

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,**

Appellees/Defendants,

Appeal from the United States District Court
District of Montana

BRIEF OF AMICI CURIAE SUPPORTING APPELLEE R-CALF USA
PETITION FOR REHEARING

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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.

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Identity and Interests of *Amici Curiae*

The *amici* are entities with national, state or local constituencies or private interests. All *amici curiae* seek to have the USDA's Administrative Rule declared void to protect the public health, the presumed BSE-free US cattle herd, sound administrative rulemaking precedent, consumer confidence in the food supply, and the American economy. Each *amici curiae* seeks to keep the northern US border closed to importation of cattle from Canada's known-to-be diseased herd until, and unless, the concerns articulated in this Brief are reasonably addressed. This Brief does not repeat segments of Appellee R-Calf's Petition for Rehearing. The *amici* seek to express a broad public policy and public health-oriented perspective. Each has been authorized by action of its Board of Directors or governing officers to join this Brief.

NATIONAL ORGANIZATIONS

1. The Organization for Competitive Markets ("OCM"), Lincoln, NE, is a nonprofit research and education corporation focusing on agricultural antitrust and trade issues.
2. Western Organization of Resource Councils ("WORC"), Billings, MT, is a regional network of seven grassroots community organizations that include 9,500 members and 46 local chapters in Colorado, Idaho, Montana, North Dakota, Oregon, South Dakota, and Wyoming. WORC focuses on family farm and environmental issues.
3. Women Involved in Farm Economics ("WIFE"), Burdett, KS. WIFE, formed in 1976, represents women vitally interested in agriculture and food quality issues. It is a national organization with state chapters.

REGIONAL and STATE ORGANIZATIONS

4. Cattle Producers of Washington, Soap Lake, WA, is a nonprofit corporation representing cattle producers in Washington State.
5. Colorado Independent Cattlemen's Association, LaJunta, CO, is a nonprofit corporation representing cattle producers in Colorado.
6. Dakota Resource Council, Dickinson, ND, is a nonprofit corporation representing the interests of North Dakota farmers, ranchers and citizens on environmental and agricultural issues in.
7. Dakota Rural Action, Brookings, SD, is a nonprofit corporation representing the interests of farmers, ranchers and citizens on environmental and agricultural issues in South Dakota.
8. Independent Cattlemen of Nebraska, Hyannis, NE, is a nonprofit corporation representing cattle producers in Nebraska.
9. Independent Beef Association of North Dakota is a nonprofit corporation representing cattle producers in North Dakota.
10. Iowa Farmers Union is a general farm organization working on behalf of Iowa farmers and ranchers.
11. Kansas Cattlemen's Association, Brewster, KS, is a nonprofit corporation representing cattle producers in Kansas.
12. Merced-Mariposa Cattlemen's Association, Merced, CA, is a central California group of cattle producers working on behalf of its members to promote the livestock industry and livestock health.
13. Mississippi Livestock Markets Association, Jackson, MS, is an association of livestock auction markets in Mississippi.
14. Montana Cattlemen's Association, Billings, MT, is a nonprofit corporation representing cattle producers in Montana.

15. Nevada Live Stock Association is a is a nonprofit corporation representing cattle producers in Nevada.
16. Oregon Livestock Producers Association, Jordan Valley, OR, is a nonprofit corporation representing Oregon cattle producers.
17. Powder River Basin Resource Council is a nonprofit organization based in Wyoming working for the preservation and enrichment of Wyoming's agricultural heritage and rural lifestyle.
18. South Dakota Stock Growers Association, Rapid City, SD, is a nonprofit corporation representing cattle producers in South Dakota.

LOCAL and PRIVATE ORGANIZATIONS

19. Franz Beefmasters, Burlington, CO, is a ranch operation.
20. Harrison County Cattlemen's Association, Bethany, MO, promotes and nurtures all phases of the live cattle industry in Missouri.
21. Kit Carson County Cattlemen's Association is an association representing cattle producers in Kit Carson County, Colorado.
22. Morrow County Livestock Growers Association, Heppner, OR, represents local livestock producers with vital interests in consumer confidence in safe beef, and in herd health.
23. Southern Tier Div. New York Beef Producers Assn., is an association representing cattle producers in New York.

