FOR PUBLICATION

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; MIKE JOHANNS, in his capacity as the Secretary of Agriculture, *Defendants-Appellants.*	No. 05-35264 D.C. No. CV 05-006 RFC OPINION

Appeal from the United States District Court
for the District of Montana
Richard F. Cebull, District Judge, Presiding

Argued and Submitted
July 13, 2005—Seattle, Washington

Filed July 25, 2005

Before: A. Wallace Tashima, Richard A. Paez, and
Consuelo M. Callahan, Circuit Judges.

Opinion by Judge Tashima

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OPINION

TASHIMA, Circuit Judge:

We must decide whether the district court erred in issuing a preliminary injunction prohibiting the implementation of a regulation of the United States Department of Agriculture ("USDA") permitting the resumption of the importation of Canadian cattle into the United States. We conclude that it did and therefore reverse the district court.

At the heart of this case lies a relatively new cattle disease caused by the practice of feeding cows, herbivores by nature, the brains and other central nervous system tissues of other

cows. Technically known as Bovine Spongiform Encephalopathy ("BSE"), this disease, popularly known as mad cow disease, has spread from farms in England to 25 countries around the world since its discovery in 1986.

As BSE spread throughout the globe during the past 20 years, USDA instituted a policy of barring the importation of ruminants[1] and ruminant products from countries where BSE was known to exist. In a final rule entitled *Bovine Spongiform Encephalopathy: Minimal Risk Regions and Importation of Commodities; Final Rule and Notice*, 70 Fed. Reg. 460 (Jan. 4, 2005) (the "Final Rule"), USDA relaxed this longstanding practice, allowing limited ruminant imports from Canada, despite the fact that two cases of BSE had been found in Canada at the time.

Plaintiff-Appellee, Ranchers Cattlemen Action Legal Fund United Stockgrowers of America ("R-CALF"), successfully blocked the implementation of the Final Rule, convincing the court below to find the rule arbitrary and capricious under the Administrative Procedure Act ("APA"), 5 U.S.C. § 706(2), and to issue a preliminary injunction prohibiting its enforcement. *See Ranchers Cattlemen Action Legal Fund United Stockgrowers of Am. v. United States Dep't of Agric.*, 359 F. Supp. 2d 1058 (D. Mont. 2005) ("*R-CALF I*"). Because we conclude that the district court applied an incorrect legal standard, we reverse.[2]

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[1]Ruminants are hoofed mammals generally defined by their four-chambered stomachs and their practice of chewing a cud consisting of regurgitated, partially digested food. Ruminants include cattle, sheep, goats, deer, giraffes, camels, llamas, and okapi, among others.

[2]On July 14, 2005, after the completion of briefing and oral argument we issued a stay of the preliminary injunction pending the resolution of this appeal. *See* Fed. R. App. P. 8(a).

I. FACTUAL AND PROCEDURAL BACKGROUND

A. Bovine Spongiform Encephalopathy

BSE was first diagnosed in England in the late 1980s. This new disease spread rapidly, infecting thousands of English cattle and eventually reaching countries all over the globe. Although the disease has since been largely contained, it continues to persist, and it resides at the center of the current lawsuit.

BSE is a species of Transmissible Spongiform Encephalopathy ("TSE"), a family of degenerative neurological diseases that affects a wide range of animals, including sheep, goats, and deer, as well as humans. Although there remains some dispute, it is widely believed that BSE and other TSEs are caused by prions, abnormally shaped and extremely hardy proteins that were only recently discovered.

TSEs have a debilitating neurological impact on their victims. After an incubation period of months or years, the diseases create myriad tiny holes in the brain, slowly deteriorating their victims' mental and physical abilities until death eventually results. In cattle, BSE has an incubation period of two to eight years, during which time the infected animal shows no outward sign of the illness. Once the disease progresses, however, infected cattle begin showing symptoms within two to three months. These symptoms can include nervousness or aggression, abnormal posture, impaired coordination, decreased milk production, and loss of body condition despite continued appetite.

At the height of the BSE epidemic in the United Kingdom, tens of thousands of cattle were confirmed to have the disease, and by some estimates the number of infected cattle in the United Kingdom may have reached into the millions. All told, there have been more than 187,000 confirmed cases of

BSE in cattle worldwide, over 95 percent of which have occurred in the United Kingdom.

Epidemiological investigations in England quickly determined that BSE was likely spread through cattle feed that was infected with the BSE agent. The blame for the contaminated feed fell squarely on the practice, common in Europe at the time, of creating high-protein cattle feed through the "recycling" of otherwise unusable cattle parts. This process is known as "rendering," and involves placing animal protein in large tanks and cooking at temperatures high enough to kill most microorganisms.[3] Although the rendering process is able to eliminate most bacterial and viral diseases, the BSE agent is resistant enough to heat and other sterilization processes to withstand the conversion into feed. Infected tissue from a single infected cow, when rendered into cattle feed, could therefore be fed to hundreds of cattle, exposing them all to the possibility of infection.

Several years after the discovery of BSE, the disease became a matter of much more serious concern. In 1996, the British government announced that a new form of TSE in humans, variant Creutzfeldt-Jakob Disease ("vCJD"), was likely caused by human consumption of cattle products that were contaminated with the BSE agent. To date, only approx-

[3]Rendering continues to this day in the United States, where approximately 50 billion pounds of tissue from dead animals are converted into animal feed each year. The breadth of the practice at one Baltimore rendering facility has been reported to include:

> Bozeman, the Baltimore City Police Department quarter horse who died last summer in the line of duty. . . . A baby circus elephant who died while in Baltimore this summer. Millions of tons of waste meat and inedible animal parts from the region's supermarkets and slaughterhouses. Carcasses from the Baltimore zoo. The thousands of dead dogs, cats, raccoons, possums, deer, foxes, snakes, and the rest that local animal shelters and road-kill patrols must dispose of each month.

Van Smith, *What's Cookin?*, Baltimore City Paper, Sept. 27, 1995.

imately 150 cases of vCJD have been identified worldwide, the vast majority of which occurred in England during the height of its BSE epidemic. Although vCJD has been diagnosed in two people in North America, in both cases the disease is believed to have been contracted in England; no case of vCJD has ever been linked to North American beef.[4]

Because BSE is a relatively new disease, and because prions are a relatively recent scientific discovery, the state of knowledge surrounding BSE is somewhat incomplete. Efforts to understand the disease fully have been hampered because current testing methodology is not particularly effective in identifying it. No live animal test for BSE exists, meaning that cows must be slaughtered before they can be tested. In addition, the tests that do exist are unable to detect the disease during the vast majority of the time a cow is infected. The earliest point at which current tests can detect the disease is two to three months before an animal starts showing clinical signs of infection. BSE has an incubation period that lasts for four to five years on average, however, during which the animal carries the disease but shows no outward symptoms.

Given these testing limitations, there remain a number of open public health questions surrounding BSE, in particular concerning the means through which the disease can be transmitted. The only documented method of BSE transmission is through the consumption of feed contaminated with the BSE agent. Some research involving both BSE and other TSEs, however, suggests that BSE may be transmitted through means other than contaminated feed. For example, in experiments on sheep, mice, and hamsters, both BSE and scrapie, a TSE disease that affects sheep, were transmitted through

[4]The single known case of vCJD in the United States occurred in a Florida woman who was born in England in 1979. It is believed she was exposed to BSE before she moved to the United States in 1992. Similarly, the single case of vCJD in Canada occurred in a man who had stayed in the United Kingdom on multiple trips.

whole blood transfusion. At least one case of vCJD is also believed to have been transmitted through human blood transfusion. Other studies have suggested that prions can be exchanged through saliva, while still others suggest that BSE may be transmitted maternally.

Despite the highly infectious nature of the BSE agent, evidence suggests that meat from cows infected with BSE may be safely consumed by humans because BSE does not occur in all parts of its host. Specifically, the BSE agent appears not to exist in muscle tissue of cattle. Rather, the disease is generally confined to the central nervous system — the brain, spinal cord, eyes, dorsal root ganglia, and trigeminal ganglia[5] — although it has also been found in the tonsils and distal ilium, a part of the small intestine, of cattle. Research on other TSEs, however, calls into question whether the BSE agent is truly limited to these tissues. Specifically, some research has suggested that sheep infected with scrapie may have prions in their muscle tissue.

