

No. 06-35512

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, *et al.*,
Defendants-Appellees.

On Appeal from the United States District Court
for the District of Montana, D.C. No. CV-05-00006-RFC

BRIEF OF APPELLANT

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**RANCHERS CATTLEMEN
ACTION LEGAL FUND
UNITED STOCKGROWERS
OF AMERICA'S
RULE 26.1 CORPORATE
DISCLOSURE STATEMENT**

Pursuant to Fed. R. App. P. 26.1, Plaintiff-Appellant Ranchers Cattlemen Action Legal Fund United Stockgrowers of America (“R-CALF USA”) hereby states that it is a non-profit corporation organized under the laws of the State of Montana. R-CALF USA has no parent corporation, and no publicly traded company owns 10 percent or more of the stock of R-CALF USA.

Dated: December 26, 2006

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JURISDICTIONAL STATEMENT

Plaintiff-appellant Ranchers Cattlemen Action Legal Fund United Stockgrowers of America (“R-CALF”) filed the underlying action, seeking judicial review under the Administrative Procedure Act, 5 U.S.C. § 706, invoking the district court’s jurisdiction under 28 U.S.C. § 1331 (federal question). The district court order granting summary judgment in favor of defendants U.S. Department of Agriculture and Mike Johanns, in his capacity as Secretary of Agriculture (“USDA”) and against R-CALF was entered April 6, 2006. This Court has jurisdiction to review that final decision of the district court under 28 U.S.C. § 1291. R-CALF filed its notice of appeal on June 5, 2006, within the 60 days allowed under Fed. R. App. P. 4(a)(1)(B) for filing a notice of appeal in a case in which the United States is a party.

ISSUES PRESENTED FOR REVIEW

Whether the district court erred when it denied R-CALF’s motion for summary judgment and granted USDA’s motion for summary judgment based solely on this Court’s decision vacating a preliminary injunction

issued before the motions for summary judgment were filed, and without considering the merits of those motions and supporting affidavits?

STATEMENT OF FACTS

This case concerns a decision by the United States Department of Agriculture (“USDA”) Animal and Plant Health Inspection Service (“APHIS”) to lift a ban on the importation of live cattle and edible bovine products from Canada for human consumption. In a final rule published January 4, 2005 and titled “Bovine Spongiform Encephalopathy, Minimal-Risk Regions and Importation of Commodities; Final Rule and Notice,” 70 Fed. Reg. 460 (the “Final Rule”) (Excerpts of Record (“ER”) Tab 2), USDA reversed a May 29, 2003, APHIS decision banning imports of cattle and edible bovine products from Canada, after a Canadian cow was confirmed to have bovine spongiform encephalopathy (“BSE”), commonly known as “Mad Cow Disease.”¹

BSE is a degenerative, invariably fatal neurological disorder of cattle that results from infection by an unconventional transmissible agent. BSE

¹ Federal Register notices to which the Court may need to refer are included in the Addendum to this brief, except for the challenged regulation, which is included in the Excerpts of Record at Tab 2.

was not known to exist in the United States until the discovery in late 2003 of an infected dairy cow in Washington State that had previously been imported from Canada. *See* 68 Fed. Reg. 62,386 (November 4, 2003). Eating meat products contaminated with the agent for BSE is believed to cause variant Creutzfeldt-Jakob Disease (“vCJD”) in humans, a degenerative, invariably fatal neurological disease for which there is no known cure. Both BSE and vCJD are generally thought to result from infection with a type of mis-formed protein called “prions.”

Eating BSE-contaminated bovine meat and other products is believed to have resulted in the death of over 150 people in the United Kingdom and Europe, and at least three people in the United States and one person in Canada, as well. *See* 70 Fed. Reg. (ER Tab 2) at 462 and <http://www.cjd.ed.ac.uk/vcjdworld.htm>. Because of the incurable nature of this horrible, degenerative disease, fears about Mad Cow Disease decimated the market for beef from the United Kingdom in the 1990s.

Transmission of BSE can occur when cattle consume feed or supplements that contain bovine protein, typically meat and bone meal. This is believed to have been the primary route of BSE transmission in the past, and experts agree that the most important means of preventing the spread of BSE in cattle is limitations on cattle feed, so that healthy animals are not

exposed to BSE prions through feed that contains protein from animals infected with BSE. The U.S. adopted a ban on certain animal proteins in cattle feed in 1997, and Canada adopted a similar restriction in August of 1997 (the “Canadian feed ban”). *See* 70 Fed. Reg. (ER Tab 2) at 512.

USDA relies on the Canadian feed ban for its conclusion that BSE is unlikely to be spreading in the Canadian herd, and it relies on the similar feed ban in the U.S. for its conclusion that, if BSE-infected cattle are imported from Canada, there is virtually no risk that those cattle will transmit BSE to domestic cattle. *See, e.g.,* 70 Fed. Reg. (ER Tab 2) at 465; 504-505.

Once BSE was discovered in a native Canadian cow in May 2003, the United States’ largest beef export trading partner, Japan, threatened to ban imports of US beef unless that beef was positively identified as not having come from Canadian-origin cattle. *See id.* at 524. Then, after the December 2003 discovery of BSE in a Canadian-raised cow that had been imported to Washington State, Japan, Korea, Taiwan, and most of the other countries to which the U.S. exports beef banned imports of US beef because of fears that BSE had entered the United States from Canada. This had a devastating effect on U.S. exports of beef, reducing that market by billions of dollars per year. 70 Fed. Reg. (ER Tab 2) at 521. The Asian markets remained largely

closed to U.S. exports of beef even now. *Id.* at 524-25 ; *see also, e.g.*, December 6, 2006 press statement by Secretary Johanns (“...South Korean officials are determined to find an excuse to reject all beef products from the United States”), available on USDA website at <http://www.usda.gov/wps/portal/!ut/p/.s.7.0.A/7.0.1RD?printable=true&contentidonly=true&contentid=2006/12/0458.xml>.

On December 29, 2004, the same day that then-Secretary of Agriculture Ann Veneman announced the issuance of the Final Rule, the Canadian Food Inspection Agency (“CFIA”) announced publicly that yet another cow in Alberta had been tentatively identified as having BSE. That diagnosis was confirmed on January 2, 2005. On January 11, 2005, CFIA announced that a fourth cow from Alberta, this one only six years and nine months old, had been confirmed to have BSE. In 2006 alone, five additional cases of BSE have been identified in Canada. *See* CFIA statements at <http://www.inspection.gc.ca/english/anima/heasan/disemala/bseesb/comence.shtml> and <http://www.inspection.gc.ca/english/corpaffr/newcom/2006/20060823e.shtml>. This includes three cases that were found in Alberta Province in 2006, confirming the BSE hot spot there. *Id.*; *see also* ER Tab 5 (USDA analysis of BSE in cattle in North America published in April 2005 that concluded

there is a BSE “hot spot” in the province of Alberta [Exhibit 11 to Memorandum of Points and Authorities in the Support of Plaintiff’s Motion for Summary Judgment, at 25]).

Most significantly, three of the latest BSE cases were in cattle not even born until years after the Canadian feed ban went into effect in August 1997. A cow in Alberta determined to have BSE in January 2006 was born almost three years after the Canadian feed ban, as was a cow in British Columbia diagnosed in April 2006.² And another Alberta cow with BSE discovered this summer was born almost *five years* after the Canadian feed ban.³

In contrast to the nine cases of Canadian-born cattle found to have BSE, only two cases of BSE have been confirmed in cattle indigenous to the United States, both born long before the United States implemented its ban on ruminant proteins in ruminant feed. See 70 Fed. Reg. at 48,495. Because

² See CFIA reports available at <http://www.inspection.gc.ca/english/anima/heasan/disemala/bseesb/ab2006/4investe.shtml> and <http://www.inspection.gc.ca/english/anima/heasan/disemala/bseesb/bccb2006/5investe.shtml>.

