

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
Seeking To Affirm Preliminary Injunction & Order Striking Administrative Rule**

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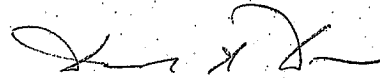
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Rule 26.1 Corporate Disclosure Statement

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.

June ^{1st}, 2005.



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Identity and Interests of *Amici Curiae*

The *amici* are 67 entities with national, state or local constituencies or private interests. They represent over 50 million US consumers, citizens and agricultural producers. 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 Brief. 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. Consumer Federation of America ("CFA"), Washington, DC, is an advocacy, research, education, and service organization. CFA works to advance pro-consumer policy on a variety of issues. CFA represents nearly 50 million citizens.
2. National Farmers Union, Washington, DC and Aurora, CO is a national, general farm organization based in Washington, DC with over 300,000 members.
3. Public Citizen, Washington, DC and Oakland, CA, is a nonprofit corporation representing 150,000 consumer and citizen members before Congress and the courts on public health and nutrition issues.

4. The Organization for Competitive Markets (“OCM”), Lincoln, NE, is a nonprofit research and education corporation focusing on agricultural antitrust and trade issues.
5. Center for Food Safety, Washington, DC, works to protect human health and the environment by curbing the proliferation of harmful food production methods and practices.
6. National Catholic Rural Life Conference (“NCRCL”), Des Moines, IA, is the lead voice for the Catholic Church on agricultural issues in the United States.
7. National Farmers Organization (“NFO”), Ames, IA. The NFO, founded in 1955 to express agricultural and rural interests on issues is now a sophisticated source for ag risk management products and seeks to assure more effective marketing techniques for producers of America’s food supply.
8. The CJD Foundation, Akron, OH, is a nonprofit corporation engaged in research, family support, health care provider education, and public policy advocacy towards greater awareness and effective responses to Creutzfeld-Jacob Disease (“CJD”), including variant CJD caused by ingesting BSE infected beef.
9. Women Involved in Farm Economics (“WIFE”), Burdett, KS. WIFE, formed in 1976, represents women vitally interested in ag and food quality issues. It is a national organization with state chapters.
10. Institute for Agricultural & Trade Policy (“IATP”), Minneapolis, MN. IAPT promotes resilient family farms, rural communities and ecosystems around the world through research and education, science and technology, and advocacy.

REGIONAL and STATE ORGANIZATIONS

11. California Farmers Union, Turlock, CA, is a general farm organization working on behalf of California farmers and ranchers.
12. Cattle Producers of Washington, Soap Lake, WA, is a nonprofit corporation representing cattle producers in Washington State.
13. Central Colorado Cattlemen's Association, Fairplay, CO, is a nonprofit corporation representing Colorado cattle producers.
14. 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.
15. 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.
16. Illinois Cattlemen's Association, Cambridge, IL, is a nonprofit association representing Illinois cattle producers.
17. Illinois Farmers Union, Springfield, IL, is a general farm organization working on behalf of Illinois farmers and ranchers.
18. Independent Cattlemen of Nebraska, Hyannis, NE, is a nonprofit corporation representing cattle producers in Nebraska.
19. Iowa Farmers Union, Ames, IA, is a general farm organization working on behalf of Iowa farmers and ranchers.
20. Just Food, New York, NY. Just Food is a non-profit organization that works to develop a just and sustainable food system in the New York City region.
21. Kansas Cattlemen's Association, Brewster, KS, is a nonprofit corporation representing cattle producers in Kansas.

22. Kansas Farmers Union, McPherson, KS, is a general farm union working in behalf of Kansas farmers and ranchers.
23. 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.
24. Michigan Farmers Union, Sparta, MI, is a general farm organization working on behalf of Michigan Farmers.
25. Minnesota Cattlemen's Association, Backus, MN, is a nonprofit association representing Minnesota cattle producers.
26. Minnesota Farmers Union, St. Paul, MN, is a general farm organization working to preserve and improve rural Minnesotan's quality of life.
27. Mississippi Livestock Markets Association, Jackson, MS, is an association of livestock auction markets in Mississippi.
28. Missouri Farmers Union, Jefferson City, MO, is a general farm organization working on behalf of farmers and ranchers in Missouri.
29. Montana Cattlemen's Association, Billings, MT, is a nonprofit corporation representing cattle producers in Montana.
30. Montana Farmers Union, Great Falls, MT, is a general farm organization working on behalf of Montana farmers and ranchers.
31. New England Small Farm Institute, Belchertown MA. The NESFI promotes small farms, healthy farming, and safe, chemical and disease-free foodstuffs.
32. Nebraska Farmers Union, Lincoln, NE, is a general farm organization working on behalf of Nebraska farmers and ranchers.
33. Nevada Livestock Association, Elko, NV, is a nonprofit corporation representing cattle producers in Nevada.

