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

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RANCHERS CATTLEMEN ACTION LEGAL FUND )  
UNITED STOCKGROWERS OF AMERICA, )

Plaintiff, )

vs. )

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

Defendants. )

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Cause No.CV-05-06-BLG-RFC

**REPLY MEMORANDUM IN  
SUPPORT OF PLAINTIFF'S  
MOTION FOR  
SUMMARY JUDGMENT  
AND OPPOSITION TO  
DEFENDANTS' CROSS-MOTION**

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- 2 N.Y. *Times*, June 26, 2005, “For Months, Agriculture Department Delayed Announcing Results of Mad Cow Case”
- 3 Declaration of Stanley B. Prusiner, M.D.
- 4 Second Declaration of Louis Anthony Cox, Jr., Ph.D. in Support of Motion for Summary Judgment
- 5 Declaration Gail Charnley, Ph.D.
- 6 Sigurdson, C., Glatzel, M., and Aguzzu, A., Letter to the Editor of Veterinary Pathology, *Veterinary Pathology* Vol. 42, 107-108 (2005)
- 7 Wells, G., Spiropoulos, J., Hawkins, S., and Ryder, S., Pathogenesis of Experimental Bovine Spongiform Encephalopathy: Preclinical Infectivity in Tonsil and Observations on the Distribution of Lingual Tonsil in Slaughtered Cattle, *Veterinary Record* (2005) 156, 401-407
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**I. RECENT EVENTS AND USDA’S ARGUMENTS HERE CONFIRM THAT USDA’S ACTIONS WARRANT CAREFUL, CRITICAL REVIEW, NOT BLIND DEFERENCE.**

R-CALF’s Memorandum in Support of its Motion for Summary Judgment (“R-CALF Memo”) pointed to a few of the multitude of cases in which the courts, including the Supreme Court, have set aside agency actions under the Administrative Procedure Act (“APA”), 5 U.S.C. § 706(2), despite the general principle of deference to agency decisions. R-CALF Memo at 5-6, 8, 10-11, 15, 17-18. Even in cases of decisionmaking involving technical subject matter, the reviewing court must carefully evaluate whether, for example, the agency acted inconsistent with the purpose and intent of its statutory authority, failed to consider relevant factors or to respond to significant public comments, relied on unsupported assumptions, provided inconsistent explanations, or offered conclusions contrary to the available facts. *Id.* The court should take a particularly hard look where an agency is abandoning a long-standing policy or where there are apparent improprieties in the procedures through which the final action was arrived at. *Id.* at 6-8. All of those factors are present in this case.

USDA argues for the first time that the Secretary has virtually unfettered discretion to decide whether to allow or prohibit imports of diseased animals and contaminated food. Memorandum in Support of Defendants’ Motion for Summary Judgment and in Opposition to Plaintiff’s Motion for Summary Judgment (“USDA Memo”) at 2-3. USDA even hints coyly that the decision may be unreviewable, without actually arguing that it is. *Id.* at 3. USDA cites no authority for that proposition, and indeed there is none. The exception to the general rule that agency decisions are reviewable to which USDA refers is a “very narrow exception...applicable in...rare instances.” *Heckler v. Chaney*, 470 U.S. 821, 830 (1985). Nor is there any indication

that USDA has ever made such a claim in other cases reviewing its actions under the Animal Health Protection Act or similarly worded statutes.<sup>1</sup>

R-CALF previously showed that USDA's decisions concerning BSE risk mitigation and Canada have been driven by consideration of inappropriate factors, namely pressure from those with economic interests to resume trade with Canada. R-CALF Memo at 7-9. USDA offers only a weak response, claiming that there was no "bad faith" (Clifford Declaration ¶14), and in no way counteracting the Inspector General's conclusion that riskier products were allowed to be imported to "address[] industry concerns that permit policies were too restrictive for trade" without documenting any assessment of the risks. Audit Report (Exhibit 1 to Reply Memorandum in Support of Preliminary Injunction), at 7, 8.<sup>2</sup> Faced with the damning fact that, less than two months after USDA's own group of BSE experts recommended a comprehensive set of precautions before importing Canadian beef, USDA resumed imports without regard to almost all the recommendations, USDA simply asserts that new information and subsequent consultations justified a more relaxed approach.<sup>3</sup> Yet no one can point to that additional information, and the results of those consultations were not recorded.

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<sup>1</sup> See, e.g., *Ganadera Industrial, S.A. v. Block*, 727 F.2d 1156, 1158-59 (D.C. Cir. 1984) (reviewing USDA rule promulgated under Section 20(g) of Meat Inspection Act, 21 U.S.C. § 620(g), which provides that the Secretary "may prescribe terms and conditions under which [certain animals] may be imported for slaughter and human consumption") (emphasis added); *Cactus Corner, LLC v. USDA*, 346 F. Supp. 2d 1075, 1094-95 (E.D. Cal. 2004) (reviewing USDA action under authority of Plant Protection Act, 7 U.S.C. § 7711(c)(1), which provides that "[t]he Secretary may issue regulations to allow the importation [of certain plant pests]") (emphasis added).

