
IN THE UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

RANCHERS CATTLEMEN ACTION LEGAL FUND
UNITED STOCKGROWERS OF AMERICA,
Plaintiff-Appellee,

v.

UNITED STATES DEPARTMENT OF AGRICULTURE,
Animal and Plant Health Inspection Service; et al.,
Defendants-Appellants.

On Appeal from the United States District Court
for the District of Montana

BRIEF FOR APPELLANTS

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No. 05-35264

RANCHERS CATTLEMEN ACTION LEGAL FUND
UNITED STOCKGROWERS OF AMERICA,
Plaintiff-Appellee,

v.

UNITED STATES DEPARTMENT OF AGRICULTURE,
Animal and Plant Health Inspection Service; et al.,
Defendants-Appellants.

BRIEF FOR APPELLANTS

STATEMENT OF JURISDICTION

Plaintiff invoked the jurisdiction of the district court pursuant to 28 U.S.C. § 1331. On March 3, 2005, the district court entered a preliminary injunction barring the implementation of a United States Department of Agriculture (USDA) regulation. Excerpts of Record (ER) 108-137. A timely notice of appeal was filed on March 17, 2005. ER 413-415; Fed. R. App. P. 4(a)(1)(B). The order granting the preliminary injunction is appealable under 28 U.S.C. § 1292(a)(1).

STATEMENT OF THE ISSUES

1. Whether the district court erred in setting aside the determination of the Secretary of Agriculture, made on the basis of notice-and-comment rulemaking, that it is not necessary to ban Canadian cattle less than 30 months old and certain beef products to avoid dissemination in this country of Bovine spongiform

encephalopathy (BSE), commonly known as "mad cow disease."

2. Whether the court erred in holding that the rulemaking violated the Regulatory Flexibility Act.

3. Whether the court erred in holding that the rulemaking violated the National Environmental Policy Act.

4. Whether the court erred in concluding that an injunction was required to avoid dissemination of BSE on the basis of its decision to set aside the Secretary's contrary determination.

STATEMENT OF THE CASE

Bovine spongiform encephalopathy is a neurological disease in cattle, transmitted through animal feed containing protein from other infected animals. The disease was described and diagnosed for the first time in the United Kingdom in 1986. Based on the knowledge available at the time, the Secretary of Agriculture restricted imports from all countries in which BSE occurred, expanding the restrictions over time to include additional countries which were determined to present an undue risk of introducing BSE into the United States.

In January 2005, the Secretary for the first time adopted a comprehensive scheme for evaluating the risks posed by ruminants and ruminant products from nations in which BSE has occurred as well as cattle from nations in which it has not occurred to date. The new regulations drew on the scientific knowledge developed since BSE was first diagnosed as well as the standards and guidelines developed by international bodies with the

participation of the United States. The rule, promulgated after notice and comment, explained that the occurrence of BSE in another country would not, of itself, present an absolute bar to imports of ruminants and ruminant products. Instead, the risk would be assessed in light of the effectiveness of that nation's regulatory scheme as well as domestic safeguards ensuring against the introduction of the disease. Imports would be permitted only if the foreign nation had adopted crucial risk mitigation procedures. In particular, because BSE is transmitted by the recycling of infected animal tissue, a ban on ruminant protein in ruminant feed would be essential. In addition, the Secretary would consider whether the nation conducted effective surveillance to ensure compliance and detect possible outbreaks, and whether it had responded swiftly and effectively to diagnosed cases of BSE.

Applying these criteria, the Secretary concluded that restrictions on Canadian cattle under 30 months old, imported for purposes of slaughter, were not necessary to preclude dissemination of BSE in United States livestock. The Secretary noted Canada has had an effective feed ban in place since 1997, conducts surveillance far exceeding international standards, and responds rapidly and effectively to identified instances of BSE.

To further ensure against the possible dissemination of BSE, the Secretary permitted only importation of cattle under 30 months of age. Because BSE has an extended incubation period,

animals of this age would not have developed significant levels of infectivity in their tissues, even if exposed. Moreover, cases of BSE in very young cattle have been linked to extremely high doses of infectious material, and none has occurred in Canada. Because Canadian cattle under 30 months old would be born and reared long after the feed ban was in place, it is highly unlikely they would have been exposed to BSE at all, much less exposed at levels that would result in a case of BSE at 30 months of age. As the Secretary stressed, the isolated instances of BSE in Canadian cattle had been traced to cattle born before or near the time the feed ban was instituted, and none of the cows - each of which was six or seven years old - would have been subject to import under the new rule.

The Ranchers Cattlemen Action Legal Fund United Stockgrowers of America (R-CALF) filed suit to enjoin the rule before its effective date in March 2005. The district court granted a preliminary injunction barring implementation of the rule. The court held that R-CALF was likely to succeed on its claims that the rule violated the Administrative Procedure Act, the National Environmental Policy Act, and the Regulatory Flexibility Act and that the balance of harms favored injunctive relief.

This is an appeal from the preliminary injunction.

STATEMENT OF FACTS

I. BACKGROUND.

A. The Animal Health Protection Act.

The Animal Health Protection Act, 7 U.S.C. § 8301 et seq., provides that the Secretary of Agriculture “may prohibit or restrict . . . the importation or entry of any animal . . . if the Secretary determines that the prohibition or restriction is necessary to prevent the introduction into or dissemination within the United States of any pest or disease of livestock.” 7 U.S.C. § 8303(a)(1). The Animal and Plant Health Inspection Service (APHIS) is the agency within the Department of Agriculture that regulates the importation of animals and animal products to guard against the introduction of various animal diseases to the United States.

B. Bovine Spongiform Encephalopathy.

Bovine spongiform encephalopathy, commonly known as “mad cow disease,” is a progressive and fatal neurological disorder of cattle. See generally ER 109 (District Court Opinion (Op.) at 2); 70 Fed. Reg. 460, 461-62 (Jan. 4, 2005). BSE was first diagnosed in the United Kingdom (U.K.) in 1986, and over 95% of all BSE cases have occurred in the U.K., where the epidemic peaked in 1992 and 1993. Id. at 461-62.

Since the disease was first diagnosed, scientists have concluded that it is a member of the family of diseases known as

transmissible spongiform encephalopathies (TSE) and believe that the infectious agents in this family are prions, which are an abnormal form of normal cellular proteins. Id. at 461. With respect to BSE, this abnormality is spread from one cow to another not through normal forms of contact, but by one animal's ingestion of the infected protein of another animal. Ibid.; see also id. at 486 ("In cattle, oral ingestion of feed contaminated with the BSE is the only documented route of field transmission of the disease."). This disease spread as a result of the practice, once prevalent in the U.K., of including rendered ruminant products in cattle feed.

Human exposure to BSE through consumption of contaminated cattle products can cause variant Creutzfeldt-Jakob Disease (vCJD), a chronic and fatal neurodegenerative disease. Id. at 462. In total, about 153 probable and confirmed cases of vCJD have been identified worldwide, most of which are linked to exposure in the U.K. Ibid. Since more than 1 million cattle may have been infected with BSE during the epidemic in the U.K., the relatively small number of British cases of vCJD suggests there is a substantial species barrier that may protect humans from widespread illness due to BSE. Research indicates "that the level or amount of infective tissue required to infect humans may be 10,000 times greater than the amount needed to infect cattle," ER 63 (Engeljohn Dec. ¶ 15); see also 70 Fed. Reg. at 462, 505. There have been no probable or confirmed cases of vCJD from

Canadian beef.

C. USDA's Response to the United Kingdom Epidemic.

In response to the BSE epidemic in the U.K., the Secretary began restricting the importation of live ruminants and most ruminant products from regions affected with BSE or presenting a BSE risk. See, e.g., 56 Fed. Reg. 19794 (Apr. 30, 1991) (interim rule); 56 Fed. Reg. 63865 (Dec. 6, 1991) (final rule); see also 70 Fed. Reg. at 462. When new cases appeared in additional countries, those nations were simply added to the regulations.

When a cow infected with BSE was diagnosed in Alberta, Canada in May 2003, an interim rule was issued adding Canada to the list of countries affected with BSE, thereby halting imports of Canadian cattle and most Canadian beef. See 68 Fed. Reg. 31,939, 31,940 (May 29, 2003).

II. THE PRESENT RULEMAKING.

In November 2003, the Secretary issued a proposed rule that for the first time set out a comprehensive approach to determining what regions pose a "minimal risk" of introducing BSE to the United States through the importation of ruminants and ruminant products. 68 Fed. Reg. 62,386 (Nov. 4, 2003). The proposed rule explained why the infected cow discovered in May 2003 did not require a total ban on live cattle imports. Id. at 62,389-62,390. During the pendency of the rulemaking, in December 2003, a case of BSE was diagnosed in Washington State in

a cow of Canadian origin. The Secretary addressed that case in a subsequent Federal Register notice. See 69 Fed. Reg. 10,633 (Mar. 8, 2004); ER 111 (Op. at 4). Although the Secretary did not believe that discovery of the new case altered the relevant analysis, he nonetheless reopened and extended the comment period on the proposed rule until April 7, 2004. 69 Fed. Reg. at 10,633. In total, the agency received 3,379 public comments. See 70 Fed. Reg. at 465.