Despite the fact that it has only been known to exist for 20 years, the geographic range of BSE is substantial. From England, it has spread to cattle in most of Europe, as well as in the Middle East, Japan, and Canada. 9 C.F.R. § 94.18(a)(1) (2003). As of the date of the district court's opinion, however, BSE had never occurred in a cow native to the United States. That changed on June 24, 2005, when the Secretary of Agriculture announced that a cow in Texas had tested positive for BSE. *Statement by Dr. John Clifford Regarding the Epidemiological Investigation into the recently confirmed BSE case* (June 29, 2005), *available at* http://www.aphis.usda.gov/lpa/issues/bse/bse.html. A subsequent investigation revealed that the cow was born in the United States approximately 12 years ago.

[5]Trigeminal ganglia are clusters of nerve cells connected to the brain that lie close to the exterior of the skull. Dorsal root ganglia are clusters of nerve cells attached to the spinal cord and contained within the bones of the vertebral column.

B. United States Regulation of BSE

The federal government has implemented a number of safety measures to minimize the threat of BSE to U.S. citizens and livestock. These precautions consist of an interlocking regulatory framework overseen by three different federal agencies. First and foremost, since 1997, the Food and Drug Administration ("FDA") has overseen a feed ban that prohibits the feeding of ruminant protein to other ruminants. *See* 21 C.F.R. § 589.2000 (2005). Such feed bans are generally the first line of defense against the spread of BSE, and they have been highly effective in other countries. The prevalence of BSE in the United Kingdom, for example, dropped drastically after it implemented its feed ban.

Critics, however, question whether the FDA feed ban is truly effective. *See, e.g.*, Thomas O. McGarity, *Federal Regulation of Mad Cow Disease Risks*, 57 Admin. L. Rev. 289, 307 (2005). Given the highly infectious and resilient nature of the BSE agent, these critics argue that the FDA feed ban has "gaps" that could result in the use of feed derived from rendered cattle protein as feed for cattle. For example, cattle are allowed to be fed human "plate waste" from establishments such as amusement parks, despite the fact that this plate waste may contain beef products. In addition, the feed ban allows rendered cattle protein to be fed to non-ruminants, such as pigs and chickens. Thus, BSE could be spread through mislabeled feed or through misfeeding on a farm. Finally, waste from the floor of chicken coops is commonly scooped up and fed to cattle; uneaten chicken feed or chicken droppings that contain the BSE agent could therefore be fed to cattle via this procedure.

An agency within USDA, Food Safety and Inspection Services ("FSIS"), oversees a second line of defense against BSE. FSIS promulgates regulations to ensure that the nation's food supply of meat, eggs, and poultry is safe. *See* http://www.fsis.usda.gov/About_FSIS/index.asp. These regulations

restrict certain cattle parts from being incorporated into the human food supply. For example, FSIS regulations prohibit the use of "downer" cattle[6] as human food because inability to stand is a common BSE symptom. 9 C.F.R. § 309.2 (2005). FSIS regulations also prohibit those cattle parts that have demonstrated BSE infectivity, known as specified risk materials ("SRMs"), from being used in human food.[7] 9 C.F.R. § 310.22 (2005). Finally, FSIS regulations prohibit certain methods of slaughter and butchering thought to increase the risk of contaminating meat with central nervous system tissues.[8]

[6]Non-ambulatory or "downer" cattle are cattle that "cannot rise from a recumbent position or that cannot walk." 9 C.F.R. § 309.2(b) (2005). FSIS banned these cattle from the human food supply because "surveillance data from European countries in which BSE has been detected indicate that non-ambulatory cattle are among the animals that have a greater incidence of BSE than other cattle." *Prohibition of the Use of Specified Risk Materials and Requirements for the Disposition of Non-Ambulatory Disabled Cattle*, 69 Fed. Reg. 1862, 1862 (January 12, 2004) ("*FSIS SRM Rule*").

[7]Because BSE infectivity spreads as a cow ages, current regulations define only the distal ilium and tonsils of all cattle to be SRMs. 9 C.F.R. § 310.22(a) (2005). The brain, spinal cord, and other central nervous system components are only considered to be SRMs in cattle of 30 months of age and older. *Id.*

[8]Specifically, FSIS regulations prohibit the use of "air-injection captive bolt stunning," a process through which a metal bolt and compressed air are driven into the cranium of cattle, because the practice poses a risk of contaminating edible meat with central nervous system tissue. *See* 9 C.F.R. § 310.13(a)(2)(iv)(C) (2005). The regulations also prohibit the use of "Advanced Meat Recovery" systems and the labeling of "mechanically separated beef" as meat. *See FSIS SRM Rule*, 69 Fed. Reg. at 1866. The former "is a technology that enables processors to remove the attached skeletal muscle tissue from livestock bones without incorporating a significant amount of bone or bone product into the final meat product." *Id.*; *see also Meat Produced by Advanced Meat/Bone Separation Machinery and Meat Recovery (AMR) Systems*, 69 Fed. Reg. 1874, 1876 (Jan. 12, 2004). The latter "is a paste-like and batter-like meat product produced by forcing [beef] bones with attached edible meat under high pressure through a sieve." *See* http://www.fsis.usda.gov/oa/pubs/lablterm.htm.

Another branch of USDA, Animal and Plant Health Inspection Services ("APHIS"), provides the final link in the regulatory framework. APHIS promulgates regulations designed to protect the United States from the introduction of BSE from other countries. To achieve this goal, until the Final Rule was promulgated, APHIS banned the importation of all ruminants and ruminant products from countries where BSE was known to exist. *See* 9 C.F.R. §§ 93.401, 94.18 (2003).

APHIS has also been actively involved in the development of international guidelines to fight the spread of BSE. In this role, APHIS works with the Office International des Epizooties ("OIE"), the organization recognized by the World Trade Organization as responsible for the development and periodic review of standards, guidelines, and recommendations with respect to animal health and "zoonoses" (diseases that are transmissible from animals to humans).

C. Factual Background

Early this year, APHIS announced its decision to relax its ban on the importation of ruminants and ruminant products from countries where BSE was known to exist. The genesis of this policy change occurred on May 20, 2003, when a cow in Alberta was diagnosed with BSE. This represented not only the first case of BSE native to North America, but it wreaked havoc on the highly integrated beef market that exists between the United States and Canada. Shortly after the infected cow was announced, then Secretary of Agriculture Veneman issued an Emergency Order adding Canada to the list of regions where BSE was known to exist. *Change in Disease Status of Canada Because of BSE*, 68 Fed. Reg. 31,939 (May 29, 2003). Under the regulations then in effect, all imports of live ruminants or ruminant meat products from Canada were prohibited. *See* 9 C.F.R. §§ 93.401, 94.18 (2003).

Beginning in August 2003, the Secretary incrementally began moving to reopen the border to Canadian ruminants

and ruminant products and to reestablish the voluminous North American beef trade. On August 8, 2003, the Secretary announced that she would begin allowing certain "low-risk" ruminant products to be imported into the United States from Canada, the most significant of which was "[b]oneless bovine meat from cattle under 30 months of age." *See* Final Rule, 70 Fed. Reg. at 536; USDA News Release No. 0281.03 (Aug. 8, 2003), *available at* http://www.usda.gov/wps/portal.

On November 4, 2003, the Secretary published notice of a proposed rule, seeking to amend the regulations governing the importation of ruminants from countries where BSE is known to exist. *Bovine Spongiform Encephalopathy; Minimal Risk Regions and Importation of Commodities*, 68 Fed. Reg. 62,386 (Nov. 4, 2003). The proposed rule would have allowed the importation of ruminants from countries in a newly created category — "regions that present a minimal risk of introducing [BSE] into the United States via live ruminants and ruminant products." *Id.* The new regulation proposed to designate only Canada as a minimal-risk region. *Id.* The comment period for the proposed rule was set to expire on January 5, 2004. *Id.*

A month and a half after the Secretary published the notice of proposed rule, on December 23, 2003, a cow in Washington State was diagnosed with BSE. *Bovine Spongiform Encephalopathy; Minimal Risk Regions and Importation of Commodities*, 69 Fed. Reg. 10,633 (Mar. 8, 2004). An investigation revealed that the cow was born in Canada and was imported into the United States in 2001. *Id.* at 10,634. Given that the cow was born before Canada's feed ban went into effect in 1997, USDA determined that the likeliest cause of its BSE infection was contaminated feed. *Id.* Nevertheless, in response to this discovery USDA reopened the comment period for its proposed rule for an additional 30 days, extending it until April 7, 2004. *Id.* at 10,633.

