FOR PUBLICATION

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

RANCHERS CATTLEMEN ACTION LEGAL FUND UNITED STOCKGROWERS OF AMERICA, *Plaintiff-Appellant,* v. U.S. DEPARTMENT OF AGRICULTURE, *Defendant-Appellee.*	No. 06-35512 D.C. No. CV-05-00006-RFC OPINION

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

Argued and Submitted
July 13, 2007—Portland, Oregon

Filed August 28, 2007

Before: Cynthia Holcomb Hall and Milan D. Smith, Jr.
Circuit Judges, and Kevin Thomas Duffy,* Senior Judge.

Opinion by Senior Circuit Judge Hall

*The Honorable Kevin Thomas Duffy, Senior United States District Judge for the Southern District of New York, sitting by designation.

COUNSEL

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OPINION

HALL, Senior Circuit Judge:

This case involves a challenge to the government's regulation of Canadian cattle imports in the wake of the "mad cow disease" scare of the late 1990s. Ranchers Cattlemen Action Legal Fund United Stockgrowers of America ("R-CALF-USA" or "R-CALF") argues that the United States Department of Agriculture ("USDA") issued an arbitrary and capricious rule relaxing a ban on Canadian beef and cattle imports. *See Bovine Spongiform Encephalopathy; Minimal-Risk Regions and Importation of Commodities*, 70 Fed. Reg. 460 (January 4, 2005) (hereinafter "the Final Rule").

R-CALF argues that recent incidents of mad cow disease in the Canadian herd, and in American cows imported from the Canadian herd, cast doubt on the agency's rulemaking procedure. With additional references to scientific studies and international regulations, R-CALF challenges the agency's

assessment that the "multiple, interlocking safeguards" implemented by both the United States and Canada will be effective at preventing human infection domestically.

The district court granted summary judgment to the USDA, and we have jurisdiction to review this order under 28 U.S.C. § 1291. The facts have been provided in prior related decisions and will not be recited exhaustively here. *See Ranchers Cattlemen Action Legal Fund United Stockgrowers of Am. v. United States Dep't of Agric.*, 359 F. Supp. 2d 1058 (D. Mont.) (hereinafter "*R-CALF I*"), *rev'd* 415 F.3d 1078 (9th Cir. 2005) (hereinafter "*R-CALF II*").

We affirm.

Background

Commonly referred to as "mad cow disease," Bovine Spongiform Encephalopathy ("BSE") is a degenerative neurological disease that was first discovered in 1986 and has since infected more than 187,000 cattle worldwide, with 95 percent of the cases occurring in England. In the mid-1990s, public health officials discovered that cattle feeding practices were the likely cause of an outbreak of BSE in England. At the time, cattle feed typically contained recycled or "rendered" cattle parts that gave it a higher protein content.[1]

In 1996, the British government discovered that consumption of BSE-contaminated meat could could cause variant Creutzfeld-Jakob Disease (vCJD) in humans. There have been approximately 150 human cases of vCJD, including one case in the United States in a woman who had probably contracted the disease while living in England. Scientists are still learning how these diseases develop, incubate and spread. *See R-CALF II*, 415 F.3d at 1086.

[1]*See generally* PL 107-9 Federal Inter-agency Working Group, "Animal Disease Risk Assessment, Prevention, and Control Act of 2001 (PL 107-9), Final Report," January 2003.

The Food and Drug Administration and the USDA responded to the BSE outbreak with new regulations.[2] These rules prohibited the use of mammalian proteins in cattle feed, *see* 21 C.F.R. § 589.2000, and prohibited the use of "specified risk materials" — such as cattle brains, spinal cords, and nerve tissue — in human food, *see* 9 C.F.R. § 310.22. The USDA, working closely with the World Organization for Animal Health, developed guidelines and proposed protective measures to prevent the spread of BSE to the United States. *See* 70 Fed. Reg. at 463.[3] Chief among these measures was a ban on imports of all cattle products from countries where BSE was known to exist. *See* 9 C.F.R §§ 93.401, 94.18 (2003). The USDA added Canada to this list of countries in May 2003, after a cow in Alberta was diagnosed with BSE. *Change in Disease Status of Canada Because of BSE*, 68 Fed. Reg. 31939 (May 29, 2003). Though Canada had instituted its own feed ban in 1997, it was likely that the cow had been exposed before the ban and that the disease had incubated for a period of years.[4] The USDA estimates that the disease has an incubation period of two to eight years. 70 Fed. Reg. at 470.

