

No. 06-35512

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IN THE UNITED STATES COURT OF APPEALS  
FOR THE NINTH CIRCUIT

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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

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**REPLY BRIEF OF APPELLANT**

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## **SUMMARY OF ARGUMENT**

Having succeeded in its appeal of the district court's grant of a preliminary injunction in this case, USDA now wants to make that success broader than it was, both by its terms and as a matter of law. This Court's decision overturning the preliminary injunction did not resolve the case on the merits, and in fact it could not have, given that many hundreds of pages of evidence and arguments were presented to the district court after the preliminary injunction proceedings. In vacating the preliminary injunction, this Court remanded the matter to the district court so that the lower court could consider the facts and arguments in the case in light of the correct legal standard for review of USDA's action.

USDA's assertions to the contrary, that simply did not happen, because the district court misapprehended its responsibility on remand. The district court gave no indication of considering the evidence and arguments submitted on cross-motions for summary judgment, and its only stated reasons for granting summary judgment to USDA concerned this Court's decision in the preliminary injunction appeal. The only appropriate remedy for that failure is for this Court to remand the matter to the district court.

Notwithstanding the substantial analysis and documentation that went into the Final Rule, it violated the Administrative Procedure Act (“APA”), 5 U.S.C. § 706(2), in numerous ways. It was based on considerations not appropriate under the relevant statute. It was inconsistent with expressed congressional intent. USDA’s explanations for the Final Rule, including its abandonment of prior findings that a ban on imports from countries with BSE is necessary to protect the U.S. cattle herd, were internally inconsistent and inconsistent with other statements of USDA and other federal government agencies. And a number of the key assumptions on which USDA’s decision-making was based have been shown to be without basis and clearly inaccurate, consistent with Plaintiff /Appellant Ranchers Cattlemen Action Legal Fund United Stockgrowers of America’s (“R-CALF’s”) earlier comments on the proposed rule.

BSE is too singular and critical a threat to the U.S. cattle herd to allow USDA to relax BSE protections without taking a hard look at USDA’s analysis, the assumptions on which it relied, and the considerations it applied. It is too serious a threat to ignore subsequent facts that demonstrate the inaccurate premises on which it is based. Had the district court conducted the necessary thorough, in-depth inquiry, it would have concluded

that the Final Rule was adopted in violation of the Administrative Procedure Act.

## ARGUMENT

### **I. The District Court Abdicated Its Responsibility To Consider the Facts and the Law Supporting R-CALF's Claims.**

#### **A. The District Court Did Not Conduct the Analysis Required by *R-CALF II* and the Administrative Procedure Act.**

USDA mischaracterizes R-CALF's position, claiming that R-CALF argues that the district court "accorded undue weight to" this Court's opinion in the preliminary injunction appeal and asserts that the district court's view of R-CALF's "contentions was wrongly colored by this Court's decision, to which [R-CALF] attaches little significance." USDA Br. at 40-41. USDA may be attempting to recast the argument in that way because it has no answer to the numerous cases cited in R-CALF's opening brief that show that an opinion overturning a preliminary injunction does not at all "tie the district court's hands" when assessing the case on the merits. R-CALF Br. at 23-26, 45-46.<sup>1</sup>

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<sup>1</sup> USDA also mischaracterizes the *R-CALF II* decision itself, calling it "this Court's prior decision upholding USDA's rule." USDA Br. at 30.

In fact, R-CALF argues that the district court did not follow this Court's opinion in *Ranchers Cattlemen Action Legal Fund United Stockgrowers of America v. U.S. Dept. of Agriculture*, 415 F.3d 1078 (9<sup>th</sup> Cir. 2005) ("*R-CALF II*"). *R-CALF II* held "that a preliminary injunction was unwarranted in this case," *id.* at 1093. It directed the district court to apply "the correct legal standard" in reviewing USDA's action at 70 Fed. Reg. 460 (Jan. 4, 2005) (the "Final Rule") pursuant to the Administrative Procedure Act ("APA"), 5 U.S.C. § 706(2), noting that there must be a "thorough, probing, in-depth' inquiry into the validity of regulations." *Id.*; R-CALF Br. at 17-18. The *R-CALF II* Court explained that the district court "should have evaluated whether there was an adequate basis in the administrative record for USDA's conclusion that the risks were acceptable." 415 F.3d at 1100.

That is not, however, what happened on remand. USDA claims that there is no evidence that the district court did not fully consider all of the facts and arguments made in the summary judgment proceedings and the totality of the administrative record. USDA Br. at 42-43. But it is clear from the language of the district court's 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 Tab 10,

that the district court concluded that no such analysis was necessary in light of the *R-CALF II* decision. The “Analysis” portion of the order was only two pages. *Id.* It does not contain any findings of fact or any discussion of the specific arguments and evidence presented in the summary judgment proceedings. It contains no commentary on the extensive expert declarations presented by both sides; no discussion of R-CALF’s allegations that other government reports or other statements by USDA were inconsistent with USDA’s statements supporting the Final Rule. Additionally, the district court cancelled the hearing on the cross-motions for summary judgment, which it had considered necessary for evaluation of the contested issues in the case, after this Court issued its initial decision vacating the preliminary injunction. *See* R-CALF Brief at 10-11.