On April 19, 2004, USDA moved, without public notice, to expand the types of ruminant products eligible to be imported from Canada.[9] *Ranchers Cattlemen Action Legal Fund United Stockgrowers of Am. v. United States Dep't of Agric.*, 2004 WL 1047837 (D. Mont. 2004) ("*R-CALF TRO*"). R-CALF sued to prevent this move, and the district court granted a temporary restraining order on April 26, 2004, barring the Secretary from proceeding with that plan. *Id.*

On January 4, 2005, USDA published its Final Rule. The agency, after having considered 3,379 comments from interested parties, proceeded with its plan to reopen the border to Canadian ruminants and ruminant products. Final Rule, 70 Fed. Reg. at 460, 469. Among other provisions, the Final Rule allowed the importation of Canadian cattle under 30 months of age provided the cattle were immediately slaughtered or fed and then slaughtered.[10] *Id.* at 548. The Final Rule also permitted the importation of beef products from Canadian cattle of all ages. *Id.* at 461, 465. The rule was scheduled to go into effect on March 7, 2005. *Id.* at 460.

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[9]Specifically, USDA issued a memorandum stating that, effective April 19, 2004, all existing permits to import meat from Canada "will be deemed to cover all edible bovine meat products (bone-in, boneless, ground meat, further processed)," provided each shipment is accompanied by a statement that the meat was processed in "establishments that are certified to FSIS as eligible for export to the United States." *R-CALF TRO*, 2004 WL 1047837 at *2. USDA also published a table identifying "Low Risk Canadian Products." That table included "boneless, bone-in, ground meat, and further processed bovine meat products," bovine tongue, bovine hearts, kidneys, and tripe, and bovine lips." *Id.*

[10]According to *amicus* Pioneer, Inc., a family-owned feedlot, the cattle industry is generally comprised of three parts: ranchers, who breed cattle and grow them until they reach approximately 650 pounds; feedlots, which purchase cattle from ranchers and feed them high protein feed until they reach approximately 1,150 pounds; and meat packers, which purchase cattle from feedlots and process them for human consumption. Thus, the Final Rule allowed Canadian cattle either to be sold to a feedlot for feeding or to be sold directly to a meat packing company for slaughter.

At roughly the same time that USDA published its Final Rule, two additional cases of BSE were confirmed in Alberta — one on January 2, 2005, and another on January 11. *Bovine Spongiform Encephalopathy; Minimal Risk Regions and Importation of Commodities; Finding of No Significant Impact and Affirmation of Final Rule*, 70 Fed. Reg. 18,252, 18,254 (Apr. 8, 2005). One of these cows, like the two previous Canadian cattle diagnosed with BSE, was born before Canada's feed ban; the other, however, was born shortly thereafter. *Id.* at 18,258. Once again, USDA attributed the infections in both cows to contaminated feed manufactured before Canada's feed ban went into effect. *Id.* at 18,255. Nonetheless, USDA indefinitely suspended the implementation of the portion of its Final Rule that permitted the importation of beef products from cattle over 30 months of age.[11] *Bovine Spongiform Encephalopathy; Minimal Risk Regions and Importation of Commodities; Partial Delay of Applicability*, 70 Fed. Reg. 12,112 (Mar. 11, 2005).

D. Procedural History

Six days after USDA published the Final Rule, R-CALF filed this action, seeking to enjoin the rule's implementation.[12] In its complaint, R-CALF alleged that USDA's rulemaking violated the Administrative Procedure Act ("APA"), the Regulatory Flexibility Act ("RFA"), and the National Environmental Policy Act ("NEPA"). On February 1, 2005, three weeks after filing its complaint, R-CALF filed its application for a preliminary injunction to enjoin the Final Rule *pendente lite*.

[11]As mentioned above, an additional cow in the United States tested positive for BSE on June 24, 2005. Because this cow was approximately 12 years old, USDA has attributed its infection to contaminated feed it was exposed to before the U.S. feed ban came into effect.

[12]R-CALF describes itself as a non-profit cattle association that represents U.S. "cattle producers, cattle backgrounders, and independent feedlot owners" on issues concerning international trade and marketing.

On March 2, 2005, the district court issued a preliminary injunction, barring USDA from implementing its Final Rule. *See R-CALF I*, 359 F. Supp. 2d at 1074. The district court's primary reason for enjoining the Final Rule was its finding that the rule was arbitrary and capricious in violation of the APA. *Id.* at 1063-69; *see also* 5 U.S.C. § 706(2). The district court's overarching concern was that USDA, "ignoring its statutory mandate to protect the health and welfare of the people of the United States, established its goal of re-opening the border to the importation of live beef from Canada and thereafter attempted to work backwards to support and justify this goal." *R-CALF I*, 359 F. Supp. 2d at 1066. Given the agency's "preconceived intention, based upon inappropriate considerations, to rush to reopen the border regardless of uncertainties in the agency's knowledge," the district court found the Final Rule to be arbitrary and capricious. *Id.* at 1074.

The district court specifically based its determination that the Final Rule was arbitrary and capricious under the APA on six independent grounds. First, the court found that USDA failed adequately to quantify the risk of Canadian cattle to humans, instead relying on a qualitative statement that the risk was "low" or "very low." *Id.* at 1064-65. Without a quantitative assessment, the district court felt that it "ha[d] no way of assessing the merits of the USDA's actions." *Id.* at 1065.

Second, the district court held that USDA had erroneously calculated the prevalence of BSE in the Canadian herd. *Id.* at 1065-66. USDA had divided the number of cases in the last 12 months (two) by the total size of the Canadian herd over 24 months of age (5.5 million) to arrive at a prevalence rate of approximately 0.4 cases per million head of adult cattle. Final Rule, 70 Fed. Reg. at 464. The district court rejected this calculation, however, and instead adopted R-CALF's measure of 5.5 cases per million head.[13] *R-CALF I*, 359 F. Supp. 2d at 1066.

[13]To achieve the rate of 5.5 cases per million head, R-CALF calculated the prevalence of BSE among tested cattle in Alberta (one in 3,000) and

Third, the district court found that USDA's reliance on the Canadian feed ban was unjustified. *Id.* at 1066-68. The court found that the science was uncertain in this area and that methods of BSE transmission other than consumption of contaminated feed may exist. *Id.* at 1066. It also found that the feed ban had not been in place an adequate amount of time, and that it was not fully effective because it allowed both bovine blood and rendered animal fat in cattle feed. *Id.* at 1067-68.

Fourth, the court found that USDA's reliance on the removal of SRMs to protect human health was also unjustified. *Id.* at 1068. According to the district court, evidence indicated that "it is no longer reasonable to presume that there is no risk of exposure to BSE infectious agents once an SRM removal requirement is in place." *Id.*

Fifth, the district court found that USDA's failure to ban the importation of pregnant cows was arbitrary and capricious. *Id*. at 1069. According to the district court, BSE may be transmitted both maternally and through fetal bovine blood. *Id.* Thus, because the Final Rule did not require heifers to be pregnancy checked as a condition of entry into the United States, calves born to imported cattle could become "a vector for BSE infection in the U.S." *Id.*

Finally, the district court found that USDA had failed to respond adequately to comments recommending mandatory BSE testing for Canadian cattle. *Id*. Because testing can identify a BSE infection up to three months before the cow shows outward signs of the disease, the court found that testing

divided it by 60, the assumed amount by which tested cattle will have BSE over untested cattle (because tested cattle, which show outward signs of the disease, are more likely to have BSE than the population at large). The result is one infected cow per 180,000 head of cattle, or approximately 5.56 per million."

would be useful because it would "detect some cases of BSE that would otherwise go undetected." *Id.* In light of the "irreparable injury" that it believed a case of BSE would cause, the court viewed USDA's actions as arbitrary and capricious. *Id.*

In addition to finding the Final Rule arbitrary and capricious under the APA, the district court also relied on two other bases for enjoining its implementation. First, the court held that USDA had failed to satisfy NEPA's procedural requirements, both by failing to make its environmental assessment available for public review and comment before the Final Rule was published, and by failing to prepare an environmental impact statement. *Id.* at 1069-71. Second, the court concluded that USDA had violated the RFA by failing to consider whether product labeling or voluntary BSE testing would have mitigated the Final Rule's impact on small businesses. *Id.* at 1071-73.