A. The Need To Revisit Prior Practice.

The final rule issued on January 4, 2005, 70 Fed. Reg. 460, incorporated the advances in scientific knowledge and the work of the international community in responding to BSE. Id. at 463 (“A significant amount of research has been conducted on BSE since the disease was initially identified.”).

The Secretary noted the proven effectiveness of control measures adopted in response to early epidemiological work that identified contaminated feed as the only documented method of spreading the disease between cattle. In particular, feed bans preventing the recycling of the agent have been overwhelmingly successful even in Europe where exposure is assumed to be the highest. Ibid. The Secretary also explained that studies had identified specific tissues such as those from the brain and spinal cord as particularly likely to harbor the infectious agent. By removing these tissues, the greatest potential source of infection can be removed from the food chain. 70 Fed. Reg. at

463. The Secretary declared that "[t]his increased body of knowledge provides a sound and compelling scientific basis for more focused regulatory restrictions with regard to BSE than those we have been operating under." Ibid.

The Secretary also cited the evolution of BSE guidelines adopted by the Office International des Epizooties (OIE), also referred to as the World Organisation for Animal Health. As the Secretary noted, the OIE is recognized by the World Trade Organization (WTO) as the international organization responsible for development and periodic review of standards, guidelines, and recommendations with respect to animal health and diseases. The United States, which is a member of the OIE, has been actively involved in the development of OIE guidelines. The OIE guidelines reject the assumption that the occurrence of BSE, of itself, requires suspension of cattle or beef imports from that nation, and instead provides a system of risk classification. Ibid.

The Secretary also cited complementary regulatory activity undertaken by the Food and Drug Administration and the Department of Agriculture's Food Safety and Inspection Service (FSIS), which create additional barriers to introduction of BSE into the food chain even if a case of the disease occurs. As the Secretary noted, the risk posed by importation of cattle or beef cannot be considered without reference to the overall regulatory framework now in place. 70 Fed. Reg. at 465-66.

B. Relevant Criteria For Evaluating Risk.

The regulation sets out the criteria that will guide the Secretary in determining whether a nation poses a "minimal risk" so that a complete ban of live cattle and beef imports is not required.

First, the nation must have in place risk mitigation measures adequate to prevent widespread exposure and/or establishment of the disease. These measures include import restrictions sufficient to minimize the possibility of introduction of the agent and a ban on the feeding of ruminant protein to ruminants that is effectively enforced. In addition, the nation must conduct surveillance for BSE at levels meeting or exceeding OIE recommendations.

Second, if BSE has been detected, the nation must have conducted an epidemiological investigation sufficient to confirm that the measures it has in place are sufficient to prevent the further introduction or spread of BSE.

Third, if BSE has been detected, the nation must have taken additional risk mitigation measures, as necessary, and must continue to take such measures. 70 Fed. Reg. at 463.

C. Risk Posed By Canadian Cattle Under 30 Months.

Applying these criteria, the Secretary concluded that no basis existed for continuing to restrict all live cattle imports from Canada.

The Secretary explained that Canada had instituted appropriate risk mitigation measures, including a feed ban instituted in August 1997. Canada has met or exceeded the OIE-recommended level of BSE surveillance for the past 7 years. See id. at 468.

The Secretary then addressed Canada's response to reported incidents of BSE in a cow in Alberta in May 2003, and in a cow of Canadian origin in Washington State in December 2003. Canada and the United States conducted a rigorous epidemiological investigation of both occurrences and concluded the animals were born before the implementation of the feed ban in 1997, with exposure most likely occurring before or near that time. Id. at 468-69; 68 Fed. Reg. at 62,389-62,390 (explaining May 2003 cow "was born before the implementation of the feed ban").

Finally, the Secretary noted that Canada has taken additional risk mitigation measures based on a risk analysis. In July 2003, responding to the recommendations of an international review team of animal disease experts, Canada began requiring animal tissue posing special risks (known as SRMs, see infra at 23, 39-40) be removed at slaughter, several months before the United States established similar requirements. Canada had also repeatedly increased its level of BSE surveillance and testing. 70 Fed. Reg. at 468.

As noted, the Secretary permitted importation only of cattle under 30 months. The cattle must be accompanied by a certificate

from a Canadian government veterinarian establishing that the animals are less than 30 months old and have been subject to a ruminant feed ban. Id. at 480, 548. They may only be imported through designated entry ports, and, if they are being sent to a feedlot, they must be permanently marked to identify them as having been imported from Canada. Id. at 479 (branding country of origin), 482 (government seals affixed to conveyance at port of entry). Animals sent to a feedlot must be slaughtered before they reach 30 months of age. Id. at 485. The final rule was scheduled to go into effect on March 7, 2005. Id. at 460.

In January 2005, two more BSE-infected cows were discovered in Alberta. The timing of these incidents prevented the Secretary from addressing them in the preamble to the final rule, but Canada's investigation confirmed that one cow was born in 1996 and most likely was exposed to feed produced prior to Canada's August 1997 feed ban. The investigation also disclosed that the second cow was born in 1998 and is likely to have consumed feed produced prior to the August 1997 feed ban or shortly thereafter. See 70 Fed. Reg. 18,252, 18,255, 18,258 (Apr. 8, 2005) (Addendum 7, 10). In response, the Secretary delayed the applicability of the portion of the rule that would have permitted the importation of certain Canadian beef products derived from cattle 30 months of age or older. 70 Fed. Reg. 12,112 (Mar. 11, 2005) (Addendum 1); ER 122-123 (Op. at 15-16). It bears noting, however, that USDA's analysis and conclusions

with regard to risk had already acknowledged and accounted for the possibility that additional animals with BSE born at or near the time the feed ban was implemented would be identified. The mitigation measures were designed with this possibility in mind. See 70 Fed. Reg. at 514.

III. DISTRICT COURT PROCEEDINGS.

Plaintiff Ranchers Cattlemen Action Legal Fund United Stockgrowers of America (R-CALF) brought this action seeking declaratory and injunctive relief against the USDA prohibiting it from implementing the new rule. After filing its complaint, R-CALF sought a preliminary injunction against the implementation of the rule.

The district court granted the injunction. It held that R-CALF was likely to succeed in demonstrating that the final rule violated the APA because it was arbitrary and capricious in several different respects. ER 115-124 (Op. at 8-17). The district court also held that R-CALF was likely to succeed on its claim under the National Environmental Policy Act, ER 125-128 (Op. at 18-21), and the Regulatory Flexibility Act, ER 129-131 (Op. at 22-24). Finally, in the district court's view, the balance of the harms and the public interest tipped in R-CALF's favor. ER 131-133 (Op. at 24-26). Accordingly, it preliminarily enjoined the final rule.

SUMMARY OF ARGUMENT

I. The Secretary of Agriculture concluded that an absolute ban on live ruminants and ruminant products is not required to prevent dissemination of BSE in the United States. The district court enjoined all imports as specified in the rule because it believed that assessment was incorrect.

The Secretary of Agriculture is no less committed to avoiding dissemination of BSE than the district court. The only question is whether the district court erred as matter of law in its evaluation of the regulation and impermissibly substituted its evaluation of risk for that of the Secretary.

As shown below, the record leaves no doubt that the court did precisely that, ignoring detailed explanations and scientific data and turning instead to unfounded speculation and patently erroneous calculations. Because an injunction cannot properly be premised on an error of law, reversal would be required for that reason alone. Here, however, the legal error cannot be divorced from the court's assessment of irreparable harm. Because the court had no basis for setting aside the Secretary's determination that a total ban is not required, it likewise had no reason to conclude that maintenance of such a ban is required to preclude dissemination of BSE.

Although the court speculated that its injunction might avoid economic harm to plaintiffs, it is beyond dispute that the continued restrictions on imports results in enormous hardship to

the domestic meat processing industry. The injunction enhances the economic position of the plaintiffs, who are its only real beneficiary, while inflicting harm on others. At the same time, the injunction strains relations between the United States and Canada, which have cooperated closely to achieve the shared goal of avoiding dissemination of BSE.

In raising the specter of a health threat to humans, the court ignored the relevant science. There have been no probable or confirmed cases of vCJD from Canadian beef. Indeed, all evidence indicates there is a substantial species barrier to human transmission and the amount of infective tissue required to infect humans may be 10,000 times greater than the amount needed to infect cattle. Moreover, because the Secretary's rule would permit only the importation of cattle products from which SRMs are removed and live cattle under 30 months old under specified conditions, the dreadful possibilities contemplated by the district court's decision have no nexus to the reality confronting the Secretary.

II. The governing statute vests broad authority in the Secretary to restrict imports when he believes such restrictions are necessary, and there is no suggestion that the Secretary failed to adhere to any applicable statutory standard. Nor can there be any serious question that the agency explained every aspect of its decision in detail, drawing on the vast body of scientific knowledge developed since the disease was first

diagnosed in the late 1980s, the international guidelines developed with the active participation of the United States, and the thousands of comments submitted during the rulemaking.

Consistent with international standards, the Secretary concluded that the occurrence of BSE in another country does not, of itself, require that all imports of ruminants and ruminant products be banned. The salient question, the Secretary explained, was whether that country had in place a regulatory scheme comparable to that in the United States, which minimizes the possible development of BSE in the first instance and ensures that it will not be disseminated if it in fact occurs. Because BSE is transmitted by recycling infected tissue in cattle feed, the establishment of a feed ban like that in place in the United States and Canada is of crucial importance. The country must also conduct adequate testing and demonstrate its ability to respond to and isolate any instance of the disease.