<sup>2</sup> USDA offers no explanation at all for the incident in which a decision to ban ground beef and other processed meats from Canada was reversed solely because industry groups objected. R-CALF Memo at 9 n.6. And Clifford's claims that USDA did not really let in bone-in cuts of Canadian beef or ignore this Court's TRO and preliminary injunction (USDA Memo at 5 n. 3, Clifford Declaration at 15) are directly contrary to the Audit Report. See *id.* at 10, 12.

<sup>3</sup> Cf. R-CALF Memo at 8-9 with USDA Memo at 4 n.3. Remarkably, Dr. Clifford claims (Clifford Decl. ¶12) that the risk mitigation recommendations of the TSE Working Group were

Very recent events provide even more reasons for the Court to be skeptical of USDA's "don't worry, we think it's OK" approach to risk assessment. On June 24, 2005 Agriculture Secretary Johanns confirmed that a 12-year-old beef cow in the United States had BSE, even though testing in November 2004 with what USDA then called the "gold standard" test, immunohistochemistry (IHC), showed it was not infected. Exhibit 1. Not only were USDA's assurances that the cow was not afflicted with BSE (and consequent failure to take immediate steps to respond to the case) wrong, they were misleading. USDA knew that another, more sensitive test called the Western blot, used in the UK and Europe, was available. And USDA's action on June 10, 2005, announcing that the cow presumptively was infected with BSE because a recent Western blot test came back positive, belied USDA's previous assertions that the IHC test was definitive. See Exh. 1 at 1, 4; see also N.Y. *Times*, June 26, 2005, "For Months, Agriculture Department Delayed Announcing Results of Mad Cow Test," Exh. 2. Worse still, we now learn that USDA actually did perform a more sensitive test in 2004 that came up positive, but failed to prepare any written report on it, and did not reveal it to the public because it was "experimental." Exh. 1 at 3, 8; Exh. 2. As Representative Henry Waxman commented, USDA's approach to BSE "appears to be more public relations than public health." Washington *Post*, June 25, 2005, "Retesting Reveals Mad Cow Case," A01. These facts alone would be alarming, but, combined with the information about USDA's inappropriate considerations in addressing BSE that has previously been revealed in this case, they thoroughly undercut USDA's argument that its qualitative conclusions that the risks of the Final Rule are acceptable should suffice.

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adopted when USDA began issuing permits for importing Canadian products, when a simple comparison of those recommendations (under 24 months, elimination of plate waste exemption to feed ban, etc.) to USDA's announcement of approved imports belies that assertion. *Cf.* R-CALF Memo Exh. 5 at AR009392C, *F with* R-CALF Memo Exh. 6 at 2; see also R-CALF Memo at 8-9.

## **II. USDA’S CLAIM THAT THE FINAL RULE CARRIES ACCEPTABLE RISK FAILS TO MEET EVEN MINIMAL CRITERIA FOR REASONED RULEMAKING.**

USDA asserts that the Final Rule presents an acceptable risk to U.S. cattle and U.S. consumers. But USDA has failed to conduct the kind of risk assessment necessary to make that assertion, or to allow the public and this Court to judge whether the risk is acceptable. USDA does not know how prevalent BSE is in Canada, despite its grand claims.<sup>4</sup> USDA does not know how much tissue from an infected cow must be ingested to cause vCJD in a human. *See, e.g.*, Declaration of Stanley B. Prusiner, M.D., the world’s foremost expert on prions and a Nobel Prize winner for his work on prion diseases such as BSE, Exh. 3 at ¶¶13, 21. The Harvard Risk Assessment, on which USDA greatly relies, was never intended to address risks to human health and concluded that sufficient data were not available to analyze the risk of introduction of introducing BSE into the U.S. from Canadian cattle. AR003700; AR008426. USDA has not even decided for itself, yet alone informed the public, what would be an acceptable number of cases of BSE in animals or vCJD in humans as a result of the Final Rule. 70 Fed. Reg. 460, 473 (Jan. 4, 2005). *See Ober v. Whitman*, 243 F.3d 1190, 1195 (9<sup>th</sup> Cir. 2001) (court will defer to agency’s judgment of *de minimis* air pollution sources only if agency provided a full explanation of its *de minimis* levels); *Harlan Land Co. v. U.S. Dept. of Agriculture*, 186 F. Supp. 2d 1076, 1094-95 (E.D. Calif. 2001) (failure to define “negligible risk”).

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<sup>4</sup> USDA offers, for example, Dr. Stark’s conclusion that “In my judgment, the prevalence of BSE-positives among younger Canadian cattle is now essentially zero.” Stark Decl. ¶30. That conclusion merits no credence at all. Stark is an expert in seismic risk assessment who apparently has no knowledge about BSE at all other than reading about it for purposes of preparing his declaration. *See id.* Appendix A. A professional witness (whose undergraduate degree, though he does not list it, was in Philosophy) who claims to be expert at everything from water treatment to employment discrimination, Stark essentially offers the Court a book report on BSE, as he is expert neither on BSE nor on animal and human health risk assessment. With respect to the cited claim in particular, data simply do not exist that would allow one to draw that conclusion. *See, e.g.*, Cox Second Declaration in Support of Summary Judgment (“Cox IV”), Exh. 4, ¶33.

