United States District Court,
D. Montana, Billings Division.
RANCHERS CATTLEMEN ACTION LEGAL FUND UNITED STOCKGROWERS OF AMERICA, Plaintiff,
v.
UNITED STATES DEPARTMENT OF AGRICULTURE, Animal and Plant Health Inspection
Service, and Mike Johanns, in His Capacity as the Secretary of Agriculture, Defendants.

No. CV-05-06-BLG-RFC
March 2, 2005

A. Clifford Edwards, Taylor S. Cook, Edwards Frickle Anner-Hughes & Cook, Billings, MT, Russell S. Frye, William L. Miller, Collier Shannon Scott, Washington, DC, for Plaintiff.

William W. Mercer, Mark Steger Smith, Office of the U.S. Attorney, Scott G. Gratton, John W. Ross, Brown Law Firm, Billings, MT, Philip C. Olsson, Patricia E. Pahl, Olsson Frank & Weeda, Donna S. Fitzgerald, Lisa A. Olson, Marcia Tiersky, James J. Gilligan, Daniel Meron, Mayer Brown Rowe Maw LLP, Thomas L. Sansonetti, Washington, DC, for Defendants.

ORDER OF PRELIMINARY INJUNCTION

Cebull, District J.

The application of the Plaintiff for Preliminary Injunction is GRANTED.

IT IS HEREBY ORDERED that the implementation of the Final Rule published on January 4, 2005, entitled "Bovine Spongiform Encephalopathy, Minimal Risk Regions and Importation of Commodities; Final Rule and Notice," 70 Fed. Reg. 460 is preliminarily enjoined.

IT IS FURTHER ORDERED that the parties are to meet for the purpose of providing the Court with a proposed schedule for trial on the merits for permanent injunction. This proposal is due within ten (10) days from the date of this Order.

This Order is supported by the Opinion filed separately herewith.

The Clerk of Court is directed to notify the parties of the making of this Order.

OPINION
BACKGROUND

This case 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. A final rule was published on January 4, 2005, titled "Bovine Spongiform Encephalopathy, Minimal Risk Regions and Importation of Commodities; Final Rule and Notice," 70 Fed. Reg. 460 (the "Final Rule"). In the Final Rule, the 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 has filed an Application for Preliminary Injunction, seeking to enjoin the Final Rule until the lawfulness of the Rule can be reviewed 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). 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. Because of the incurable nature of this 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 International Agricultural Trade and Policy

Center of the University of Florida, Exhibit 6 to Plaintiff's Memorandum.

On May 29, 2003, the USDA 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). Those 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 or APHIS may issue specific permits for ruminants or ruminant products to be brought into the United States in specific cases, where the Administrator determines that the action will not endanger livestock or poultry in the United States. *Id.*

The effect of this May 29, 2003 rule was that Canadian cattle and Canadian beef were banned from importation into the United States. On August 8, 2003, Secretary of Agriculture Ann Veneman announced the 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 calves under 36 weeks, and fresh or frozen bovine liver. Attachment J to Exhibit 5 of Plaintiff's Memorandum.

On November 4, 2003, the USDA commenced 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"). The 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.*

The 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). Among other things, that notice stated: "We now believe 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 the equivalent measures are in place to ensure that SRMs ["specific 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 provision we proposed in November 2003 regarding the importation of beef." *Id.* at 10,635. Plaintiff and over 3000 others submitted written comments on the proposal. 70 Fed. Reg. 465.

On April 26, 2004, this Court issued a Temporary Restraining Order prohibiting the USDA from permitting importation from Canada of all edible bovine meat products beyond those authorized by the USDA's action of August 8, 2003 from cattle under the age of 30 months. On May 5, 2004 that Temporary Restraining Order was converted into a preliminary injunction, that was set to expire five days after Plaintiff is notified of final agency action on the rulemaking proposed on November 4, 2003, 68 Fed. Reg. 62,386, and reopened on March 8, 2004, 69 Fed. Reg. 10,633.

