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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,                               | ) | CV-05-06-BLG-RFC   |
|  | ) |                    |
| vs.                                      | ) | DEFENDANTS'        |
|  | ) | OPPOSITION TO      |
| UNITED STATES DEPARTMENT OF AGRICULTURE, | ) | PLAINTIFF S MOTION |
| et al.,                                  | ) | FOR A PRELIMINARY  |
| Defendants.                              | ) | INJUNCTION         |
|  | ) |                    |

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**TABLE OF CONTENTS**

**PAGES**

INTRODUCTION ..... 2

BACKGROUND ..... 3

ARGUMENT ..... 4

    PLAINTIFF'S REQUEST FOR A PRELIMINARY INJUNCTION SHOULD  
    BE DENIED ..... 4

I.    PLAINTIFF IS UNLIKELY TO SUCCEED ON THE MERITS  
    OF ITS CLAIMS ..... 4

    A.    The Standard of Review of Agency Action Under the  
          Administrative Procedure Act Is Highly Deferential, and  
          Plaintiff Fails to Show a Violation of the Standard ..... 4

    B.    APHIS s Rule Is Based On The Overwhelming Weight  
          Of Scientific Evidence ..... 6

    C.    Plaintiff's APA Arguments Are Without Merit And Present  
          No Basis for Questioning the Scientific Evidence on Which  
          the Rule Is Based ..... 9

        1.    The very low risk need not be numerically quantified ..... 9

        2.    Canada s Surveillance Level Exceeds International  
              Standards and Is Proportionate to That of the United States ..... 12

        3.    The International Scientific Consensus Is That the Feed  
              Ban Is a Highly Effective Mitigation Measure ..... 13

        4.    SRMs Are the Only Known Souce of Transmission  
              In Cattle ..... 17

        5.    Plaintiff s Challenge to the Proposal to Allow Imports  
              of Beef from Cattle Over Thirty Months of Age Is Not Ripe ..... 18

        6.    The Regulations Do Not Allow the Import of Pregnant Cows ..... 19

        7.    Mandatory Testing for All Cattle Would Produce False  
              Negative Results ..... 19

|      |  |    |
|------|--|----|
| 8.   | USDA Allowed Ample Opportunity For And Received Public Comment on Alleged Adverse Economic Impacts and Consumer Backlash ..... | 20 |
| D.   | Defendant Has Satisfied Regulatory Flexibility Act Requirements .....  | 21 |
| E.   | Plaintiff s National Environmental Policy Act (NEPA) Claims Must Fail .....  | 25 |
| 1.   | The Standard of Review Under NEPA Is Deferential .....   | 25 |
| 2.   | 31The Court Lacks Jurisdiction Over Plaintiff s NEPA Claims .....  | 27 |
| a.   | Plaintiff Has Failed To Establish Standing Under Article III to Maintain Its NEPA Claim .....                                  | 27 |
| b.   | Plaintiff s Assertion of Economic Injury Cannot Support Standing to Bring Claim Based on NEPA .....                            | 29 |
| 3.   | APHIS Was Not Arbitrary or Capricious in Issuing An EA Instead of an EIS .....   | 31 |
| II.  | RCALF HAS NOT DEMONSTRATED A THREAT OF IMMINENT INJURY OR HARM TO ITS MEMBERS .....  | 35 |
| III. | THE RULE SERVES THE PUBLIC INTEREST AND THE BALANCE OF HARDSHIPS TIPS SHARPLY IN DEFENDANTS' FAVOR .....                       | 37 |
|      | CONCLUSION .....   | 38 |

## TABLE OF AUTHORITIES

| <u>CASES</u>  | <u>PAGES</u> |
|---|--------------|
| <u>ANR Pipeline Co. v. Federal Energy Regulatory Commission,</u><br>205 F.3d 403 (D.C. Cir. 2000) .....         | 30           |
| <u>Amoco Product Co. v. Village of Gambell,</u><br>480 U.S. 531 (1987) .....                                    | 34           |
| <u>Arizona Cattle Growers' Association v. Cartwright,</u><br>29 F. Supp. 2d 1100 (D. Ariz. 1998) .....          | 29           |
| <u>Baltimore Gas &amp; Electric Co. v. Natural Res. Def. Council, Inc.,</u><br>462 U.S. 87 (1983) .....         | 5, 25        |
| <u>Bell v. Bonneville Power Admin.,</u><br>340 F.3d 945 (9th Cir. 2003) .....                                   | 29           |
| <u>Cactus Corner v. United States Department of Agriculture,</u><br>346 F. Supp. 2d 1075 (E.D. Cal. 2004) ..... | 10           |
| <u>California Forestry Association v. Thomas,</u><br>936 F. Supp. 13 (D.D.C. 1996) .....                        | 30           |
| <u>Cantrell v. City of Long Beach,</u><br>241 F.3d 674 (9th Cir. 2001) .....                                    | 27           |
| <u>Caribbean Marine Services Co. v. Baldrige,</u><br>844 F.2d 668 (9th Cir. 1988) .....                         | 18, 35, 37   |
| <u>Citizens for Public Forestry v. USDA,</u><br>341 F.3d 961 (9th Cir. 2003) .....                              | 32           |
| <u>Citizens to Preserve Overton Park, Inc. v. Volpe,</u><br>401 U.S. 402 (1971) .....                           | 6            |
| <u>Clark v. Securities Industrial Association,</u><br>479 U.S. 388 (1987) .....                                 | 29           |
| <u>Clear Channel Outdoor Inc. v. City of Los Angeles,</u><br>340 F.3d 810 (9th Cir. 2003) .....                 | 4            |
| <u>Connecticut v. Massachusetts,</u><br>282 U.S. 660 (1931) .....   | 35           |
| <u>Department of Transportation v. Public Citizen,</u><br>124 S. Ct. 2204 (2004) .....                          | 34           |

|  |        |
|--|--------|
| <u>Douglas County v. Babbitt</u> ,<br>48 F.3d 1495 (9th Cir. 1995) .....   | 29     |
| <u>Ethyl Corp. v. EPA</u> , 541 F.2d 1 (D.C. Cir.), <u>cert. denied</u> ,<br>426 U.S. 941 (1976) .....                               | 5      |
| <u>Florida Power &amp; Light Co. v. Lorion</u> ,<br>470 U.S. 729 (1985) .....  | 5      |
| <u>Forest Conservation Council v. United States Forest Service</u> ,<br>66 F.3d 1489 (9th Cir. 1995) .....                           | 34     |
| <u>Greenpeace Action v. Franklin</u> ,<br>14 F.3d 1324 (9th Cir. 1992) .....   | 5      |
| <u>Ground Zero Ctr. for Non-Violent Act v. United States Department of the Navy</u> ,<br>383 F.3d 1082 (9th Cir. 2004) .....         | 18     |
| <u>Harlan Land Co. v. United States Department of Agriculture</u> ,<br>186 F. Supp. 2d 1076 (E.D. Cal. 2001), cited by .....         | 10, 33 |
| <u>Hunt v. Washington State Apple Advertising Commission</u> ,<br>432 U.S. 333 (1977) .....  | 28     |
| <u>Idaho Farm Bureau Federation v. Babbitt</u> ,<br>58 F.3d 1392 (9th Cir. 1995) .....   | 4      |
| <u>Inland Empire Public Lands Council v. Glickman</u> ,<br>88 F.3d 697 (9th Cir. 1996) .....   | 5      |
| <u>Kern v. BLM</u> ,<br>284 F.3d 1062 (9th Cir. 2002) .....  | 25, 26 |
| <u>Kingman Reef Atoll Investments, L.L.C. v. United States Department of Interior</u> ,<br>195 F. Supp. 2d 1178 (D. Haw. 2002) ..... | 30     |
| <u>Knowles v. United States Coast Guard</u> ,<br>924 F. Supp. 593 (S.D.N.Y. 1996) .....  | 29     |
| <u>Lujan v. Defenders of Wildlife</u> ,<br>504 U.S. 555 (1992) .....   | 27, 28 |
| <u>Lujan v. National Wildlife Federation</u> ,<br>497 U.S. 871 (1990) .....  | 29     |
| <u>Morongo Band of Mission Indians v. FAA</u> ,<br>161 F.3d 569 (9th Cir. 1998) .....  | 26, 27 |
| <u>National Coalition for Marine Conservation</u> ,<br>231 F. Supp. 2d 119 (D.D.C. 2002) .....                                       | 22     |

|  |            |
|--|------------|
| <u>Nevada Land Action Association v. United States Forest Service,</u><br>8 F.3d 713 (9th Cir. 1993) ..... | 29, 30, 31 |
| <u>Public Citizen v. United States Dep't of Transp.,</u><br>316 F.3d 1002, Pl. Br. at 30 .....             | 34         |
| <u>Puna Speaks v. Edwards,</u><br>554 F. Supp. 117 (D. Haw. 1982) .....                                    | 27         |
| <u>Robertson v. Methow Valley Citizens Council,</u><br>490 U.S. 332 (1989) .....                           | 25, 26     |
| <u>Sammartano v. First Judicial District Ct.,</u><br>303 F.3d 959 (9th Cir. 2002) .....                    | 4          |
| <u>Save Our Sonoran, Inc. v. Flowers,</u><br>381 F.3d 905 (9th Cir. 2004) .....                            | 29         |
| <u>Southwest Voter Registration Education Project v. Shelley,</u><br>344 F.3d 914 (9th Cir. 2003) .....    | 4          |
| <u>State of California v. Block,</u><br>690 F.2d 753 (9th Cir. 1982) .....                                 | 32         |
| <u>Texas v. United States,</u><br>23 U.S. 296 (1998) .....   | 18, 20     |
| <u>U.S. Cellular Corp. v. F.C.C.,</u><br>254 F.3d 78 (D.C. Cir. 2001) .....                                | 22         |
| <u>United States v. Alpine Land &amp; Reservoir Co.,</u><br>887 F.2d 207 (9th Cir. 1989) .....             | 5          |
| <u>Walczak v. EPL Prolong, Inc.,</u><br>198 F.3d 725 (9th Cir. 1999) .....                                 | 4          |
| <u>Warth v. Seldin,</u><br>422 U.S. 490 (1975) .....   | 27         |
| <u>Western Radio Services Co. v. Espy,</u><br>79 F.3d 896 (9th Cir. 1996) .....                            | 29, 30     |
| <u>Wetlands Action Network v. U.S. Army Corps of Eng'rs,</u><br>222 F.3d 1105 (9th Cir. 2000) .....        | 5, 26      |
| <b>STATUTES AND REGULATIONS:</b>   |            |
| 9 C.F.R. § 93.436 .....  | 19         |
| 9 C.F.R. § 95.4 .....  | 16         |

