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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,	Cause No. _______________
vs.	
UNITED STATES DEPARTMENT OF AGRICULTURE, ANIMAL AND PLANT HEALTH INSPECTION SERVICE, et al.,	**MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF PLAINTIFF'S APPLICATION FOR TEMPORARY RESTRAINING ORDER AND PRELIMINARY INJUNCTION**
Defendants.	

STATEMENT OF THE CASE

This action concerns a decision by the United States Department of Agriculture ("USDA") Animal and Plant Health Inspection Service ("APHIS"), without any prior notice, to lift a ban on the importation of all edible bovine meat from Canada for human consumption, effective April 19, 2004. That ban was previously in place to minimize the risk of adverse effects, on the health of American cattle and of American meat consumers, from cattle infected with bovine spongiform encephalopathy ("BSE"), commonly known as "Mad Cow Disease," which had been discovered in a native cow in Canada.

BSE is a progressive, fatal neurological disorder of cattle that results from infection by an unconventional transmittable 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) (Exhibit 1 to this Memorandum). Eating meat products contaminated with the agent for BSE is believed to cause variant Creutzfeldt-Jakob Disease ("vCJD") in humans, a fatal neurological disease for which there is no known cure. Eating contaminated bovine meat and other products is believed to have resulted in the death of over 100 people in the United Kingdom and a number of people 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 beef products imported into the United States caused the largest consumers of American beef, Japan and Korea, to cut off most imports of beef from the United States.

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* Exhibit 3 to this Memorandum. (Exhibit 4 is the transcript of a media briefing on the decision by Secretary Veneman and other USDA employees, and Exhibit 5 is the Questions and Answers document for the decision that was posted on the APHIS website at that time.)

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. 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 the 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 6 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. The re-opened public comment period ended April 7, 2004. *Id*. at 10,634. Plaintiff, Ranchers Cattlemen Action Legal Fund United Stockgrowers of America ("R-CALF USA"), and hundreds of others submitted written comments on the proposal.

On April 17, 2004, Reuters News Agency reported that a Canadian official had stated the previous day that the United States had decided to allow imports of ground beef and beef on the bone effective April 19. Reuters reported that USDA spokeswoman Alisa Harrison said she had no knowledge of an imminent announcement of changes to rules on beef imports currently banned because of BSE, stating "we are not at that stage with the Canadian rule." *See* Exhibit 7 to this Memorandum. Nevertheless, on April 15, 2004 USDA posted on the APHIS website a memorandum to "U.S. Importers, Brokers and Other Interested Parties" from Karen A. James-

Preston, Director, Technical Trade Services, National Center for Import and Export, 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." Exhibit 8 to this Memorandum is a copy of that memorandum as it appeared on the APHIS website on April 15, 2004.[1]

The APHIS website also included a table of "Low Risk Canadian Products" and "required risk mitigations." Exhibit 9 to this Memorandum is a copy of that table as it appeared on the APHIS website on April 19, 2004. The list includes bovine liver, tongue, heart, kidney, tripe, and lips, and "bovine meat and meat products including: boneless, bone-in, ground meat, and further processed bovine meat products." The only "required risk mitigations" are that the meat be for edible use (not for use in animal feed or pet food) and that the shipment be accompanied by a Canadian Food Inspection Agency document "stating USDA and CFIA agreed upon certification statements." Exhibit 9 at notes 3, 4. While it is not clear from this table or Ms. James-Preston's memorandum, a USDA official explained on April 21 that the import ban has been lifted for all edible bovine meat products, even if they come from cattle over 30 months of age. Declaration of Trent W. Thomas, Exhibit 10 to this Memorandum. As of April 21, 2004, USDA had posted no press release for this action, no description of what the "USDA and CFIA agreed upon certification statements" are or how they mitigate the risk, no explanation of the

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[1] Plaintiff did not learn of the USDA action until April 19, 2004, and USDA still has not publicly announced the action, but the APHIS website indicates that Ms. James-Preston's memorandum was posted April 15. Secretary Veneman was quoted in *Congress Daily* as stating the decision was made by a technical team on April 16. We refer to it herein as the "April 19, 2004 action."

scientific or other basis for the decision, and no justification for taking this action at a time when USDA had a pending rulemaking addressing importation of the very same materials.