On December 29, 2004, then Secretary of Agriculture Veneman announced the issuance of a final rule creating a category of regions with minimal risk 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. A Final Rule was published on January 4, 2005, titled "Bovine Spongiform Encephalopathy, Minimal Risk Regions and Importation of Commodities; Final Rule and Notice," 70 Fed. Reg. 460.

More importantly, on December 29, 2004, the CFIA announced publicly that another cow in Alberta had been tentatively identified as having BSE. That diagnosis was confirmed on January 5, 2005. On January 11, 2005, CFIA announced that a fourth cow from Alberta, this one six years and nine months old, had been confirmed to have BSE. Bullard declaration, Exhibit 5 at 7-8 and Attachments L-M to Plaintiff's Memorandum. 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 the 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. The Final Rule is to become effective on March 7, 2005.

Plaintiffs have filed an Application for Preliminary Injunction in order to prevent the import of live cattle less than 30 months of age and most kinds of bovine meat and other tissue from Canada for human consumption from Canada, which is expected to take effect on March 7, 2005.

STANDARD OF REVIEW

The traditional critena 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 hard ships 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 (9th Cir.1980); *Textile Unlimited Inc. v. A.B.M.H. and Co., Inc.*, 240 F.3d 781, 786 (9th Cir. 2001). However, The Ninth Circuit has ruled that 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; *Stuhlbarg Int'l Sales Co., Inc. v. John D. Brush and Co., Inc.,* 240 F.3d 832, 840-41 (9th Cir. 2001). These two tests 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.

ANALYSIS

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

A. Arbitrary and Capricious Actions under the Administrative Procedure Act

When reviewing an agency action such as the Final Rule in this case under the Administrative Procedure Act ("APA"), a court must "hold unlawful and set aside agency actions, findings and conclusions found to be--(A) arbitrary, capricious, and abuse of discretion, or otherwise not in accordance with law..." 5 U.S.C. § 706(2). In *Motor Vehicle Mfrs. Ass'n v. State Farm Mutual*, 463 U.S. 29, 43, 103 S. Ct. 2856, 77 L.Ed.2d 443 (1983), the Supreme Court held that an agency acts in a way that is arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law when it has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.

The scope of review under the "arbitrary and capricious" standard is narrow and a court is not to substitute its judgment for that of the agency. Nevertheless, the agency must examine the relevant data and articulate a satisfactory explanation for its action including a "rational connection between the facts found and the choice made." *Burlington Truck Lines v. United States*, 371 U.S. 156, 168, 83 S. Ct. 239, 245-246, 9 L. Ed. 2d 207 (1962). In reviewing that explanation, we must "consider whether the decision was based on a consideration of the relevant factors and whether there has been a clear error of judgment." *Bowman Transp. Inc. v. Arkansas-Best Freight System*, 419 U.S. 281, at 285, 95 S. Ct. 438, 42 L .Ed. 2d 447 (1974); *Citizens to Preserve Overton Park v. Volpe*, 401 U.S. 402, at 416, 91 S. Ct. 814, 28 L.Ed.2d 136 (1971).

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," ' *Arizona 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, 109 S. Ct. 1851, 104 L.Ed. 2d 377 (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*, 390 U.S. 278, 291-92 (1965).

The Supreme Court has stated that, "[i]f Congress established a presumption from which judicial review should start, that presumption . . . [would be] *against*

changes in current policy that are not justified by the rulemaking record," (Emphasis in original.) *Motor Vehicle Mfrs. Ass'n,* 463 U.S. at 42. *Accord, Int'l Brotherhood of Teamsters v. United States,* 735 F.2d 1525, 1532 (D.C. Cir.1984). Where an increased risk to human health is at issue, as it clearly is in this case, it is particularly critical that the USDA be required to provide its conclusion that its action carries an acceptable risk to public health and 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. Cal. 2001).