34. North Dakota Farmers Union, Jamestown, ND, is a general farm organization working on behalf of North Dakota farmers and ranchers.
35. Northern Plains Resource Council, Billings MT promotes healthy agriculture and the welfare of producers and their resources, including livestock, on the nation's northern plains.
36. Oregon Livestock Producers Association, Jordan Valley, OR, is a nonprofit corporation representing Oregon cattle producers.
37. Pennsylvania Farmers Union is a general farm organization working on behalf of Pennsylvania farmers.
38. Rocky Mountain Farmers Union, Denver CO, is a general farm and ranch association representing the interests of producers of all commodities in Colorado, Wyoming and New Mexico.
39. South Dakota Farmers Union, Huron, SD, is a general farm organization working on behalf of South Dakota farmers and ranchers.
40. South Dakota Livestock Marketing Association is an association of livestock auction markets in South Dakota.
41. South Dakota Stockgrowers Association, Rapid City, SD, is a nonprofit corporation representing cattle producers in South Dakota.
42. South Montana Angus Association, Bozeman, MT, promotes beef production and healthy livestock.
43. Texas Farmers Union, Waco, TX, is a general farm organization working on behalf of Texas farmers and ranchers.
44. Utah Farmers Union, Howell, UT, is a general farm organization working on behalf of the farmers and ranchers of Utah.
45. 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.

46. Wisconsin Farmers Union, Chippewa Falls, WI, is a general farm organization working on behalf of Wisconsin farmers and ranchers.

LOCAL and PRIVATE ORGANIZATIONS

47. Crowley-Kiowa-Lincoln Counties Cattlemen's Association is an organization of cattle producers in eastern Colorado with vital interests in herd health and consumer food supply confidence.
48. Eagle County Cattlemen's Association, Burns, CO, is a nonprofit corporation representing cattle producers in Eagle County, Colorado.
49. Franz Beefmasters, Burlington, CO, is a ranch operation.
50. Harding County Stockgrowers Association, Buffalo, SD, is an association representing cattle producers in Harding County, South Dakota.
51. Harrison County Cattlemen's Association, Bethany, MO, promotes and nurtures all phases of the live cattle industry in Missouri.
52. Henry County Beef Association, Cambridge, IL, is a nonprofit association representing cattle producers in Henry County, Illinois.
53. Kit Carson County Cattlemen's Association is an association representing cattle producers in Kit Carson County, Colorado.
54. Lincoln County Stockman's Association, Ordway, CO, is an association representing cattle producers in Lincoln, Colorado.
55. Modoc County Cattlewomen, Alturas CA, promote beef quality and beef and livestock safety.
56. Morrow County Livestock Growers Association, Heppner, OR, represents local livestock producers with vital interests in consumer confidence in safe beef, and in herd health.

57. Muddy Valley Ranch LLC, a private ranching company. Kimmi Lewis, principal.
58. Mundell Ranch, Walsh, CO, is a ranch operation.
59. 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.
60. Schreiber Ranch, Woodrow, CO is a ranch operation.
61. Sheridan County Chamber of Commerce, Sheridan, WY works to actively promote a positive business and economic climate in Sheridan County.
62. Southeast Wyoming Cattle Feeders Association is a nonprofit corporation representing cattle producers in southeast Wyoming.
63. Southwestern Colorado Livestock Association is a nonprofit corporation representing cattle producers in Colorado.
64. Spokane County Cattle Producers, Cheney, WA, is an association representing cattle producers in Spokane County, Washington.
65. Stirling T. Spencer of the Bar Z Ranch, Carrizozo, NM, is a cattle rancher.
66. Washington County Stockman's Association, Woodrow, CO, is an association representing cattle producers in Washington County, Colorado.
67. Wilda Wisconsin Independent Livestock Dealers Association, Viola, WI, is a nonprofit association representing independent livestock dealers in Wisconsin.

