

IN THE UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

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

v.

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

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

BRIEF FOR APPELLEES

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IN THE UNITED STATES COURT OF APPEALS
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No. 06-35512

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

v.

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

BRIEF FOR APPELLEES

STATEMENT OF JURISDICTION

Plaintiff invoked the jurisdiction of the district court pursuant to 28 U.S.C. § 1331. Supplemental Excerpts of Record (SER) 4 (Complaint at 4 ¶ 6). On April 6, 2006, the district court issued a final order granting summary judgment to the government. Excerpts of Record (ER) Tab 10. A timely notice of appeal was filed on June 2, 2006. ER Tab 11; Fed. R. App. P. 4(a)(1)(B).

STATEMENT OF THE ISSUE

Whether the district court erred in sustaining 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."

STATEMENT OF THE CASE

This case concerns a Final Rule issued by USDA on January 4, 2005. See 70 Fed. Reg. 460 (ER Tab 2). The Rule for the first time permits the importation of certain cattle and beef products from countries that are determined to present only a "minimal risk" of introducing BSE into the United States. The Rule also determined that Canada is such a "minimal risk" region.

The Rule was adopted after a five month notice-and-comment period, and after the agency considered 3,379 public comments. It is accompanied by a preamble of more than 80 Federal Register pages explaining the scientific bases for the Rule. Specifically, the preamble discusses the recently discovered evidence about BSE on which the new regulation is based, including how the disease spreads and how it can be prevented. The preamble thoroughly examines the multiple, overlapping measures taken in both Canada and the United States to mitigate the spread of the disease, and sets forth in detail the bases for USDA's conclusion that Canada poses only a "minimal risk" of introducing and spreading BSE into the United States. Ibid.

Plaintiff challenged the Rule as arbitrary and capricious under the APA, and argued further that it violated the National Environmental Policy Act (NEPA) and the Regulatory Flexibility Act. The district court agreed with plaintiff, and entered a preliminary injunction barring the government from enforcing the Rule.

This Court reversed, concluding that the Secretary's determinations had "a sound basis in the administrative record" and that the district court committed legal error "by failing to respect the agency's judgment and expertise," and had improperly "substituted its judgment for" that of the agency. R-CALF v. USDA, 415 F.3d 1078, 1093-94 (9th Cir. 2005).

Following this Court's decision, the district court considered cross-motions for summary judgment. Presented with substantially the same arguments already addressed by this Court, the district court observed that "[t]he Ninth Circuit has reviewed the Final Rule and has concluded that 'the Secretary [of Agriculture] had a firm basis'" for the Rule. ER Tab 10 at 4. The court granted summary judgment for the government, and plaintiff appeals from that judgment.

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 charged with regulating 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 R-CALF, 415 F.3d at 1085-87; 70 Fed. Reg. 460, 461-62 (Jan. 4, 2005). BSE was first diagnosed in the United Kingdom (U.K.) in 1986, and more than 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 it is generally accepted 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 other animals recycled in cattle feed. Ibid.; see also id. at 486 ("In cattle, oral ingestion of feed contaminated with the BSE agent 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. R-CALF, 415 F.3d at 1085-86.

Human exposure to BSE through consumption of contaminated cattle products can cause variant Creutzfeldt-Jakob Disease (vCJD), a chronic and fatal neurodegenerative disease. 70 Fed. Reg. at 462. Of the total number of probable and confirmed cases of vCJD have been identified worldwide, most were linked to exposure in the U.K. Ibid.; R-CALF, 415 F.3d at 1086. 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 Tab 3 at 8 (Engeljohn Decl. ¶ 15); see also 70 Fed. Reg. at 462, 505; R-CALF, 415 F.3d at 1096 ("The limited nature of the vCJD outbreak indicates that there may be a substantial species barrier that prevents BSE from easily infecting humans."); id. at 1097 (noting data "suggest[ing] a substantial species barrier that may protect humans").

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). 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, which 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 BSE agent have been overwhelmingly successful, even in Europe where exposure is assumed to be the highest. Ibid.; R-CALF, 415 F.3d at 1087 ("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 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. See R-CALF, 415 F.3d at 1088 (acknowledging agency’s work with OIE). The OIE guidelines reject the assumption that the occurrence of BSE, by itself, requires suspension of cattle or beef imports from that nation, and instead provides a system of risk classification. 70 Fed. Reg. at 463.

