UNITED STATES DISTRICT COURT
DISTRICT OF SOUTH DAKOTA
NORTHERN DIVISION

RANCHERS CATTLEMEN ACTION LEGAL FUND, UNITED STOCKGROWERS OF AMERICA, et al.,	)	
	)	CIV-07-1023
Plaintiffs,	)	
vs.	)	
UNITED STATES DEPARTMENT OF AGRICULTURE, et al.,	)	
Defendants.	)	

DEFENDANTS' OPPOSITION TO PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION

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INTRODUCTION

Plaintiffs fail on all four prongs of the preliminary injunction standard, and their motion for a preliminary injunction should be denied. Plaintiffs are unlikely to succeed on the merits because the USDA rule at issue, which would lift the ban on imports of Canadian cattle 30 months of age or older (the "OTM Rule"), is based on overwhelming evidence that the proposed imports are safe. The OTM Rule builds incrementally upon a prior rule that for over two years has permitted certain Canadian bovine imports, based on measures enacted here and abroad that prevent transmission of Bovine Spongiform Encephalopathy (BSE). The Ninth Circuit has twice considered – and upheld – the earlier rules, finding that they were based on sound science and took all relevant factors into account. RCALF v. USDA, 499 F.3d 1108 (9th Cir. 2007); RCALF v. USDA, 415 F.3d 1078 (9th Cir. 2005). The OTM Rule is founded on the same sound science and expert agency assessments.

Plaintiffs' attack on the OTM Rule is more notable for what it does not challenge than for what it does. The Ninth Circuit snuffed out plaintiffs' challenges to the science of the earlier import rules. Consequently, plaintiffs do not dispute the efficacy of the mitigation measures underlying the OTM Rule. Instead, they concoct imaginary inconsistencies or omissions in the rulemaking process.

Plaintiffs' speculative claims of irreparable harm echo the allegations rejected by the Ninth Circuit, which found no support in the record for alarmist predictions of injury to U.S. consumers, the cattle herd, or the beef industry (and which, following the resumption of Canadian imports over two years ago, never came to pass). RCALF, 415 F.3d at 1104-05. USDA's risk analysis, which was independently peer-reviewed by recognized experts in the field, found no more than a negligible risk of BSE from OTM imports over the next 20 years. Plaintiffs show no risk of harm, much less certain and great harm, if imports resume for the few weeks or months it will take this Court to review the OTM Rule on the merits. Finally, the balance of harms and the public interest favor denying a preliminary injunction, since the resumption of OTM imports would be safe and benefi-

cial to the U.S. economy, and, given the negligible risk to human and animal health, there is no valid reason under the Animal Health Protection Act (AHPA) to preclude imports of OTM cattle and beef.

BACKGROUND

The factual and legal background is contained in the Statement of Facts in Support of Defendants' Opposition to Plaintiffs' Motion for Preliminary Injunction ("Def. Stmt. of Facts"), filed herewith.

ARGUMENT

A court evaluating a request for a preliminary injunction must consider (1) the threat of irreparable harm to the movant; (2) the balance between this harm and the harm to other parties if the injunction is granted; (3) the movant's probability of success on the merits; and (4) the public interest. Dataphase Sys., Inc. v. C L Sys., Inc., 640 F.2d 109, 113 (8th Cir. 1981) (*en banc*). Although "in each case all of the factors must be considered to determine whether on balance, they weigh towards granting the injunction," Calvin Klein Cosmetics Corp. v. Lenox Labs., Inc., 815 F.2d 500, 503 (8th Cir. 1987), the movant in all events "is required to show the threat of irreparable harm," Baker Elec. Co-op., Inc. v. Chaske, 28 F.3d 1466, 1472 (8th Cir. 1994), the absence of which "is, by itself, a sufficient ground upon which to deny a preliminary injunction." Gelco Corp. v. Coniston Partners, 811 F.2d 414, 418 (8th Cir. 1987). The movant bears the burden of establishing the propriety of this extraordinary remedy. Baker Elec. Co-op., 28 F.3d at 1472; see also North Dakota v. U.S. Army Corps of Engineers, 270 F. Supp. 2d 1115, 1119 (D.N.D. 2003). Here, plaintiffs fall far short of meeting their burden, and their motion for an injunction should be denied.

I. PLAINTIFFS ARE UNLIKELY TO SUCCEED ON THE MERITS.

A. Review Under the Administrative Procedure Act Is Highly Deferential.

All the claims raised in plaintiffs' motion for a preliminary injunction are governed by the Administrative Procedure Act (APA), which provides for limited judicial review of agency action.

See 5 U.S.C. §§ 702, 706. Under the APA, a court may overturn an agency action only if it was "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law," or in excess of statutory jurisdiction or authority. 5 U.S.C. §§ 706(2)(A), (C); Voyageurs Nat'l Park Ass'n v. Norton, 381 F.3d 759, 763 (8th Cir. 2004) (citation omitted). Under the arbitrary and capricious standard, a court must accord "great deference to the policy decisions made by the agency," South Dakota v. Ubbelohde, 330 F.3d 1014, 1031-32 (8th Cir. 2003), and cannot disturb the agency's decision "[a]s long as the agency provides a rational explanation" for its action. Henry v. U.S. Dep't of the Navy, 77 F.3d 271, 272 (8th Cir. 1996). A court must evaluate an agency's decision based on the administrative record that was before the agency at the time of its decision, see Fla. Power & Light Co. v. Lorion, 470 U.S. 729, 743 (1985); see also Voyageurs, 381 F.3d at 766, according particular deference where, as here, an agency is "making predictions, within its area of special expertise, at the frontiers of science." Baltimore Gas & Elec. Co. v. Natural Res. Def. Council, Inc., 462 U.S. 87, 103 (1983); see also Marsh v. Or. Natural Res. Council, 490 U.S. 360, 378 (1989). Plaintiffs fail to meet their heavy burden under the APA to prove that the OTM Rule is anything but reasonable, within USDA's discretion, and in accordance with law.[1/]