1. Has the USDA failed to Adequately Assess the Impact of its Action on Human Health?

Plaintiff's first argument in support of preliminary injunction is that the USDA has failed to adequately assess the impact of its action on human health. Plaintiff alleges that by issuing the Final Rule, the USDA has provided no assurance that the risk to human health is minimized and the 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. Plaintiffs argue that failure to do so renders the USDA's action arbitrary and capricious.

The Animal Health Protection Act directs the Secretary of the 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).

Plaintiff participated in the public comment and period on the Proposed Rule and thoroughly reviewed the documents the USDA relied upon for the Proposed Rule. Evidence presented by Plaintiff indicates that rather than perform a quantitative assessment of the risk of various options, the USDA made assumptions of 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. Neither the Harvard risk assessment nor the USDA Risk Analysis contain an assessment of the risk of consumer contracting vCJD from consuming Canadian beef, other than subjective conclusions that the risk will be "low" or "very low." Additionally, 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 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 the USDA's actions.

This is similar to the case of *Harlan Land Co. v. USDA,* 186 F. Supp. 2d 1076, where 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.

Here, APHIS appears to have applied the same arbitrary approach to a decision that subjects the entire U.S. beef industry to potentially catastrophic damages and that presents a genuine risk of death for U.S. consumers. Therefore, the evidence demonstrates, in all probability, that the USDA's failure to conduct a proper risk assessment, and its failure to articulate any standards by which it has judged the risks of those potentially fatal outcomes to be acceptable, renders its action arbitrary and capricious and unsupported by the record. *Id.* It is particularly critical that the USDA 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. In light of the lack of information indicating the USDA has fulfilled its statutory mandate to protect the health and welfare of the people of the United States, Plaintiff has a substantial likelihood of prevailing on the merits and demonstrating the Final Rule violated the APA.

2. Was the USDA's Assumption that the BSE Incidence in Canada is Very Low Unsupported and Demonstrably Wrong?

The USDA characterizes the incidence of BSE in the Canadian herd as "minimal," "low," or "very low." However, the evidence indicates that Canada has not conducted sufficient testing for BSE to accurately assess the rate of BSE infection in Canada. To date, Canada has tested approximately 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. In contrast, the United States 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. Defendants respond that Canada has met or exceeded

the level of testing recommended by O.I.E. Terrestrial Animal Health Code Appendix 3.8.4 for the past 7 years and because the Canadian cattle population is multiple times smaller than that of the U.S., Canada need not test the same number of animals as the U.S.

The discovery of four animals raised in Alberta province stricken with BSE during the past year and a half is inconsistent with the USDA's assertion that the BSE incidence rate in Canada is "very low" or "minimal." Evidence strongly indicates that 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 would put Canada on par with a number of European countries with a BSE problem. The testing also indicates that if Canada were to ship 1.7 million head of cattle a year to the U.S., as it did in 2002 prior to the discovery of BSE in Canada, it is a virtual certainty that Canadian cattle infected with BSE would be imported into the U.S. Moreover, the record demonstrates an import number of 2-3 million head of cattle from Canada during the remainder of 2005. This causes a potentially catastrophic risk of danger to the beef consumers in the U.S. and is contrary to the direction of the Animal Health Protection Act which directs the Secretary of the 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).

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 10,635. Now there are two additional cases of BSE found in Canadian cattle and the USDA announced those discoveries did not affect its risk assessment. It appears that regardless of what the testing shows, APHIS will not abandon its assumption that the incidence of BSE in the Canadian herd is minimal. The 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. As pointed out by Plaintiff, it is not credible that the magnitude of risk does not depend on how large a portion of Canadian cattle are discovered to have BSE. Cox Declaration at 7-8.

The facts strongly suggest that the USDA, ignoring its statutory mandate to protect the health and welfare of the people of the United States, established its goal of re-opening the border to the importation of live beef from Canada and thereafter attempted to work backwards to support and justify this *goal.* Accordingly, the Court finds Plaintiff 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; *Blue Mountain Biodiversity Project v. Blackwood,* 161 F.3d 1208, 1211 (9th Cir.1988).