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 interlocking safeguards provided by the overall regulatory framework now in place. 70 Fed. Reg. at 465-66.

B. Relevant Criteria For Evaluating A Region's Risk.

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

First, the region 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 region must conduct surveillance for BSE at levels meeting or exceeding OIE recommendations.

Second, if BSE has been detected, the region 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 region 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 and beef imports from Canada.

The Secretary explained that Canada had instituted appropriate risk mitigation measures, including a feed ban instituted in August 1997. See R-CALF, 415 F.3d at 1089-90 (noting Canada's feed ban went into effect in 1997); 70 Fed. Reg. at 467. Canada has for years met or exceeded the OIE-recommended level of BSE surveillance. 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. These investigations revealed that 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").

The Secretary further 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 specified animal tissues that could have infectivity (known as SRMs) to 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.

To further ensure against the possible dissemination of BSE, the Secretary permitted importation of cattle only if they are under 30 months of age. This age limitation is important 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; SER 80. Of cattle that developed BSE during the epidemic in the U.K., only 0.01 percent were less than 30 months old. See SER 80; see also SER 46-48 (Ferguson Decl. ¶ 11). Moreover, such animals would be born long after Canada implemented its feed ban in 1997 and adopted a regulatory regime that is comparable to that in the United States. Thus, little risk exists that any imported cattle 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. SER 81.

Imported 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. 70 Fed. Reg. at 480, 548. They may be imported only 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). 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). 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 would be identified. The mitigation measures were designed with this possibility in mind. See 70 Fed. Reg. at 514.

III. PRIOR PROCEEDINGS.

A. District Court Preliminary Injunction.

Plaintiff Ranchers Cattlemen Action Legal Fund United Stockgrowers of America (R-CALF) brought this action seeking

declaratory and injunctive relief against USDA prohibiting it from implementing the new rule. SER 34. On March 2, 2005, the district court granted a preliminary injunction barring the government from enforcing USDA's new Rule.

The district court held that R-CALF was likely to succeed in demonstrating that the final rule violated the APA, because the rule (in the court's view) was arbitrary and capricious in several different respects. The district court also held that R-CALF was likely to succeed on its claim under NEPA and the Regulatory Flexibility Act, and that the balance of the harms and the public interest tipped in R-CALF's favor.

B. This Court's Decision.

In a comprehensive opinion, this Court reversed the district court's judgment and vacated the injunction. See 415 F.3d 1078 (9th Cir. 2005).

The Court explained that the district court had fundamentally misunderstood the judicial role in review of agency action under the APA: "the district court committed legal error by failing to respect the agency's judgment and expertise" and "repeatedly substituted its judgment for the agency's, disagreeing with USDA's determinations even though they had sound basis in the administrative record." Id. at 1093-94. This Court then proceeded to carefully and thoroughly address and reject each of the six ways in which the district court found the agency to have acted arbitrarily.

First, the Court reversed the district court's ruling that the agency's "minimal risk" category was arbitrary because it lacked quantitative standards. The Court held that requiring a quantitative standard "was incorrect" because no statute mandated such an approach. Id. at 1097. Moreover, given the comprehensive evidence before the agency, the administrative record was more than adequate to support USDA's conclusion that Canada poses a minimal risk. Id. at 1096-97.

Second, the district court "impermissibly substituted its judgment for that of the agency" in concluding that USDA had incorrectly calculated the prevalence of BSE in Canada. Id. at 1097. As the Court noted, USDA's calculation was based on internationally accepted guidelines and was well supported by the administrative record. Id. at 1097-98.

Third, the Court reversed the district court holding that USDA had arbitrarily placed reliance on Canada's feed ban, which the district court believed was ineffective. This Court disagreed, holding that "[t]he trial court's criticisms of Canada's feed ban are * * * baseless" and "incorrect," id. at 1098, and that "the district court gave no reason for rejecting USDA's expert scientific opinion" on the efficacy of Canada's feed ban, id. at 1099.

Fourth, this Court held that the agency had reasonably concluded, based on the record, that removing SRMs would be an effective means of combating the spread of BSE, rejecting the

district court's contrary determination. Id. at 1099.