B. The OTM Rule Is Reasonable and Based on the Best Scientific Evidence[2/]

The OTM Rule, like its predecessor published in January 2005, is prudent, carefully structured, and based on sound science as well as a rigorous and independently peer-reviewed analysis

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[1/] Plaintiffs filed a letter on November 20, 2007 (dkt. no. 30), purportedly informing the Court of new authority that supports their motions for interim relief. This letter contravenes the Court's Standard Operating Procedures, ¶ 18 (counsel shall "not try to accomplish by a letter what should be addressed by a motion with supporting papers"), and raises issues under the National Environmental Policy Act which are not mentioned at all in plaintiffs' motions. Therefore, defendants do not respond to plaintiffs' letter herein but reserve the right to do so when appropriate.

[2/] The facts supporting Section B are set forth in Def. Stmt. of Facts ¶¶ 23-38, which in the interest of economy are incorporated by reference and summarized herein only briefly.

of all relevant factors. The BSE rules are premised on a series of interlocking, overlapping, and sequential barriers to the introduction and establishment of BSE in the United States. 72 Fed. Reg. 53,314, 53,333, col. 3 (Sept. 18, 2007); see also RCALF, 499 F.3d at 1116; RCALF, 415 F.3d at 1095. The cumulative effects of these barriers, see 72 Fed. Reg. at 53,333-34, reduce to a "negligible" level the BSE risk to the United States, id. at 53,334. See also RCALF, 499 F.3d at 1116 (approving this "holistic approach"); RCALF, 415 F.3d at 1095 (acknowledging "the cumulative effects of the multiple, interlocking safeguards"). The OTM Rule's requirements, and the mitigation measures in place in the United States and Canada have proven effective throughout the world and are consistent with the international scientific consensus reflected in the guidelines of the World Organization for Animal Health (OIE). 72 Fed. Reg. at 53,315-16, 53,333, col. 3; Def. Stmt. of Facts ¶ 23.

The OTM Rule allows importation of live cows from BSE minimal-risk regions only if born on or after the date of effective enforcement of a ruminant-to-ruminant feed ban. 72 Fed. Reg. at 53,314, col. 1. Under this rule, the likelihood of BSE exposure and establishment in the U.S. cattle herd due to infectivity introduced by Canadian imports is negligible, id. at 53,315, col. 3, 53,316, col. 1, 53,329, cols. 2-3, 53,334, col. 1; 72 Fed. Reg. 1102, 1109 (Jan. 9, 2007), a conclusion confirmed by an external peer review panel of experts in the field, id. at 53,315-16. The reasons for this are the a very low prevalence of BSE in Canada, id. at 53,329, col. 2, 53,334, col. 1; id. at 1108; Canada's effective enforcement of its feed ban, 72 Fed. Reg. at 53,330, col. 2; id. at 1106; and the multiplicative risk-reduction effect of the sequential barriers to the transmission of BSE, id. at 53,331, cols. 1-2, 53,333-34, cols. 3, 1; id. at 1109. Even assuming the highly unlikely possibility that BSE prevalence in Canada remained constant rather than decline over the next 20 years, the risk that BSE would become established in the United States under the OTM Rule is negligible. Id. at 53,334, col. 1; id. at 1109. These conclusions are not only rationally based, Ubbelohde, 330 F.3d at 1031-32, they have been endorsed by recognized experts who found APHIS's risk assessment

rigorous and consistent with internationally accepted standards. 72 Fed. Reg. at 53,315-16. See Def. Stmt. of Facts ¶¶ 20-21, 24.

1. Very Low Level of BSE Prevalence in Canada

When it assessed the potential BSE risk from importing live Canadian cows, APHIS found that Canada is maintaining risk mitigation measures adequate to prevent widespread exposure and/or establishment of BSE. 72 Fed. Reg. at 1107-08; RCALF, 499 F.3d at 1115-16; id. at 1121 (upholding USDA's decision to designate Canada a minimal-risk country). Its risk assessment also indicated a very low level of BSE prevalence in Canada. 72 Fed. Reg. at 53,334, col. 1; id. at 1108; see also RCALF, 415 F.3d at 1095 (noting "the low incidence of BSE in Canadian cattle"). See Def. Stmt. of Facts ¶ 25. The OTM Rule took into account the BSE-infected cattle that were born in Canada after March 1, 1999, but these isolated incidents did not undercut the conclusion that March 1, 1999, should be considered the effective enforcement date of Canada's feed ban. 72 Fed. Reg. at 53,319, cols. 2-3, 53,330, col. 3, 52,221, col. 1; id. at 1108. See Def. Stmt. of Facts ¶ 26. APHIS expects that BSE prevalence in Canada will continue to decline over the next 20 years from its present minimal level, 72 Fed. Reg. at 53,328, col. 1, 53,334, col. 1; id. at 1108, thereby decreasing both the possibility of introducing BSE into the United States and the negligible risk of its spread to U.S. cattle or consumers. Id. at 53,334, col. 1; id. at 1108. See Def. Stmt. of Facts ¶ 27.