ARGUMENT

The proposed amici parties support Appellee's Request for a Rehearing en banc because this proceeding involves a question of exceptional importance. All parties have been contacted and consent to the Amici Parties' brief filing.

I. USDA APHIS is a Public Health and Safety Agency

Americans consume sixty-two (62) pounds of beef per year, more than virtually any other food stuff. The U.S. Department of Agriculture is vigorously seeking to dismantle the public and animal health safety standards which have successfully prevented diseases such as avian flu, food and mouth disease, blue tongue, brucellosis, and, now, bovine spongiform encephalopathy (BSE) from entering the United States and contaminating its food supply.

The proposed amici parties believe the Three-Judge Panel wrongfully found the District Court's preliminary injunction decision invalid. Though the standard of review was abuse of discretion, the Panel substituted its judgment for that of the District Court.

The USDA is a public safety agency charged with protecting the public and animal health. The Agency did not rely on hard data about risks, but rather on speculation, assumptions, guesses, and subjective conclusions that the risks are acceptable. The Court thus owes USDA's action no deference. *Ober v. Whitman*, 243 F3d 1190, 1195 (9th Cir 2001). The purpose of judicial review is not to

rubber-stamp Agency decisions, but “to check arbitrary or inconsistent administrative action.” *Lichter v. United States*, 334 US 742, 770-771 (1948). The Three-Judge Panel attempted to delve into the facts of this case on review of a preliminary injunction, and they accepted USDA assertions that do not withstand more detailed scrutiny. Moreover, recent scientific developments and recent actions by USDA only heighten the need for caution concerning BSE.

II. BSE Is a Particularly Dangerous Disease for Which Unverified Assumptions and Subjective Assurances of Minimal Risk Should Not Suffice.

BSE is an unusual, highly infectious, inevitably fatal disease that has devastated the cattle sector in many countries and has already lead to over 140 deaths. The record indicates that ingestion of as little as one microgram of infected tissue—about the size of a grain of sand—can be sufficient to cause this fatal disease in cattle. AR001658, AR002671.

The Amici Parties believe the Three-Judge Panel did not fully appreciate the terrible nature of this disease. The decision describes BSE as having been “largely contained.” *R-CALF v USDA*, 415 F.3d 1078, 1085 (2005). The record shows hundreds of new cases in the United Kingdom each year, though the annual rate has diminished. In most of the 13 additional countries where BSE has arisen since 2000, there is no clear pattern showing decreased incidence. The decision states the vast majority of human vCJD cases, caused by consuming meat from cattle

with BSE, occurred in England “during the height of the BSE epidemic. *Id* at 1086. This is simply wrong. The height of the BSE epidemic, according to USDA, was 1992-93. 70 *Fed Reg* at 462. The *first* case of vCJD was not identified until 1996. *Id*. And Spain and the Netherlands identified their first cases of vCJD apparently resulting from domestic exposure to BSE only this year.

The Three-Judge Panel apparently also believed incorrectly that it is significant that “no case of vCJD has ever been linked to North American beef.” 415 F.3d at 1086. Since vCJD may not be diagnosed for 10 years or more after exposure to BSE, see AR001799, AR001823, it is far too soon to know if any cases of vCJD have been caused by the BSE infectivity that has been circulating in the Canadian herd in recent years.

The Panel may have underestimated the potential for rapid spread of the disease, as well. As noted above, only a tiny amount of infected tissue contaminating cattle feed can lead to additional cases of BSE. The Panel stated that infected tissue from a single cow could be fed to “hundreds of cattle,” *R-CALF v USDA*, 415 F3d *supra* at 1085-86, but that is a grave understatement. The record shows that infected tissue from the 1993 case of BSE in Canada may have been distributed to 1800 *farms*.

The World Health Organization warned in 2002 that “BSE is a threat that must be taken seriously by all.” AR 001297. The peculiar nature of the disease

makes it difficult to detect and manage and can “mask epidemic spread.” *Id.* The Three-Judge Panel appears not to have recognized the critical importance of assuring that any relaxation of BSE protections is fully justified. The preliminary injunction should have been allowed to stand while the relaxed rules on imports from Canada could be fully evaluated by the District Court.