|                                  |    |
|----------------------------------|----|
| 40 C.F.R. §§ 1500-1508 .....     | 25 |
| 40 C.F.R. § 1500.1(b) .....      | 25 |
| 40 C.F.R. § 1500.2(e) .....      | 25 |
| 40 C.F.R. § 1501.3 .....         | 26 |
| 40 C.F.R. § 1501.4(e) .....      | 26 |
| 40 C.F.R. § 1508.9 .....         | 26 |
| 5 U.S.C. § 604(a) .....          | 22 |
| 5 U.S.C. §§ 702, 706 .....       | 4  |
| 5 U.S.C. §§ 706(2)(A), (C) ..... | 4  |

The National Environmental Policy Act:

|  |    |
|--|----|
| 42 U.S.C. §§ 4321 <u>et seq.</u> , .....       | 25 |
| 42 U.S.C. § 4332(2)(C) .....                   | 26 |
| 68 Fed. Reg. 62,386, 62, 386 (Nov. 2003) ..... | 32 |
| 70 Fed. Reg. 554 (Jan. 4, 2005) .....          | 32 |
| 70 Fed. Reg. 3183 (Jan. 21, 2005) .....        | 32 |

## INTRODUCTION

Plaintiff brought this action to invalidate a regulation which is based on a 12,650 page administrative record, and the analysis by teams of experts, over a span of 14 months, of all relevant information and more than 3000 public comments. The rule, issued by the Animal and Plant Health Inspection Service (APHIS) of the United States Department of Agriculture (USDA), creates a minimal-risk region category, designates Canada as a bovine spongiform encephelopathy (BSE) minimal-risk region, and allows the importation of Canadian cattle under 30 months of age and beef from such cattle. Plaintiff has now filed a motion for a preliminary injunction to enjoin the March 7, 2005 implementation of the Rule, essentially on grounds that it has not been properly thought out and will cause the introduction and spread of BSE.

Plaintiff's motion for a preliminary injunction fails on all prongs of the preliminary injunction standard. First, plaintiff is unlikely to succeed on the merits, because scientific evidence overwhelmingly shows that the proposed imports are safe. The track record of both Canada and the United States proves that their risk mitigation measures to prevent the spread of BSE are effective. Since the first discovery of BSE more than 25 years ago, no one has ever contracted a case of variant Creutzfeldt-Jakob disease (vCJD), the human counterpart to BSE, from consumption of Canadian or U.S. beef. Also, the United States has never had an indigenous case of BSE, and Canada's four isolated cases of BSE pale in comparison to the estimated potential 1 million cases in more than twenty countries worldwide. The rule enhances the strict safeguards which are already in place to provide the utmost protection to animals and humans. By any measure, the BSE risk in Canada is exceedingly low. In addition, the Secretary of Agriculture has postponed the import of beef from cattle 30 months of age and over until the 2005 outbreaks are evaluated by Canada and the United States, a step consistent with USDA's scrupulousness in protecting animal and human health.

Second, plaintiff's allegation of a threatened vCJD outbreak is based on the most extreme

speculation. Against all scientific and statistical odds, it assumes that every one of the interlocking, overlapping and sequential risk mitigation measures that form a barricade against the introduction or establishment of BSE in the United States will fail. Moreover, plaintiff's alleged economic injuries are founded less on any actual harm than on the view that its advantage in the domestic beef market since the interim halt to importations in May 2003 is an entitlement rather than a windfall. Plaintiff has also ignored the countervailing benefits of the rule which will produce a net gain for the U.S. economy.

Finally, the public and defendants have an interest in seeing that Congress' purposes in enacting the Animal Health Protection Act are carried out. The rule was not intended to guarantee profits to any sector of the livestock industry. Rather, its purpose is to prevent disease, which Congress recognized would protect not only animal and human health, but also foreign commerce and the livestock industry as a whole. The injury to the public interest in granting plaintiff's request to enjoin the rule far outweighs any purely conjectural harm to plaintiff. For these reasons, plaintiff's motion for a preliminary injunction should be denied.

## **BACKGROUND**

The factual and legal background is contained in the Statement of Facts in Support of Defendants' Opposition to Plaintiff's Motion for a Preliminary Injunction, filed herewith and incorporated herein.

## **ARGUMENT**

### **PLAINTIFF'S REQUEST FOR A PRELIMINARY INJUNCTION SHOULD BE DENIED**

In evaluating plaintiff's request for injunctive relief, this Court must determine whether plaintiff has shown either (1) a combination of probable success on the merits and the possibility of irreparable harm; or (2) that serious questions are raised and the balance of hardships tips in its favor. See Southwest Voter Registration Educ. Project v. Shelley, 344 F.3d 914, 917 (9th Cir. 2003) (en banc); Clear Channel Outdoor Inc. v. City of Los Angeles, 340 F.3d 810, 813 (9th Cir.

2003). The district court must also consider whether the public interest favors issuance of the injunction. Shelley, 344 F.3d at 917; Sammartano v. First Judicial Dist. Ct., 303 F.3d 959, 965 (9<sup>th</sup> Cir. 2002). Under this approach, the Court assesses the issues as part of a continuum: the less certain the district court is of the likelihood of success on the merits, the more plaintiffs must convince the district court that the public interest and balance of hardships tip in their favor. Shelley, 344 F.3d at 917; see Walczak v. EPL Prolong, Inc., 198 F.3d 725, 731 (9<sup>th</sup> Cir. 1999). Plaintiff fails to satisfy these standards under any formulation.

## **I. PLAINTIFF IS UNLIKELY TO SUCCEED ON THE MERITS OF ITS CLAIMS**

### **A. The Standard of Review of Agency Action Under the Administrative Procedure Act Is Highly Deferential, and Plaintiff Fails to Show a Violation of the Standard**

Most of plaintiff's claims are governed by the Administrative Procedure Act, which provides for limited judicial review of agency action. See 5 U.S.C. §§ 702, 706. Under the APA, a court may overturn agency action only if the action was "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law," or in excess of its statutory jurisdiction or authority. 5 U.S.C. §§ 706(2)(A), (C); Idaho Farm Bureau Fed'n v. Babbitt, 58 F.3d 1392, 1401 (9<sup>th</sup> Cir. 1995). The standard of review is highly deferential and presumes an agency's action to be valid. Ethyl Corp. v. EPA, 541 F.2d 1, 34 (D.C. Cir.), cert. denied, 426 U.S. 941 (1976). Thus, a reviewing court must determine whether the agency has considered the relevant factors and articulated a rational connection between the facts found and the choice made. Baltimore Gas & Elec. Co. v. Natural Res. Def. Council, Inc., 462 U.S. 87, 105 (1983). Consequently, so long as there is a rational basis, an agency's decision will only be overturned if the agency committed a clear error in judgment. Wetlands Action Network v. U.S. Army Corps of Eng'rs, 222 F.3d 1105, 1114-15 (9<sup>th</sup> Cir. 2000) (quoting Marsh v. Oregon Natural Resources Council, 490 U.S. 360, 378 (1989)).

Moreover, it is axiomatic that, in all but exceptional situations, a court must evaluate an agency's decision based on the administrative record that was before the agency at the time of its decision. See Florida Power & Light Co. v. Lorion, 470 U.S. 729, 743 (1985); see also Inland Empire Pub. Lands Council v. Glickman, 88 F.3d 697, 703 (9th Cir. 1996).

A particularly deferential standard of review is especially appropriate where, as here, an agency is "making predictions, within its area of special expertise, at the frontiers of science." Baltimore Gas, 462 U.S. at 103. Moreover, "[w]hen specialists express conflicting views, an agency must have discretion to rely on the reasonable opinions of its own qualified experts even if, as an original matter, a court might find contrary views more persuasive." Greenpeace Action v. Franklin, 14 F.3d 1324, 1332 (9th Cir. 1992). See also United States v. Alpine Land & Reservoir Co., 887 F.2d 207, 213 (9th Cir. 1989) (Deference to an agency's technical expertise and experience is particularly warranted with respect to questions involving . . . scientific matters. ). Plaintiff fails to meet its heavy burden to prove that APHIS has failed this standard. See Citizens to Preserve Overton Park, Inc. v. Volpe, 401 U.S. 402, 415 (1971).

**B. APHIS's Rule Is Based On The Overwhelming Weight Of Scientific Evidence**

The final rule at issue is reasonable and based on overwhelming scientific evidence that the mitigation measures already in place and those imposed by the rule will prevent the introduction of BSE and mitigate any remaining risk of BSE entering or spreading within the United States. The regulations erect a series of interlocking, overlapping, and sequential barriers inserted at critical points, each of which reduces the risk to the United States cattle population and to human health. AR 8343-45; Declaration of Lisa A. Ferguson ("Ferguson Dec.") ¶¶ 11-12 (attached as Exhibit 2). Taken together, these measures create a virtually impenetrable barrier to the introduction or spread of BSE and its human counterpart, vCJD, in the United States. See Ferguson Dec. ¶ 11-12, 17.