³ See <http://www.inspection.gc.ca/english/corpaffr/newcom/2006/20060713e.shtml>.

of concerns about the greater risk of BSE in Canada, the Republic of Korea, Singapore, and Egypt do not allow imports from the United States to contain beef or cattle of Canadian origin, and Korea prohibits any imports from U.S. slaughterhouses that also process Canadian beef, unless they have an approved procedure for segregating the Canadian carcasses.⁴

STATEMENT OF THE CASE

For many years, USDA has had a strict policy of prohibiting imports of cattle and beef from any country where bovine spongiform encephalopathy (“BSE”) is known to exist. *See* 70 Fed. Reg. (ER Tab 2) at 462. That policy initially was applied to Canada on May 29, 2003, 68 Fed. Reg. 31,939, after the discovery of BSE in a native-born Canadian cow.

Under intense pressure from the Canadian government and some U.S.-based meat packers (who also operate packing plants in Canada), on August 8, 2003, the Secretary of Agriculture announced that USDA would grant blanket permits for the importation of certain meat products from

⁴ *See* USDA notices available at <http://www.ams.usda.gov/lsg/arc/ARC1030M.pdf>; <http://www.ams.usda.gov/lsg/arc/ARC1030L.pdf>; <http://www.ams.usda.gov/lsg/arc/ARC1030E.pdf>; and <http://www.ams.usda.gov/lsg/arc/KoreaCanadianCattle.pdf> .

Canada that were judged to be of low risk. *See* 70 Fed. Reg. (ER Tab 2) at 536; district court’s March 2, 2005 opinion supporting its preliminary injunction order, *Ranchers Cattlemen Action Legal Fund United Stockgrowers of America v. United States Dept. of Agriculture*, 359 F. Supp. 1058, 1059 (“*R-CALF I*”). R-CALF later learned that USDA, without any notice to the public, was allowing other, higher-risk bovine products from Canada. On April 26, 2004, at R-CALF’s request, the district court issued a Temporary Restraining Order, prohibiting importation from Canada of all edible bovine meat products beyond those authorized by USDA’s action of August 8, 2003. *See Ranchers Cattlemen Action Legal Fund United Stockgrowers of America v. U.S. Dept. of Agriculture*, 415 F.3d 1078, 1089 (9th Cir. 2005) (“*R-CALF II*”).

On January 4, 2005, USDA published a regulation reversing long-standing USDA policy and allowing imports of cattle and beef, subject to certain restrictions, from a country known to have BSE in its cattle herd—Canada. “Bovine Spongiform Encephalopathy, Minimal Risk Regions and Importation of Commodities; Final Rule and Notice,” 70 Fed. Reg. 460 (the “Final Rule”) (ER Tab 2). That regulation was scheduled to go into effect on March 7, 2005. *Id.* On January 11, 2005, R-CALF USA filed an action

in the district court for the District of Montana, seeking to enjoin the rule's implementation. *See R-CALF II*, 415 F.3d at 1090.

R-CALF USA filed an application for a preliminary injunction on February 1, 2005, USDA filed an opposition and R-CALF replied, and the district court issued a preliminary injunction at the end of a hearing held March 2, 2005. *Id.* The district court's opinion supporting the issuance of a preliminary injunction was published at *Ranchers Cattlemen Action Legal Fund United Stockgrowers of America v. United States Dept. of Agriculture*, 359 F. Supp. 1058 ("*R-CALF I*"). USDA appealed the issuance of the preliminary injunction.

As the Court noted during oral argument in R-CALF II, briefing of the preliminary injunction motion and related matters in the district court and briefing of the appeal of the preliminary injunction proceeded very quickly, with R-CALF's initial Memorandum in Support of its motion for preliminary injunction filed before USDA filed a 27- volume administrative record, containing 12,560 pages, on February 18, 2005.

USDA also filed a "Supplemental Administrative Record," consisting of three binders of documents and two CDs, on June 15, 2005, after both R-CALF and USDA had filed their initial motions for summary judgment and

supporting memoranda. D. Ct. Docket No. 132; *cf.* Nos. 103, 118. The Supplemental Administrative Record added approximately 1000 pages, and most of the items included were documents generated by USDA after issuance of the Final Rule. *See id.* Among those documents was a Federal Register notice in which USDA, because of the discovery of two additional cases of BSE in Canadian cattle in December 2004 and January 2005, suspended the portion of the Final Rule that allowed imports of meat from Canadian cattle that are thirty months of age and older at slaughter. 70 Fed. Reg. 12,112 (March 11, 2005). Also included was a “Finding of No Significant Impact and Affirmation of Final Rule,” which provided additional arguments in support of USDA’s promulgation of the Final Rule and was published April 8, 2005, 70 Fed. Reg. 18,252.

Pursuant to a Joint Proposed Scheduling Order that R-CALF USA and USDA filed on March 16, 2005, the district court issued an order dated March 17, 2005, establishing a schedule for the filing of cross-motions for summary judgment and supporting briefs and declarations, and setting July 27, 2005 as the date for oral argument on those motions. Pursuant to that Scheduling Order, as modified, the parties filed approximately 100 pages of briefs and hundreds of pages of declarations and attachments thereto from USDA officials and outside experts. *See* D. Ct. Docket Nos. 103, 118, 140,

and 150 (excerpts at ER Tabs 4, 6, 7, and 9). As noted above, USDA also filed a supplement to the administrative record in the midst of briefing on the cross-motions for summary judgment, on June 15, 2005. *Id.* No. 132.

USDA's final filing in the Summary Judgment proceedings, its reply in support of its cross-motion for summary judgment, was filed in the district court on July 13, 2005, the same day that oral argument was heard on its appeal of the preliminary injunction. *Id.* No. 150.

On July 14, 2005, this Court issued an order stating that the panel in *R-CALF II* had decided that the preliminary injunction order should be vacated, and staying the Preliminary Injunction Order pending an opinion setting forth the reasons for the Court's reversal of the Preliminary Injunction Order. That opinion was issued on July 25, 2005 and amended August 17, 2005, 415 F.3d 1078. In the meantime, with the argument on the pending cross-motions for summary judgment scheduled for July 27, 2005, the district court issued an order on July 20, 2005, canceling the scheduled argument on the cross-motions for summary judgment in light of this Court's July 14, 2004 order, and stating that the district court would "determine whether further hearings are necessary" after receipt of the Ninth Circuit's opinion. D. Ct. Docket No. 157.