Based on the above, the district court found that R-CALF had raised "very serious questions on the merits." *Id.* at 1074. The district court also found that R-CALF, and the American public, would be irreparably harmed by allowing the importation of Canadian beef. *Id.* at 1073-74. The court specifically found that the introduction of BSE into the United States would cause irreparable harm to the American public because of the increased risk of vCJD to consumers of beef. *Id.* at 1073. Further, it found that the association with Canadian beef would stigmatize all U.S. meat, causing a "serious, irreparable impact on ranchers in the U.S. and the U.S. economy." *Id*. Finally, the district court found that the NEPA violation, in and of itself, would cause irreparable harm and warranted preliminary injunctive relief. *Id.*

In light of its determination that R-CALF was likely to succeed on the merits, and that the balance of hardships tipped in R-CALF's favor, the district court issued a preliminary injunction barring implementation of the Final Rule. *Id.* at 1074. Two weeks later, USDA filed this timely appeal.

II. ANALYSIS

"A district court's order granting a preliminary injunction is subject to limited review." *Price v. City of Stockton*, 390 F.3d 1105, 1109 (9th Cir. 2004). We will reverse "only where the district court abused its discretion or based its decision on an erroneous legal standard or on clearly erroneous findings of fact." *Id.* A reviewing court should generally refrain from reviewing "the underlying merits of the case." *Southwest Voter Registration Educ. Project v. Shelley*, 344 F.3d 914, 918 (9th Cir. 2003) (en banc). Rather, "[a]s long as the district court got the law right, it will not be reversed simply because the appellate court would have arrived at a different result if it had applied the law to the facts of the case." *Earth Island Inst. v. United States Forest Serv.*, 351 F.3d 1291, 1298 (9th Cir. 2003).

"The standard for granting a preliminary injunction balances the plaintiff's likelihood of success against the relative hardship to the parties." *Clear Channel Outdoor, Inc. v. City of Los Angeles*, 340 F.3d 810, 813 (9th Cir. 2003). This circuit has recognized two different sets of criteria for preliminary injunctive relief. Under the traditional test, a plaintiff must show: "(1) a strong likelihood of success on the merits, (2) the possibility of irreparable injury to plaintiff if preliminary relief is not granted, (3) a balance of hardships favoring the plaintiff, and (4) advancement of the public interest (in certain cases)." *Save Our Sonoran, Inc. v. Flowers*, 408 F.3d 1113, 1120 (9th Cir. 2005). The alternative test requires that a plaintiff demonstrate "*either* a combination of probable success on the merits and the possibility of irreparable injury *or* that serious questions are raised and the balance of hardships tips sharply in his favor." *Id.* (emphasis in original). "These two formulations represent two points on a sliding scale in which the required degree of irreparable harm increases as the probability of success decreases. They are not separate tests but rather outer reaches of a single continuum." *Id.*

As we conclude below, the district court's finding that R-CALF had a strong likelihood of success on the merits was premised on legal error. Further, we disagree with the district court's assessment of the irreparable harm threatened by the Final Rule. Thus, we hold that a preliminary injunction was unwarranted in this case.

A. Likelihood of Success on the Merits

The district court identified three distinct grounds for its finding that R-CALF had a strong likelihood of success on the merits: (1) that the Final Rule was arbitrary and capricious under the APA; (2) that USDA had failed to satisfy NEPA's procedural requirements; and (3) that USDA had failed adequately to consider the Final Rule's effect on small businesses, as required by the RFA. None of these grounds withstands scrutiny.

1. Administrative Procedure Act

The APA provides that a court, when reviewing agency action, shall "hold unlawful and set aside agency action, findings, and conclusions found to be . . . arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706. An agency's action violates this standard if

> the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.

City of Sausalito v. O'Neill, 386 F.3d 1186, 1206 (9th Cir. 2004) (quoting *Motor Vehicles Mfrs. Ass'n v. State Farm Mut. Auto Ins. Co.*, 463 U.S. 29, 43 (1983)).

[1] Regulations are presumed to be valid, and therefore review is deferential to the agency. *Nat'l Ass'n of Home Builders v. Norton*, 340 F.3d 835, 841 (9th Cir. 2003). All that is required is that the agency have "considered the relevant factors and articulated a rational connection between the facts found and the choices made." *Id.* Further, "[t]he court is not empowered to substitute its judgment for that of the agency." *Ariz. Cattle Growers' Ass'n v. United States Fish & Wildlife Serv.*, 273 F.3d 1229, 1236 (9th Cir. 2001). Deference to the informed discretion of the responsible federal agencies is especially appropriate, where, as here, the agency's decision involves a high level of technical expertise. *Id.*

While review is therefore deferential, it is not toothless; courts must conduct a "thorough, probing, in-depth" inquiry into the validity of regulations. *Nat'l Ass'n of Homebuilders*, 340 F.3d at 841. This inquiry must be "searching and careful" to ensure that the agency decision does not contain a clear error of judgment. *City of Sausalito*, 386 F.3d at 1206; *Nat'l Ass'n of Homebuilders*, 340 F.3d at 841. In performing this inquiry, the court is not allowed to uphold a regulation on grounds other than those relied on by the agency. *Ariz. Cattle Growers' Ass'n*, 273 F.3d at 1236 ("The reviewing court may not substitute reasons for agency action that are not in the record.").

[2] The district court failed to abide by this deferential standard. Instead, the district court committed legal error by failing to respect the agency's judgment and expertise. Rather than evaluating the Final Rule to determine if USDA had a basis for its conclusions, the district court repeatedly substituted its judgment for the agency's, disagreeing with USDA's determinations even though they had a sound basis in the administrative record, and accepting the scientific judgments of R-CALF's experts over those of the agency. For example, in assessing the prevalence of BSE in the Canadian herd, the district court rejected USDA's calculation and accepted the

prevalence rate provided by R-CALF's expert, completely without explanation. *R-CALF I*, 359 F. Supp. 2d at 1066.

The district court's lack of deference may be attributable to its misreading of the Animal Health Protection Act ("AHPA"), 7 U.S.C. § 8301 *et seq.*, the statute under which the Final Rule was promulgated. Based on the AHPA's statement of congressional findings, 7 U.S.C. § 8301, the district court appears to have imposed a requirement on USDA that its Final Rule present no additional risk to human or animal health.[14] *See R-CALF I*, 359 F. Supp. 2d at 1065 ("The [AHPA] directs the Secretary of the USDA to protect the health and welfare of the people of the United States."). The AHPA is, in fact, based upon congressional findings that "the prevention, detection, control, and eradication of diseases and pests of animals are essential to protect . . . animal health [and] the health and welfare of the people of the United States." 7 U.S.C. § 8301(1). The provision of the Act under which the Final Rule was promulgated, however, states only that "the Secretary [of Agriculture] may prohibit or restrict . . . the importation or entry of any animal, article, or means of conveyance . . . if the Secretary determines that the prohibition or restriction is necessary to prevent the introduction into

[14]While the district court never explicitly stated that it was imposing such a "zero-risk" requirement, its reasoning suggests that it did. For example, the court faulted the agency for "presum[ing] that there is no risk of exposure to BSE infective agents once an SRM removal requirement is in place." *R-CALF I*, 359 F. Supp. 2d at 1068. Similarly, the court found the Final Rule arbitrary and capricious because the agency refused to act to remove the "small probability" that BSE could be transmitted from a pregnant Canadian cow to its offspring. *Id.* at 1069.

Indeed, the district court appears to have required USDA to disprove all scientific uncertainty associated with BSE. It noted, for example, that there is no "conclusive scientific proof" that cattle feed is the only method of BSE transmission. *Id.* at 1066. In other areas of the opinion, any level of scientific uncertainty surrounding a USDA decision rendered that decision an "assumption." *E.g.*, *id.* at 1066, 1067, 1068; *see also id.* at 1074 (criticizing USDA for acting despite "uncertainties in the agency's knowledge of the possible impacts on human and animal health").

or dissemination within the United States of any pest or disease of livestock." 7 U.S.C. § 8303(a)(1).