SUMMARY OF ARGUMENT

On April 19, 2004, USDA, without any prior notice, lifted a ban on the importation of most kinds of bovine meat and other tissue from Canada for human consumption, effective immediately. This action is an exception to the general policy of the United States (and many other nations) not to allow importation of beef from countries, such as Canada, known to have cattle infected with BSE, commonly known as "Mad Cow Disease." As a result of USDA's action, plaintiff R-CALF USA and its members will be immediately and irreparably harmed.

USDA lacks a sound scientific basis for subjecting U.S. consumers to the risk of contracting variant Creutzfeldt-Jakob Disease ("vCJD"), a fatal neurological disease for which there is no known cure, from Canadian bovine meat and meat products. USDA's April 19, 2004 action carries with it no requirement that Canadian beef be labeled to indicate the country of origin, so consumers will have no way of knowing whether they are consuming meat from a country where at least two confirmed cases of Mad Cow Disease have occurred. Because it is almost impossible to produce bone-in meat and ground meat without the possibility of the meat being contaminated with spinal cord and other neurological materials believed to carry the agent for BSE, USDA's decision to allow importation of those products from Canada increases the risk of contracting vCJD from the U.S. meat supply, as well as reinforcing and increasing the perception of consumers that U.S. meat carries that increased risk.

Thus, the importation of Canadian meat and meat products authorized by USDA's April 19, 2004 action creates serious, irreparable harm for R-CALF USA's members. Once these

Canadian products begin to be imported into the United States, where they will be intermingled with domestically produced meat, R-CALF USA members would have no way of protecting themselves against the increased risk of vCJD associated with those products. Moreover, the adverse public perception that will accompany importation of these Canadian meat products will adversely affect public perceptions of U.S. beef and will further diminish the export market for U.S. beef, resulting in reduced demand for the cattle that are the source of revenue for R-CALF USA's members. These irreparable harms can be avoided by preliminarily enjoining USDA's decision to lift the prohibition on importation of those Canadian meat products. Such a preliminary injunction would have little if any adverse effect on defendants. Any adverse effect a preliminary injunction might have on the retail price of beef because of reduced supply is speculative, at best, and insufficient to outweigh the increased risks to human health and the adverse effects on the demand for U.S. cattle that will result from USDA's April 16 action.

There is a substantial likelihood that R-CALF USA will prevail on the merits. USDA's action was taken without any notice or opportunity for public comment, and without any public explanation of a scientific basis for the action. Nor was there any public explanation for USDA's departure from its decision in May to ban importation of all ruminant products from Canada and its subsequent decision in August to issue permits for importation of Canadian beef only for muscle cuts off the bone derived from animals under 30 months of age. Even more tellingly, USDA's April 19, 2004 action was taken without complying with notice-and-comment rulemaking procedures required by the Administrative Procedure Act ("APA"), at a time when USDA was in the middle of notice-and-comment rulemaking on the very question of whether importation should be allowed for bone-in and ground meat and other meat products from Canada, 68 Fed. Reg. at 62,394-95, and whether to allow meat from cattle over 30 months of

age, 69 Fed. Reg. at 10,635. This blatant end-run around APA procedures makes a mockery of that rulemaking and evidences the procedural inadequacy of USDA's April 19, 2004 action.

USDA also failed to evaluate essential factors needed to inform its decision, including the economic impact on cattle growers of the expanded Canadian beef imports and the increased risk to human health from importing bone-in and ground meat and meat from cattle more than 30 months old. USDA neither explained the precautions that would be applied nor explained why any such precautions are adequate to address the increased risk of exposure to BSE that necessarily accompanies the decision to allow imports of meat from a country known to have BSE infection. USDA's near-total failure to explain the basis for its decision and to consider factors it is required by statute to evaluate renders its action clearly arbitrary and capricious.

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 (9th Cir. 1980); *Textile Unlimited, Inc. v. A..BMH and Co., Inc.*, 240 F.3d 781, 786 (9th 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; *Stuhlbarg Int'l Sales Co., Inc. v. John D. Brush and Co., Inc.*, 240 F.3d 832, 840-41 (9th 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 (Dist. Mont. 2002). Furthermore, the plaintiff must show that there is a significant threat of irreparable injury. I*d.* 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. The standard for issuing a temporary restraining order is substantially identical to the standard for issuing a preliminary injunction. *Stuhlbarg Int'l Sales*, 240 F.3d at 840 n. 7.

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

A. USDA's Action Is Unlawful and Must Be Set Aside, Pursuant to 5 U.S.C. § 706(2)(D), Because it Was Taken Without Observance of Procedure Required by Law.