3. Was the USDA's Reliance on the Canadian Feed Ban 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.

There is a general consensus among experts 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"). These assumptions are subject to uncertainty, even though the USDA does not acknowledge that uncertainty in explaining the basis for the Final Rule. Plaintiff argues that recent scientific data suggests that BSE prions may be transmitted by blood and perhaps saliva and scientific understanding of transmissibility of BSE is still evolving.

The O.I.E. specifies that in order 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. The USDA inexplicably 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.* The USDA then concluded that, since Canada's feed ban has been place for a little over 7 years, it provides assurance that BSE is not spreading in the Canadian herd. *Id.* The 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 appears to be arbitrary and capricious and inconsistent with the USDA's responsibility to protect American cattle and consumers.

The USDA's suggestion that the Canadian feed ban has been effective for over seven years is not consistent with the facts. The USDA has attempted 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 by asserting that the cow was probably exposed to feed that had been manufactured prior to the Canadian feed ban, which did not require disposal of stocks of such feed. Thus, Canada has had an effective feed band for substantially less than seven years. Again, Plaintiff is likely to succeed on its claim that the Final Rule is unacceptable, arbitrary and capricious. *Motor Vehicle Mfrs. Ass'n.*, 463 U.S. at 43.

If the 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 could have contracted the BSE infection after the effective date of the Canadian feed ban, since in each case more than 4.2 years have elapsed since implementation of the feed ban at the time the animal exhibited signs of and was tested to have BSE. Because of this, the 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.

Additionally, the 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 not complete as they both allow bovine blood to be used in cattle feed. 70 Fed. Reg. at 491. The USDA has acknowledged the possible transmission of BSE through blood (*see, e.g.*, 70 Fed. Reg. at 502), and there is growing information that vCJD can be transmitted through blood as well. The Food and Drug Administration has recognized a need to upgrade current feed regulations to eliminate the use of mammalian blood, but it has not yet done so. *See* 69 Fed. Reg. 42,288, 42,292-93 (July 14, 2004).

Unlike European countries, the U.S. and Canada allow rendered animal fat in cattle feed. APHIS has acknowledged that: "Based on scientific information 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 importing Canadian cattle with their known potential for BSE infection creates minimal or no risk 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 v. United States*, 371 U.S. 156, 167, 83 S. Ct. 239, 9 L. Ed. 2d 207 (1962).

The 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 effectiveness of the Canadian and U.S. feed bans are inconsistent with the facts available to the USDA. Since the USDA based the Final Rule largely on this assumed effectiveness and failed to justify this assumption in light of all the contrary evidence, Plaintiff is likely to be able to demonstrate that the Final Rule is arbitrary and capricious under the APA.

4. Did the USDA Arbitrarily Assume that SRM Removal Eliminates all Risks?

Central to the USDA's rationale for allowing the import of Canadian cattle and beef is the assumption that removal from the carcass of certain material where most of the BSE infectivity is believed to reside (SRMs) will shield consumer from exposure to BSE. Plaintiff contends that the USDA failed to respond adequately to comments demonstrating that current scientific knowledge calls that assumption into question. Plaintiff submitted extensive comments and 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. The USDA's failure to explain clearly why these concerns do not undercut its reliance on SRM removal requirements for the protection of public health from Canadian imports again underscores Plaintiff's likelihood of success on the merits.

5. The USDA's Decision to Disallow Imports of Beef from Cattle 30 Months or Older.

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. Plaintiff contends that there is no basis for the USDA's decision to allow imports of beef from cattle over 30 months of age. On February 9, 2005, the Secretary of Agriculture announced in a press release that he was delaying the implementation of the portion of the rule regarding meat from animals 30 months of

age or older. The Secretary took this action because "ongoing investigation into the recent finds of BSE in Canada in animals over 30 months are not complete." Defendant asserts that Plaintiff's challenge to that portion of the final rule is not ripe because of the Secretary of Agriculture's announcement. However, the Court was assured during the hearing by counsel for the USDA that such regulation changing the Final Rule with respect to meat from cattle 30 months or older will be filed today (March 2, 2005).