Judge Cebull’s conclusion that his “hands are tied” by the *R-CALF II* decision, ER Tab. 10 at 4, hardly constitutes the application of the correct legal standard to the administrative record that the *R-CALF II* Court indicated should occur in this case. While the opinion granting USDA summary judgment does not say specifically that the district court was treating the *R-CALF II* decision as if it established the “law of the case” on

the merits of R-CALF's claims, *see* USDA Br. at 41, it certainly appears that it did, contrary to established precedent. *See* R-CALF Br. at 23-24.<sup>2</sup>

*City of Anaheim, Calif. v. Duncan*, 658 F.2d 1326, 1328 n.2 (9th Cir. 1981), described a similar situation to the present case: “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....The parties presented additional, albeit somewhat cumulative, evidence on their motion for summary judgment. They are entitled to a hearing on the merits.” (Citations omitted.) R-CALF USA did not get that hearing on the merits to which it was entitled, and which was contemplated by the *R-CALF II* decision.<sup>3</sup>

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<sup>2</sup> USDA's suggestion that the Court's reliance on *R-CALF II* in *Cactus Corner, LLC v. U.S. Dept. of Agriculture*, 450 F.3d 428, 433-34 (9th Cir. 2006), demonstrates that *R-CALF II* resolved this case on the merits is a *non sequitur*. The fact that the *R-CALF II* decision contains an interpretation of the Animal Health Protection Act as not requiring a quantification of acceptable risk or a risk assessment for a decision on import restrictions, and that this interpretation was relied upon in *Cactus Corner*, *see* 450 F.3d at 433-34, says nothing about whether the *R-CALF II* decision constituted a legal conclusion, binding on the district court on remand, that the issuance of the Final Rule met the requirements of either the Animal Health Protection Act or the Administrative Procedure Act.

<sup>3</sup> Review of this technical matter, with its voluminous record and filings below, by this Court, based on the limited briefing and excerpts of the administrative record available here, is not a substitute for the in-depth weighing of the facts that should have occurred at the district court. *See*,

**B. Substantial New Arguments and Evidence Were Presented to the District Court at the Summary Judgment Stage.**

USDA justifies its assertion that the district court did not need to do any more on remand than state that the *R-CALF II* decision had already resolved the matter by claiming over and over again that R-CALF failed to present any significant new information or arguments not presented at the preliminary injunction stage and presented “substantially the same arguments considered and rejected by this Court.” USDA Br. at 41; *see also id.* at 29. But that simply is untrue. R-CALF’s opening brief detailed a portion of the mass of information and arguments presented to the district court that was not presented either to the district court or to this Court during the proceedings leading up to the preliminary injunction and the appeal of the preliminary injunction. R-CALF Br. at 24-34. (Nor, understandably, did the *R-CALF III* opinion say that R-CALF had presented no arguments or evidence not addressed in the preliminary injunction proceedings.) Additionally, by the time the district court granted summary judgment to USDA, there had been important new factual developments that

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e.g., *Abdul-Jabbar v. General Motors Corp.*, 85 F.3d 407, 410 (9th Cir. 1996). The district court should be directed to perform the analysis that this Court’s *R-CALF II* opinion describes as necessary for review under the APA, 5 U.S.C. § 706(2), of USDA’s action. *See R-CALF II*, 415 F.3d at 1093.

demonstrated and confirmed the inaccuracy of key USDA assumptions underlying the Final Rule and important new statements by USDA or other federal government agencies that contradicted statements USDA offered in support of the Final Rule.<sup>4</sup> R-CALF brief at 34-44. (It would have been appropriate for the district court to consider those new developments in APA review of the Final Rule, as described in Section III, *infra*.)

USDA offers that R-CALF “was free to make additional legal arguments or to introduce new relevant exhibits” after the *R-CALF II* decision or to “identify errors in this Court’s reasoning that might justify review of its analysis by the district court or this Court.” USDA Br. at 41. But indeed that is exactly what happened, as described in R-CALF’s opening brief. *See also, e.g.*, Plaintiff’s Motion to Set Motions for Summary Judgment for Argument at nn. 2-3, pp. 8-9, 11-17 (Appellant’s Supplemental Excerpts of Record (“ASER”) Tab C). But when R-CALF did so, USDA told the district court that R-CALF should not be permitted to make additional arguments and that those arguments should be “disregarded.”

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<sup>4</sup> Contrary to the assertions of *amici*, R-CALF’s arguments for remand of the Final Rule are not based exclusively or even predominantly on information not available to USDA at the time the rule was issued in January 2005 and amended in March 2005, 70 Fed. Reg. 12,112 (March 11, 2005), as reflected below. In any event, these assertions conflict directly with USDA’s assertion that R-CALF’s briefing in this Court offers nothing new, see USDA Br. at 41.

Defendants' Opposition to Plaintiff's Motion To Set Motions for Summary Judgment for Argument (Dist. Ct. Docket #167) at 3; *see also id.* at 7 (objecting to a statutory argument because R-CALF "has not heretofore raised it in this litigation").<sup>5</sup>

**II. USDA's Decision To Lift the Ban on Imports from Canada Deserves (But Has Not Received) Thorough Scrutiny.**

USDA would like this Court, based almost entirely on conclusions from preliminary proceedings, simply to shrug and say "the Secretary had some basis for his exercise of discretion, and that is good enough." But that simplistic and conclusory approach is not appropriate under the APA and is not consistent with congressional directives and the unique nature of BSE.

Contrary to USDA's description, this case is not about whether the Secretary was required to impose a ban on imports from Canada. *See* USDA Br. at 19. Import restrictions had already been determined by the Secretary to be "necessary to prevent the introduction" of BSE from countries known to have BSE, including Canada. 7 U.S.C. § 8303(a)(1); R-CALF Br. at 7.