Even with these measures in place, the rule limits imports to cattle under 30 months old for purposes of slaughtering before they attain that age. This age limitation is of critical importance because BSE has a long incubation period and animals of this age would not have developed significant levels of infectivity even if exposed. 70 Fed. Reg. at 483; 68 Fed. Reg. at 62,390; ER 320. Moreover, such animals would be born long after Canada implemented a feed ban and adopted a regulatory regime that is comparable to that in the United States. Thus,

little risk exists that the cows would have been exposed to BSE at all, much less at the levels that would produce a case of BSE in cattle under 30 months old. As the Secretary explained, the isolated instances of BSE in Canada have occurred in the rapidly decreasing population of cattle born before or near the time that the feed ban was instituted. When instances have been identified, Canada has immediately taken appropriate steps and nothing suggests that these instances reflect a broader dissemination of the disease or failures in the regime that has been in place since 1997. Because the infected cattle were all well over 30 months of age, none would have been eligible for importation under the rule.

Far from according deference to the Secretary's scientific judgment, the district court ignored the detailed explanations contained in the regulation and the studies on which they were based, reaching mistaken conclusions based on inaccurate calculations and a series of erroneous premises.

III. The court's invalidation of the regulation under the Regulatory Flexibility Act (RFA) underscores its willingness to ignore settled limitations on judicial review of executive action. The RFA requires that an agency consider comments. It does not alter the terms of the statutory authority at issue or impose new substantive requirements. The court invalidated the regulation because the Secretary purportedly failed to consider requiring a country-of-origin label and a regime of optional

slaughterhouse testing for BSE. The rule in fact addressed both these issues. Contrary to the district court's view, nothing in governing law required the agency to adopt these suggestions.

IV. The district court similarly erred in enjoining operation of the rule on the basis of asserted failures to comply with procedural requirements of the National Environmental Policy Act (NEPA). Plaintiff R-CALF is an association of stock growers created to protect the economic interests of its members, and the injury claimed here is economic. As this Court has made clear, however, purely economic injury does not fall within the zone of interests protected by NEPA and is insufficient to establish prudential standing. Similarly, because R-CALF's mission is at best marginally related to environmental concerns, it cannot establish the requisite organizational standing to pursue its NEPA challenge.

In any event, plaintiff's NEPA claims are without merit. Contrary to the district court's ruling, the agency provided greater opportunity for comment than would be required. Having received comments on its proposed rule and environmental assessment, the agency was not required to solicit another round of comments. That it issued its final rule and final environmental assessment before that additional round was completed did not deprive any commenter of the ability to present concerns to the agency. Moreover, in issuing its finding that the rule will have no significant environmental impact, the

agency addressed all comments, most of which duplicated comments received earlier. R-CALF's assertion that the agency failed to examine some impacts from the rule is particularly wide of the mark because it provided no comments pertaining to those alleged impacts during the comment periods on the environmental assessments. Indeed, the district court wrongly reproved the agency for failing to address issues that no commenter presented.

STANDARD OF REVIEW

This Court reviews the grant of a preliminary injunction for abuse of discretion. Southwest Voter Registration Educ. Project v. Shelley, 344 F.3d 914, 918 (9th Cir. 2003) (en banc). "The district court's interpretation of the underlying legal principles, however, is subject to de novo review and a district court abuses its discretion when it makes an error of law." Ibid.

ARGUMENT

"To obtain a preliminary injunction, a party must demonstrate either: (1) a likelihood of success on the merits and the possibility of irreparable injury; or (2) that serious questions going to the merits were raised and the balance of hardships tips sharply in its favor." Clear Channel Outdoor v. City of Los Angeles, 340 F.3d 810, 813 (9th Cir. 2003) (internal quotation marks omitted).

It is common ground that avoiding a credible threat of

dissemination of BSE is of paramount importance. The district court could find such a threat only by setting aside the Secretary's determination that a ban on importation of cattle products and live cattle under 30 months old is not necessary to avoid dissemination of the disease. Because that ruling is wholly without basis, the court's assessment of the merits and its assessment of the harms are equally flawed.

I. NO BASIS EXISTS FOR SETTING ASIDE THE BSE RULE

A. The Regulation Is Entitled To the Utmost Deference.

The governing statute provides that the Secretary of Agriculture "may prohibit or restrict" the importation of ruminants or ruminant products "if the Secretary determines that the prohibition or restriction is necessary to prevent the introduction . . . of any pest or disease of livestock." 7 U.S.C. § 8303(a)(1). The statute provides no standards by which to measure the Secretary's exercise of discretion, and establishes no circumstances in which the Secretary is required to impose an importation ban. As this Court has recognized, the use of the word "may" connotes 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) (citing *Tashima v. Administrative Office of the United States Courts*, 967 F.2d 1264, 1273 (9th Cir. 1992)), for the proposition that a statute's use of the word "may" demonstrates a "congressional intent to give [the]

decisionmaker discretion"); Adams v. FAA, 1 F.3d 955, 956 (9th Cir. 1993). Indeed, the decision to close the borders closely resembles the type of enforcement decision that is not susceptible to judicial review. Heckler v. Chaney, 470 U.S. 821, 830 (1985).

The broad grant of authority reflects the nature of the determination that the Secretary is entrusted to make. See generally H. Conf. Rep. No. 107-424, reprinted in 2002 U.S.C.C.A.N. 141 (noting Congress had not included definition of disease to give the Secretary maximum flexibility and avoid diversion of resources in litigation). As this Court has emphasized, when "a court reviews an agency action 'involv[ing] primarily issues of fact,' and where 'analysis of the relevant documents requires a high level of technical expertise,' we must 'defer to the informed discretion of the responsible federal agencies.'" Vigil v. Leavitt, 381 F.3d 826, 833 (9th Cir. 2004) (citations omitted); see also United States v. Alpine Land & Reservoir, 887 F.2d 207, 213 (9th Cir. 1989) ("Deference to an agency's technical expertise and experience is particularly warranted with respect to questions involving . . . scientific matters."). A court should be particularly reluctant to second-guess an agency's judgment when, as here, an agency is "making predictions, within its area of special expertise, at the frontiers of science." Baltimore Gas & Elec. v. Natural Res. Def. Council, 462 U.S. 87, 103 (1983). As this Court has

recognized, “[w]hen specialists express conflicting views, an agency must have discretion to rely on the reasonable opinions of its own qualified experts even if, as an original matter, a court might find contrary views more persuasive.” Greenpeace Action v. Franklin, 14 F.3d 1324, 1332 (9th Cir. 1992).

B. Based On An Extensive Record, The Secretary Concluded That When Effective Safety Measures Are In Place, Occurrences of BSE Do Not Of Themselves Require An Absolute Ban Of All Cattle and Beef Imports From The Region.

1. The Secretary engaged in a comprehensive analysis of the risks posed by regions in which cases of BSE have been identified, examining the agency’s past practice and fully setting out the basis for the new regulation.

The agency’s practice of barring all imports of ruminants and most ruminant products from countries in which BSE has occurred arose in response to the BSE epidemic in the United Kingdom in the late 1980s and early 1990s. 70 Fed. Reg. at 461-62. At that point, the very existence of the disease had only been recently established and the efficacy of controls to prevent its dissemination had yet to be established.

Since that time, the scientific understanding of the disease and its management have been transformed, and a variety of controls have been established in the United States and in other nations, including Canada, that guard against dissemination of the disease if it should occur.

The overwhelming efficacy of risk mitigation procedures has now been firmly established. As the Secretary noted, after early epidemiological work identified the crucial role of contaminated feed in spreading the disease, feed bans that prevent the recycling of the infective agent have been overwhelmingly successful even in Europe where exposure is assumed to be the highest. Id. at 463.

Measures adopted by the Food and Drug Administration and USDA's Food Safety and Inspection Service also ensure that an occurrence of BSE would not result in dissemination of the disease. Id. at 465-66. Since 1997, the FDA has regulated feed mills, renderers, protein blenders, other feed production sources and ruminant feeders to prevent the recycling of potentially infectious tissue through ruminant feed. See 21 C.F.R. § 589.2000. The FDA's inspections have revealed a high level of compliance with the feed ban. 70 Fed. Reg. at 466.

In January 2004, USDA's Food Safety and Inspection Service adopted three rules to prevent the BSE agent from entering the human food supply. See 69 Fed. Reg. 1861 (Jan. 12, 2004); see also 70 Fed. Reg. at 466. First, FSIS designated certain cattle tissues as special risk materials, or "SRMs," and prohibited their use in human food. In cattle 30 months and older, SRMs include the brain, skull, eyes, spinal cord, and certain other nervous system tissues. SRMs also include the tonsils and distal ileum of all cattle. The FSIS rule requires slaughterhouses to

ensure that SRMs are completely removed from the carcass and segregated from edible product. The FDA subsequently adopted similar rules to prohibit the use of certain cattle products, including SRMs, in FDA-regulated products, including dietary supplement and cosmetics.

Second, FSIS prohibited products produced by Advanced Meat Recovery systems from being labeled as "meat." FSIS found that the technology employed by these systems, which allows processors to remove skeletal muscle tissue from bones, sometimes included spinal cord and nervous system tissue.