2. Canada's Effective Enforcement of a Feed Ban

In order for BSE to be transmitted to cattle in the United States from a live bovine imported from another country, 72 Fed. Reg. at 53,333, col. 3; id. at 1104, col. 3, an infected bovine must actually enter the United States. 72 Fed. Reg. at 53,331, col. 2; id. at 1104. Given the low prevalence of BSE in Canada, the risk mitigation measures in place there, 9 C.F.R. § 94.19; 72 Fed. Reg. at 53,334, col. 1; id. at 1104, and the "extremely low likelihood" under the OTM Rule that cattle born in Canada on or after March 1, 1999, will have been exposed to BSE, 72 Fed. Reg. at 53,329,

col. 3, the OTM Rule ensures that the BSE risk to the United States from the import of OTM cattle remains "negligible," id. at 53,316, col. 1; id. at 53,346, col. 3. See Def. Stmt. of Facts ¶ 28-29.

Experience worldwide in countries with BSE has demonstrated that feed bans are effective control measures, and the prevalence of BSE globally continues to decline because of them. 72 Fed. Reg. at 53,327, col. 2; id. at 1105; see also RCALF, 415 F.3d at 1087. See Def. Stmt. of Facts ¶ 30. USDA confirmed that overall compliance with the Canadian feed ban is good, and the feed ban is reducing the risk of transmission of BSE in the Canadian cattle population. 72 Fed. Reg. at 53,328, col. 1, 53,330, col. 2; id. at 1106; see also RCALF, 415 F.3d at 1095, 1098 (noting the effectiveness of Canada's feed ban and finding criticisms of it "baseless"). See Def. Stmt. of Facts ¶¶ 31-32. In determining the date of effective enforcement of the feed ban, APHIS allowed an additional 12 months beyond the estimated 6-month practical implementation period following the August 1997 establishment of the feed ban so that most old feed could cycle out of the system. 72 Fed. Reg. at 53,330, col. 2. Prohibiting imports of Canadian bovines that were born before March 1, 1999, provides an appropriate additional mitigation to what was already an extremely low risk of introduction of BSE from Canada. Id. at 1107. See Def. Stmt. of Facts ¶ 33.

3. Additional Sequential Barriers to Transmission of BSE and Assessment of Risk to Human Health

If an infected Canadian bovine were imported into the United States, each in a series of additional mitigations would have to be breached for that bovine to infect a U.S. cow or for consumers to be exposed to BSE. 72 Fed. Reg. at 53,330, col. 3; id. at 1109. Such mitigations include slaughter controls and disposal requirements, rendering inactivation, feed manufacturing and use controls, removal of SRMs from the human food chain, and biological limitations to susceptibility. Id. at 53,333, col. 3; id. at 1109. These mitigations work sequentially and are multiplicative in their effects, so however small the chances that BSE-infected material would survive the first barrier, the

likelihood of its eventually infecting a U.S. animal or consumer would diminish significantly with each subsequent mitigation. Id. at 53,333-34, cols. 3-1; id. at 1109. See Def. Stmt. of Facts ¶ 34.

Assuming the most likely scenario that the prevalence of BSE in Canada will continuously decrease, APHIS found a negligible likelihood of BSE exposure and establishment in U.S. cattle or infection of humans as a consequence of these sequential barriers to infectivity. 72 Fed. Reg. at 1109. See Def. Stmt. of Facts ¶ 35. Because of the risk-reduction effects, BSE would be extremely unlikely to enter commercial animal feed and thereby infect U.S. cattle or to result in human exposure to the BSE agent, particularly in view of the species barrier that may protect humans from widespread illness due to BSE. 70 Fed. Reg. 460, 505, cols. 2-3 (Jan. 4, 2005). In an updated risk assessment conducted in 2005, USDA's Food Safety and Inspection Service (FSIS) concluded that removal of SRMs almost completely eliminates potential human exposure to the BSE agent. 72 Fed. Reg. at 38,726, col 1. See Def. Stmt. of Facts ¶ 37. An independent peer review by recognized experts in the field reached identical conclusions, 72 Fed. Reg. at 53,315-16; see Def. Stmt. of Facts ¶¶ 20-21, a fact that plaintiffs have failed to address, much less refute.

The AHPA provides that the Secretary "may prohibit or restrict the importation of any animal . . . if the Secretary determines that the prohibition or restriction is necessary to prevent the introduction into or dissemination within the United States of any pest or disease of livestock." 7 U.S.C. § 8303(a)(1) (emphasis added). Thus, while the AHPA gives the Secretary "wide discretion in dealing with the importation of plant and animal products," RCALF, 415 F.3d at 1094, "open borders are a default under the AHPA, and the Secretary can close them only if 'necessary' to prevent livestock disease." Id. at 1095. Given the great deference owed to the Secretary's determination, based on sound science, that banning imports of OTM cattle from Canada is unnecessary because of the "negligible" risk involved, Baltimore Gas, 462 U.S. at 103, and the Secretary's broad discretion under the AHPA, the OTM Rule should be upheld. See RCALF, 415 F.3d at 1100

(upholding USDA's decision that risks from BSE "were insufficiently significant to justify the continued exclusion of Canadian cattle").

