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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,	)	Cause No.CV-05-06-BLG-RFC
	)	
vs.	)	
	)	
UNITED STATES DEPARTMENT OF AGRICULTURE,	)	<b>MEMORANDUM OF POINTS</b>
ANIMAL AND PLANT HEALTH INSPECTION	)	<b>AND AUTHORITIES IN</b>
SERVICE, et al.,	)	<b>SUPPORT OF PLAINTIFF'S</b>
	)	<b>MOTION FOR</b>
	)	<b>SUMMARY JUDGMENT</b>
Defendants.	)	

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## **BACKGROUND**

This action concerns a decision by the United States Department of Agriculture (“USDA”) Animal and Plant Health Inspection Service (“APHIS”) to lift a ban on the importation of live cattle and edible bovine products from Canada. In a final rule published January 4, 2005, USDA reversed a May 29, 2003, APHIS action that had the effect of banning imports of cattle and edible bovine products from Canada, after a Canadian cow was confirmed to have bovine spongiform encephalopathy (“BSE”), commonly known as “Mad Cow Disease.” 70 Fed. Reg. 460 (the “Final Rule”), Exhibit 1 to Memorandum in Support of Application for Preliminary Injunction (“PI Memo”).<sup>1</sup>

Since 1989, USDA policy has been to prohibit imports of live cattle from countries where BSE is known to exist. 70 Fed. Reg. at 462. As recently as January 2003 USDA told Congress it is one of the three key strategies protecting the United States from BSE. AR1510-11; AR009305-306; AR009343; USDA, Assessment of the Canadian Feed Ban, February 2005 (Exhibit 1) at 2. On May 29, 2003, USDA, acting “on an emergency basis” to prevent the introduction of BSE into the United States,” applied that policy to Canada by issuing regulations that include Canada on a list of regions where BSE is known to exist, based on a case of BSE in the Province of Alberta reported by the Canadian Food Inspection Agency (CFIA). 68 Fed. Reg. 31,939, 31,940 (PI Memo Exhibit 2). The Final Rule reverses the longstanding USDA policy and allows imports of certain Canadian cattle and edible bovine products.

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<sup>1</sup> Many of the documents referenced here are attached as exhibits for the convenience of the Court. So as not to burden the Court with even more paper, documents already submitted to the Court at the preliminary injunction stage are not attached again here. Also in the interest of brevity, because BSE and the human disease believed to be caused by eating BSE-contaminated meat products, variant Creutzfeldt-Jakob Disease (“vCJD”), were described in detail in the PI Memo, as was the regulatory history of the Final Rule, that background is not repeated here.

On December 29, 2004, the CFIA announced publicly that yet another cow in Alberta had been tentatively identified as having BSE. That diagnosis was confirmed on January 2, 2005. On January 11, 2005, CFIA announced that a fourth cow from Alberta, this one only six years and nine months old, had been confirmed to have BSE. 70 Fed. Reg. 18,252, 18,258 (April 8, 2005). While these discoveries did not cause USDA to revise or seriously reconsider much of the Final Rule, on February 9, 2005 Secretary Johanns announced the suspension of the portion of the rule allowing imports of beef products from cattle that were 30 months of age or older at slaughter (attached to Defendants' "Statement of Facts" in opposition to preliminary injunction), to allow for further investigation of the two recent cases in Canada and for the development of a plan for resuming imports in 30 month and over cattle and beef from such cattle. *Id.* That portion of the rule was formally suspended indefinitely on March 11, 2005, 70 Fed. Reg. 12,112. The remainder of the Final Rule was to become effective on March 7, 2005, but this Court enjoined its implementation on March 2, 2005.

Several facts about BSE make it a particularly problematic disease to address. Only a minute amount of BSE-infected tissue – as little as one milligram in a single exposure – is needed to infect cattle with BSE. CFIA 2002 Risk Assessment at AR002671. This has been likened to a grain of sand. AR001658. That such a small amount of material can transmit the disease makes the prevention of contamination in slaughtering plants and feed mills problematic. The amount of BSE-infected tissue needed to cause vCJD and human is unknown, but for worst-case risk assessment purposes should be considered as little as for cattle. *See* Exhibit 2 to this Memorandum ("Cox Declaration III") at 22-24.

BSE has a long incubation period, and thereafter it may be 10 years or more before a human exhibits vCJD from eating the BSE-contaminated meat. *Cf.* Harvard Study at 13, 37

(AR001799, 001823). BSE may take a long time to become established and recognized; indeed, just since 2000 BSE has been identified in the cattle herds in 13 additional countries, including countries distant from the presumed origination of the disease in the UK, such as Japan, Israel, in Canada, despite current risk mitigation measures in place in most countries. *See* AR001300.

These characteristics prompted the World Health Organization to issue this warning in 2002:

Of all the lessons learned from the BSE epidemic in the UK, one in particular stands out: BSE is a threat that must be taken seriously by all. . . Countries with no detected case of BSE should not become complacent in the face of a potential global epidemic. The extremely low initial incidence and the low within-herd incidence of BSE cases, long incubation period, and non-specific nature of the early clinical signs can delay the detection of the first cases of disease and mask epidemic spread.

AR001297.

Both the United States and Canada believe that the only significant potential source of BSE in either the U.S. or the Canadian cattle herd is the importation of infected cattle or cattle products. 68 Fed. Reg. at 62386; CFIA 2002 Risk Assessment at AR002526. Accordingly, both have prohibited imports of cattle and most bovine products from countries known to have or at risk of having BSE. 70 Fed. Reg. at 462; CFIA Risk Assessment at AR002578. Canada has a different risk profile from the U.S., however, because of its imports of cattle from the UK.

A cow in Canada that had been imported from the UK was found to have BSE in December 1993.<sup>2</sup> Canada imported 182 cattle from the UK between 1982 and 1990, including at least 10 originating from herds in the UK known to be infected with BSE, two of which were confirmed to be herd mates of the BSE-positive cow discovered in Canada in 1993. *See* AR002560-61. Importantly, CFIA states that all of these cattle were potentially rendered into

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<sup>2</sup> Canada did not make BSE a reportable disease until November 1990, so it may be that the BSE-positive cow detected in Canada in December 2003 that had been imported from the U.K. was not the first BSE case in that country. AR002540, AR002560.

feed produced prior to Canada's ban on feeding rendered ruminants to other ruminants. *Id.* In contrast, none of the cattle the U.S. imported from the UK after 1980 came from a farm on which there was a case of BSE in animals from the same birth cohort, Harvard Study at AR001784, and the only BSE case detected in imported (or native) cattle in the U.S. came from Canada.

### **SUMMARY OF ARGUMENT**

The Final Rule is an exception to longstanding policy of the United States (and many other nations) not to allow importation of cattle or beef from countries, such as Canada, known to have cattle infected with BSE. USDA lacks a sound scientific basis for subjecting U.S. consumers to the risk of contracting vCJD from Canadian bovine meat and meat products and subjecting the U.S. cattle industry to the risk of BSE. USDA has failed to assess in a meaningful way both the human health risks and the risks to U.S. cattle and producers of the Final Rule and has failed to explain the criteria by which it determined those risks to be acceptable. In attempting to explain away the risks, USDA made critical assumptions that were inconsistent with scientific data before the agency and, in some cases, inconsistent with other USDA assumptions and conclusions. USDA failed to exercise the caution in protecting domestic animal and human health that its statutory mandates require, relaxing prior requirements and abandoning more-conservative positions without adequate justification.