Following denial of its petition for rehearing in the preliminary injunction appeal on October 13, 2005, R-CALF USA asked the district court, on January 6, 2006, to re-schedule the hearing on the cross-motions for summary judgment that had been postponed by the district court's order of July 20, 2005, and to give full consideration to and decide its motion for summary judgment. *See id.* Nos. 163, 164, and 174. Instead, the district court issued a four-page order dated April 5, 2006, denying R-CALF USA's motion for summary judgment and granting USDA's cross-motion for summary judgment ("*R-CALF III*"). ER Tab10. The "Analysis" portion of the order was only two pages. *Id.*

The district court opinion in *R-CALF III* contains no analysis of, nor any indication that the district court considered, the arguments and declarations presented during briefing on the summary judgment motions. It contains nothing described as, or appearing to be, findings of fact. Instead, the only basis for the district court's grant of summary judgment to USDA was its understanding of the effect of the Ninth Circuit's decision on the preliminary injunction appeal in *R-CALF II*:

The Ninth Circuit has reviewed the Final Rule and has concluded that "the Secretary [of Agriculture] 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.” *Rancher’s Cattlemen Action Legal Fund v. United States Dept. of Agriculture*, 415 F.3d 1078, 1095 (9th Cir. 2005). Based upon this, the District Court’s hands are tied. The Ninth Circuit has instructed this Court to “abide by this deferential standard,” and “respect the agency’s judgment and expertise.” Therefore, Plaintiff’s Motion for Summary Judgment... is **DENIED** and Defendants’ Motion for Summary Judgment...is **GRANTED**.

R-CALF III (ER Tab 10) at 4. R-CALF filed a timely notice of appeal of the district court’s decision. D. Ct. Docket No. 184 (ER Tab 11).

SUMMARY OF ARGUMENT

The district court decision in *R-CALF III* should be reversed because it is based on the incorrect conclusion that this Court already resolved the merits of R-CALF’s claims, presented in R-CALF’s motion for summary judgment, that the Final Rule should be struck down under the Administrative Procedure Act. *Cf.* Memorandum in Support of Plaintiff’s Motion for Summary Judgment (ER 4) at 1, 4-6.

The *R-CALF II* opinion reversing the preliminary injunction rests on two legal conclusions: “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” and “that R-CALF has failed to make the requisite showing of irreparable harm.” 415 F.3d at 1105.

The second of these conclusions was irrelevant for the district court’s resolution of R-CALF’s claims on the merits—the Administrative Procedure Act does not require a showing of irreparable harm before a court strikes down an agency action that is arbitrary, capricious, an abuse of discretion, or otherwise not according to law. *Cf.* 5 U.S.C. § 706(2).

The first of the two conclusions on its face does not dispose of R-CALF’s claims on the merits, merely observing that the Final Rule would “likely” be upheld by the district court once “the correct legal standard” for review of the Final Rule was applied. 415 F.3d at 1105. This observation is not a substitute for the district court reviewing all the evidence and briefs and applying the correct legal standard to the facts to determine whether the Final Rule complies with the Administrative Procedure Act.

ARGUMENT

I. Standard of Review

This court reviews a district court’s grant or denial of summary judgment *de novo*. *Ground Zero Ctr. for Non-Violent Action v. U.S. Dep’t of Navy*, 383 F.3d 1082, 1086 (9th Cir. 2004). This means that the Court must “view the case from the same position as the district court.” *Ka Makani O*

Kohala Ohana Inc. v. Water Supply, 295 F.3d 955, 959 (9th Cir. 2002)
(quoting *Sierra Club v. Babbitt*, 65 F.3d 1502, 1507 (9th Cir. 1995)).

The district court, in reviewing USDA's action under the Administrative Procedure Act ("APA"), 5 U.S.C. § 706(2), must "hold unlawful and set aside" USDA action that was "arbitrary, capricious, and abuse of agency discretion, or otherwise not in accordance with the law," or that was taken "without observance of procedure required by law." *Id.* "An agency's action is arbitrary and capricious if the agency fails to consider an important aspect of a problem, if the agency offers an explanation for the decision that is contrary to the evidence, if the agency's decision is so implausible that it could not be ascribed to a difference in view or be the product of agency expertise, or if the agency's decision is contrary to the governing law." *Lands Council v. Powell*, 395 F.3d 1019, 1026 (9th Cir. 2005) (internal citations omitted). An agency action is unlawful under the APA if the agency "relied on factors which Congress has not intended it to consider" or changed its view without explaining its reasons for doing so. *Motor Vehicle Manufacturers' Ass'n v. State Farm Automobile Insurance Co.*, 463 U.S. 29, 43, 56 (1983).

The agency must provide sufficient “findings and analysis...to justify the choice made,” articulating a “rational connection between the facts found and the choices made.” *Burlington Northern Truck Lines, Inc. v. United States*, 371 U.S. 156, 167-68 (1962); *see also NAHB v. Norton*, 340 F.3d 835, 841 (9th Cir. 2003) (same); *Ober v. Whitman*, 243 F.3d 1190, 1195 (9th Cir. 2001) (requiring a “full explanation” of the basis for the decision). A key aspect of providing an adequate explanation for a rule is explaining and justifying the assumptions on which the rule was based. *See California v. FCC*, 905 F.2d 1217, 1244 (9th Cir 1990); *Ober*, 243 F.3d at 1195.

Providing an internally inconsistent justification for a rule is another reason the agency’s decision may be found arbitrary and capricious, despite the agency’s expertise, since the decision therefore was “not founded on a reasoned evaluation of the relevant factors.” *Defenders of Wildlife v. U.S. EPA*, 420 F.3d 946, 959 (9th Cir. 2005) (citations omitted).

USDA has a special obligation here to explain why it chose to abandon its prior decisions that a ban on imports of cattle from countries afflicted with BSE was the only way to protect the U.S. cattle herd. *See California v. FCC*, 905 F.2d 1217, 1234 (9th Cir. 1990); *Nat’l Conservative Political Action Comm. v. FEC*, 626 F.2d 953, 959 (D.C. Cir. 1980); *Greater Boston Television Corp. v. FCC*, 444 F.2d 841, 852 (D.C. Cir. 1970), *cert.*

denied 403 U.S. 923 (1971) (“new rule constituting a departure from past policy or practice amplifies the need for adequate explanation”).

II. This Court’s decision in *R-CALF II* did not resolve R-CALF USA’s claims on the merits.

A. The *R-CALF II* opinion does not on its face obviate further consideration of the merits by the district court.

The question that this Court considered in *R-CALF II* was “whether the district court erred in issuing a preliminary injunction prohibiting the implementation of” the Final Rule. 415 F.3d at 1084. The opinion in *R-CALF II* therefore considered whether, in its motion for a preliminary injunction, R-CALF had demonstrated “a strong likelihood of success on the merits” or “probable success on the merits” combined with “the possibility of irreparable injury” or a “balance of hardships [that] tips sharply in [R-CALF’s] favor.” *Id.* at 1092.

The Court concluded that the district court did err in issuing a preliminary injunction because “the district court applied an incorrect legal standard,” and therefore it reversed the district court. *Id.* at 1084; *see also* 1093 (“the district court’s finding that R-CALF had a strong likelihood of success on the merits was premised on legal error”), 1105. The *R-CALF II* Court was not presented with, and did not decide, whether R-CALF could

prove its case on the merits or whether USDA was entitled to summary judgment. The case was remanded to the district court for that purpose.

In considering whether R-CALF had demonstrated the likelihood of success on the merits necessary to support its request for a preliminary injunction, the *R-CALF II* Court stated that: “the Final Rule will likely survive judicial scrutiny under the correct legal standard.” 415 F.3d at 1105; *see also id.* at 1084; 1093 (district court’s finding “was premised on legal error”). The conclusion is on its face not a decision that “the correct legal standard,” when applied to facts and arguments presented to the district court in a motion for summary judgment or at trial, would necessarily prevent a decision that the Final Rule was arbitrary and capricious, and abuse of discretion, or not otherwise in accordance with law, or was issued without adherence to proper procedures. *See* 5 U.S.C. § 706(2). To the contrary, the statement contemplates that there will be further proceedings in which the district court will apply “the correct legal standard” to all of the arguments and evidence in the case.