Yet still, USDA insists that the risks to U.S. cattle and consumers are minimal and acceptable. Dr. Cox, in his previous declarations as well as the one attached here, has explained that basic principles of health risk assessment require an estimate of how great the risk really is and the uncertainties in the assumptions going into that assessment. Exh. 4 at, e.g., ¶¶ 6, 12-13, 21. Dr. Gail Charnley, an internationally recognized expert in risk assessment and risk management who chaired a Commission on Risk Assessment and Risk Management mandated by Congress, explains that such “[q]ualitative descriptions of risk in the absence of quantitative descriptions provide an inadequate basis upon which to make decisions about safety.” Exh. 5 ¶2 (citing National Academy of Sciences). “Simply asserting that in the opinion of the regulatory agency...the risk of importing BSE-infected cattle is ‘low’ and the screening system preventing same is ‘highly effective’—and both are therefore acceptable – is inconsistent with modern risk management practices” and “is unsupportable scientifically and ethically.” Id. ¶¶2, 3.

USDA’s qualitative claims are especially unreliable in light of the facts that (1) there are insufficient, and in some cases nonexistent, data to support those claims, and (2) USDA and its consultants assert the claims in obviously over-confident terms. As an example of the first point, USDA asserts that mitigation measures such as SRM removal have been demonstrated to be “highly effective” at reducing BSE risks. But SRM removal has been practiced only in the last couple of years, and any empirical demonstration of its effectiveness in preventing vCJD in humans, or even BSE in cattle, would have to wait years until the relevant incubation periods have passed. Similarly, USDA declarant Ferguson asserts that the prevalence of BSE in Canada is “extremely low,” but that conclusion is not based on empirical data, but rather on theories about the effectiveness of various measures Canada has taken. Second Ferguson Decl. ¶7. As Dr. Cox has pointed out, USDA persists in these extreme statements about the absence of risk as

if in denial about the facts that there have been four confirmed cases of BSE in Canadian-raised cattle in two years and a BSE-infected cow has already entered the U.S. from Canada (with devastating effects). Exh. 4 ¶¶26, 44, 49.

USDA's Memo in Support of its Motion for Summary Judgment is full of extreme statements about the lack of risk of the Final Rule: claims that the mitigation measures in place "virtually eliminate any risk" and "prevent the introduction of BSE" into the U.S. *Id.* at 1, 5 Clifford Decl. ¶4. USDA now claims not only that the risk will be acceptable, but that there will be "no measurable risk to human health or animal health" and that mitigation measures are "virtually impenetrable." USDA Memo at 1, 6. These absolute statements demonstrate that indeed USDA has not made a reasonable assessment of risks based on actual data, which do not permit such unqualified conclusions. Dr. Charnley's expert opinion is that such absolute statements "are irresponsible and are likely to lead others to doubt the credibility of USDA's conclusions." Exh. 5 ¶4. USDA's own documents, as well as the expert conclusions of Dr. Prusiner and Dr. Cox, do not support those overstatements, either, as we review below.<sup>5</sup>

### **III. USDA'S KEY ASSUMPTIONS REMAIN UNJUSTIFIED.**

#### **A. Prevalence of BSE in Canada.**

It is essential, when assessing the risk of resuming imports of beef and cattle from Canada, to estimate the prevalence of BSE infection in Canadian cattle, including those cattle that

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<sup>5</sup> As Dr. Cox's attached declaration ably points out, much of USDA's response to R-CALF uses a straw man attack. R-CALF never argued that only zero risk is acceptable, *see* USDA Memo at 1 (although, while Dr. Stark seems unaware of it, zero risk from BSE in Canada is an option in this case—the U.S. need not permit Canadian imports). Exh. 4 at ¶¶9-12; Exh. 5 ¶5. R-CALF has not ignored the fact that some of the risk mitigation measures in place are additive; but that does not mean that USDA need not consider the limitations of each, and it does not eliminate the risk that, in some instances, all of them could fail. Exh. 4 ¶¶ 21, 41-45. R-CALF demonstrated that USDA's assumptions about the efficacy of the measures are unproven and that there is a real possibility that the "overlapping mitigation measures" are not foolproof, and yet USDA made no attempt to quantify the risk of failure.

will be imported into, or slaughtered in Canada for export to, the U.S. USDA's failure to come up with a consistent story even about this central issue demonstrates the arbitrary and capricious nature of its conclusion that the Final Rule presents acceptable risks.

USDA's Memo in Support says that it is impossible to determine the prevalence of BSE in Canada. *Id.* at 14, citing Hueston Decl. Yet Dr. Stark knows (it is "essentially zero" in young cattle and less than 6.25 per million in older cattle). Stark Decl. ¶¶9, 30. And Dr. Ferguson claims that Canada's testing is "well-suited to making an accurate determination regarding prevalence of BSE in Canada...." Second Ferguson Declaration ¶13. (On the other hand, the first Ferguson Declaration claimed it was unnecessary and almost foolish even to try to determine the true prevalence of BSE in Canada (*id.* ¶7), despite the fact that the TSE Working Group memo she authored in June 2003 stated that, until the "true prevalence of BSE in Canada" can be determined, "it will be impossible to quantify how much additional risk" imports of various beef products present. R-CALF Memo Exh. 5 at AR009392A.) This is precisely the kind of double-speak that renders a rule arbitrary and capricious.