Third, FSIS prohibited the use of certain stunning devices that posed a risk of driving fragments of brain tissue into an animal's circulatory system, where they might become lodged in edible tissues. 70 Fed. Reg. at 466.

The most authoritative independent study to date, conducted even prior to the latest protections introduced by FSIS, concluded that the domestic controls in effect as of 2001 minimized the risk of the spread of BSE even if it were introduced into the country in the first instance. ER 173-182. The study, conducted by the Harvard Center for Risk Analysis and the Center for Computational Epidemiology at Tuskegee University, "quantified potential human exposure" to BSE by "analyz[ing] the risk that BSE would spread if introduced into the United States." 70 Fed. Reg. at 505-06. The Harvard-Tuskegee Study "evaluated the potential for the establishment and spread of BSE in this

country if 10 infected cows were introduced into the United States” and concluded that “based on the preventive measures already in place,” it would be “extremely unlikely” for BSE “to become established in the United States,” id. at 506. Indeed, even assuming the “worst case values,” the Study predicted that “the results were not substantially different” and still predicted an “extremely small potential for human exposure.” Ibid. Furthermore, as the Secretary noted, “[w]ith the additional safeguards implemented in the United States in 2004 . . . this already small potential is reduced even further.” Ibid.

In considering appropriate criteria, the Secretary also looked to the experience of the OIE in developing international guidelines, an effort in which the United States has been actively involved. The OIE guidelines reject the premise that occurrence of BSE, of itself, requires suspension of all cattle and beef imports, and instead provides a system of risk classification. 70 Fed. Reg. at 463.

2. The criteria adopted by the final regulation, like criteria adopted by the OIE guidelines, focus on a region’s employment of efficacious risk mitigation measures and response to detected cases of BSE. Risk mitigation measures must include an effective ban on the feeding of ruminant protein to ruminants, coupled with surveillance for BSE at levels that meet or exceed OIE recommendations. If BSE has been detected, the region must

conduct an epidemiological investigation sufficient to confirm that the measures it has in place are sufficient to prevent the further introduction or spread of BSE and must, on an ongoing basis, take additional risk mitigation measures as appropriate. Ibid.

The scope of permissible live cattle imports is subject to a further limitation: cattle must be under 30 months old and can be imported only for purposes of slaughter before they reach the age of 30 months. This restriction is crucial because BSE has an incubation period of several years. Of cattle that developed BSE during the epidemic in the U.K., only 0.01 percent were less than 30 months old. See ER 320; ER 77 (Ferguson Dec. ¶ 11).

Moreover, all evidence indicates that the expected incubation period for Canadian cattle would be significantly longer. The period of incubation varies directly with the amount of infected material consumed. In the rare cases in which BSE has occurred in cattle less than 30 months old, the disease has been linked to the consumption of a relatively large dose of the BSE agent at an early age. ER 320-321. The level of infectious agent in the feed supply in the U.K. prior to the BSE epidemic dwarfs the level of such material present in feed subject to a feed ban such as those in Canada and the United States. ER 77, 82-83 (Ferguson Dec. ¶ 11, 15-16). Indeed, no case of BSE in an animal aged 30 months or less has occurred in the U.K. since 1996. ER 319. With respect to Canadian cattle, the 30-month

rule also ensures that all cattle imported will have been born long after Canada imposed its feed ban in 1997. The cattle are thus extremely unlikely to have been exposed to BSE at all, much less at the levels that would result in a case of BSE before the age of 30 months. ER 321.

C. The Secretary's Determination That A Total Ban On Canadian Cattle and Beef Imports Is Not Necessary To Prevent Dissemination of the Disease in the United States Is Fully Supported by the Record.

Applying these criteria, the Secretary concluded that imports of beef and live cattle under 30 months old from Canada would not result in the introduction of BSE into the U.S. and that a ban on all imports was not justified. As the agency explained, Canada began restricting imports of live cattle from the U.K. and Ireland in 1990. In 1993, Canada traced and killed all of the cattle that it had been imported from the U.K. and Ireland. In 1996, Canada prohibited the import of live ruminants from any country that was not free of BSE. 70 Fed. Reg. at 467.

In 1997, Canada banned the feeding of mammalian protein to ruminants. Ibid. Canadian authorities inspect all feed manufacturing and rendering facilities on a regular basis, and the inspections verify high levels of compliance with the feed ban. Id. at 468. In addition, Canada has far exceeded the OIE-recommended level of BSE surveillance. Whereas OIE guidelines specify testing of about 300 cattle each year, Canada last year

tested 23,500, see *ibid.*,¹ and expects to test at least 30,000 cattle in 2005, a level of surveillance that far exceeds international standards and is in proportion to the number of cattle tested in the United States, *id.* at 469; ER 314-315. Indeed, Canada has taken some risk mitigation measures even in advance of the United States, requiring that "special risk materials" or SRMs, such as the tonsils and distal ileum be removed from cattle at slaughter even before such restrictions became effective in the United States. As the USDA explained, with these measures in place, "the likelihood of the spread and establishment of BSE in Canada" is "negligible." 70 Fed. Reg. at 468.

Canada's response to the detection of cases of BSE fully comports with the regulation's expectations. Following reported cases of BSE in May 2003 and December 2003, Canada and the United States conducted epidemiological investigations and concluded that the animals were born before the implementation of the feed ban in 1997, with exposure most likely occurring before or near that time. The investigations identified the feed that likely gave rise to the infection, and herds that might have been exposed to that feed were destroyed. Post-mortem tests showed no further evidence of infection. See 68 Fed. Reg. at 62,389-62,390

¹ Canada's most recent figures for 2004 are found at <http://www.inspection.gc.ca/english/anima/heasan/disemala/bseesb/surv/surve.shtml> (last visited Apr. 12, 2005).

(May 2003 cow); 69 Fed. Reg. at 10,634 (December 2003 cow).

Although the publication of the final rule pre-dated the discovery of two more BSE-infected cows in Alberta in January 2005, those discoveries in no way undermine the rationale of the regulation. Canada's investigation confirmed that one cow was born in 1996 and most likely was exposed to feed produced prior to Canada's August 1997 ban. The investigation also disclosed that the second cow was born in 1998 and is likely to have consumed feed produced prior to the August 1997 ban or shortly thereafter. 70 Fed. Reg. at 18,255, 18,258 (Addendum 7, 10). Like the other two cases of BSE in 2003, neither of these cows would have been eligible for importation under the rule. It bears noting, however, that USDA's analysis and conclusions with regard to risk had already acknowledged and accounted for the possibility that additional animals with BSE that were born at or near the time the feed ban was implemented would be identified. The mitigation measures were designed with this possibility in mind. See 70 Fed. Reg. at 514.

D. In Impermissibly Substituting Its Judgment For That Of The Secretary, The District Court Ignored The Explanations And Data In The Rule and the Administrative Record.

As shown below, each of the bases cited by the district court for setting aside the regulation is independently flawed. More fundamentally, however, the court misconceived its role. The governing statutory language, which the court did not cite,

provides that the Secretary may prohibit or restrict imports when he determines it to be necessary. When the Secretary proceeds through comprehensive rulemaking and sets out the basis for his actions in cogent detail, a court has no license to second-guess the Secretary's determination.

The court appeared to believe that its inquiry was materially changed because the Secretary previously banned all cattle imports from Canada. The district court cited the Supreme Court's statement in Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 41-42 (1983), that because a "settled course of behavior embodies the agency's informed judgment that, by pursuing that course, it will carry out the policies committed to it by Congress," there is "a presumption that those policies will be carried out best if the settled rule is adhered to." However, the court paid no heed to the context in which the statement was made or the Supreme Court's holding. In State Farm, the agency, implementing a congressional directive to promulgate automobile safety standards, had issued regulations requiring installation of air bags. It then rescinded its requirements without altering its view of the efficacy of airbags. As then-Justice Rehnquist's concurrence observed, "the agency should explain why it declined to leave those requirements intact," but "[i]n this case, the agency gave no explanation at all." Id. at 58. The Court made absolutely clear that the governing standard of review was not altered. It did not require

the Secretary to overcome a presumption that the previous rule had been correct. It simply held that the agency was required to provide a reasoned explanation for its actions.

In sharp contrast, the Secretary here explained his reasoning in full, and the district court did not conclude otherwise: it simply disagreed with the reasoning. Moreover, unlike State Farm, the decision here is based on advances in scientific knowledge. The Secretary's original regulations were issued when it was impossible to evaluate risk based on the proven efficacy of mitigation procedures. The present rulemaking was the first occasion in which the agency addressed such procedures and incorporated them into its regulations. Here, the Secretary was in no way relaxing import requirements, but merely substituting equally effective measures based on sound science to achieve the same level of protection.

Finally, the decision here is different in kind than that in State Farm. There, Congress had required promulgation of a safety standard and the issue, broadly speaking, was whether that standard should include air bags. Here, the Secretary must make what are, in effect, a series of discretionary determinations regarding the risks posed by various ruminant and ruminant product imports, and there is no reason to believe that an approach first adopted when the world reacted with panic and considerable ignorance to the U.K. epidemic should be thought to have any particular or continuing validity.

As shown below, the district court adopted each of seven erroneous theories advanced by plaintiffs, none of which withstands scrutiny.

1. "Quantitative" Determination of Risk.