This Court has previously discussed precisely the situation here, where an appellate court, in deciding that the criteria for a preliminary injunction have not been met, states that the evidence presented at the

preliminary injunction stage does not show a likelihood of success on the merits: “Rulings-predictions-as to the likely outcome on the merits made for preliminary injunction purposes do not ordinarily apply as the law of the case....” *Humanitarian Law Project v. U.S. Department of Justice*, 352 F.3d 382, 393 (9th Cir. 2003) (quoting 18 Wright, Miller & Cooper, Federal Practice and Procedure § 4478.5 (2002)). The district court, however, concluded that its “hands are tied” by the decision in *R-CALF II*. *R-CALF III* (ER Tab 10) at 4. Based on that erroneous conclusion, the district court declined to re-schedule the previously canceled argument on the cross-motions for summary judgment and ruled upon them without any analysis of the evidence and arguments that had been presented subsequent to the preliminary injunction hearing. *See id.*

The statement from the *R-CALF II* opinion that the district court felt compelled its preemptory grant of summary judgment to USDA was 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.” *Id.*, quoting 415 F.3d at 1095. But even if that conclusion were binding on the district court’s consideration of the merits of the case, it does not come close to resolving the issue presented by

R-CALF's complaint: whether the issuance of the Final Rule was consistent with the APA.

The Animal Health Protection Act, 7 U.S.C. § 8301, *et seq.*, the authority USDA cited for the Final Rule, *see* 70 Fed. Reg. (ER Tab 2) at 551, authorizes the Secretary of Agriculture to “prohibit or restrict...the importation or entry” of cattle “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.” *Id.* at § 8303(a)(3). Whether the Final Rule was “otherwise not in accordance with law” or “in excess of statutory jurisdiction, authority, or limitations, or short of statutory right” under the APA, 5 U.S.C. § 706(2)(A), (C), thus rests on whether the restrictions on Canadian beef and cattle imports eliminated by the Final Rule remain necessary to prevent the introduction or dissemination of BSE into the United States cattle herd, not whether Canadian imports would “significantly increase the risk of BSE to the American population.” *Cf. R-CALF III* (ER Tab 10) at 4.⁵

⁵ In fact, important aspects of USDA's argument in support of the Final Rule, relied upon by the *R-CALF II* panel in reversing the preliminary injunction, while relevant to the issue of irreparable harm, had nothing to do with whether the Final Rule would prevent the introduction of BSE into the U.S.

The question of whether the Final Rule was arbitrary and capricious, in violation of 5 U.S.C. § 706(2)(A), even if it was within USDA's statutory authority, also is not resolved by a conclusion 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." *See R-CALF III* (ER Tab 10) at 4, quoting 415 F.3d at 1095. As discussed in Section I., *supra*, an agency action may be held to be arbitrary and capricious for numerous reasons, such as having been reached after consideration of inappropriate factors; failure to provide an adequate explanation, including an explanation for departures from past conclusions; failure to explain key assumptions; and inconsistent explanations or statements in the record.

Although the *R-CALF II* panel believed that the *R-CALF I* opinion granting the preliminary injunction was based on the district court's

cattle herd—the critical issue for assessing whether the Final Rule is consistent with the Animal Health Protection Act's directory 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). For example, USDA's heavy reliance on removal of "Specified Risk Materials" from the carcass prior to further butchering as a risk mitigation measure addresses the risk of humans consuming BSE-contaminated meat, not the risk of cattle eating contaminated feed. *See R-CALF II*, 415 F.3d at 1096, 1099.

“fundamentally flawed” interpretation of the Animal Health Protection Act as containing a "strict requirement that the USDA regulation remove all risk of BSE entering the United States,” 415 F.3d at 1095, the converse is not true, i.e., just because USDA may allow some level of risk that it considers reasonable when it authorized resumption of imports from Canada does not mean that USDA’s decision-making or its explanation of the basis for the final rule is not arbitrary and capricious. In the consideration on the merits to which R-CALF was entitled, the district court could have considered all of the arguments presented by R-CALF, and all of the possible grounds for concluding, that USDA’s action in promulgating the Final Rule was arbitrary and capricious.

B. A decision reversing a preliminary injunction does not as a matter of law dictate the resolution on the merits

Fed. R. Civ. P. 56(c) contemplates that a hearing will be held on a motion for summary judgment. *Id.* (motion for summary judgment must be served at least 10 days “before the time fixed for the hearing”). The fact that a preliminary injunction was issued in this case and then vacated by the Court of Appeals does not make it unnecessary or inappropriate to hold such a hearing, nor does it eliminate the need for the district court to resolve R-CALF’s summary judgment motion on the merits. (In this case, since no

witnesses were to be called, the parties and the Court anticipated that the hearing would consist of oral argument by counsel.) Obviously, the Court of Appeals was reviewing an interlocutory order that did not purport to resolve the merits of the case and that was entered before the merits of the case had been fully briefed.

Actions related to a preliminary injunction do not bind the district court with respect to a decision on the merits. Wright and Miller, *Federal Practice and Procedure*, Section 2962, 437-438 (2004), observes that the decision of both the trial and appellate court on whether to grant or deny a preliminary injunction does not preclude the parties in any way from litigating the merits of the case. The Ninth Circuit has reiterated that self-evident proposition, stating that “we have not departed from the general rule that a decision on a preliminary injunction does not constitute the law of the case and the parties are free to litigate the merits.” *City of Anaheim, Calif. v. Duncan*, 658 F.2d 1326, 1328 n.2 (9th Cir. 1981) (citing *Ross-Whitney Corp. v. Smith, Kline and French Labs*, 207 F.2d 190, 194 (9th Cir. 1953) (a “ruling on the motion for a preliminary injunction leaves open the final determination of the merits of the case”)). *See also, e.g., S. Or. Barter Fair v. Jackson County*, 372 F.3d 1128, 1136 (9th Cir. 2004).

In *Golden State Transit Corp. v. City of Los Angeles*, 754 F.2d 830 (9th Cir. 1985), *rev'd on other grounds*, 475 U.S. 608 (1986), for example, this Court flatly rejected an argument that a decision rejecting a preliminary injunction compelled a similar decision on the merits: “The City argues that our prior decision on the preliminary injunction is law of the case and reconsideration of it is barred. This assertion is wrong. As a general rule, decisions on preliminary injunctions do not constitute law of the case and ‘parties are free to litigate the merits.’” 754 F.2d at 832 n.3 (quoting *City of Anaheim*, 658 F.2d at 1328 n.2). In *Golden State Transit*, this Court previously had reversed the grant of a preliminary injunction, based on a holding that taxi cab franchise renewal was a matter of such local interest that it could only be preempted by federal law if there was a “compelling congressional direction” (which the Court could not find). *Id.* at 832-33. When the case came back on appeal on the merits, though, the Court looked at the issues again and determined that its earlier conclusion was wrong. *Id.*

This Court’s opinion in *R-CALF II* concluded that the district court should not have granted R-CALF a preliminary injunction, because R-CALF had not shown a substantial likelihood of prevailing on the merits and because R-CALF had not proved it would be irreparably harmed in the absence of a preliminary injunction. 415 F.3d at 1105. The opinion did not

by its terms decide the claims presented in R-CALF's complaint, nor could it have. Indeed, if the district court's view that the *R-CALF II* decision reversing the preliminary injunction obviated the need for further consideration of the merits of the case were correct, then in most cases where a preliminary injunction was appealed and overturned, no remand to the district court to consider the merits would be necessary, since the appellate court's judgment that no likelihood of success on the merits was demonstrated by the arguments and evidence presented at the preliminary injunction stage would preclude full consideration of the merits in subsequent district court proceedings.⁶

Moreover, even if the R-CALF II panel's conclusions about the sufficiency of USDA's justification for the Final Rule being the context of the preliminary injunction appeal did constitute "the law of the case" for purposes of the district court's consideration of the merits following reversal of the preliminary injunction, "the law of the case is a discretionary doctrine" which does not limit the Court's power to address an issue.