USDA has failed to comply with the National Environmental Policy Act and the Regulatory Flexibility Act. Its environmental assessment largely followed its decisionmaking, rather than informing it as NEPA requires. And USDA virtually ignored the Regulatory Flexibility Act, declining to consider suggested provisions for the Final Rule that would mitigate

adverse economic effects on small businesses simply because those suggestions did not relate directly to animal health and may be implemented later.

BSE is a pernicious disease that is not completely understood. Nor is the prevalence of BSE in Canada. USDA is obliged to secure the health of U.S. cattle, the well-being of the domestic cattle industry, and the health of U.S. consumers by continuing the maximum level of protection against BSE that the U.S. has enjoyed until now, rather than presuming that a problem will not occur from resumption of Canadian imports. As the Commissioner of the Utah Dept. of Agriculture & Food admonished USDA: “The potential devastation to a rural America and to American producers is simply too large a risk....This particular risk can be managed; and should be managed in favor of American agriculture.” Exhibit 3 at AR000311.

## **ARGUMENT**

### **I. USDA’S ACTION WARRANTS THE COURT’S CAREFUL, CRITICAL REVIEW**

When reviewing an agency action such as the Final Rule under the Administrative Procedure Act (“APA”), the Court must “hold unlawful and set aside agency actions, findings, and conclusions found to be – (A) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law....” 5 U.S.C. § 706(2). An agency action is arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law when it fails to apply criteria for its action contained in relevant statutes, applies criteria for its decision not authorized by its statutory authority, fails to consider relevant information, fails adequately to explain the basis for its action or to respond to important public comments, acts inconsistent with the purpose and intent of the statutes granting it authority, or offers an explanation for its action counter to the evidence before it. *See, e.g., Motor Vehicle Mfrs. Ass’n v. State Farm Mutual*, 463 U.S. 29, 43 (1983).

In considering whether an agency acted in an arbitrary and capricious manner, a court must “carefully review the record to ‘ensure that agency decisions are founded on a reasoned evaluation of the relevant factors,’” *Ariz. Cattle Growers' Ass'n v. United States Fish & Wildlife Service*, 273 F.3d 1229, 1236 (9th Cir. 2001) (quoting *Marsh v. Or. Natural Res. Council*, 490 U.S. 360, 378 (1989)). Courts should not “‘rubber-stamp . . . administrative decisions that they deem inconsistent with a statutory mandate or that frustrate the congressional policy underlying a statute,’” *id.* (quoting *NLRB v. Brown*, 380 U.S. 278, 291-92 (1965)).

Judicial review begins with a presumption against the relaxation of safety standards. *See Motor Vehicle Mfrs. Ass'n v. State Farm Mutual*, 463 U.S. 29, 42 (1983) (reviewing relaxation of passive restraint requirements in cars); *accord, Int'l Brotherhood of Teamsters v. United States*, 735 F.2d 1525, 1531 (D.C. Cir. 1984). Moreover, where, as here, an agency provides no data to support its assumptions and its conclusions, its decision is not entitled to deference. *Ober v. Whitman*, 243 F.3d 1190, 1195 (9<sup>th</sup> Cir. 2001). Where increased risk to human health is at issue, as it clearly is with respect to USDA's decisions concerning imports from a country known to have BSE, it is particularly critical that USDA be required to provide not only its conclusion that its action carries an acceptable risk to public health, but also the specific basis for that conclusion and the data on which each of the agency's critical assumptions is based. *See Harlan Land Co. v. U.S. Dept. of Agriculture*, 186 F. Supp. 2d 1076, 1094-95 (E.D. Calif. 2001).

USDA had a special obligation here to explain why it chose to abandon its prior decision to ban imports of cattle and bovine products from Canada once BSE was discovered there, which reflected USDA policy since 1989 of excluding ruminants and ruminant products from countries where BSE is known to exist (70 Fed. Reg. at 462). *See Nat'l Conservative Political Action Comm. v. FEC*, 626 F.2d 953, 959 (D.C. Cir. 1980); *Greater Boston Television Corp. v. FCC*,

444 F.2d 841, 852 (D.C. Cir. 1970), *cert. denied* 403 U.S. 923 (1971). USDA's pre-existing policy was not some quickly considered, interim decision. Prior to issuance of the Proposed Rule, USDA had for many years asserted that the ban on imports of cattle and beef products from countries where BSE is known to exist was one of three key elements of the policy that has kept the United States BSE-free. *See, e.g.*, Federal Inter-agency Working Group, Final Report, January 2003, Animal Disease Risk Assessment, Prevention, and Control Act of 2001 (P. L. 107-9), see AR001510-11; see also Exhibit 4 at 2. Even now, USDA recognizes that Canada's ban on imports of live animals from countries with BSE is one of the key measures that has reduced Canada's BSE risk level. 70 Fed. Reg. at 18,254.

USDA's Office of Inspector General ("OIG") recently completed a report, "Animal and Plant Health Inspection Service Oversight of the Importation of Beef Products from Canada," ("Audit Report") (Exhibit 1 to Reply Memorandum in Support of Preliminary Injunction ("Reply Memo")), describing the OIG's audit of USDA's oversight of the importation of beef products from Canada after the May 2003 detection of BSE in a native Canadian cow.<sup>3</sup> This report indicates numerous cases where USDA expanded imports from Canada based on a desire to respond to industry requests to expand trade, rather than on scientific determinations that the products presented minimal risk. For instance, the Audit Report explains that in October 2003 USDA listed certain edible bovine products as part of a chart of eligible "low-risk" Canadian product, without explaining why these products were considered to be low-risk, especially when

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<sup>3</sup> The Court can and should take judicial notice of this official document. *See, e.g., Blair v. City of Pomona*, 223 F.3d 1074 (2000) (taking judicial notice of Christopher Commission report on police misconduct in Los Angeles); *Barron v. Reich*, 13 F.3d 1370, 1377 (9th Cir. 1994) (report of an administrative body is clearly something court can take judicial notice of); *Military Toxics Project v. EPA*, 146 F.3d 948, 954 (D.C. Cir. 1988) (taking notice of a "policy document from the EPA and two reports from the General Accounting Office" appended to brief that were "not part of the administrative record.").

the APHIS Transmissible Spongiform Encephalopathy (TSE) Working Group had concluded that some of the products, e.g. bovine tongues and bone-in beef, were “moderate risk.” *See* Audit Report at 10-12.

The Audit Report shows that USDA officials desired to satisfy “industry concerns that permit policies were too restrictive for trade” instead of using careful, reasoned scientific judgments to conclude that certain products presented minimal risks. *See id.* at 7-8, 10; *see also id.* at 12 (APHIS clandestinely allowed imports of bone-in beef beginning November 25, 2003, but “did not ... provide any documentation to explain why these products were considered low-risk”). USDA did not take the issue seriously even after this Court issued a temporary restraining order on April 26, 2004, continuing for months to authorize imports of prohibited products that had previously been classified as higher risk and to issue or maintain permits that should have been cancelled. *See id.* at 10, 23.

