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

RANCHERS CATTLEMEN ACTION LEGAL FUND	)	CV-05-06-BLG-RFC
UNITED STOCKGROWERS OF AMERICA,	)	
	)	
Plaintiff,	)	
	)	DEFENDANTS'
vs.	)	REPLY IN SUPPORT OF
	)	MOTION FOR
UNITED STATES DEPARTMENT OF AGRICULTURE,	)	SUMMARY JUDGMENT
et al.,	)	
Defendants.	)	
	)	

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## INTRODUCTION

Plaintiff's latest attack on the Rule is long on invective and short on substance. In the record before this Court, defendants have presented overwhelming scientific evidence that the importation of Canadian cattle and beef is safe. Against these facts, plaintiff offers three new declarants who predictably disagree with USDA. Their declarations cannot be taken seriously. None of these declarants claims to have read any part of the Administrative Record ("AR"), two have no real knowledge of BSE, and the third clearly distances himself from this case by never mentioning the Rule or Canada in his declaration. Most importantly, none of these declarants asserts that the importation of Canadian cattle or beef under the Rule is unsafe.

The record shows that Canada and the United States ("U.S.") have a complete set of mitigations and requirements in place that will block the introduction of BSE into the United States' herd. Simply raising a myriad of hypothetical risks, as plaintiff has, with no evidence to show that they are likely to occur individually, let alone in unison, does not make plaintiff's case a plausible one. Plaintiff offers only a series of purely conjectural "what-if's" that are not consistent with reality. The Rule should therefore be upheld.

## ARGUMENT

### I. USDA'S RULE IS VALID

#### A. The Secretary Is Entitled To A High Degree Of Deference, And Plaintiff's Declarants Should be Disregarded

Plaintiff fundamentally misconstrues the mandate of the Animal Health Protection Act ("Act"), which is to prevent the introduction of BSE into the animal herds of the United States, not to prevent the importation of a single infectious molecule or infected cow. See, e.g., Pl. Reply at 8 ("it is a virtual certainty that BSE prions will be imported"). The Act gives the Secretary of USDA broad discretion to regulate imports if necessary "to prevent the introduction or dissemination within

the United States of any pest or disease of livestock . . . .” 7 U.S.C. § 8303(a)(1) (emphasis added).

Thus, while preventing any BSE from entering the U.S. is certainly the goal, the critical issue is whether the series of interlocking, overlapping mitigation measures here and in Canada will prevent any such entry from resulting in disease among livestock. See, e.g., Cactus Corner v. U.S. Dep’t of Agriculture, 346 F. Supp. 2d 1075, 1089, 1103 (E.D. Cal. 2004) (finding that USDA acted within the scope of its authority where the Secretary determined that it was not necessary to prohibit the importation of clementines from Spain in order to prevent the introduction into or dissemination within the United States of a plant pest).

Moreover, the Act states that “the Secretary may prohibit or restrict” imports, 7 U.S.C. § 8303(a) (emphasis added), connoting that the decision is entrusted to the agency’s discretion. See, e.g., United States v. George, 85 F.3d 1433, 1437 (9th Cir. 1996). The decision not to regulate imports, and not to close the border to Canadian beef, closely resembles a “decision not to take enforcement action” that “should be presumed immune from judicial review” under the APA. Heckler v. Chaney, 470 U.S. 821, 832 (1985).<sup>1/</sup> Even if judicial review is available here, however, deference is “particularly warranted” because the case involves scientific matters within the agency’s area of special expertise. U.S. v. Alpine Land & Reservoir, 887 F.2d 207, 213 (9th Cir. 1989); see also Baltimore Gas & Elec. v. Natural Res. Def. Council, 462 U.S. 87, 103 (1983) (“When examining this kind of scientific determination . . . a reviewing court must generally be at

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<sup>1/</sup> Contrary to plaintiff’s claim, Pl. Reply at 1, the decision may be unreviewable under Heckler. A possible distinction between the instant case and Heckler is that the Secretary has chosen to erect a regulatory framework regarding the opening of the Canadian border, whereas in Heckler, the agency’s decision not to undertake certain enforcement actions was not accompanied by any agency rules. While USDA’s rule may therefore be subject to some judicial oversight because it is an exercise of the agency’s power, albeit not its “coercive” power, see Heckler, 470 U.S. at 832, the degree of deference should be very high in view of the limitation on judicial review imposed in Heckler and the fact that the rule embodies scientific judgments within the agency’s area of expertise.

its most deferential”).

### 1. Plaintiff’s 3 New Declarations Should Be Disregarded Or Stricken

There is no room in an APA case for battling scientists. “When 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.” See, e.g., Marsh v. Oregon Natural Res. Def. Council, 490 U.S. 360, 378 (1989); see also Greenpeace Action v. Franklin, 14 F.3d 1324, 1332 (9th Cir. 1992). While explanatory testimony regarding technical terms or complex subject matter may be allowed, see Nat’l Audubon Soc’y v. U.S. Forest Serv., 46 F.3d 1437, 1447 n.9 (9th Cir. 1993), plaintiff’s three new declarants, Drs. Prusiner, Weaver, and Charnley, do not even pretend to explain the scientific or technical issues in this case or explain why the agency should have reached a different conclusion based on the extensive AR.<sup>2/</sup> Indeed, none of these declarants professes to have read any part of the AR. Instead, plaintiff has essentially taken an opinion poll of the scientists on its payroll, and the results of that poll, predictably, are that they disagree with the agency.<sup>3/</sup>

Their opinions, however, second-guess the agency and are based on speculation rather than scientific fact. Dr. Prusiner speculates, for example, that we “should” assume that there is no species barrier, Prusiner Dec. ¶ 13, we “should” assume BSE behaves the same way in cattle as in other mammals regarding the tissues in which it resides, id. ¶ 14, and that we “should not

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<sup>2/</sup> While Dr. Cox’s declarations suffer from some of the same infirmities as those of these three new declarants, Dr. Cox has made at least some effort to comment on the AR supporting this rulemaking.