Canada's risk mitigation measures pre-date the first detection of BSE in a native cow and include longstanding import restrictions on live cattle and beef products, a feed ban equivalent to that in the United States with a high level of compliance, and a BSE surveillance system that meets or exceeds international standards. AR 8051-52, 8324-29. In addition, Canada has consistently conducted rigorous epidemiological investigations of the BSE-infected cattle discovered in May and December 2003, and an investigation of the two instances discovered in January 2005 is ongoing. AR 8052-53, 8328. Canada was ahead even of the United States in imposing an SRM removal requirement in 2003, and has implemented other enhanced measures for tracking BSE. AR 8328. It expects to test at least 30,000 cattle in 2005, a level of surveillance which far exceeds international standards set by the OIE and is in proportion to the number of cattle tested in the United States. AR 8053, 8324-25. It has been scientifically proven that these measures will prevent the establishment or spread of BSE in Canada.

Aside from the effective measures in place in Canada to prevent the spread of BSE, there are a series of domestic barriers to its transmission. These include slaughter controls requiring the removal of SRMs and the use of processing techniques that prevent the contamination of human food, an effective feed ban to avoid the spread of BSE among cattle, as well as restrictions on the movement of imported cattle to ensure that their region of origin can be traced and that they are slaughtered before the age of 30 months, before infectious levels of BSE are likely to have developed. AR 8050, 8343, 9958; Ferguson Dec. ¶ 15-16. In addition, live cattle imported from Canada and any other minimal-risk region, by definition, must be less than 30 months old and have been subject to a feed ban. AR 8132. Similarly, imported beef must have been subject to specified slaughter controls implemented by the minimal-risk region to prevent the contamination by, and spread of, BSE infectivity. AR 8134-35. The overwhelming scientific consensus is that these measures virtually eliminate any risk that BSE will be introduced or spread to cattle or humans. Ferguson Dec. ¶ 15-16.

In view of these safeguards, it comes as no surprise that the Harvard-Tuskegee study, a comprehensive analysis conducted by many of the world's foremost experts in risk analysis and computational epidemiology, concluded that there is a very low risk of BSE becoming established or spreading if it is introduced into the United States. AR 1787-2388. Canada reached a similar conclusion in its risk assessment regarding the likelihood that BSE would spread or become established in Canada in view of the risk mitigation measures in place. AR 2512-2875. Canada, which APHIS has consistently found to be reliable in its investigations and risk assessments, determined the likelihood to be negligible. AR 8052.

The age restriction prohibiting the import of cattle 30 months of age and older creates another barrier to infectivity, since infectious levels of BSE are highly unlikely to develop in Canadian cows under thirty months. AR 8329; Ferguson Dec. ¶¶ 15-16. The average age at which cows developed signs of BSE in the United Kingdom outbreak was 4.2 years. AR 8329-8331; Ferguson Dec. ¶ 11. However, the expected incubation period in Canada could be much longer, given the high levels of infectivity circulating in the United Kingdom at the time of the study. Ferguson Dec. ¶ 11. The slight possibility of infection developing in cattle less than 30 months of age has been linked to the consumption of a relatively large dose of the BSE agent at an early age. AR 8330. Consequently, the younger cases have occurred primarily in countries, unlike Canada, where there are significant levels of circulating infectivity. AR 8331; Ferguson Dec. ¶¶ 15-16. There has not been a case of BSE in a cow under thirty months of age since 1996, and the youngest cow ever discovered to have BSE was 20 months old back in 1992. AR 8329. Therefore, cattle under 30 months of age are highly unlikely to carry infectious levels of BSE. AR 8329-8331.

Empirical proof of the effectiveness of the safeguards in place in Canada and the United States lies in the fact that despite the discovery of BSE in Europe over 25 years ago, not a single case of BSE has ever been diagnosed in an indigenous cow in the United States. AR 8048.

Surveillance activities here and in Canada have served their intended purpose by uncovering the four cases in Canadian origin cattle before they spread and epidemiological investigations have tracked, and are tracking, the source of the infectivity to prevent any further dissemination. AR 8052-53, 8324-25. Investigations by Canada and the United States have led to the reasonable conclusion that the four cases resulted from feed produced before or shortly after the feed ban went into effect in Canada. AR 8328; Ferguson ¶ 11. Moreover, the occurrence of two instances of BSE in 2003 and two in 2005 in Canadian origin cattle falls well below international guidelines for a minimal risk region. AR 8048. None of the four BSE-infected cows would have been allowed entry into the United States under the regulation.

**C. Plaintiff's APA Arguments Are Without Merit And Present No Basis for Questioning the Scientific Evidence on Which the Rule Is Based**

Plaintiff attacks the rule from nearly every angle, but plaintiff's arguments are without merit, nor do they raise valid questions about the scientific basis for the rule.

**1. The very low risk need not be numerically quantified**

Plaintiff argues that USDA failed to assess the impact of its rule on human health by quantitatively defining the term "very low" in its risk assessment. Memorandum of Points and Authorities in Support of Plaintiff's Application for Preliminary Injunction ("Pl. Br.") at 10-11. Plaintiff cites no legal or scientific authority whatsoever for the proposition that USDA should have engaged in a quantitative analysis. To the contrary, both qualitative and quantitative risk assessment methods are valid under internationally accepted scientific standards incorporated into the OIE Guidelines for Import Risk Analysis involving trade in animals and animal products. AR 8088; Declaration of David Wilson ("Wilson Dec.") ¶ 7 (attached as Exhibit 5). Likewise, Codex Alimentarius, the international standard-setting organization for food safety, provides that food safety risk analysis may be either qualitative or quantitative. AR 8088. APHIS used a combined and integrated approach that examined the overall effectiveness of control mechanisms in place and provides a more scientifically sound analysis of BSE risk. AR

8057, 8090, 8096. As the court stated in Cactus Corner v. United States Department of Agriculture, 346 F. Supp. 2d 1075, 1109 (E.D. Cal. 2004), where APHIS seeks to eliminate all risks of introduction through sound science, "there is no level of 'acceptable' risk or 'numeric threshold' to quantify." Id.<sup>1/</sup> Even if there were a numeric standard, Canada would surely meet it because no one has ever caught vCJD from eating Canadian beef.

APHIS took into account all scientifically and internationally recognized risk and risk mitigation factors, including: (1) the low number of infected products that might conceivably be imported from Canada even without the mitigations applied by the rule, given the longstanding import and feed restrictions in place in Canada; (2) the low reported incidence rate in Canada coupled with its active targeted surveillance program both of which satisfy and far exceed the OIE guidelines for a minimal BSE risk country or zone; (3) the risk reduction from mitigation measures imposed by the rule; (4) the very low likelihood of infected tissue contaminating animal feed or human food as a result of safeguards imposed by Canada and the United States, including prohibitions on nonambulatory cattle and SRMs in human food, and animal feed restrictions; (5) and the very low likelihood that any tissue would contain infectious levels of the BSE agent, or be present in sufficient quantities to cause infection in susceptible animals. AR 8089; Ferguson Dec. ¶¶ 9, 11-12. APHIS also relied on the Harvard-Tuskegee Study's quantitative analyses of the risk of BSE spreading if introduced into the United States. AR 8089; Ferguson Dec. ¶¶ 5-6. The established scientific evidence shows overwhelmingly that BSE is highly unlikely to be introduced into the United States from Canada. AR 8089; Ferguson Dec. ¶¶ 5, 9. Plaintiff cites no authority for questioning APHIS's approach, and contrary to plaintiff's

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<sup>1/</sup> The court in Cactus Corner distinguished Harlan Land Co. v. United States Dep't of Agriculture, 186 F. Supp. 2d 1076 (E.D. Cal. 2001), cited by plaintiff for the proposition that defendant has failed to define "negligible risk." Pl. Br. at 11. The present case is based on a 12,650-page administrative record which includes extensive scientific studies and analyses which defendant expressly relied upon to explain its conclusions, whereas the Harlan Land administrative record offered no supporting scientific justification for its conclusion that the risk posed by the proposed rule would be negligible. See Cactus Corner, 346 F. Supp. 2d at 1106.

assertions, which are not supported by science, Canada's BSE risk is exceedingly low. Ferguson Dec. ¶ 9.

Plaintiff is incorrect in asserting that defendant failed to quantitatively assess the impact on human health.<sup>2/</sup> Pl. Br. at 10. The Harvard-Tuskegee Study quantified potential human exposure. AR 8089; Ferguson Dec. ¶ 6. Based on conditions that predated the recent implementation of safeguards by Canada and the United States, the Study concluded that only a small amount of potentially infective tissues would likely reach the human food supply. AR 8089; Ferguson Dec. ¶ 6. More importantly, the subsequently implemented safeguards (most critically, the SRM-removal requirement) and evidence that compliance with feed restrictions in the United States is better than estimated make the possibility of contamination far less likely. AR 8089; Ferguson Dec. ¶ 6. Although certain quantitative information is not available, there is as well a substantial species barrier that protects humans from infection, so the possibility of humans contracting vCJD is all the more unlikely.<sup>3/</sup> AR 8087, 8089; Ferguson Dec. ¶ 6. Contrary to plaintiff's claim, such information allows an appropriate assessment of the effects of the rulemaking on human health. AR 8089; Ferguson Dec. ¶ 6. Plaintiff points to no evidence to the contrary, and its own estimate of the potential for human exposure is grossly misleading and based on seriously flawed assumptions. Ferguson Dec. ¶¶ 6, 17.

Plaintiff suggests USDA's conclusion that BSE incidence in Canada is very low should also be quantified, Pl. Br. at 11, but no country in the world is attempting to quantify the true prevalence of BSE in its entire cattle population because current testing methodology limits the

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<sup>2/</sup> Plaintiff bases this assertion on the declaration of Dr. Cox, who has no apparent experience working with veterinary medicine or BSE specifically, Ferguson Dec. ¶ 2, and whose representations therefore are not founded on experience in the area most relevant to this case.

