Docket No. 05-35264

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

Ranchers Cattlemen Action Legal Fund
United Stock Growers of America,

Appellee/Plaintiff,

v.

United States Department of Agriculture,
Animal and Plant Health Inspection Service, and
Mike Johanns, in his capacity as the
Secretary of Agriculture,

Appellants/Defendants.

Appeal from the United States District Court
District of Montana

BRIEF OF AMICI CURIAE CENTER FOR FOOD SAFETY, COMMUNITY NUTRITION INSTITUTE, CONSUMER FEDERATION OF AMERICA, INSTITUTE FOR AGRICULTURE AND TRADE POLICY, PUBLIC CITIZEN SUPPORTING APPELLEE R-CALF USA'S PETITION FOR REHEARING EN BANC

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Rule 26.1 Corporate Disclosure Statement

All *amici curiae* corporations are not-for-profit corporations owned by neither parent nor publicly traded corporations. Not all *amici curiae* are corporations. The *amici curiae* are more specifically identified in the "Identity and Interests of *Amici Curiae*" below.

William B. Rostov

September 29, 2005.

IDENTITY AND INTEREST OF THE AMICUS CURIAE

Amici, Center for Food Safety, Community Nutrition Institute, Consumer Federation of America, Institute for Agriculture and Trade Policy, and *Public Citizen,* are non-profit consumer, public interest, and scientific organizations providing advocacy, education, scientific research, and services on a wide-variety of issues, including public health, product and food safety, and nutrition. Collectively the *amici* represent thousands of members. *Amici* jointly file this brief pursuant to Fed. R. App. P. 29(a) in support of Plaintiff-Appellees' petition for a rehearing and suggestion for rehearing *en banc* to provide this Court with an analysis of the science forming the basis of the Panel's decision.

ARGUMENT

INTRODUCTION

Respectfully, the panel decision in *R-CALF v USDA*, 415 F3d 1078 (9th Cir. 2005) ("*R-CALF*") overturning the District Court's preliminary injunction and upholding the United States Department of Agriculture's ("USDA") Bovine Spongiform Encephalopathy; Minimal-Risk Regions and Importation of Commodities; Final Rule and Notice ("Final Rule"), 70 Fed. Reg. 460 (Jan. 4, 2005) lacked a scientific basis. In its ruling, the Panel analyzed six independent

grounds by which the District Court found that the agency's issuance of the Final Rule was arbitrary and capricious. *R-CALF* at 1091. The Panel erred in its analysis because the scientific record undermines at least two independent evidentiary bases relied upon by USDA for the Final Rule.

First, the Panel erred in its interpretation of the effectiveness of Specified Risk Materials ("SRM") Removal. The only evidence considered by the Court to support the USDA's SRM removal is inconsistent with the final rule and does not justify the conclusions maintained in the final rule. Second, the Panel erred in reviewing the effectiveness of the Canadian feed ban. It did not understand the science underlying different feed bans or that the USDA *ignored* its own scientific recommendations. The panel not only reviewed "the underlying merits of the case" contrary to binding precedent of this Circuit, but repeatedly erred in its review of the scientific record. *Southwest Voter Registration Educ. Project v. Shelley*, 344 F.3d 914, 918 (9th Cir. 2003) (en banc).

Finally, since the Court vacated the preliminary injunction, dangerous meat has entered the United States from Canada, despite USDA's express assurances that it would not happen. As a result, this case involves questions of exceptional importance and should be reheard. Fed. R. App. P. 35(a)(2).

I. THE DECISION'S UPHOLDING OF USDA'S SRM REMOVAL IS UNDERMINED BY THE ONLY EVIDENCE THAT USDA AND THE PANEL RELIED UPON FOR THE FINAL RULE AND THUS REQUIRES REHEARING.

Unfortunately, the Panel upheld USDA's flawed interpretation of the only scientific evidence alleged to support the USDA's rule governing SRM removal, when in fact the evidence undermined the USDA's approach. The Panel relied upon a single piece of evidence, the Harvard-Tuskegee Study, Rev. 2003, ("Study"), when it reversed the District Court's finding that the Final Rule governing "SRM removal" was ineffective. *R-CALF* at 1099. SRM are the high-risk tissues from slaughtered animals that can harbor BSE and that are not to be used in human food or animal feed. In upholding the Final Rule, the Panel's entire holding was:

> USDA's conclusion that SRM removal is effective, however, had support in the administrative record. *See* Final Rule, 70 Fed. Reg. at 467 (discussing Harvard-Tuskegee Study, which concluded that SRM removal would reduce human exposure to BSE by 95 percent).

Id. at 1099.