<sup>3/</sup> By contrast, defendants’ declarants explain the scientific issues in this case and why defendants’ conclusions were justified and scientifically sound. Their statements are grounded in the AR and are supported by citations to it. The Court must decide whether the agency’s decision was reasonable based on the AR, not on the opinions of plaintiff’s third party declarants. Florida Power & Light Co. v. Lorion, 470 U.S. 729, 743-44 (1985) (holding that judicial review should be “based on the record the agency presents to the reviewing court.”).

underestimate” the value of testing all slaughtered animals, id. ¶ 20. These views are not only conjectural but are also scientifically unsound because, for example, the testing of healthy animals is grossly inefficient and uninformative. AR 8059, 8118, 9473; Hueston II Dec. ¶ 5.2 (Exhibit 1). Indeed, in view of Dr. Prusiner’s failure to mention Canada – or USDA’s rule – even once in his declaration, see Hueston II Dec. ¶ 5.2, let alone draw any connection between his abstract assertions and the rule, his opinions have no relevance to this case. Dr. Prusiner’s declaration serves primarily as a thinly veiled sales pitch for his own company, which manufactures a commercial test that could profitably be used for the blanket testing of millions of cattle he so strongly endorses. Prusiner Dec. ¶¶ 17, 20.

Dr. Weaver’s declaration is similarly nothing but an unsupported expression of his disagreement with USDA’s conclusion that Canada’s surveillance is highly effective and exceeds OIE standards. His apparently limited knowledge of BSE is gleaned from reviewing current literature “as much as possible” and hosting one meeting. Weaver Dec. ¶ 1. It comes as no surprise, then, that he completely misinterprets OIE guidelines. See Hueston II Dec. ¶ 7.5. Dr. Weaver’s conclusions are wrong, see id. ¶¶ 7.1-7.7, and provide no basis for rejecting USDA’s determinations. See Marsh, 490 U.S. at 378.

Dr. Charnley’s declaration is also irrelevant and equally useless. Her background and experience are in policy, Charnley Dec. ¶ 1, and she has no knowledge of BSE. Not surprisingly, her declaration, which is little more than an abstract discussion about “policy” decisions, id. ¶ 2, merely parrots plaintiff’s arguments. Dr. Charnley admits that Canada’s screening system “may indeed be highly effective” but opines that there is no “transparent” basis for USDA’s decision that it is. Id. ¶ 2. However, Dr. Charnley makes no claim to having looked at the AR in this case. Because she has failed to examine the record showing that the Canadian screening system is in fact highly effective, see, e.g., AR 8051-8053, 8324; Hueston Dec. ¶¶ 7.1-7.7, it is understandable that

she has such a poor grasp of USDA's decision.

Thus, plaintiff's declarations point to no evidence in or outside the AR, that undermines the validity of the scientific studies on which defendants rely or the general scientific framework of the Final Rule. Thus, they supply no basis for this Court to conclude that the science, or the agency's application of it, is inaccurate, insufficient, or unreliable. See Cactus Corner, 346 F. Supp. 2d at 1113.

## **2. Plaintiff's Allegations Of Bad Faith Are Unfounded**

Based on misrepresentations of the Inspector General's Audit Report, plaintiff argues that the Secretary deserves no deference because he acted in bad faith. First, the Audit Report did not find that the rule was driven by pressure from those with economic interests in resuming trade with Canada. Pl. Reply at 2 (citing Audit Report at 7-8). After the Secretary began issuing import permits for certain categories of boneless beef in August 2003, permits were issued for processed versions of the same beef as equally safe. Audit Report at 7. The Audit Report imputes no bad faith to the decision to admit processed beef. Rather, it merely observes that APHIS's own memorandum of the decision not only noted that the decision "maintained consistency by allowing the entry of meat from animals less than 30 months of age regardless of processing," but also that "the decision addressed industry concerns that permit policies were too restrictive for trade."<sup>4/</sup> Id.

Second, the Audit Report did not conclude that defendants allowed riskier products to be imported in response to industry pressure. Pl. Reply at 2. Again, the Report simply recited APHIS's own acknowledgment of the obvious fact that a breakdown in certain safety precautions at meat processing plants could result in higher-risk meat products crossing the border. Audit Report at 7.

Third, the Audit Report did not find that USDA allowed bone-in beef imports in violation of

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<sup>4/</sup> The protection of livestock-related industries and foreign commerce are valid objectives under the Animal Health Protection Act. 7 U.S.C. § 8301(1)(C), (E); 8301(5)(B).

the Court's orders. See Pl. Reply at 2 n.2. Rather, it accurately states that the only bone-in beef allowed into the United States originated in the "United States, New Zealand, or Australia," and was merely processed in Canada and then exported to the United States. Audit Report at 12. The preliminary injunction expressly allowed the import of such non-Canadian beef, stating: "Ruminant products originating in a BSE-free region or from the United States that are processed in Canada and exported to the United States shall not be deemed Canadian products . . . ." May 5, 2004 Order ¶ 2.