<sup>3/</sup> Scientific evidence shows that the cases of vCJD contracted during the European epidemic were the result of extremely high levels of exposure to BSE that would not be present in Canada or the United States due to the risk mitigation measures now in place, and every one of the cases of vCJD, without exception, resulted from the ingestion of SRMs, the central nervous system tissues which are the repositories of BSE infectivity. Ferguson Dec. ¶ 17.

ability to detect infectivity before an animal exhibits clinical signs. AR 8096; Ferguson Dec. ¶¶ 7-9. However, such a measurement is not necessary to determine whether risk mitigation policies are appropriate or need to be changed, a decision which is more accurately based on an integrated evaluation of all the control mechanisms in place in a region to determine their overall effectiveness. AR 8096; Ferguson Dec. ¶¶ 7-9. Plaintiff points to no contrary evidence.

The notion that Canada's prevalence rate is 5.5 cases per million, Pl. Br. at 13, is based on a flawed analysis by Dr. Cox which improperly extrapolates data from one geographic area in Canada to the whole country, and which fails to calculate incidence rates over a single given year. Ferguson Dec. ¶ 8. Dr. Cox's estimated incidence rate of 5.5 cases per million therefore conflicts with the incidence rate of 0.33 cases per million for 2003 calculated by the OIE, and with the incidence rate for the last twelve month period of 0.36 cases per million. Ferguson Dec. ¶ 8.

## **2. Canada's Surveillance Level Exceeds International Standards and Is Proportionate to That of the United States**

Plaintiff argues that Canada conducted insufficient testing and the finding of four cattle puts Canada on par with European countries with a BSE problem. Pl. Br. at 12-14. Both assertions are baseless. Canada has met or exceeded the level of testing recommended by the OIE Terrestrial Animal Health Code Appendix 3.8.4 for the past 7 years; has steadily increased its surveillance level, testing 5,727 cattle in 2003, and 15,800 through December 1, 2004; and plans to test 30,000 in 2005. AR 8060, 8324-25. Because the Canadian cattle population is multiple times smaller than that of the United States, Canada need not, as plaintiff suggests, Pl. Br. at 12, test the same number of animals as the United States (where testing of over 200,000 has been announced) to reach an equivalent level of testing. AR 8060. Surveillance testing of 30,000 animals in Canada is therefore equivalent to the U.S. target of sampling 240,000 to 300,000. AR 8060.

The notion that cattle showing no signs of BSE should be tested is misguided. Pl. Br. at 12. Experience in the United Kingdom and other parts of Europe has shown that testing in a high risk population, i.e., cattle that are nonambulatory, dead on the farm, or showing clinical signs of BSE, is the method most likely to disclose the presence of BSE in a herd. AR 8074; Ferguson Dec. ¶ 10. According to the international and scientific consensus, the testing of apparently healthy cattle is the least likely to produce accurate results, since current testing methodology can only detect BSE a few months before an animal exhibits clinical signs. AR 8096; Ferguson Dec. ¶ 10. The key to effective surveillance is therefore to examine the population of animals where the disease is likely to occur, which is the policy and practice in both the United States and Canada. AR 8075. Plaintiff offers no scientific or other authority suggesting that testing apparently healthy animals in a region like Canada is effective for animal health purposes.

### **3. The International Scientific Consensus Is That the Feed Ban Is a Highly Effective Mitigation Measure**

Plaintiff argues that USDA wrongly relied on the feed ban because bovine protein may not be the only means of transmission of BSE. Pl. Br. at 15. Plaintiff concedes that experts do agree that the most important means of preventing the spread of BSE in cattle is limitations on cattle feed. Pl. Br. at 14; see also AR 8098 ( The best scientific evidence . . . is that BSE is spread primarily by contaminated feed and that prohibiting the feeding of ruminant-origin protein to ruminants prevents disease spread ). What plaintiff also fails to point out, however, is that oral ingestion of feed contaminated with BSE is the only documented route of field transmission of the disease in cattle. AR 8070. Plaintiff points to studies showing blood carries infectivity, but there is no scientific evidence that BSE will enter the food chain through bovine blood. AR 8075; Declaration of Daniel L. Engeljohn ("Engeljohn Dec.") ¶ 16 (attached as Exhibit 1).

Plaintiff also contends that Canada's feed ban is inadequate because it has only been in place for approximately 7.5 years. Pl. Br. at 15. USDA considered the length of the feed ban within the context of the many other control measures Canada had in place at the time of diagnosis (e.g., effectiveness of surveillance, import controls, and feed ban), and the actions it took after May 2003 (e.g., epidemiological investigations, depopulation, and SRM removal). AR 8080. Furthermore, because 7 years represents the 95<sup>th</sup> percentile of the incubation period distribution, there is a rational basis for APHIS's conclusions regarding the adequacy of Canada's feed ban. AR 8080, 8327. Cattle born and hypothetically exposed to feed produced prior to the August 1997 feed ban are now at least 7 years old and cannot be imported into the United States under this rule. AR 8099, 8107.

Plaintiffs allege that USDA's rejection of international standards in departing from the 8-year guideline is arbitrary and capricious. Pl. Br. at 14-15. Plaintiff's interpretation of the OIE guidelines, as well as the application of those guidelines, is wrong. The current version of the OIE Terrestrial Animal Health Code ( Code ) recognizes five BSE status classifications: BSE free, provisionally free, minimal risk, moderate risk, and high risk. Wilson Dec. ¶ 6. Under existing policy, OIE only examines a member country's claim as being BSE free or provisionally free. Id. Assessment of any other BSE status is a matter between the respective importing and exporting countries, but OIE expects the importing country to conduct a comprehensive risk assessment and to fully consider and evaluate its outcome, as well as the other factors set forth in the Code. Id. ¶¶ 7, 9.

Thus, in applying OIE guidelines to the BSE status classification of the exporting country, such as guidelines regarding the duration of a feed ban, an importing country should identify and evaluate all of the potential factors for BSE occurrence and management, and their historic perspective, in the exporting country. Wilson Dec. ¶¶ 7, 9. OIE would consider it inappropriate for the importing country to apply each criterion as an item on a checklist and to

conclude that the exporting country fails to qualify for a particular risk status merely because it does not meet a listed criterion. Id. ¶¶ 7, 9. Rather, the importing country would be expected to assess whether an alternative risk management measure could be applied to achieve the same level of protection. Id. ¶¶ 7, 9. For example, a deficiency in the length of a feed ban could be addressed through restrictions on the age of live cattle imported. Id. ¶¶ 7, 9.

This is precisely the approach taken by APHIS in designating Canada as a minimal risk region in this rule. Plaintiff's assertion that Canada does not qualify as a minimal risk region under international guidelines is premised upon the erroneous assumption that the guidelines should be applied in a rigid, inflexible manner, a position that has been firmly rejected by the OIE itself. Ironically, the position advocated by plaintiff—banning the importation of all live ruminants and ruminant products from a country that has detected BSE within its herd—is clearly contrary to OIE guidelines because the OIE does not recommend a complete ban on trade in live cattle and meat, even from exporting countries which present a high BSE risk. Wilson Dec. ¶ 8.

As alleged proof of the ineffectiveness of the feed ban, plaintiff mistakenly argues that because the mean incubation period for BSE is 4.2 years, all four Canadian-origin cows infected with BSE could have been born after the 1997 implementation of the ban. Pl. Br. at 16; Cox Dec. ¶ 15. Plaintiff's assumptions in applying the mean rate of incubation to determine the date of exposure to BSE in the four Canadian cattle are incorrect and scientifically unsound. Ferguson Dec. ¶ 11. Animals affected by BSE are typically infected well before they are 1 year old. Id. The incubation period of BSE (i.e., the time it takes for the animal to exhibit clinical signs of the disease) is contingent on the dose of the infectious agent that the animal consumes. Id. This incubation period is generally 7 to 8 years. Id. In the United Kingdom, the mean incubation period was 4.2 years. Id. The fact that Canadian cattle found positive for BSE were all older indicates low initial exposure, so their expected incubation period would be longer. Id.

Accordingly, the Canadian cows were most likely affected before, and in the case of the latest discovered cow, shortly after the implementation of the feed ban.

Plaintiff suggests that animal fat in cattle feed can spread BSE. Pl. Br. at 17. However, the uncontroverted science says tallow creates a risk of transmission only if it is contaminated with protein. AR 8085. OIE therefore recommends allowing the import of protein-free tallow without restriction, regardless of the BSE status of the exporting country. AR 8085.

Accordingly, 9 C.F.R. § 95.4 authorizes the importation only of tallow that is free of animal protein. AR 8085.

Plaintiff's suggestion that Canada is not complying with the feed ban is erroneous. Pl. Br. at 18. CFIA has verified high levels of compliance with the feed ban by routine inspections of both renderers and feed mills. AR 8098-99, 8327. Plaintiff alludes to instances of noncompliance in the United States as evidence of Canada's noncompliance with its feed ban. Pl. Br. at 18. However, despite allegedly significant noncompliance in the United States, not a single indigenous case of BSE has been detected in the United States. Similarly, in Canada, the feed ban has been effective, despite plaintiff's speculation about alleged lapses in compliance, and the BSE incidence rate is well below the OIE guideline for minimal-risk regions. AR 8094, 8096, 8322-23. As the Harvard-Tuskegee Study showed, the risk of BSE spreading into the United States is extremely low even if the feed ban is leaky, because of all the other risk control mechanisms in place. AR 8339; Ferguson Dec. ¶¶ 11, 14.