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<sup>5</sup> Perhaps inadvertently, USDA inaccurately describes R-CALF's motion for summary judgment as a motion for "summary judgment on remand." USDA Br. at 15. Obviously, R-CALF moved for summary judgment months before the *R-CALF II* decision and remand. After the remand, R-CALF sought to bring the district court up to date and to comment on the implications of the *R-CALF II* decision for its summary judgment motion (*see* ASER Tab C), and at that point USDA objected to the additional arguments.

The Final Rule at issue in this case was a decision to relax import restrictions, abandoning USDA's prior determinations that, because the "causative agent of BSE is not completely characterized," "there is no treatment for the disease," and there "is no vaccine to prevent BSE nor is there a test to detect the disease in live animals" (all statements equally true today), import restrictions "are the most effective means available for ensuring that BSE does not enter the United States...." 62 Fed. Reg. 65,747, 65,748 (Dec. 16, 1997); *see also* 66 Fed. Reg. 52,483 (Oct. 16, 2001) and 67 Fed. Reg. 44,016, 44,017 (July 1, 2002) (similar); R-CALF Brief at 30 n. 10 (noting other USDA statements that a ban on imports was critical to preventing the introduction of BSE). USDA followed this rationale up through its 2003 ban of imports of cattle and meat from Canada once BSE was found there, even though the principal mechanism that USDA now says protects U.S. cattle from BSE infection as a result of importing potentially infected cattle from Canada, the ruminant-to-ruminant feed ban, was already in place from 1997 on. *See* 70 Fed. Reg. at 466; *see also* 66 Fed. Reg. 52,483 (Oct. 16, 2001) and 67 Fed. Reg. 12,833 March 20, 2002) (applying same approach when BSE was first found in cattle in Japan and Austria).

Thus, this case is about whether, under the APA, it was arbitrary and capricious or otherwise not in accordance with law for the Secretary to

reverse prior determinations and conclude that it is no longer “necessary” to ban imports of cattle and beef from Canada to “prevent the introduction into” the United States of BSE. *See* 7 U.S.C. § 8303(a)(1). Under APA precedent, in order not to be arbitrary and capricious such a reversal of position must be fully justified; it cannot simply be upheld based on USDA’s claim to unbridled deference. *See, e.g., California v. FCC*, 905 F.2d 1217, 1234 (9th Cir. 1990); *Lynch v. Dawson*, 820 F.2d 1014, 1021 (9<sup>th</sup> Cir. 1987); *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”). It also must be consistent with and implement statutory directives. The Final Rule is neither.

USDA uses unclear language in many places in its responsive brief (e.g., measures to “guard against” BSE, USDA Br. at 4), apparently to paper over the fact that USDA’s action adopting the Final Rule constitutes an abandonment of the statutory directive to prevent “introduction” of animal diseases, deciding instead to accept introduction of BSE into the United States from Canada, in the interest of promoting trade, and focus instead on measures to control the “dissemination” or spread of BSE once it has been introduced from Canada. *Cf.* 7 U.S.C. § 8303(a)(1). This decision to

implement only half of the Animal Health Protection Act's ("AHPA'S") directives for imports is inconsistent with the language of the Act.

It is also inconsistent with the emphasis Congress has placed on preventing the introduction of BSE in particular. Although, as USDA notes (USDA Br. at 34), the Animal Disease Risk Assessment, Prevention, and Control Act of 2001, P.L. 107-9, 115 Stat. 11, is a reporting statute, among its stated purposes is "to prevent . . . bovine spongiform encephalopathy, and related diseases" from entering the United States. *Id.* at Sec. 2. The Act's sponsor, Senator Orrin Hatch, stated, "No case of BSE has ever been identified in the United States. This bill is intended to continue that success into the future." 147 Cong. Rec. S3709 (April 6, 2001). Regarding one of two reports required of the Secretary of Agriculture pursuant to this Act, Senator Hatch stated: "A chief goal of that report is to help devise a coordinated plan to prevent the introduction of FMD and BSE into the United States and to help identify the proper corrective steps if FMD and BSE find their way into our country." *Id.* (emphasis added).

USDA's decision to lift the ban on imports of Canadian cattle and accept the likelihood of BSE-infected cattle being introduced into the United States from Canada is thus contrary to both the language of the AHPA and

the congressional intent expressed in the enactment of P.L. 107-9.<sup>6</sup> *See, e.g., Motor Vehicle Mfrs. Ass'n v. State Farm Mutual*, 463 U.S. 29, 52-56 (1983) (no deference when agency emphasized cost of automatic seatbelts in contrast to congressional intent that passenger safety be primary concern).

Nor should the Court accept the notion implicit in the arguments of USDA and *amici*, that the Court should defer to USDA's judgment that the controlled risk of introducing BSE into the U.S. cattle herd should be considered acceptable when measured against the benefits of free trade with Canada. *See, e.g.,* amicus brief of Nat'l Meat Ass'n, et al., at 13. USDA has stated in another rulemaking concerning BSE and imports of meat that it "does not have the authority to restrict trade based on its potential market access effects. Under its statutory authority, [USDA] may prohibit or restrict

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<sup>6</sup> Moreover, USDA's action in the Final Rule is contrary to the 2003 report it made to Congress, as required by P.L. 107-9, which stated that one of the three primary goals of the U.S. BSE strategy was to "[p]revent the agent of BSE from entering the United States and infecting U.S. cattle," explaining that the Harvard Risk Assessment indicated that the two most important measures for preventing the introduction and spread of BSE in the U.S. are the ban on imports of live cattle and meat and bone meal from the UK and Europe (the countries known to have BSE at that time) and the U.S. ruminant-to-ruminant feed ban. *See* Federal Inter-agency Working Group, Final Report, Animal Disease Risk Assessment, Prevention, and Control Act of 2001, Title X, Subtitle E of PL 107-171, January 2003 (ASER Tab A), at AR009305, 9306. *See also id.* at AR009305 (describing the need for measures to prevent amplification of BSE in the U.S. herd "were it to penetrate the primary BSE safeguards at the U.S. borders" (emphasis added), AR009307; R-CALF Br. at 33 and n. 10.