Fifth, the Court rejected the conclusion that the agency acted arbitrarily in failing to ban cattle of breeding age. This Court pointed out that the rule does not permit importation of cattle for breeding; rather, the rule requires that after importation, cattle must be immediately slaughtered or fed and then slaughtered. Ibid.

Sixth, this Court concluded that USDA had acted reasonably in declining to impose mandatory BSE testing of all Canadian cattle, given the substantial limitations of BSE testing, especially testing clinically normal cattle. Id. at 1099-1100; see also id. at 1086 (noting that "current testing methodology is not particularly effective in identifying" BSE).

This Court also reversed the district court's invalidation of the rule based on plaintiff's claims under the Regulatory Flexibility Act, see id. at 1100-02, and under NEPA, see id. at 1102-04.

C. District Court Summary Judgment Decision.

On remand, the parties cross-moved for summary judgment. On April 6, 2006, the district court entered a final judgment granting summary judgment to the government. ER Tab 10. As discussed below, plaintiffs offered substantially the same arguments already addressed by this Court. The court found no basis for departing from this Court's reasoning, noting that this Court reversed and vacated the preliminary injunction because the

agency had a "firm basis" for its rule and that it was necessary to respect the agency's scientific judgment and expertise. Id. at 4.

On June 2, 2006, plaintiff filed a timely notice of appeal. ER Tab 11. On August 18, 2006, the government filed a motion for summary affirmance, which an Appellate Commissioner denied on November 14, 2006.

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. After reviewing the administrative record and the Secretary's extensive administrative decision, this Court concluded that the rule had "a sound basis in the administrative record," R-CALF v. USDA, 415 F.3d 1078, 1093-94 (9th Cir. 2005), and concluded that a variety of legal challenges mounted by plaintiff lacked legal merit.

Plaintiff offers no basis for concluding that this Court's decision was wrong in any respect or that other grounds exist for holding the regulation invalid.

As this Court noted, 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 disease surveillance and demonstrate its ability to respond to and isolate any instance of the disease. The Secretary's conclusion is also supported by authoritative risk analyses, which concluded that the preventative measures in place in both the United States and Canada made it "extremely unlikely" that BSE would become established in the U.S.

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 important because BSE has a long incubation period and animals of this age would

not have developed significant levels of infectivity even if exposed. 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 cattle 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.

II. Plaintiff urges that the district court gave short shrift to its arguments and attached undue weight to this Court's decision. This Court reviews the grant of summary judgment de novo and can evaluate the merits of plaintiff's contentions. Plaintiff's request for a remand is without basis.

Contrary to plaintiff's suggestion, the district court did not believe it was powerless to consider plaintiff's contentions. Instead, it recognized that this Court had already examined and rejected plaintiff's legal contentions, that it was not free to ignore this Court's decision, and that plaintiff had offered no persuasive ground for holding the regulation invalid in light of the Court's reasoning.

Although plaintiff urges that this Court's prior decision was not "law of the case," the district court never invoked the law of the case doctrine. Whether or not the decision is "law of the case," the district court was not free to disregard this Court's decision. This Court has discretion to treat the previous ruling as law of the case, see Hilao v. Estate of

Marcos, 103 F.3d 767 (9th Cir. 1996), and, in any event, plaintiff offers no reason for rejecting any aspect of the Court's reasoning or holding the regulation invalid.

STANDARD OF REVIEW

"This court reviews de novo the district court's grant of summary judgment upholding an agency decision." Northern Alaska Environmental Ctr. v. Kempthorne, 457 F.3d 969, 975 (9th Cir. 2006).

ARGUMENT

I. THE SECRETARY'S FINAL RULE WAS A REASONABLE EXERCISE OF HIS BROAD REGULATORY AUTHORITY THAT IS FIRMLY BASED ON THE VOLUMINOUS ADMINISTRATIVE RECORD.

A. The Regulation Is Entitled To Great 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 statute's use of the word "may" confers "wide discretion" on the Secretary to deal with import restrictions and "does not impose any requirement on USDA" to implement particular restrictions.

R-CALF, 415 F.3d at 1094.