[3] The AHPA was only recently enacted, in 2002, and, as of yet, there are few reported cases interpreting its provisions. Nonetheless, the statute's terms indicate a congressional intent to give the Secretary wide discretion in dealing with the importation of plant and animal products. More to the point, the AHPA does not impose any requirement on USDA that all of its actions carry no associated increased risk of disease. Indeed, the statute's use of the word "may" suggests that the Secretary is given discretion over such decisions as whether to close the borders. *See, e.g.*, *United States v. George*, 85 F.3d 1433, 1437 (9th Cir. 1996) (statute's use of term "may" "indicates that we should review a district court's decision . . . for abuse of discretion"). Although sparse, the AHPA's legislative history also supports this view. *See* H.R. Conf. Rep. 107-424, *reprinted in* 2002 U.S.C.C.A.N. 141, 388 (in order to best protect against animal disease, "a regulatory definition of disease should be left to the discretion of the Secretary," which will allow "the agency to have maximum flexibility to focus its resources and respond to new or emerging disease threats"). It is also notable that open borders are a default under the AHPA, and the Secretary can close them only if "necessary" to prevent livestock disease. *See* 7 U.S.C. § 8303.

[4] The structure of the AHPA is therefore inconsistent with the district court's strict requirement that the USDA regulation remove all risk of BSE entering the United States. Because the district court interpreted the statute to contain such a requirement, its analysis of the Final Rule's compliance with the APA was fundamentally flawed.[15]

[15]We are in no way, of course, implying that the Secretary has unlimited powers to open and close the borders as he sees fit. As the AHPA's structure indicates, however, the Secretary has considerable discretion to decide when an open or closed border is appropriate. Absent a strong showing that the Secretary is not exercising that discretion consistent with the statutory requirements, his judgment should not be overturned.

Our own review of the Final Rule leads us to conclude that the Secretary had a firm basis for determining that the resumption of ruminant imports from Canada would not significantly increase the risk of BSE to the American population. In conducting this review, we believe it is appropriate to view the BSE prevention measures currently in place as part of a comprehensive system. Thus, rather than follow the "divide and conquer" strategy of analyzing each protective component of the regulatory system in isolation, we evaluate the cumulative effects of the multiple, interlocking safeguards.

USDA's comprehensive protections begin, first, with the low incidence of BSE in Canadian cattle. This assures that if any infected cattle are imported, the number will be relatively small.[16] Next, Canada's feed ban, which USDA considers effective, and its import restrictions on cattle from areas with high BSE rates, ensure that Canada's prevalence rate will not rise dramatically. Canada also takes other measures, such as BSE testing and epidemiological investigations, that help it find and understand the source of BSE in its cattle population, which helps it further minimize the prevalence of BSE in its herd. These steps ensure, as USDA found, that Canada's already low rate of BSE is decreasing. Final Rule, 70 Fed. Reg. at 464.

From the already low prevalence rate in the Canadian herd as a whole, USDA permits the importation of only a subset of those animals that are extremely unlikely to have BSE — those under 30 months of age. In England, only 0.01 percent of those animals diagnosed with BSE were under 30 months of age. *Meat Produced by Advanced Meat/Bone Separation Machinery and Meat Recovery (AMR) Systems*, 69 Fed. Reg. 1874, 1875 (Jan. 12, 2004). In addition, USDA's scientific evidence suggests that Canadian cattle under 30 months of

[16]For example, assuming two million cattle enter the United States from Canada per year, less than one would be expected to have BSE based on Canada's prevalence rate of 0.4 cases per million head of adult cattle.

age will be far less likely to be in the advanced stages of BSE, given that the incubation period of BSE depends on the amount of BSE agent to which an animal has been exposed. Based on Canada's low BSE rate and its feed ban, Canadian cattle should have a much lower exposure than English cattle, resulting in a correspondingly greater incubation period. Thus, the age restriction further reduces the risk of introduction of BSE from Canada's herd.

Inside the United States, the risk of dissemination of BSE is addressed by the requirement that Canadian cattle be immediately slaughtered or fed and then slaughtered before they reach the age of 30 months. Again, because of BSE's lengthy incubation period, this age limit helps to ensure that BSE will not progress in any infected animals before they are slaughtered. Once they are slaughtered, the FDA's feed ban ensures that they will not be fed to other cattle, preventing further dissemination of the disease if, in fact, an imported cow were infected.

As for human health, cattle slaughtered in the United States are subject to FSIS regulations designed to minimize the risk that any infectious material will enter the human food supply. These regulations largely prohibit parts of the central nervous system and other cattle parts that have shown BSE infectivity from contaminating human food. In addition, FSIS has placed restrictions on the manner in which cattle may be slaughtered — air compression devices are banned to protect against the possibility that they might inject parts of the brain into the bloodstream. FSIS regulations also require the removal of all SRMs from slaughtered cattle, and they restrict the use in human food of "mechanically separated beef" and meat obtained from "Advanced Meat Recovery" systems.

The final defense against human BSE infection is biological. The limited nature of the vCJD outbreak indicates that there may be a substantial species barrier that prevents BSE from easily infecting humans. Indeed, the fact that there have

been only slightly over 150 confirmed cases of vCJD worldwide — orders of magnitude less than the number of cases of BSE in cattle — suggests that humans likely do not contract the disease easily.

[5] This regulatory system, with its numerous overlapping and complementary safeguards, is designed to minimize the risk of BSE to American livestock and consumers. Thus, substantial evidence supports USDA's conclusion that these protections will effectively achieve that goal. Further, a comprehensive study commissioned by USDA, known as the "Harvard-Tuskegee Study," evaluated the likely effects of the introduction of BSE into the United States. The study concluded that, if 10 infected cows were imported into the United States from Canada, on average only three new cases of BSE would result and the disease was "virtually certain" to be eradicated from the United States within 20 years.

Instead of evaluating the BSE safeguards as part of a larger system, the district court parsed the regulations and faulted USDA for any risk that a given step failed to remove. The district court listed six specific grounds as the bases for its finding that the Final Rule was arbitrary and capricious. We examine each of them *seriatim* and conclude that none of them supports its conclusion.

a. Lack of quantitative standards

The district court faulted USDA for "ma[king] assumptions of qualitative judgments," rather than performing "a quantitative assessment of the risk of various options." *R-CALF I*, 359 F. Supp. 2d at 1065. It concluded that, "[p]resented with the USDA's conclusions that the risks to U.S. cattle and consumers are 'low' without any definition as to what that means and why the risks presented by the Final Rule are acceptable, this Court has no way of assessing the merits of the USDA's actions." *Id.*

[6] The district court's imposition of such a bright-line prohibition on qualitative standards was incorrect. The Supreme Court has made clear that courts should not upset agency decisions, even those announced with "less than ideal clarity," if "the agency's path may reasonably be discerned." *Alaska Dep't of Envtl. Conservation v. EPA*, 540 U.S. 461, 496 (2004) (internal quotation marks omitted); *see also Vigil v. Leavitt*, 381 F.3d 826, 833 (9th Cir. 2004); *Nat'l Ass'n of Homebuilders*, 340 F.3d at 846. Moreover, the AHPA does not require the Secretary to quantify a permissible level of risk or to conduct a risk assessment.

[7] Under this standard, the administrative record is an adequate basis for discerning USDA's conclusions. For example, USDA's conclusion that the prevalence of BSE in the Canadian herd is "very low" is supported by its observation that "Canada's incidence rate of two infected cattle in 2003 out of a population of 5.5 million cattle over 24 months of age [is well below] OIE's recommendation of less than two infected cattle per million during each of the last four consecutive 12-month periods within the cattle population over 24 months of age." Final Rule, 70 Fed. Reg. at 464. Similarly, the "very low" risk of a consumer contracting vCJD is supported by its finding that "the removal of SRMs effectively mitigates the BSE risk to humans." *Id.* at 465. Indeed, the Harvard-Tuskegee Study, one of the centerpieces of USDA's rulemaking, concluded that SRM removal "would reduce . . . potential human exposure to BSE by 95 percent." *Id.* at 467.