As noted above, USDA's April 19, 2004 action was taken without notice and opportunity for public comment, as required by 5 U.S.C. § 553. A decision with such broad public health and economic consequences should not be taken "in the dark," as USDA's April 19, 2004 action was.[2] Shockingly, USDA took the April 19 action at the same time it was ostensibly reviewing the extensive public comments received on its November 4, 2003 proposal, which proposal specifically addressed importation of most of the bovine products covered by the April 19 action

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[2] USDA may argue that this was merely the granting of a permit on a case-by-case basis as authorized by its May 29, 2003 rulemaking. USDA's April 19, 2004 action was not a case-specific permit decision upon an application by an individual permit holder, however, as the May 29, 2003 regulations authorized. *See* 68 Fed. Reg. at 31,940. Moreover, USDA's May 29, 2003 action itself was not issued after notice-and-comment rulemaking. *Id*. (While that may have been justified for the ban on importation of Canadian cattle and meat products, because of emergency, that would not excuse failure to follow notice-and-comment procedures for the portion of the May 29, 2003 rule that allows importation subject to permit in specific cases; no emergency was identified associated with the issuance of such permits. Moreover, USDA never responded to after-the-fact comments it solicited on the interim final, emergency rule.)

and the appropriate conditions under which such importation could be allowed, if any; many of those comments had been received less than two weeks earlier. *See* pp. 3-4, *supra*. Thus, USDA's April 19 action constituted an end-run around required rulemaking procedures. USDA has offered no explanation for why it believed, as recently as March 8, 2004, that a rulemaking was appropriate on this subject and yet has now concluded it can take action without completing the rulemaking and without adequate review or response to public comments.[3] 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. USDA Failed To Explain its Departure from Prior Determinations.

As noted above, on May 29, 2003 USDA concluded that it was necessary, on an emergency basis, to ban, except for case-by-case permits, importation of Canadian cattle and beef products. 68 Fed. Reg. 31,939. That decision was consistent with other USDA decisions to ban importation of beef from countries where BSE had been discovered in native herds. *Id.* It also was consistent with the approach many other countries have taken to try to minimize the risk of contamination of cattle and of vCJD from consuming contaminated beef. On August 8, 2003, USDA announced that it would begin issuing permits for certain products from Canada, including boneless bovine meat from cattle under 30 months of age and bovine liver. Exhibit 3. Secretary Veneman said that this decision was based on a "thorough scientific analysis" that "determined that the risk to public health is extremely low." Exhibit 4 at 1.

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[3] *See also* Transcript of August 8, 2003 Media Briefing, in which Secretary Veneman stated, when explaining the decision to lift the import ban for certain boneless cuts of meat from cattle less than 30 months old: "We will continue to prohibit entry into the United States of certain other Canadian products, notably live cattle, <u>until a rulemaking process is completed</u>." Exhibit 4 at 2 (emphasis added)..

In contrast, the April 19, 2004 memorandum from Ms. James-Preston (Exhibit 8) offers no explanation at all for why the determinations last year to allow importation only of off-the-bone products no longer apply. Since those previous decisions, an additional case of BSE has been discovered in a Canadian cow in Washington State. There certainly is nothing obvious that would justify a decision to lift the ban on importation of other types of bovine meat and meat products. Bone-in meat and ground meat necessarily carry a higher risk of BSE contamination than boneless muscle cuts of meat. *See* Declaration of Louis Anthony Cox, Ph.D., Exhibit 11 to this Memorandum, at 4; Declaration of Gary Weaver, D.V.M., Ph.D., J.D., Exhibit 12 to this Memorandum. Allowing importation of meat products from cattle over 30 months old appears to be especially imprudent, as multiple studies recognize this is the age group posing the highest risks of BSE contamination. *Id.*

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 (9th Cir. 2001). 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 Harlan Land Co. v. U.S. Dept. of Agriculture*, 186 F. Supp. 2d 1076, 1094-95 (E.D. Calif. 2001). 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 increased incidents of BSE in Canada 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).[4] For all these reasons, USDA has not adequately explained its April 19, 2004 decision. R-CALF USA therefore has a substantial likelihood of prevailing on its claim that the USDA action was arbitrary and capricious and an abuse of discretion under 5 U.S.C. § 706(2)(A).