the importation or entry of any animal or article when the agency determines it is necessary to prevent the introduction or dissemination of a pest or disease of livestock.” 70 Fed. Reg. 73,905, 73,914 (Dec. 14, 2005); *see also id.* at 73,916 (USDA does not have authority to restrict trade” based on issues such as competition between imported beef and domestic beef).<sup>7</sup>

Taking USDA at its word, weighing the trade effects of continuing the ban on imports from Canada, *see* 70 Fed. Reg. at 536-39, constituted the consideration of an inappropriate factor under the statute, which necessarily means the Final Rule was issued in violation of the APA and should be remanded.<sup>8</sup> *See, e.g., R-CALF II*, 415 F.3d at 1093; *Motor Vehicle Mfrs.*, 463 U.S. at 43, 56.

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<sup>7</sup> *Cf.* 70 Fed. Reg. at 73,914 (declining to tie import restrictions under the AHPA to country-of-origin labeling requirements, because the latter “is a retail labeling program and as such does not address food safety or animal health concerns”).

<sup>8</sup> Similarly, USDA could not lawfully reopen imports of cattle from a country with a BSE problem, like Canada, if restricting imports remained “necessary to prevent the introduction or dissemination within the United States of” BSE in “*livestock*,” *see* 7 U.S.C. § 8303(a)(3) (emphasis added), just because it found that, despite the likely introduction of BSE into the U.S. herd, the anticipated risk to *human* health was not significant. *See R-CALF Brief* at 20; *cf. R-CALF III* (ER Tab 10) at 4 (concluding that the district court’s “hands are tied” because the Ninth Circuit “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.’” (quoting 415 F.3d at 1095)).

USDA (and *amici*) refer repeatedly to the voluminous administrative record and the lengthy Federal Register preamble for the Final Rule, as if the Court should conclude that the rulemaking satisfied the APA based solely on the number of words USDA used. Nor is it sufficient for a reviewing court simply to “determine if USDA had a basis for its conclusions.” *R-CALF II*, 415 F.3d at 1093-94. The “‘searching and careful,’” “‘thorough, probing, in-depth’ inquiry into the validity” of the regulations that the APA requires must involve more than that. *See R-CALF II*, 415 F.3d at 1093 (citations omitted). Under the APA, courts must, and regularly do, strike down agency actions that are supported by an extensive record and analysis, because the agency, e.g.: (1) did not consider all of the relevant information; (2) considered factors that Congress did not intend it to consider; (3) failed to respond adequately to public comments; (4) provided an insufficient explanation of its decision-making; (5) failed adequately to explain a departure from previous factual or policy determinations; (6) provided an internally inconsistent rationale for its decision; or (7) relied on assumptions that were inaccurate or unsupported. *See R-CALF Br.* at 15-16, 38, and nn.8 and 9. The Final Rule fails on a number of these criteria.

Review of a USDA decision to lift protections that had been provided against BSE deserve particularly careful scrutiny. BSE is an invariably fatal

disease, highly infectious, for which there is no cure and no vaccine.

Declaration of Dr. Stanley Prusiner, ER Tab 8 ¶ 9. The BSE infectious agent is very potent and very difficult to destroy. *Id.* ¶ 11. The disease is extraordinarily difficult to manage because only a tiny amount of infected tissue can infect another animal, and there are no tests available to determine whether live cattle are infected before they are imported or before they are slaughtered, and even post-mortem tests are not sensitive enough to detect BSE infection in many instances. 62 Fed. Reg. 65,747, 65,748; *Baur v. Veneman*, 352 F.3d 625, 639 (2d Cir. 2003); ER Tab 8 ¶¶ 11, 21-22; ASER Tab A at AR009303. Discovery of a single BSE-infected cow in the United States, which had been imported from Canada, cost the U.S. cattle industry billions of dollars. R-CALF Br. at 4; see also ASER Tab A at AR009304-305. BSE simply is not a case where USDA’s analysis and explanation can be “close enough for government work,” and where the reviewing court can avoid the hard look at USDA’s rationale that the APA requires.<sup>9</sup>

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<sup>9</sup> For example, when presented with the fact that USDA, in support of the Final Rule, said that removal of specified risk materials (“SRMs”) from an infected animal at slaughter reduces the potential human exposure to infected tissue by 95 percent, when in fact its own contemporaneous documents and the statements of its experts estimated the exposure was only reduced by 80 percent, *see* R-CALF Br. at 45-46, USDA implies that this internal inconsistency and understatement of the residual risk by 75 percent is not worth worrying about, and does not make the rule arbitrary and

**III. R-CALF Has Demonstrated that the Final Rule Failed To Meet the Requirements of the APA and the AHPA.**

USDA does not dispute, nor could it, R-CALF's demonstration that the district court was presented with voluminous evidence and arguments in support of the cross-motions for summary judgment that were not presented to the district court nor to this Court during the preliminary injunction proceedings and appeal. *See* R-CALF Br. at 28-34. USDA instead asks this Court to engage in the fiction that the district court considered all this evidence and arguments—despite the lack of any indication in *R-CALF III* that it did—and then to look at some of the arguments and conclude with a broad brush that USDA had sufficient basis for its action.