C. Plaintiffs' Arguments Present No Basis for Invalidating the Rule

Plaintiffs' attacks on the Rule are without merit. They wholly fail to show that USDA's determinations are unreasonable or that they lack a solid basis in the administrative record and in sound science. See RCALF, 415 F.3d at 1094; Ubbelohde, 330 F.3d at 1031-32.

1. Public Notice and an Opportunity To Comment Were Provided as to Imports of OTM Beef

Plaintiffs allege that the OTM Rule did not comply with the APA because, they claim, it amended the January 2005 minimal-risk region rule without an opportunity for public comment. Plaintiffs' Motion for Preliminary Injunction ("Pl. Br.") at 9. This is an incorrect characterization of the rulemaking proceedings at issue in this case. Following completion of a risk analysis, in November 2003, APHIS issued a proposed rule that would designate Canada as a BSE minimal-risk region and allow the importation of cattle under 30 months of age and beef derived from such cattle. 68 Fed. Reg. 62,386 (Nov. 4, 2003). APHIS squarely put at issue for public comment whether imports of Canadian cattle and/or beef should be allowed, and, if so, what age restrictions, if any, should apply. Id. at 62,394-95.

Accordingly, APHIS could have issued a final rule with a different age restriction, depending on the record as the rulemaking progressed. See, e.g., United Steelworkers v. Marshall, 647 F.2d 1189, 1221 (D.C. Cir. 1980) (holding that "a final rule may properly differ from a proposed rule and indeed must so differ when the record evidence warrants the change"); Int'l Harvester Co. v. Ruckelshaus, 478 F.2d 615, 632 n.51 (D.C. Cir. 1973); In re: Operation of the Mo. River Sys. Litig., 363 F. Supp. 2d 1145, 1174 (D. Minn. 2004) ("An agency can make even substantial changes from the proposed version, as long as the final changes are in character with the original scheme and a

logical outgrowth of the notice and comment."). Nevertheless, as discussed below, the Agency did engage in another round of notice and comment on this issue.

In March 2004, APHIS amended and reopened the comment period on its November 2003 proposed rule. In recognition of rules adopted by FSIS in January 2004, and already in place in Canada, requiring removal of SRMs at slaughter, APHIS specifically amended its November 2003 proposal to allow the importation of beef derived from cattle of any age. APHIS stated:

> The [SRM] measures taken by FSIS do not restrict the slaughter of cattle in the United States based on the age of the animals – i.e. meat from cattle 30 months of age or older will continue to be allowed into the human food supply. However, measures are in place to ensure that SRMs from such cattle do not enter the food supply. We now believe it would not be necessary to require that beef imported from BSE minimal-risk regions be derived only from cattle less than 30 months of age, provided equivalent measures are in place to ensure that SRMs are removed when the animals are slaughtered, and that such other measures as are necessary are in place. We believe such measures are already being taken in Canada. We invite comment from the public regarding this change to the provisions we proposed in November 2003 regarding the importation of beef.

69 Fed. Reg. 10,633, 10,635 (March 8, 2004). Thus, the public, including plaintiffs, were specifically given notice and the opportunity to comment on USDA's view that, when appropriate food safety measures are in place, imports of beef derived from cattle of any age from a BSE minimal-risk region should be allowed. As indicated, the March 8, 2004 proposal specifically "invite[d] comment from the public" regarding this change to the provisions proposed in November 2003. Id. at 10,635.

On January 4, 2005, based on the extensive rulemaking record before it, APHIS issued a final rule which allowed the importation of live cattle from Canada under 30 months of age and beef products derived from cattle of any age. 70 Fed. Reg. at 548-551. On February 9, 2005, following the discovery of two additional BSE-infected cattle in Canada, the Secretary of Agriculture, sua sponte, announced that he was delaying the date of applicability, until further notice, of the provisions of the January 2005 final rule relating to beef products derived from cattle 30 months of age

or older. A notice of the temporary delay of applicability was published in the Federal Register on March 11, 2005. Id. at 12,112.

Although the effective date of the rule was delayed, no change in the substance of the January 2005 final rule was contemplated or noticed in the March 11, 2005 Federal Register document. Thus, APHIS was entirely accurate in stating that the proposed OTM Rule was not intended to and "would not change regulations regarding the importation of beef from Canada." 72 Fed. Reg. at 1123, col. 3. See Pl. Br. at 9. The agency went on to acknowledge, however, that the applicability of provisions relating to OTM beef was still delayed. 72 Fed. Reg. at 1123, col. 3.

The January 9, 2007 proposed OTM rule did, however, indicate that the Secretary might soon decide to lift this delay and, therefore, considered the economic effects of lifting the delay simultaneously with the publication of a final rule. 72 Fed. Reg. at 1123, col. 3. At the conclusion of that analysis, the Agency indicated that "[r]emoval of the delay of applicability, thereby allowing importation of Canadian beef from cattle slaughtered at 30 months or older, is a decision that will be taken at the discretion of the Secretary of the U.S. Department of Agriculture." Id. at 1125, col. 1. USDA did, in fact, lift the delay of applicability in the September 18, 2007 final rule. Id. at 53,316. The key fact is that the OTM beef provisions had already been subject to a thorough notice and comment opportunity, as the APA requires, when the January 2005 rule was promulgated.