III. The Panel Failed to Recognize USDA’s Rule is Devoid of Scientific Method or Safety Assurance

Federal agencies charged with protecting Americans from avoidable risks in items ingested, injected, or inserted in the body, or used in proximity to it, must use a scientific method in rule making. USDA conceded that it has no objective standards for determining whether to allow imports from a country known to have BSE, rather it wants the “flexibility” of a “case by case” approach from cattle it believes are an “overall minimal risk.” 70 *Fed Reg* 471, AR008055. USDA claims subjectivity is good, “in order to make rationale decisions, USDA needs the flexibility to make case by case determinations regarding the animal health status of particular regions.” 70 *Fed Reg* 471, AR008055. The undefined, subjective “negligible risk” standard has been held insufficient in fruit imports. *Harlan Land Co. v. USDA*, 186 F Supp 2d 1076, 1085-87 (CD Cal 2001). Cattle are at least as risky as fruit, but USDA choose to proceed without a standard.

The USDA’s own Food Safety Inspection Service (FSIS) requires objective, quantified methods and data for meat safety. Meat is adulterated if it “...bears or contains any such poisonous or dilatory substance which may render it injurious to health.” 9 CFR Pt 301.2.

FSIS has identified its own standards for addressing public health problems. FSIS states this on its web site, which are violated in the proposed rule: “FSIS

believes that a public health regulatory agency should embody at least eight key attributes.”¹

FSIS Attributes	Challenged Rule
“The first attribute is a public health orientation.”	The Rule’s orientation is economic, favoring Canadians over Americans. The Rule does not demonstrate a public health orientation.
“The second attribute is a regulatory strategy built on science-based systems to achieve public health goals.”	The Rule contains no science-based regulatory system. GOA found the science lacking.
“The third attribute is adopting measures of success to gauge progress in achieving its public health goals.”	The Rule contains no method to measure its success whatsoever.
“The fourth attribute is an open and inclusive manner for the conduct of business, as evidenced by public meetings with constituency groups on issues that bear on the Agency’s goals.”	APHIS allowed high-risk meat imports in 2003 and 2004 without public meetings or rule making; no public meetings were held. The rule calls for no meetings.
“The fifth attribute is the assurance that each of its organizational elements contribute to the achievement of the Agency’s public health goals. For FSIS, this means that public health-related activities have a priority claim on its inspection, laboratory, administrative, and other resources.”	The Rule does not coordinate USDA or other federal agencies. It provides no prioritization of USDA resources to the Rule or its enforcement. It lets untested cattle come south from Canada’s infected herd. It assigns no USDA personnel to enforcement or monitoring.
“The sixth attribute is the employment of public health professionals.”	The Rule is silent on this topic.
”The seventh attribute is the development of external relationships to mobilize other public health resources.”	No external relationships are provided or mentioned in the Rule, except to leave it to Canada.
“The eighth attribute is the use of scientific data to make decisions and allocate resources.”	The Rule uses gross observations and calls them science, but describes, and requires, no scientific methodology.

¹ 66 Fed Reg 30684, *FSIS-A Public Health Approach to Processing Inspection*.

There is no dispute USDA has performed no quantitative assessment of BSE risk from Canadian cattle. The Panel believed the District Court was imposing a “zero risk requirement” wrongfully. *R-CALF v USDA*, 415 F3d *supra* at 1094, fn 14 (2005). But USDA never quantified the risk requirement it was actually imposing. This is a fatal flaw, showing the lack of USDA ability to determine how much risk it is requiring US producers and consumers to undertake. USDA failed to follow the procedures it previously established for addressing public health risks.

IV. USDA Has no Science-based Measure of Verification.

The USDA creates, for the first time ever, a “minimal-risk region” designation for Canada allowing cattle imports from this known BSE region that “took additional mitigation measures [not defined] as necessary [not defined], following a BSE outbreak based on risk analysis [no method described] of the outbreak.” (AR97). The rules justification is populated with faith-based, nonscientific words, e. g., “likely” (used 109 times), “expect” (96 uses), “possible, possibly” (103 uses), “could” (90 uses), “assume” (58 uses). The Rule lacks precision, methodology, objectivity, and science. The Rule’s terms are the stuff of speculation; not the data of science. “Science increases our power in proportion as

it lowers our pride.”² Science is “organized knowledge.”³ USDA’s Rule has none of it.