The low risk of a human developing vCJD is also supported by USDA's observation that "the number of cases of vCJD identified to date suggest a substantial species barrier that may protect humans from widespread illness due to BSE." *Id.* at 462. It is also supported by anecdotal evidence of vCJD outbreaks in other parts of the world. In Switzerland, for example, the BSE rate in 1995 was 73.6 cases per million head of cattle, and has been above 20 for most of the past 10 years, *see* http://www.oie.int/eng/info/en_esbincidence.htm,

yet Switzerland has not identified a single case of vCJD. Finally, no case of vCJD has ever been attributed to Canadian beef or to the North American meat supply.

b. Prevalence of BSE in Canada

The district court concluded that "Canada has not conducted sufficient testing for BSE to accurately assess the rate of BSE infection in Canada." *R-CALF I*, 359 F. Supp. 2d at 1065. It also concluded that the actual rate of BSE in Canada was "greater than 5.5 cases per million head of cattle . . . [putting] Canada on par with a number of European countries with a BSE problem." *Id.* at 1066. Based on this number, the district judge found that the importation of "2-3 million head of cattle from Canada during the remainder of 2005" presented a "potentially catastrophic risk of danger to the beef consumers in the U.S." *Id.*

[8] The district court, in this instance, impermissibly substituted its judgment for that of the agency. The USDA, in its Final Rule, calculated Canada's BSE prevalence rate to be between 0.3 and 0.4 per million head of cattle. Final Rule, 70 Fed. Reg. at 464. The district court gave no reason for departing from this calculation and, instead, adopting the calculation of R-CALF's expert wholesale. The district court did so even though R-CALF's calculation contained the same type of unexplained assumptions that the court found fatal to the Final Rule. For example, R-CALF's expert assumed that cattle with outward signs of BSE are 60 times more likely to have the disease than cattle with no symptoms, and assumed that the prevalence rate of BSE in Alberta was representative of the rate in Canada as a whole.

[9] USDA, on the other hand, based its calculation of Canada's BSE rate on OIE guidelines; indeed, the OIE website lists Canada's 2003 incidence rate as 0.33 and its 2004 rate as 0.149. *See* http://www.oie.int/eng/info/en_esbincidence.htm. The district court erred by departing from USDA's method of

calculation, which was supported by the administrative record, without providing any reason. *Marsh v. Or. Nat. Res. Council*, 490 U.S. 360, 378 (1989) ("When specialists express conflicting views, an agency must have discretion to rely on the reasonable opinions of its own qualified experts even if, as an original matter, a court might find contrary views more persuasive."); *Nat'l Wildlife Fed'n v. United States Army Corps of Eng'rs*, 384 F.3d 1163, 1177 (9th Cir. 2004).

c. Effectiveness of Canadian feed ban

The district court also questioned USDA's reliance on the Canadian feed ban. First, it found that there was "no conclusive scientific proof" that consumption of infected feed is the only method of BSE transmission, commenting that transmission may occur through blood and saliva. *R-CALF I*, 359 F. Supp. 2d at 1066-67. Second, the court found evidence that the feed ban had not been effective, both because the ban had only been in place for seven years and because the 4.2-year average incubation period of BSE suggested that the infected Canadian cows had contracted BSE well after the feed ban was put in place. *Id.* at 1067. Finally, the court found gaps in the ban, finding that both bovine blood and rendered animal fat were allowed in animal feed and that both could transmit BSE. *Id.* at 1067-68.

As to the first reason, the USDA explicitly considered scientific evidence on alternative theories of transmission and rejected them, finding that "oral ingestion of feed contaminated with the BSE is the only documented route of field transmission of the disease." Final Rule, 70 Fed. Reg. at 486; *see also id.* at 491 (discussing infectivity of blood).

[10] The trial court's criticisms of Canada's feed ban are also baseless. The district court's main criticism is that Canada's feed ban had been in place for only seven and a half years, not the eight years recommended by OIE guidelines. Applying such a strict reading of OIE guidelines, however,

was incorrect. According to a declaration submitted by the Head of the International Trade Department of OIE, OIE recommends that an importing country evaluate the exporting country's risk mitigation measures as a whole, and "would not consider it appropriate for the importing country to apply each criterion as an item on a checklist." Thus, "a deficiency in the length of time a feed ban has been effectively applied could be addressed through restrictions on the age of live cattle imported." The Final Rule reveals that this is precisely the approach that USDA took. *See, e.g.*, Final Rule, 70 Fed. Reg. at 463 (discussing multiple criteria used to evaluate a potential minimal-risk region); *id.* at 548 (restricting imports of Canadian cattle to those under 30 months of age).

Nor do we agree that the 4.2-year average incubation period demonstrates the ineffectiveness of Canada's feed ban. USDA explained that the incubation period of BSE in cattle depends upon the level of exposure the cattle have to the BSE agent. The 4.2-year figure was obtained from analyzing cattle during the BSE epidemic in England, which represents the highest level of exposure to BSE in history. Cows in Canada can be expected to have a longer incubation period because of their significantly lower levels of BSE exposure.

[11] Finally, the district court also erred in criticizing the Canadian feed ban based on its "gaps," which allow blood and rendered animal fat in cattle feed. As discussed above, USDA considered BSE transmission through blood and determined that the science did not support ingestion of blood as a means of transmission. *Id.* at 491. USDA also considered transmission through fat and concluded that, provided the fat is not impure, it poses no risk of transmission of BSE. *Id.* at 500-01 (discussing potential transmission of BSE through tallow). Again, the district court gave no reason for rejecting USDA's expert scientific opinion.

d. Effectiveness of SRM removal

[12] The district court also found that R-CALF had presented sufficient evidence to establish that "it is no longer rea-

sonable to presume that there is no risk of exposure to BSE infectious agents once an SRM removal requirement is in place." *R-CALF I*, 359 F. Supp. 2d at 1068. USDA's conclusion that SRM removal is effective, however, had support in the administrative record. *See* Final Rule, 70 Fed. Reg. at 467 (discussing Harvard-Tuskegee Study, which concluded that SRM removal would reduce human exposure to BSE by 95 percent).

e. Maternal transmission of BSE and fetal blood serum

The district court also found the Final Rule arbitrary and capricious because it "does not prohibit cattle of breeding age from being bred either before or after entering the U.S.," and "there is a small probability that BSE can be transmitted maternally." *R-CALF I*, 359 F. Supp. 2d at 1069. In addition, the court found USDA's prohibition of fetal blood serum to be inconsistent with the possibility of allowing pregnant cows to be imported into the United States. *Id.*

[13] Contrary to the district court's findings, however, USDA has made it abundantly clear that cattle may not be imported for breeding under the new regulations. Instead, they must be immediately slaughtered, or fed and slaughtered before they reach 30 months of age. Final Rule, 70 Fed. Reg. at 548-49. Furthermore, USDA discussed the concerns that the district court raised, and found that they were not sufficient to justify addressing. *Id.* at 515 ("Although 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.").

We also find that there is a basis for USDA's disparate treatment of fetal blood serum. As the district court acknowledged, fetal blood serum is used for "bovine vaccine production" and "bovine embryo transfer." *R-CALF I*, 359 F. Supp. 2d at 1069. Because the serum is injected directly into an ani-

mal's bloodstream, it carries a higher risk of transmitting BSE, and "might pose a risk of livestock if used in" these applications. Final Rule, 70 Fed. Reg. at 502. Thus, any inconsistency in the USDA's approach to offspring of imported Canadian cattle and fetal blood serum has an adequate explanation in the record.

f. Mandatory testing of Canadian cattle

Finally, the district court held that it was arbitrary and capricious for the agency not to require all Canadian cattle to be screened for BSE, because the screening test could identify some animals with BSE that would not otherwise be identified. *R-CALF I*, 359 F. Supp. 2d at 1069. The Final Rule, however, contains a lengthy comment in which USDA responded to requests for testing of Canadian cattle. Final Rule, 70 Fed. Reg. at 475-76. USDA explained that, because testing can only detect the disease two to three months before a cow starts demonstrating clinical signs of the disease, a cow may be infected and thus produce a false negative on a test. *Id.* Because of the long incubation period of BSE, and the relatively short window in which non-targeted testing is effective, the USDA did not consider testing to be a "food safety" measure. *Id.* Rather, testing was best used to determine if BSE exists in a country and to determine its prevalence — goals that can both be achieved by targeted testing of animals with clinical signs of BSE. *Id.*

[14] Over the past few years, USDA's policies regarding BSE testing have been subject to a high degree of criticism. *See, e.g.*, *Mad Beef Policy*, Los Angeles Times, Jul. 1, 2005; McGarity, *supra*, at 337-40. These criticisms have generally focused on USDA's refusal to allow voluntary testing of cattle, rather than its refusal to require mandatory testing of Canadian cattle. Although these criticisms are not without their valid points, we do not believe that they are so powerful as to render USDA's testing policy invalid. USDA's approach to BSE testing — that, until better tests are developed, pro-

phylactic measures such as the feed ban and SRM removal are the best methods of protecting human and animal health — is defensible. While its wisdom may be subject to debate on the merits, its choices are not so lacking support in the administrative record as to be "arbitrary and capricious."

g. Conclusion

In sum, USDA decided to reopen the border to Canadian ruminants after making a reasoned determination that the importation of a small number of BSE-infected cattle into this country would not pose a serious risk to humans or livestock. As part of its determination, USDA necessarily decided that the risks inherent in the uncertainty surrounding the current scientific understanding of BSE were insufficiently significant to justify the continued exclusion of Canadian cattle. Rather than criticizing USDA for allowing these risks as a part of its policy, the district court should have evaluated whether there was an adequate basis in the administrative record for USDA's conclusion that the risks were acceptable.