C. USDA Failed Adequately To Assess the Effects of its Action on Cattle Producers.

There is no indication that USDA evaluated the economic impact of its April 19, 2004 action on livestock producers, such as R-CALF USA members, and related industries. As noted above, importation of meat products from Canada is addressed as part of the November 4, 2003 rulemaking, which was re-opened on March 8, 2004. To the extent that USDA has performed any analysis of the economic impact of allowing importation of such products on livestock growers and related industries, that economic impact analysis should have been part of the administrative record and made available for public review as part of the comment period for that rulemaking. The only economic assessment made available in that rulemaking, however, did not address the adverse economic impact 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

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[4] USDA also has not attempted to rationalize the April 19, 2004 decision with its repeated assurances to Congress of USDA's robustness against the spread of BSE, most notably by way of the USDA's January 2003 BSE report to Congress in which the USDA touted its longstanding policy of prohibiting imports from countries known to have BSE. This report stated that, "Since 1989, APHIS has prohibited the importation of live ruminants from countries where BSE is known to exist in native cattle. Other products derived from ruminants (for example, meat and meat products, …, meat-and-bone meal, …, fats and glands are also prohibited from entry, except under special conditions or under USDA permit for scientific or research purposes"

in the U.S. food supply. *See* Declaration of John J. VanSickle, Ph.D., Exhibit 13 to this Memorandum, at 2-4. In fact, according to Dr. VanSickle, Director of the International Agricultural Trade and Policy Center of the University of Florida, both of these effects on U.S. cattle growers would be significant, as would be the effects the action will have on associated industries and their productive output and the impact it will have on employment and business closures. *Id.*; *see also* Declaration of John D. Stewart, Exhibit 14 to this Memorandum, at 1, 3.

The Animal Health Protection Act, 7 U.S.C. § 8301 *et seq.*, which APHIS implements, obligates the Secretary of USDA "to protect the agriculture, environment, economy, and health and welfare of the people of the United States." 7 U.S.C. § 8301(5)(B)(iii). The Animal Health Protection Act contains a specific congressional finding that the prevention, detection, control, and eradication of diseases in animals is essential to protect, *inter alia*, "the economic interests of the livestock and related industries of the United States; …" 7 U.S.C. § 8301(1). USDA has failed in its duty to protect the economic interests of R-CALF USA's members, by failing to evaluate at all the substantial adverse effects of allowing imports of higher-risk meat products from Canada. This failure to apply the statutory factors renders USDA's April 19 action arbitrary and capricious. *See Motor Vehicle Mfrs. Ass'n v. State Farm Mutual*, 463 U.S. at 43.

D. USDA Failed Adequately To Assess the Impact of its Action on Human Health.

As noted above, 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 April 19, 2004 action provides no assurance that the risk to human health is minimized, and USDA has not explained the basis for its implicit conclusion that the increased risk 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).

As noted previously, USDA has an ongoing rulemaking that includes a proposal to allow importation of various cuts of beef, including most of those addressed in the April 19, 2004 action. That existing rulemaking was just re-opened on March 8, 2004, and the comment period expired less than two weeks ago. *See* 69 Fed. Reg. 10,633. Thus, to the extent USDA has made any assessment of the threat to human health presented by importation of the higher-risk Canadian beef products, that risk assessment should have been included in the administrative record for review and comment as part of the rulemaking process.

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* Cox Declaration, Exhibit 11, at 3-7. 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. *Id.* at 5. Neither the Harvard risk assessment nor the USDA Risk Analysis contained an assessment of the risk of consumers contracting vCJD from consuming Canadian beef. *Id*. at 3-6.

These and other limitations of USDA's analysis of risk, at least that which was made available to the public as part of the rulemaking, renders USDA's April 19 action arbitrary and capricious.[5] Moreover, its failure to state clearly the assumptions on which its risk assessment

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[5] *See* Cox and Weaver Declarations. Even Secretary Veneman's own Advisory Committee on Foreign Animal and Poultry Diseases stated that: "It is imperative that the Secretary has … more precise risk assessments in order to make appropriate regulatory decisions." Exhibit 15 at 2 (available at http://www.aphis.usda.gov/lpa/issues/bse/bse_sec_adv_comm.doc).

was based violate fundamental principles of risk assessment and render the action arbitrary and capricious. *See* Cox Declaration, Exhibit 11, at 3-7; *Harlan Land Co. v. USDA*, 186 F. Supp. 2d at 1094-95. 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 USDA's April 19, 2004 action violated the Administrative Procedure Act.