The district court began by quarreling with the very notion that the Secretary could analyze the import question in terms of minimal risk. In the district court's view, the Secretary was required to provide a quantitative definition of "minimal." ER 116-117 (Op. at 9-10). The Secretary, the court opined, offered only inherently "subjective conclusions" that cannot be verified by "support in the administrative record," leaving courts unable to "asses[s] the merits" of the agency's actions. ER 116 (Op. at 9).

This reasoning is difficult to fathom. The Secretary's reasoning is laid out in detail and supported by a variety of scientific studies discussed in the rule. The overarching point of the regulation is that interlocking safety measures will prevent the risk of introduction and dissemination of BSE. It is unclear why or how that conclusion should or could be restated in quantitative form, although some of the many studies in the record, like the Harvard-Tuskegee study, provide quantitative risk analysis. See 70 Fed. Reg. at 504-05.

Indeed, the record abounds in highly relevant numbers. The regulation, for example, permits imports only of cattle under 30 months. Canadian cattle of that age would have been born and

reared under a rigorous regulation regime substantially identical to that in the United States, and none of the cases of BSE in Canada have involved cattle even close to that age. In other words, the Secretary found no reason to believe that cattle subject to importation will have BSE or that they pose any particular risks at all.

Moreover, the court's reasoning stands the statutory language on its head. The Secretary "may prohibit or restrict" the importation of an animal "if the Secretary determines that the prohibition or restriction is necessary[.]" 7 U.S.C. § 8303(a)(1). That language does not remotely suggest that the Secretary is required to state his ultimate conclusion in mathematical form. As this Court has noted, "[e]ven when an agency explains its decision with 'less than ideal clarity,' we 'will not upset the decision on that account 'if the agency's path may reasonably be discerned.'" Vigil, 381 F.3d at 833 (quoting Alaska Dep't of Env'tl. Conservation v. EPA, 540 U.S. 461, 497 (2004)). This Court has never suggested that requisite clarity is absent when an agency examines relevant studies and lays out its reasoning in detail.

Disregarding relevant authority, the district court relied on Harlan Land Co. v. USDA, 186 F. Supp. 2d 1076, 1094 (E.D. Cal. 2001), in which the district court held that the risk analysis relied on by the Department of Agriculture was flawed because the authors had failed to explain "what information and data was

used" at each step of the analysis. Id. at 1094. Even on its own terms, the decision provides no support for the district court's ruling.

2. Rate of BSE Incidence in Canada.

Although the Secretary concluded that Canada's testing for BSE had been exemplary, the district court concluded that "Canada has not conducted sufficient testing for BSE." ER 117 (Op. at 10). The district court based this conclusion on the fact that Canada has tested only 40,000 cattle, while the United States has tested 200,000.

As the court was obliged to acknowledge, however, this disparity in absolute numbers reflects the fact that the Canadian cattle population is many times smaller than the American cattle population. As the Secretary observed, Canada has met or exceeded OIE guidelines for surveillance in every year since 1995. 70 Fed. Reg. at 512.

Believing that Canadian testing had been inadequate, the district court then conducted its own calculation of the incidence of BSE in Canada. See ER 117-118 (Op. at 10-11). It noted that four Canadian cattle from Alberta out of approximately 40,000 tested had been diagnosed with BSE in the past year and a half and then extrapolated that result over the entire Canadian cattle population for only one year, finding an incidence of BSE of 5.5 per million.

This exercise was misconceived in every respect. Its

calculation of the incidence of BSE rested on at least two mistaken premises. First, the court had no basis for extrapolating testing results in Alberta (the area in which BSE has occurred) over the entire cattle population, thereby creating an artificially inflated incidence. The approach has no more merit than an attempt to identify the incidence for Canada as a whole based on testing from a province where no incident of BSE has ever been reported. See ER 72 (Ferguson Dec. ¶ 8). The court further increased the incidence of BSE by accruing cases from more than one year. Internationally accepted practice under OIE guidelines measures incidence on the basis of incidents arising in a single year. That is the case in the European countries invoked by the court as a basis of comparison. If Canada's BSE incidence is measured by year in accordance with accepted practice, the incidence rate in 2003 was 0.33 cases per million, and in the last 12 months it was 0.36 cases per million, as compared to the 5.5 cases per million found by the district court. ER 72-73 (Ferguson Dec. ¶ 8). Canada's incidence rate is well below the relevant OIE guidelines for minimal risk regions. 70 Fed. Reg. at 464.

Apart from these erroneous calculations, the court ignored the fact that none of the cattle infected with BSE would have been eligible for import under the Secretary's rule because they were older than 30 months. It likewise gave no heed to the fact that the incidence of BSE provides substantial confirmation that

the prevalence in Canada is exceedingly low because all the cows were born before or shortly after the time the feed ban was instituted, thereby removing the only known source of BSE transmission in cattle. 68 Fed. Reg. at 62,389 - 62,390; 70 Fed. Reg. at 468-69; 70 Fed. Reg. at 18255, 18258 (Addendum 7, 10).

3. Sufficiency of Canadian Feed Ban

With equal lack of justification, the court concluded that the Secretary had no basis for believing Canada's feed ban to be adequate.

First, the court questioned the significance of a feed ban at all, opining that "there is no conclusive scientific proof" that cattle feed is the "only route" of BSE exposure because "recent scientific data suggests" that BSE may be "transmitted by blood and perhaps saliva." ER 119 (Op. 12). The court found that the Secretary had acted arbitrarily because it "did not acknowledge" these possibilities. Ibid.

If the district court meant to suggest that the Secretary did not address this issue, it was quite wrong, as the court recognized later in its opinion. See ER 121 (Op. at 14) ("The USDA has acknowledged the possible transmission of BSE through blood."). However, the Secretary, unlike the district court, did not believe that scientific evidence on this point is ambiguous. The Secretary observed that some "recent scientific studies have indicated that blood may carry some infectivity for BSE," but that "those studies have concerned blood transfusions." 70 Fed.

Reg. at 491. Moreover, those blood transfusions involved only sheep and mice, and USDA concluded that these studies cannot be extrapolated to the transmission of BSE in cattle - a view that is the "consensus among scientists involved in this work," particularly those within the European Commission Scientific Steering Committee. ER 63 (Engeljohn Dec. ¶ 16). As the Secretary explained, "[i]n cattle oral ingestion of feed contaminated with the BSE is the only documented route of field transmission of the disease." 70 Fed. Reg. at 486 (emphasis added).

The district court then questioned the efficacy of the Canadian feed ban on various grounds. The court noted that the feed ban "allow[s] rendered animal fat in cattle feed," ER 121 (Op. at 14), and observed that tallow infected with BSE may create a risk of the transmission of BSE. Ibid. (citing 70 Fed. Reg. at 501).

As the Secretary explained, however, because the agent of BSE is an abnormal form of a normal protein, animal fat poses a risk only if it contains protein. See 70 Fed. Reg. at 461 (agent of BSE is abnormal form of protein); id. at 501 ("risks associated with tallow will result from protein impurities that may be present in the end product"). Thus, USDA permits importation of tallow from a minimal risk region such as Canada only if it is protein free, that is, has a maximum level of insoluble impurities of 0.15% by weight. Id. at 500-01. As the

Secretary noted, the Canada's feed ban "prohibits materials that are comprised of protein" while exempting non-protein animal products. Id. at 491.

The district court further concluded that Canada's feed ban had not been in place for a sufficient period, noting that OIE's risk-assessment guidelines recommend that a feed ban should have been in place for at least eight years. ER 119 (Op. at 12). Canada's feed ban was instituted in August 1997, somewhat less than eight years before the Secretary's rule was scheduled to take effect in March 2005. The agency concluded that this small difference did not alter the relevant analysis in light of "all of the actions Canada has taken to prevent the introduction and control the spread of BSE (e.g., import controls, level and quality of surveillance, effectiveness of feed ban, epidemiological investigation of detected cases, and depopulation of herds possibly exposed to suspected feed sources)." 70 Fed. Reg. at 470. Finally, the OIE does not recommend that the United States reject Canada for minimal-risk region status merely because its feed ban has not been in place for 8 years. Instead, the OIE would expect the United States to conduct a risk analysis to determine whether an alternative risk mitigation measure, such as restricting the age of live cattle imported, could be applied to achieve the same level of protection. See ER 106A (Wilson Dec. ¶ 7). This is precisely what the USDA did.

The court speculated that the reported incidence of BSE

might demonstrate that the feed ban lacked efficacy. The court conjectured that the four infected Canadian cows could have become infected after the feed ban was put in place in 1997 by subtracting 4.2 years from the age of the animal at death. The mean figure of 4.2 years for the onset of BSE infectivity was based on data collected in the U.K. epidemic, which represented the most intense exposure to BSE that has ever occurred. As discussed, when cattle are subject to lower doses than those documented in the U.K., the incubation period is more extended. ER 319-321. This is entirely consistent with the views of the U.S. and Canadian scientists who investigated the cases and concluded that the exposure occurred before or shortly after the feed ban was implemented in 1997.

4. Removal of SRMs

The district court found that "current scientific evidence" calls into question whether the removal of SRMs from the cattle's carcass means that there is "no risk of exposure to BSE." ER 122 (Op. at 15). It found the USDA's "failure to explain clearly why these concerns do not undercut its reliance on SRM removal requirements" to be arbitrary and capricious. Ibid.