This Audit Report, showing both improper procedures and apparent disregard for conclusions of the agency’s own experts on the risk of BSE, demonstrates that the presumption of deference to agency action need not be applied to USDA decisions concerning imports from Canada. *Gifford Pinchot Task Force v. U.S. Fish and Wildlife Service*, 378 F.3d 1059 (9th Cir. 2004) (improprieties in process overcame presumption that administrative record was complete); *Ariz. Cattle Growers’ Ass’n*, 273 F.3d at 1236 (court need not rubber-stamp agency action inconsistent with statutory mandate and congressional policy).

This conclusion is reinforced by comparing the conclusions of APHIS’ own TSE Working Group to statements by top USDA officials in connection with resuming imports of certain Canadian products. In August 2003, when announcing that imports of certain products, including boneless beef from cattle under 30 months of age, would be allowed, the Secretary of

Agriculture described those products as “extremely low” risk and said that resumption of imports of these products was based on a thorough review by USDA experts. Transcript of Aug. 8, 2003 USDA Media Briefing, Exhibit 5 to PI Memo, Attachment J at 1-2. In fact, the APHIS TSE Working Group, the group of USDA experts tasked with assessing BSE risks and mitigation measures, concluded that boneless cuts of meat were only “low risk” if from animals under 24 months of age, *and* if other mitigation measures had been implemented. *See* APHIS TSE Working Group Memorandum to Deputy Administrator Ron DeHaven (June 16, 2003), AR009392A (Exhibit 5 to this Memorandum), at AR009392F, AR009392I; *cf.* Exhibit 6.

Just as significantly, the TSE Working Group stated that, even for “low risk” products, “[s]ignificant trade in the commodities currently prohibited because of BSE should not resume unless and until” seven criteria were met.<sup>4</sup> Most of those criteria had not been met when USDA reopened trade in Canadian beef products two months later and in fact have still not been met.<sup>5</sup>

Thus, USDA moved forward to reopen trade in a broad range of commodities, to satisfy the interests of some segments of the beef industry, claiming that these products were “low risk” and that allowing imports of these products from Canada was justified because of the opinion of USDA experts that this resumption was safe, when in fact USDA’s action was directly contrary to the conclusions of its BSE risk mitigation experts. This history on the Canadian BSE issue

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<sup>4</sup> AR009392C. It also concluded: “If additional BSE cases are identified in Canada additional steps will be necessary.” More BSE cases were found; additional steps were not implemented.

<sup>5</sup> *See* AR009392C, AR009392F. *E.g.*, requirement to remove brain and spinal cord prior to processing cattle under 24 months of age (FSIS rule only requires removal at 30 months and older, 69 Fed. Reg. 1862 (Jan. 12, 2004)); requirement of “elimination of the U.S. plate waste exemption,” which allows waste from poultry feeding, which can include ruminant protein, to be used in feeding ruminants (*see* Exhibit 1 at 2, Exhibit 4 at 3).

deprives USDA of any claim it may have had that the Court should defer now to USDA's public pronouncements about the safety of the Final Rule.<sup>6</sup>

## **II. USDA'S ACTION WAS ARBITRARY, CAPRICIOUS, AND AN ABUSE OF DISCRETION.**

### **A. USDA failed adequately to assess the impact of its action on human health.**

The Animal Health Protection Act directs the Secretary of USDA to protect the health and welfare of the people of the United States. 7 U.S.C. § 8301(5)(B)(iii); *see also* 7 U.S.C. § 8301(1)(B). USDA also has an obligation under the Federal Meat Inspection Act, 21 U.S.C. § 602, to “ensure a high level” of safety in meat products. *United States v. Mullens*, 583 F.2d 134, 139 (5th Cir. 1978). The Final Rule provides no assurance that the risk to human health is minimized, and USDA has not explained the criteria and basis for its conclusion that the increased risk presented by imports of Canadian cattle and beef is acceptable. Its failure to do so renders its action arbitrary and capricious. *See Harlan Land Co. v. USDA*, 186 F. Supp. 2d at 1085-87 (APHIS failed to define “negligible risk” in allowing citrus imports).

None of the documents USDA relied upon for the Final Rule contains an adequate assessment of the impact on human health of importation of Canadian beef. *See* Declaration of Louis Anthony Cox, Jr., Exhibit 7 to PI Memo (“Cox Declaration I”) at 3-5, 7-12; *see also* Exhibit 5 to PI Memo Attachment E Exh. B. Rather than perform a quantitative assessment of the risks of various options, USDA made assumptions and qualitative judgments. USDA's risk assessment assumed that the prevalence of BSE in the Canadian herd is “very low,” without any

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<sup>6</sup> Similarly, *cf.* an October 2, 2003 “Decision Memorandum for the Administrator” of APHIS, AR010514 (Exhibit 7 to this Memorandum) *with* a similar memorandum dated October 21, 2003, AR010546 (Exhibit 8), where the Administrator of APHIS reversed himself and chose a much higher-risk option, where the only major difference in the pros and cons of the options stated in the two memoranda is that the later Decision Memorandum indicates that the National Food Processors Association and other industry groups wanted the higher-risk option.

apparent support in the administrative record. *See, e.g.*, Cox Declaration I at 5-6. It relied on numerous assumptions for which it failed to demonstrate justification. *Id.* at 7-8. Neither the Harvard risk assessment nor USDA's Risk Analysis contained an assessment of the risk of vCJD from consuming Canadian beef, other than subjective conclusions it will be "low" or "very low." *Id.* at 4, 7-12. Indeed, APHIS stated in the preamble to the Final Rule that it "has set no specific thresholds for an acceptable number of cases in humans or animals." 70 Fed. Reg. at 473.

APHIS' own TSE working group concluded 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. Exhibit 5 at 1 (AR009392A). Canada has not yet conducted the kind of testing necessary to determine the prevalence of BSE in the Canadian herd, nor in potential "hot spots" in Canada. Cox Declaration I at 6-7; Exhibit 2 at 22-24.

Presented with USDA's conclusions that the risks to U.S. cattle and consumers are "low," without any definition of what that means and why the risks presented by the Final Rule are acceptable, members of the public and this Court have no way of assessing the merits of USDA's action. Would the Final Rule be reasonable if it resulted in one additional case of BSE in the United States? Ten additional cases? Would the perceived benefits of the Final Rule outweigh a probability of causing one more death from vCJD in this country? Ten more deaths?

APHIS' action in this case is remarkably similar to its action in another reported case, *Harlan Land Co. v. USDA*, 186 F. Supp. 2d 1076, 1087. (E.D. Calif. 2001) There, although APHIS had prepared a "risk assessment" and had supplemented it before issuing a final rule, APHIS persisted in applying an undefined standard of "negligible risk," despite public comments (like those of R-CALF on the subject rule) that this concept was undefined and impossible to determine. *Cf. id.* at 1085-86 with PI Memo Exh. 5 Attach. E. Here, APHIS applied the same

arbitrary approach to a decision that subjects the entire U.S. beef industry to potentially terrible damage and that presents a real, although unquantified, risk of death for U.S. consumers.