⁶ Under Fed. R. Civ. P. 65(a)(2), a district court judge may order the trial on the merits accelerated and consolidated with the preliminary injunction hearing, but that did not happen in this case, and indeed, as noted at p. 10, *supra*, extensive briefing on the merits occurred after the preliminary injunction hearing at the joint request of the parties.

Humanitarian Law Project v. U.S. Department of Justice, 352 F.3d 382, 393 (9th Cir. 2003) (citing *Leslie Salt Co. v. United States*, 55 F.3d 1388, 1393 (9th Cir.), *cert. denied* 516 U.S. 955 (1995)). *See also Golden State Transit*, 754 F.2d at 832 n.3 (court may exercise its discretion to hear contrary authority on applicable issues of law decided in previous appeal). Thus, the district court, and this Court on appeal from a district court decision on the merits, would not be bound to follow a previous decision on the merits of the case in *R-CALF II*, if indeed there had been one, since it is within the court’s discretion to decide whether to treat matters resolved on a prior appeal as the law of the case. *See Humanitarian Law Project*, 352 F.3d at 393; *see also City of Los Angeles Harbor Div. v. Santa Monica Baykeeper*, 254 F.3d 882, 888 (9th Cir. 2001) (law of the case doctrine “‘is discretionary, not mandatory,’ and is in no way a ‘limit on [a court’s] power.’” (quoting *United States v. Houser*, 804 F.2d 565, 567 (9th Cir. 1986))).⁷

⁷ Also, a critical factor in *Humanitarian Law Project* was that “the plaintiffs presented no evidence in addition to that submitted in their earlier motion for a preliminary injunction to support their later motion for a permanent injunction.” 352 F.3d at 393. That certainly is not the case here, as explained in the following section. In contrast, because the defendant in *Humanitarian Law Project* asserted that it had submitted additional evidence in the subsequent district court proceedings, the Court of Appeals could not apply the law of the case doctrine and did consider, in the appeal of the

C. The R-CALF II panel did not have before it all of the arguments and evidence presented to the district court in support of summary judgment.

As noted in Section III, *infra*, a great deal of argument and reference to evidence was presented in the summary judgment proceedings that was not considered in, and in some cases not even available at the time of, the district court's decision to issue the preliminary injunction, nor even in the briefs filed in the appeal of the preliminary injunction in this Court. Some of the arguments that were not presented in the very early stages of this litigation for the preliminary injunction proceeding are very important, such as reference to other statements of congressional intent, USDA official statements that contradict statements made in support of the Final Rule, and empirical evidence (discovery of BSE in younger cattle in Canada) flatly contradicting USDA's assumption that any remaining BSE-infected cattle in Canada would be few and would have been exposed to BSE prior to Canada's 1997 ruminant-to-ruminant feed ban. *See* Section III, *infra*.

It is logical and appropriate that all of this information should be considered by the district court in deciding whether to grant summary

permanent injunction, whether the district court had properly addressed that additional evidence. *Id.*

judgment on the merits to either party. The district court's decision in *R-CALF III* ignored that information and in effect granted summary judgment based on preliminary proceedings in the case. This Court need not decide now whether all of the additional arguments and information presented in the summary judgment proceedings constitute admissible evidence that properly should be considered—that is the district court's job. But clearly *R-CALF* has a right to have all of its arguments and evidence at least considered by the district court, rather than being dismissed as irrelevant under a misinterpretation of this Court's action in *R-CALF II*.

III. Remand to the District Court would not be a futile act.

This Court might choose not to send this case back to the district court if it were obvious that, even after consideration of all of the evidence, the district court could reach only one conclusion. It is hard to see how that judgment could ever be made in the abstract, without reviewing all of the filings made in the district court and the voluminous administrative record. But in any event in this case there are important arguments and evidence that neither the district court nor this Court ever considered.

A. Important evidence and legal arguments were not presented at the preliminary injunction stage.

In the summary judgment proceedings, the parties submitted approximately 100 pages of argument to the district court. (The Tables of Contents of R-CALF USA's and USDA's initial memoranda supporting summary judgment and reply memoranda, D. Ct. Docket Nos. 103, 118, 140, and 150, are included at ER Tabs 4, 6, 7, and 9) Except for R-CALF USA's initial memorandum in support of its motion for summary judgment, all of the other memoranda were filed after the USDA filed its reply brief in *R-CALF USA II* on June 9, 2005. *See* ER 12 (District Court Docket).

Both R-CALF USA and USDA submitted hundreds of pages of exhibits in support of their motions for summary judgment. *See* Exhibits 3-6. These included numerous declarations of USDA witnesses and outside experts that were not part of the preliminary injunction proceedings and appeal. USDA, for example, submitted two declarations each from outside consultants, Philip B. Stark and William D. Hueston, who had not previously submitted a declaration nor otherwise been mentioned in the case, in addition to numerous declarations of USDA employees. R-CALF USA also submitted new declarations, including a 10-page declaration by Stanley B. Prusiner, M.D., winner of the 1997 Nobel Prize for Medicine for his discovery of the infectious protein agents (which he named "prions") that

cause fatal neurodegenerative diseases, such as BSE in cattle.⁸ See ER Tab 8.

USDA and R-CALF USA alike made reference in the summary judgment proceedings to the Supplemental Administrative Record, which USDA did not even file until after the preliminary injunction had been issued, see pp. 9-10, *supra*, and to amendments to the Final Rule that were published April 8, 2005, 70 Fed. Reg. 18,252, more than a month after the

⁸ It would be appropriate for the district court at least to consider whether to rely on such post-issuance information discussing the technical basis for the Final Rule. For example, in *Love v. Thomas*, 858 F.2d 1347 (9th Cir. 1988), this Court stated: “The court may find it necessary to review additional material to explain the basis of the agency’s action and the factors the agency considered,” and “the court may consider, particularly in highly technical areas, substantive evidence going to the merits of the agency’s action where such evidence is necessary as background to determine the sufficiency of the agency’s consideration.” *Id.*, 858 F.2d at 1356. See also, e.g., *Bunker Hill Co. v. Environmental Protection Agency*, 572 F.2d 1286, 1292 (9th Cir. 1977) (“in the often difficult task of reviewing administrative regulations, the courts are not straitjacketed to the original record in trying to make sense of complex technical testimony”); *Asarco, Inc. v. U. S. EPA*, 616 F.2d 1153, 1160 (9th Cir. 1980) (“It will often be impossible, especially when highly technical matters are involved, for the court to determine whether the agency took into consideration all relevant factors unless it looks outside the record to determine what matters the agency should have considered but did not.”); *Independent Meat Packers Ass’n v. Butz*, 526 F.2d 228, 239 (8th Cir. 1975), *cert. denied*, 424 U.S. 966 (1976) (court reviewing agency action should consider “the administrative record already in existence supplemented, if necessary, by affidavits, depositions, or other proof of an explanatory nature”).

preliminary injunction hearing. R-CALF USA also directed the district court's attention to "technical amendments" to the Final Rule published March 14, 2006, 71 Fed. Reg. 12,994, which R-CALF USA argued demonstrate that USDA inaccurately characterized the Final Rule to the district court in briefing on the application for a preliminary injunction and in briefing before this Court in *R-CALF II*. See Addendum of Regulations.