In August 2003, the agency partially changed course and announced that certain "low-risk" cattle products could be imported from Canada, including meat from cows under 30 months of age. *See* 70 Fed. Reg. at 536. In November 2003, it also announced a proposed rule creating a new category of "minimal risk" regions — a category that would include Can-

[2]The FDA is under the Department of Health and Human Services. The USDA acted through two subsidiary agencies, the Food Safety and Inspection Service and the Animal and Plant Health Inspection Service. We will refer to actions by these agencies as actions by the USDA.

[3]This organization is also called the Office International des Epizooties, or "OIE." It is responsible for the development of standards and recommendations regarding animal health and "zoonoses" (diseases that are transmissible from animals to humans). *See* 70 Fed. Reg. at 463.

[4]Scientists thus far believe that BSE is caused by protein-based infectious agents called "prions." 70 Fed. Reg. at 461.

ada and possibly other countries. *See Bovine Spongiform Encephalopathy; Minimal Risk Regions and Importation of Commodities*, 68 Fed. Reg. 62386 (Nov. 4, 2003).

Shortly before the comment period on this rule was to end, a Canadian-born cow in Washington state was diagnosed with BSE, likely caused by feed ingested before the Canadian feed ban went into effect. The USDA reopened the comment period in March with an expiration date of April 7, 2004. *See Bovine Spongiform Encephalopathy; Minimal Risk Regions and Importation of Commodities*, 69 Fed. Reg. 10,633 (Mar. 8, 2004). By the close of the comment period, the agency had received 3,379 comments. *See* 70 Fed. Reg. at 465.

On January 4, 2005, after a struggle with R-CALF over an interim regulation,[5] the USDA published the Final Rule, which modified existing regulations to allow imports of Canadian cattle under 30 months of age for purchase by feedlots or meat packing companies. *See id.* at 548; 9 CFR §§ 93.420, 93.436, 94.0, 94.18, 94.19, 95.4; *R-CALF II*, 415 F.3d at 1090 n.10. The rule at this stage also allowed in Canadian beef products from cattle of all ages. 70 Fed. Reg. at 494.

Shortly after the rule was published, two older cows in Alberta were diagnosed with BSE, and the USDA attributed the disease to contaminated feed manufactured before the Canadian feed ban. The USDA then announced its intention to suspend the part of the rule that would relax the ban on

[5]The USDA had moved, without public notice, to expand the types of ruminant products eligible to be imported from Canada. R-CALF sued to prevent this move, and the district court granted a temporary restraining order on April 26, 2004. *See Ranchers Cattlemen Action Legal Fund United Stockgrowers of Am. v. United States Dep't of Agriculture*, 2004 WL 1047837 (D. Mont. April 26, 2004). The USDA included a formal version of this amendment in the Final Rule but ultimately suspended its implementation. *See Bovine Spongiform Encephalopathy; Minimal-Risk Regions and Importation of Commodities; Partial Delay of Applicability*, 70 Fed. Reg. 12,112 (March 11, 2005).

meat from cattle over 30 months old. *See Bovine Spongiform Encephalopathy; Minimal-Risk Regions and Importation of Commodities; Partial Delay of Applicability*, 70 Fed. Reg. 12,112 (March 11, 2005).

The Final Rule was set to go into effect on March 7, 2005, but was blocked by a preliminary injunction from the district court in *R-CALF I*, a ruling stemming from related proceedings in this case.