USDA's failure to conduct a proper risk assessment and its failure to articulate any standards by which it has judged the risks of these severe outcomes to be acceptable—especially where increased risk to human health is at issue--renders its action arbitrary and capricious and unsupported by the record. *Id.* at 1084, 1094-95.

**B. USDA's assumption that the BSE incidence in Canada is very low was unsupported and is demonstrably wrong.**

USDA variously characterizes the incidence of BSE in the Canadian herd as "minimal," "low," or "very low." Unfortunately, this is little more than wishful thinking. Canada has not conducted sufficient testing for BSE to assess accurately the rate of BSE infection in Canada. Cox Declaration I at 6-7; Cox Declaration III at 22-24; see also OIE guidelines, AR010064. To date, Canada has tested on the order of 40,000 head of cattle in the past decade, and almost exclusively cattle with outward signs of possible BSE. *See* 70 Fed. Reg. at 476. In the past year and a half, four cases of BSE have been identified in cattle born and raised in Canada. 70 Fed. Reg. 18,252, 18,258 (April 8, 2005) (Exhibit 9). In contrast, the U.S. has tested over 300,000 native cattle considered at risk of BSE just in the past year and has never found a single case. *See* 70 Fed. Reg. at 476; APHIS, [http://www.aphis.usda.gov/lpa/issues/bse\\_testing/test\\_results.html](http://www.aphis.usda.gov/lpa/issues/bse_testing/test_results.html).

The discovery, in a relatively short time, of four animals raised in Alberta province stricken with BSE is inconsistent with USDA's assertion that the BSE incidence rate in Canada is "very low" or "minimal." Cox Declaration I at 5-6. If the testing so far has been representative of the Canadian herd, Canada could have a BSE prevalence on the order of 6.25 cases per million

head of cattle.<sup>7</sup> Cox Declaration III at 23-24. If, once the ban on Canadian cattle imports is lifted by the Final Rule, Canada ships about 1.7 million head of cattle a year to the U.S., as it did in 2002 before the discovery of BSE in Canada, then it is a virtual certainty that Canadian cattle infected with BSE will be imported into the U.S. if the prevalence is as high as 6.25 per million head. *Id.* at 24. On the other hand, the BSE prevalence would have to be more than two orders of magnitude less (0.03 infected animals per million head) to keep the probability of importing BSE-infected cattle below 5% per year.

When a second Canadian-raised cow was found with BSE in Washington State, APHIS claimed that this discovery would not affect its risk analysis. 69 Fed. Reg. at 10,636; PI Memo Exh. 5 Attach. B at 1. Dr. Cox, an expert in statistics and risk analysis, tells us what would for most people be intuitive: saying that a second observed event in a relatively short period of time doesn't affect the risk analysis violates principles of sound statistics and risk assessment. PI Memo Exh. 5 Attach. E Exh. B at 12. Now, there have been two additional cases of BSE found in Canadian cattle, and USDA announced that those discoveries do not affect its risk assessment literally within hours of the Canadian government's announcement of the positive test results. *See* PI Memo Exh. B Attachs. L-M. In other words, APHIS will not abandon its assumption that the incidence of BSE in the Canadian herd is minimal, regardless of what testing shows. Again, Dr. Cox tells us what should be obvious: USDA's assumption that the incidence of BSE in Canada is minimal or very low is inconsistent with discovering BSE in four animals from Alberta

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<sup>7</sup> The BSE incidence rate reported by the OIE does not reflect the true prevalence of BSE in a country and is not therefore useful for risk assessment purposes. The OIE reports number of cases of BSE found per year per million head of cattle, which is greatly influenced by how many animals are tested annually. (If relatively few are tested, the OIE-reported incidence rate may be very low or zero, despite considerable BSE infection in the herd.) Cox Declaration III at 22-23. In contrast to other countries with BSE, Canada tests only a very small subset of its herd. *See* Exhibit 10 to this Memorandum.

in a relatively short time, and “[i]t is not credible that the magnitude of the risk does not depend on how large a portion of Canadian cattle are discovered to have BSE.” Cox Declaration I at 7-8.

Despite the initial bravado of USDA officials in the face of two more discoveries of BSE in Canada just before and just after publication of the Final Rule, just a month later USDA concluded that these discoveries did warrant reconsideration of the risk of importing BSE-infected products from Canada, suspending the portion of the rule related to the highest-risk products, those from animals 30 months of age and older at slaughter. This confirms just what R-CALF’s experts, USDA’s own experts, and other commenters have been saying: not enough is known about the prevalence of BSE in Canada to determine whether the risk of resuming imports is acceptable. If it were, there would have been no need to suspend a portion of the Final Rule.<sup>8</sup>

USDA’s claims, without sufficient data, that the incidence of BSE in Canada is very low, that accepting cattle and meat from Canada therefore carries essentially no incremental risk, and that additional cases of BSE do not affect its assessment of the BSE risks associated with resuming imports of cattle and beef products from Canada are simply inconsistent with the facts. For that reason, R-CALF USA is likely to succeed on its claim that the Final Rule is arbitrary and capricious. *See, e.g., Ariz. Cattle*, 273 F.3d at 1236 (court should not credit agency “conclusions

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<sup>8</sup> USDA’s flip-flops on the OTM issue demonstrate the arbitrary nature of USDA’s qualitative conclusion that the risk from the Final Rule is minimal. USDA first proposed to exclude beef from cattle that were 30 months of age or older when slaughtered in Canada, indicating that this would minimize the risk of infectious levels of BSE and is accepted internationally by various countries. 68 Fed. Reg. 62391, 62394. In fact, this was considered so important that USDA proposed to allow imports only if the cattle were slaughtered in a separate establishment or otherwise avoided contamination or co-mingling with meat from OTM cattle. Four months later, USDA published a statement that it now believed--despite the discovery of an additional BSE-infected cow of Canadian origin and without having conducted a new risk assessment--that imports of beef from OTM cattle should be allowed, as it was in the Final Rule. 69 Fed. Reg. at 10635. USDA indicated that additional discoveries of BSE in Canada would not change its position, 70 Fed. Reg. at 514, but shortly after publication of the Final Rule, it suspended imports of beef from OTM cattle to reconsider the risk in light of two additional cases of BSE in Canada.

that do not have a basis in fact”); *Blue Mountains Biodiversity Project v. Blackwood*, 161 F.3d 1208, 1211 (9th Cir. 1998) (court need not forgive a clear error of judgment).<sup>9</sup>

### **C. USDA’s near-total reliance on the Canadian feed ban was unjustified.**

Transmission of BSE can occur when cattle consume feed or supplements that contain bovine protein, typically meat and bone meal. While this is believed to have been the primary route of BSE transmission in the past, there is no conclusive scientific proof that it is the only route, and it is unknown what other routes of transmission may be available. *See, e.g.*, Cox Declaration I at 8.