2. Notice and Comment Were Provided as to the Assessment of Human Health Risks Associated With the Import of OTM Beef

Plaintiffs also allege that USDA never presented for public comment an assessment of the human health risks associated with beef derived from Canadian cattle 30 months of age or older. Pl. Br. at 10. This too is incorrect. As plaintiffs note, id., the November 2003 proposed rule was based, in part, on a human health risk assessment conducted by the Harvard Center for Risk Analysis and the Center for Computational Epidemiology at Tuskegee University, and APHIS's analysis of

that assessment. See RCALF, 499 F.3d at 1116 (citing study). Several comments were filed concerning this risk assessment, to which APHIS provided a comprehensive response in the January 2005 rule. 70 Fed. Reg. at 505, col. 2, 506, col. 2-3, 507, col. 1. APHIS concluded that infectious levels of BSE were unlikely to be introduced into the United States from Canada, and that, even if they were, BSE would be extremely unlikely to enter commercial animal feed and thereby infect U.S. cattle or to result in human exposure to the BSE agent. Id. at 505, col. 3. Due to the substantial species barrier that may protect humans from widespread illness due to BSE, see Def. Stmt. of Facts ¶ 4, USDA found it all the more unlikely that there would be any measurable effects on human health from small amounts of infectivity entering the food chain. 70 Fed. Reg. at 505, col. 2.

Furthermore, following publication of FSIS's interim rule relating to SRM removal, FSIS conducted a risk assessment to develop baseline and mitigation estimates of the potential human exposure to the BSE agent which updated the Harvard-Tuskegee study. See RCALF, 499 F.3d at 1116 (citing to update). A peer review of the updated model and the resulting assessment was completed in September 2005. In July 2006, FSIS published a notice in the Federal Register announcing the availability of the updated risk assessment and requested public comment. 71 Fed. Reg. 39,282 (July 12, 2006). The notice also announced a public meeting to discuss the updated risk assessment. Id. Plaintiff RCALF participated in this process and filed extensive comments with FSIS regarding the risk assessment and the conclusions drawn therefrom. See http://www.fsis.usda.gov/PDF/BSE_ Risk_Assess_Response_Public_Comments.pdf. In July 2007 FSIS published a comprehensive discussion of the updated risk assessment with its SRM final rule. See 72 Fed. Reg. 38,700, 38,724-26 (July 13, 2007).

Based on the results of the 2005 model, FSIS concluded that removal of SRMs almost completely eliminates potential human exposure to the BSE agent. Id. at 38,726, col 1. The results of FSIS's assessment and its conclusions would be applicable for all beef products whether derived

from OTM or under-thirty-month ("UTM") cattle of U.S. or Canadian origin. Id. at 53,336, col.1-2. Therefore, there is no merit to plaintiffs' claim that USDA never presented a human health risk assessment for public comment.

3. The OTM Rule Complies With the Animal Health Protection Act

The allegation that the Secretary acted outside his broad authority under AHPA, 7 U.S.C. § 8303(a)(1), Pl. Br. at 12, is baseless. The Ninth Circuit rejected a similar argument by RCALF, holding that the AHPA confers "wide discretion" on the Secretary in dealing with imports and "does not impose any requirement on USDA that all of its actions carry no associated increased risk of disease." RCALF, 415 F.3d at 1094. Moreover, the statute's use of the word "may" clearly provides discretion to the Secretary to decide "whether to close the borders" at all. Id.; see 7 U.S.C. § 8303(a)(1). Given the absence of any legal requirement to impose import restrictions, and given that "open borders are a default under the AHPA," RCALF, 415 F.3d at 1095, the Secretary has not exceeded his authority by removing restrictions he deems unnecessary.[3/] See Batterson v. Francis, 432 U.S. 416, 428 (1977) (a rule exceeds the agency's authority only if it "bears no relationship to any recognized concept" of the statutory terms at issue); Mourning v. Family Pub. Servs., Inc., 411 U.S. 356, 369 (1973) (a regulation falls within the scope of agency authority "so long as it is reasonably related to the purposes of the enabling legislation").

Plaintiffs' assertion that USDA believes 2 to 75 new cases of BSE will occur in U.S. cattle over the next 20 years, Pl. Br. at 12, is erroneous and mischaracterizes APHIS's findings in this rulemaking. APHIS performed both qualitative and quantitative evaluations of the potential BSE

[3/] Plaintiffs argue that USDA's restrictions are improperly based on a desire to normalize trade with Canada and to encourage other countries to lift restrictions on exports of beef from the United States to those countries. Pl. Br. at 13. However, "open borders are a default under the AHPA, and the Secretary can close them only if 'necessary' to prevent livestock disease." RCALF, 415 F.3d at 1095 (citing 7 U.S.C. § 8303). Once the Secretary concluded that restrictions were not necessary, he quite properly acted to restore normal trade so far as possible.

risk of importing live Canadian cows. The quantitative evaluation was based on a "model simulation" of an "extremely unlikely scenario" in which BSE prevalence in Canada remains constant over the next 20 years. 72 Fed. Reg. at 53,347, col. 1; id. at 1109, col. 2.