Prior Proceedings

On January 10, 2005, six days after the Final Rule was published, R-CALF filed a complaint alleging that the USDA's rulemaking violated the Administrative Procedure Act (APA), the Regulatory Flexibility Act, and the National Environmental Policy Act. It applied for a preliminary injunction, which the district court granted on March 2, 2005. *See R-CALF I*, 359 F. Supp. 2d at 1074. The district court found that R-CALF had demonstrated a likelihood of success on its claim that the rule was arbitrary and capricious, in violation of the APA. *See* 5 U.S.C. § 706(2). While an initial appeal to this court was pending, the parties filed cross-motions for summary judgment with the district court.

We reversed the preliminary injunction ruling on July 14, 2005, and issued a final amended opinion on August 17, 2005. *See R-CALF II*, 415 F.3d 1078. (We found that the district court had not accorded adequate deference to the USDA's determinations and concluded that the agency "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.* at 1095.

In light of this order and opinion, the district court postponed, and ultimately never scheduled, a hearing on the cross-motions for summary judgment. It denied R-CALF's motion

for summary judgment, and granted summary judgment to the USDA on April 5, 2006.

The district court's order set out the deferential standard of review and provided only one paragraph of analysis. It quoted this court's holding in *R-CALF II*, and then stated: "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.' " It offered no analysis of the record, which had been supplemented several times while the preliminary injunction appeal was pending.

R-CALF filed its timely appeal of the district court's decision on June 2, 2006. Only the APA claim is before us.

A Second Remand is Unnecessary

R-CALF argues that the district court improperly determined it was bound by our decision reversing the preliminary injunction, and therefore R-CALF requests that we remand to the district court for analysis of the record that was developed in support of the motion for summary judgment.

R-CALF correctly points out that the ruling on the motion for a preliminary injunction "leaves open the final determination of the merits of the case." *Ross-Whitney Corp. v. Smith Kline & French Labs.*, 207 F.2d 190, 194 (9th Cir. 1953). This rule acknowledges that "decisions on preliminary injunctions are just that — preliminary — and must often be made hastily and on less than a full record." *S. Ore. Barter Fair v. Jackson County*, 372 F.3d 1128, 1136 (9th Cir. 2004) (citation omitted).

Accordingly, the district court should abide by "the general rule" that our decisions at the preliminary injunction phase do not constitute the law of the case. *See id.*; *see also City of Anaheim v. Duncan*, 658 F.2d 1326, 1328 n.2 (1981). Any of

our conclusions on pure issues of law, however, are binding. *See This That And The Other Gift And Tobacco, Inc. v. Cobb County*, 439 F.3d 1275, 1284-85 (11th Cir. 2006); 18 Charles Alan Wright & Arthur R. Miller, Federal Practice and Procedure § 4478.5 (2002) ("A fully considered appellate ruling on an issue of law made on a preliminary injunction appeal . . . become[s] the law of the case for further proceedings in the trial court on remand and in any subsequent appeal."). The district court must apply this law to the facts anew with consideration of the evidence presented in the merits phase. *See Ross-Whitney,* 207 F.2d at 199; *accord Washington Capitols Basketball Club, Inc. v. Barry*, 419 F.2d 472, 476 (9th Cir. 1969).

[1] This administrative law case presents a thornier issue because this court has reviewed the administrative record for the purpose of the injunction, and, with some narrow exceptions, neither we nor the district court may consider any other evidence. *See Asarco, Inc. v. E.P.A.*, 616 F.2d 1153, 1160 (9th Cir. 1980). For summary judgment, R-CALF has presented only new, extra-record evidence, of arguable relevance to this court's review. Still, technically, the district court was not bound by our earlier conclusions.