[15] Our review of the record leads us to conclude that the risks inherent in the Final Rule are small, and that the rule likely is supported by an adequate administrative record. We therefore conclude that the district court erred in finding that R-CALF has a strong likelihood of success on the merits of its APA claim.

2. Regulatory Flexibility Act

We also conclude that the district court erred in concluding that R-CALF has a strong likelihood of success on its claim under the RFA. The RFA was passed in 1980 to "encourage administrative agencies to consider the potential impact of nascent federal regulations on small businesses." *Assoc. Fisheries of Maine, Inc. v. Daley*, 127 F.3d 104, 111 (1st Cir. 1997). In certain cases, it requires agencies to publish an "initial regulatory flexibility analysis" at the time a proposed rule

is published, and a "final regulatory flexibility analysis" at the time a final rule is published. 5 U.S.C. §§ 603, 604. Judicial review is available only of the final analysis. 5 U.S.C. § 611.

The RFA requires that a final analysis contain the following:

> (1) a succinct statement of the need for, and objectives of, the rule;
>
> (2) a summary of the significant issues raised by the public comments in response to the initial regulatory flexibility analysis, a summary of the assessment of the agency of such issues, and a statement of any changes made in the proposed rule as a result of such comments;
>
> (3) a description of and an estimate of the number of small entities to which the rule will apply or an explanation of why no such estimate is available;
>
> (4) a description of the projected reporting, recordkeeping and other compliance requirements of the rule, including an estimate of the classes of small entities which will be subject to the requirement and the type of professional skills necessary for preparation of the report or record; and
>
> (5) a description of the steps the agency has taken to minimize the significant economic impact on small entities consistent with the stated objectives of applicable statutes, including a statement of the factual, policy, and legal reasons for selecting the alternative adopted in the final rule and why each one 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).

The RFA imposes no substantive requirements on an agency; rather, its requirements are "purely procedural" in nature. *United States Cellular Corp. v. FCC*, 254 F.3d 78, 88 (D.C. Cir. 2001); *see also Envtl. Defense Ctr., Inc. v. United States EPA*, 344 F.3d 832, 879 (9th Cir. 2003), *cert. denied*, 541 U.S. 1085 (2004) ("Like the Notice and Comment process required in administrative rulemaking by the APA, 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."). To satisfy the RFA, an agency must only demonstrate a "reasonable, good-faith effort" to fulfill its requirements. *United States Cellular*, 254 F.3d at 88; *Alenco Communications, Inc. v. FCC*, 201 F.3d 608, 625 (5th Cir. 2000); *Assoc. Fisheries*, 127 F.3d at 114.

The district court faulted USDA for considering only two alternatives in its final regulatory flexibility analysis: "leaving the regulations unchanged or modifying the import requirements by either requiring that imported beef come from cattle slaughtered at less than 30 months of age or continuing to prohibit the entry of live ruminants." *R-CALF I*, 359 F. Supp. 2d at 1072; *see also* Final Rule, 70 Fed. Reg. at 543. The district court held that the agency erroneously rejected the alternatives of a country-of-origin labeling program and voluntary testing of slaughtered Canadian cattle. *R-CALF I*, 359 F. Supp. 2d at 1072.

[16] The district court erred in concluding that USDA did not meet the RFA's requirements. The Final Regulatory Flexibility Analysis, available at http://www.aphis.usda.gov/lpa/issues/bse/risk_assessment/03-080-3_econ_analysis.pdf, reveals that USDA conducted a detailed economic assessment of the impact of its proposed rule on small businesses. It concluded that the majority of businesses affected by the proposed Final Rule would qualify as small businesses, and that

the effect of the Final Rule was likely to vary depending upon the sector of the cattle industry the business occupied, rather than the size of the business. The negative economic effects the rule would create would generally affect those on the supply side of the beef industry — primarily ranchers — while those on the production side — feedlots and meat packers — would tend to benefit from the rule. In this respect, the alternatives identified by the district court would not necessarily ease the burden on small businesses; rather, they would reallocate the rule's burden to small businesses in different sectors of the beef industry. *Cf. Assoc. Fisheries*, 127 F.3d at 115 (where the majority of businesses affected by a rule are small businesses, "Congress's desire to have agencies write rules that distinguish . . . between big and small businesses has diminished relevance.").

More importantly, the specific concerns the district court raised were considered by USDA in its response to comments on the rule. USDA rejected the first alternative — the implementation of a country-of-origin labeling program — because it did not consider such a program to concern food safety or animal health. Final Rule, 70 Fed. Reg. at 533. USDA rejected the second alternative, voluntary BSE testing, because it does not consider such testing reliable enough to be used as a food safety measure, as discussed above. *See* Part II.A.1.f, *supra*. Given that USDA discussed and rejected these alternatives in the body of its Final Rule, the agency did not err in failing to consider them as alternatives in its final regulatory flexibility analysis. *See Assoc. Fisheries*, 127 F.3d at 115 ("[S]ection 604 does not require that [a final regulatory flexibility analysis] address every alternative, but only that it address significant ones.").

3. National Environmental Policy Act

NEPA was enacted in 1970 to "promote efforts which will prevent or eliminate damage to the environment and biosphere." 42 U.S.C. § 4321; *see also Robertson v. Methow Val-*

ley Citizens Council, 490 U.S. 332, 348 (1989) ("Section 101 of NEPA declares a broad national commitment to protecting and promoting environmental quality."). Like the RFA, NEPA does not impose any substantive requirements on an agency's decision; rather, it mandates only a process that the agency must follow. *Id.* at 350 ("NEPA itself does not mandate particular results, but simply prescribes the necessary process.").

Under NEPA's procedural requirements, an agency must prepare a "detailed statement" on the environmental impact of a proposed rule when that rule is a "major Federal action[ ] significantly affecting the quality of the human environment." 42 U.S.C. § 4332. NEPA provides no private right of action to enforce its requirements. *Stratford v. FAA*, 285 F.3d 84, 88 (D.C. Cir. 2002). Thus, to bring suit to vindicate NEPA's requirements, a plaintiff must rely on the provisions of the APA that confer "standing to an 'aggrieved party' within the meaning of the substantive statute upon which the claim is based." *Id.*; *see also* 5 U.S.C. § 702; *Clarke v. Sec. Indus. Ass'n*, 479 U.S. 388, 394-96 (1987).

