others commented to USDA that requiring that Canadian cattle slaughtered in the U.S. or in Canada for export to the U.S. to be tested for BSE could help mitigate the risks and adverse effects of the Proposed Rule. See Exhibit 5 Attachments E, F, and G. USDA acknowledged that the standard BSE screening test can identify BSE infection months before the animal has outward signs of BSE. 70 Fed. Reg. at 475. In fact, the Canadian-raised cow found to have BSE in Washington State would never have been tested for BSE if it had been screened for symptoms of BSE only. *See* Exhibit 5 at 8 and Attachment N.

USDA rejected mandatory testing because it cannot detect BSE infection until the disease has progressed fairly far. 70 Fed. Reg. at 475. But the fact that it cannot detect some cases of BSE does not mean testing has no value, since it would detect some BSE cases that would otherwise go undetected. USDA’s failure to give careful consideration to the benefits (and costs) of mandatory testing, or at least its failure to explain to the public why these benefits do not justify mandatory testing, in the face of such severe consequences from any case of BSE that is missed, was arbitrary and capricious and in violation of the Administrative Procedure Act.

## **8. USDA's action was taken without observance of procedure required by law.**

The Final Rule was promulgated without notice and opportunity for public comment, as required by the Administrative Procedure Act, 5 U.S.C. § 553, because the public had little or no meaningful opportunity to comment on a number of key aspects of the rule. The Final Rule therefore must be set aside under 5 U.S.C. § 706(2), which requires the Court to “hold unlawful and set aside agency actions, findings, and conclusions found to be – ... (D) without observance of procedure required by law;...” 5 U.S.C. § 706(2). It is essential that there be full opportunity for public comment about a proposed decision with such broad public health and economic consequences. Yet USDA relied on numerous documents concerning the projected risks of reopening the border to Canadian cattle and beef that were not made available to the public until the Final Rule was issued (or, in the case of the Final Environmental Assessment, even later than that).

One example of USDA's failure to provide adequate notice and opportunity for public comment concerns the kind of Canadian meat products that may be imported into the United States. As explained above, a key element of the Proposed Rule was the prohibition on imports of edible bovine products from cattle 30 months of age or greater at slaughter (the “30-month restriction”). *See* 68 Fed. Reg. at 62,390-91. This restriction was based both on the assumption that younger animals, born after Canada enacted its feed ban, would not have been exposed to potentially contaminated feed, and on the assumption that, since recognizable symptoms of BSE generally occur two to six years after infection, levels of BSE contamination will be low even in infected cattle under 30 months of age. *Id.*

The March 8, 2004 Federal Register Notice reopening the comment period for the proposed rule also made a significant, substantive change to the proposed rule – it eliminated the

30-month restriction. The March 8, 2004 notice was too vague to allow meaningful public comment, merely stating that APHIS no longer believed the 30-month restriction was necessary, because removal of SRMs and “such other measures as are necessary” were already being taken in Canada. 69 Fed. Reg. at 10,635. There was no explanation to the public of, and thus no opportunity to comment on, the scientific basis for relaxing the 30-month restriction that APHIS had proposed and that its 2003 Risk Analysis had concluded was “a useful dividing line for purposes of mitigating risk” and a way to mitigate “risks associated with age.” APHIS October 2003 Risk Analysis (Exhibit 5 Attachment A) at 16-18. The risk analysis performed for the Proposed Rule, to the extent it addressed human health risks at all, was predicated on the 30-month restriction. The February 2004 APHIS Veterinary Services Explanatory Note updating the October 2003 Risk analysis, which was referenced in the March 8, 2004 Federal Register notice, essentially just contained the same conclusory statement as the Federal Register notice. *See* Exhibit 5 Attachment B pp. 9-10. Thus, the public had no opportunity to comment on USDA’s analysis of the increased risk associated with lifting the 30-month restriction, if in fact there was any such risk analysis, prior to publication of the Final Rule.