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

A preliminary injunction is necessary to preserve the *status quo ante* and prevent irreparable harm. The introduction of BSE into the United States is irreversible and is sufficient to justify a finding of significant irreparable harm. The indisputable fact is that Canadian cows have been found to have BSE, and no American-bred cows have (despite much more extensive testing in the U.S.). USDA's decision to reverse its longstanding position of prohibiting importation of all meat from a country known to have BSE, and now allow the import of all edible bovine meat products from Canada, regardless of age, 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.

A. Importation of Canadian Beef Products Will Increase the Risk of Fatal, Irreversible Disease in Humans.

Because there is known BSE infection in the Canadian herd, consuming beef from Canada carries with it an elevated risk of vCJD. Although there may be some risk from consuming boneless skeletal muscle from a BSE-contaminated cow, experts believe the risk is increased for bone-in or ground beef products allowed into the U.S. under USDA's April 19

action. *See* Cox Declaration, Exhibit 11, at 4; Weaver Declaration, Exhibit 12; Q& A document, Exhibit 5, at 4. Likewise, most experts believe that the risk of contracting vCJD is substantially higher from a cow over 30 months of age. Cox Declaration at 4; Weaver Declaration. Although USDA has not quantified or estimated the incidence of BSE in Canadian cows (other than to assert it is very low), the fact that Canada has tested only a small fraction of the number of cows the United States has tested, and has identified two cases of BSE in the past year, suggests that the incidence of BSE could be significant. Cox Declaration, Exhibit 11, at 5-6.

If consumption of the Canadian beef products allowed in by USDA's April 19, 2004 decision were to result in cases of vCJD in humans, there is no known cure, and it is a painful, debilitative, degenerative disease. See generally *World Health Organization Fact Sheet No. 180*, revised Nov. 2002 (Exhibit 16 to this Memorandum). Enjoining the importation of Canadian beef until the potential health effects of that decision can be assessed could prevent a quintessential "irreparable harm."

B. The Adverse Economic Impact of USDA's Decision Will Be Substantial and Irreversible.

Regardless of any actual adverse health effects, the perception that the U.S. meat supply is not free of BSE agents, as a result of USDA's April 19, 2004 decision to allow most types of Canadian meat products to be imported, will have a serious, irreparable impact on R-CALF USA's members and on the U.S. economy. This is not mere speculation: the discovery of BSE contamination in UK cows and meat triggered devastating losses to the beef production industry in Great Britain and other European countries. *See* VanSickle Declaration, Exhibit 13, at 4. More recently, discovery of BSE in Canadian cows has greatly curtailed demand for Canadian beef. Even more to the point, discovery of BSE in Canadian cows had already caused our largest

trading partners, Japan and Korea, to demand that any exports to those countries be demonstrated to be free of beef originating in Canada, and their markets still are largely closed to American beef. Declaration of William L. Bullard, Jr., Exhibit 17 to this Memorandum, at 3; Stewart Declaration, Exhibit 14, at 1, 3; VanSickle Declaration, Exhibit 13, at 4. Discovery of BSE in Canada last spring, and then in a Canadian-born cow in December, caused substantial reduction in domestic demand for beef. Bullard Declaration, Exhibit 17, at 2-3.

USDA's April 19 action likely will be understood by consumers in the U.S. and abroad as increasing the risk of BSE agents entering the U.S. meat supply. *Id*. at 5; *see also* VanSickle Declaration, Exhibit 13, at 3-4 and Stewart Declaration, Exhibit 14, at 3. Because USDA has not required or recommended procedures for distinguishing U.S.-raised beef and beef from Canada, Canadian beef and beef products will be intermingled in the U.S. meat supply, causing fears about consumption of U.S. meat generally (as happened with Japan and Korea). Bullard Declaration, Exhibit 17, at 4. As a result, U.S. cattle producers will suffer substantial commercial harm, with large losses in unemployment and possible closures. Van Sickle Declaration, Exhibit 13, at 3-4; *see also* Stewart Declaration, Exhibit 14, at 3. Once the additional Canadian meat products are in the U.S., the stigma will attach to all U.S. meat. Neither the Canadian meat nor the stigma could be removed from the U.S. meat supply, and the substantial, irreparable injury will have occurred. Even USDA has acknowledged that allowing Canadian beef into the U.S. could result in loss of export markets for U.S. producers, including R-CALF USA members, costing them on the order of $2 billion per year. 68 Fed. Reg. at 63,299.