ARGUMENT

I. Administrative Rules Devoid of Facts, Methods and Consistency Cannot Survive Judicial Scrutiny

A. USDA APHIS is a Public Health & Safety Agency.

Public interest groups, cattle producer and consumer groups, collectively representing more than 50 million consumers and producers, join as *amici curiae* because the nation's human and bovine populations are jeopardized by baseless USDA action. The USDA is a public health agency. 7 USC § 8301; 61 Fed Reg 19025. USDA may not make rules fraught with unquantified or unverified risks. *Whitman v. American Trucking Ass'n*, 531 US 57 (2001) (clean air regulations); *Anderson v. Evans*, 350 F3d 815, 371 F3d 815 (9th Cir 2003) (NEPA whale hunting regulations). The *amici* join R-Calf's request USDA's rule, 9 CFR pts. 93-95, ("Rule") to open the nation's northern border to BSE-diseased live cattle importation, be stricken. The Rule fails APA standards for judicial review: it is devoid of (1) facts to support assumptions, (2) rational connection between facts found and choices made, and (3) reliable data consistent with other agencies' rules.

B. Public Health & Safety Agencies Must Use the Scientific Method, Not Conjecture, to Make Rules.

Courts disfavor relaxing safety standards where Congress expressed its intent for the agency to protect safety. *Motor Vehicle Mfrs. Ass'n v. State Farm*

Mut., 463 US 29, 42 (1983). Congress did so with the USDA. 7 USC § 8301.¹ A rule fails the test if the agency uses irrelevant factors, ignores important facts, exhibits inconsistency, reveals implausibility, or constructs unrelated connections between facts and conclusions. *Motor Vehicle Mfrs. Assn.*, 463 US at 42.

Men must turn square corners when they deal with the Government. [H]owever, ... '[i]t is no less good morals and good law that the Government should turn square corners in dealing with the people than that the people should turn square corners in dealing with their government.'

United States v. Winstar Corp., 518 US 839, n.31 (1996) (internal citations omitted). Without data, the Court owes an agency no deference. *Ober v. Whitman*, 243 F3d 1190, 1195 (9th Cir 2001). Administrative agency actions do not turn square corners when they are "arbitrary, capricious, ... abuse ...discretion, or otherwise [act] not in accordance with law." 5 USC § 706(2)(A). The challenged Rule is a short cut, not a square turn, with public health and safety.

C. The Challenged Public Health & Safety Rule Uses Conjecture, Not Science, for its Justification.

The Rule will allow 1.7 million cattle to be imported from Canada. Its herd is

¹ "Congress finds: (1) the prevention, detection, control, and eradication of diseases and pests of animals are essential to protect-- (A) animal health; (B) the health and welfare of the people; (C) the economic interests...; (D) the environment of the United States; and (E) interstate commerce and foreign commerce of the United States in animals...." 7 USC § 8301

Known to carry BSE—a little understood deadly disease.² Cattle from a diseased herd will come into the US, ending a ban designed to protect US health interests, though the Rule expresses no rationale for the admitted risk. The US herd is not known to harbor BSE-infected cattle.³ USDA's action is a whimsical shortcut taken for no expressed reason in an area where a "square turn" is vital to US human and herd health. The Rule is at odds with other federal agency public health and safety decisional methods. It favors foreign over domestic interests. It subjects American cattlemen and consumers to risks with no reward. Its very nature begs the question unanswered by USDA: Why take the admitted BSE risk?

Our country bans pharmaceutical imports from Canada because FDA "cannot provide adequate assurance to the American public that the drug products delivered ... are the same products approved by FDA."⁴ USDA's Rule relies on an unproven feed ban⁵ in a foreign country and contains no assurance to Americans the imported Canadian cattle are BSE free. It establishes no procedure to verify or

² "Early in the illness, patients ... experience psychiatric symptoms.... Neurological signs, including unsteadiness, difficulty walking and involuntary movements, develop ... and, by the time of death, patients become ... immobile and mute." *Fact Sheet -Variant Creutzfeldt-Jakob disease*, World Health Organization, www.who.int/mediacentre/factsheets/fs180/en/.

³ See, Plaintiff's Supplemental Excerpt of Record ("SER") 120, 121.

⁴ *FDA Position on Foreign Drug Imports*, U.S. Food and Drug Administration, Office of Regulatory Affairs, www.fda.gov/ora/import/default.htm.