USDA's declarants, none of whom is an expert in health risk assessment modeling like Dr. Cox, labor mightily to discredit his estimates of the prevalence of BSE in Canada and the likelihood of importing cases of BSE to the U.S. under the Final Rule. His attached declaration definitively disposes of those attacks. Regardless, though, USDA's approach, rather than being protective of U.S. animal and consumer health, assumes away BSE in Canada, essentially acting as if the four cases in Alberta cattle found in the past year never existed.<sup>6</sup>

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<sup>6</sup> For example, the latest case in Canada, born seven months after Canada enacted its feed ban, is just assumed to relate to pre-feed-ban feed. Dr. Ferguson makes this assumption because a link to potentially contaminated feed suspected in other cases, while not established, has "not been completely ruled out." Second Ferguson Decl. ¶14. This type of reverse presumption, just like the assertion that each case of BSE discovered is a demonstration that "the firewalls work," rather

Dr. Cox's analysis is straightforward, and the conclusions do not change much over a wide range of assumptions. We know there is BSE in Canada, and USDA's insistence that there is virtually no risk of importing BSE into the United States is simply not credible. No amount of good intentions will substitute for solid data showing that BSE really has been virtually eliminated in Canada, and until then USDA must justify its conclusion that the risk is acceptable by telling the public what the chances are of infection in imported cattle, in the domestic herd, and in consumers.

USDA assumes that there is a "cluster" of BSE infectivity in Alberta, but then somehow tries to make this into a good thing, despite the fact that the majority of cattle and beef imported into the U.S. come from Alberta. AR002529-33 (over 70% of the beef slaughter in federally inspected facilities in Canada is in Alberta). Why should the U.S. be importing from Alberta, if there is a cluster of BSE infection there?

R-CALF's position does not depend on a series of speculative, and often counterintuitive, assumptions, as USDA's does. Despite the complex mathematical theory, Dr. Cox's point is a simple one: we know there is BSE in Canada, and Canada has not conducted nearly enough tests to know how prevalent the BSE is. Unless we assume that somehow the very limited testing to date in Canada happened to catch all of the infected animals, even those without clinical symptoms of BSE, then we should assume that there are additional cases of BSE in Canada and, given the anticipated importation of millions of Canadian cattle and billions of pounds of Canadian beef over the next few years, it is a virtual certainty that BSE prions will be imported into the U.S. under the Final Rule. Cox IV, Exh. 4, ¶4. USDA's refusal to estimate the amount

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than a warning that other cases of BSE may be out there but undetected, is entirely inconsistent with the public policy USDA is supposed to be implementing. (See also Second Ferguson Decl. ¶9 (ignoring "best information" that no cattle imported from UK to U.S. came from farms with BSE, to conclude nevertheless that they could have, and so Canada is no different from the U.S.)

of BSE prions that will be imported, and to estimate the potential for adverse effects from those imports, renders its qualitative assurances that the risks are acceptable arbitrary and capricious.

**B. Information about Canada’s feed ban undercuts assumptions in the Final Rule.**

USDA now says that the average incubation period for BSE in Canada is estimated to be 6-8 years.<sup>7</sup> It has been less than eight years since Canada’s feed ban went into effect, and much less than eight years since it began to be effective, according to USDA’s view of the born-after-the-ban cow found in Alberta this year. See R-CALF Memo at 16. We know that BSE was circulating in Canada, and we know that cattle exposed to contaminated feed before the feed ban became effective may not, even with an average incubation time, have developed outward signs of BSE yet. How can resuming imports from Canada be justified under those circumstances?

USDA also now claims (in another *post hoc* rationalization that this Court must ignore) that what really matters, at least as much as the time since the Canadian feed ban was enacted, is the fact that it was enacted before the first “native case” of BSE. USDA Memo at 18; Second Ferguson Decl. ¶11; Hueston Decl. ¶¶13.4-13.5. This makes no sense: at least one of the cattle imported from the UK, and likely more, was rendered and entered into the Canadian feed system around 1993, with confirmed cattle exposure to that feed. As a result, there likely was another generation of BSE-infected cattle resulting from those incidents, and these cattle very well may have been slaughtered and entered the ruminant feed chain again before the Canadian feed ban began to be implemented. (And, since Canada was only testing hundreds of cattle per year, those cattle likely would not have been caught by Canada’s surveillance system at the time.) USDA’s

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<sup>7</sup> USDA Memo at 17. Part of the basis for this speculation is Table 2 in Dr. Hueston’s declaration (i.e., part of one big *post hoc* rationalization, which the Court should ignore. *Burlington Truck Lines, Inc. v. United States*, 371 U.S. 156, 168 (1962).) Examination of that table, though, does not support Hueston’s claim that lower doses lead to longer incubation: the range of incubation periods is essentially the same for doses of 10, 1, or 0.1 grams. Perhaps Dr. Stark, the newly-minted BSE expert, had some other justification for his proclamation: “I estimate the incubation time in Canada around the time of the feed ban to be 6 to 8 years.” Stark Decl. ¶26.

assertion that what really matters is that the Canadian feed ban was implemented before the first discovery of a native case (which likely was the second or third generation of BSE in Canada) makes no sense and thus renders the Final Rule arbitrary and capricious.