However, the "most likely scenario" is that "the prevalence of BSE in the standing adult cattle population in Canada will continuously decrease" over the next 20 years, due to an effectively enforced feed ban. Id. at 53,322, cols. 1, 2, 53,323, cols. 2, 3, 53,364, col. 3; id. at 1108, col. 2, 1109, col. 3. Using the most likely scenario, APHIS concluded that the likelihood of BSE exposure and establishment in the U.S. cattle herd is negligible. Id. at 1109, col. 2. Plaintiffs ignore this conclusion and cite only to the highly unlikely outcomes of the quantitative assessment. Thus, it is simply incorrect to assert that "USDA is set to allow . . . imports that it believes will produce BSE infection in 2 to 75 U.S.-born cattle, lasting over a 20-year period. Pl. Br. at 12.

In addition, since APHIS has, in fact, concluded that the possibility that this rule will lead to the infection of U.S. cattle is negligible and highly unlikely under any reasonable scenario, APHIS has not, as plaintiffs claim, Pl. Br. at 12, adopted or substituted a new standard for regulating imports under the AHPA. Rather, it has crafted a regulation which will "prevent the introduction into or dissemination within the United States" of BSE. 7 U.S.C. § 8303(a)(1).

4. USDA Considered and Responded to Comments Concerning Differences in SRM Disposal Requirements.

Plaintiffs' argument that USDA failed to consider or respond to comments regarding the purported incentive to dump live Canadian cattle into the U.S. market to avoid the allegedly greater costs associated with SRM disposal in Canada, Pl. Br. at 13-14, is erroneous. USDA directly addressed this issue and determined that the value of salvageable SRMs in the United States is relatively minor, and that the income from SRMs to be gained by selling an animal in the United States rather than in Canada would represent less than 1 percent of the projected price of the animal

at slaughter. 72 Fed. Reg. at 53,360, col. 1. Consequently, it found that Canada's SRM removal requirements "may make the U.S. market more attractive, but not appreciably." Id. at 53,360, cols. 1-2. Plaintiffs' claim that USDA "ignored" this issue, Pl. Br. at 14, is therefore simply wrong.

Furthermore, the alleged adverse economic impact of the OTM Rule on U.S. cattle producers, Pl. Br. at 14, does not relate to animal health, and "APHIS does not have the statutory authority to restrict trade based purely on its potential economic impact, market effects, or quantity of products expected to be imported." Id. at 53,352-53. Rather, under the AHPA, the Secretary may only restrict imports "when [he] determines it is necessary to prevent the introduction or dissemination of a pest or disease of livestock." Id. at 53,353, col. 1; 7 U.S.C. § 8303(a)(1). See Covad Commc'ns Co. v. FCC, 450 F.3d 528, 550 (D.C. Cir. 2006) (agency need not respond to every comment; a failure to respond is significant only insofar as it demonstrates a failure to consider relevant factors).

5. USDA's Statements Regarding Surveillance and Testing Are Consistent.

Plaintiffs allege a series of inconsistent statements by USDA regarding BSE surveillance and testing. The statements are neither contradictory, however, nor do they show the OTM Rule to be without a rational basis. Plaintiffs contend that USDA stated that increased surveillance in Canada since 2006 was responsible for the increased number of BSE detections since early 2006, and that this statement was inconsistent with the data on BSE testing and prevalence offered in support of the rule. Pl. Br. at 15. This claim is incorrect. The data does in fact show an increase in positive test results that corresponds with the increase in testing from 1999 through 2006. Pl. Br. Exhibit 3 Attach. 14, Table 2. Furthermore, USDA's statement challenged by plaintiffs did not refer to an increase in testing since 2006, but rather, responded to a comment that Canada had experienced an increase in the number of BSE cases since it had instituted a feed ban in 1997. 72 Fed. Reg. at 53,329, col. 3. USDA pointed out that an "increased number of BSE cases have been detected in

Canada as that country has increased surveillance for the disease." Id. There is no inconsistency between USDA's statement and the surveillance data covering the years 1999 through 2006.

Plaintiffs also allege, erroneously, that it is inconsistent for USDA to take the position that surveillance results and investigations of BSE cases show the effectiveness of Canada's feed ban, while also acknowledging that those surveillance results do not distinguish BSE prevalence among birth-year cohorts. Pl. Br. at 16. Distinguishing among birth-year cohorts is but "one way" of many, however, to demonstrate the effect of a feed ban. 72 Fed. Reg. at 53,328, col. 2. Therefore, the inability to distinguish BSE prevalence among birth-year cohorts with surveillance data does not preclude an accurate evaluation of the effectiveness of a feed ban. As USDA reasonably found, the effectiveness of the feed ban has unequivocally been demonstrated. 72 Fed. Reg. at 53,324-25; id. at 1105. In the absence of an effective feed ban, the prevalence of BSE in Canada could be expected to increase over time. Id. USDA stated, however, that "[w]e have no evidence that such an increase has occurred, but we do have data that the feed ban is being enforced." Id.; see also id. at 1106, col. 1-2 (inspection records and observations show "that overall compliance with the feed ban is good, and that the feed ban is reducing the risk of transmission of BSE in the Canadian cattle population."). Moreover, the data's inability to distinguish BSE prevalence among birth-year cohorts is due to the fact that "the overall prevalence [in Canada] is so low," id. at 53,328, col. 2, a fact supportive of the OTM Rule.