The opinion attacks a straw man. The agency has never claimed that it is "reasonable to presume that there is no risk of exposure to BSE infectious agents" once SRMs are removed. Ibid. The removal of SRMs is one of a multitude of overlapping and inter-dependent mitigation measures on which USDA's rule

relies. See, e.g., 70 Fed. Reg. at 542 (“Removal of SRMs at slaughter and other required risk-mitigating measures of the rule will ensure that beef entering from Canada satisfies animal health criteria the same as or equivalent to those required in the United States.”) (emphasis added).

The agency was entirely correct in believing that removal of SRMs is an important part of USDA’s overall mitigation scheme. SRMs are “[t]issues that have demonstrated infectivity,” and they “must be removed and disposed of as inedible” precisely because they pose an increased risk of BSE. Id. at 502. Ignoring the actual significance of the SRM regulation, the district court improperly disregarded its role in a comprehensive regulatory framework.

5. Breeding of Imported Cattle

The district court concluded that the rule improperly fails to “prohibit cattle of breeding age from being bred either before or after entering the U.S.,” “does not require any calves born by imported Canadian cattle to be euthanized,” and “does not require the spaying of heifers or castration of bulls, nor does it require heifers to be pregnancy checked as a condition of entry into the U.S.” ER 123 (Op. at 16). In this way, the court believed, the agency had opened “a vector for BSE infection in the U.S.” Ibid.

The court’s ruling pays no heed to the fact that the regulation permits live cattle to enter the United States

only for immediate slaughter or for feeding and then immediate slaughter. See 70 Fed. Reg. at 485 (“[W]e are making no changes in this final rule to allow the importation of cattle from BSE minimal-risk regions other than those for immediate slaughter, or for feeding [and then] slaughter, at less than 30 months of age.”). And to ensure that imported cattle who would be fed before slaughter were not diverted for breeding, the agency’s rule requires the “conveyance carrying feeder cattle from the U.S. port of entry to a feedlot [to be] sealed in the region of origin with seals of the national government of the region of origin.” Id. at 482. The conveyances would remain sealed until the cattle arrive at the feedlot, where they are unsealed by an accredited veterinarian or government official. Ibid. Thus, breeding of Canadian cattle in the United States is a practical impossibility; imported cattle will be either immediately slaughtered or fed and then immediately slaughtered. See id. at 484 (“In effect, this provided for the continued prohibition on the importation of breeding cattle.”); id. at 485 (“at this time we are not providing for the importation of such [breeding] animals from BSE minimal-risk regions”); id. at 515 (“Breeding cattle of any age may not be imported into the United States from Canada under this rule.”).

Moreover, the scientific basis of the district court’s fears is highly questionable. As the agency noted, “[a]lthough some evidence suggesting maternal transmission exists, such

transmission has not been proven and, if it occurs at all, it occurs at very low levels not sufficient to sustain an epidemic.” Id. at 515.

6. Fetal Bovine Serum

The court held that USDA acted in an arbitrary and capricious manner “[b]y failing to issue regulations” to prohibit the importation of fetal bovine serum when the agency had stated in its preamble that it was necessary to do so. ER 123-123 (Op. at 16-17). That ruling disregards the fact that existing regulations already prohibit the importation of fetal bovine serum. See 9 C.F.R. § 95.4(d) (prohibiting the importation of “serum albumin, serocolostrum, amniotic liquids or extracts, and placental liquids derived from ruminants that have been in any region listed in § 94.18(a)”).

7. Mandatory BSE Testing

The district court also found the rule arbitrary and capricious because, in its view, the USDA failed “to give careful consideration to the benefits and costs of mandatory testing.” ER 124 (Op. at 17). Once again, the administrative record is flatly to the contrary. The Secretary explained that “no live animal tests exist for BSE.” 70 Fed. Reg. at 475; see also id. at 485. With current testing methods, testing clinically normal cattle at slaughter provides little useful information for surveillance purposes because current testing methods can detect

a positive case of BSE only 2 to 3 months before the animal begins to demonstrate clinical signs. Id. at 475. Thus, even if infection were present, testing clinically normal adult animals at slaughter would not be likely to disclose the presence of the infectious agent. In fact, such testing likely results in 92% false negatives. See ER 75 (Ferguson Dec. ¶ 10); 70 Fed. Reg. at 475, 534. This fact also explains why such testing is not a food safety test and is not deemed appropriate for the purposes suggested by R-CALF. See infra at 45.

II. THE RULEMAKING FULLY SATISFIED THE REQUIREMENTS OF THE REGULATORY FLEXIBILITY ACT.

The court's invocation of the Regulatory Flexibility Act to invalidate the regulation only highlights the extent to which it disregarded the Secretary's careful response to all relevant issues and comments.

The RFA requires agencies to consider the effect that their regulations will have on small entities, including small businesses. See generally Washington v. Daley, 173 F.3d 1158, 1171 (9th Cir. 1999). When applicable, it requires an agency to make available for public comment an initial regulatory flexibility analysis describing a proposed rule's effect on small businesses, 5 U.S.C. § 603(a), while discussing significant alternatives that could accomplish the same objectives while reducing any significant economic impact on small businesses, id. § 603(c). The final regulatory flexibility analysis must

describe steps taken to minimize that impact and must explain why it rejected "other significant alternatives" proposed by commenters. Id. § 604(a)(5). As this Court has explained, "the analyses required by the RFA are essentially procedural hurdles; after considering the relevant impacts and alternatives, an administrative agency remains free to regulate as it sees fit." Environmental Defense Center v. EPA, 344 F.3d 832, 879 (9th Cir. 2003).

The district court found that the agency had violated the RFA in two respects. First, it held that USDA "did not consider" that the rule's effect on small businesses could have been mitigated by requiring Canadian cattle or beef products to be labeled with their country of origin, "so that consumers could choose not to purchase those products." ER 129-130 (Op. at 22-23). However, contrary to the district court's declaration, the agency did explicitly consider a labeling requirement. See 70 Fed. Reg. at 533. It noted that, effective in 2006, the Farm Security and Rural Investment Act of 2002, Pub. L. No. 107-171 § 10816, 116 Stat. 134, 535, will require USDA "to implement a mandatory country of origin labeling program (COOL)." 70 Fed. Reg. at 533. See 7 U.S.C. § 1638a ("a retailer of a covered commodity shall inform consumers . . . of the county of origin of the covered commodity"); id. § 1638(2)(A)(i) (beef is a covered commodity). Inasmuch as Congress has separately imposed a labeling requirement and has determined its appropriate effective

date, the agency did not believe it appropriate to adopt another requirement in connection with this regulation. The agency further explained that a labeling alternative was "not a food safety or animal health measure" at all, 70 Fed. Reg. at 533, but a consumer information and marketing device that does not, in and of itself, do anything to ensure that food is safe or animals are free of disease.

The district court also mistakenly concluded that USDA "did not assess" the alternative of "allowing slaughter facilities to voluntarily test cattle for BSE," an alternative that "would mitigate the adverse effects on small businesses of diminished consumer confidence." ER 130 (Op. at 23). To the contrary, USDA noted that it "has considered carefully the possibility of allowing private companies to conduct their own BSE testing." 70 Fed. Reg. at 534. It rejected that alternative, however, because private testing would be inconsistent with the agency's "mandate to ensure effective, scientifically sound testing for significant animal diseases and to maintain domestic and international confidence in U.S. cattle and beef products." Ibid. As explained above, supra at 43, the agency noted that such testing is ineffective and will produce little useful information.

III. THE ADOPTION OF THE BSE RULE DID NOT VIOLATE NEPA.

The National Environmental Policy Act requires federal agencies to examine the environmental effects of proposed federal actions, and to inform the public of the environmental concerns

that were considered in the agency's decisionmaking. "NEPA itself does not mandate particular results, but simply prescribes the necessary process." Robertson v. Methow Valley Citizens Council, 490 U.S. 332, 350 (1989). See also Natural Resources Defense Council v. EPA, 859 F.2d 156, 169 (D.C. Cir. 1988) ("NEPA does not * * * expand the range of final decisions an agency is authorized to make," and "does not expand an agency's substantive powers.").

Under NEPA, an agency must prepare a detailed, comprehensive "environmental impact statement" only if a proposal is a "major Federal action[] significantly affecting the quality of the human environment." 42 U.S.C. § 4332(2)(C). Regulations promulgated by the Council on Environmental Quality ("CEQ") provide that an agency may prepare an environmental assessment ("EA") to determine whether a proposed action is likely to have a significant impact on the environment and whether an EIS is necessary. 40 C.F.R. §§ 1501.3, 1501.4. The EA is to be a concise document containing sufficient evidence and analysis for the agency to determine whether to prepare an EIS or a finding of no significant impact ("FONSI"), if it determines through the preparation of an EA that the proposed action will not have a significant effect on the quality of the human environment. 40 C.F.R. §§ 1501.4(b), 1508.9(a)(1), 1508.13.

A. R-CALF Lacks Standing To Pursue Its NEPA Claims.

A plaintiff with standing to challenge an underlying rule may not have prudential standing to challenge NEPA compliance. Purely economic injury falls outside the "zone of interests" that NEPA is intended to protect. Nevada Land Action Ass'n v. United States Forest Serv., 8 F.3d 713, 716 (9th Cir. 1993). As the Court explained, "[t]he purpose of NEPA is to protect the environment, not the economic interests of those adversely affected by agency decisions." Ibid.