The Food and Drug Administration (FDA) does utilize objective standards in protecting food safety.⁴ The Agency prohibits disease-causing food additives, unless they are Generally Recognized As Safe. (GRAS).⁵ FDA applies objective science for GRAS determinations; it does not stoop to empty phrases like “we believe” or “in all likelihood.” Here, the USDA not only has no objective quantification method, but relies upon a feed ban the Government Accountability Office has concluded is not reliable⁶ and the USDA’s own Office of Inspector General has determined the portion of the rule applying to Canadian meat packers is unable to be checked by USDA, and thus unreliable.⁷ USDA’s only “study” supportive of the Rule was released in 2001 and updated in 2002 and 2003.⁸ But core data is inexplicably excluded regarding the actual BSE-disease cattle

² C. Bernard, *Intro a la Medicine Experimentale* (1865).

³ Herbert Spencer, *Education II* (1861).

⁴ “The FDA is responsible for protecting the public health by assuring the safety, efficacy, and security of humans and veterinary drugs, biological products, medicine devices, our nation’s food supply, cosmetics, and products that emit radiation.” FDA *Mission Statement*, www.fda.gov/opacom/morechoices/mission.html.

⁵ See, 21 *USC* § 201(s), 409; 21 *CFR* Pt 170.3(i) 170.30.

⁶ *Mad Cow Disease*, Government Accountability Office, GAO-05-101.

⁷ Audit Report: APHIS Oversight of the Importation of Beef Products from Canada, USDA Office of Inspector General, Report No. 33601-01-Hy, Feb 2005, www.usda.gov/oig/webdocs/33601-01-HY.pdf.

⁸ 70 *Fed Reg* 467; AR008051.

discovered in Canada. The first infected Canadian-born cow was discovered on May 20, 2003 (an imported cow tested positive for BSE in December 1993); the second December 23, 2003⁹; the third December 29, 2004; the fourth January 11, 2005.¹⁰ None of this is in the studies.

USDA admits noncompliance with its feed ban creates a pathway for entry, yet assumes, or hopes, compliance is high.¹¹ The Harvard-Tuskegee study, upon which the Panel relied, calls noncompliance with the feed ban, either by feed producers or through misfeeding on the farm, one of the biggest uncertainties in its risk assessment, noting that feed ban noncompliance is being investigated as the explanation why cattle born after enactment of a feed ban in Europe continue to contract BSE. AR00381. But, GAO found in 2002:

Federal actions do not sufficiently ensure that all BSE-infected animals or products are kept out, or that if BSE were found, it would be detected promptly and not spread to other cattle through animal feed or enter the food supply.¹²

⁹ 70 *Fed Reg* 464; AR00848.

¹⁰ SER 20 to 21.

¹¹ 70 *Fed Reg* 466, AR008050-51

¹² *Mad Cow Disease, Improvements in the Animal Feed Ban and Other Regulatory Areas Would Strengthen US Prevention Efforts*, General Accounting Office, GAO-02-183, p 3, www.gao.gov/new.items/do2183.pdf.

GAO released a follow-up report finding little evidence of effective feed ban compliance.¹³ USDA omitted this report from the Administrative Record, though it was released to the public in February of 2005.

USDA relies heavily upon FDA inspection records, stating, “Conditions or practices warranting regulatory sanctions had been found in less than one percent of inspected facilities.”¹⁴ But GAO removes any basis for USDA’s conclusions stating:

Given these data concerns and compliance unknowns, FDA’s data should not be used to project industry compliance; and, any time those data are cited they should be in complete and accurate context.¹⁵

The Panel was not free to find USDA had sufficient data to show the feed ban was effective.

The GAO further concluded the Food and Drug Administration does not require firms processing prohibited feed to notify the Agency, FDA does not systematically test feed (but merely examines some records), and FDA fails to report inspection results in a reliable and accurate way. Thus, USDA’s assumption, and the Panel’s reliance on the assumption that feed ban compliance is high, is unsupported in the record. This foundational assumption is without data, objectivity, and is wrong. The Panel also ignored the fact that the latest cow with

¹³ See, 2005 GAO Report, *supra*.

¹⁴ 70 *Fed Reg* 466, AR008050

¹⁵ See, 2005 GAO Report, *supra*

BSE found in Alberta Province was born seven months *after* the Canadian feed ban, as were literally thousands of cattle in Europe (Transcript of Preliminary Injunction Hearing at 40-42, SER 275-77), confirming the District Court's concerns about the effectiveness of the feed ban. Cf. 415 F.3d at 1098-99.