Lastly, plaintiffs say the Secretary's September 24, 2007 letter, confirming that Canada does not test cohorts as part of its epidemiological investigations, conflicts with the OTM Rule preamble, which states that it does. Pl. Br. at 16. Canada has always traced and euthanized cohorts of BSE-positive animals, and had also tested cohorts for BSE until 2006. Since 2006, however, Canada has

continued to euthanize but has ceased testing cohorts as unnecessary under international standards.[4] The alleged conflict between the Secretary's letter and the preamble therefore stems from a minor error in the preamble, which failed to reflect the change in Canada's practice. However, because Canada's destruction of cohorts eliminates them as a source of potential infectivity in the feed or food chain, its discontinuation of cohort testing is, contrary to plaintiffs' assertions, Pl. Br. at 16, is of no import to the assumptions underlying the Rule. 72 Fed. Reg. at 53,314; 70 Fed. Reg. at 460. A thorough epidemiological investigation includes tracing cohort animals and destroying them to prevent them from entering the food or feed chain. 72 Fed. Reg. at 53,348, col. 1, 53,352, col. 2; see also 68 Fed. Reg. at 62,389, col. 1. Testing cohorts, however, is not an essential element of an epidemiological investigation, nor necessary to confirm the adequacy of BSE control measures. Pl. Br. Exhibit 3, Attach. 16 at 3 (Secretary's Sept. 24, 2007 letter). Hence, Canada's decision to discontinue testing of cohorts does nothing to undermine the rule's scientific validity or rationality.

6. USDA Considered and Responded to Comments About Testing

Plaintiffs' claim that USDA did not respond to comments that all OTM Canadian cattle should be tested for BSE, or explain the reasons why testing should not be required, Pl. Br. at 17-18, is patently untrue. USDA has reasonably concluded that such testing has no basis in science and would not be effective. In response to comments, USDA explained that because of the long incubation period for BSE, "there is a long period during which testing an infected animal would produce negative but incorrect results." 72 Fed. Reg. at 53,339, cols. 2-3. For animals of any age, with SRM removal requirements in place, testing apparently normal animals "does not provide any significant additional public health protective measure," and indeed, "can be counter-productive since measures

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[4] See Canadian Food Inspection Agency, Report on the Investigation of the Seventh Case of [BSE] in Canada, available at http://www.inspection.gc.ca/english/anima/heasan/disemala/bseesb/ab2006/7investe.shtml (last viewed Nov. 15, 2007).

such as SRM removal requirements may not be sufficiently emphasized due to the perceived total reliability of the testing." Id. at 53,339, col. 3. USDA reasonably concluded as follows:

> Given that testing of clinically normal, apparently healthy cattle does not provide meaningful data, combined with the conclusions of the risk assessment concerning the extremely low likelihood of release and negligible likelihood of exposure and establishment in the U.S. cattle population, testing these animals at slaughter . . . is not appropriate at this time.

Id. Though plaintiffs may disagree with this conclusion, the Agency nevertheless carefully considered the comments and explained fully, based on sound science, why testing of all Canadian OTM cattle would not provide any significant protection to animal or public health. See RCALF, 415 F.3d at 1099-1100 (rejecting argument that USDA's testing policy undermined January 2005 rule).

The allegation that USDA ignored evidence concerning the European testing of OTM cattle, Pl. Br. at 17, is also untrue. The data referenced by plaintiffs is contained in one of a comprehensive set of European Commission reports evaluated by USDA in preparing the final rule. 72 Fed. Reg. at 53,375, col. 2. Moreover, the article by Heim and Kihm referenced in USDA's response to the comments, id. at 53,339, col. 3, and cited by plaintiffs in their motion, Pl. Br. at 17 ("2003 paper"), specifically discussed testing in European countries and observed that "[s]ince 2001, several countries in Europe perform blanket testing of all cattle over 30 months of age or even younger." 72 Fed. Reg. at 53,339, col. 3, 53,375, col. 3. However, as to this practice, the article concluded: "Whether this action offers a measurable increase in safety for the consumer or whether it is more a measure to restore consumer confidence is questionable." Id. at 53,339, col. 3. It is therefore clear from the record that USDA was fully engaged in the evaluation of this issue in formulating the final rule and comprehensively addressed comments relating to testing.

7. The OTM Rule Is Fully Consistent With Existing Regulations

Plaintiffs' claim that it is arbitrary and capricious for USDA to consider Canada a minimal-risk region in the OTM Rule because USDA has allegedly acknowledged that Canada has "wide-

spread exposure and/or establishment" of BSE, Pl. Br. at 18, is plainly wrong and without merit. USDA has specifically rejected this proposition. 72 Fed. Reg. at 53,318, col. 1. The mere existence of some cases of BSE in a region does not constitute the "establishment" of the disease or prevent the region from qualifying as minimal-risk. Id. at 53,318, col. 1-2; 68 Fed. Reg. at 62,388. In fact, a minimal-risk region is defined by regulation as one that is not BSE-free. 9 C.F.R. § 94.0; see also 70 Fed. Reg. at 462-63. What qualifies a region as minimal-risk is not the absence of BSE, but the existence and maintenance of appropriate mitigation measures (i.e., import restrictions, surveillance, and a feed ban) to prevent widespread exposure and/or establishment of the disease. 9 C.F.R. § 94.0.