⁵ USDA presumes BSE is passed only by human or bovine ingestion of diseased brain or spinal cord tissue. The ban prohibits feeding bovine tissue to bovines.

police Canadian practices.⁶ The Rule consciously rejects objective, scientific standards in favor of *ad hoc* decision-making.⁷ It relies upon Canada's promise to mimic a nonscientific US meat byproducts feed ban to ensure safety. This reliance is misplaced; a US GAO report⁸ and Canadian disclosures prove feed ban noncompliance and unreliability.⁹

This Court "... shall review [this] whole record or those parts of it cited by a party, and due account shall be taken of the rule of prejudicial error." 5 USC § 702(2). Judicial review's purpose is "to check arbitrary or inconsistent administrative action." *Lichter v. United States*, 334 US 742, 770-771 (1948).

II. The Rule Arbitrarily & Capriciously Subjects the US to Health Risks Because it is Devoid of a Scientific Method of Safety Assurance.

A. The Rule Ignores USDA Health & Safety Criteria.

The US does not allow Canadian prescriptions for lack of safety standards. Pharmaceuticals are injected in *small* quantities to prevent or remedy illness. Yet, the Rule allows cattle imports, despite scientific certainty cattle will bring a deadly disease. Beef is ingested in *large* quantities --62 lbs / person / year.¹⁰

⁶ SER 20 (stating Canadian Food Inspection Agency establishes noncompliance).

⁷ 70 *Fed Reg* 464.

⁸ *Id.*

⁹ See n.5, *supra*.

¹⁰ USDA Econ Res Serv, 2003 per capita food consumption statistical table, www.ers.usda.gov/data/foodconsumption/FoodAvailQueryable.aspx#midForm.

The Rule is unprecedented in creating a “minimal-risk region” (AR 96) covering Canada. The “minimal-risk region” designation allows cattle imports from a 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.” (AR 97). The Rule’s 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.”¹¹ Science is “organized knowledge.”¹² USDA’s Rule has none of it.

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 the scientific method – and reject subjective case-by-case judgments – in rule-making. USDA concedes the Rule has no standards; it wants the “flexibility” of a “case-by-case” approach for cattle from what it believes is an “overall minimal risk.”¹³ USDA claims subjectivity is good: “In order to make rational decisions, USDA needs the flexibility to make case-by-case determinations regarding the

¹¹ C. Bernard, *Intro a la Medicine Experimentale* (1865).

¹² Herbert Spencer, *Education II* (1861).

¹³ 70 *Fed Reg* 471, AR008055.

animal health status of particular regions.”¹⁴ “Negligible risk” is impermissible in fruit imports. *Harlan Land Co v. USDA*, 186 FSupp2d 1076, 1085 (CD Cal 2001). Cattle are at least as risky as fruit. With no standard for risks to be assessed case-by-case, the Rule fails. *Ober*, 243 F3d at 1195.

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 deleterious substance which may render it injurious to health.” 9 *CFR* pt 301.2. No meat may be imported without compliance. *Id.* pt 327.3. But the challenged Rule lets whole diseased animals enter US ports. The EPA allows no minimal risk in drinking water standards; scientific methods and actual data are required. EPA rules entirely disallow harmful pathogens in drinking water.¹⁵ No “minimum risk” level, case-by-case, or subjective agency judgment is permitted with water because pathogens in it can cause human death. So can diseased cows, and their beef.

USDA’s FSIS is a sibling sub-agency to APHIS. “FSIS believes that a public health regulatory agency should embody at least eight key attributes.”¹⁶

APHIS ignores these criteria. This is caprice.

¹⁴ 70 *Fed Reg* 471, AR008055.

¹⁵ *List of Drinking Water Contaminants & MCLs*, EPA, www.epa.gov/safewater/mcl.html#mcls.

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

FSIS Attributes

Challenged Rule

<p>“The first attribute is a public health orientation.”</p>	<p>The Rule’s orientation is economic, favoring Canadians over Americans. The Rule does not demonstrate a public health orientation.</p>
<p>“The second attribute is a regulatory strategy built on science-based systems to achieve public health goals.”</p>	<p>The Rule contains no science-based regulatory system. GAO found the science lacking.</p>
<p>“The third attribute is adopting measures of success to gauge progress in achieving its public health goals.”</p>	<p>The Rule contains no method to measure its success whatsoever.</p>
<p>“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.”</p>	<p>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.</p>
<p>“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.”</p>	<p>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.</p>
<p>“The sixth attribute is the employment of public health professionals.”</p>	<p>The Rule is silent on this topic.</p>
<p>“The seventh attribute is the development of external relationships to mobilize other public health resources.”</p>	<p>No external relationships are provided or mentioned in the Rule, except to leave it to Canada.</p>
<p>“The eighth attribute is the use of scientific data to make decisions and allocate resources.”</p>	<p>The Rule uses gross observations and calls them science, but describes, and requires, no scientific methodology.</p>