R-CALF USA asked the district court to take judicial notice of, *e.g.*, a press conference involving Appellee Secretary Johanns and other USDA officials that took place after briefing in this Court in *R-CALF II* was complete and scientific articles and commentary published after the preliminary injunction proceedings in the district court (Exhibits 1, 6, and 7 to Reply Memorandum in Support of Plaintiff's Motion for Summary Judgment and Opposition to Defendants' Cross-Motion) and to a USDA analysis of BSE in cattle in North America published in April 2005 that concluded there is a BSE "hot spot" in the province of Alberta (Exhibit 11 to Memorandum of Points and Authorities in the Support of Plaintiff's Motion for Summary Judgment (ER Tab 5), at 25).⁹

⁹ This district court could take judicial notice of USDA Federal Register notices, publications, and other statements, as well as scientific journals, law

New legal arguments were advanced in the briefing of the cross-motions for summary judgment that were not discussed in the preliminary injunction proceedings or appeal, as well. For example, R-CALF USA argued for the first time in its Memorandum in Support of Summary Judgment that USDA's assumption that the Canadian feed ban was "highly effective" was inconsistent with record evidence about the practical difficulties of enforcing a feed ban, experience in other countries, USDA's own published assessment of the effectiveness of the Canadian feed ban, and a Government Accountability Office study showing incomplete effectiveness of the similar U.S. feed ban. *Cf.* Exhibit 8 (excerpt of Memorandum in Support) *with* 415 F.3d at 1098. R-CALF USA also argued that the explanation USDA provided for the Final Rule was

reviews, and the like. This is true even in a case such as this concerning whether an agency acted arbitrarily, capriciously, or not in accordance with law under the APA. *See, e.g., City of Sausalito v. O'Neill*, 386 F.3d 1186, 1223 (9th Cir. 2004) (court could take judicial notice of a state agency document in an action for judicial review under the APA of a National Park Service final action); *Barron v. Reich*, 13 F.3d 1370, 1377 (9th Cir. 1994) (court could take judicial notice of and consider a policy in a Department of Labor field operations handbook); *Military Toxics Project v. EPA*, 146 F.3d 948, 954 (D.C. Cir. 1988) (in an action for judicial review under the APA of an Environmental Protection Agency action, a "policy document from the EPA and two reports from the General Accounting Office" appended to a brief that were "not part of the administrative record" were nevertheless "judicially cognizable apart from the record").

inconsistent with the Animal Disease Risk Assessment, Prevention, and Control Act of 2001, P.L. 107-9, and its legislative history. *See* Exhibit 1 at 5 n.2.

R-CALF also asked the district court to consider whether the record supported USDA's claim that new scientific developments warranted departure from its previous policy banning all imports from countries with BSE. The principal device that USDA now claims will provide adequate protection to U.S. cattle if BSE-infected cattle are imported from Canada, the prohibition on feeding ruminant protein to other ruminants, has been in place since 1997. 70 Fed. Reg. at 466. Yet USDA has said repeatedly since then that, because of the unique nature of BSE, importation and rendering of BSE-infected cattle, followed by misfeeding to U.S. cattle, is one of the primary risks for introduction of BSE into the United States, and a ban on imports from all countries with BSE is an essential defense.¹⁰ The "Harvard Study" on which USDA principally relied for support in its relaxation of

¹⁰ *See, e.g.*, 66 Fed. Reg. 52,483 Oct. 16, 2001 ("emergency" interim rule banning imports from Japan, affirmed at 67 Fed. Reg. 8181 (Feb. 22, 2002)); 63 Fed. Reg. 406 (Jan. 6, 1998); 62 Fed. Reg. 65,747, 65,748 (Dec. 16, 1997). USDA also repeatedly praised Canada's policy of banning imports of cattle from all countries where BSE is known to exist as a key measure reducing Canada's BSE risk. *See, e.g.*, 70 Fed. Reg. at 464, 467, 486; 70 Fed. Reg. 18,252, 18,254 (April 8, 2005).

BSE protections for Canada, was first completed in 2001 and relies on scientific studies reported primarily in the 1990s. *See, e.g.*, 70 Fed. Reg. at 466-67. Thus, it does not appear that USDA was relying in the Final Rule on new information that was unavailable when USDA in recent years repeatedly reaffirmed the importance of the ban on imports of cattle from BSE-afflicted countries. The district court still should determine whether, in light of those facts, USDA has justified its departure in the Final Rule from previous determinations that a ban on imports from countries known to have BSE was “necessary” under the Animal Health Protection Act, since the lack of sufficient explanation for such a departure renders a rule arbitrary and capricious. *See pp. 15-16, supra.*

B. Subsequent facts not considered in the Preliminary Injunction proceedings confirm the inaccuracy of key USDA assumptions.

At virtually the same time as USDA promulgated the Final Rule, discoveries of new cases of BSE in Canada undercut USDA’s assumption that the prevalence of BSE in Canada was a very low and decreasing. *See pp. 5-6, 27, 31, supra.* As a direct result of the two new BSE cases in Canada reported in early January 2005, USDA promptly suspended the imports of beef from cattle over 30 months of age at the time of slaughter that had been authorized by the Final Rule. *See* “Bovine Spongiform

Encephalopathy; Minimal-Risk Regions and Importation of Commodities; Partial Delay of Applicability,” 70 Fed. Reg. 12,112 (March 11, 2005).

As noted in the Statement of Facts, Canada has now found eight cases of BSE in Canadian-born cattle that died in Canada, in addition to the one case of BSE in a cow that had been imported from Alberta Province to Washington State at over four years of age. *See* pp. 5-6, *supra*. In just the past year, three additional cases have been found in Alberta Province, confirming the BSE hot spot there. *Id.*

Most significantly, three of the latest BSE cases were in cattle not even born until years after the Canadian feed ban went into effect in August 1997. A cow in Alberta determined to have BSE in January 2006 was born almost three years after the Canadian feed ban, as was a cow in British Columbia diagnosed in April 2006.¹¹ And another Alberta cow with BSE discovered this summer was born almost *five years* after the Canadian feed

¹¹ *See* <http://www.inspection.gc.ca/english/anima/heasan/disemala/bseesb/ab2006/4investe.shtml> and <http://www.inspection.gc.ca/english/anima/heasan/disemala/bseesb/bccb2006/5investe.shtml>.

ban.¹² These facts directly contradict USDA's assumption that the Canadian feed ban had been effective to prevent exposure of cattle to the BSE infective agent in cattle feed for almost eight years at the time it promulgated the Final Rule. *See, e.g.*, 70 Fed. Reg. at 485 (decision to allow imports of under-thirty-month-old cattle based on assumption they could not have been exposed to potentially contaminated feed because they were born after Canada's feed ban), 513-14, 516; *compare with R-CALF II*, 415 F.3d at 1097 (accepting USDA's assertion that the Canadian feed ban has been effective and will result in decreasing prevalence of BSE in Canada).¹³

Although USDA said in the preamble to the Final Rule that it anticipated there might be a few more cases of Canadian cattle exposed to BSE-contaminated feed before the Canadian feed ban, *see, e.g.*, 70 Fed. Reg. at 485, USDA's support for the Final Rule relied in part on the lack of BSE cases found prior to the end of 2004 in younger cattle. *See* 70 Fed. Reg. at

¹²*See*

<http://www.inspection.gc.ca/english/corpaffr/newcom/2006/20060713e.shtml>

¹³ See also July 13, 2006 press statement by Secretary Johanns (“...the diagnosis of BSE in an animal born roughly four and half years after the implementation of the 1997 ruminant-to-ruminant feed ban does raise questions that must be answered.”) available at <http://www.usda.gov/wps/portal/usdahome?contentidonly=true&contentid=2006/07/0249.xml>.