Experts do agree that the most important means of preventing the spread of BSE in cattle is limitations on cattle feed, so that healthy animals are not exposed to BSE prions through feed that contains protein from animals infected with BSE. The U.S. adopted a ban on certain animal proteins in cattle feed in 1997, and Canada adopted a similar restriction in August of 1997 (the “Canadian feed ban”). USDA relies on the Canadian feed ban for its conclusion that BSE is unlikely to be spreading in the Canadian herd, and it relies on the similar feed ban in the U.S. for its conclusion that, if BSE-infected cattle are imported from Canada, there is virtually no risk that those cattle will transmit BSE to domestic cattle. In fact, USDA says the feed ban is a “crucial element” in preventing the spread of BSE. 70 Fed. Reg. at 467.

The O.I.E. specifies that, to be considered a region with minimal risk of BSE, a country must have had in place and been enforcing a ban on feeding of ruminant protein to ruminants for

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<sup>9</sup> USDA’s risk assessment also did not address the possibility of heterogeneity or a BSE “hot Spot” in Canada, although this could significantly increase the risk of introducing BSE to the United States. Cf. Cox Declaration III at 15-18 with 70 Fed. Reg. at 509. USDA now believes there is a hot spot in Alberta. Exhibit 11 at 25; Transcript of Preliminary Injunction Hearing, March 2, 2005, at 57, 85. When an agency’s rationale for its actions is clearly inconsistent with the facts, the action is arbitrary and capricious. *Motor Vehicle Mfrs. Ass’n*, 463 U.S. at 43 (1983).

at least eight years. 70 Fed. Reg. at 470. USDA rejected those international guidelines because the 8-year time period “may be conservative,” asserting that the incubation period for BSE infection in cattle is generally less than 7 years. *Id.* USDA then concluded that, since Canada’s feed ban has been in place for a little over 7 years, it provides assurance that BSE is not spreading in the Canadian herd. *Id.* USDA attempted to convince the O.I.E. to adopt its view of the appropriate duration of an effective feed ban in order to be considered a minimal risk country, but the O.I.E. was not convinced. 70 Fed. Reg. at 474. USDA’s rejection of international standards because they “may be conservative,” and its substitution of a criterion that the feed ban must have been in place for approximately the same length of time as the maximum expected incubation of BSE (i.e., virtually no safety factor) is itself arbitrary and capricious and inconsistent with USDA’s responsibility to protect American cattle and consumers.

Beyond that, though, USDA’s suggestion that the Canadian feed ban has actually been *effective* for over seven years is inconsistent with the facts. In attempting to explain away the discovery of an additional case of BSE in Canada in a cow born after the Canadian feed ban was in place, USDA claimed that this event did not undercut its confidence in the effectiveness in the Canadian feed ban, because the cow probably was exposed to feed that had been manufactured prior to the Canadian feed ban, which did not require that stocks of such feed be disposed of. Thus, by USDA’s own admission, Canada has had an *effective* feed ban for substantially less than even seven years. USDA’s assertion that the Canadian feed ban is effective and has been in place for a sufficient length of time, when in fact Canadian cattle apparently could have been fed ruminant protein much more recently than the seven years that the USDA is necessary, renders USDA’s conclusion, that the risk presented by the Final Rule is acceptable, arbitrary and capricious. *Motor Vehicle Mfrs. Ass’n*, 463 U.S. at 43. In fact, as recently as 2003 a Canadian

cow with BSE made its way into livestock feed distributed to around 1800 farms, with only 204 of those farms inspected, despite a finding that over 4 percent of the 204 inspections revealed “there was likely systematic or routine exposure to the suspect feed.” Exhibit 1 at 13-14.

Moreover, if USDA is correct that the mean incubation period for BSE infection in Canada is 4.2 years, then each of the four Canadian-origin cattle confirmed to have BSE certainly could have contracted the BSE infection after the effective date of the Canadian feed ban, since in each case more than 4.2 years had elapsed since implementation of the feed ban at the time the animal exhibited signs of and was tested to have BSE. *See* Cox Declaration I at 7. USDA’s assertion that the Canadian feed ban is effective and has been in place long enough to make the risk of additional cases of BSE insignificant is at odds with the facts and therefore arbitrary and capricious. *See, e.g., Ariz. Cattle Growers*, 273 F.3d at 1236.

USDA treats the Canadian and U.S. feed bans as virtually complete barriers to the further propagation of known cases of BSE infection in Canada and to infection of the U.S. herd if a BSE-infected Canadian cow enters the United States. USDA asserts that this reliance is reasonable because of the demonstrated effectiveness of the feed ban in other countries. 70 Fed. Reg. at 463. The facts belie that assertion, however. As Exhibit 12 shows, in the UK there have been tens of thousands of cattle found to have BSE that were born after the UK’s implementation of a feed ban similar to that in the United States and Canada. In fact, there have been hundreds of cases of BSE in cattle born five or more years after the UK feed ban. *Id.*; *see also* Exhibit 13 at 49, 56. “BSE cases continue to be diagnosed in other parts of the world in animals well past the implementation of feed bans.” Exhibit 14 at AR000388; *see also* Cox Declaration III at 4.

USDA’s “Analysis of Risk—Update for the Final Rule” states: “Cases of BSE found in animals born after the feed ban would suggest either that the feed ban was ineffective or that

there were noncompliance issues.” Id. at 9 (AR008327); see also AR009302. Thus, the UK and EU experience does not support USDA’s conclusion that a feed ban is effective in eliminating the risk of the spread of BSE, and the discovery this year of the Canadian cow born nearly eight months after the feed ban renders USDA’s assertion that the Canadian feed ban has been effective since August 1997 unsupported. An agency decision that is not, at a minimum, based on "reasonable extrapolations from some available evidence" is arbitrary and capricious. *Natural Resources Defense Council v. Thomas*, 805 F.2d 410, 432 (D.C. Cir. 1986).

Part of the reason that other countries have found many cases of BSE in cattle born long after enactment of the feed ban is that there is noncompliance with the feed ban and cross-contamination of feed with prohibited materials, either because equipment at the feed mill or transportation equipment is not sufficiently cleaned between types of feed, or because the feed intended for non-ruminants is mis-fed on the farm. See, e.g., AR012107-108. In its 2005 assessment of Canada’s feed ban, USDA indicates that, from 2002 through 2003, 5.8 percent of Canada’s feed mills were sufficiently non-compliant with Canada’s BSE rules to warrant regulatory sanctions. During 2004 through 2005, there remained 3.8 percent of Canada’s feed mills meeting this level of objectionable conditions or practices. Exhibit 1 at 37; see also 27. Many commenters with practical experience emphasized the difficulty of enforcing an effective feed ban.<sup>10</sup> The U.S. General Accounting Office also recently concluded that problems with

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<sup>10</sup> See, e.g., Exhibit 14 at AR000388 (“cross contamination and lack of farm level compliance represents a risk and was one of the reasons BSE was diagnosed in some other countries”), AR000389 (cross-contamination was source of BSE cases in Europe), AR000391 (noncompliance with Canadian feed ban at one of the suspected farms with BSE); Exhibit 15 at AR000371 (European Commission noting “experience within the EU has shown that implementation of a ruminant to ruminant feed ban is very difficult to achieve due to cross contamination or accidental feeding on farms with different species....” See also Exhibit 2 at 4-5; report of the Secretary’s International Review Team at AR008029-30.

oversight and enforcement of the feed ban “continue to limit the effectiveness of this critical BSE firewall and could place U.S. cattle at risk for BSE.” Exhibit 1 at 5.