As the Court also emphasized, “[d]eference 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.” R-CALF, 415 F.3d at 1093. See also Vigil v. Leavitt, 381 F.3d 826, 833 (9th Cir. 2004) (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’”) (citations omitted); 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 Mitigation Measures Are In Place, Occurrences of BSE Do Not Of Themselves Require An Absolute Ban Of All Cattle and Beef Imports From The Region.

It is common ground that avoiding a credible threat of dissemination of BSE is of paramount importance. The final rule is faithful to that goal, while permitting limited importation of cattle and beef products from Canada. The rule is amply supported by the agency's expert scientific analysis regarding BSE and how to stop its introduction and dissemination, including new information discovered in the last several years. And the rule's determination that Canada poses only a minimal risk of spreading BSE in the United States reasonably relies on a "comprehensive system" of "multiple, interlocking safeguards" that mitigate against the introduction and dissemination of BSE into the United States. R-CALF, 415 F.3d at 1095.

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; R-CALF, 415 F.3d at 1087.

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. 70 Fed. Reg. at 465-66; R-CALF, 415 F.3d at 1087-88. 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 specified risk materials, or "SRMs," and prohibited their use in human food. R-CALF, 415 F.3d at 1088. 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 various FDA-regulated products, including dietary supplements and cosmetics.

Second, FSIS prohibited mechanically separated beef from being used for human consumption and strengthened the requirements for beef products produced by Advanced Meat Recovery systems. 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; R-CALF, 415 F.3d at 1088.

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. SER 56-65 (Harvard-Tuskegee Study). 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; *see R-CALF*, 415 F.3d at 1096 (discussing Harvard-Tuskegee Study). 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." 70 Fed. Reg. at 506. 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. As noted above (supra at 11), this restriction is important because BSE has an incubation period of several years, see R-CALF, 415 F.3d at 1086 ("BSE has an incubation period that lasts for four or five years on average."), and thus cattle under 30 months are unlikely to have significant levels of infectivity, even if exposed. Indeed, 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. SER 80-81. 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. SER 46-48, 51-53 (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. SER 79. 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. SER 81.

C. The Secretary's Determination That A Total Ban On Canadian Cattle and Beef Imports Is Not Necessary To Prevent Introduction and 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 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; see R-CALF, 415 F.3d at 1098-99 (noting efficacy of Canada's feed ban). In addition, Canada has far exceeded the OIE-recommended level of BSE surveillance. Whereas OIE guidelines specify testing of approximately 300 cattle each year, in 2004 Canada tested 23,500, see 70 Fed. Reg. at 468, and in each of 2005 and 2006 tested more than 55,000 cattle.¹ This level of surveillance far exceeds international standards and is in proportion to the number of cattle tested in the United States, id. at 469; SER 74-75. Indeed, Canada has taken some risk mitigation measures even in advance of the United States, requiring that "specified risk materials" or SRMs, such as brain, spinal cord, 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

¹ Canada's figures for 2004 through 2007 are found at <http://www.inspection.gc.ca/english/anima/heasan/disemala/bseesb/surv/surve.shtml> (last visited Feb. 26, 2007).

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 (May 2003 cow); 69 Fed. Reg. at 10,634 (December 2003 cow); R-CALF, 415 F.3d at 1089 (discussing USDA investigations).

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; R-CALF, 415 F.3d at 1090 (noting USDA investigation). 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. Plaintiff's Objections to the Rule are Meritless.

Plaintiff offers objections to the Rule that echo, with only minor variations, the arguments already rejected by this Court.

1. Plaintiff mistakenly contends that the discovery of Canadian cattle diagnosed with BSE demonstrates that Canada is not a "minimal risk" region. See Br. 2-6, 27, 34-35. The premise of the "minimal risk" region is that BSE might have been detected in the area. See 70 Fed. Reg. at 549-50 (9 C.F.R. § 94.0) (definition of "bovine spongiform encephalopathy (BSE) minimal-risk region"). The point of the regulation is that importation of certain cattle and beef products may be permitted even from regions where BSE has been detected, so long as specified mitigation measures are in place. That approach is consistent with OIE guidelines, which 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. See 70 Fed. Reg. at 463.