V. The Panel Misunderstood Some of the Facts in the Record and Presented to the District Court

Despite precedent in this Circuit that a reviewing court should not delve into the merits of the claim below when reviewing a preliminary injunction, the Three-Judge Panel did so, and its opinion contains numerous incorrect factual assertions.

For example, the Panel said that there was no justification for the District Court's findings about the prevalence of BSE in Canada, and its rejection of USDA's conclusion that the incidence rate is only 0.149 per million head of cattle. 415 F.3d at 1097-98. But the District Court was presented with evidence that USDA's calculation was simply the ratio of cases found to total cattle population—a ratio that is lower the fewer cattle are tested. Cf. 415 F.3d at 1091.

The District Court made the understandable factual finding that the discovery of four BSE-infected cattle in Alberta Province in a year and a half was inconsistent with USDA's assertion that the BSE incidence in Canada is "minimal" and with the claimed incidence rate of 0.149 per million (in a total Canadian herd of 5.5 million). See 359 F. Supp.2d at 1066 and 70 *Fed Reg* at 512. The relevant question—which the Panel either misunderstood or ignored—is not how many

cases of BSE have been detected in Canada's limited sampling of less than 1% of its herd, but how many Canadian cattle are likely to be infected...which USDA did not even attempt to determine.

The Three-Judge Panel criticized the District Court's reliance on R-CALF's expert's supposedly unsupported assumption that cattle being tested in Canada are 60 times more likely to have BSE than cattle with no symptoms, when that assumption was explained by R-CALF's expert (Supplemental Excerpts of Record at 187-188) *and* by USDA's own declarant, Dr. Ferguson (BSE incidence in dead and "downer" cattle 50-100 times more likely than in apparently healthy cattle). Likewise, the Three-Judge Panel chastised the District Court for relying on the "unexplained assumption" that the BSE prevalence rate in Alberta Province was representative, 415 F.3d at 1097-98, when the record showed that the majority of cattle and beef imported from Canada comes from Alberta. *See, e.g.*, AR002529-33 (SER11-15).

In fact, it was USDA's action that was based on unsupported assumptions, and the Three-Judge Panel accepted them uncritically. For example, the District Court's factual conclusion that R-CALF had presented sufficient evidence to call into question USDA's assumption that "SRM removal" minimizes the risk to consumers of eating meat from BSE-infected cattle was rejected by the Three-

Judge Panel, based on a USDA-sponsored study “which concluded that SRM removal would reduce human exposure to BSE by 95 percent.” 415 F.3d at 1099.

The study merely *assumed* the extent to which SRM removal works, Harvard-Tuskegee Study, 2003, AR003756-60, AR003764-66. SRM removal is a new technique, and no data exists on its effectiveness in reducing human disease risk, especially given the years-long incubation period in humans.

In addition, since SRM removal was not yet required in the United States, the Harvard-Tuskegee Study assumed SRM removal requirements similar to those in Europe, which are much more stringent than those adopted in the US (e.g., removal from cattle over 6 months of age, rather than the US requirement to remove most SRMs only after 30 months). AR003809, AR003736. The District Court recognized this (Transcript of Preliminary Injunction Hearing at 85-85, SER307-309); the Three-Judge Panel did not.¹⁶

VI. Recent Information Further Shows Why the Three-Judge Panel Should Not Have Deferred to the Lack of USDA’s Assertions

Recent developments highlight ways in which the Three-Judge Panel’s assumptions (or its rubber-stamping of USDA’s assumptions) are inconsistent with the facts:

¹⁶ The Harvard-Tuskegee Study also assumed that SRMs would be removed from both the human food chain and the animal feed chain, reducing the possibility of feeding infected tissue to cattle, but the USDA regulations do not require that SRMs be excluded from animal feed. Cf. AR003809.