USDA continues to claim that Canada's feed ban is highly effective, citing in part the fact that "only" seven farms likely had ruminants that were exposed to feed contaminated with the carcass of the BSE-positive cow discovered in Canada in 2003. USDA Memo at 18. "Pretty good" just won't do for a disease as difficult to control as BSE; at a minimum, USDA owes the public an explanation of what the risks are, not just an assertion that the Canadian and U.S. feed bans are "highly effective." See Charnley Decl., Exh. 5 ¶2-3.<sup>8</sup>

A feed ban that allows recycling of ruminant protein through poultry litter and plate waste, in the case of the U.S., and through bovine blood, in the case of both countries, cannot be assumed to prevent the spread of BSE, as USDA has assumed. Dr. Prusiner, the world-reknowned BSE expert, is convinced that blood may carry BSE prions and with it infectivity. Prusiner Decl. ¶14. The Food and Drug Administration issued a Federal Register notice recognizing the need to close these loopholes, and the TSE Working Group set that as a precondition for resuming trade. R-CALF Memo at 19 and n.11; R-CALF Memo Exh. 5 at AR009392C. USDA has utterly failed to explain why it is reasonable to bring potentially BSE infected cattle into the U.S. before the loopholes have been closed.

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<sup>8</sup> There is scant comfort in Dr. Ferguson's observation that all four of the native Canadian BSE cases that have been identified were born during a fairly short period of time, between October 5, 1996 and March 21, 1998. Second Ferguson Decl. ¶15. According to USDA's view of the BSE incubation period in Canada, any cattle born after that time may well not even have developed symptoms yet. Dr. Ferguson's conclusion about the risk of intentional or accidental noncompliance at feed mills and renderers is curious, also: She concludes that compliance at Canadian rendering plants "has been 100%" because they must be in compliance to obtain a permit. Id. at ¶11. But the study she references concludes that 12.5-23% of the rendering plants inspected from 2002-2005 had noncompliance issues! R-CALF Memo Exh. 1 at 29-30, AR012624-25.

**C. The assumption that under-thirty-month cattle are risk-free is unjustified.**

USDA has fairly arbitrarily concluded that cattle under 30 months of age present virtually no risk when imported into the U.S. or slaughtered in Canada to produce beef for the U.S. USDA assumes away the 21 and 23 month old BSE cases found in Japan recently, based on Dr. Hueston's opinion (and his report of *post hoc*, extra-record telephone conversations). There is simply no reason for doing so, other than that they do not fit USDA's preconceived notions. Dr. Prusiner, the renowned BSE expert who is familiar with the Japanese testing, has no doubt that the two cows had BSE. Nor does the Japanese government, apparently. Prusiner Decl. ¶18.

In any event, whether younger cattle are likely to show clinical signs of BSE is not dispositive of whether they present a risk of contaminating the feed supply and of transmitting prions that could cause vCJD in humans. The Japan-United States Working Group acknowledged this possibility (Final Report, Japan - United States BSE Working Group, July 22, 2004 at 4 (AR001621)), as did the Secretary's International Review Team, *see* AR008026. Dr. Prusiner states that "it is neither safe nor scientifically justified to assume that all cattle under 30 months of age present no risk of harboring BSE prions and thus, cannot cause vCJD in humans." Prusiner Decl. ¶21 USDA's insistence that under-thirty-month cattle cannot present a risk of BSE renders the Final Rule arbitrary and capricious, just as do USDA's flip-flops about whether cattle thirty months of age and older should be excluded. *Cf.* USDA Memo at 15 n.10.

**D. The assumption that SRM removal removes any risk remains unjustified.**

The Final Rule only requires removal of the small intestine and the tonsils from Canadian cattle imported into the U.S. or slaughtered in Canada for export to the U.S. As noted above, the assumption that there cannot be significant infectivity in the brain, spinal column, etc. because the Canadian cattle will be under 30 months of age is not justified. In any event, since we do not know how much infected tissue is necessary to infect humans, the fact that near-clinical levels of

BSE prions may not be present does not mean that there is insufficient infectivity to be a hazard. *See* Prusiner Decl. ¶¶14-16. While BSE prions have not been found in bovine muscle, that likely is a function of analytical sensitivity; all the other information points to the likelihood that they are there. *Id.*; *see also* Exh. 6. It is USDA, not R-CALF, whose actions are speculative and contrary to science. *Cf.* USDA Memo at 19.

USDA's assumption that removal of the small intestine and the tonsils removes any potential for transmission to humans also is unjustified given USDA's refusal to evaluate the potential for contamination of tongue with tonsil tissue. USDA claims this possibility "is eliminated by current slaughter techniques." USDA Memo at 20; *see also* AR010034 (FSIS concludes no new slaughter procedure necessary). In fact, one of the very articles cited by Dr. Hueston examined over 250 bovine tongues intended for human consumption and found tonsillar tissue in the vast majority, in some cases "even after the most rigorous trimming of the root of the tongue." Exh. 7. USDA cannot simply assume this risk away by stating, without record support, that it is eliminated.