This is not the kind of “thorough, probing, in-depth inquiry into the validity of regulations” that the APA demands and that BSE risks, in particular, warrant. *See R-CALF II* at 1093 (internal quotation omitted). Nor is it reasonable to ask this Court to perform the type of review that the district court should have in this case. USDA's position that no remand to

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capricious, because the risk in any event is “very small.” *See* USDA Br. at 34. Thankfully, most of the human health risks USDA and other agencies address are considered to be small, but that does not exempt them from the APA requirements for a reasoned analysis and clear, consistent explanation. If the risk in fact is four times as great as USDA asserted in the preamble to the proposed and final rules, the public has a right to know that, and to have USDA's explanation, in conjunction with issuance of the Final Rule, that such higher risk is acceptable.

the district court is necessary is a bit like a parent finding that a child failed to do his homework...and reprimanding the child by the parent doing the homework herself. Remand to the district court is appropriate here.

Nevertheless, even a cursory review would allow this Court, if it wished, to conclude now that USDA's promulgation of the Final Rule was arbitrary and capricious under the APA, because it relied on assumptions that are clearly inaccurate, provided inconsistent explanations of its actions, considered factors not appropriate under the AHPA, and failed adequately to explain its reversal of a prior determination that banning imports was a key factor to prevent the introduction of BSE into the United States. And the appropriate remedy for those failures is not to conclude that the Secretary had discretion to decide to lift the import ban regardless, as USDA seems to suggest, but to remand the Final Rule to USDA for further consideration and explanation, using current information and relying on appropriate factors.

**A. Key Assumptions on Which the Final Rule Was Based Are Demonstrably Inaccurate.**

The APA requires an agency to fully explain and justify assumptions on which a rule is based. *See, e.g., California v. FCC*, 905 F.2d 1217, 1244 (9th Cir 1990); *Ober v. Whitman*, 243 F.3d 1190, 1195 (9<sup>th</sup> Cir. 2001); *National Ass'n of Home Builders v. Norton*, 340 F.3d 835, 841 (9<sup>th</sup> Cir.

2003). In this case, a number of the assumptions that were fundamental to USDA's stated justification for the Final Rule were incorrect.

When it comes to the health of the U.S. cattle herd, the “multiple, interlocking safeguards upon which the rule is predicated” (USDA Br. 31) are basically four: (1) very low incidence of BSE in Canada, (2) an effective feed ban in Canada that will cause BSE to continue to decline, (3) cattle under 30 months of age will be unlikely to have BSE (especially because the effective feed ban in Canada means the incubation period in Canada will be longer than in English cattle), and (4) an effective feed ban in the United States will prevent any BSE-infected Canadian cattle imported into the United States from getting into U.S. cattle feed. *See R-CALF II*, 415 F.3d at 1095-96. An inadequate justification for any one of those assumptions would mean that USDA had not provided the reasoned evaluation the APA requires, but in this case all four assumptions were incorrect.

### **1. Low and decreasing incidence in Canada**

R-CALF's opening brief described the two cases of BSE in Alberta that were announced just after the Final Rule was signed (bringing the total to four cases in Canadian-born cattle), as well as the five additional cases that were identified in 2006 alone. *Id.* at 5-6. R-CALF also explained that

a majority of the latest cases were born years after Canada's 1997 feed ban was supposedly effective to prevent further exposure to BSE. *Id.* at 6.

Even since R-CALF's opening brief in this case, Canada has found yet another case of BSE, and this one again in a bull born in Alberta years after Canada's 1997 feed ban supposedly eliminated exposure to BSE. See <http://www.inspection.gc.ca/english/anima/heasan/disemala/bseesb/ab2007/9investe.shtml>. Moreover, Canada determined that one of the cows born into the same herd in the same timeframe (and therefore likely consuming the same feed) was exported to the United States in 2002. *See id.*

BSE has now been found in 10 native Canadian cattle (9 that died in Canada and one that died in Washington State), out of approximately 150,000 tested, with half of them born after Canada's 1997 feed ban and more than half discovered in the last 15 months. *See id.* USDA's assumption that the prevalence of BSE in Canada is "very low," 70 Fed. Reg. at 528, based on the two cases (both born before 1997) discovered prior to signing the Final Rule, has proven to be inaccurate.<sup>10</sup> The empirical evidence also

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<sup>10</sup> *Amicus* Government of Canada points to a new USDA estimate of the prevalence of BSE in Canada of 6.8 animals per 10 million adult cattle, claiming even that is an overestimate. Canada Br. at 20-21. Since there are only about 5.5 million adult cattle in Canada, 70 Fed. Reg. at 468, and

clearly does not support USDA's assumption that the prevalence of BSE in Canada is declining rapidly.<sup>11</sup>

While USDA now claims that its assessment of the risk of Canadian imports assumed that there would be additional cases like this (USDA Br. at 12, 29-30), that is simply untrue. To the contrary, it assumed the possibility of additional cases discovered in Canada "if any, to be very low" (70 Fed. Reg. at 516); and "the likelihood of the spread and establishment of BSE in Canada, both before and after the 1997 feed ban, was negligible" (70 Fed. Reg. at 468). USDA further assumed there would not be continuing exposure to BSE, nor infection, of Canadian cattle after the 1997 Canadian feed ban, and in fact USDA's analysis stated explicitly that the discovery of such cattle would indicate that the feed ban was not effective as USDA assumed. *See* R-CALF Br. 36-37. Contrary *post hoc* assertions of counsel cannot remedy that inconsistency between USDA's explanation of the basis for the Final Rule and the facts that have demonstrated its inaccurate assumptions. *See Defenders of Wildlife v. Norton*, 258 F.3d at 1145 n. 11;

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Canada discovered six cases in the past 15 months alone, such a new USDA estimate that flies in the face of actual experience is scant comfort.