Though the district court erroneously determined otherwise, remand is not the only option available at this stage of the litigation. Our review of a summary judgment order proceeds de novo, *see The Lands Council v. Powell*, 395 F.3d 1019, 1026 (9th Cir. 2005), and in administrative appeals, where the court reviews only the record before the agency, "[t]he factfinding capacity of the district court is . . . typically unnecessary to judicial review of agency decisionmaking." *Fla. Power & Light Co. v. Lorion*, 470 U.S. 729, 744 (1985). Simply put, this court's task on appeal is the same as the district court's task in the initial review: "Both courts are to decide, on the basis of the record the agency provides, whether the action passes muster under the appropriate APA standard of review." *Id.*

[2] Because all of R-CALF's new evidence is outside the administrative record and of very limited use, and because we agree with amici that extension of this litigation will aid R-CALF in its attempt to "create, on a rolling basis, a one-sided evidentiary record that supersedes USDA's administrative record," Brief of the Government of Canada at 15, we decide to reach the merits of this case.

Legal Standard

Under the APA, an agency action may be set aside only if it is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A). We must determine whether the agency "considered the relevant factors and articulated a rational connection between the facts found and the choices made." *City of Sausalito v. O'Neill*, 386 F.3d 1186, 1206 (9th Cir. 2004) (citation omitted). This standard of review is "highly deferential, presuming the agency action to be valid and affirming the agency action if a reasonable basis exists for its decision." *Indep. Acceptance Co. v. California*, 204 F.3d 1247, 1251 (9th Cir. 2000) (citations omitted).

In its paradigmatic statement of this standard, the Supreme Court explained that an agency violates the APA if it has "relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." *Motor Vehicle Mfrs. Ass'n v. State Farm Mutual Auto. Ins. Co.*, 463 U.S. 29, 43 (1983).

The USDA's Rulemaking Proces

The Animal Health Protection Act authorizes the Secretary of Agriculture to ban imports of animals if "necessary to prevent the introduction . . . of any pest or disease of livestock."

7 U.S.C. § 8303. We previously remarked that the statutory language "indicate[s] a congressional intent to give the Secretary wide discretion in dealing with the importation of plant and animal products." *R-CALF II*, 415 F.3d at 1094. The statute does not contain a strict requirement that the USDA eliminate all risk that BSE will enter the country. *Id.*

The Final Rule at issue in this case establishes a lower tier of import restrictions for regions that pose a "minimal-risk" of exporting BSE to the United States. Though the World Organization for Animal Health would have based any lower-risk designation on the statistical incidence rate of BSE in a given country, the USDA disagreed with "holding a country to a rigid criterion without consideration of compensatory risk reduction measures," such as surveillance programs. 70 Fed. Reg. at 464. The agency instead defined a minimal-risk region as one that had (1) implemented risk mitigation measures (including import restrictions, surveillance and a feed ban) before BSE was detected in the country, (2) conducted an epidemiological investigation after BSE was detected, and (3) took additional risk mitigation measures after the BSE outbreak. *See* 9 C.F.R. § 94.0. The USDA did not establish numerical criteria.

[3] The agency accordingly designated Canada as a "minimal-risk region" based on the following documents, actions and considerations:

> •Regulations in the U.S., specifically the bans on the use of "specified risk materials" in human food from cattle over 30 months old, and the ban on meat from non-ambulatory cattle. 70 Fed. Reg. at 466.
>
> •The 2003 Revised Harvard-Tuskegee Study of BSE risk in the U.S., which concluded that there was a "very low risk" of BSE becoming established domestically if it were introduced. The study found that bans on U.K.-imported cattle and feed bans were

the most effective measures to prevent BSE introduction, and that the biggest risks for human exposure to BSE were non-compliance with the feed bans, use of other infected farm animals in feed, and use of high-risk tissues in products for human consumption. *Id.* at 467.

•A memorandum from researchers at the Harvard Center for Risk Analysis, which updates the model from the Harvard-Tuskegee Study. *Id.*

•Measures taken by Canada prior to the discovery of BSE in 2003, including import restrictions on U.K. cattle and Canada's 1997 feed ban. Because most infected cattle show clinical signs of BSE within seven years of infection, any cattle born before the feed ban would show clinical signs before the time of the Final Rule and therefore would be detected by surveillance. *Id.* at 467-68.