USDA policies so fitting for FSIS must apply to all its sub-agencies. The FSIS policy is intended to ensure agency square-turns on health issues, not turns on

whims. To permit importation of 1.7 million cattle¹⁷ from the diseased Canadian herd without inspection, under a Rule that ignores USDA's own criteria for a public health agency, is surely action that displays "caprice,' in 'an arbitrary and unpredictable fashion,' or through 'arbitrary' or 'freakish' [regulation]." *Beard v. Banks*, 124 SCt 2504 (2004) (Stevens, J., dissenting).

The USDA's Rule is not "founded on a seasoned evaluation of relevant factors." *Arizona Cattle Growers Ass'n v. US Fish & Wildlife Svc.*, 273 F3d 1229, 1236 (9th Cir 2001). The Agency is to exercise sound discretion, not whim and caprice. This is not a complex requirement for valid rulemaking; nor is it a new idea for good governance. "[D]iscretion here means sound legal discretion, and not mere will, whim and caprice, it must be applied to a discernment and corresponding allotment..." *Brown v. Van Bramm*, 3 US 344, 350 (1797).

B. FDA and Other Public Health & Safety Rules Use Science to Assure Objective Verifiability. The Challenged Rule Does Not.

The Food and Drug Administration ("FDA"), like USDA, protects food safety.¹⁸ The agency prohibits disease-causing food additives, unless they are Generally Recognized as Safe ("GRAS").¹⁹ To the FDA, "safe" means a

¹⁷ SER 121.

¹⁸ "The FDA is responsible for protecting the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation." FDA Mission Statement, www.fda.gov/opacom/morechoices/mission.html.

¹⁹ See, 21 USC §§ 201(s), 409; 21 CFR pts. 170.3 (i), 170.30.

reasonable certainty in the minds of competent scientists the substance is not harmful under its intended conditions of use.²⁰

FDA applies objective science for GRAS determinations; it does not stoop to empty phrases like “we believe” or “in all likelihood.” Specific data proving food additive safety includes characteristics of the substance, estimated dietary intake, and the consuming population.²¹ FDA performs food consumption surveys to estimate exposure to substances; it “link[s] food intakes with independently-determined concentrations of the substances in foods;” it considers “very short-term, or even single exposures, especially for contaminants associated with acute toxic effects;” and “evaluates data concerned with lifetime exposures to the substance.”²² No exposure or toxicity considerations appear in the USDA Rule.

USDA “suggests” the ban against feeding beef byproducts to cattle protects humans from BSE. The agency relies upon a feed ban the GAO concluded is not reliable²³ and a Canadian meat packer system not able to be checked by USDA.²⁴

²⁰ 21 *CFR* pt. 170.3(i).

²¹ *Frequently Asked Questions About GRAS*, FDA Center for Food Safety and Applied Nutrition, Dec. 2004, www.cfsan.fda.gov/~dms/grasguid.html#Q1.

²² Michael J. DiNovi and Paul M. Kuznesof, “Estimating Exposure To Direct Food Additives And Chemical Contaminants in the Diet,” FDA Office of Premarket Approval, June 18, 2001, www.cfsan.fda.gov/~dms/opa-cg8.html#survey.

²³ *Mad Cow Disease*, supra, Government Accountability Office, GAO-05-101.

²⁴ *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.

USDA mentions verification processes but has no estimated dietary intake in its Rule, and prescribed no standards for either. This is a fatal flaw. *Ober*, 243 F3d at 1195.

Pharmaceutical drugs undergo rigorous tests; they are scientific and methodological. It is not the conclusion drugs may be safe, but the methodologies of testing, formulating and compounding that must be scientific. The scientific method leads to the conclusion that a drug is, or is not, safe.²⁵ So it is with everything ingested, injected or inserted into the body.²⁶ The FDA uses objective standards for evaluating food safety and issuing rules. 21 *CFR* pt 130. Oysters, for example, are subject to specific FDA testing criteria. 21 *CFR* pt 161.130. Yet, the USDA's Rule (AR 94) contains a conclusion; it has no scientific method in it.