USDA repeatedly claims that mitigation measures contemplated by the Final Rule, such as SRM removal, have been demonstrated to be highly effective. Such demonstration is not apparent, though: SRM removal requirements have not been in place nearly long enough to see an effect, in light of incubation periods. Moreover, all countries with BSE (except Canada) remove the brain, spinal column, etc. at 12 months and over, not 30 months as USDA requires. *See* R-CALF Memo Exh. 13 at AR001570.

**E. The assumption that there is a large "species barrier" is unjustified.**

Part of the basis for USDA's assertion that there is virtually no risk to humans even if BSE-contaminated cattle and meat are imported from Canada is its claim that there is a very large "species barrier," meaning it takes a relatively large amount of infective tissue to cause vCJD.

This assumption is contrary to guidance concerning BSE risk assessment from other organizations and is not supported by scientific experts. Harvard Study, Rev'd Oct. 2003, AR003707 (assume no species barrier for worst-case modeling); Prusiner Decl. ¶13. While there may be a substantial species barrier, it has not been proven, and it cannot be shown by comparing diagnosed cases of vCJD to estimated historical exposure, as Dr. Hueston attempts to do. *Id.* at 12-13; Exh. 8. Simply assuming that humans are many orders of magnitude less sensitive than cattle, as USDA does, is arbitrary and capricious.

#### **IV. OIE GUIDELINES DO NOT SUPPORT USDA'S ACTION**

USDA has placed considerable reliance on comparison of its actions to the guidelines of the OIE, which it asserts were “meticulously developed” from scientific information. Second Ferguson Decl. ¶2. USDA makes reference to recent revisions to the OIE guidelines (which obviously could not have been the basis for USDA's action in January). *See* USDA Memo at 29 n.22. But if USDA is going to refer to those new OIE guidelines, it ought to refer to all of them, because they clearly would not support Canada being placed in the lowest-risk (“negligible”) category, nor even in the medium-risk (“controlled risk”) category. *See* Weaver Decl., Exh. 9, App. A, and Exh. 10.

#### **V. CANADIAN CATTLE PRESENT A HIGHER RISK OF BSE THAN DOMESTIC CATTLE.**

As noted above, Secretary Johanns announced June 24 that an older cow that was slaughtered in November 2004 had been retested and determined to be positive for BSE. We do not yet know for certain whether that cow was born in the U.S. or in Canada, but even assuming that it is a domestic case, it does not change the fact that imports of cattle or beef from Canada carry an incremental risk of BSE. The fact that USDA has tested almost 400,000 cattle in the past year and found only one case of BSE, while the Canadians have tested about 60,000 and

found four infected cattle, suggests that the incidence of BSE in the U.S. is “significantly lower” than in Canada. *See* Cox IV, Exh. 4, ¶53. Also, the fact that the U.S. case reportedly was born long before implementation of the U.S. feed ban, while the latest Canadian case was born seven months after the Canadian feed ban, suggests a greater cause for concern with respect to Canadian cattle.

Canadian cattle present a higher BSE risk profile than U.S. cattle for numerous reasons, set forth in Attachment B to Dr. Weaver’s declaration (Exh. 9). A major difference, as described above, is that the Canadian feed ban was not put into place until four years after the first case of BSE in Canada. The factors laid out in Dr. Weaver’s declaration support the test results, suggesting reasons that might contribute to the higher incidence of BSE found in Canada.

The occurrence of a potential domestic case of BSE only increases the need to be vigilant about importation of additional BSE from Canada. USDA has said that the most likely sources of BSE infection in the United States was importation of infected animals or infected animal products. 68 Fed. Reg. 62,386 (Nov. 4, 2003). The U.S. needs to do all it can to avoid both, which would include avoiding imports from Canada until the Canadians have conducted enough testing to conclude that BSE indeed is extremely rare in Canada. *See* Cox IV Decl., Exh. 4, ¶¶50-51. Minimizing the potential for BSE infection for nearly 100 million head of cattle spread out across the United States is a daunting task, without importing millions of additional cattle from Canada with an as-yet-uncertain potential for BSE infection.

## **VI. USDA FAILED TO SATISFY THE NATIONAL ENVIRONMENTAL POLICY ACT**

USDA’s arguments that R-CALF lacks standing to raise National Environmental Policy Act (“NEPA”) issues are desperate. The Verified Complaint alleged injury to R-CALF members as a result of environmental impacts associated with the Final Rule. The fact that R-CALF

members also have economic interests in the Final Rule does not deprive them of standing.<sup>9</sup> Similarly, the fact that R-CALF's primary purpose is to further its members' economic interests does not mean that R-CALF as an organization is prohibited from acting to protect its members' environmental and health interests in matters connected to the cattle industry (which, of course, are ultimately linked to their economic interests, as well). There should be no question that R-CALF can and will vigorously pursue claims related to its members' well-being.

Contrary to USDA's protestations, the instant case is similar to those where an environmental assessment is prepared after the agency has already committed to a course of action, as was rejected in *Save the Yaak v. Block*, 840 F.2d 714, 718 (9<sup>th</sup> Cir. 1988). The Finding of No Significant Impact that addressed the environmental impacts R-CALF raised in this litigation was not prepared until long after the USDA had committed to a course of action. This is far from a case where there were just "two minor procedural defects in the rulemaking process." *Safari Aviation v. Garvey*, 300 F.3d 1144, 1152 (9<sup>th</sup> Cir. 2002).