Plaintiff implies that USDA acted in bad faith by allegedly failing to disclose why it decided to issue import permits for boneless beef starting in August 2003 notwithstanding the TSE Working Group recommendations. Pl. Reply at 2. Defendants did consider the recommendations, AR 8373-8380; Clifford Dec. ¶¶ 9-10, and the reasons for resuming imports are all disclosed in USDA's October 2003 Risk Analysis, AR 3644-3651. Moreover, the claim that USDA's decision to issue permits was improper or unsafe rings hollow since plaintiff entered into a May 4, 2004 stipulation in which plaintiff expressly agreed to the import of all Canadian beef designated for import as of August 2003. RCALF v. USDA, No. CV-04-51-BLG-RFC (D. Mont.), May 4, 2004 Stipulation ¶ 2.

Plaintiff argues that because a cow with BSE was recently discovered in Texas, the Court should accord no deference to USDA in this case. Pl. Reply at 3. This argument is specious. The finding of the Texas cow does not prove in any sense that the rule is unreasonable or Canadian cattle or beef are unsafe. Similarly, plaintiff's contention that USDA used unreliable testing methods is incorrect. Plaintiff is now struggling to distinguish Texas from Canada so that it can justify banning Canadian imports. In fact, the profiles of the U.S. and Canada are not substantially dissimilar. U.S. beef is neither more nor less safe than the Canadian beef that would be imported under the rule. See Hueston II Dec. ¶ 9.3.

**B. The Rule Is Supported By Scientific Fact, And Plaintiff's Case Is Based On Nothing But Conjecture**

That plaintiff's arguments amount to little more than fear-mongering for the sake of keeping

the border closed to competition is apparent from a comparison of the scientific facts on which the rule is based with the speculation on which plaintiff's arguments are founded. In its reply brief, plaintiff takes issue with the following facts but fails to refute them with any hard evidence.

**Fact #1: Prevalence in Canada is low and empirically is zero among cattle that would be imported under the Rule**

The rule permits the importation only of cattle under 30 months of age or beef from such cattle. AR 8049, 8132-8135. Four older Canadian cows have been discovered to have BSE. AR 12576. The cows were born before or shortly after the 1997 feed ban. AR 12576; Hueston II Dec. ¶ 8.3. That the four cows did not manifest symptoms of BSE until they had reached at least 72 months of age indicates a low level of infectivity in Canada even before the ban, because if a high level of infectivity were circulating, younger cows would be manifesting symptoms by now. AR 8329-8331. No cows under 30 months of age have ever been found to have BSE in Canada, and none have been found in the United Kingdom ("UK") since 1996, or in the EU since 2001 despite millions of tests performed worldwide. Statement of Facts in Support of Defendants' Opposition to Plaintiff's Motion for a Preliminary Injunction ("Facts") ¶ 5; Hueston II Dec. ¶ 8.2. Therefore, the level of infectivity in Canada among young cattle is essentially zero, and the risk of importing BSE-positive cattle under the rule is empirically zero. Hueston II Dec. ¶¶ 6.1-6.8, 8.3.

Plaintiff contends that USDA does not know the true prevalence of BSE in Canada. Pl. Reply at 4, 7. However, nothing in the Act requires that true prevalence be known. What matters is that USDA has substantial information to conclude that BSE is extremely rare in Canada.<sup>5/</sup> AR

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<sup>5/</sup> The existence of a cluster in Alberta, see Pl. Reply at 8, does not justify banning imports from Canada. The cluster consisted of four animals born before or shortly after the feed ban. AR Epi ¶ 7.1; Ferguson II Dec. ¶ 14. Their exposure was traced to contaminated feed, probably from the same source, and their birth cohorts were destroyed. AR Epi ¶¶ 7.1, 7.2; Ferguson II Dec. ¶ 14. These cows offer no basis for believing infectivity is high throughout Alberta or elsewhere in Canada. AR 8096; Ferguson II Dec. ¶¶ 14-15. Instead, their long incubation period indicates low infectivity – even before the feed ban. AR 8329-8331.

8096; Hueston II Dec. ¶¶ 7.1-7.7, 8.3. The apparent contradiction plaintiff points out is manufactured from statements taken out of context. Pl. Reply at 7. It is consistent for USDA to state that Canada's testing is well-suited to making an accurate determination regarding prevalence of BSE, i.e., an accurate enough determination to know that prevalence in Canada is low, while at the same time acknowledging that the exact prevalence of BSE can never be known. AR 8096, 8325, 8329, 12841; Ferguson I Dec. ¶ 7.

Dr. Cox's attempt to quantify the prevalence among animals that would be imported fails miserably because it ignores the effects of the feed ban and age on infectivity. See Stark I Dec. In his newest declaration, Dr. Cox still fails to correct the most blatant error in his original calculation which led to his estimate that there would be 6.25 BSE-positives per million imported from Canada under the rule.<sup>6/</sup> Stark II Dec. ¶ 3. He claims that if a million cattle per year were imported, it is virtually certain that we would import BSE. He refuses to admit that – according to his own formula – the correct number is actually billions, and it would take 7 to 110 centuries to import a BSE-positive cow. Id. ¶¶ 5, 8.