#### **4. SRMs Are the Only Known Source of Transmission In Cattle**

Plaintiff alleges that USDA arbitrarily assumed that the removal of SRMs eliminates all risk when there might allegedly still be exposure to BSE from other sources such as muscles or other non-nervous system (i.e., non-SRM) tissue, blood, or saliva. Pl. Br. at 19; Cox Dec. ¶ 17. The broad scientific consensus is that infectivity is contained in SRMs, and their removal is the single most effective step to minimizing the risk of BSE transmission to humans. AR 9959-

9971; Engeljohn Dec. ¶¶ 5-7; Ferguson Dec. ¶ 6. USDA's experts were already familiar with the research RCALF offered on this subject. Engeljohn Dec. ¶ 18. They considered it carefully, along with a very large body of additional research and studies, but found no scientifically justifiable basis for changing the rule. Engeljohn Dec. ¶ 18. See Marsh, 490 U.S. at 378 (finding that agency has the discretion to rely on the reasonable opinions of its own qualified experts ); Ground Zero Ctr. for Non-Violent Act v. United States Dep't of the Navy, 383 F.3d 1082, 1090 (9<sup>th</sup> Cir. 2004) ( Agencies are normally entitled to rely upon the reasonable views of their experts over the views of other experts. ).

The scientific studies on which plaintiff relies involve sheep, but there is no evidence that findings on sheep can be extrapolated to cattle. Engeljohn Dec. ¶ 15; Ferguson Dec. ¶ 13. Even if they could, however, the species barrier would prevent the relatively low level of infectivity that resides in sheep muscle from posing any appreciable threat to animal or human health. Engeljohn Dec. ¶ 15; Ferguson Dec. ¶ 17. There is a similar scientific consensus regarding the fact that transmission of infectivity through the blood of sheep cannot be extrapolated to cattle, Engeljohn Dec. ¶ 16, and plaintiff offers no evidence to the contrary. Finally, the broadly held scientific view based on epidemiological studies and reports is that BSE cannot be transmitted through saliva. Engeljohn Dec. ¶ 17. Again, plaintiff presents no evidence which proves otherwise. Id.

##### **5. Plaintiff's Challenge to the Proposal to Allow Imports of Beef from Cattle Over Thirty Months of Age Is Not Ripe**

Plaintiffs contend that there is no basis for USDA's decision to allow imports of beef from cattle over 30 months of age. Pl. Br. at 20. This claim is premature and presents no basis for emergency injunctive relief now that the Secretary has delayed the implementation date of the portion of the rule which would allow such imports. See Caribbean Marine Servs. Co. v. Baldrige, 844 F.2d 668, 674 (9<sup>th</sup> Cir. 1988). Until the agency takes final action, plaintiff's claim is not ripe for review. See Texas v. United States, 523 U.S. 296, 300 (1998) ( A claim is not

ripe for adjudication if it rests upon contingent future events that may not occur as anticipated, or indeed may not occur at all. ) (internal quotation marks omitted).<sup>4/</sup>

#### **6. The Regulations Do Not Allow the Import of Pregnant Cows**

Plaintiff argues that the rule fails to prevent cattle from being bred before or after entering the United States, or to specify the proper disposition of fetuses. Pl. Br. at 24. While the regulation does not expressly prohibit breeding, however, it does so implicitly, since live cattle are permitted to enter the United States only for immediate slaughter or for feeding, but not for breeding. See AR 8132; 9 C.F.R. § 93.436. Moreover, there is no direct scientific evidence for maternal transmission of BSE, AR 8416, and plaintiff points to none.

#### **7. Mandatory Testing for All Cattle Would Produce False Negative Results**

Plaintiffs contend that USDA wrongly rejected mandatory testing for all cattle. Pl. Br. at 26. However, the international scientific community has concluded that testing of every animal is not scientifically justified, and in fact, is the least likely to produce meaningful results. AR 8059; Ferguson Dec. ¶ 10. Current testing methods can detect a positive case of BSE at the earliest 2 to 3 months before the animal begins to demonstrate clinical signs, and the average incubation period is generally very long, about 4 years. AR 8059; Ferguson Dec. ¶¶ 10-11. Thus, testing an infected animal that has not demonstrated clinical signs of the disease would incorrectly produce negative results. AR 8059; Ferguson Dec. ¶¶ 10-11. There is no scientific evidence or opinion that testing of all cattle is an effective surveillance measure, and plaintiff points to no evidence or opinion that it is. If BSE is present but too early to detect, mitigation measures such as feed bans and the removal of SRMs will prevent the spread in cattle and avoid human exposure. AR 8059.

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<sup>4/</sup> Even if the claim were ripe, it offers no basis for relief. The removal of SRMs reduces the risk of transmission from cattle of any age, Ferguson Dec. ¶ 10, and it is unlikely that cattle over 30 months of age would be susceptible to the potentially low level of infectivity that would potentially be present in Canada. Ferguson Dec. ¶¶ 7, 9, 13, 16.

**8. USDA Allowed Ample Opportunity For And Received Public Comment on Alleged Adverse Economic Impacts and Consumer Backlash**

Plaintiff argues that USDA did not allow public comment on the adverse economic impacts of the rule on RCALF's members and other producers from the alleged influx of Canadian beef and the increased perception of risk of BSE contamination in food.<sup>5/</sup> Pl. Br. at 28. Contrary to plaintiff's claim, however, defendants allowed and received public comment on both of these issues. APHIS addressed at least 16 issues that were raised concerning the economic impact of increased Canadian beef imports. See AR 8101-04. In responding to the comments, APHIS indicated that the loss to cattle producers would be offset by gains to U.S. buyers of feeder cattle sold at lower average prices due to the increased supply. AR 8104. APHIS found that the benefit to U.S. consumers would outweigh any potential harm to U.S. livestock producers, and the net change in welfare within the United States will be positive. AR 8104. Plaintiff's declarant Dr. Vansickle predicts negative effects on plaintiff's sector of the livestock industry, see Vansickle Dec. ¶¶ 8-10, 12, 16, but fails to give any substantial consideration to the countervailing positive effects which result in a net gain for the economy. Declaration of Frank Fillo ("Fillo Dec.") ¶ 8 (attached as Exhibit 3). These include the positive effects on employment and income in the animal feed, animal production, and animal product processing industries that more than offset the losses estimated by Dr. Vansickle.<sup>6/</sup> Fillo Dec.

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<sup>5/</sup> Plaintiff also contends that the March 8, 2004 notice was too vague to allow public comment on the removal of the 30-month restriction. Pl. Br. at 26. This claim is not ripe given the Secretary's postponement of the effective date of that portion of the rule. See Texas v. United States, 523 U.S. at 300. In any event, there is no merit to the claim, given that defendant notified the public of its intention to allow imports of beef from cattle over 30 months and provided a one month comment period. AR 3837-40.

<sup>6/</sup> The negative effects predicted by Dr. Vansickle will be smaller than he estimated, now that the Secretary has delayed the import of beef from cattle over 30 months of age. Fillo Dec. ¶ 6. The fact that benefits may accrue to fed-cattle consumers more than individual U.S. consumers, see Vansickle Dec. ¶ 9, has no bearing on USDA's conclusion that the overall benefit to the U.S. economy outweighs the harm to cattle producers. In any event, it is contrary to sound economic theory to assume that all welfare gains due to price reductions would be captured by meat packers and supermarket chains. Fillo Dec. ¶ 7.

¶ 8. There is no support for Dr. Vansickle's contention that cattle producers are already weakened, see Vansickle Dec. ¶¶ 8, 17, when in fact their returns for 2004 were at a 30-year high, and they would, as Dr. Vansickle concedes, enjoy a net economic benefit of \$66-74 million through 2009. Fillo Dec. ¶ 5.

Similarly, APHIS responded to comments relating to alleged consumer concerns due to the perception that U.S. beef is unsafe. See AR 8106-07. APHIS observed that U.S. consumer demand remained strong when imports of Canadian boneless beef resumed in August 2003 after the discovery of BSE in a Canadian cow, and it remains strong despite the imposition of import bans by over 70 countries on U.S. cattle and beef, with no domestic share loss to other protein sources. AR 8106; Fillo Dec. ¶ 4. In fact, the United States has continued to import nearly as much Canadian beef since the discovery of BSE in North America as it did before (96% of average beef imports), and there has been no resulting loss of consumer confidence. Fillo Dec. ¶ 4. APHIS does not expect this climate to change in light of increased imports from Canada under the new rule. AR 8106.

#### **D. Defendant Has Satisfied Regulatory Flexibility Act Requirements**

The Regulatory Flexibility Act (RFA) requires that when an agency promulgates a final rule, it must prepare a final regulatory flexibility analysis that contains a description of the steps the agency has taken to minimize the significant economic impact on small entities and reasons why the other significant alternatives to the rule were rejected. 5 U.S.C. 604(a). Because the RFA is purely procedural in nature, U.S. Cellular Corp. v. F.C.C., 254 F.3d 78, 88 (D.C. Cir. 2001), it does not provide plaintiffs with a remedy for defendant's "failure" to choose a different alternative. See National Coalition for Marine Conservation, 231 F. Supp. 2d. 119, 143 (D.D.C. 2002) (stating that "the RFA does not give plaintiff the authority to determine which alternative best meets the agency's goals.").

Plaintiff alleges that USDA failed to satisfy the Regulatory Flexibility Act because it did

not consider alternatives such as a labeling requirement for country of origin, or voluntarily testing by slaughter facilities. Pl. Br. at 34. These assertions are without merit. Under section 10816 of the Farm and Security and Rural Investment Act of 2002 and the 2002 Supplemental Appropriations Act, USDA is already required to implement a country of origin labeling program, and in October 2003 it issued a proposed rule to that effect. AR 8117. By law the implementation of this program is scheduled to occur in September 2006. AR 8117. It is reasonable for APHIS not to delay implementation of the rule until then. AR 8117. Plaintiff s declarant speculates that a labeling requirement would be an effective mitigation measure, but he is in error. Vansickle Dec. ¶ 18. While labeling provides consumers with additional information, it is neither a food safety nor an animal health measure. Fillo Dec. ¶ 12. Finally, Dr. Vansickle fails to consider the enormous costs that would be imposed on consumers and businesses as a result of this labeling alternative.