## **VII. USDA FAILED TO SATISFY THE REGULATORY FLEXIBILITY ACT**

USDA again largely just attacks a strawman, claiming that R-CALF is arguing that the Regulatory Flexibility Act ("RFA") required USDA to require or allow BSE testing and require country of origin labeling (COOL) as part of the Final Rule. To the contrary, R-CALF has pointed out that USDA has an obligation to consider alternatives such as those, that would have mitigated the adverse economic impact on small businesses, and USDA failed to evaluate those alternatives in terms of their potential economic benefit for small businesses. R-CALF Memo at

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<sup>9</sup> *Presidio Golf Club v. Nat'l Park Serv.*, 155 F.3d 1153, 1158 (9<sup>th</sup> Cir. 1988). USDA also wrongly accuses R-CALF members of "snapping up Canadian cattle at prices depressed by the preliminary injunction in this case." USDA Memo at 1, 27. If USDA were focused on substance rather than innuendo and *ad hominem* attacks, it would have seen that the article (hardly evidence in any event) referred to purchases after USDA imposed an import ban in May 2003, not after R-CALF's preliminary injunction in this case which issued just before the article was published.

26-27. To extent USDA evaluated them at all, its reasons for rejecting these mitigation measures were nonsensical and failed to meet the minimum requirements of the APA. *Id.* at 23-24, 26-28.

If the United States is to allow cattle with a greater potential for BSE infection to be imported into the United States, then testing of those cattle at slaughter would provide useful information. *Id.* at 27; Prusiner Declaration ¶¶18-20. USDA cannot simply ignore the experience of numerous other countries that have found a substantial increase in the identification of cases of BSE when they began testing many or all cattle, rather than just those that are non-ambulatory or showing signs of BSE. R-CALF Memo 23-24. Moreover, researchers at Kansas State University have modeled the costs and benefits of testing and found a substantial potential net benefit. R-CALF Memo Exh. 17 Attachment A at 5. (Note also that the cost of testing is only half what amicus Canadian Cattlemen’s Ass’n asserts, and only a couple of cents a pound.) *See also* Exhibit 11 to this memo re. the economic value of COOL.

## **VIII. IF THE FINAL RULE IS HELD UNLAWFUL, USDA MUST NOT BE ALLOWED TO CONTINUE TO SIDE-STEP THE RULEMAKING PROCESS THROUGH BLANKET ISSUANCE OF “PERMITS.”**

### **A. R-CALF can pursue its claim for injunctive relief against blanket permitting under 9 C.F.R. § 93.40(a).**

USDA offers little in the way of substantive defense of its subversion of its existing regulations through the issuance of thousands of permits to import otherwise-prohibited products from Canada, opting instead to interpose procedural objections. USDA and *amici* falsely claim that they were ambushed by R-CALF’s request for summary judgment on its demand that blanket permits for the importation of certain Canadian beef products (“boxed beef”) be enjoined. The Verified Complaint in this action could hardly be more clear: the second claim for relief is that the Court grant “an injunction enjoining implementation of that final action [the Final Rule] and enjoining the importation into the United States of all live cattle of Canadian origin and all edible

bovine meat products derived from cattle of Canadian origin.” Moreover, since the Final Rule would supercede the permits that have been issued for boxed beef (Clifford Decl. ¶14), the portions of the Verified Complaint addressing the inadequacy of USDA’s justification for allowing imports under the Final Rule apply to the very same imports of boxed beef that currently are being allowed by permit. The Verified Complaint noted that allowing boxed beef imports from Canada was a departure from longstanding U.S. policy, *id.* ¶¶15, 23; indicated that health protection measures like the import ban should not be relaxed without a thorough assessment of the risks, *id.* ¶ 24; and noted that USDA has insufficient basis for relaxing import bans, *id.* ¶¶23-24.

Moreover, R-CALF’s concerns about the Final Rule described in the Verified Complaint would remain unaddressed if the Court only vacated the Final Rule and left USDA free to circumvent that decision in the rulemaking process by issuing more permits. USDA and others have no basis for claiming that the requirements of notice pleading were not met to allow R-CALF to pursue its stated claim for relief and seek an injunction prohibiting all imports until USDA conducts a proper rulemaking.

*Amici* Alberta Beef Producers (“ABP”) also argue that R-CALF is precluded from seeking to enjoin imports of boxed beef because R-CALF has failed to join allegedly indispensable parties, companies that have been issued permits to export boxed beef from Canada to the U.S. None of the cases cited by ABP in support of this argument applies to facts such as the instant case. They all involved limited *private* rights of action aimed at garnering relief primarily for the *specific* plaintiffs. R-CALF alleges that USDA had no authority to issue the 1000+ permits it has issued for imports of classes of meat products from Canada. The permittees have no right to permits that were issued *ultra vires*, and the question of USDA’s statutory

authority to use 9 C.F.R. § 93.40(a) in the manner it has, and to avoid rulemaking by creating exceptions that swallow up the current rule, does not depend on any facts concerning an individual permittee.<sup>10</sup>