Dr. Cox's mantra is that "the first cow has already crossed the border" and therefore the probability of importing BSE from Canada is 100%. Stark II Dec. ¶ 12. However, the relevant issue here is future probability under a rule which only allows the importation of under-30-month cattle. See id. ¶ 12. Since the Canadian cow that "already crossed the border" would be banned under the rule, Dr. Cox's observation is immaterial.<sup>7/</sup> See id. ¶ 12. Finally, Dr. Cox's prognostications are

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<sup>6/</sup> Dr. Cox has offered at least 4 or 5 different estimates. Stark II Dec. ¶ 9 (Exhibit 2).

<sup>7/</sup> Plaintiff ignores the fact that while there may still be BSE in Canada, Pl. Reply at 8, (as there may be in the U.S.) the relevant issue is whether the importation of under-30-month cattle and beef is safe in view of risk mitigation measures and other restrictions under the rule.

Plaintiff also erroneously asserts that the four Canadian BSE cases were discovered over the "past year," Pl. Reply at 7, when in fact there have been only 2 in the past year, and 2 in 2003.

littered with “escape hatches” that render his conclusions meaningless. See id. ¶ 6 (e.g., “it appears that a failure rate of several BSE-positive cattle per year may be quite realistic”(emphasis added), Cox IV Dec. at 34 and additional examples cited therein). In sum, his estimate rests on profoundly subjective assumptions that are hidden behind a veil of rhetoric and the illusion of mathematical rigor.<sup>8/</sup> Stark II Dec. ¶ 8. At least one administrative law judge has found that Dr. Cox’s “credibility is severely compromised and his testimony cannot be relied on.” Initial Decision, Docket No. 00N-1571, Department of Health and Human Servs., March 16, 2004, at 15 (Exhibit 4).<sup>9/</sup>

Plaintiff accuses USDA of not declaring what number of BSE or vCJD cases are acceptable. Pl. Reply at 4. It is USDA’s position that none are acceptable, and the rule is based on scientific evidence indicating there will be none, although this outcome cannot be guaranteed with absolute mathematical certainty because zero risk is unattainable. AR 8118; Ferguson III Dec. ¶ 11; see Cactus Corner, 346 F. Supp. 2d at 1110 (holding that the agency was not required “to unnecessarily

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<sup>8/</sup> Plaintiff calls Dr. Stark a professional witness with no expertise concerning BSE. In fact, however, Dr. Stark is a professor of statistics at one of the world’s most highly respected universities, and Dr. Cox is the witness for hire, viz., his living depends primarily on pleasing the clients he serves (like plaintiff) through his consulting company. And despite a vitae of some 42 pages none of his experience or background involves BSE except in connection with this litigation. So if particularized expertise with BSE is plaintiff’s sine qua non, Pl. Reply at 4 n.4, plaintiff should withdraw Dr. Cox forthwith.

Plaintiff also fails to understand that statistics is the lingua franca of modern science because the techniques apply to problems in a wide variety of disciplines ranging from archeology to zoology. Similarly, statistical techniques are valuable in a wide variety of consulting projects. Dr. Stark’s expertise in statistics arises from his having been a professor at a major university for more than 17 years, published 45 papers in refereed scientific literature, served on the editorial boards of 3 major scientific journals, and given 130 invited lectures at universities and scientific meetings in 16 countries. See Fed. R. Civ. P. 702. His reliance on and references to the AR are necessary for him to evaluate whether Dr. Cox’s conclusions are correct in view of the scientific facts underlying the rule. As plaintiff and its declarants have apparently forgotten, the issue in this litigation is whether the AR justifies the agency’s decision. See Florida Power & Light Co., 470 U.S. at 743-44.

<sup>9/</sup> This is in part because he “chang[ed] his position” on the same issue when he switched clients as a consultant, “alter[ed] quoted material from published articles,” made an “indiscriminate use of quotation marks,” and “edit[ed] referenced material.” Exhibit 4 at 13-15.

restrict trade on the basis that all risk is not (nor may it ever be) capable of being eliminated entirely,” where the agency showed the extent to which risk would be eliminated “to as reasonable a degree of certainty as practical utilizing sound science and available technology”). Any alleged health risk presented by vCJD pales in comparison to other health risks that consumers regularly assume. Stark II Dec. ¶ 13. There has never been a single vCJD death attributed to beef consumed in Canada or the U.S..<sup>10/</sup>

Plaintiff says it has never argued that only zero risk is acceptable. Pl. Reply at 6 n.5. However, given that the risk of importing BSE from Canadian cattle or beef now approaches zero, their demand for an even lower risk indicates they will settle for nothing except zero, an unattainable goal which serves only as an excuse for arguing that the border should be closed, see, e.g., Charnley Dec. ¶ 5 (stating that risk “can be avoided entirely by continuing to ban imports”), and plaintiff is the only obvious beneficiary of such an unjustified, unreasonable, and unscientific policy.

**Fact #2: The feed ban blocks BSE from spreading in Canada or the U.S.**

Canada implemented the feed ban in 1997. Facts ¶ 13. Consumption of contaminated feed is the primary, if not the only way cattle are infected with BSE, and the feed ban halts the amplification of infectivity. AR 8070, 8075, 8098; Ferguson I Dec. ¶ 11; Ferguson II Dec. ¶¶ 10-11; Engeljohn I Dec. ¶ 16; Hueston I Dec. ¶¶ 6.1, 6.7, 10.1-10.8; Hueston II Dec. ¶ 2.2. For example, the number of new BSE cases in the UK by year of birth declined precipitously by 65% the first year (1989) after the feed ban was introduced, and declined by 84% between 1987 and 1990. Hueston I Dec. ¶ 10.3 & Figure 2; Hueston II Dec. ¶ 2.2. Empirical data demonstrate that feed bans are effective, AR 8051-53; Facts ¶ 14; Ferguson II Dec. ¶¶ 13-15; Hueston I Dec. ¶¶ 11.5, 11.6, Hueston

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<sup>10/</sup> And at the same time plaintiff rails against allegedly unsafe Canadian cattle, its members are profiting from the purchase of that very same cattle at artificially depressed prices, an accusation that draws much bluster from plaintiff but not a denial. See Pl. Reply at 15 n.9.