a. World Organization for Animal Health (OIE) BSE testing recommendations have been updated and are now more rigorous than the testing levels prescribed by the USDA's regulations.¹⁷

b. USDA belatedly announced (after over six months and only with a specific requirement from the USDA Inspector General for a retesting of samples) the first United States case of BSE in a native US animal born four to five years before the US implemented its meat and bone meal feed ban;¹⁸

c. Public Citizen, a non-profit organization, revealed USDA's own safety reports showing over 1,000 violations of the Agency's BSE risk mitigation measures by US meat packers,¹⁹ contradicting the USDA assumption, adopted by the Three-Judge Panel, that SRM removal will be effective in virtually eliminating the risk to consumers from BSE-infected cattle. 415 F.3d at 1096, 1099;

d. Within three weeks of the border reopening, Canada exported an animal older than legally allowed under the USDA's regulation. The animal was nevertheless slaughtered in the US with tissues designated as high risk for BSE intact. The meat was recalled more than two weeks after it was produced.²⁰ Media

¹⁷ See, 2005 OIE Terrestrial Animal Health Code, Appendix 3.8.4 *et seq.*, www.oie.int/eng/normes/mcode/enchapitre3.8.4.htm.

¹⁸ *Id.*

¹⁹ See, *BSE Non-Compliance Record Analysis*, Public Citizen, Aug. 18, 2005, www.citizen.org/cmep/foodsafety/madcow/articles.cfm?ID=13903.

²⁰ See, FSIS Recall Notice, Aug. 19, 2005, www.fsis.usda.gov/NEWS&Events/Recall0322005release/index.asp.

reports indicate the Agency does not know how much meat may have been consumed after the meat was distributed to six states. This reality undercuts severely the Three-Judge Panel's assumption that the age restriction in the rule will make the introduction of BSE from the Canadian herd far less likely (415 F.3d at 1095-96) and that it compensates for the fact that Canada's feed ban was in place for a shorter time than recommended by the OIE (415 F.3d at 1098);

e. Recent news reports indicate Canada also exported eight pregnant cattle for slaughter to the United States, raising concerns about the disposition of the fetal blood serum contained in the fetuses that is considered too high a risk by the USDA for import into the US from countries with BSE.²¹ The District Court identified this risk, which has already been borne out; the Three-Judge Panel criticized the District Court for that finding, 415 F.3d 1099;²²

f. New scientific research published in September 2005 shows that BSE infectivity has now been found in additional bovine tissues not presently listed as specified risk materials by the USDA.²³ Once again, this is a short-coming of the

²¹ See Pete Hisey, *Canadian Shipment Included 8 Pregnant Cows, Meating Place*, Aug. 24, 2005

²² Note also that the Three-Judge Panel accepted USDA's assertion that maternal transmission of BSE was not a concern "sufficient to justify addressing," 415 F.3d at 1099, while the Harvard-Tuskegee Study said there was evidence of maternal transmission of BSE, and assumed that 10% of calves borne of infected cattle during the last portion of their lives would be infected with BSE. AR003750.

²³ See Anne Buschmann & Martin H. Gruschup, *Highly Bovine Spongiform Encephalopathy, Sensitive Transgenic Mice Confirm the Essential Restriction of*

rule that the District Court identified, and the Three-Judge Panel simply adopted USDA's unsupported assertion that the limited SRM removal requirement in place would provide sufficient protection against BSE (see 415 F.3d at 1099);

g. New scientific research published in August 2005 has, for the first time, detected prions in blood,²⁴ contrary to the assumptions underpinning the USDA's rule that the Three-Judge Panel uncritically accepted in overruling the District Court's findings. 415 F.3d at 1099;

h. New scientific research published in July 2005 showing that infection by the disease agent that causes BSE may be reached through the accumulation of sub-infectious dosages over time. The researcher stated, "Repeated injection of low prion doses thus constitute a risk for development for prion disease even if the same total dose inoculated in a single challenge does not induce the disease."²⁵

i. The USDA now is proposing to further relax the United States BSE import restrictions for a country (Japan) that does not even meet the minimal

Infectivity to the Nervous System in Clinically Diseased Cattle, the *Journal of Infectious Diseases*, 192:934-42, Sep. 1, 2005.

²⁴ See Joaquin Castilla, et al., *Detection of Prions in Blood*, *Nature Medicine*, doi: 10.1038/mn 1286, Aug. 28, 2005.