Contrary to the Court's holding, the USDA's conclusion was not supported by the record. The Study's conclusion concerning the effectiveness of SRM removal was based on the express assumption that the U.S. would adopt SRM

removal regulations that would "mimic the UK SRM Ban." Study at 111. The USDA, however, rejected this United Kingdom SRM ban.

The UK SRM removal requirement is more stringent than that contained in the Final Rule in several ways. First, the UK prohibits the use of SRMs composed of the brain, spinal cord and vertebral column, gut, and eyes from all cattle over six months of age for use in either human food or animal feed. Study at 38.[1] The Final Rule, however, only requires the removal of tonsils and small intestines from Canadian cattle less than 30 months old, and only prohibits SRMs from human food, not from animal feed as does the UK SRM ban. *See* 70 Fed. Reg. 465. Consequently, the Final Rule relies upon a study that actually rejects the type of ban adopted by the USDA and is without scientific basis.

Second, the UK prohibits meat products produced by Advanced Meat Recovery ("AMR") systems for use in both human food and animal feed. Study at 96. The Final Rule, however, does not prohibit the use of AMR on Canadian cattle for use in either human food or animal feed. *See* 70 Fed. Reg. 466. ("[T]he skull and vertebral column from cattle younger than 30 months of age are allowed to be used in AMR systems."). Third, the Final Rule does not prohibit the rendering of

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[1] *See* 70 Fed. Reg. 467 (AR 8051). (Final Rule acknowledging that the high-risk tissues included in the Study's evaluation included "the brain, spinal cord and

animals that die on the farm for use in animal feed, even though the UK's SMR ban included "a prohibition on the rendering of animals that die on the farm." Study at 106. The Study was clear about the danger of this approach: "[I]f the BSE is introduced into the U.S., the greatest potential source [of] feed contamination is animals that die prior to being sent to slaughter (animals that die on the farm) and are rendered . . . *Hence, a single breach of the feed ban can introduce expose [sic] cattle to a substantial amount of BSE infectivity*." Study at 111 (emphasis added).

In sum, the Final Rule's failure to adopt a UK-like SRM ban for animal feed allows more potentially BSE-infected materials into human and animal food and renders the Panel's holding that the USDA's SRM ban would decrease human exposure to BSE by 95 percent without scientific support.

II. THE COURT MISUNDERSTOOD THE EFFICACY OF THE FEED BANS AND IMPROPERLY OVERTURNED THE PRELIMINARY INJUNCTION.

The Panel also disagreed with the District Court's finding that "USDA's reliance on the Canadian feed ban" was unjustified. *R-CALF* at 1098. Specifically, the Panel's decision noted that "[f]irst and foremost," in the U.S. regulatory regime designed "to minimize the threat of BSE to U.S. citizens and livestock, "the Food and Drug Administration ("FDA") has overseen a feed ban that prohibits the

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vertebral column, 'gut,' and eyes.").

feeding of ruminant protein to other ruminants," meaning the FDA prohibits certain slaughter products to be used as feed for other animals. *Id.* at 1087. The Final Rule permits a Canadian feed ban that is equivalent to the requirements established by the FDA. *See* AR 8132; 8135.

Respectfully, the Court's decision misinterprets the scientific record. The Panel failed to appreciate that the Final Rule *rejected* the conclusions of the USDA's own findings concerning the U.S. feed ban as well as those of the FDA and the Canadian government. In fact, USDA developed its own Transmissible Spongiform Encephalopathy ("TSE") Working Group to "provide technical analyses of the risk of BSE to the United States, [and make] recommendations regarding actions that should be taken in response to these risks."[2] USDA also requested an International Review Team ("IRT") to recommend measures that could be taken by the United States to provide additional public or animal health benefits. Both of these expert groups discredited the less stringent approaches of the U.S. and Canadian feed bans.

The TSE Working Group recommended that significant trade in Canadian cattle commodities should not resume until "[a]dditional BSE risk mitigation steps

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[2] P.L. 107-9 Interagency Working Group Report to Congress, 2003, at 46 (AR 9311).

are put in place in the US to address" the need for "SRM removal from . . . animal food." AR 9392C. Similarly, the IRT concluded:

> Considering the BSE situation in North America, the subcommittee [IRT] believes the partial (ruminant to ruminant) *feed ban that is currently in place is insufficient to prevent exposure of cattle to the BSE agent.*

AR 8029 (emphasis added). The IRT recommended nine specific improvements to the current feed ban. *Id.* at 8029-8030; *see also id.* at 8052. Additionally, both the Canadian government (on which the USDA relied) and the FDA (whose feed ban was the model for the Canadian feed ban) now acknowledge that the feed ban permitted in the Final Rule is dangerously deficient. The Canadian Food Inspection Agency (CFIA) admitted that "there is a need to strengthen the key points [of the feed ban] crucial to preventing spread [sic] of the disease."[3] Subsequent to *R-CALF*, in a September 19, 2005 speech, FDA Commissioner, Lester M. Crawford, announced that FDA would be making amendments to modify the FDA's feed ban, which the Canadian feed ban matched:

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[3] Canadian Gazette, Vol. 138, No. 50, December 2004 at AR 9735. *See id.* at 9735 (Canadian government admitting that its feed ban "provides opportunities for prohibited proteins to be accidentally included in or cross-contaminate feeds for ruminants . . . [and] opportunities for misuse of feed on farms with multiple species represent an area of vulnerability within the framework of the current ban").