•A 2002 assessment of BSE risk in Canada, finding that the 665 cattle imported from Europe between 1979 and 1997 resulted only in a "low potential" for introduction of BSE infection. *Id.* at 468.

•A 2003 epidemiological investigation and report after BSE detection, which found little exposure to BSE and determined that Canada's protective measures were effective and proposed additional measures. *Id.*

•Additional measures taken in Canada, including a ban on specified-risk materials from cattle at slaughter, a new epidemiological investigation, and increased surveillance. *Id.* at 468-69.

•The agency's update to its own risk analysis of Canada that provides a more detailed analysis of its rules and their application to Canada. *Id.* at 469.

In its later affirmation of the Final Rule, the USDA emphasized that "the cumulative effect of all the measures in place in Canada and the United States . . . is an extremely effective set of interlocking, overlapping and sequential barriers to the introduction and establishment of BSE in the United States." *Bovine Spongiform Encephalopathy; Minimal-Risk Regions and Importation of Commodities; Finding of No Significant Impact and Affirmation of Final Rule*, 70 Fed. Reg. 18,252, 18,255 (April 8, 2005).

[4] We endorsed this holistic approach at the preliminary injunction phase, when we chose to "evaluate the cumulative effects of the multiple, interlocking safeguards" instead of following a "divide and conquer" strategy. *R-CALF II*, 415 F.3d at 1095. Because this approach represents a legal conclusion about the construction of the regulations, it is the law of the case, and therefore we adopt it for our decision now.

R-CALF's Allegations

R-CALF initially brought five claims for declaratory and injunctive relief but appeals only on the basis of its first APA claim, in which it argues that the Final Rule is arbitrary and capricious because it is based on faulty assumptions about the efficacy of the American and Canadian feed and import restrictions.

[5] As we evaluate each argument under this claim, we will consider whether R-CALF's new evidence is relevant to our review. It is an established rule that "the focal point for judicial review should be the administrative record already in existence, not some new record made initially in the reviewing court." *Camp v. Pitts*, 411 U.S. 138, 142 (1973). Under limited circumstances, however, extra-record evidence can be admitted and considered.

At the district court level, extra-record evidence is admissible if it fits into one of four "narrow" exceptions: (1) if admis-

sion is necessary to determine whether the agency has considered all relevant factors and has explained its decision, (2) if the agency has relied on documents not in the record, (3) when supplementing the record is necessary to explain technical terms or complex subject matter, or (4) when plaintiffs make a showing of agency bad faith. *Southwest Ctr. for Biological Diversity v. U.S. Forest Serv.*, 100 F.3d 1443, 1450 (9th Cir. 1996) (internal punctuation omitted). R-CALF also relies heavily on one statement in the case law that extra-record information might be admitted if it tends to show that the agency relied on assumptions that were "entirely fictional or utterly without scientific support." *Ass'n of Pac. Fisheries v. E.P.A.*, 615 F.2d 794, 812 (9th Cir. 1980).

In *Asarco, Inc. v. E.P.A.*, 616 F.2d 1153 (9th Cir. 1980), the benchmark case on this issue in this circuit, the district court had held a four-day hearing, which included testimony from two experts who had not helped the agency make the challenged decision. This court disapproved because this testimony was "plainly elicited for the purpose of determining the scientific merit of the EPA's decision." *Id.* at 1161. Considering evidence outside this record is inappropriate, we explained, because it "inevitably leads the reviewing court to substitute its judgment for that of the agency." *Id.* at 1160. Under the APA, courts must refrain from de novo review of the action itself and focus instead on the agency's decision-making process. *Id.* at 1158.

[6] Under these principles, R-CALF's arguments can only carry the day if they show flaws in the USDA's approach, rather than in its predictions. We address each of R-CALF's arguments in turn below.