²⁵ See Catherine Jacquemot, et al., *High Incidents of Scrapie Induced by Repeated Injections of Subinfectious Prion Doses*, *Journal of Virology*, July 2005, pp. 8904-8908.

criteria the Agency established a few months ago under its Minimal Risk Region Rule;²⁶

j. Despite its very stringent BSE mitigation measures, Japan has identified two additional cases of BSE in the last few months. And in the UK, 13 of the 85 cattle detected with BSE so far this year were born after the UK's strengthening of its feed ban (beyond the requirements of the US and Canadian feed bans), and authorities are investigating a "cluster" of three young infected cattle born long after the feed ban.²⁷ These facts belie the Three-Judge Panel's conclusion that BSE has been largely contained and that the ban on feeding ruminant protein to ruminants will "prevent" further dissemination of BSE from Canadian cattle in the US. Cf. 415 F.3d at 1096;

k. Japan's Ministry released a report concluding that 9 of the 20 cases of BSE found in Japan would not have been identified by USDA's testing program, because they did not show outward signs of disease.²⁸ (USDA only tests cattle that die from suspicious causes, are unable to walk, or exhibit symptoms of

²⁶ See *Proposed Rule, Importation of Whole Cuts of Boneless Beef from Japan*, 70 *Fed Reg* 48,494 (Aug. 18, 2005).

²⁷ See Steve Connor, *BSE Cluster Triggers Fears Over Contaminated Feed*, Independent Online (UK), July 20, 2005, <http://news.independent.co.uk/uk/environment/article300340.ece>.

²⁸ See Mari Yamaguchi, *Japan Questioning Safety of U.S. Beef*, Associated Press July 15, 2005, www.contracostatimes.com/mld/cctimes/12140483.htm?template=contentModules/printstory.jsp.

neurological disorders.) This confirms the District Court’s conclusion that R-CALF likely could show it was arbitrary and capricious for USDA not to have given more serious consideration to mandatory or voluntary testing for BSE, since it would identify additional cases of infected cattle—a conclusion that the Three-Judge Panel decided (without the requisite finding that the District Court abused its discretion, by the way) should be overturned. Cf. 415 F.3d at 1099-1100; and

1. The major US beef export markets, including the number 1 and 3 countries: Japan and Korea, remain closed. In addition, some significant export markets that have reopened have done so only after requiring conditions that the United States must certify that the beef exported from the US does not originate from countries, like Canada, with BSE.²⁹ But the District Court’s conclusion that resuming imports of Canadian cattle would have this effect on US exports was dismissed by the Three-Judge Panel as “overstated.” 415 F.3d at 1105.

These events and studies show the USDA’s assumptions, guesses, and hopes do not rise to the level of data allowing for a finding the objective scientific method was used. All agree that consequences of BSE infection are serious. There are dataless gaps in proven noncompliance with each and every step of the USDA’s so-called Risk Mitigation System.

²⁹ See, USDA Export Requirements for Egypt, www.ams.usda.gov/lsg/arc/ARC1030E.pdf. See also, USDA Export Requirements for the Philippines, www.ams.usda.gov/lsg/arc/ARC1030H.pdf.

VII. Conclusion

The public, and the Amici Parties, believe the Panel's opinion produces extremely negative ramifications and constitutes a rubber stamp of USDA's rule. Protecting the nation's cattle herd and the public from BSE is critical. The USDA rule therefore deserves a critical review, rather than blind acceptance of USDA assertions. An En Banc rehearing is necessary to uphold reasonable standards of judicial review to determine whether the sixty-two pounds of beef consumed by each and every American are truly safe.

Dated this ___ day of _____, 2005.

Respectfully submitted,

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Certificate of Compliance

Pursuant to FRAP 32(a)(7)(C) and Rule 32 of the Ninth Circuit Rules of Appellate Procedure, I certify:

A. This brief contains 3730 words, excluding the parts of the brief exempted by FRAP 32(a)(7)(B)(iii).

B. The foregoing Amicus Brief complies with the typeface requirements of FRAP 32(a)(5) and the type style requirements of FRAP 32(a)(6) because it is prepared in a proportionally spaced typeface using Microsoft Word 2000 (XP), in Times New Roman 14 point font.

September 16, 2005.

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CERTIFICATE OF SERVICE

I hereby certify that, on the 16 day of September 2005, I have caused a copy of the foregoing BRIEF OF AMICI CURIAE SUPPORTING APPELLEE R-CALF USA PETITION FOR REHEARING to be served by placing it in the U.S. mail or consigning it to an express delivery service, addressed to:

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