[17] To narrow the wide range of potential plaintiffs who may assert a "procedural injury" under this section of the APA, the Supreme Court has adopted a "zone of interests" test.[17] *See id.* at 397 n.12 (stating that the purpose of the zone of

[17]R-CALF incorrectly argues that the Supreme Court's decision in *Bennett v. Spear*, 520 U.S. 154 (1997), drastically narrowed the applicability of the zone of interests test. In *Bennett*, the Court considered the specific question of standing under the Endangered Species Act's citizen-suit provision, not the APA. *Id.* at 161-62. It expressly found that the "ESA's citizen-suit provision . . . negates the zone-of-interests test" based on its language and its purpose. *Id.* at 164-66. Thus, *Bennett* simply does not address actions under NEPA. Indeed, this court has continued to use the zone of interests test to evaluate the standing of NEPA plaintiffs after *Bennett*. *See Save Our Sonoran*, 408 F.3d at 1119; *Cantrell v. City of Long Beach*, 241 F.3d 674, 679 (9th Cir. 2001); *see also Stratford*, 285 F.3d at 88 (applying the zone of interest test in a NEPA action).

interests test is "to exclude those plaintiffs whose suits are more likely to frustrate than to further statutory objectives"). This test imposes the requirement, beyond constitutional standing requirements, that a plaintiff assert an interest "arguably within the zone of interests to be protected or regulated by the statute or constitutional guarantee in question." *Nev. Land Action Ass'n v. United States Forest Serv.*, 8 F.3d 713, 715-16 (9th Cir. 1993). Thus, to assert a claim under NEPA, a plaintiff must allege injury to the environment; economic injury will not suffice. *Id.* at 716 ("[A] plaintiff who asserts purely economic injuries does not have standing to challenge an agency action under NEPA."); *Stratford*, 285 F.3d at 88 ("[A] NEPA claim may not be raised by a party with no claimed or apparent environmental interest."); *W. Radio Serv. Co. v. Espy*, 79 F.3d 896, 902-03 (9th Cir. 1996) ("NEPA's purpose is to protect the environment, not the economic interests of those adversely affected by agency decisions.") (internal quotation marks omitted). A plaintiff can, however, have standing under NEPA even if his or her interest is primarily economic, as long as he or she also alleges an environmental interest or economic injuries that are "causally related to an act within NEPA's embrace." *Port of Astoria, Or. v. Hodel*, 595 F.2d 467, 476 (9th Cir. 1979).

The injuries alleged in R-CALF's complaint do not fall within NEPA's zone of interests. R-CALF points to only one paragraph in its complaint to justify its standing under NEPA. Every allegation in this paragraph, however, concerns the economic interest of R-CALF members except the following: "R-CALF USA members will also be adversely affected by the increased risk of disease they face when Canadian beef enters the U.S. meat supply."

[18] We conclude that this alleged harm is insufficient to fall within NEPA's zone of interests. As mentioned above, "NEPA's purpose is to protect the environment." *W. Radio Serv. Co.*, 79 F.3d at 902; *see also Stratford*, 285 F.3d at 88 ("[A] NEPA claim may not be raised by a party with no

claimed or apparent environmental interest."). More specifically, NEPA is concerned with harm to the physical environment: "If a harm does not have a sufficiently close connection to the physical environment, NEPA does not apply." *Metro. Edison Co. v. People Against Nuclear Energy*, 460 U.S. 766, 778 (1983); *cf. Cantrell*, 241 F.3d at 679 ("In NEPA cases, we have described this 'concrete interest' test as requiring a 'geographic nexus' between the individual asserting the claim and the location suffering an environmental impact."). R-CALF's claimed interest, however, has no connection to the physical environment; rather, it is solely a matter of human health. While it is true that NEPA contains references to human health in its statement of policy, *see* 42 U.S.C. § 4321, as the Supreme Court has explained, those references are to the statute's goals, not its means. *Metro. Edison Co.*, 460 U.S. at 773 ("[A]lthough NEPA states its goals in sweeping terms of human health and welfare, those goals are the *ends* that Congress has chosen to pursue by *means* of protecting the physical environment."). Here, R-CALF has failed to show any relationship between risks to human health and environmental harms. *Cf. Port of Astoria*, 595 F.2d at 476.

[19] Because R-CALF has failed to allege any connection to injury to the physical environment, its injury falls outside of NEPA's zone of interests. Even assuming R-CALF's alleged injury could satisfy the zone of interests test, however, its NEPA claim must fail for the additional reason that R-CALF lacks organizational standing to assert a NEPA challenge.

> An association has standing to bring suit on behalf of its members when its members would otherwise have standing to sue in their own right, the interests at stake are germane to the organization's purpose, and neither the claim asserted nor the relief requested requires the participation of individual members in the lawsuit.

Friends of the Earth, Inc. v. Laidlaw Envtl. Serv. (TOC), Inc., 528 U.S. 167, 181 (2000) (citing *Hunt v. Wash. State Apple Advertising Comm'n*, 432 U.S. 333, 343 (1977)). R-CALF fails the second of these three elements.

As mentioned above, R-CALF is a "non-profit cattle association representing over 12,000 U.S. cattle producers on issues concerning international trade and marketing." As is evident from the paragraph in its complaint that discusses standing, economic issues are highly relevant to its purpose. We do not see the connection, however, between the purported environmental interest that R-CALF attempts to raise here and the "trade and marketing" interests it is organized to protect.

[20] We therefore hold that R-CALF lacks standing to bring a NEPA challenge to the Final Rule. Thus, the district court erred in permitting R-CALF to proceed with its NEPA claim and in concluding that it had a likelihood of success on that claim.[18]

B. Balance of Hardships

After finding that R-CALF had demonstrated a strong likelihood of success on the merits, the district court found that the Final Rule carried a definitive risk of causing "significant irreparable harm." *R-CALF I*, 359 F. Supp. 2d at 1073. The district court identified three ways in which the Final Rule would cause such harm: the increased risk of vCJD to American beef consumers, unspecified environmental injury stemming from USDA's failure to comply with NEPA, and injury to the U.S. beef industry and the U.S. economy that would result from a "stigma" that tainted Canadian beef would inflict upon the U.S. meat supply. *Id.* We believe the district

[18]Given our holding that R-CALF lacks standing to bring a NEPA claim, we need not address the district court's conclusion that the possibility of environmental harm justifies its preliminary injunction.

court's calculus overstated the harm that would result from the rule.

[21] If the Canadian herd were to have a higher infection rate than the U.S. herd, the importation of Canadian cattle might pose some increased risk to the health of the U.S. population, however slight. Even assuming, however, that the introduction of a fatal disease into the United States would constitute irreparable harm, *cf. Harris v. Board of Supervisors*, 366 F.3d 754, 766 (9th Cir. 2004) (accepting as irreparable harm "pain, infection, amputation, medical complications, and death"), the record does not justify the conclusion that the Final Rule makes such harm likely, or even probable. Rather, based on the low incidence of BSE in the Canadian herd, the numerous safeguards against BSE in this country, the lack of any Canadian cattle under 30 months of age found with BSE, and the lack of any case of vCJD attributable to Canadian beef, any increased risk to human and animal health created by the Final Rule is negligible.

[22] In retrospect, the district court's concern over the possibility of "stigma" harming the American beef industry appears to be overstated. The record does not support the district court's alarmist findings that the "irreparable economic harm" the district court foresaw from the stigma of Canadian beef will actually befall the American beef industry. Following the case of BSE diagnosed in a Washington State cow in 2003, consumer demand for, and confidence in, American beef remained strong. Final Rule, 70 Fed. Reg. at 522. According to USDA, American demand for beef in 2004 is estimated to have increased seven to eight percent over 2003 levels. Yet, Canadian beef was flowing into this country throughout 2004 under permits issued by USDA.[19] This evi-

[19]The district court's April 26, 2004, temporary restraining order prevented USDA only from expanding the categories of Canadian beef that could be imported under existing importation permits. The court explicitly limited its order to "all edible bovine meat products beyond those authorized by USDA's action of August 8, 2003 (boneless bovine meat, boneless Veal (meat), and bovine liver) from cattle under the age of 30 months." *R-CALF TRO*, 2004 WL 1047837 at *9.

dence belies the district court's prediction of catastrophic injury to the U.S. beef industry.[20]

C. Preliminary Injunction

[23] Contrary to the district court's conclusion, we conclude that the Final Rule will likely survive judicial scrutiny under the correct legal standard; thus, R-CALF has not shown a likelihood of success on the merits of its action. We also conclude that R-CALF has failed to make the requisite showing of irreparable harm. For these reasons, we must reverse the district court's preliminary injunction. *See Kootenai Tribe v. Veneman*, 313 F.3d 1094, 1125-26 (9th Cir. 2002).

III. CONCLUSION

For the foregoing reasons, the district court's grant of a preliminary injunction is

REVERSED.

[20]Indeed, the district court's finding of irreparable economic harm is undermined by the industry itself. Numerous *amici curiae* briefs have been filed in this case by organizations representing large sectors of the American meat industry, all of whom seek reversal of the preliminary injunction. If the Final Rule posed a true risk of exposing American beef to an irreparable stigma one would not expect to see such a broad coalition of industry members supporting its implementation.