<sup>11</sup> Also, USDA's assumption that an effective Canadian feed ban would cause a sharp decline in BSE cases in Canada obviously has not been borne out in practice, with no indication of decreasing incidence from 2003 to 2007.

*Pinto v. Massanari*, 249 F.3d 840, 847 (9<sup>th</sup> Cir. 2001); *SEC v. Chenery Corp.*, 318 U.S. 80, 87 (1943). This Court should follow the same approach in this case as it did in *Norton*, rejecting an agency decision that relies on an assumption about future developments which in fact did not come to pass.<sup>12</sup> See 258 F.3d at 1146.

## 2. Effective Canadian feed ban beginning in 1997

A central element of USDA's justification for allowing imports from Canada was its conclusion that Canada had an effective ruminant-to-ruminant feed ban beginning in the fall of 1997.<sup>13</sup> See 70 Fed. Reg. at 467, 476, 515. Although the *R-CALF II* opinion rejected the trial court's concerns about the limitations of the Canadian feed ban, 415 F.3d at 1098-99, actual experience now demonstrates conclusively that Canada has not had an effective feed ban since 1997 as USDA assumed. There now have

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<sup>12</sup> The suggestions of *amici* that the fact that more infected cattle have been found in Canada mean Canada's "system is working" are nonsensical. We simply do not know how many more infected cattle there may be in Canada, but what we do know is that there is no indication that their numbers are decreasing, other than the hopes and wishful thinking of many. See, e.g., amicus brief of the Government of Canada at 24-25, claiming that "the safety of beef from [Canadian cattle] has been demonstrated in practice" simply because Canada has shipped 1.8 million cattle to the U.S. since BSE was discovered in Canada.

<sup>13</sup> Despite the following argument, presented in R-CALF's opening brief, USDA inexplicably states: "Plaintiff offers no reason to reach a different conclusion in this appeal." USDA Br. 31.

been as many cases born after the feed ban as before, some three and four *years* after the feed ban, and USDA itself said that any cases in cattle born after the feed ban would be evidence that the feed ban was ineffective. R-CALF Br. at 41-42.

USDA has even acknowledged (and prior to discovery of the latest case in a bull born approximately three years after the feed ban) that Canada's feed ban was not effective before March 1999, 72 Fed. Reg. 1102, 1109 (Jan. 9, 2007), although even that proposed cutoff date is certainly dubious, in light of the fact that four of the 10 BSE cases found in native Canadian cattle were born between 2000 and 2002.

Given the clear inaccuracy of one of the central assumptions underpinning the Final Rule, the APA requires that the Final Rule be vacated and remanded. *See, e.g., Ass'n of Pacific Fisheries v. Environmental Protection Agency*, 615 F.2d 794, 812 (9<sup>th</sup> Cir. 1980); *Defenders of Wildlife v. Norton*, 258 F.3d at 1146. Assertions by *amici* that the Court must ignore the subsequent facts and USDA admissions (which confirm concerns about the effectiveness of Canada's feed ban that R-CALF expressed in comments on the proposed rule) would have this Court perform a meaningless judicial review with blinders on. Neither logic nor case law supports that result. As

the D.C. Circuit stated in *Amoco Oil Co. v. Environmental Protection Agency*, 501 F.2d 722, 729 (D.C. Cir. 1974):

Rule-making is necessarily forward-looking, and by the time judicial review is secured events may have progressed sufficiently to indicate the truth or falsity of agency predictions. We do not think a court need blind itself to such events, at least when the events are evidenced by public testimony given to a governmental body. A contrary rule would convert the reviewing process into an artificial game.

*Id.* at 729 (cited by this Court in *Ass'n of Pacific Fisheries*).

### **3. Under-30-month cattle unlikely to carry BSE**

The R-CALF II opinion states that cattle under 30 months of age “are extremely unlikely to have BSE.” 415 F.3d at 1095. This is an inaccurate statement. Cattle under 30 months of age are unlikely to display clinical signs of BSE or to be identified with current BSE test methods, but USDA itself assumes that BSE infection usually occurs in the first year or so of life. *See* ER Tab 5 pp. 5, 25. In fact, USDA assumes, based on available data, that parts of an infected animal—the tonsils and the distal ileum (part of the gut)—carry potentially infectious levels of BSE as early as six months post-exposure and therefore must be removed at slaughter regardless of whether cattle are under 30 months of age. *See* 70 Fed. Reg. at 483, ER Tab 3 ¶¶ 6, 7. Thus, infected tissue from imported cattle under 30 months of age can enter the animal feed system (SRMs can be and are used for animal feed

other than for ruminants) and, through cross-contamination or cross-feeding, be fed to U.S. cattle.

Additionally, USDA's assumption that under-30-month Canadian cattle are unlikely to carry significant infection because Canada's low BSE incidence and effective feed ban result in a long BSE incubation period for Canadian cattle, *see R-CALF II*, 415 F.3d at 1095-96, is also demonstrably wrong, both because of the inaccuracies in USDA's assumption about Canada's BSE incidence rate and the effectiveness of Canada's feed ban noted above, and because actual experience in Canada shows that the BSE incubation period in recent years has not been substantially greater than the 4.2-year average in the UK, *cf. R-CALF II*, 415 F.3d at 1098-99, or the "about 5 years" general incubation period in Europe referenced at 70 Fed. Reg. at 475. Even if one assumed that the four youngest Canadian cattle determined to have BSE in the past 15 months (*see R-CALF Br.* at 5-6) immediately consumed contaminated feed as soon as they were weaned (at about six months of age; i.e., assuming they had the longest possible incubation period), the average incubation period for those cases would still only be about 5 years.