1) The BSE Incidence Rate in Canada: R-CALF argues that the agency relied on a Canadian report that used an insufficient sample size based on data collected in 2001, before the Canadian and American BSE-infected cows were discovered. The district court agreed, *R-CALF I*, 359 F. Supp. 2d at 1065-

66, but we held that the district court improperly substituted its judgment for the agency's, *see R-CALF II*, 415 F.3d at 1097. We found that the USDA had based its calculations on international standards, and that the World Organization for Animal Health had ranked Canada in its minimal risk range in 2003. *Id.* at 1098.

[7] R-CALF argues now that "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 cattle having been diagnosed in just the past year." R-CALF argues that this post-decision empirical data shows that the USDA was relying on faulty assumptions that lacked scientific support.

[8] While these new incidents are certainly cause for concern, they do not suggest that the agency made an incomplete or unreasoned review of the evidence before it in 2004. The agency was entitled to rely on the reasonable opinion of its experts at that time, *see Marsh v. Ore. Natural Res. Council*, 490 U.S. 360, 378 (1989), and the agency continues to monitor BSE in Canada, *see Bovine Spongiform Encephalopathy; Minimal-Risk Regions; Importation of Live Bovines and Products Derived From Bovines*, 72 Fed. Reg. 1102 (Jan. 9, 2007). Because the Final Rule does not anticipate an incidence rate of zero in Canada or the U.S., these subsequent BSE cases do little to impugn the agency's decision-making process. If recent cases have cast doubt on the agency's scientific predictions, the proper remedy is to petition to reopen rulemaking under 5 U.S.C. § 553(e), not to challenge the existing rule as arbitrary and capricious.[6]

2) The Effectiveness of the Canadian Feed Ban: R-CALF argues that BSE may be transmitted through blood and saliva, not just contaminated feed, that one of the BSE-infected cows

[6]R-CALF's related argument about the risk of BSE entering the United States also fails for these reasons.

was rendered into feed, and that the recent diagnoses of BSE show that the feed ban is not working because of alleged noncompliance. The district court credited this argument, *see R-CALF I*, 359 F. Supp. 2d at 1066-67, but we held that the agency had properly considered and rejected these alternative theories of transmission. *R-CALF II*, 415 F.3d at 1098. We also held that it was appropriate for the agency to assume the longer incubation rates for BSE in Canada to explain the more recent cases of infected cattle. *Id.*

[9] R-CALF now argues that the recent incidents of BSE in cows born after the feed ban prove that the feed ban is ineffective. It also argues that a government study on the U.S. feed ban shows some noncompliance. *See* United States Government Accountability Office, *Mad Cow Disease — FDA's Management of the Feed Ban Has Improved, but Oversight Weaknesses Continue to Limit Program Effectiveness*, Feb. 2005. It also refers to a statement by Secretary Johanns suggesting that there are "questions that must be answered" about the number of BSE incidents in Canada and remarking that South Korea has continued to close its borders to American beef. These post-decisional statements are far outside the record and of little persuasive weight.

[10] Though these recent incidents in younger cattle certainly cast doubt on the effectiveness of the feed ban, the agency — at the time it made its decision — properly relied on studies from both the World Organization for Animal Health and the Harvard Center on Risk Analysis finding that feed bans were the most effective way to prevent the spread of BSE, *see* 70 Fed. Reg. at 463, 467, and, again, considered them as a part of a system of safeguards, not as a sole preventative measure. It bears repeating that the agency did not assume 100 percent effectiveness of its measures. *See* 70 Fed. Reg. at 511.