II Dec. ¶ 2.2; and that the Canadian feed ban is equivalent to the feed ban in the United States, AR 8060, 8324-25; Ferguson II Dec. ¶ 13; and that it meets OIE recommendations, AR 8052; Facts ¶ 15. The tiny percentage of noncompliance incidents (fewer than 2% of inspections in 2003-2004) have consisted largely of inadequate record keeping procedures rather than any feed safety issue. AR 8051-52, 12598-599; Facts ¶ 14.

Plaintiff takes a series of pot shots at the feed ban based on speculative unknowns rather than scientific facts. Plaintiff first argues that the U.S. should not resume imports from Canada because cattle exposed to contaminated feed prior to the feed ban may not have developed outward signs of BSE yet. Pl. Reply at 9. This argument goes nowhere because any of the cows allegedly exposed to contaminated feed would be too old to be imported under the rule. Contrary to plaintiff's assertion, it is not "much less" than 8 years since Canada's feed ban became effective. Id. Empirical evidence indicates that the feed ban is effective given that the youngest BSE-positive Canadian cow was born seven months after the imposition of the ban in 1997. AR 8051-53, 12577-579, 12594-633.

The potential exposure of ruminants on seven farms to contaminated feed containing the carcass of the May 2003 cow does not indicate that the feed ban is ineffective. See Pl. Reply at 10. The contaminated feed was poultry and hog feed, and the potential ruminant exposure included sheep and goats. Pl. SJ Br. Exhibit 1 at 13-14. There is no evidence that any cattle were exposed to BSE through this feed. Similarly, plaintiff argues that rendering plants inspected from 2002-2005 had compliance issues, Pl. Reply at 10 n.8, but ignores the important fact that these were actually administrative issues, and they did not rise to the level of compliance infractions that created any contamination risk. AR 12598, 12599; Ferguson II Dec. ¶ 11. Thus, the suggestion that this created a safety problem is purely speculative.

Plaintiff argues that Canada's risk profile is higher than that of the U.S. Pl. Reply at 14. As Dr. Ferguson explains in detail, there is no basis to conclude that there is any significant difference

in the risk profiles of the U.S. and Canada based on the distinctions offered by plaintiff. Ferguson III Dec. ¶¶ 7, 8 (Exhibit 3).

**Fact #3: The empirical incidence of BSE in under-30-month Canadian cattle is zero, and under-30-month cattle are highly unlikely to pose a risk to cattle or humans**

There have been no cases of BSE in under-30-month cattle in the UK since 1996, or in the EU since 2001 despite millions of tests. AR 8329; Facts ¶ 5; Ferguson II Dec. ¶¶ 19-20; Hueston I Dec. ¶¶ 10.4-10.5, 12.4; Hueston II Dec. ¶ 8.2. No animal under 30 months of age born in Canada and only a handful worldwide since 1998 have been confirmed with BSE. AR 8335; Hueston I Dec. ¶ 12.4; Hueston II Dec. ¶¶ 8.2, 8.3. Any BSE in under-30-month cattle resides in the tonsils and distal ileum, which are removed at slaughter. AR 8332-33; Engeljohn II Dec. ¶ 5(c), (d); Hueston I Dec. ¶¶ 8.3, 9.1. The likelihood of BSE appearing in under-30-month cattle in Canada approaches zero, and current empirical prevalence is zero. AR 8329-31; Ferguson I Dec. ¶¶ 15-16; Hueston II Dec. ¶¶ 8.2-8.3.

According to plaintiff, under-30-month cattle may present a risk because two young Japanese cows had BSE. Pl. Reply at 11. Plaintiff relies on Dr. Prusiner. Id. But Dr. Prusiner carefully hedges his statement, merely observing that “[i]t has been confirmed that two Japanese cows were diagnosed with BSE.” Prusiner Dec. ¶ 18. He fails to declare that the diagnosis was reliably confirmed and correct in his opinion. The fact is that both Japanese cows were declared positive based on questionable results of a test that has not been internationally validated. Hueston II Dec. ¶ 8.1. They have never been confirmed as BSE-positive using the internationally validated confirmatory test, and they tested negative in all other tests performed. Id. Thus, scientific data regarding the two Japanese cows indicates that they were in fact BSE-negative rather than positive. Id. Therefore, they provide no basis for concluding that under-30-month cattle are unsafe.

**Fact #4: The removal of SRMs protects public health**

The removal of SRMs upon slaughter effectively prevents infective tissue from entering the human food supply and protects human health. AR 8338, 8368, 9959, 9965; Facts ¶ 19; Engeljohn I Dec. ¶ 14; Engeljohn II Dec. ¶¶ 5(a), 7-9; Hueston I Dec. ¶¶ 9.2-9.4 Hueston II Dec. ¶¶ 2.3, 4.1-4.2. Empirical data from the UK showing a dramatic reduction in vCJD following the implementation of slaughter regulations support this conclusion. Hueston II Dec. ¶¶ 2.3, 4.1, Figure 1. Canada and the United States both have comprehensive SRM removal requirements that are effectively enforced. Facts ¶¶ 20, 22.