This Court was fully aware that Canadian cattle had been

diagnosed with BSE both before and after issuance of the Final Rule. Five of the diagnosed cattle now relied upon by the plaintiff were known at the time of this Court's prior decision upholding USDA's rule. See R-CALF, 415 F.3d at 1088 (cow discovered in May 20, 2003); id. at 1089 (Dec. 23, 2003 cow); id. at 1090 (Jan. 2 and 11, 2005 cows); id. at 1087, 1090 n.11 (June 24, 2005 cow). Plaintiff argued in the prior appeal that the agency's rule is arbitrary in light of these infected Canadian cows, and that argument is no more persuasive now than it was then.

The discovery of additional infected cows in the time since this Court's decision does not alter the analysis. As noted above (supra at 12, 29), USDA's analysis recognized the possibility that additional infected cows might enter the United States, and concluded, if this occurred, it would not cause BSE to be spread in this country. 70 Fed. Reg. at 514 ("Even if an infected cow did enter the United States, the Harvard-Tuskegee Study indicates it would be unlikely to lead to the spread of BSE in cattle or to human exposure to the BSE agent.").

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.

In short, given the multiple, interlocking safeguards upon which the rule is predicated, Canada poses a minimal risk of spreading BSE in this country even if infected cows from Canada entered the United States. Thus, plaintiff’s reliance on a few additional infected cows is misplaced, and certainly does not show that USDA’s rule is arbitrary or capricious. Moreover, all the infected cows were well over 30 months old, and thus could not have been imported into the United States even under USDA’s rule.

2. Plaintiff (Br. 33-34) appears to question the agency’s reliance on the Harvard-Tuskegee Study, suggesting that it is outdated because it was completed in 2001 and relied on studies from the 1990s. But the Study was updated once in 2003, see 70 Fed. Reg. at 467, and again in 2004, ibid. (discussing Gray & Cohen memorandum), as plaintiff acknowledges, see Br. 41 (noting 2004 modification to Harvard-Tuskegee Study).

3. Plaintiff also questions USDA’s conclusion that Canada’s feed ban is effective. See Br. 32. This is the same argument that was raised in the prior appeal and rejected by this Court. See R-CALF, 415 F.3d at 1098 (rejecting criticism of Canada’s feed ban as “baseless”). Plaintiff offers no reason to reach a different conclusion in this appeal. Indeed, plaintiff

admits that "experts agree that the most important means of preventing the spread of BSE in cattle is limitations on cattle feed." Br. 3.

Plaintiff refers to a GAO study,² but that study does not assist plaintiff's attack on Canada's feed ban. The Study does not even discuss the Canadian feed ban at all, but simply suggests ways to improve the enforcement of the U.S. feed ban. Plaintiff also refers (Br. 32) to "experience in other countries," but as the final rule noted, "[c]ontinued monitoring and surveillance in Europe - where the exposure is assumed to be the highest - have demonstrated the effectiveness of control measures that have been enacted, such as feed bans that prevent the recycling of the agent." 70 Fed. Reg. at 463. This Court emphasized the same point in the prior appeal. R-CALF, 415 F.3d at 1087 ("[F]eed 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."). Finally, plaintiff states that there are "practical difficulties of enforcing a feed ban." Br. 32. But the agency's examination showed that Canada strongly enforces its feed ban and has a high rate of compliance. 70 Fed. Reg. at 467-68 ("Canada

² GAO, Mad Cow Disease (February 2005). The GAO Study is attached as Exhibit 4 to plaintiff's district court summary judgment motion, and is reproduced at SER 156-193.

has provided information, including statistics on compliance, demonstrating that an effective feed ban is in place * * * Canadian government authorities inspect rendering facilities, feed manufacturers, and feed retailers to ensure compliance with the feed ban. * * * [I]nspections have shown a high level of compliance.”).

4. Plaintiff objects (Br. 20) that the final rule exceeds the agency’s authority under the Animal Health Protection Act (AHPA), 7 U.S.C. § 8301 et seq. But the AHPA states only that the Secretary “may” prohibit or restrict animal importations if he determines it is necessary to prevent dissemination of an animal disease, 7 U.S.C. § 8303(a)(1), thus conferring broad discretion on the agency to determine whether restrictions are necessary and what form they should take. As this Court declared in rejecting the contention that the final rule is contrary to the AHPA, “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.” R-CALF, 415 F.3d at 1094. See also Cactus Corner v. USDA, 450 F.3d 428, 433 (9th Cir. 2006) (same). Nothing in the AHPA compels the Secretary to retain permanently the prior

restrictions on Canadian cattle and beef products imports.