Even products distant from people, but posing risks of residual presence in their food, are approved for use, or prohibited as unsafe, only after full, professional use of the scientific method.²⁷ The challenged Rule occupies lonely space as an overt weak link in the regulation of matters impacting public health. It

²⁵ 21 *CFR* pt. 211.

²⁶ For example, *see*, 21 *CFR* pt. 801.430 (adopting ASTM standards for measuring condom strength for FDA approval, and tampon absorbency for the same purpose), 16 *CFR* pt. 1610 *et seq* (clothing flammability testing standards) 21 *CFR* pt. 872 and 67 *Fed Reg* 7620 (special test procedures for dental fillings material).

²⁷ *See, e.g.*, 40 *CFR* pt. 180 (pesticide standards of the EPA). The agency must disapprove pesticides "unless a validated scientific method is available to detect residues of the pesticide in food". 67 *Fed Reg* at 30069. Similar criteria are required by the CDC and others. *See, e.g.*, 67 *Fed Reg* at 47371-02 (scientific method required to assure measures of effectiveness to protect health).

regulates out of belief, not science.²⁸ And, the Rule does so arbitrarily in the face of a known risk. If BSE is vectored into this nation, thousands of cattle producers, millions of cattle, tens of millions of people and billions of dollars are at risk. The countervailing “reward” for this risk is not expressed in the Rule.

III. The Rule Arbitrarily Subjects the US to Health Risks because it is Devoid of a Scientific Method of Safety Assurance

A. USDA’s Justification for the Rule Allowing Importation of Cattle from a Diseased Herd is Unfounded, Unsafe and Arbitrary.

USDA’s only “study” supportive of the Rule was released in 2001, and updated in 2002 and 2003.²⁹ But it inexplicably excluded core data of actual BSE diseased cattle in Canada. The first infected Canadian cow was discovered on May 20, 2003; the second December 23, 2003³⁰; the third December 29, 2004; the fourth January 11, 2005.³¹ None of this is in the study. USDA held to a firm anti-BSE cattle policy after the first infection. Its spokesman assured Congress, “if it isn’t safe, we don’t import it,”³²; he even bet his job on it. He lost his bet; but kept his job. The post-Canadian border closure infections quintupled the May 2003

²⁸ The *amici* are aware of no legally permissible “faith-based” rulemaking in the public health area.

²⁹ 70 *Fed Reg* 467; AR008051.

³⁰ 70 *Fed Reg* 464; AR00848.

³¹ SER 20-21.

³² Dr. Charles Lambert, USDA Undersecretary of Marketing and Regulatory Programs, Hearing Before the Committee on Agriculture House of Representatives June 30, 2003, www.agriculture.house.gov/hearings/108/10812.pdf, p 21.

total of one. In January 2005, the rate of infection thus became one case per 10,000 tested, *i.e.*, a prevalence rate equating Europe.³³

The Rule does not provide for inspection, testing or preventive measures upon importation of Canadian cattle. Its only risk control measure is imported cattle must come through a Port of Entry.³⁴ Ports of Entry do not, and cannot, perform tests for BSE.³⁵ Two permissible Ports of Entry are in downtown Detroit, MI and Buffalo, NY.³⁶ They cannot handle cattle.

The OIE considers cattle sources as minimally risky with below 2 cases / million head.³⁷ Canada found 4 BSE-positives among less than 40,000 head tested, all in Alberta.³⁸ This rate is above 2 per million, and similar to Europe's; cattle from there cannot come here.³⁹ An opened border means 1.7 million cattle / year will enter – a near statistical certainty BSE will reach the US in one year.⁴⁰

B. USDA's Reliance on a Feed Ban is not Scientifically Supported and is Debunked by the GAO.

USDA thinks Canada's 1997 feed ban is sufficient protection for imports because it is like the US feed ban. It is not. The US herd is free of BSE insofar as

³³ SER 123.

³⁴ AR 100, 102.

³⁵ AR 100, 102.

³⁶ AR 102.

³⁷ 70 *Fed Reg* 464; AR00848.

³⁸ SER 122, 123.

³⁹ SER 123.