Plaintiff contends that SRM removal has been practiced for too short a time to be deemed highly effective at reducing the risk of BSE. Pl. Reply at 5. This is incorrect. The effectiveness of SRM removal has been recognized as an effective risk mitigation measure worldwide and its efficacy has been demonstrated empirically in the UK since 1989. AR 8331, 8368, 9961; Hueston II Dec. ¶¶ 2.3, 4.1-4.3. Plaintiff argues that BSE prions have not been found in meat simply because tests are too weak to find them. Pl. Reply at 12. This is pure conjecture.<sup>11/</sup> Plaintiff's speculative assertion that tonsil tissue could "potential[ly]" contaminate tongue, *id.* ignores the fact that the residual tonsil tissue present in tongue has never been shown to carry infectivity. AR 8082, 8368, 9965; Hueston II Dec. ¶ 4.2.

There is also no public health basis for the mandatory testing of all cattle. AR 8059, 8069; Hueston II Dec. ¶¶ 5.1, 5.2, 8.2. In fact, the substantial epidemiological data show that testing of healthy cattle is a grossly inefficient strategy for finding BSE. AR 8059, 8069; Hueston II Dec. ¶ 5.2; Stark Dec. ¶ 13 n.55. On the other hand, the effectiveness of SRM removal is demonstrated by scientific data that shows vCJD plummeted after the imposition of the SRM-removal

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<sup>11/</sup> Dr. Prusiner's speculation that infectivity could be present in bovine blood has similarly not been documented. See Hueston II Dec. ¶ 5.1.

requirement. Hueston II Dec. ¶ 4.1, Figure 1. Dr. Prusiner faults USDA for not requiring blanket testing.<sup>12/</sup> Prusiner Dec. ¶ 19. Most notably, however, Dr. Prusiner does not assert that blanket testing would be 100% reliable or result in zero risk that BSE could ever enter the food supply. He does not even say it would give any appreciably greater protection to consumers than the rule already provides.

**Fact #5: There is a substantial species barrier**

There have been fewer than 200 cases of vCJD worldwide since 1996. Facts ¶ 6. About 95% of those were linked to exposure in the UK. Id. This relatively small number occurred despite the infection of an estimated 1 million cattle in the UK, id., and 54 million cattle infectious doses, AR 8045-46; Hueston I Dec. ¶ 7.3; Hueston II Dec. ¶ 6.2. To become infected, humans may need 10,000 times the level of infective tissue necessary to infect cattle. Facts ¶ 6; Engeljohn I Dec. ¶ 15; Ferguson I Dec. ¶ 6. Empirical studies support the existence of a substantial species barrier. AR 8046, 8089, 8363; Hueston II Dec. ¶ 6.1-6.3.

Plaintiff's declarants are contradictory and hedge their assertions carefully. They claim, on the one hand, that "some [consumers] probably are" protected by a formidable species barrier, Cox IV Dec. at 43, and on the other, that what we know "is not sufficient" to establish a species barrier,<sup>13/</sup> Prusiner Dec. ¶ 13. However, the science and the data do in fact show that the dose

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<sup>12/</sup> Dr. Cox jumps on this bandwagon perhaps too eagerly: he recommends mandatory testing of imported under-30-month cattle despite his self-contradictory view that "BSE prion contamination cannot be detected in younger cattle except in rare cases," Cox IV Dec. p. 37, See Hueston II Dec. ¶¶ 8.3, 9.2.2.

<sup>13/</sup> Dr. Prusiner's assertion that USDA should assume that "one infectious unit (or dose) of prions is sufficient to cause vCJD in humans," Prusiner Dec. ¶ 13, fails to specify whether the "infectious unit" to which he is referring is the amount required to infect humans or the amount required to infect cattle. If he means the former, his statement is tautological. If he means the latter, his assumption contradicts the empirical and scientific data, which show that the infectious dose required to infect humans is substantially greater than the infectious dose required to infect cattle. AR 8383; Hueston II Dec. ¶¶ 6.1-6.3.

required to infect humans is substantially greater than the dose required to infect cattle. AR 8383; Hueston II Dec. ¶ 6.1-6.3. Against this solid evidence that a species barrier exists, AR 12580; Hueston II Dec. ¶¶ 6.1-6.3, plaintiff offers nothing but Dr. Prusiner's speculation, which completely disregards statistically sound assessments of exposure risk. Hueston II Dec. ¶¶ 6.1-6.3, 9.2.1.

When all is said and done, plaintiff has pointed to no evidence within (or even outside of) the AR which could support the conclusion that the rule is irrational rather than the product of reasoned decisionmaking based on scientific evidence from which it can reasonably be concluded (at the very least) that imports of Canadian cattle and beef under the rule present a minimal risk of introducing BSE into the U.S.. Therefore, plaintiff's challenge under the APA should be rejected.

### **C. The Rule Comports With The Regulatory Flexibility Act**

Plaintiff argues that USDA failed to evaluate the alternatives of testing and country of origin labeling in terms of their potential economic benefit for small businesses. Pl. Reply at 15.