515 (“because the two [at that time] BSE-infected animals were born before the feed ban, there is no evidence to suggest that the feed ban is ineffective”).¹⁴ Similarly, in its Risk Analysis supporting the Final Rule, USDA stated: “Another indication of an effective feed ban can be derived from epidemiologic investigations of diagnosed cases. Cases of BSE found in animals born after the feed ban was implemented would suggest either that the feed ban was ineffective or that there were noncompliance issues.” ER Tab 1 p. 9. Thus, the discovery of multiple cases of BSE in Canada that must have been exposed to contaminated feed long after Canada enacted its feed ban is a key fact affecting the accuracy of USDA’s rationale for the Final Rule.

Moreover, rather than supporting USDA’s key assumptions about the low and declining prevalence of BSE in Canada, data not available during the preliminary injunction proceedings and appeal indicate, if anything, an increasing prevalence of BSE, with five of the nine cases in Canadian-born

¹⁴ *See also* 70 Fed. Reg. at 415 (“We disagree that the possible presence of additional animals in Canada, infected before implementation of the Canadian feed ban, present risks that have not been addressed for this rulemaking. As stated in several other comments, it is possible that cattle born before Canada initiated its feed ban in August of 1997 may still exist in Canada.”).

cattle having been diagnosed in just the past year. *Cf.* citations on pp. 5-6, *supra*, with *R-CALF II*, 415 F.3d at 1097 (adopting USDA’s claim that the rate of BSE in Canada is decreasing).

The district court should be directed to consider whether those empirical facts render USDA’s assumptions about the prevalence about BSE in Canada and about the effectiveness of Canada’s feed ban since 1997 arbitrary and capricious. *See Ass’n of Pacific Fisheries v. Environmental Protection Agency*, 615 F.2d 794, 812 (9th Cir. 1980) (party challenging regulation may use “post-decisional data” in studies that “showed that the Agency proceeded upon assumptions that were entirely fictional or utterly without scientific support”); *Defenders of Wildlife v. Norton*, 258 F.3d 1136, 1146 (9th Cir. 2001) (Interior Department’s assumption that threatened lizard would be protected by Conservation Agreements in designated Management Areas was insufficiently supported in light of evidence that, a year after the rule designating lizard as protected, Management Areas had still not been designated).

C. Subsequent Federal Register notices show the irrationality of USDA’s purported justifications for the Final Rule.

As noted at pp. 9-10, *supra*, on June 15, 2005, after the district court issued the preliminary injunction and after briefing was completed in the

appeal of the preliminary injunction to this Court, USDA also filed a “Supplemental Administrative Record.” The Supplemental Administrative Record included the Federal Register notice in which USDA, because of the discovery of two additional cases of BSE in Canadian cattle in December 2004 and January 2005, suspended the portion of the Final Rule that allowed imports of meat from Canadian cattle that are thirty months of age and older at slaughter. 70 Fed. Reg. 12,112 (March 11, 2005). Also included was a “Finding of No Significant Impact and Affirmation of Final Rule,” which provided additional arguments in support of USDA’s promulgation of the Final Rule and was published April 8, 2005, 70 Fed. Reg. 18,252.

This Court in *R-CALF II* referenced both the March 11, 2005 and the April 8, 2005 Federal Register notices (*see R-CALF II*, 415 F.3d at 1090), but obviously they were not considered by the district court in issuing its March 2, 2005 preliminary injunction opinion. The district court opinion noted that USDA intended to suspend imports of beef from cattle 30 months of age and older as a result of the discovery of two additional BSE cases around the time the Final Rule was issued, but only by way of concluding that its opinion on the preliminary injunction motion need not address R-CALF’s objections to imports of beef from such cattle. *See R-CALF I*, 359 F. Supp. at 1068. Neither the district court nor this Court addressed the

implications, in terms of whether USDA provided a sufficient rationale for the Final Rule, of the fact that, in spite of the USDA's claim that the Final Rule provided "multiple, interlocking safeguards" against the risks of BSE infection in Canadian cattle to U.S. cattle and consumers (*see R-CALF II*, 415 F.3d at 1095) and its statement that it expected there could be additional cases of BSE in Canada (*see 70 Fed. Reg. (ER Tab 2)* at 514-516, USDA nevertheless immediately back-pedaled on its decision to allow imports of beef from cattle 30 months of age and older when additional cases of BSE were discovered in Canada. That lack of USDA confidence in the circumstances that it claimed, only weeks before in the Final Rule, made the ban on cattle and beef from Canada no longer "necessary," is something that should be fully evaluated by the district court in considering R-CALF's assertion that the Final Rule is arbitrary and capricious.

R-CALF also asked the district court to consider statements in Federal Register publications by USDA and the Food and Drug Administration ("FDA") that are inconsistent with the stated rationale for the Final Rule. For example, on October 6, 2005, FDA proposed amendments to the ruminant-to-ruminant feed ban, 70 Fed. Reg 58,569 (the "feed ban amendments"). In addition to reinforcing many of the concerns that R-CALF USA has expressed about the incomplete protection offered by the

feed ban and that USDA has ignored (*see, e.g.*, 70 Fed. Reg. at 58,577-78), the feed ban amendments reveals another glaring inconsistency in USDA's support for the Final Rule.

The preamble to the feed ban amendments refers to a 2004 modification that USDA made to the Harvard-Tuskegee model, which then estimated that the interim final rules published by USDA (requiring removal of Specified Risk Material ("SRM"), the tissues most likely to have high concentrations of BSE infectivity) and by FDA (the partial feed ban) "reduced human exposures to infectious materials by an average of 80 percent." 70 Fed. Reg. at 58,587, citing "Ref. 26," an April 7, 2004 USDA report. Yet USDA claimed in the Final Rule, and represented to the Ninth Circuit, that banning SRMs from human and animal food alone reduces human exposure to BSE by 95 percent, based on the 2003 Harvard-Tuskegee modeling. *See* 70 Fed. Reg. at 467 (AR008051); *R-CALF II*, 415 F.3d at 1099. In yet another apparently inconsistent statement, USDA submitted a declaration of a USDA official in support of its motion for summary judgment stating that SRM removal might reduce the risk by only 80%. *See* Englejohn Declaration I (ER 3) at 8. These are precisely the kind of inconsistencies that the district court should evaluate in deciding whether

inconsistent explanations or inaccurate factual assumptions rendered the Final Rule arbitrary and capricious.¹⁵

USDA also issued amendments to the Final Rule this year that bear directly on its claim that the Final Rule presented no risk of BSE transmission from importation of pregnant cattle. In the Summary Judgment proceedings, R-CALF pointed out that USDA's explanation for the Final Rule is inconsistent in that it recognized that there is a small probability that BSE can be transmitted maternally, which is why USDA euthanized the two offspring of the Canadian-origin BSE-infected cow discovered in Washington State (*see* 70 Fed. Reg. at 530), and yet the Final Rule did not prohibit the importation of pregnant cattle, nor contain any means for determining if pregnant cattle were being imported. *See, e.g.*, R-CALF's Memorandum in Support of Summary Judgment at 26.