6. Are the USDA's Actions Concerning Canadian Bred Hefers and Fetal Blood Serum Inconsistent?

The Final Rule prohibits breeding stock from entering the U.S., but does not prohibit cattle of breeding age from being bred either before or after entering the U.S. This creates the potential pathway through which BSE could enter the U.S. As stated by Defendants, it is apparent that the USDA does not intend to allow breeding cattle into the U.S. (70 Fed. Reg. at 484, 485), but 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. Given the estimate that two million Canadian cattle will be imported in the U.S. in 2005, it is highly likely that a percentage of both heifers imported for direct slaughter and heifers imported for further feeding will be pregnant.

The Final Rule, consistent with the O.I.E., recognizes that there is a small probability that BSE can be transmitted maternally. 70 Fed. Reg. at 530. However, because the 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 U.S.

The USDA stated in the Final Rule that it would not accept the uncertain risk associated with importation of Fetal Blood Serum (FBS), which is used in bovine vaccine production and bovine embryo transfer. 70 Fed. Reg. at 502. The 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.* By failing to issue regulations consistent with the intent expressed in the preamble, and failing to address this problem, in spite of the USDA's conclusion that fetal blood may transmit BSE, the USDA has acted arbitrarily and capriciously, which indicates probable success on the merits for Plaintiff. *See, e.g. Burlington Truck Lines, Inc. v. United States*, 371 U.S. 156, 167, 83 S.Ct. 239, 9 L. Ed. 2d 207 (1962).

7. Did the USDA Fail to Respond Adequately to Comments Suggesting Mandatory BSE Testing of Canadian Cattle?

Plaintiff and others commented to the 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. The 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. The USDA rejected mandatory testing because it cannot detect BSE infection until the disease has progressed. *Id.* However, this does not mean that mandatory testing has no value, since it would detect some cases of BSE that would otherwise go undetected. The 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 the possibility of irreparable injury from any case of BSE that is not identified is arbitrary and capricious and Plaintiff has a probability of success on the merits of showing this was in violation of the APA.

B. Did the USDA Fail to Satisfy Procedures Required by the National Environment[al] Policy Act?

The USDA argues that Plaintiff does not have standing to make a (National Environmental Policy Act) NEPA argument. In order for Plaintiff to have standing they must meet three elements: (a) plaintiff must have suffered an "injury in fact" which is concrete and particularized, and "actual or imminent," not "conjectural" or "hypothetical;" (b) there must be a causal connection between the injury and the conduct complained of--the injury has to be "fairly ... trace[able] to the challenged action of the defendant, and not ... th[e] result [of] the independent action of some third party not before the court;" (c) it must be "likely," as opposed to merely "speculative," that the injury will be "redressed by a favorable decision." *Lujan v. Defenders of Wildlife* Based upon these elements, this Court finds that Defendant has standing to make a NEPA challenge.

The National Environmental Policy Act of 1969 ("NEPA"), 42 U.S.C. §§ 4321 *et seq.*, requires that federal agencies 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 the 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. If a Finding of No Significant Impact (FONSI) is made after the matter is analyzed in an environmental assessment, then no EIS is required. 40 C.F.R. § 1501.4(e).