However, USDA did evaluate these alternatives and determined that they were inconsistent with the basis and purpose of the rule and were not appropriate or warranted by the facts. AR 8117-8118; Fillo Dec. ¶¶ 12-13. USDA rejected these alternatives, in part, because they would not provide any significant protection to animal and public health and because it would be inappropriate to adopt measures that are little more than marketing tools.

### **D. Plaintiff's NEPA Claim Fails**

Plaintiff insists it has standing to pursue its NEPA claim because it purportedly asserts both economic and environmental injury to its members. Pl. Reply at 14-15. As explained in defendants' opening brief, plaintiff's allegation that its members will be harmed because they are beef eaters and will face an "increased risk of disease," Compl., ¶ 2, only underscores its failure to demonstrate the requisite organizational standing. Def. SJ Brief at 23-24.

Moreover, plaintiff's citation to the Ninth Circuit opinion in Presidio Golf Club v. National

Park Service, 155 F.3d 1153, 1158 (9th Cir. 1988), fails to advance its case. There, the Ninth Circuit held that a golf club fell within NEPA's zone of interests because its own incorporation papers defined the club's purpose as, inter alia, "improv[ing] and maintain[ing] . . . grounds and buildings for athletic purposes," which implied the "corollary purpose of maintaining an environment, . . . ." Id. at 1158. Here, in contrast, the Complaint defines plaintiff's purpose as representation of over 12,000 U.S. cattle producers on issues concerning international trade and marketing." Compl. at ¶ 2. Likewise, its self-defined "mission is to represent the U.S. cattle industry in national and international trade and marketing issues to ensure the continued profitability and viability of U.S. independent cattle producers." The Official R-CALF USA Website, <http://www.r-calfusa.com/> (last visited July 11, 2005). By its own terms, R-CALF's purposes and mission are not even remotely analogous to the golf club in Presidio Golf Club, and R-CALF fails to demonstrate the requisite prudential standing. Nevada Land Action Ass'n v. U.S. Forest Serv., 8 F.3d 713, 716 (9th Cir. 1993) (holding that a plaintiff asserting purely economic injury does not have standing to challenge an agency action under NEPA).

Even if plaintiff had standing, its NEPA claim is without merit. See Def. SJ Br. at 24. Plaintiff contends that the Ninth Circuit's holding in Safari Aviation v. Garvey, 300 F.3d 1144, 1152 (9th Cir. 2002) is inapplicable here because this is purportedly not a case where there were two "minor procedural defects." Pl. Reply at 15. On the contrary, Safari Aviation supports USDA's actions here. There, the Ninth Circuit held that FAA's failure to consider plaintiff's comments on its final rule was harmless, when the "main thrust" of plaintiff's comments had been extensively commented on and discussed in previous rule-making proceedings, and when most of the same points were made by another group, and the FAA specifically referenced those comments in its

rulemaking. 300 F.3d at 1152.<sup>14/</sup>

Likewise, as explained in defendants' opening brief, APHIS provided ample notice and opportunity for the public to comment on both of its environmental assessments for the rule. Def. SJ Br. at 25-26. The agency provided more than 100 days of public comment on the environmental issues raised by the Rule, and received only 13 public comments on the Final EA, most of which duplicated comments already received in response to the initial EA and proposed Rule. AR 12573-12574. The agency addressed all of those comments in its FONSI on April 8, 2005. *Id.*<sup>15/</sup> In light of the publication of the FONSI, the Secretary issued an Affirmation of Final Rule which ratified the final Rule. AR 12573. Plaintiff has failed to demonstrate a violation of NEPA.

## **II. The Court Should Reject Plaintiff's Belated Attempt To Invalidate Import Permits Issued Under Pre-Existing Rules**

### **A. Plaintiff Has Raised No Claim To Void the Permit Process**

Neither in R-CALF I, nor at the preliminary injunction stage of this litigation, did plaintiff raise any challenge to the importation of boneless beef products pursuant to permits issued in accordance with the Secretary's announcement of August 2003. And by its own admission, plaintiff's complaint raises no freestanding claim against the August 2003 permitting process. Pl. Reply at 16. Plaintiff requests relief on this subject only in its prayer for relief, but such an

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<sup>14/</sup> Contrary to plaintiff's suggestion, Pl. Reply at 15, defendants do not rely on the portion of the Safari Aviation opinion discussing two "minor procedural defects." There, the court found the procedural issue raised by the "defects" mooted by expiration of the rule. 300 F.3d at 1152. Moreover, defendants' opening brief also explained that plaintiff's citation to Save the Yaak Comm. v. Block, 840 F.2d 714, 718 (9th Cir. 1988) is inapplicable here. Def. SJ Brief at 25.

<sup>15/</sup> The agency also addressed additional issues raised in R-CALF's Complaint which were never submitted by R-Calf or any other commenter during the comment period for either the draft or final EA. AR 12581. Those new issues cannot properly be made part of this case. Vermont Yankee Nuclear Power Corp. v. Natural Resources Defense Council, Inc., 435 U.S. 519, 553 (1978) (holding that persons challenging an agency's compliance with NEPA must structure their participation to alert the agency to the parties' positions and contentions); accord, Dep't of Transp. v. Public Citizen, 124 S. Ct. 2204, 2212 (2004).

afterthought is insufficient to raise for the first time now a claim challenging imports of Canadian beef authorized by permit. The three counts of plaintiff's complaint challenge the substance of the Final Rule, not import permits issued after the August 2003 announcement. A fair reading of the complaint demonstrates that it mentions the August 2003 announcement twice, and only in passing, to provide context for plaintiff's challenges to the Final Rule. See Verified Comp. ¶¶ 15, 32.