#### **4. U.S. feed ban protects domestic cattle from imported BSE.**

Even if USDA's most optimistic assumptions about the preceding three barriers to BSE infection of the U.S. cattle herd had been accurate, USDA still acknowledged that some BSE-infected cattle could be introduced into the United States if the ban on Canadian imports were lifted. USDA Br. at 29-30. Sidestepping its previous determinations that a ban on imports from countries with BSE was "necessary" to prevent the introduction of BSE into the United States, USDA relied in large part on a risk assessment that concluded that, once BSE infected cattle from Canada entered the United States, the disease would not propagate due to the U.S. ruminant-to-ruminant feed ban.<sup>14</sup> *See* 70 Fed. Reg. at 512-24. That risk assessment assumed, however, that the U.S. feed ban is highly effective at preventing cattle protein from being recycled and fed to cattle. *See* ASER Tab B at AR003777 (showing "base case," the one whose results USDA described in support of the Final Rule, assumed very low probability of contamination or

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<sup>14</sup> Of course, as noted above, USDA never explained why the same 1997 U.S. feed ban was considered inadequate to protect against the possibility of BSE from imported cattle getting into U.S. cattle feed in previous decisions to ban imports. *See, e.g.*, 66 Fed. Reg. 52,483 (October 16, 2001) (BSE could be established in the U.S. if BSE-infected cattle are imported into the U.S. and materials carrying the BSE agent are fed to U.S. cattle); *see also* p. 10 *supra*.

mis-feeding). But USDA's assertion that the U.S. feed ban was "highly effective" had little support in the record.

R-CALF's reference to the GAO report "Mad Cow Disease: FDA's Management of the Feed Ban Has Improved, but Oversight Weaknesses Continue to Limit Program Effectiveness" on p. 32 of its opening brief and more extensive discussion in its briefing in the district court was not an "attack on Canada's feed ban," as USDA suggested in its brief at 32. Rather, the GAO report directly contradicts USDA's assertion that the U.S. feed ban is effective. That report concluded that FDA "is overstating industry's compliance with the animal feed ban and understating the potential risk of BSE for U.S. cattle...." SER189; *see also* SER157. Importantly, GAO found that FDA simply did not have enough information to justify conclusions about a high rate of compliance. SER164-65, 167, 189. This followed on a 2002 GAO report that "FDA's data on inspections were so severely flawed that the agency could not know the extent of industry compliance." SER163.

Proceeding on the assumption that the U.S. feed ban will be highly effective at keeping BSE-contaminated tissue from Canadian cattle out of U.S. cattle feed, when available data are insufficient to support that

assumption, is arbitrary and capricious. The importance of that unsupported assumption is highlighted by the experience in Canada (whose feed ban USDA has described as equivalent to the U.S. ban, 70 Fed. Reg. at 467, 491): USDA assumed that Canada's feed ban had been effective since 1997 in keeping BSE contamination out of Canadian cattle feed, but that obviously was not the case. USDA must not be allowed to engage in such wishful thinking when exposing the U.S. cattle herd to the risk of a devastating disease.<sup>15</sup>

**B. Inconsistencies in Statements Supporting the Final Rule Render it Arbitrary and Capricious.**

The APA requires that an agency action be founded on a reasoned evaluation of the facts and the relevant factors under the statute. If the agency's explanation for its action is internally inconsistent or inconsistent with other statements by that agency or other federal government agencies, it has not demonstrated that reasoned evaluation. *See, e.g., Defenders of Wildlife v. U.S. EPA*, 420 F.3d 946, 959 (9<sup>th</sup> Cir. 2005) (agency's inconsistent explanations may render rule arbitrary and capricious). In this case,

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<sup>15</sup> Note also that USDA's reliance on the great reduction in BSE in the UK and Europe following feed bans there, USDA Br. 32, is misleading: those countries implemented a much more stringent feed ban, keeping ruminant protein out of all animal feed, and thus removing the potential for cross-contamination or mis-feeding that seems to have caused the continued problems in Canada. *See* Harvard Study, ASER Tab B at AR003736-3739.

inconsistencies about key considerations render the Final Rule arbitrary and capricious.

Perhaps the biggest inconsistency is USDA's decision, only weeks after stating that imports of beef from cattle that were 30 months of age and older when slaughtered in Canada are safe, to suspend all such imports after the discovery of two additional cases of BSE in Alberta. *See* R-CALF Br. at 44-45. If indeed USDA anticipated additional cases would be discovered, *see* USDA Br. 29-30, then why would that discovery trigger suspension of the rule? Simply dismissing this inconsistency as "an abundance of caution," USDA Br. at 37 fails to explain an action that indicates a lack of USDA confidence in the confidently-stated conclusions of the Final Rule.

Another inconsistency already described above is the contrast between USDA's current position—that the discovery of a half-dozen new BSE cases in the last year and a half, with a number born years after BSE exposure in Canada supposedly ceased, is irrelevant—and USDA's logical conclusion, reflected in the preamble to the Final Rule and in its Risk Analysis for the Final Rule, that BSE cases in Canada born before its feed ban do not necessarily indicate inadequacies of the feed ban, but those born after the feed ban would. *See* R-CALF Br. at 35-37. USDA really offers no

explanation for that discrepancy. Merely repeating that USDA concluded that Canada strongly enforces its feed ban, USDA Br. at 32, does not substitute for engaging the facts of continued BSE exposure long after this strong enforcement began.<sup>16</sup>

USDA also essentially acknowledges that it told the public that SRM removal would reduce human exposure by 95%, when its own experts were saying it would reduce exposure by only 80%. *Compare* R-CALF Br. at 45 and 46 *with* USDA Br. at 34-35. Perhaps “the conclusion is the same” in either case, USDA Br. at 35, but the public has a right to know what the facts really are and what assumptions USDA really is relying on, and USDA’s inconsistent statements of such a key assumption render the Final Rule arbitrary and capricious.