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 Forest Service*, 227 F.3d 1170, 1176-77 (9th Cir. 2000); 5 U.S.C. § 706(2)(A). This standard requires a court "to ensure that an agency has taken the requisite "hard look" at the environmental consequences of its proposed action, carefully reviewing the record to ascertain whether the agency decision is founded on a reasoned evaluation of the relevant factors." *Wetlands Action Network v. United States Army Corps of Eng'rs,* 222 F.3d 1105, 1114 (9th Cir. 2000) (internal quotations and citations omitted). In assessing an agency's decision not to prepare an initial EIS, the Ninth Circuit employs a "rule of reason" test to determine if the agency has considered the significant aspects of the probable environmental consequences. *Id.* Under this standard the court must ensure the agency took a "hard look" at these consequences. *Id.; Wetlands Action Network,* 222 F.3d at 1114.

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 (9th Cir.1994).

In this case, the 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, the 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 was signed. *Cf. id. with* 70 Fed. Reg. at 543, 553. Despite public comment requesting that APHIS prepare an EIS, no EIS was prepared.

Once Plaintiff pointed out that in its Complaint that the FEA relied on an outdated risk analysis that fails to take into account subsequent developments and scientific discoveries, the 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.

The USDA has neglected to provide the public the opportunity to comment on the FEA because the FEA was published after the Final Rule was signed. The public comment procedures required by NEPA are "at the heart of the NEPA review process" and the USDA has failed to provide such procedure to the public by finalizing the rule and then requesting comment on the FEA. *California v. Block,* 690 F.2d 753, 770 (9th Cir. 1982).

The risk analysis on which the FEA relies does not provide any quantitative assessment of the risk of importing BSE-infected cattle from Canada, transmission of BSE from those cattle to animals in the U.S., or infection of humans with vCJD as a result of importation of BSE-infected cattle or meat. APHIS lacked a meaningful basis for the conclusions in the FEA that the Final Rule would not have a significant environmental impact because its "consequences with regard to animal health, human health, an the environment continue to be minimal or low..." *See Harlan Land Co.,* 186 F. Supp. 2d at 1097-98. Furthermore, decision makers and the public have been deprived of the opportunity to form a judgment about whether the risk is acceptable.

Additionally, Plaintiff points to several direct and indirect effects of allowing the import of Canadian cattle which APHIS failed to assess. The USDA estimates a flood of close to 2 million head of cattle from Canada in 2005 if Canadian beef is allowed to be brought into this country. 70 Fed. Reg. 540. That would result in approximately 35,000 truck round-trips between Canadian ranches and feedlots to slaughter facilities in the U.S. Plaintiff argues this substantial increase in traffic will result in environmental damage the USDA has not attempted to assess. The Ninth

Circuit recently enjoined a Department of Transportation action because it failed to assess just this type of environmental impact. *See 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 Citizens*, 541 U.S. 752, 124 S. Ct. 2204, 159 L. Ed. 2d 60 (June 7, 2004). Obviously, APHIS did not take a sufficiently "hard look" at the environmental effects of the increased truck traffic and increased holding of cattle associated with the Final Rule.

By failing to prepare an EIS, basing its FEA on inaccurate or unsupported assumptions and on an outdated and superseded risk analysis, taking final action before its revised environmental assessment was made available to the public for review and comment, failing to assess all the impacts of the rule (including the impacts due to increased truck traffic), and bringing an additional 2 million head of cattle into a limited number of feedlots and slaughter facilities, the USDA failed to comply with its obligations under NEPA. Where an agency has failed to conduct an analysis of the environmental impacts of its proposed action required by NEPA, or when that analysis is based on inaccurate or outdated information and assumptions, NEPA requires a stay of the agency action until the required analysis can be completed. *See Idaho Sporting Congress, Inc. v. Alexander*, 222 F.3d 562, 569 (9th Cir. 2000).