⁴⁰ *Id.*

is known. Canada's is not. GAO says the feed ban is unproven. USDA has no different data. Canada Food Inspection Agency studies in 2004 showed 1,832 cattle may have been exposed to the May 2003 BSE-infected cow, which was processed into animal feeds under Canada's feed ban's age limit.⁴¹ The infected cow, discovered January 11, 2005, was younger than the Canadian feed ban.⁴² Our domestic feed ban is *presumed* successful to prevent BSE transmission to humans.⁴³ Domestic compliance is not measured in the risk analysis.⁴⁴ USDA admits noncompliance with the feed ban creates a pathway for entry, yet assumes, or hopes, compliance is high.⁴⁵ 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.⁴⁶

GAO released a follow-up report finding too little evidence to show effective feed ban compliance.⁴⁷ This report was omitted from the Administrative Record, but released days later. USDA relies heavily on FDA inspection records, stating "conditions or practices warranting regulatory sanctions had been found in

⁴¹ SER 20.

⁴² SER 20-21.

⁴³ 70 *Fed Reg* 467, AR008051.

⁴⁴ Cohen, et al., *Evaluation of the Potential for Bovine Spongiform Encephalopathy in the United States*, Harvard Center for Risk Analysis, November 26, 2001, p 98.

⁴⁵ 70 *Fed Reg* 466, AR008050-51.

⁴⁶ *Mad Cow Disease, Improvements in the Animal Feed Ban and Other Regulatory Areas Would Strengthen U.S. Prevention Efforts*, General Accounting Office, GAO-02-183, p 3, www.gao.gov/new.items/d02183.pdf.

⁴⁷ See, 2005 GAO Report, *supra*.

less than 1 percent of inspected facilities.”⁴⁸ But GAO removes any basis for this conclusion:

Given these data concerns and compliance unknowns, FDA’s data should not be used to project industry compliance; and, anytime those data are cited, they should be in a complete and accurate context.⁴⁹

FDA agreed with GAO that feed ban compliance efforts are inadequate because there is: (1) No uniform procedure to identify firms subject to the feed ban; (2) Failure to collect test results from states that sample feed; (3) Failure to label feed properly relating to ruminant consumption prohibition; (4) Failure to notify USDA and the states when prohibited feed was fed to cattle; (5) Failure to verify or exclude cross-contamination between feed types in feed carrying vehicles; and (6) Failure to identify high risk feed salvagers.⁵⁰ USDA is at odds with GAO and FDA over the feed ban. GAO and FDA used science for their work; USDA did not.

GAO concluded FDA 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. Yet, USDA’s assumption of “high compliance” with the feed ban is the major flaw of the Rule. USDA’s foundational assumption is without data, or objectivity, and is wrong. The Agency takes a short cut with public health and safety in the

⁴⁸ 70 *Fed Reg* 466, AR008050.

⁴⁹ See, 2005 GAO Report, *supra*.

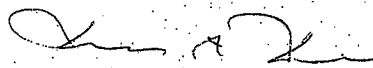
⁵⁰ *Id.* at 32.

challenged Rule. Such a short cut is unprecedented, unwarranted, unjustified, and unlawful. The Rule, 9 *CFR* pts. 93-95, should not stand.

Conclusion

The USDA is a public health and safety agency. It is obligated to regulate scientifically and logically, not to act on what may or might occur. More than whim is required. This is an ancient requirement; one populating this nation's law for more than 200 years, and predating the USDA. The USDA's Rule, 9 *CFR* Pt 93-95, is (a) without a basic risk reward analysis, (b) devoid of the scientific method. (c) contrary to rule making criteria used by USDA itself to protect the public. and (d) inconsistent with other federal agency findings.

The Rule has no scientific basis. It is "a clear error of judgment," *Bowman Transp. Inc. v. Arkansas-Best Freight System*, 419 US 281, 285 (1974), and should be declared invalid.



6-1-05

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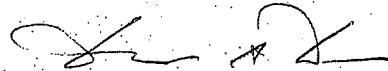
Certificate of Compliance

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

A. This brief contains 3033 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.

June st /, 2005.



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Affidavit of Service

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I, David A. Domina, being first duly sworn, state the following items were sent UPS Next Day Air to the Clerk of the United States Court of Appeals for the Ninth Circuit:

1. Original Brief for Amicus Curiae;
2. 15 copies of Amicus Curiae's Brief.

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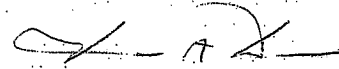
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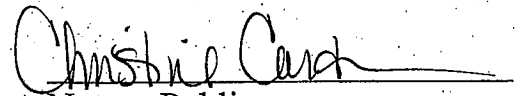
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