Plaintiff's NEPA claims are premised on allegations of economic injury to its members. See ER 3 (Compl. at 3, ¶ 2); see also ER 47-49 (Bullard Dec. ¶¶ 4-9); ER 40-43 (Vansickle Dec. ¶¶ 6-14). That asserted harm reflects R-CALF's mission, which is to protect the economic interests of its members. R-CALF "is a nonprofit cattle association representing over 12,000 U.S. cattle producers on issues concerning international trade and marketing." ER 3 (Compl. at 3 ¶ 2). As its website explains, "R-CALF USA's 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 April 12, 2005). The purely economic harms alleged by plaintiff fail to bring it within the zone of interests protected by the statute.

For related reasons, R-CALF also cannot demonstrate

organizational standing. R-CALF not only fails to allege environmental harms particular to R-CALF's members, Lujan v. Defenders of Wildlife, 504 U.S. 555, 560-61 (1992), but it cannot meet its burden of showing that the interests it seeks to protect are "germane to the organization's purpose." Hunt v. Washington State Apple Adver. Comm'n, 432 U.S. 333, 343 (1977). As an organization formed to protect economic interests, any alleged environmental concerns are at best "marginally related" to R-CALF's organizational purpose. Clarke v. Securities Indus. Ass'n, 479 U.S. 388, 399 (1987). See generally Town of Stratford v. FAA, 285 F.3d 84, 89 (D.C. Cir. 2002).

Plaintiff's unsubstantiated allegation that its members will be harmed because they are beef eaters and will face an "increased risk of disease," ER 3 (Compl. at 3, ¶ 2), only underscores its failure to demonstrate the most basic elements of organizational standing. R-CALF is not an association of beefeaters: it is an association of stockgrowers. That some of its members may eat beef is wholly irrelevant to the organization's composition and purpose, which has nothing to do with protecting the environment for beefeaters.

B. Plaintiff's NEPA Claims Are Without Merit.

The Secretary's finding that the regulation will have no significant environmental impact, like the regulation itself, is subject to deferential review. See Greenpeace Action v. Franklin, 14 F.3d 1324, 1331-32 (9th Cir. 1992). As in other

aspects of its decision, the court found a series of purported failures, none of which has any basis.

1. USDA Allowed Sufficient Public Comment On Its Environmental Assessment

Contrary to the district court's understanding, the agency provided ample opportunity for public comment on its environmental assessment. Although no regulation specifically requires that USDA have a formal notice and comment period for the publication of an environmental assessment, several CEQ regulations address public involvement in the NEPA process, and this Court has held these regulations "to mean that the public must be given an opportunity to comment on draft EAs and EISs." Citizens for Better Forestry v. USDA, 341 F.3d 961, 970 (9th Cir. 2003) (citation omitted). This Court has "not established a minimum level of public comment and participation required by the regulations governing the EA and FONSI process." Ibid.

The agency issued its original draft EA (ER 158) for public comment simultaneously with the proposed rule which was published on November 4, 2003, and provided a public comment period of sixty days for this EA. 68 Fed. Reg. at 62,386, 62,400. The Final EA, issued on January 4, 2005 (ER 278), announced the commencement of another thirty-day comment period, 70 Fed. Reg. 554 (Jan. 4, 2005). That comment period was extended an additional 14 days following the discovery of several citation errors in the first version of the Final EA. 70 Fed. Reg. 3183

(Jan. 21, 2005). In total, therefore, the agency allowed more than 100 days of public comment on the environmental issues raised by the Rule, including 45 days of comment following the publication of the Final EA.

The court nevertheless held that the agency "neglected to provide the public the opportunity to comment on the [Final EA] because the [Final EA] was published after the Final Rule was signed." ER 127 (Op. at 20 (citing California v. Block, 690 F.2d 753, 770 (9th Cir. 1982))).

The agency's call for comments following the Final EA exceeded its obligations under NEPA, which required only the initial comment period following the October 2003 draft EA. The agency is permitted to revise its environmental compliance documents by elaborating on issues presented by the initial draft without triggering a new round of comments each time. "[T]o avoid perpetual cycles of new notice and comment periods, a final rule that is a logical outgrowth of the proposal does not require an additional round of notice and comment even if the final rule relies on data submitted during the comment period." Building Indus. Ass'n v. Norton, 247 F.3d 1241, 1246 (D.C. Cir. 2001). Because the Final EA was nearly double the length of the first draft, the agency in its discretion concluded that a second round of comments would be helpful. It did not, by so doing, render its EA invalid on procedural grounds.

The district court erred in ignoring this framework and

looking instead to Block, in which this Court relied on a CEQ regulation pertaining specifically to draft environmental impact statements, which does not create an obligation to recirculate an EA for public comment after an initial comment period on the draft EA. Block, 690 F.2d at 769-70 (citing 40 C.F.R. § 1500.7(a) (1977)).

In any event, the district court's ruling in this respect has been overtaken by events. The agency received thirteen public comments after the publication of the Final EA, most of which duplicated comments filed in the rulemaking and received in response to the initial EA and proposed rule. 70 Fed. Reg. at 18,252-18,253 (Addendum 4-5). The agency addressed those comments prior to issuing a FONSI on April 8, 2005. Id. at 18,252. The agency also addressed additional issues raised in R-CALF's Complaint which were never submitted as part of the comment process (although R-CALF was one of the many organizations which participated in the comment process).

In light of the publication of the FONSI, the Secretary issued an Affirmation of Final Rule which ratifies the final rule. 70 Fed. Reg. 18,252 (Addendum 4). Any procedural objections that R-CALF might raise as to the timing of the agency's NEPA compliance can no longer serve as the basis for an order barring implementation of the rule. See Safari Aviation v. Garvey, 300 F.3d 1144, 1150 (9th Cir. 2002).

2. The Risk Analysis In The Final Environmental Assessment Was Not Flawed

The district court incorrectly concluded that the EA was required to provide a quantitative assessment of the risk of introducing BSE and relied on an outdated risk analysis. That ruling has no greater substance than the court's holding that the Secretary was required to represent his ultimate determination of risk in quantitative form. When deciding whether to issue a FONSI or prepare an EIS for a particular agency action, the agency only needs to decide whether the impact of the action will be significant; nothing in NEPA or its implementing regulations requires the agency to engage in quantitative rather than qualitative assessments of risk. See 42 U.S.C. § 4332(2)(C); 40 C.F.R. §§ 1501.4, 1508.27. The "hard look" requirement of NEPA mandates only that there be a "reasonably thorough discussion of the significant aspects of the probable environmental consequences." Block, 690 F.2d at 761. "NEPA does not demand that every federal decision be verified by reduction to mathematical absolutes for insertion into a precise formula." Sierra Club v. Lynn, 502 F.2d 43, 61 (5th Cir. 1974). All that can be demanded is a disclosure sufficient to enable the agency to make an informed decision and take environmental issues into account. See Bicycle Trails Council v. Babbitt, 82 F.3d 1445, 1464 (9th Cir. 1996) (EA on closing trails to bicycles could rely on comments of hikers and others regarding user conflicts; agency

did not have to carry out a "survey or study performed scientifically to determine how many conflicts occur and how and why they occur."); Northern Plains Resource Council v. Lujan, 874 F.2d 661, 666 (9th Cir. 1989) (NEPA "merely requires that [the agency] estimate the impacts" of a proposed project and its alternatives).

Moreover, because review of an agency's NEPA compliance is deferential, "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." Marsh v. Oregon Natural Resources Council, 490 U.S. 360, 378 (1989). In developing the rule and the EA, the USDA relied on a comprehensive analysis of the risk that included both qualitative and quantitative components that included the Harvard-Tuskegee Study and Canada's 2002 quantitative risk assessment. 70 Fed. Reg. at 464. USDA, therefore, took the requisite "hard look" at the potential impacts of the rule - namely whether allowing the importation of Canadian cattle and beef under the terms of the rule risked the introduction of BSE into the United States - and concluded that there were no significant impacts. NEPA requires no more. See Greenpeace Action, 14 F.3d at 1332.

Nor, contrary to the district court's understanding, did the agency rely on an outdated risk assessment. A transcription error in the FEA released on January 4, 2005, resulted in the

omission of several references to an updated agency risk analysis. The agency corrected those errors in its citations, published a new Federal Register notice of the availability of the corrected FEA on January 21, 2005, and extended the public comment period on the corrected FEA an additional 14 days to February 17, 2005. 70 Fed. Reg. at 3184; see also 70 Fed. Reg. at 18,252 (Addendum 4). The agency had time to consider the comments before the effective date of the final rule and any error associated with the transcription problems was harmless.

3. The Agency Was Not Required To Consider Other Impacts Of Importing Canadian Cattle

The district court incorrectly concluded the EA should have analyzed the impacts from the potential increase in truck traffic and holding of feeder cattle awaiting slaughter. No commenter raised these concerns, and, as the Supreme Court has explained, a commenter that does not raise such an objection to an EA during the comment period "forfeit[s]" the objection and cannot raise it in subsequent litigation. Department of Transp. v. Public Citizen, 124 S. Ct. 2204, 2214 (2004). It is "incumbent upon intervenors who wish to participate [in the NEPA process] to structure their participation so that it is meaningful, so that it alerts the agency to the intervenors' position and contentions." Vermont Yankee Nuclear Power v. Natural Resources Defense Council, 435 U.S. 519, 553 (1978). Even commenters who make "cryptic and obscure reference to matters that 'ought to be'

considered and then, after failing to do more to bring the matter to the agency's attention, seek[] to have that agency determination vacated" on the grounds that the agency did not consider those matters cannot prevail on those arguments in court. Id. at 554.