Because USDA failed to set forth, for public review and comment, the basis for its reversal of position and determination that the risk mitigation provided by the 30-month restriction is unnecessary and inappropriate, it failed to apply the procedure required by law with respect to a central element of the Final Rule. Similarly, USDA’s reliance on an Environmental Assessment that apparently had not been prepared nor made available to the public at the time the rule was issued, as explained in the discussion of USDA’s non-compliance with the National Environmental Policy Act, below, also represents a clear violation of rulemaking procedures required by the Administrative Procedure Act. So too does USDA’s failure to make available for public comment a thorough economic impact assessment; the draft economic assessment

released for the comment period did not address, and so did not allow comments on, the key adverse economic impacts on R-CALF USA's members and other producers from the influx of Canadian beef and from the increased perception of risk of BSE contamination in the U.S. food supply. See Exhibit 5 Attachment E Exh. A (report of Dr. VanSickle) at 2-4. These facts make it clear that R-CALF USA is likely to prevail on its claim that USDA has violated the Administrative Procedure Act, 5 U.S.C. § 553.

**B. Failure to Satisfy Procedures Required by the National Environmental Policy Act**

The National Environmental Policy Act of 1969 ("NEPA"), 42 U.S.C. §§ 4321 *et seq.*, requires that federal agencies, such as USDA, prepare an Environmental Impact Statement ("EIS") for any major federal action significantly affecting the quality of the human environment. 42 U.S.C. § 4332(C). Council on Environmental Quality and USDA implementing regulations also provide for the preparation of an "environmental assessment" to support a finding that the proposed action will not have a significant impact on the environment, and therefore, will not be the subject of an EIS. See, e.g., 40 C.F.R. § 1501.3 and 7 C.F.R. pt. 372.

Review of NEPA actions is governed by the APA, under which a court must determine whether the agency's implementation was "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." *Hells Canyon Alliance v. United States Forest Serv.*, 227 F.3d 1170, 1176-77 (9<sup>th</sup> Cir. 2000); 5 U.S.C. § 706(2)(A). Accordingly, a court must ensure that the agency adequately considered and disclosed the environmental impacts of its actions. *Hells Canyon Alliance*, 227 F.3d at 1177. In assessing an agency's decision not to prepare an initial EIS, the Ninth Circuit employs a "rule of reason" test to determine whether the agency has considered the significant aspects of the probable environmental consequences. *Id.* Under this

standard the court must ensure that the agency took a “hard look” at these consequences. *Id.*; *Wetlands Action Network v. United States Army Corps of Eng'rs*, 222 F.3d 1105, 1114 (9th Cir. 2000).

NEPA requires that the environmental effects of the government action be considered “to the fullest extent possible.” 42 U.S.C. § 4332. NEPA regulations and case law require the disclosure of all foreseeable direct and indirect impacts. 40 C.F.R. § 1502.16; *City of Davis v. Coleman*, 521 F.2d 661, 676 (9th Cir. 1975). The purpose of NEPA is to ensure that an agency has at its disposal all relevant information about the environmental impacts of a project before the agency moves forward with its decision. *Salmon River Concerned Citizens v. Robertson*, 32 F.3d 1346, 1356 (9<sup>th</sup> Cir. 1994).

USDA prepared an environmental assessment in connection with the Proposed Rule, dated October 2003. Because circumstances subsequently changed, including relaxations in some of the protections in the Proposed Rule, USDA revised its environmental assessment in December 2004, almost doubling its length. *See* 70 Fed. Reg. at 554. This “Final Environmental Assessment” (“FEA”) was not made available to the public for review and comment, however, until after the final rule had been signed. *Cf. id. with* 70 Fed. Reg. at 543, 553. Despite public comment requesting that APHIS prepare an EIS, no EIS was prepared.

The FEA is woefully inadequate. In fact, once R-CALF USA pointed out in its Complaint in this action that the FEA relied on an outdated (2003, supplemented with an Explanatory Note in February 2004) risk analysis that fails to take into account subsequent developments and scientific discoveries, USDA made further revisions to the citations in the FEA, long *after* issuance of the Final Rule, in an attempt to address this error, but made no substantive changes in its assessment. *See* Exhibit 5 at 6 and Attachments H and I. In addition