Indeed, there are no factual statements in the complaint alleging that the permit process is illegal or ultra vires. The Final Rule covers a far broader range of beef imports than the August 2003 permitting process which, by its terms, is strictly limited to a small class of boneless beef products.

This difference has not been lost on the Court. TRO at 8 (noting the difference between the August 2003 announcement and the rulemaking).

The complaint is directed solely toward invalidating the Final Rule, and halting all beef imports authorized pursuant to pre-existing rules is an improper remedy for the causes of action plaintiff has actually pled. See Wilco Corp. v. Willis Indus., 567 F. Supp. 352, 355 (N.D. Ill. 1983) (noting that "familiar pleading principles teach the prayer for relief is not part of the cause of action itself, which is a function of the facts alleged in the complaint."). Plaintiff has failed to amend its complaint or put defendants on notice of its claim, and the 34-page complaint never mentions the claimed illegality of the permit process. This prayer for relief should be stricken or simply ignored.

Plaintiff's claim that its concerns would be "unaddressed if the Court only vacated the Final Rule" should not be taken seriously. After all, plaintiff itself agreed that this limited permitting process should remain in place in May 2004. May 4, 2004 Stipulation of the Parties ¶ 4, 04-51 (D. Mont.). Moreover, if the Court leaves the permit process in place while striking down the Final Rule, it would limit the number of importable beef products. Plaintiff's forecast that a parade of horrors will occur if the permit process authorized by regulation remains viable is without foundation. The August 2003 permit process has been in place for nearly two years without any

adverse consequences. The relief plaintiff requests is extraordinary and could wreak havoc in livestock- and beef-related industries and in our international trade relations. The Court should not grant this relief.

**B. Notice and Comment Rulemaking Was Not Required Because the Challenged Permitting Process is Conducted Under and Consistent with Existing Regulations**

Even if the Court considers plaintiff's challenge to the permit process, which allowed limited categories of boneless beef to be imported from Canada, the Court should uphold the permit process for two independent, but related, reasons. First, the permitting process is entirely consistent with the regulations as written. Plaintiff erroneously contends that the August 2003 program violates the regulatory requirement for a "case-by-case" decision to issue a permit. This argument entirely ignores defendants' demonstration that the permit process was in fact individualized and required that each individual seeking to import low-risk products separately apply for a permit. Clifford Dec. ¶ 9. Furthermore, defendants examine each permit application and must, in each and every case, determine if the imports would be safe. *Id.* The August 2003 permit process therefore did create a case-by-case system that fully complied with the regulation.

Second, plaintiff's argument that notice and comment was required is fundamentally flawed because, defendants did not issue a rule, much less a legislative rule requiring notice and comment, but merely construed an existing rule to encompass boneless beef. As discussed, that interpretation is consistent with the express terms of the rule and the discretion it accords to the Secretary and must, therefore, be upheld. *Thomas Jefferson Univ. v. Shalala*, 512 U.S. 504, 512 (1994) (internal quotations and citation omitted) (stating that an agency's interpretation of its own regulations in the discharge of its regulatory responsibilities must be given "controlling weight unless it is plainly

erroneous or inconsistent with the regulation."<sup>16/</sup>

Finally, Plaintiff erroneously argues that the Court has held notice and comment rulemaking was required to institute the August 2003 permitting process. Pl. Reply at 20. As an initial matter, the Court's earlier decision was issued before the defendants even had an opportunity to file a brief to argue its position, and it provided temporary relief, not a ruling on the merits. In fact, the Court's temporary relief was addressed to an expansion of the types of beef that could be imported that occurred through an April 2004 administrative decision, not the August 2003 announcement. See TRO at 3 ("Plaintiffs . . . challenge to an undated memorandum" from April 2004). The Court did not, however, hold that notice and comment rulemaking was required to import beef starting in August 2003. The grounds on which the Court issued its TRO against the April 2004 memorandum have no bearing here. Indeed, the Court was particularly concerned about the timing of the April 2004 decision because it occurred after commencement of the November 2003 rulemaking and contemplated the same subject matter as the rulemaking. Id. at 7-9. Obviously, these concerns have no relation to the August 2003 permit process. Drawing a distinction between the two, the Court even noted that the August 2003 permit process was limited to a select number of products, while the remainder would be subject to the rulemaking. See id. at 8. Because this permit process is consistent with the regulation's plain meaning and the discretion it affords the Secretary to allow imports by permit, plaintiff's challenge should be summarily rejected, if the Court considers it at all.

## CONCLUSION

For the foregoing reasons, defendants' motion for summary judgment should granted.

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<sup>16/</sup> Even if the Secretary's August 2003 announcement could be considered to be a rule, it would be an interpretive rule, for which no notice and comment is required. 5 U.S.C. § 553(b)(A). The Secretary merely "advise[d] the public of the agency's construction of the statutes and rules which it administers," which is "a prototypical example of an interpretive rule." Chief Prob. Officers v. Shalala, 118 F.3d 1327, 1333 (9th Cir. 1997). Moreover, agency policies and interpretations are allowed to change over time. See id. at 1337 (agency is free to change its interpretation without notice and comment as long as such change is not inconsistent with a regulation having the force of law).

Dated: July 13, 2005

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I hereby certify that on July 13, 2005, copies of Defendants' Reply in Support of Motion for Summary Judgment were served upon plaintiff's counsel by first-class mail, postage prepaid, as follows:

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