Contrary to plaintiff s claim, APHIS has also carefully considered the possibility of allowing private companies to conduct their own testing. AR 8118. However, APHIS reasonably views such testing as having no basis in science. AR 8118; Fillo Dec. ¶ 13. Private testing of all slaughter cattle is inconsistent with USDA s mandate to ensure effective, scientifically sound testing for significant animal diseases and to maintain domestic and international confidence in U.S. cattle and beef. AR 8118; Fillo Dec. ¶ 13. This conclusion is underscored by plaintiff s speculative and lukewarm endorsement of private testing as a measure that would appear to mitigate somewhat the risk of BSE from Canadian imports. Vansickle Dec. ¶ 18. Moreover, currently available post-mortem tests, although useful for disease surveillance, are not appropriate as food safety indicators. AR 8118; Fillo Dec. ¶ 13. Again, Dr. Vansickle fails to consider the costs associated with such a program. Fillo Dec. ¶ 13.

Finally, plaintiff argues that defendants estimate of the effects of U.S. consumer concerns is low in comparison to experiences in other countries, and that defendants did not

assess the economic consequences of continued restrictions on U.S. exports. Pl. Br. at 34. Plaintiff relies on the Vansickle declaration for these assertions. However, Dr. Vansickle's prediction that consumer demand could decline contradicts actual experience in the United States and Canada, where consumer demand remains strong and safety scares have been short-lived. Fillo Dec. ¶¶ 4, 11. His prediction is based on the drop in consumer demand in Europe following the discovery of BSE, but that comparison is inapposite, since the magnitude of the problem in Europe dwarfs the 4 cases of BSE in North America since 2003. Outbreaks occurred in 20 European countries with 180,687 cases in Great Britain alone, and 147 cases of vCJD between 1005 and 2004. Fillo Dec. ¶ 11. By contrast, no one in Canada (or the U.S.) has ever contracted vCJD from consumption of Canadian (or U.S.) beef. Fillo Dec. ¶ 11. It is therefore not surprising that European consumers have had a much stronger negative reaction to the presence of BSE in their cattle populations. Fillo Dec. ¶ 11.

Dr. Vansickle surmises that beef exports will continue to decline based on the fact that they declined by 82.4% between 2003 and 2004 (when 70 countries banned U.S. beef). Pl. Br. at 34; Vansickle Dec. ¶ 12. This conjecture fails to account for the fact that increased domestic demand compensates for lost exports when excess domestic supply causes prices to decline. Fillo Dec. ¶ 9. Dr. Vansickle also grossly overstates the effect of lost exports on the general economy and fails to factor in the employment gains from processing additional Canadian cattle at U.S. slaughter plants. Fillo Dec. ¶ 9.<sup>7</sup>

Furthermore, contrary to plaintiff's claim, see Pl. Br. at 34, it is reasonable to conclude that the creation of the minimal-risk category and inclusion of Canada in that category may increase U.S. exports over the longer term. The previous all-or-nothing regime under which

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<sup>7</sup> Dr. Vansickle asserts that Canada's alleged failure to meet the international standards of OIE for a minimal-risk region will contribute to a lack of foreign confidence in the safety of U.S. beef. This reflects a fundamental misunderstanding of the OIE standards, which are guidelines to structure risk assessment rather than a checklist of mandatory criteria. Wilson Dec. ¶ 7.

imports are completely banned from regions where BSE is found halts trade even with regions like the United States itself, where any BSE risk is extremely low due to longstanding effective mitigation measures. AR 8046. The final rule defines a new classification for minimal-risk regions with the objective of facilitating safe trade in animals and animal products. By setting an example and following it, the United States will benefit from more responsible foreign import policies if other countries follow suit.<sup>8/</sup>

## **E. Plaintiff s National Environmental Policy Act (NEPA) Claims Must Fail**

### **1. The Standard of Review Under NEPA Is Deferential**

The National Environmental Policy Act (NEPA), 42 U.S.C. §§ 4321 et seq., requires federal agencies to examine the environmental effects of proposed federal actions and to inform the public of the environmental concerns that went into the agency's decision-making. See Baltimore Gas v. Natural Res. Def. Council, 462 U.S. 87, 97 (1983). Regulations promulgated by the Council on Environmental Quality, 40 C.F.R. §§ 1500-1508, provide guidance in the application of NEPA, and they are entitled to substantial deference. Robertson v. Methow Valley Citizens Council, 490 U.S. 332 (1989).

The NEPA process requires that environmental information be available and subject to comment, review and analysis by both public officials and citizens prior to decisions being made on federal proposals for action. 40 C.F.R. § 1500.1(b). The process is designed to "identify and assess the reasonable alternatives to proposed actions that will avoid or minimize adverse effects of these actions upon the quality of the human environment." 40 C.F.R. § 1500.2(e). The process ensures the agency took a hard look at the environmental consequences of its action. Kern v. BLM, 284 F.3d 1062, 1067 (9<sup>th</sup> Cir. 2002). Because NEPA is essentially a procedural

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<sup>8/</sup> Plaintiff alleges that Canada s restrictions on U.S. imports are stronger than U.S. restrictions on Canadian imports. See Vansickle Dec. ¶ 13. This is erroneous. Canada has never prohibited the importation of U.S. cattle for slaughter and has allowed the import of feeder calves since April 2004. Fillo Dec. ¶ 10. Furthermore, recently proposed Canadian import regulations would significantly expand access for U.S. cattle and beef, and once effective, will be more liberal than those of the United States. Id.

statute, it does not require an agency to reach a particular result based on the information it collects and analyzes. Robertson, 490 U.S. at 350-51; Morongo Band of Mission Indians v. FAA, 161 F.3d 569, 575 (9<sup>th</sup> Cir. 1998) ( NEPA exists to ensure a process, not a result. )

NEPA requires agencies to prepare environmental impact statements (EISs) on all proposals for "major federal actions significantly affecting the quality of the human environment," and outlines the contents of such statements. 42 U.S.C. § 4332(2)(C). As an initial matter, an agency may prepare an Environmental Assessment (EA) to determine whether the environmental impact of a proposed action is significant enough to warrant preparation of an EIS. See 40 C.F.R. § 1501.3; id. § 1501.4(c), (e); id. § 1508.9. An EA is a concise public document that should briefly describe the proposal, examine alternatives, consider environmental impacts, and provide a listing of individuals and agencies consulted. 40 C.F.R. § 1508.9. If a Finding of No Significant Impact (FONSI) is made after the matter is analyzed in an EA, then no EIS is required. 40 C.F.R. § 1501.4(e).

An agency's decision not to prepare an EIS is reviewed for abuse of discretion, and will be set aside only if it is arbitrary and capricious. Kern, 284 F.3d at 1070 (citing Marsh v. ONRC, 490 U.S. 360, 376-77 (1989)). The arbitrary and capricious 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 (9<sup>th</sup> Cir. 2000) (internal quotations and citations omitted). This standard of review is deferential, and the Court should not substitute its judgment for that of the agency. Id. APHIS's decision should only be overturned if the agency committed a clear error in judgment. Id. (citations omitted). This Court is not required to determine whether the project will have significant environmental effects, but whether the agency has reasonably concluded that it will not. Puna Speaks v. Edwards, 554 F. Supp. 117,

121 (D. Haw. 1982). Moreover, the agency is entitled to deference on technical issues within its area of expertise. Morongo Band of Mission Indians v. FAA, 161 F.3d 569, 576 (9<sup>th</sup> Cir. 1998).

## **2. The Court Lacks Jurisdiction Over Plaintiff s NEPA Claims**

This Court should dismiss plaintiff s claims solely on the grounds that plaintiff lacks standing to bring its claims. Not only has plaintiff failed to allege sufficient injury to support Article III standing under NEPA, plaintiff s assertion of economic injury falls outside the zone of interest that NEPA was designed to protect.

### **a. Plaintiff Has Failed To Establish Standing Under Article III to Maintain Its NEPA Claim**

The critical threshold inquiry in the invocation of the jurisdiction of the federal courts is whether plaintiffs have demonstrated a case or controversy between themselves and defendants within the meaning of Article III of the United States Constitution. Warth v. Seldin, 422 U.S. 490, 498 (1975). To establish standing, plaintiffs bear the burden of demonstrating, at an irreducible minimum, that: (1) they have suffered a concrete and particularized injury which is actual and imminent rather than conjectural or hypothetical; (2) the injury was caused by or is fairly traceable to the action of the defendants; and (3) a favorable decision by the court is likely to redress the injury. Lujan v. Defenders of Wildlife, 504 U.S. 555, 560-61 (1992).

The mere violation of a procedural requirement does not permit any and all persons to sue the government, and procedural injury alone, in the absence of a threat to a concrete interest of plaintiffs, is insufficient to establish standing. Lujan, 504 U.S. at 572-73; Cantrell v. City of Long Beach, 241 F.3d 674, 679 (9<sup>th</sup> Cir. 2001). Moreover, in a NEPA case, the concrete interest requires a geographic nexus between the individual asserting the claim and the location suffering an environmental impact. Cantrell, 241 F.3d at 679 (citing Douglas County v. Babbitt, 48 F.3d 1495, 1500 n.5 (9<sup>th</sup> Cir. 1995)).