In a related argument, R-CALF claims that the agency incorrectly assumed that the Canadian feed ban, which

exempted products made from animal blood or fat, would be as effective as the European feed ban, which does not have these exemptions. The agency expressly considered this argument and rejected it because Canada's feed ban was equivalent to the feed ban in the United States, which also allowed these products. 70 Fed. Reg. at 491. The agency's research showed that about 96% of the "infectivity" of any given cow was contained in certain tissues, and that the only examples of blood transmission of BSE occurred in blood transfusions. *Id.*

[11] As we noted in our preliminary injunction ruling, the agency properly relied on studies rejecting the idea of transmission through tallow, and we held that the district court erred when it criticized the "gaps" in the Canadian feed ban. *See R-CALF II*, 415 F.3d at 1099. R-CALF does not offer any evidence or arguments to support a different result at this phase. In light of the science available at the time, the agency's partial reliance on the feed ban was justified.[7]

Finally, R-CALF argues that the agency showed its own lack of confidence in the feed ban when it suspended the part of the Final Rule allowing meat products from cattle over 30 months old. This argument fails as well. While the Final Rule prohibited importing *cattle* over 30 months of age, *see* 9 C.F.R. §§ 93.436 (a)(1), (b)(1), and banned the use of specified risk materials from cows over 30 months of age, *see* 9 C.F.R. 310.22 (a)(1), it allowed meat products from cattle of any age, *see* 70 Fed. Reg. at 494. The Final Rule, however, stated that international guidelines recommended allowing meat from cattle of any age as long as there were measures

[7]For these reasons, we also reject R-CALF's related argument that the agency assumed that cattle under 30 months old would not be infected with BSE because this claim is an implicit attack on assumptions about the feed ban.

in place to segregate highly infective tissues from the nervous system. *Id.*[8]

Two months after issuing the Final Rule, the agency decided to suspend this part of the rule and continue to ban beef derived from older cattle. *See* 70 Fed. Reg. 12,112. It essentially left in place the pre-2004 practice of allowing in meat from cattle under 30 months of age. *See* 70 Fed. Reg. at 536.

R-CALF argues that this change of heart shows the agency's "lack of confidence" in its initial assumptions about the effectiveness of the feed ban, the ban on specified risk materials, and the BSE incubation period. To be considered by the courts, however, this evidence would have to show a "lack of reasons" for the parts of the rule that are currently being challenged, rather than a subsequent "lack of confidence" in them. R-CALF has failed to make a connection between the uncertainty about this provision and the lack of justification for any other provisions of the Final Rule.

[12] *3) Blood Transmission*: R-CALF claims that the agency incorrectly assumed that the ban on "specified risk materials" in products for human consumption would eliminate the risk of BSE in spite of information that BSE can also be transmitted by blood that affects other tissues. R-CALF points out that the agency continues to ban fetal bovine serum, *see* 70 Fed. Reg. at 502-03, but, it argues, inconsistently permits the use of tallow in cattle feed, *see id.* at 500-01.

[8]It did not provide a citation to any provision from the World Organization for Animal Health guidelines, and the current guidelines do not appear to "recommend" allowing beef imports from older cattle. *See* OIE Terrestrial Animal Health Code, 2.3.13.10 (stating that meat products may be imported from cattle that were born after the imposition of an appropriate feed ban). *See* http://www.oie.int/downld/SC/2007/en_chapitre_2.3.13. pdf.

[13] The agency's commentary in the Final Rule explains that fetal bovine serum "might pose a risk for livestock if used in certain applications such as bovine vaccine production or bovine embryo transfer, or for other products brought into direct exposure with ruminants." 70 Fed. Reg. at 502. In *R-CALF II*, we noted the special risk posed by the serum because it is injected directly into the bloodstream. *R-CALF II*, 415 F.3d at 1099. The agency's ban on fetal bovine serum represents caution in the face of unknown risk. It does not imply a more general finding of risk from feed products that may have come into contact with cattle blood. As the agency explains in the Final Rule, cattle blood only appears to pose a risk when it is directly transfused into other cattle. *See* 70 Fed. Reg. at 491. Regarding the agency's decision to allow imports of tallow, the agency was entitled to follow international standards and previous practices requiring that the tallow be protein-free and accompanied by certification. *See id.* at 501. In light of our previous endorsement of the feed ban, we find that the agency has justified its different treatment of tallow, fetal bovine serum, and cattle feed.