C. Has there been a Failure to Satisfy the Regulatory Flexibility Act?

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 consider the steps the agency has taken to minimize the significant economic impact on small entities, including a statement of the factual, policy, and legal reasons for selecting the alternative adopted in the final rule and why each of the other significant alternatives to the rule considered by the agency which affect the impact on small entities was rejected. 5 U.S.C. § 604(a)(5). Section 604 commands an agency to give explicit consideration to less onerous options. *Associated Fisheries, Inc. v. Daley*, 127 F.3d 104, 114 (1st Cir.1997). In 1996, Congress provided for judicial review of an agency's compliance with the RFA. 5 U.S.C. § 611(a)(1). 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. The USDA admits that the Final Rule will primarily affect small businesses. 70 Fed. Reg. at 543. Many ranchers are small businesses within the meaning of the RFA. 5 U.S.C. §§ 601-612. The USDA estimates that the Final Rule has a present value cost of close to $3 billion for U.S. producers.

The USDA considered only two alternatives, leaving the regulations unchanged or modifying the import requirements by either requiring that imported beef come from cattle slaughtered at less than 30 months of age or continuing to prohibit the entry of live ruminants. 70 Fed. Reg. at 543.

First, the 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. *Id.* Under section 10816 of the Farm and Security Rural Investment Act of 2002 and the 2005 Supplemental Appropriations Act, the USDA is required to implement a country of origin labeling program (COOL), and a proposed rule to that effect was issued in October 2003. However, the implementation of that labeling program is scheduled to occur in September 2006, long after the Final Rule will go into effect.

The USDA argues in response to COOL: "While labeling provides consumers with additional information, it is neither a food safety nor an animal health measure." (Defendant's opposition brief at p. 19). Such a statement is misleading; certainly allowing U.S. consumers to chose whether or not they are willing to accept the "negligible," "very low," "highly unlikely" risk posed by the consumption of Canadian beef as it relates to food safety. Any labeling should take place immediately upon opening of the Canadian border to allow consumers the opportunity to make an informed choice when purchasing beef. The cost of said labeling would be minimal compared to the risks associated with eating beef of an unknown origin potentially contaminated with BSE. Second, the USDA's RFA did not 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 Canadian and U.S. meat supplies. The USDA states that private testing of all slaughter cattle is inconsistent with the USDA's mandate to ensure effective, scientifically sound testing for significant

animal diseases and to maintain domestic and international confidence in U.S. cattle and beef. However, this is contrary to rational thinking because any private testing would actually assist in assuring proper testing for animal diseases and increase consumer confidence, both domestically and internationally, in U.S. cattle and beef.

Either of those alternatives might have substantially mitigated the adverse economic effect of the Final Rule. By offering only two alternatives, the USDA did not make a good-faith effort to assess all significant alternatives. Because of this, there is probable success by Plaintiff in their argument that the USDA failed to comply with the Regulatory Flexibility Act.

II. WILL PLAINTIFF LIKELY SUFFER IRREPARABLE HARM IF DEFENDANTS ARE NOT ENJOINED?

If this preliminary injunction is not granted, the introduction of BSE into the U.S. will be irreversible and is sufficient to justify a finding of significant irreparable harm. Canadian cows have been found to have BSE, while no American-bred cows have. Allowing the import of Canadian cattle into the U.S. increases the potential for human exposure to material containing the agent for BSE in this higher-risk meat. This has substantial, irreparable consequences for cattle growers and also for all consumers of beef in or from the U.S. If consumption of beef products from Canadian cattle that the Final Rule will allow to enter the U.S. food supply were to result in cases of vCJD in humans, there is no known cure, and it is invariably fatal. Prohibiting the importation of Canadian cattle and beef through the imposition of a preliminary injunction enjoining the implementation and enforcement of the Final Rule published January 4, 2005, titled "Bovine Spongiform Encephalopathy, Minimal Risk Regions and Importations of Commodities" will maintain the status quo, preventing the possibility of quintessential irreparable harm to the citizens of the United States.