USDA responds that there is a high level of compliance with the feed ban. But as Dr. Cox’s analysis shows, even relatively infrequent noncompliance can produce occasional cases of BSE transmission given the large number of animals and the potency of the BSE agent, contradicting USDA’s assumption of virtually no risk. Exhibit 2 at 4-7, 16-17; *cf.* Exhibit 4 at 8.

USDA’s reliance on both the U.S. and the Canadian feed bans to protect against the spread of BSE is also misplaced because those feed bans are incomplete. Both allow bovine blood to be used in cattle feed, 70 Fed. Reg. at 491, although USDA acknowledges the possible transmission of BSE through blood (*see, e.g.*, 70 Fed. Reg. at 502) and the need to eliminate mammalian blood from ruminant feed (AR010848). Another important loophole in the feed bans concerns poultry feed. Bovine protein can be used for poultry feed, and poultry waste in turn is used in animal feed, including potentially cattle feed. *See* PI Memo Exh. 5 App. F at 7-8. Canada already bans poultry wastes from ruminant feed. 70 Fed. Reg. at 467. Both USDA and the Food and Drug Administration (FDA) have recognized the need for new rulemaking to eliminate the exemption for mammalian blood and poultry litter and plate waste, but that has not happened.<sup>11</sup>

USDA treats the feed bans as an absolute “firewall” for BSE transmission. Yet USDA does not claim that there is no risk of BSE transmissions from these loopholes in the U.S. and

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<sup>11</sup> *See* 69 Fed. Reg. 42,288, 42,292-93 (July 14, 2004); 70 Fed. Reg. at 466, 504; “Explanatory Note—Risk Analysis” at 3-4 (AR008009-10). Similarly, USDA’s own International Review Team responding to the discovery of the BSE-infected cow in Washington State concluded that “...the partial ruminant to ruminant feed ban that is currently in place [in the U.S. and Canada] is insufficient to prevent exposure of cattle to the BSE agent” and recommended, among other things, a ban on poultry litter and plate waste in ruminant feed AR008029-30 (avoiding cross-contamination down to the tiny concentrations at which ruminant tissue can be effective is “virtually impossible to deliver”). USDA also has recognized a presumably small, but unknown, risk of transmission to offspring (i.e., bypassing the feed ban entirely). *See* 70 Fed. Reg. at 530.

Canadian feed bans, but instead pointed out that FDA, APHIS, and FSIS are considering what improvements are needed to the U.S. feed ban. 70 Fed. Reg. at 466, 504. USDA's decision to move ahead with the Final Rule, based on an assumption that the Canadian and U.S. feed bans are complete barriers without first having addressed this important potential route for the spread of BSE within the United States under the Final Rule, renders the Final Rule arbitrary, capricious, and an abuse of discretion.

**D. USDA arbitrarily assumed that SRM removal eliminates all risks despite scientific evidence to the contrary.**

Central to USDA's rationale for relaxing the ban on imports of Canadian cattle and beef is its assumption that removal from the carcass of certain materials where most of the BSE infectivity is believed to reside (SRMs) will effectively shield consumers from exposure to BSE. USDA has failed to respond adequately to comments demonstrating that current scientific knowledge calls that assumption into question. USDA's decision to rely on this questionable assumption, rather than take the cautious approach of assuming that there might still be exposure to the BSE infectious agent even if there are regulations requiring SRM removal, was inconsistent with the congressional intent evidenced in the Animal Health Protection Act, 7 U.S.C. §§ 8301 *et seq.* and the Meat Inspection Act, 21 U.S.C. §§ 601 *et seq.*

As modified March 11, 2005, the Final Rule only requires removal of the small intestine and tonsils of Canadian cattle imported pursuant to the Final Rule or slaughtered in Canada and exported to the U.S. under the Final Rule (CNS tissue such as the brain and spinal column are not included within the definition of "SRMs" for cattle under 30 months of age). 70 Fed. Reg. at 461. Despite the fact that numerous cattle under 30 months of age have been found to have BSE in the UK, Europe, and Japan, as discussed in the following section, and four cases of BSE have been found in Canada in the last two years with very limited testing, the Final Rule would allow the

brain of 29-month-old Canadian cattle to be used in food. USDA has not attempted to quantify the risk to human health from that scenario, but it definitely is not zero. USDA's actions with respect to SRM removal are inconsistent with the facts and did not protect public health.<sup>12</sup>

R-CALF USA submitted extensive comments, including copies of numerous reports on the latest scientific research on the occurrence and transmission of BSE and related prions, which indicate that it is no longer reasonable to presume that there is no risk of exposure to BSE infectious agents beyond the tissues defined as SRMs. PI Memo Exh. 5 Attachs. E, F, and G. Some of those studies are summarized succinctly in Dr. Cox's Declaration I at 8-9. The Centers for Disease Control has acknowledged that the risk of humans getting vCJD from eating muscles cuts from potentially BSE-infected cattle "cannot be precisely determined." Cox Declaration III at 11. USDA's failure to explain clearly why these concerns do not undercut its almost-exclusive reliance on SRM removal requirements for the protection of public health from Canadian imports violated the Administrative Procedure Act.

**E. USDA's assumption that Canadian cattle under 30 months of age will be free of BSE was arbitrary and capricious.**

The Final Rule, as modified on March 11, does not allow imports of Canadian cattle 30 months of age or older ("OTM [over thirty months] cattle") nor beef from such cattle slaughtered in Canada. The 30-month restriction was based on USDA's assessment that products from these younger cattle would have the lowest risk of exposing consumers to BSE. 70 Fed. Reg. at 483; 68 Fed. Reg. at 62,390-91. USDA's March 11, 2005 suspension of the portion of the rule allowing imports of OTM cattle was also presumably based on an assumption that the younger

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<sup>12</sup> BSE infectivity has been found in bovine tonsils, which are required to be removed under the Final Rule, but may also travel to the tongue. AR001650. Nor has USDA seriously evaluated contamination of the tongue with tonsil material while slaughtering under 30-month cattle.

cattle have a low risk of carrying BSE infectivity that could affect the U.S. herd. The 30-month restriction was based on the assumption that younger animals, born after Canada enacted its feed ban, would not have been exposed to BSE. As explained above, while the feed ban reduces the likelihood of BSE exposure substantially, it does not eliminate it, and based on experience in other countries and, recently, in Canada, even cattle born five years or more after Canada enacted its feed ban still may be exposed to the BSE prions circulating in Canada.

The 30-month restriction is also based on the assumption that, since recognizable symptoms of BSE generally occur in cattle older than 30 months, levels of BSE contamination would be low even in infected cattle if the cattle were slaughtered at under 30 months of age. *See, e.g.*, 68 Fed. Reg. at 62,390-91; 70 Fed. Reg. at 513, 514. USDA admits there have been numerous cases of animals under 30 months of age showing outward signs of BSE, but it claims those are exceptions, in which high levels of infectivity in the UK in the early 1990s resulted in some animals receiving high doses, resulting in reduced incubation time. 70 Fed. Reg. at 512.