ABP's position would lead to clearly inappropriate results: so long as an agency issued many permits, the lawfulness of the permitting process could never be challenged because it would be infeasible to join all of the permittees. Indeed, courts have recognized that Fed. R. Civ. P. 19 claims of failure to join an indispensable party do not apply to actions, such as this one, seeking to protect the public welfare. *See, e.g., Nat'l Licorice Co. v. NLRB*, 309 U.S. 350, 363 (1940); *Connor v. Burford*, 848 F.2d 1441, 1460 (9th Cir. 1988) (groups could challenge the manner in which environmental statutes had been applied to oil and gas leases without joining some of the otherwise necessary lessees); *see also Am. Greyhound Racing, Inc. v. Hull*, 305 F.3d 1015, 1025-26 (9th Cir. 2002); *N. Alaska Env'tl. Center v. Hodel*, 803 F.2d 466, 468-69 (9th Cir. 1986).<sup>11</sup>

As the Eastern District of California aptly summarized:

In public rights cases, what is at stake by definition are...national statutory, or national administrative issues. Almost by the nature of the issues tendered by

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<sup>10</sup> ABP's assertion that permittees have justifiably relied on having their permits continued in the future is not credible: the permit process was described as an interim measure until the Final Rule was completed; conditions for issuing permits in the interim were changed several times; and committing to supply products beyond the duration of a permit cannot be considered justifiable reliance. *See* ABP Brief at 9-10.

<sup>11</sup> ABP attempts to distinguish *Hodel* from the present case by alleging that the miners in that case only had pending mining plans, not existing ones. ABP Amicus Br. at 9 n.3. A closer reading of the facts in *Hodel* reveals that, in fact, many of the miners did have existing mining plans. *See N. Alaska Env'tl. Center v. Hodel*, 1985 Env'tl. L. Rep. 21048, No. J85-009 CIV (D. Alaska July 24, 1985) (noting that the case fell within the "public exception" to Rule 19, and that of the 39 plans of operation that had been submitted, 26 were approved as of the date of oral argument on plaintiff's motion for preliminary injunction), *aff'd*, 803 F.2d 466, 467 (9th Cir. 1986) (miners either had "approved or pending operations plans"). Thus, ABP's proffered distinction is misplaced.

such litigation, the number of persons who will be affected as a practical matter is very large, and almost certainly a substantial number of those persons cannot be served in one district. To hold that such persons nevertheless must be joined or the case dismissed “would effectively preclude such litigation against the government.”

*Sierra Club v. Watt*, 608 F. Supp. 305, 324-325 (E.D. Cal. 1985).

ABP also asserts that R-CALF cannot challenge the lawfulness of the permitting process because USDA has not prepared an administrative record for its issuance of permits. R-CALF’s challenge does not depend on the specifics of individual permitting decisions, however, but rather on the lack of authority for a process which turned the exception into the rule.

**B. Establishing criteria for permits and issuing thousands of permits for billions of pounds of imports is inconsistent with 9 C.F.R. § 93.40(a).**

Coming up with a list of “allowed products” that are not subject to the general ban on imports from countries with BSE is a rulemaking process, not a case-specific permit process. USDA’s actions recognized the rulemaking nature of its use of the permitting process, but failed to comply with the APA. See, e.g., R-CALF Memo Exh. 6; Exh. 8 at 4, AR010549 (concluding that APHIS should “[a]llow the import of processed meat such as ground meat,” even though that would increase the possibility of importing “higher risk product” and would represent “a significant change in policy without opportunity for public comment”); OIG Audit Report at 6.

These actions were purportedly under the authority of 9 C.F.R. § 93.40(a), which provides that: “the Administrator may upon request in specific cases permit ruminants or products to be brought into or through the United States under such as conditions as he or she may prescribe, when he or she determines in the specific case that such action will not endanger the livestock or poultry of the United States.” These actions were not case-by-case determinations in response to specific requests, however, as provided for in 9 C.F.R. § 93.40(a), but were blanket statements

that certain types of products would be “allowed.”<sup>12</sup> APHIS’ actions also bypassed the rulemaking necessary to modify existing USDA policy concerning imports from countries where BSE is known to exist (which rulemaking resulted in the Final Rule), and constituted final agency action without complying with the Administrative Procedure Act. This Court so held in issuing the April 26, 2004 Temporary Restraining Order in *Ranchers Cattlemen Action Legal Fund United Stockgrowers of America v. U.S. Dept. of Agriculture, et al.*, No. CV-04-51-BLG-RFC. That conclusion also justifies the injunction of further permitting of imports of boxed beef until a new rulemaking is completed.

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Respectfully submitted,

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<sup>12</sup> Contrary to Dr. Clifford’s declaration, ¶14, the Inspector General’s Audit Report did not confirm USDA’s interpretation of its permitting authority, but rather noted the permit system “was originally designed to allow for the import of research quantities (generally small amounts)” and that the USDA General Counsel’s Office advised APHIS to issue permits on an exception basis rather than as a general practice. Audit Report at 21, 22.

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## CERTIFICATE OF SERVICE

I certify that on June 28, 2005, I served true and correct copies of Plaintiff's Reply Memorandum in Support of Summary Judgment and Opposition to Defendants' Cross-Motion, by first-class mail, postage prepaid on the following:

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