¹⁵ *See also, e.g.*, preamble to USDA rule allowing imports of boneless beef from Japan, 70 Fed. Reg. 73,905 (Dec. 14, 2005), stating that animal surveillance for BSE "is not a mitigation measure." *Id.* at 73,914. In contrast, USDA stated numerous times in the preamble to the Final Rule that animal surveillance is a key "BSE risk mitigation measure." 70 Fed. Reg. at 463, 470, 471, 486, 510, 515, 516; ER 1 at p. 3-4 [USDA Risk Analysis document for Final Rule].

One of the reasons for the “technical amendments” published on March 14, 2006 is “to prohibit explicitly the importation of pregnant bovines from BSE minimal-risk regions” and “to prohibit the importation of pregnant sheep and goats from Canada,” as well as to require by rule that “certificates accompanying bovines, sheep, and goats imported from Canada must state that the animals covered by the certificate are not pregnant.” 71 Fed. Reg. at 12,996, col. 1. Although USDA asserts that it always intended to prohibit importation of pregnant cattle, sheep, and goats, “the regulatory text of the final rule does not explicitly address whether pregnant bovines, sheep, or goats may be imported for immediate slaughter or for movement to a feedlot for subsequent movement to slaughter.”¹⁶

USDA told this Court during the preliminary injunction appeal that the district court incorrectly viewed importation of pregnant heifers as a vector for BSE infection (*see* Brief for Appellants in Ninth Cir. No. 05-35264, at 40-41), asserting that the Final Rule “affords *no opportunity* to

¹⁶ 71 Fed. Reg. at 12,995, col. 3. Grasping at straws USDA implies that, although the Final Rule did not contain the prohibition on import of pregnant ruminants that is imposed by these technical amendments, that was the effect of a statement in the preamble to the Final Rule that importation of cattle *for breeding purposes* was not allowed and because offspring *born in the United States* somehow “would not have been *imported* in compliance with the final rule.” *See id.*

divert heifers for breeding or *for births from pregnant cows.*” Reply Brief for Appellants in Ninth Circuit No. 05-35264, at 14-15 (emphasis added). The *R-CALF II* Court then accepted USDA’s inaccurate description of the Final Rule. *See* 415 F.3d at 1099.

The March 14, 2006 “technical amendments” thus bear directly on a contested issue in this case—first, USDA claimed the Final Rule presented no risk of BSE from importing pregnant Canadian cattle; then this year, USDA promulgated a rule to mitigate that risk. They also demonstrate the need for a hearing on the merits of R-CALF’s claims, so that the district court can evaluate the implications of these and other inconsistent statements USDA has made in the underlying rulemaking and in this case. *Cf. Defenders of Wildlife v. U.S. EPA*, 420 F.3d at 959 (agency’s inconsistent explanations may render rule arbitrary and capricious).

As R-CALF USA has noted above, a court reviewing USDA action under the APA may take judicial notice of USDA and FDA Federal Register notices and other official documents not included in the administrative record for the action. As this Court did in *Defenders of Wildlife v. Norton*, 258 F.3d at 1146, the district court should have the opportunity to assess whether such Federal Register notices demonstrate that inaccurate

assumptions or statements in support of the Final Rule render it arbitrary and capricious.

D. Consideration of facts and arguments not presented in the preliminary injunction proceedings could result in judgment in R-CALF's favor on the merits.

The fact that the Court in *R-CALF II* decided that R-CALF USA had not shown a likelihood of success on the merits to support a preliminary injunction in no way means that the *R-CALF II* decision addressed, much less disposed of and prevented the district court's consideration of, facts and arguments that were not even presented in connection with the application for preliminary injunction or USDA's appeal of the preliminary injunction.

As this Court has explained:

Decisions on preliminary injunctions require the District Court to assess the plaintiff's likelihood of success on the merits, not whether the plaintiff has actually succeeded on the merits. *See City of Anaheim v. Kleppe*, 590 F.2d 285, 289-90 (9th Cir. 1978); *Beal v. Stern*, 184 F.3d 117, 129-30 (2d Cir. 1999). Additionally, decisions on preliminary injunctions are just that—preliminary—and must often be made hastily and on less than a full record. *University of Texas v. Camenisch*, 451 U.S. 390, 395... (1981). Thus, even though the facial challenge presented to the District Court here involved primarily issues of law, we see no reason why the court should have deviated from the general rule that decisions on preliminary injunctions “are not binding at trial on the merits,” *id.*, and do not constitute law of the case,...

Southern Ore. Barter Fair, 372 F.3d at 1136 (citing *Golden State Transit*, 754 F.2d at 832 n.3). *See also Pitt News v. Pappert*, 379 F.3d 96, 104 (3d Cir. 2004) (law of the case doctrine does not require “a panel hearing an appeal from the entry of a final judgment to follow the legal analysis contained in a prior panel decision addressing the question whether a party that moved for preliminary injunctive relief showed a likelihood of success on the merits”); *Royal Ins. Co. of America v. Quinn-Capital Corp.*, 3 F.3d 877, 881 (5th Cir. 1993) (factual determinations made during an interlocutory appeal of a preliminary injunction are not law of the case).

R-CALF is entitled under the APA to have the district court make the requisite “thorough, probing, in-depth review” of the basis for the regulation in question in this case. *See R-CALF II*, 415 F.3d at 1093 (citations omitted). This Court should direct the district court now to consider all of the evidence and arguments available to it to determine whether USDA has provided a rational explanation for the Final Rule. *See California v. FCC*, 905 F.2d at 1244; *Ober*, 243 F.3d at 1195; *Defenders of Wildlife v. U.S. EPA*, 420 F.3d at 959.

CONCLUSION

For the reasons set forth above, the district court's denial of R-CALF's motion for summary judgment and grant of summary judgment for USDA should be reversed, and the case should be returned to the district court, for application of the legal standards for judicial review of USDA action under the APA discussed in *R-CALF II* and other decisions of the U.S. Supreme Court and this Court, to the arguments and evidence available to the district court.

Dated: December 26, 2006

Respectfully submitted

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**CERTIFICATE OF COMPLIANCE PURSUANT TO
NINTH CIRCUIT RULE 32(E)(4)**

STATEMENT OF RELATED CASES

ADDENDUM OF REGULATIONS

62 Fed. Reg. 65,747 (Dec. 16, 1997)

63 Fed. Reg. 406 (Jan. 6, 1998)

66 Fed. Reg. 52,483 (Oct. 16, 2001)

67 Fed. Reg. 8181 (Feb. 22, 2002)

68 Fed. Reg. 31,939 (May 29, 2003)

70 Fed. Reg. 12,112 (March 11, 2005)

70 Fed. Reg. 18,252 (April 8, 2005)

70 Fed. Reg. 58,569 (Oct. 6, 2005)

70 Fed. Reg. 73, 905 (Dec. 14, 2005)

71 Fed. Reg. 12,994 (March 14, 2006)

CERTIFICATE OF SERVICE

I hereby certify that, on the 26th day of December, 2006, I have caused two copies of the Appellant's Opening Brief and one copy of Appellant's Excerpts of Record to be served by placing them in the U.S. Mail, postage prepaid, addressed to:

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