Dr. VanSickle states that the worst-case impact of the USDA action allowing more and higher-risk meat in from Canada would occur if there is also an additional discovery of BSE in Canada. Dr. VanSickle's expert opinion is that this would "severely cripple the cattle and

ranching industry with lower returns that would be difficult to recover." VanSickle Declaration, Exhibit 13, at 4. Based on the impact that the BSE outbreak had on the British economy, the impact on the U.S. of a loss of confidence that the U.S. meat supply is BSE-free could be as large as $46.4 billion in a worst-case scenario. *Id.* Even a small fraction of that impact would be enough to justify a preliminary injunction to delay the entry of more and higher-risk products from Canada into the U.S. meat supply.[6]

III. SERIOUS QUESTIONS ARE RAISED AND THE BALANCE OF HARDSHIPS FAVORS THE GRANTING OF AN INJUNCTION.

A. Serious Questions Have Been Raised by Plaintiff's Papers.

Under the Ninth Circuit standard for evaluating preliminary injunctions, the 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. Clearly in this case, as explained above, very serious questions on the merits have been raised and the balance of the hardships tips in favor of the Plaintiff. Therefore, a preliminary injunction is warranted.

B. The Balance of the Harms Strongly Favors Plaintiff.

There is not any significant harm to the defendant or to any other party in maintaining the *status quo ante*. A preliminary injunction would impose minimal burdens on USDA to communicate the stay of its authorization of Canadian meat imports. The public would continue to be protected from BSE agents in Canadian cattle, as no increased exposure would be allowed.

[6] Using an economic impact model used by APHIS, but accounting for all of the impacts, Dr. VanSickle estimates that the increased imports of Canadian beef allowed by USDA's April 19 action will have a total negative impact on U.S. economic output of $5.8 billion and cost 50,874 American jobs, aside from any BSE concerns. Exhibit 13 at 3. This alone will force the failure of many cattle growing businesses. *Id*. at 4. Loss of exports from BSE concerns could reduce U.S. output by as much as $16.1 billion and cause 140,068 lost jobs. *Id*. at 3.

Given the congressional directive in the Animal Health Protection Act that the Secretary "protect the agriculture, environment, economy, and health and welfare of the people of the United States," 7 U.S.C. § 8301(5)(B)(iii), the public welfare is clearly favored by an action that prevents any additional exposure to potentially contaminated Canadian beef.

USDA may assert that importation of Canadian beef will increase the supply and reduce the cost to the consumer of beef. But current demand for beef is being met, and any projected effect on retail prices is speculative, at best. USDA estimates that allowing imports of Canadian beef would only reduce beef prices by 5 -6 cents a pound. 68 Fed. Reg. at 62,399; VanSickle Declaration, Exhibit 13 at 3. In any event, any modest lowering of meat prices over the short term would not outweigh the benefits to the public of having a U.S. meat supply free of meat from a country known to have BSE.

In contrast, the harm to R-CALF USA members and the public is substantial and immediate. The stigma that will be associated with the U.S. meat supply when it becomes co-mingled with all cuts of beef, from cattle of all ages, from a country known to have BSE will have a devastating effect on R-CALF USA's members. We already have examples, with the response to contamination of the UK meat supply with BSE and the reaction of Korea and Japan to the possibility of Canadian beef in U.S. exports, of the clear adverse effects R-CALF USA's members face. A single beef producer has suffered lost revenue of more than $200,000 per day as a result of the loss of the Japanese export market because of the perception that U.S. meat may have BSE contamination. Stewart Declaration, Exhibit 14 at 3. The projected loss of over 50,000 jobs and the adverse impact on the balance of trade will affect everyone. See Declarations of VanSickle (Exhibit 13) and Bullard (Exhibit 17). Moreover, the clear public interest in minimizing the risk of humans contracting vCJD weighs heavily against any hasty

decision to allow importation of potentially contaminated meat. Not only R-CALF USA's employees and members, but also members of the general public will be exposed to the increased risk of vCJD resulting from the importation of additional types of meat from Canada.

CONCLUSION

R-CALF USA has demonstrated the numerous procedural and substantive shortcomings of USDA's attempt to circumvent the Administrative Procedure Act and allow importation of Canadian beef without due regard for the economic impact on U.S. producers or the increased, un-assessed risks to human health. The serious irreparable harm that will occur when Canadian meat enters and is mixed with the U.S. meat supply justifies issuance of a temporary restraining order and a preliminary injunction.

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Respectfully submitted,

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*Motions for admission *pro hac vice* pending