This assumption is wrong in several ways, though. First, evidence in the Administrative Record indicates that:

Incubation periods for TSEs are much more variable for oral exposure with a fixed dose than for intracerebral inoculation. It is also likely that the majority of cattle in the UK epidemic were exposed to low dose levels. There is an absence of knowledge in the low dose range. But low dose exposure is likely to have a greater effect on the risk of infection than on the mean incubation period.

BSE, Prince, Rev. Sci. Tech. Off. Int. Epiz., 2003 at AR012102. Secondly, in 2003 Japan detected two cases of BSE in cattle that were less than 30 months old, one at 23 months of age and the other at 21 months of age. Notwithstanding USDA's claim that younger cases were only likely to be present in countries "with significant levels of circulating infectivity" (70 Fed. Reg.

at 512), these younger cases in Japan were detected after Japan had tested 3,159,408 cattle, of which only 11 diagnosed cases of BSE had been detected. Final Report, Japan - United States BSE Working Group, July 22, 2004 at 2 (AR001619).

Moreover, even in sub-clinical stages of BSE (without outward signs), the BSE infective agent still resides in the animal (USDA assumes most cases are infected at an early age), and USDA recently agreed with experts from Japan that the significance of such lower levels of BSE for health of consumers is “unclear.” *Id.* at 4 (AR001621). The international panel convened by the Secretary of Agriculture to evaluate U.S. BSE safeguards also acknowledged this, in recommending that the U.S. should remove the brain, spinal column, etc. from all cattle 12 months of age or older: “A cutoff of 12 months represents a recognition of the fact that some cattle under 30 months of age may be slaughtered with infectivity present.” AR008026.

By indulging in assumptions that are contrary to the facts before it, and by treating the 30-month restriction like a complete barrier rather than just a step that reduces the risk, USDA has acted arbitrarily and capriciously.

**F. USDA failed to respond adequately to comments suggesting mandatory BSE testing of Canadian cattle.**

R-CALF USA and others commented to USDA that requiring that Canadian cattle slaughtered in the U.S. or in Canada for export to the U.S. be tested for BSE could help mitigate the risks and adverse effects of the Proposed Rule. USDA acknowledged that the standard BSE screening test can identify BSE infection months before the animal has outward signs of BSE.<sup>13</sup> USDA rejected mandatory testing because it cannot detect BSE infection until the disease has

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<sup>13</sup> 70 Fed. Reg. at 475. In fact, the Canadian-raised cow found to have BSE in Washington State would never have been tested for BSE if it had been screened for symptoms of BSE only. *See* PI Memo Exh. 5, at 8 and Attachment N.

progressed fairly far. 70 Fed. Reg. at 475. But the fact that it cannot detect some cases of BSE does not mean testing has no value, since it would detect some BSE cases that would otherwise go undetected. Dr. Stanley Pruisner, who won the Nobel Prize for discovering prions, pointed out recently that neither of the under 30 month old cattle found with BSE in Japan would have been identified without Japan's policy of testing all animals at slaughter, as "[n]either animal showed outward signs of neurological dysfunction." Exhibit 16 at AR012125.<sup>14</sup> USDA's failure to give careful consideration to the benefits (and costs) of mandatory testing, or at least its failure to explain to the public why these benefits do not justify mandatory testing, in the face of such severe consequences from any case of BSE that is missed, was arbitrary and capricious and in violation of the Administrative Procedure Act.

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

The National Environmental Policy Act of 1969 ("NEPA"), 42 U.S.C. §§ 4321 *et seq.*, requires that federal agencies, such as USDA, prepare an Environmental Impact Statement ("EIS") for any major federal action significantly affecting the quality of the human environment. 42 U.S.C. § 4332(C). Council on Environmental Quality and USDA implementing regulations also provide for the preparation of an "environmental assessment" to support a finding that the proposed action will not have a significant impact on the environment, and therefore, will not be the subject of an EIS. *See, e.g.*, 40 C.F.R. § 1501.3 and 7 C.F.R. pt. 372.

USDA prepared an environmental assessment in connection with the Proposed Rule, dated October 2003. Because circumstances subsequently changed, including relaxations in

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<sup>14</sup> *See also* EU "Report on the assessment of the Geographical BSE-risk of Canada" at 5 (AR011790), concluding that data from Switzerland and the UK indicate that it is likely that testing only "symptomatic BSE-suspects, will not detect more than half or one third of all clinical cases, or even fewer."

some of the protections in the Proposed Rule, USDA revised its environmental assessment in December 2004, almost doubling its length. *See* 70 Fed. Reg. at 554. This “Final Environmental Assessment” (“FEA”) was not made available to the public for review and comment, however, until after the final rule had been signed (See 70 Fed. Reg. at 543) and then was modified again, extending the comment period to February 17, 2005. 70 Fed. Reg. 3183 (January 21, 2005). Finally, three months after publication of the Final Rule, USDA published a new Finding of No Significant Impact, evaluating for the first time some environmental impacts, including those raised by R-CALF USA in this case, and “affirmed” the provisions of the Final Rule. 70 Fed. Reg. 18,252, 18,258 (April 8, 2005).

NEPA is intended to assure that environmental impacts may be considered as policy is developed, not after a final regulation is issued. Accordingly, an environmental assessment that is prepared after the agency has already committed to a course of action does not satisfy NEPA. *Save the Yaak v. Block*, 840 F.2d 714, 718 (9<sup>th</sup> Cir. 1988). In those circumstances, the Court should remand the FONSI to the agency and instruct it to prepare a new environmental assessment. *Metcalf v. Daley*, 214 F.3d 1135, 1143-45 (9<sup>th</sup> Cir. 2000).

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

The Regulatory Flexibility Act (“RFA”) requires an agency to carefully consider the economic impact a rule will have on small entities by conducting a final regulatory flexibility analysis. This analysis must include a description of the steps the agency has taken to minimize the economic impact on small entities and a statement of why each of the other significant alternatives to the rule considered by the agency which affect the impact on small entities was rejected. 5 U.S.C. § 604(a)(5). “Section 604 does not command an agency to take specific substantive measures, but, rather, only to give explicit consideration to less onerous options....”

*Associated Fisheries, Inc. v. Daley*, 127 F.3d 104, 114 (1<sup>st</sup> Cir. 1997). A court should determine whether an agency made “a reasonable, good-faith effort to canvass major options and weigh their probable effect.” *Associated Fisheries*, 127 F.3d at 114.

USDA admits that the Final Rule will primarily and disproportionately affect small businesses. 70 Fed. Reg. at 525, 543. It estimates that the Final Rule, as amended, will cost U.S. cow/calf producers over \$500 million per year, and that is even assuming that it will not have a significant impact on export markets or on domestic demand.<sup>15</sup> 70 Fed. Reg. at 541-42. USDA failed to comply with the requirements of the RFA because it did not make a reasonable effort to evaluate significant options that would have mitigated this severe impact on small businesses.