Plaintiff also suggests (Br. 32-33) that the final rule is inconsistent with the Animal Disease Assessment, Prevention, and Control Act of 2001, Pub. L. No. 107-9, 115 Stat. 11. That statute does no more than impose a requirement that the Secretary report to Congress certain information about BSE, and furnishes no basis for plaintiff's challenge.

5. In the prior appeal, plaintiff challenged USDA's reliance on the removal of SRMs (those parts of cattle at risk of containing BSE). This Court rejected that argument because the efficacy of SRM removal was well supported in the administrative record, as the Harvard-Tuskegee Study showed that SRM removal would reduce human exposure by 95%. See R-CALF, 415 F.3d at 1099.

Plaintiff argues that the 95% figure is inconsistent with a different study indicating that SRM removal reduces human exposure by only 80%. See Br. 41.

Plaintiff's argument is once again wide of the mark. All the sources cited by plaintiff are consistent with USDA's conclusion that Canadian cattle and beef imports present only a very small risk of spreading BSE in the United States, and that removing SRMs reduces that risk even more. See ER Tab 3 at 8 (Engeljohn Decl. at 8 ¶ 14) ("With regard to the USDA's food safety rules issued in January 2004, our analysis concluded that the mitigation measures, specifically the SRM mitigations, would

reduce the already extremely low risk of BSE exposure by at least 80 percent."); 70 Fed. Reg. 58,570, 58,587 (Oct. 6, 2005) ("The potential human exposure to infectious materials from consuming beef is already small [and] the two interim rules issued in January 2004 reduced human exposure to infectious materials by an average of 80 percent."); 70 Fed. Reg. at 467 (noting "a very low risk exists of BSE becoming established or spreading should it be introduced into the United States," and that "a ban on SRMs * * * from inclusion in human and animal food would reduce * * * potential human exposure to BSE by 95 percent * * *.").

The precise figures vary from study to study, see 70 Fed. Reg. at 58,587 (80% figure relying on a USDA preliminary analysis); 70 Fed. Reg. at 467 (95% figure relying on 2003 Harvard-Tuskegee Study), but the conclusion is the same.

6. In the prior appeal, the district court found that the final rule arbitrarily ignored the possibility of BSE spreading through pregnant cows. While the final rule did not expressly prohibit importation of cattle for breeding purposes, the rule in effect did so. As this Court noted in the prior appeal, under the final rule "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." R-CALF, 415 F.3d at 1099.

After this Court's decision, the agency issued a "technical amendment" to the final rule, making express what had been

implicit in the final rule - that "[t]he final rule does not allow the importation of breeding cattle * * * from minimal-risk regions * * * and the rule allows the importation of bovines * * * for slaughter only." 71 Fed. Reg. 12,994, 12,995 (Mar. 14, 2006). The amendment explains that "the regulatory text of the final rule does not explicitly address whether pregnant bovines * * * may be imported for immediate slaughter or for movement to a feed lot for subsequent movement to slaughter." Ibid. The technical amendment simply "prohibit[s] explicitly" what was implicitly prohibited in the original final rule. Id. at 12,996.

Plaintiff urges (Br. 42-44) that the amendment reflects inconsistent positions. But the USDA has always taken the view that cattle could not be imported for breeding purposes; the technical amendment only makes explicit what was implicit in the original final rule. It is difficult, in any event, to understand plaintiff's objection. Plaintiff believes that importation of pregnant cows should be barred. The agency's rule makes explicit that it does precisely what plaintiff believes should be done.³

7. Plaintiff contends without explanation (Br. 40) that USDA's decision to limit beef imports to those from cattle under

³ Similarly, plaintiff points (Br. 40-41) to an FDA proposed rule that would strengthen the feed ban in the United States. For the reasons explained in this brief, USDA's reliance on the existing U.S. feed ban is well supported by science, and plaintiff never explains why a proposal to improve the feed ban would be arbitrary or capricious.