Nowhere in plaintiff s papers supporting its motion is there any discussion of harm to an

environmental interest of plaintiff purportedly caused by the Final Rule. Defenders of Wildlife, 504 U.S. at 562-63 (the party seeking review must be among the injured).<sup>9/</sup> In fact, plaintiff does not even attempt to specify the geographic location of the environmental damage that they contend the Final Rule will cause. For example, plaintiff contends that APHIS violated NEPA by failing to consider the air pollution and other environmental damage that will be generated by the 35,000 truck trips from Canada that plaintiff contends will be generated by the Final Rule. Pl. PI Br. 30; Pl. Exh. 5 at ¶ 21.<sup>10/</sup> Plaintiff also contends that APHIS violated NEPA by failing to assess the environmental impacts associated with holding and feeding an additional 2 million head of cattle until slaughter. Pl. Br. at 30. Plaintiff fails to identify, however, any harm to it from these alleged impacts, and plaintiff fails to demonstrate any geographic nexus between any alleged environmental damage and itself. Plaintiff has thus failed to demonstrate the requisite injury-in-fact caused by the alleged NEPA violation.

**b. Plaintiff's Assertion of Economic Injury Cannot Support Standing to Bring Claim Based on NEPA**

Not only must plaintiff demonstrate that it meets Article III requirements for standing, but plaintiff must also demonstrate that its alleged injuries fall within the "zone of interests" that NEPA was designed to protect. Lujan v. National Wildlife Fed'n, 497 U.S. 871, 883 (1990); Bell v. Bonneville Power Admin., 340 F.3d 945, 951 (9<sup>th</sup> Cir. 2003) (plaintiff must establish an injury in fact within NEPA's zone of interests); Nevada Land Action Ass'n v. United States Forest Serv., 8 F.3d 713, 716 (9<sup>th</sup> Cir. 1993); Western Radio Servs. Co. v. Espy, 79 F.3d 896, 902-903 (9<sup>th</sup> Cir. 1996). The "zone of interests" test "exclude[s] those plaintiffs whose

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<sup>9/</sup> Moreover, plaintiff cannot rest their standing on the allegation of increased harm to the health of the U.S. population from importation, see e.g. because there has been no showing that such an injury would be particular to plaintiff, Lujan, 504 U.S. at 560-61, and no showing that as an association, plaintiff's purpose is to protect the U.S. population from any risks of such imports. Hunt v. Washington State Apple Advertising Comm'n, 432 U.S. 333, 343 (1977) (establishing the test for associational standing).

<sup>10/</sup> Before May 2003, the border was completely open to trucks carrying cattle of all ages and beef products from Canada, with no restrictions on such imports.

suits are more likely to frustrate than to further statutory objectives." Clark v. Securities Indus. Ass'n, 479 U.S. 388, 397 n.12 (1987).

NEPA was enacted in order to "promote efforts which will prevent or eliminate damage to the environment and biosphere and stimulate the health and welfare of man." Douglas County v. Babbitt, 48 F.3d 1495, 1499 (9th Cir. 1995) (quoting NEPA, 42 U.S.C. § 4321). The purpose of NEPA is to protect the environment, not the economic interests of those adversely affected by agency decisions. Nevada Land Action, 8 F.3d at 716. Thus, to assert standing under NEPA, a plaintiff must allege an injury to an aesthetic or recreational interest in a particular place, animal or plant species. Save Our Sonoran, Inc. v. Flowers, 381 F.3d 905, 911 (9<sup>th</sup> Cir. 2004); Douglas County, 48 F.3d at 1501 (NEPA's zone of concern is for the environment); Arizona Cattle Growers Ass'n v. Cartwright, 29 F.Supp.2d 1100, 1109 (D. Ariz. 1998) (plaintiff must allege an environmental injury to have standing under NEPA); Knowles v. United States Coast Guard, 924 F.Supp. 593, 599 (S.D.N.Y. 1996) (NEPA's zone of interests has [] been construed to encompass claims for injury to the recreational use, aesthetics, or well-being of the human environment); Kingman Reef Atoll Invs., L.L.C. v. United States Dep't of Interior, 195 F.Supp.2d 1178, 1186 (D. Haw. 2002) (noting that NEPA's zone of interests would include environmental or conservation interests of plaintiffs).

A plaintiff who asserts purely economic injuries does not have standing to challenge an agency action under NEPA. Nevada Land Action Ass'n, 8 F.3d at 716; Western Radio Servs. Co., 79 F.3d at 902-903<sup>11/</sup>; ANR Pipeline Co. v. Federal Energy Regulatory Comm'n, 205 F.3d 403, 407-08 (D.C. Cir. 2000); Kingman Reef Atoll Invs., L.L.C., 195 F.Supp.2d at 1185-86; California Forestry Ass'n v. Thomas, 936 F. Supp. 13, 20-22 (D.D.C. 1996) (holding that plaintiffs whose interests are inconsistent, or at best, "accidentally" aligned with NEPA lack

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<sup>11/</sup> The Court in Western Radio Services Co. also distinguished a prior Ninth Circuit decision in which the panel held that a plaintiff's purely economic injuries nevertheless granted standing because they were causally related to an act that lies within NEPA's embrace. 79 F.3d at 903 (quoting Port of Astoria v. Hodel, 595 F.2d 467, 475 (9<sup>th</sup> Cir. 1979)).

standing to sue).

Here, the only injury plaintiff has asserted is economic injury that may result from import of ruminant products from Canada pursuant to the Final Rule. The declaration of William T. Bullard, Jr., plaintiff's Chief Executive Officer, avers that plaintiffs will suffer economic injury, both in the domestic market and with exports, if the Final Rule goes into effect. Pl. Exh. 5 at ¶¶ 4, 5, 9. Mr. Bullard's declaration explains that the prior discovery of BSE in Canadian cattle led to adverse consumer reactions, and price declines for U.S. cattle producers. *Id.* at ¶¶ 5-8. Nothing in the Bullard declaration avers any harm to plaintiff's recreational or aesthetic interests. It is clear that plaintiff's only claimed injury is to its economic interests.

Likewise, the declaration of Dr. Vansickle, Ph.D. and agricultural economist, underscores that plaintiff's true concern is economic impact. For example, his declaration discusses the anticipated [a]dverse economic impacts from the Final Rule for plaintiff, and estimates that the Final Rule will have a negative impact on U.S. cow-calf producers of \$2.5 to 3 billion. Pl. Exh. 6 at ¶¶ 7, 8. Dr. Vansickle goes on to criticize APHIS's analysis as understat[ing] the adverse effects on the economy, *id.* at ¶ 10, and contends that loss of domestic and foreign confidence in the U.S. beef supply, will, according to plaintiff, be the biggest adverse economic effect of the Final Rule. *Id.* at ¶ 11; see also ¶ 14. Finally, its Complaint makes clear that plaintiff's concern is economic harm. Complaint at ¶ 1 (alleging that U.S. cattle producers will suffer severe economic hardship); at ¶ 2 (discussing alleged adverse impacts to market).

The injuries plaintiff has articulated are purely economic, and a plaintiff who asserts purely economic injuries does not have standing to challenge an agency action under NEPA. Nevada Land Action Ass'n, 8 F.3d at 716. Plaintiff does not have standing to assert a NEPA violation.

### **3. APHIS Was Not Arbitrary or Capricious in Issuing An EA Instead of an EIS**

Even assuming plaintiff had standing to bring its NEPA count, which it does not, plaintiff

has failed to meet its burden in demonstrating that APHIS acted in an arbitrary and capricious manner in issuing an EA instead of an EIS. Plaintiff contends that APHIS's EA is flawed because: 1) APHIS purportedly failed to provide sufficient opportunity for public comments; 2) APHIS's EA purportedly relied on an out-dated risk assessment; 3) APHIS lacked a meaningful basis for its conclusions that the Final Rule would not have a significant impact on the environment; and 4) APHIS overlooked the effects on the environment from increased truck traffic and the feeding and holding of additional cattle before slaughter. Pl. Br. at 27-31. None of these contentions has merit.

First, APHIS provided sufficient opportunity for public comment.<sup>12/</sup> APHIS issued a draft EA for public comment in October 2003, regarding the proposed rule which was published on November 4, 2003, and provided a public comment period of sixty days. 68 Fed. Reg. 62,386, 62, 386 (Nov. 2003); Pl. Br. at 28. On January 4, 2005, APHIS issued a Final Rule and a Final Environmental Assessment, with a thirty-day comment period on the Final EA. AR 8251. On January 21, 2005, APHIS issued a Notice of Extension of Comment Period of Final EA for an additional fourteen days, until February 17, 2005, because APHIS had inadvertently cited the Risk Analysis incorrectly in the Final EA. AR 8286.

Both Federal Register notices make clear that APHIS will consider all comments received by the deadline. AR 8251, 8286. APHIS determined that it had time to make a decision on the EA and the public comments before the Final Rule goes into effect on March 7, 2005, i.e., that it had time to decide whether to issue a FONSI or if an EIS is necessary. If APHIS were to decide to issue an EIS, it would stay the effectiveness of the Final Rule until one

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<sup>12/</sup> As an initial matter, there is no particular public comment period required for an EA. The United States Court of Appeals for the Ninth Circuit has stated that the public should be involved or informed to some extent regarding preparation of an EA and FONSI. Citizens for Public Forestry v. USDA, 341 F.3d 961, 970 (9<sup>th</sup> Cir. 2003).

is completed.<sup>13/</sup> Thus, the public was afforded more than 100 days to comment on the EA s, which is more than sufficient opportunity for public comment.

Second, plaintiff improperly contends the Final EA is flawed because it relies on a risk analysis that 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 United States, or infection of humans as a result of import. Pl. Br. at 29. Defendants explained above why the risk analysis is not arbitrary or capricious, and also distinguished plaintiffs citation to Harlan Land Co., 186 F. Supp. 2d at 1097-1098. See supra at 30-35. Consequently, APHIS was not arbitrary or capricious in relying on the risk analysis in its final EA.<sup>14/</sup>

Furthermore, plaintiffs contend APHIS failed to consider the numerous direct and indirect effects of allowing the import of Canadian cattle, including impacts on air pollution from the likely increased number of truck trips, and the impact from feeding and holding additional cattle until slaughter. Pl. Br. at 29-30. Plaintiff fails, however, to demonstrate any substantial question as to these impacts, particularly when, as APHIS advises, before May, 2003, the border was open to such truck traffic and the import of cattle of any age and beef products from Canada. Anderson, 371 F.3d at 488.<sup>15/</sup>

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<sup>13/</sup> Plaintiff s citation to State of California v. Block, 690 F.2d 753, 770 (9<sup>th</sup> Cir. 1982), is inapposite. There, the Ninth Circuit held that the Forest Service violated NEPA by failing to advise the public during the public comment period of the agency s proposed action. Id. at 769-70. Here, in contrast, APHIS identified the proposed action in its draft EA.