The USDA's failure to comply with NEPA also presents an irreparable harm warranting preliminary injunctive relief. The Ninth Circuit has acknowledged that "environmental injury, by its nature, can seldom be adequately remedied by money damages and is often permanent or at least of long duration, i.e., irreparable. If such injury is sufficiently likely, therefore, the balance of harms will usually favor the issuance of an injunction to protect the environment." *Earth Island Inst. v. U.S. Forest Serv.*, 351 F.3d 1291, 1999 (quoting *Amoco Prod. Co. v. Village of Gambell*, 480 U.S. 531, 545, 107 S. Ct. 1396, 94 L. Ed. 2d 542 (1987). In this case, the alleged environmental injury is sufficiently likely and the balance of harms weighs in favor of protection of the environment.

Furthermore, the perception that the U.S. meat supply is not free of BSE agents, as a result of the Final Rule's reopening the border to Canadian cattle and meat, will have a serious, irreparable impact on ranchers in the U.S. and the U.S. economy. It will be similar to the discovery of BSE contamination in UK cows and meat, which triggered devastating losses to the beef production industry in Great Britain and other European countries. This was also the result in Canada with the discovery of BSE in Canadian cows. Discovery of BSE in Canadian cows has already caused Japan and Korea to demand that any exports to those countries be free of beef originating in Canada, and their markets still are largely closed to American beef.

Imports allowed from Canada under the Final Rule will likely be understood by consumers in the U.S. and abroad as increasing the risk of BSE agents entering the U.S. meat supply. Once the Canadian meat products are in the U.S., the stigma will attach to all U.S. meat, unless the Canadian meat can be distinguished from U.S. meat. Once the Canadian beef is allowed to intermingle with U.S. meats it will open a flood of speculation and neither the contaminated meat nor the stigma associated with contaminated meat could be removed from the U.S. cattle industry and the substantial, irreparable injury will have occurred.

III. HAVE SERIOUS QUESTIONS BEEN RAISED AND DOES THE BALANCE OF HARDSHIPS FAVOR THE GRANTING OF A PRELIMINARY INJUNCTION?

Under the Ninth Circuit standard for evaluating preliminary injunctions, a plaintiff may, in the alternative, prove that an injunction is warranted if serious questions are raised and the balance of hardships tips sharply in its favor. *Los Angeles Mem'l Coliseum Comm'n*, 634 F.2d at 1201; *Stuhlbarg Int'l Sales Co., Inc. v. John D. Brush and Co., Inc.*, 240 F.3d 832, 840-41 (9th Cir. 2001). In this case, very serious questions on the merits have been raised and the balance of the hardship tips in favor of Plaintiff. Therefore, a preliminary injunction is warranted. There will not be any significant harm to Defendant or to any other party in maintaining the *status quo ante*. The public would continue to have the current level of

protection in their food supply. Given that the Animal Health Protection Act directs the Secretary of the 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)), the well being of the public is clearly favored in an action that prevents any additional exposure to potentially contaminated Canadian beef. Further, it will prevent any potential stigma that the meat supply in the U.S. is tainted. Moreover, there is a clear public interest in minimizing the risk of humans contracting vCJD and that weighs heavily against a decision to allow importation of potentially contaminated meat.

The USDA has evidenced a preconceived intention, based upon inappropriate considerations, to rush to reopen the border regardless of uncertainties in the agency's knowledge of the possible impacts on human and animal health. Deference cannot be given to an agency that has made the decision to open the border before completing the necessary scientific analysis of risks to human health. The USDA cannot favor trade with Canada over human and animal health within the U.S. It is contrary to the direction of the Animal Health Protection Act 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).

CONCLUSION

Plaintiff has demonstrated the numerous procedural and substantive shortcomings of the USDA's decision to allow importation of Canadian cattle and beef. The serious irreparable harm that will occur when Canadian cattle and meat enter the U.S. and co-mingle with the U.S. meat supply justifies issuance of a preliminary injunction preventing the expansion of imports allowed under the Final Rule pending a review on the merits. As the States of Connecticut, New Mexico, North Dakota, Montana, Nevada, South Dakota, and West Virginia have stated in their Amicus Curiae Brief: "The threats are great. Delay is prudent and largely harmless."

The Clerk is directed to notify the parties of the making of this Opinion.