R-CALF, in a similar vein, argues that the agency's subsequent rule prohibiting imports of pregnant cattle shows that it has since come to recognize the possibility of other types of BSE transmission. *See Bovine Spongiform Encephalopathy; Minimal-Risk Regions and Importation of Commodities; Technical Amendments*, 71 Fed. Reg. 12,994 (Mar. 14, 2006). However, we previously adopted the agency's interpretation that the Final Rule, even before the amendments, banned breeding cattle. *See R-CALF II*, 415 F.3d at 1099. Moreover, the amendments specifically state that the agency is merely clarifying the Final Rule. 71 Fed. Reg. at 12,994. R-CALF is therefore incorrect that the Final Rule did not ban breeding cattle.

[14] The agency fully considered the possibility of other types of BSE transmission and gave reasons for banning some products and not others. Its analysis satisfies our review.

[15] *4) Ban on Specified Risk Materials.* R-CALF argues that more recent science shows that the ban on these cattle parts will be less effective than the agency assumed. We previously endorsed the agency's reliance on this ban because its decision was based on the Harvard-Tuskegee Study. *See R-CALF II*, 415 F.3d at 1099.[9] As R-CALF's summary judgment motion points out, the study's authors have since revised their certainty about the ban from 95% to 80%. The agency has also acknowledged the scientists' downward adjustment. *See Substances Prohibited From Use in Animal Food or* Feed, 70 Fed. Reg. 58,570, 58,587 (Oct. 6. 2005). This post-decisional revision, however, does not show that the agency, at the time it made its decision on the Final Rule, failed to consider relevant factors or rested its decision on completely baseless assumptions.[10]

5) Other Arguments: R-CALF argues that the agency assumed that non-ambulatory cattle (who are more likely to have BSE) will not be slaughtered for human consumption, but the agency stated in the Final Rule that Canada does not allow non-ambulatory cattle to be slaughtered for export, 70 Fed. Reg. at 491, and R-CALF offers no reason to distrust that statement.

R-CALF also argues that the agency relied on the Harvard-Tuskegee study's findings of low risk without considering the risk of errors and mislabeling. We find that the agency considered these risks and found them covered by existing regulation and monitoring by the USDA. *See* 70 Fed. Reg. at 499.

[9]R-CALF has also submitted a declaration from Dr. Stanley Prusiner, who discovered the "prions" that cause BSE. Dr. Prusiner makes several conclusions that run counter to the findings of the Harvard-Tuskegee study but, as in *Asarco*, this declaration serves only to attack the merit of the agency's decision and does little to suggest flaws in the process leading up to that decision.

[10]We previously held that the agency's reliance on this study gave it a "firm basis" for its assumptions that R-CALF's speculative arguments did little to undermine. *See R-CALF II*, 415 F.3d at 1095.

Finally, on summary judgment, R-CALF contends that, overall, the agency's actions were contrary to the purposes of the Animal Disease Risk Assessment, Prevention and Control Act of 2001, Pub. L. No. 107-9, 115 Stat. 11, which requires the Secretary of Agriculture to submit a report to Congress on the USDA's plans to research and monitor BSE and gauge the effectiveness of its prevention measures. This argument was not pled in the complaint, and in any event is unavailing. The Act merely requires a report on these factors, and the USDA continues to provide these reports.

[16] Therefore, under the APA standard of review, none of the claims as stated in R-CALF's complaint warrant remand to the agency.

Conclusion

[17] Having reviewed the merits of this case, we conclude that the agency considered the relevant factors and articulated a rational connection between the facts found and its decision to designate Canada a minimal-risk country. R-CALF's extra-record evidence has failed to convince us that the agency's review was unauthorized, incomplete, or otherwise improper. The district court's order granting summary judgment to the USDA is therefore

AFFIRMED.