USDA did not consider the mitigation of adverse economic effects of the Final Rule on small businesses that could have been achieved through a requirement that edible bovine products derived from Canadian cattle or imported from Canada be labeled so that consumers could choose not to purchase those products.<sup>16</sup> 70 Fed. Reg. at 543. In fact, USDA apparently

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<sup>15</sup> Dr. VanSickle’s expert opinion is that the discovery of additional cases of BSE after Canadian cattle and beef had been co-mingled with U.S. cattle and meat supply would “severely cripple the cattle and ranching industry with lower returns that would be difficult to recover.” VanSickle Declaration [1], Exhibit 6 to PI memo at 7. *See also* Fox, *et al.*, “Risks and Implications of Bovine Spongiform Encephalopathy for the United States: Insights from other Countries,” 29 *Food Policy* at 45 (2004) (Exhibit 13 to this Memorandum) (“A single case of BSE would have serious consequences for the US beef industry.” AR001565). USDA’s unsupported assertions to the contrary are inconsistent with both logic and experience. *See id.* at 52, AR001570 (after BSE was found in European cattle, “[t]he market reaction was instant and dramatic. Beef consumption fell by about 30%, and exports by the EU to non-EU countries . . . were halted.”); 54, AR001572 (after discovery of BSE in cattle in Japan, beef consumption fell 40 to 50%, with wholesale prices 30 to 60% below normal). *See also* Ex. 14 at 1.

<sup>16</sup> USDA did respond to comments expressing concern about the impact of importing Canadian beef without labeling, but it did so not by considering potential mitigation of economic impacts on small businesses but by simply stating that it “does not consider it necessary to delay implementation” of the Final Rule until a statute mandating labeling on a wide range of products goes into effect a year and a half later. 70 Fed. Reg. at 533. This is not the “serious consideration” of alternatives that Congress intended. *See Associated Fisheries*, 127 F.3d at 114.

ignored its obligation under the RFA, rejecting even considering labeling as part of the Final Rule merely because it “does not address of food safety or animal health concerns.” *Id.* at 533.

Nor did USDA’s regulatory flexibility analysis assess the extent to which allowing slaughter facilities to voluntarily test cattle for BSE would mitigate the adverse effects on small businesses of diminished consumer confidence as a result of co-mingling of Canadian and U.S. meat supplies.<sup>17</sup> 70 Fed. Reg. at 543. Either of those options might have substantially mitigated the adverse economic effects of the Final Rule. VanSickle Declaration (Exhibit 17) ¶¶ 8, 9 and Attachment A; *see also* PI Memo Exh. 6 at 7-8. Because USDA did not make a good-faith effort to assess all significant options for mitigating the impact of the Final Rule on small entities, it failed to comply with the Regulatory Flexibility Act, and the Final Rule should be remanded to USDA pursuant to 5 U.S.C. § 611(a)(1), (4).

USDA’s assertion that the Final Rule the may have beneficial effects on U.S. exports, 70 Fed. Reg. at 541, and its consequent failure to assess the impact on small businesses associated with adverse effects on export markets, was speculative and directly contrary to evidence in the record. Japan ceased importing beef from the U.S. after a BSE-positive cow was found in Washington State; before that, Japan was willing to accept beef from the U.S. with verification that it was not of Canadian origin. 70 Fed. Reg. at 524. Numerous comments on the Proposed Rule emphasized the adverse effects it would have on exports. For example, a Japanese company that sells U.S. beef in Japan commented that beef from the U.S. herd would need to be “strictly separated from the beef from Canadian origin, because Japanese consumers do not accept the mixed of Canadian beef.” Exhibit 18 (AR000366); *see also* AR001130. Subsequent experience

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<sup>17</sup> Again, USDA responded to comments without considering the mitigation of economic impacts, other than to assert without any support that withholding approval of voluntary BSE testing would actually *increase* consumer confidence. 70 Fed. Reg. at 534.

with Taiwan and Egypt has confirmed the logical proposition that importing cattle and additional beef products from Canada, which is known to have a BSE problem, will complicate, rather than ease, concerns of our trading partners about BSE. VanSickle Declaration (Exhibit 17) at ¶ 8.

**V. THE COURT SHOULD ENJOIN ALL IMPORTS OF CANADIAN CATTLE AND BEEF PRODUCTS, AS CURRENT USDA REGULATIONS REQUIRE.**

As noted above, and as the Court is aware from the previous related case, shortly after issuing a rule on May 29, 2003 that added Canada to the list of countries where BSE is known to exist, which had the effect of prohibiting imports of live ruminants and most ruminant products, the Secretary of Agriculture announced that companies that had held permits for importation of beef from Canada would be allowed to import certain products, including boneless bovine meat from cattle under 30 months of age at the time of slaughter, boneless veal from calves under 36 weeks, and fresh or frozen bovine liver. *See* Attachment J to Exhibit 5 to PI memo. This was done without a rulemaking. Subsequently, on a number of occasions, USDA expanded the list of “allowed” products, again without any notice-and-comment rulemaking. *See* Exhibit 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, Exhibit 1 to Reply Memo, 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, but were blanket statements that certain types of products would be “allowed.”<sup>18</sup> Nor, as explained above, does the record show that these actions were consistent with USDA’s experts’ view of acceptable conditions for imports from Canada. In fact, few of the steps that the APHIS TSE Working Group determined to be prerequisites to resuming imports have even now been implemented. 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.

The Audit Report documents that even after the Temporary Restraining Order was issued, APHIS continued to allow imports of unauthorized products from Canada, and around a billion pounds of boneless beef and other beef products (including ground and bone-in meat) have been imported from Canada since it became subject to USDA regulations that establish a general policy of prohibiting such imports. *Id.* at ii, 10. Far from acting on the careful, case-by-case basis contemplated by 9 C.F.R. § 93.40(a), APHIS has issued at least 1155 permits for importation of Canadian ruminant products, and “without ensuring that the agency had an appropriate system of internal controls to manage the process.” *Id.* at v. In light of this history, this Court should enjoin these unlawful departures from existing regulations and should require that USDA continue the prohibition on imports of Canadian cattle and edible bovine products required by the May 29, 2003 rule until USDA has completed a rulemaking to modify that rule.

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<sup>18</sup> According to the Audit Report, the permit system “was originally designed to allow for the import of research quantities (generally small amounts)” and was “not adequate to deal with the high volume of requests for large volumes of commercial use beef.” *Id.* at 21, 22.

## CONCLUSION

R-CALF USA has demonstrated the numerous procedural and substantive shortcomings of USDA's decision to allow importation of Canadian cattle and beef. The issuance of the Final Rule was arbitrary and capricious and an abuse of discretion. USDA also acted without complying with NEPA or the RFA. The Final Rule should be vacated and remanded to the agency, and the Court should reinstate USDA's May 29, 2003 rule that prohibits imports of Canadian cattle and beef, including vacating USDA's unauthorized wholesale exemptions from that rule for boneless beef and other products.

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Respectfully submitted,

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## CERTIFICATE OF SERVICE

I certify that on May 9, 2005, I served true and correct copies of Plaintiff's Motion for Summary Judgment and Memorandum in Support of Summary Judgment by first-class mail, postage prepaid on the following:

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