Because no commenter - including R-CALF - addressed the potential increase in truck traffic and holding of cattle awaiting slaughter during the comment periods on the original and final EAs, R-CALF may not raise these issues for the first time in litigation as grounds for attacking the agency's NEPA compliance. Public Citizen, 124 S. Ct. at 2214; see also Vermont Yankee, 435 U.S. at 554-55; Citizens for Clean Air v. EPA, 959 F.2d 839, 847 (9th Cir. 1992) (agency was not arbitrary and capricious in disregarding comments that were "more specific than were those in Vermont Yankee" but still unsupported by data).

Nor is this a case where the agency might have to consider additional issues because the EA's flaws are "so obvious that there is no need for a commentator to point them out specifically in order to preserve its ability to challenge a proposed action." Public Citizen, 124 S. Ct. at 2214. The Secretary considered the obvious factors necessary to decide whether to prepare an EIS - it took a hard look at whether designating Canada as a minimal risk region, given the numerous safety measures required by the rule, risked the introduction of BSE into the United States.

The district court's reliance on Public Citizen v.

Department of Transp., 316 F.3d 1002, 1023 (9th Cir. 2003),
overruled by Department of Transp. v. Public Citizen, 541 U.S.
752 (2004), is misplaced. In Public Citizen, unlike in this
case, commenters asked the agency to evaluate the environmental
impacts from additional truck traffic. 316 F.3d at 1023.

Moreover, the district court here essentially reasoned that
the Secretary had to consider the alleged additional truck trips
because the rule was a but-for cause of the trips - the trips
would not occur unless the Secretary lifted the moratorium on
importing Canadian cattle. See ER 127-128 (Op. at 20-21).
However, in Public Citizen, the Supreme Court explained that even
where a commenter has not forfeited an objection, a “‘but for’
causal relationship is insufficient to make an agency responsible
for a particular effect under NEPA” and that whether an agency
must consider additional information must be “based on the
usefulness of any new potential information to the decisionmaking
process.” 124 S. Ct. at 2215. Absent an explanation of how the
agency might have changed its rule in response to an evaluation
of the impacts from additional truck traffic, the district court
abused its discretion in concluding that R-CALF was likely to
succeed on the merits of its assertion that the Secretary should
have considered those impacts. See id. at 2215-16; see also
Kootenai Tribe v. Veneman, 313 F.3d 1094, 1126 (9th Cir. 2002).²

² Even if R-CALF’s trucking and cattle holding objections
were properly before the agency, they can no longer serve to

4. The Agency Was Not Required To Prepare an EIS

The district court criticized the Secretary for not preparing an EIS. ER 128 (Op. at 21). However, an EIS is only required if the proposed rule would have a significant impact on the environment. See 40 C.F.R. § 1501.4. The district court's objections on this ground mirror the errors reflected in its decision to set aside the Secretary's determination that continuing to prohibit importation of Canadian beef and cattle under 30 months old is not necessary to avoid the introduction of BSE.

The district court was similarly wide of the mark in declaring that "[d]espite public comment requesting that APHIS prepare an EIS, no EIS was prepared." ER 127 (Op. at 20). But the agency is not required to prepare an EIS because a commenter requests one. See, e.g., N. Am. Wild Sheep v. USDA, 681 F.2d 1172, 1182 (9th Cir. 1982) (public opposition to agency action is not a "controversy" under 40 C.F.R. § 1508.27(b)(4) necessitating an EIS). The agency fulfilled its NEPA obligations by

invalidate USDA's NEPA compliance because USDA incorporated concerns about the alleged impacts in its FONSI and concluded that those impacts are not significant. 70 Fed. Reg. at 18,260-18,262 (Addendum 12-14). The impacts from trucking and feedlot confinement are not significant because, among other things, the 35,000 additional truck trips that R-CALF predicted would amount to an increase of only 1/3 of one percent at border crossings where Canadian cattle are likely to come into the country, Canadian feeder cattle will be, at most, only 1.8 to 2.2 percent of fed cattle marketed annually in the United States, and neither the trucks nor the cattle are expected to concentrate at any border crossings or feedlots. Ibid.

considering the impacts of its proposed action as well as the substance of the comments it received and determining that the impacts from the rule are not significant.

IV. BECAUSE THE SECRETARY PROPERLY DETERMINED THAT AN ABSOLUTE BAN ON IMPORTS IS NOT REQUIRED TO PREVENT INTRODUCTION OF BSE, THE PRELIMINARY INJUNCTION DOES NOT SERVE THE PUBLIC INTEREST AND PROTECTS NO LEGITIMATE INTEREST OF THE PLAINTIFF.

The Secretary determined that an absolute ban on imports is not required to preclude introduction of BSE. The entry of the preliminary injunction is predicated upon the rejection of that determination. Because the district court's analysis of the regulation constitutes clear legal error, its conclusion that an injunction is required to protect the interests of plaintiffs and the public is equally without basis.

The district court's suggestion that an injunction is necessary to guard against a threat to human health is devoid of any basis. There are no probable or confirmed cases of vCJD from consuming Canadian beef, either before or after May 2003. Indeed, the evidence indicates that there is a "substantial species barrier that may protect humans from widespread illness due to BSE," 70 Fed. Reg. at 462, and research indicates that the amount of "infective tissue required to infect humans may be 10,000 times greater than the amount needed to infect cattle," ER 63 (Engeljohn Dec. ¶ 15).

Indeed, R-CALF's own members have purchased the same

Canadian cattle that it characterizes as unsafe in this lawsuit, taking advantage of prices that are artificially depressed as a result of the injunction. See, e.g., Beth Gorham, The Canadian Press (Mar. 7, 2005) ("R-CALF bought cheap cows in Canada; group's president says it's no 'big deal'").

Although the district court gave great weight to possible economic harm to ranchers that might occur under the new rule, it ignored the countervailing harms to other sectors of the economy that flow from the injunction. For example, the district court speculated, without apparent basis, that entry of Canadian beef into the U.S. will cause other countries to close (or keep closed) their borders to American cattle and beef, resulting in economic harm. ER 132 (Op. at 25). The court gave no weight, however, to the fact that USDA's rule would result in a net benefit to the U.S. economy. See ER 90-91 (Fillo Dec. ¶ 8); see also 70 Fed. Reg. at 518 (discussing the "positive impacts" the rule would have for the "wider economy").

The district court also believed that once Canadian imports were allowed to "intermingle" with U.S. beef, it would result in a "stigma" for American beef products in the minds of consumers, from which the U.S. beef industry could never recover. ER 132-133 (Op. at 25-26). That unfounded conclusion is directly at odds with the Secretary's explanation that "[t]here has been no evidence that domestic consumers" have stopped eating beef even following limited resumption of the importation of Canadian

boneless meat in August 2003. 70 Fed. Reg. at 522; see also ER 87-88 (Fillo Dec. ¶ 4). To the contrary, "all market reports indicate that consumer demand for beef remains strong . . . [and] surveys of U.S. consumers in January 2004 . . . indicated that 97 percent of consumers were aware of BSE and a record 89 percent were confident in the safety of domestic beef on the market. That confidence level increased to 91 percent in February surveys." 70 Fed. Reg. at 522.

The Secretary, unlike the district court, must deal with our trading partners. See 7 U.S.C. § 8301(5) ("[R]egulation by the Secretary and cooperation by the Secretary with foreign countries . . . are necessary to prevent and eliminate burdens on . . . foreign commerce [and] to protect the . . . economy . . . and welfare of the people of the United States."). The United States and Canada have cooperated closely in pursuing the shared goal of avoiding introduction and dissemination of BSE, and Canada has taken numerous steps to ensure that importation of its cattle and beef can resume without presenting any threat to health and safety. Remarkably, the district court refused Canada permission to file a brief as amicus curiae before enjoining exports from that nation (ER 422-423), and its decision wrongly discounts the importance of the coordinated safety efforts that remove any basis for the injunction.

CONCLUSION

For the foregoing reasons, the judgment of the district court should be reversed and the preliminary injunction vacated.

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**CERTIFICATE OF COMPLIANCE WITH FED. R. APP. P. 32(a)(7)(B)
AND NINTH CIRCUIT RULE 32-1**

Pursuant to Federal Rule of Appellate Procedure 32(a)(7)(B) and (C) and Ninth Circuit Rule 32-1, I certify that the attached Brief for Appellees is monospaced, has 10.5 or fewer characters per inch and contains no more than 13,988 words.

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CERTIFICATE OF SERVICE

I hereby certify that pursuant to Fed. R. App. P. 25(d)(2) and 31(b) and Ninth Circuit Rule 30-1.2, on April 11, 2005, I caused two copies of the foregoing brief and 1 copy of the Excerpts of Record to be served by Federal Express overnight delivery on the following:

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STATEMENT OF RELATED CASES

Counsel is aware of only one pending related case within the meaning of Ninth Circuit Rule 28-2.6. That case, No. 05-35214, is an appeal by the National Meat Association of the preliminary injunction and of the district court's denial of its motion to intervene.