<sup>14/</sup> Plaintiff contends that decision-makers and the public did not have an opportunity to form a judgment about whether the risk is acceptable. Pl. Br. at 29. Presumably, plaintiff is arguing that the public did not have an opportunity to comment on the EA s reliance on the risk analysis. On the contrary, the draft EA cited to the risk analysis prepared for the proposed rule. The final EA relies on the final risk analysis prepared for the Final Rule. As explained above, the public, including plaintiff, had sufficient opportunity to comment on the reliance of each EA on the respective risk analysis.

<sup>15/</sup> Plaintiff also fails to demonstrate how its citation to an overturned Ninth Circuit decision, Public Citizen v. United States Dep t of Transp., 316 F.3d 1002, 1021 (9<sup>th</sup> Cir. 2003), Pl. Br. at 30, advances its case. There, the Ninth Circuit held that the agency had violated NEPA by preparing an EA that did not consider the effects caused by the increased presence of

For example, plaintiff fails to explain how its reference to a Final Rule titled National Pollutant Discharge Elimination System Permit Regulation and Effluent Limitation Guidelines and Standards for Concentrated Animals Feeding Operations (CAFOs), Pl. Br. at 30 (citing 68 Fed. Reg. 7176 (Feb. 12, 2003)), demonstrates that there are substantial questions regarding environmental impacts posed by the Final Rule. Plaintiff has failed to demonstrate that APHIS acted in an arbitrary or capricious manner in issuing an EA instead of an EIS.

Finally, contrary to plaintiff's suggestion, Pl. Br. at 31, even if APHIS had violated NEPA (which it has not), an injunction does not automatically issue for a NEPA violation. A court is not mechanically obligated to grant an injunction for every violation of law, *id.* (internal cit. omitted), and should a district court find a violation of NEPA, an injunction sought by plaintiffs does not automatically issue. Forest Conservation Council v. United States Forest Serv., 66 F.3d 1489, 1496 (9<sup>th</sup> Cir. 1995). When a party seeks injunctive relief, the Court must balance the competing claims of injury and must consider the effects on each party of the granting or withholding of the requested relief. Amoco Prod. Co. v. Village of Gambell, 480 U.S. 531, 542 (1987).

## **II. RCALF HAS NOT DEMONSTRATED A THREAT OF IMMINENT INJURY OR HARM TO ITS MEMBERS.**

To prevail on its motion for preliminary injunctive relief, RCALF must show that its members will suffer immediate threatened injury if an injunction is not granted. Caribbean Marine Servs. Co. v. Baldrige, 844 F.2d at 674. Speculative injury does not constitute irreparable injury sufficient to warrant granting a preliminary injunction. *Id.* Injunctive relief

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Mexican trucks within the United States. 316 F.3d at 1012. The Supreme Court reversed, holding that the causal connection between [] issuance of the proposed regulations and the entry of Mexican trucks is insufficient to make [the agency] responsible under NEPA to consider the environmental effects of the entry. Department of Transp. v. Public Citizen, 124 S. Ct. 2204, 2217 (2004). Because the agency had no ability to prevent the entry of the trucks, the environmental effect of such entry would have no impact on the agency's decisionmaking, as it had no power to act on whatever information may be contained in the EIS. 124 S.Ct. at 2215-16.

will not be granted against [a harm] merely feared as liable to occur at some indefinite time.

Connecticut v. Massachusetts, 282 U.S. 660, 674 (1931).

Plaintiff's claims of imminent injury from health effects and economic damage are based entirely on conjecture and speculation about possible future harms, without proof of any certainly impending injuries. Caribbean Marine Servs. Co. v. Baldrige, 844 F.2d at 674. First, plaintiff contends that it will suffer harm because the importation of Canadian beef will increase the risk of vCJD. Pl. Br. at 35. Plaintiff does not even suggest, much less show, that its members, i.e., domestic cattle producers, consume Canadian beef and thereby are at risk of suffering the alleged harm. Moreover, no one has ever contracted vCJD from consumption of Canadian beef, even prior to May 2003, when there were no restrictions on Canadian imports. Thus, plaintiff's allegations are entirely speculative.

The number of safeguards in place make it highly unlikely that BSE-infected tissue would ever reach the human food supply in the United States and lead to vCJD. There is an effective feed ban in place in the United States and Canada which prevents cattle from becoming infected in the first place. If they do, however, SRMs, which are the repositories of BSE, must be removed at slaughter, so the infectivity would never go beyond the slaughterhouse walls and certainly would not pose a risk of ever contaminating human food. AR 8102. Import restrictions in the United States and Canada prevent high-risk ruminants from entering either country. In the United States these restrictions also prevent cattle or beef from cattle over 30 months from entering the country, so only younger cattle with little or no risk of carrying BSE are admitted. And an active, targeted comprehensive surveillance program is in place in both countries to detect BSE and ensure that all mitigation measures are effective. Only if every one of these barriers failed could a case of vCJD develop. Even if that possibility were anything but extremely remote, it certainly is not imminent.

The discovery of four Canadian cows with BSE does not portend imminent harm either. All four cows were over 30 months of age and therefore would have been barred from entering the United States under the new rule. The epidemiological investigations of the four positive Canadian cows revealed that the animals were infected prior to, or shortly after the implementation of the feed ban. Under these circumstances, and given the extensive mitigation measures in place in Canada and the United States, it is highly unlikely that a BSE-infected cow would ever cross the border, much less contaminate animal or human food or cause a case of BSE or vCJD.

Plaintiff's purported economic damage due to an alleged flood of cheap cattle and beef, and the alleged decrease in demand due to the public perception of contamination similarly rests on conjecture. The notion that the importation of Canadian cattle and beef will devastate domestic producers is far-fetched, given that Canadian boneless beef is already entering the country and has been imported continuously since August 2003. AR 8102-07; Fillo Dec. ¶ 4.

Furthermore, the continued importation of Canadian beef into the United States has not caused any significant decline in domestic demand. Fillo Dec. ¶ 4. In fact, the price of cows reached a 30-year high in 2004. Fillo Dec. ¶ 5. While plaintiff argues that consumer demand may plummet based on the experience of European markets, and in particular, Poland in 2000, but that drop in consumer demand in Europe resulted from an epidemic of a magnitude that dwarfs the 4 cases found in North America. The European experience cannot be extrapolated in any way to the United States or Canada. Plaintiff should instead draw a lesson from the Canadian beef market, which has remained strong despite the discovery of BSE in four Canadian cattle. Fillo Dec. ¶ 11.

In addition, as of February 2004, 97 percent of consumers were aware of BSE, yet 91 percent were confident in the safety of the domestic beef supply. So there were no discernible losses in consumer confidence or demand for domestic beef, and no domestic market share loss

to other protein sources in response to the finding of BSE in Washington State, or the resumed import of Canadian boneless beef in August 2003. AR 8106. Consumer demand for beef remains strong even in light of the fact that over 70 countries have imposed import bans on United States cattle and beef products in response to the finding of BSE in Washington State. AR 8106. Thus, plaintiff's predictions that it will be harmed by implementation of this rule are based on speculation and conjecture and not supported by any evidence that imminent harm will in fact occur. See Caribbean Marine Servs. Co. v. Baldrige, 844 F.2d at 674.

### **III. THE RULE SERVES THE PUBLIC INTEREST AND THE BALANCE OF HARSHIPS TIPS SHARPLY IN DEFENDANTS' FAVOR**

The public interest lies in ensuring that the broad purposes of the Animal Health Protection Act are carried out as Congress intended. Defendants and the public will be harmed if defendants are prevented from carrying out Congress' purposes through the new rule. The purpose of the Act is to protect animal health and facilitate safe interstate and foreign commerce in animals and animal products. The Act does not authorize animal regulation to maximize profits or erect trade barriers for any sector. The creation of a minimal-risk category and inclusion of Canada in that category is consistent with the purposes of the Act and its provisions. The rule protects animal health and benefits not only private consumers, but also all sectors of the livestock and beef industry. See Opposition by National Meat Association to Plaintiff's Motion for a Preliminary Injunction. The rule also establishes a science-based regulatory program which may hasten the opening of foreign markets to U.S. cattle and beef, thereby benefitting the domestic livestock and beef industry in the long term.

Plaintiff offers no valid reason why the import of Canadian cattle and beef should not be resumed under the rule. Plaintiff's arguments contradict overwhelming evidence from scientific studies and economic analyses that show a resumption of imports would be safe and result in a net gain for the U.S. economy. To prevent USDA from opening the borders via rules which have been promulgated only after the most careful and thorough consideration of all relevant

factors would prevent defendants from discharging their proper obligations and disserve the public interest in the process. Balanced against the possibility that USDA will be precluded from carrying out its statutory and regulatory responsibilities, the balance of hardships clearly tips in defendants' favor.

### CONCLUSION

For the foregoing reasons, plaintiff's motion for a preliminary injunction should be denied.

Dated: Feb. 22, 2005

Respectfully submitted,

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CERTIFICATE OF SERVICE

\_\_\_\_\_ I hereby certify that on February 22, 2005, a copy of the Defendants' Opposition to Plaintiff s Motion for a Preliminary Injunction was served upon plaintiff's counsel by hand-delivery as follows:

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