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<sup>16</sup> Similarly, USDA ignores the inconsistency between its pronouncements that there “may be” a substantial “species barrier” that protects humans from infection from BSE-infected meat and the conclusion of its own risk assessment experts that, for purposes of worst-case risk assessment, one should assume there is no species barrier. Instead, USDA assumes the species barrier is at the high end of the possible range. *Compare* USDA Br. 37-38 and ER Tab 3 ¶ 13 *with* Harvard risk assessment, rev’d October 2003, at 9 (ASER Tab B at AR3707). USDA also ignores the substance of Dr. Prusiner’s declaration (ER Tab 8 ¶ 13): that the relatively low incidence of vCJD in humans so far cannot legitimately be claimed as an indicator that there is a large species barrier, as USDA has used it. *Cf.* 70 Fed. Reg. at 462, 505 and ER Tab 3 ¶ 13.

There are numerous other examples of USDA at best providing a “fluid” description of the rationale for allowing imports from Canada; i.e., claiming in the Final Rule that animal surveillance (testing) is a critical “BSE risk mitigation measure” and then saying later the same year that it “is not a mitigation measure,” R-CALF Br. at 41-42 n. 15, or telling this Court that the Final Rule did not allow pregnant cattle to be imported and then later amending the Final Rule because such a prohibition was needed, R-CALF Br. at 42-44.<sup>17</sup> USDA’s failure to provide a consistent explanation, especially for a matter as potentially devastating as BSE infection of the U.S. cattle herd, makes its rulemaking arbitrary and capricious.<sup>18</sup> *See, e.g., Nat’l Ass’n of Home Builders*, 340 F.3d at 841; *Defenders of Wildlife v. U.S. EPA*, 420 F.3d at 959.

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<sup>17</sup> R-CALF’s complaint is not that USDA promulgated such an amendment, *cf.* USDA Br. 36, but that its multiple inaccurate statements of the assumptions underlying the Final Rule render that rulemaking arbitrary and capricious under the APA and its jurisprudence.

<sup>18</sup> *See also, e.g.,* USDA’s implication that cattle 30 months of age as early as the spring of 2005 would have been born “long after” Canada’s feed ban eliminated BSE exposure, USDA Br. 18, versus the fact that that one of the BSE-infected cattle detected in Alberta was not exposed to potentially contaminated cattle feed until at least mid-2002, *see* R-CALF Br. 6 and n.3.

**C. Consideration of Inappropriate Factors Makes the Final Rule Arbitrary and Capricious.**

An agency action is arbitrary and capricious if the agency bases its decision in whole or part on the consideration of factors that are inappropriate for its statutory mandate. *See, e.g., Motor Vehicle Manufacturers' Ass'n v. State Farm Automobile Insurance Co.*, 463 U.S. 29, 43, 56 (1983); *R-CALF II*, 415 F.3d at 1903. As explained above, the AHPA directs the Secretary of Agriculture to determine whether restrictions on imports are necessary to protect the health of U.S. livestock, not to promote international trade in potentially diseased animals. *See* pp. 12-14, *supra*. USDA has stated itself that it cannot base a decision about restrictions on imports under the AHPA on trade and market considerations. *Id.* at 13-14. Yet in the case of the Final Rule, USDA retreated from regulations considered necessary to prevent the introduction of BSE in the United States for the express purpose of fostering trade with Canada. *See, e.g.*, 68 Fed. Reg. 62,386, 62,400 (proposal responds to Canadian interest in reopening trade). USDA simply lacks statutory authorization to decide that continued cross-border trade in cattle is more important than preventing the introduction of a livestock disease into the United States. Its reliance on factors not appropriate under the statute renders its decision arbitrary and capricious.

Likewise, USDA's conclusion that it can accept the likely introduction of BSE into the United States, because it believes that nevertheless BSE will not spread through the U.S. herd, also reflects a failure to consider the relevant factors under the statute. See R-CALF This departure was especially arbitrary, given that it was the mere introduction of an infected cow from Canada into Washington State that devastated U.S. beef exports, without any reason to believe that BSE infectivity from that particular cow was disseminated at all to U.S. livestock. See SER160-61, 170-71.

### 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.

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Respectfully submitted

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**CERTIFICATE OF COMPLIANCE PURSUANT TO  
FED. R. APP. P. 32(a)(7)(B)**

1. This brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B)(ii) because this brief contains 7907 words. This is less than the 8400 words allowed by the Court's March 29, 2007 order.
  
2. This brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6) because this brief has been prepared in a proportionally spaced typeface using MS Word with Times New Roman font and 14-point type.

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Russell S. Frye

## CERTIFICATE OF SERVICE

I hereby certify that, on this 19th day of April, 2007, I have caused two copies of the Appellant's Reply Brief and one copy of Appellant's Supplemental Excerpts of Record to be served by placing them in the U.S.

Mail, postage prepaid, addressed to:

Michael S. Raab  
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Appellant's foregoing Reply Brief and Supplemental Excerpts of Record was also transmitted to the Court, pursuant to Fed. R. App. P. 25(a)(2)(B), by mailing it to the Clerk by U.S. Postal Priority Mail on this date.

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Russell S. Frye