30 months of age demonstrates that the rule is arbitrary and capricious. No basis exists for this assertion. Shortly before the original final rule was to go into effect, two additional infected cows were discovered in Canada. An investigation revealed that the two cows were born in 1996 and 1998, see 70 Fed. Reg. 18,252, 18,255, 18,258 (Apr. 8, 2005), and thus were over 30 months old when they were discovered to be infected. Thus, in an abundance of caution, the Secretary decided to suspend the portion of the final rule that would have permitted the importation of beef products from cattle over 30 months old. See 70 Fed. Reg. 12,112 (Mar. 11, 2005); 415 F.3d at 1089-90 (noting under 30 months restriction).

8. Finally, plaintiff makes a brief reference to a "new declaration[]" by Stanley Prusiner, see Br. 29-30, although it does not explain how this declaration demonstrates that the rule is infirm.

Indeed, the declaration (ER Tab 8) only offers the same type of arguments already rejected by this Court. For example USDA's research indicates a substantial species barrier protecting humans from BSE. See R-CALF, 415 F.3d at 1096-97 (discussing species barrier). Specifically, "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 Tab 3 at 8 (Engeljohn Decl. ¶ 15); see also 70 Fed. Reg. at 462, 505. Plaintiff's declaration questions precisely how strong the human

species barrier to BSE is. ER Tab 8 at 5. As in their previous submissions, plaintiff asks this Court to substitute its opinions for the expert judgments of the agency, an approach this Court firmly rejected. See R-CALF, 415 F.3d at 1094 (reversing the district court for "repeatedly substitut[ing] 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").

Similarly, plaintiff's declaration notes the possibility that BSE could be transmitted through bovine blood. ER Tab 8 at 6. As the Secretary noted in the final rule, 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 studies involved only the transfusion of blood from known TSE-infected animals and 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," including those within the European Commission Scientific Steering Committee. ER Tab 3 at 9 (Engeljohn Decl. ¶ 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).

Plaintiff's declaration also endorses blanket testing of all slaughtered cattle, and suggests using a test developed by a company owned by the declarant. ER Tab 8 at 7-9. Plaintiff made the same argument in the prior appeal, contending that the agency acted arbitrarily in failing to require mandatory testing. This Court rejected the argument, noting that the Secretary's rationale for rejecting mandatory testing is sufficiently supported by the administrative record. See R-CALF, 415 F.3d at 1099-1100. As the Secretary explained, "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 SER 45 (Ferguson Decl. ¶ 10); 70 Fed. Reg. at 475, 534. The agency thus reasonably rejected mandatory testing.

Lastly, plaintiff's declaration asserts that "it is neither safe nor scientifically justified to assume that all cattle under 30 months of age present no risk of harboring BSE prions and thus, cannot cause vCJD in humans." ER Tab 8 at 9-10. The

declaration misunderstands the nature of the rule. The Secretary did not conclude that there was no risk that cattle would harbor BSE prions, and this Court explicitly rejected the district court's view that the agency was required to achieve a "zero-risk" of BSE. See R-CALF, 415 F.3d at 1094 n.14.⁴

II. PLAINTIFF'S ATTACKS ON THE DISTRICT COURT PROVIDE NO REASON TO REVERSE THE GRANT OF SUMMARY JUDGMENT.

As we have shown, the rule at issue is grounded in the record and does not constitute an abuse of the Secretary's broad authority. Aside from its challenges to the merits of the regulation, discussed above, plaintiff attacks the district court's consideration of its summary judgment motions on various grounds. It argues that the court did not consider its arguments or the record evidence, see Br. at 9-10, 12-14, 19, 28, 39, did not hold a hearing on the summary judgment motions, id. at 11-12, 19, 22, 44, and accorded undue weight to this Court's prior opinion, id. at 13-18, 23-26, 45-46.

It is the last of these objections that forms the thread of plaintiff's argument. Plaintiff believes that the district court's view of its contentions was wrongly colored by this

⁴ At all prior stages of this litigation, plaintiff contended that the final rule violated not only the APA, but also NEPA and the Regulatory Flexibility Act. See, e.g., R-CALF, 415 F.3d at 1100-04. In its opening brief, however, plaintiff raises no claims or arguments relating to NEPA or the Regulatory Flexibility Act, and hence has waived any such objections. In any event, they are meritless for the reasons discussed in this Court's prior decision. Ibid.

Court's decision, to which plaintiff attaches little significance.