"With respect to BSE, CVM [the Center for Veterinary Medicine] is in the final stages of preparing amendments to the BSE feed rule . . . ."[4] In sum, this is not a case where the "district court . . . failed to respect USDA's judgment and expertise." *Id.* at 1093.

The USDA did not adopt an "expert scientific opinion," but rather ignored the scientific evidence and reserved judgment until the FDA completes its current review of the feed ban. In response to commenters' concerns that the Final Rule does not address additional measures that have been recommended by the FDA since January 2004,[5] the USDA merely said that "FDA requested additional information to help it determine the best course of action with regard to the feed ban." AR 8116; *See also id.* at 8088; USDA Response to IRT Report at AR 8040 ("FDA has announced its intent to publish an interim final rule that . . . changes . . . the current feed ban. They intend to eliminate the exemptions that allow the use of blood products and plate waste in ruminant feed. . . . to prohibit the use of poultry litter in ruminant feed and to require the use of dedicated facilities in handling prohibited products"). Thus, the USDA has postponed formulating its "expert

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[4] *Available at* http://www.fda.gov/oc/speeches/2005/nfpc0919.html.

[5] *E.g.*, banning blood, poultry litter, plate waste, and requiring dedicated manufacturing facilities in order to prevent cross-contamination. *See* AR 9451, 9452.

scientific opinion" pending further action by the FDA. Since the Final Rule was adopted without agency expert support, the Panel improperly deferred to the USDA and erred in reversing the District Court.

III. SINCE *R-CALF* VACATED THE PRELIMINARY INJUCTION, DANGEROUS MEAT HAS ENTERED THE UNITED STATES AND MAY HAVE REACHED CONSUMERS.

In addition to the inadequate protections discussed above, the USDA has not created any enforcement mechanisms to ensure that its "interlocking safeguards" actually work.[6] *R-CALF* at 1087. After the Panel vacated the preliminary injunction and within three weeks of the border reopening, Canada exported an animal older than permitted under the Final Rule. The animal was nevertheless slaughtered in the United States and, *despite the USDA's assurances that high-risk materials would not enter the human food supply*,[7] the animal was processed with SRM tissues intact. The meat was not recalled until more than two weeks after it was produced.[8] Media reports indicated that USDA did not know how much meat

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[6] USDA safety reports obtained by Public Citizen establish *over 1000 violations of the USDA's BSE risk mitigation measures by U.S. meat packers*. *See* BSE Noncompliance Record Analysis, Public Citizen, August 18, 2005, *available at* http://www.citizen.org/cmep/foodsafety/madcow/articles.cfm?ID=13903

[7] *See* Defs.' Opp. Pls.' Mot. Prelim. Inj. at 30.

[8] *See* FSIS recall notice, August 19, 2005, *available at*

may have been consumed after the meat was distributed to six states.[9]

This is a matter of critical importance and the preliminary injunction should therefore be restored to avert any further dangers to the American public.

CONCLUSION

For the reasons set forth above, *amici* respectfully request that this Court rehear and *reverse R-CALF* and reinstate the District Court's preliminary injunction pending a full resolution of this case on the merits.

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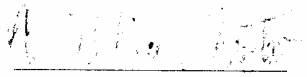
http://www.fsis.usda.gov/News_&_Events/Recall_032_2005_Release/index.asp; *available at* http://www.inspection.gc.ca/english/anima/heasan/disemala/bseesb/situatione.shtml

[9] "Beef Banned Under Mad Cow Rules is Recalled," AP (Aug. 23, 2005) *available at* http://wfrv.com/trouble/recalls_story_235114603.html.

CERTIFICATE OF COMPLIANCE

Pursuant to the rules of this Circuit, I hereby certify that the foregoing brief contains 2,077 words as computed by Microsoft Word 2003.



William B. Rostov

September 29, 2005.

CERTIFICATE OF SERVICE

I hereby certify that, on the 29 day of September 2005, I have caused a copy of the Foregoing, Brief of Amici Curiae Center for Food Safety, Consumer Federation of America and Public Citizen Supporting Appellee R-CALF USA's Petition for Rehearing En Banc to be served upon counsel for all parties, via United States Mail, First Class, postage prepaid, addressed as follows:

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