Plaintiff is quite wrong to discount this Court's previous decision. Reviewing the administrative record and further submissions of the parties, the Court addressed a series of legal holdings in a comprehensive opinion. Plaintiff was free to make additional legal arguments or to introduce new relevant exhibits to the extent doing so would be consistent with principles of review under the Administrative Procedure Act. Plaintiff could also have sought to identify errors in this Court's reasoning that might justify review of its analysis by the district court or this Court.

Instead, plaintiff presented (and presents on appeal) substantially the same arguments already considered and rejected by this Court. When the district court observed that its "hands are tied" by this Court's decision, ER Tab 10 at 4, it stated the obvious: the court was not free to reinstate its previous holding; it could not simply disregard this Court's analysis; and plaintiff offered no grounds for concluding that this Court's reasoning or its understanding of the record was incorrect.

Plaintiff's argument that this Court's prior opinion was not "law of the case," is largely beside the point. Br. 23-24. The district court gave no indication that it believed itself bound by the law of the case doctrine. Instead, the court correctly understood that it could not ignore this Court's legal analysis

and discussion of the administrative record.

In any event, the district court would not have erred in treating the prior decision as law of the case. "A fully considered appellate ruling on an issue of law made on a preliminary injunction appeal . . . does become law of the case for further proceedings in the trial court on remand and in any subsequent appeal." Wright & Miller, 18B Federal Practice & Procedure § 4478.5. Thus, in Hilao v. Estate of Marcos, 103 F.3d 767 (9th Cir. 1996), the Court's rejection of a jurisdictional argument on appeal from a preliminary injunction was treated both as both controlling law of the Circuit and law of the case. Id. at 772. The Court's full consideration of the legal issues in its prior decision in this case should be treated in the same manner. Indeed, another panel of this Court has already treated this Court's prior decision as the law of the Circuit. See Cactus Corner, LLC v. U.S. Dep't of Agriculture, 450 F.3d 428, 433-34 (9th Cir. 2006).

While plaintiff correctly points out that the law of the case doctrine is discretionary, see Br. 25-26, it is equally clear that the district court had no discretion to ignore this Court's decision.

No basis exists for plaintiff's assertion that the district court failed to consider the merits of its arguments and the record evidence. See, e.g., Br. at 19 (contending that district court "ruled upon [the cross-motions for summary judgment]

without any analysis of the evidence and arguments that had been presented subsequent to the preliminary injunction hearing”).

At the time it entered summary judgment, the court had before it all of plaintiff’s briefs, see ER Tab 12 (Docket Entry Nos. 103, 140, 164, 180), and all the record evidence, see ibid. (Docket Entry Nos. 42, 132). Plaintiff points to no statement by the court suggesting a failure to consider those arguments and evidence. A district court is presumed to have examined the arguments and evidence before it grants summary judgment, and it is not obliged to make specific notation of its review of every contention or item of evidence.

Plaintiff’s summary judgment motion, like its appellate brief, presented arguments that had already been considered by the district court and by this Court. The court did not abuse its discretion in declining to hold a hearing on these arguments, and it was not obliged to explain at length why it would not accept arguments previously examined and rejected by this Court.

CONCLUSION

For the foregoing reasons, the judgment of the district court should be affirmed.

Respectfully submitted,

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FEBRUARY 2007

**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 9992 words.

JOSHUA WALDMAN
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CERTIFICATE OF SERVICE

I hereby certify, pursuant to Fed. R. App. P. 25(d)(2) and Ninth Circuit Rules 30-1.7 and 31-1, that on February 26, 2007, I filed an original and 15 copies of the foregoing brief and five copies of the Supplemental Excerpts of Record by causing them to be sent by Federal Express overnight delivery to:

MS. CATHY CATTERSON
Clerk, United States Court of Appeals
for the Ninth Circuit
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I also hereby certify that pursuant to Fed. R. App. P. 25(d)(2) and 31(b) and Ninth Circuit Rule 30-1.7, on February 26, 2007, I caused two copies of the foregoing brief and 1 copy of the Supplemental Excerpts of Record to be served by Federal Express overnight delivery (or by U.S. mail as indicated) on the counsel listed below.

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STATEMENT OF RELATED CASES

Counsel is aware of no pending related case within the meaning of Ninth Circuit Rule 28-2.6.