In classifying Canada as a BSE minimal-risk region, USDA determined that "such mitigation measures are in place and are maintained in Canada." 72 Fed. Reg. at 1108, col. 1; see also 70 Fed. Reg. at 464, col. 2; 68 Fed. Reg. at 62,389; RCALF, 499 F.3d at 1115-16. USDA also found that Canada met the remaining criteria for a minimal risk region, i.e. that it conducts appropriate epidemiological investigations and takes additional risk mitigation measures as necessary. 9 C.F.R. § 94.0; 70 Fed. Reg. at 464; 68 Fed. Reg. at 62,390. In so doing, USDA fully took into account the fact that as of April 2007, eleven Canadian-born cows have been diagnosed with BSE, five of which were born after March 1, 1999. 72 Fed. Reg. at 53,319, cols. 2, 3. These "isolated incidents" were "not unexpected," "are not epidemiologically significant and do not contribute to further spread of BSE, especially when considered in light of the entire risk pathway and its attendant risk mitigations." Id. at 1108, col. 1-2; see also id. at 53,319, col. 2-3, 53,329, col. 3; cf. RCALF, 499 F.3d at 1117 ("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.").

Based on the demonstrated effectiveness of a feed ban such as Canada's in reducing the likelihood of BSE transmission, USDA expects that "the prevalence of BSE in Canada will continue to decline from its present minimal level." 72 Fed. Reg. at 1108, col. 2; id. at 53,318, col. 2-3. The

decline will in turn "decrease any possibility of BSE being introduced into the United States by Canadian cattle, and therefore decrease the negligible risk of the spread of BSE to U.S. cattle." Id.; see also id. at 53,316, col. 1 (noting peer reviewers' agreement that "the likelihood of establishment of BSE in the U.S. cattle population is negligible"). Contrary to plaintiffs' claim, USDA therefore based the OTM Rule on scientifically sound findings that Canada does not have "widespread exposure and/or establishment" of BSE and therefore does meet the criteria for minimal-risk regions.

Plaintiffs contend that statements in the preamble that beef may now be imported from Canada regardless of the animal's age, id. at 53,316, col. 1, 53,366, col. 1, are inconsistent with APHIS regulations prohibiting imports of beef unless it is "derived from bovines that have been subject to a ruminant feed ban equivalent" to that established in the U.S., 9 C.F.R. § 94.19(a) (2006), because of USDA's determination that the effective enforcement date of Canada's feed ban is March 1, 1999. Pl. Br. at 19. There is no inconsistency. The risk-mitigating effects of the OTM Rule derive from the fact that the cattle to be imported were born after the date of effective enforcement of the feed ban, and therefore are less likely to have been exposed to infectious material, not the cattle's age at the time of import. 72 Fed. Reg. at 1105, col. 2, 53,316, col. 3, 53,333, cols. 1-2, 53,339, col. 2, 53,346, col. 1. Thus, a 10-year-old cow (born in 1997) cannot be imported today, but a 10-year-old cow in 2011 (born in 2001) would be eligible for import. Moreover, no age restriction with respect to meat is necessary given that SRM removal requirements reduce any BSE risk to a negligible level for bovine meat and meat products. Id. at 53,316, col. 3, 53,337, col. 3, 53,348, col. 3; id. at 1106, col. 1, 1107, col. 3. Thus, plaintiffs' claims of inconsistency are incorrect.

II. PLAINTIFFS HAVE SHOWN NO THREAT OF IRREPARABLE HARM

As previously stated, to obtain preliminary injunctive relief, plaintiffs must in all events "show [a] threat of irreparable harm," Dataphase, 640 F.2d at 114 n.9, injury so "certain and great and of such imminence that there is a clear and present need for equitable relief." Iowa Utilities Bd.

v. F.C.C., 109 F.3d 418, 425 (8th Cir. 1996). "[S]peculative harm is not enough." Perkins v. City of St. Paul, 982 F. Supp. 652, 655 (D. Minn. 1997). Plaintiffs raise three specters of alleged irreparable harm – a threat to the health of U.S. consumers, a threat to the health of the U.S. cattle herd, and a threat to the health of the U.S. beef industry – but none of these bogeymen is real.

Preliminary injunctions are specifically intended to prevent irreparable harm that would otherwise occur "before a decision on the merits can be rendered." Greater Yellowstone Coalition v. Flowers, 321 F.3d 1250, 1260 (10th Cir. 2003). Yet, after analyzing the risk of importing OTM cattle under a pessimistic base-case and most unlikely scenario, USDA's model predicted a risk of importing approximately 19 BSE-infected cattle, and of two U.S. cows becoming infected, over the next 20 years. 72 Fed. Reg. at 1109. In the face of this conservative assessment, independently validated by outside experts, plaintiffs do not, and, indeed, could not show that it is even likely, much less certain, Iowa Utilities, 109 F.3d at 425, that BSE-infected cattle will cross the border and (given the panoply of safeguards in place) spread the infection to U.S. cattle or consumers in the few months it will take to decide plaintiffs' claims. Hence, no preliminary injunction should issue.

A. No Threat of Irreparable Harm to U.S. Consumer Health Exists

Plaintiffs contend that U.S. consumers will suffer harm because imports of Canadian beef will increase the risk of vCJD, Pl. Br. at 3, 22, but this claim is based on conjecture and speculation about possible future harms, without proof of any certainly impending injuries. The USDA analysis and conclusions are distinctly to the contrary. 72 Fed. Reg. at 53,336, col. 1-2, 38,700, 38,724-26. In fact, although plaintiffs fail to acknowledge it, no cases of vCJD attributable to the consumption of Canadian beef, even prior to the May 2003 restrictions on Canadian imports, have been identified. See RCALF, 415 F.3d at 1086 ("no case of vCJD has ever been linked to North American beef.")

Plaintiffs also ignore the safeguards making it highly unlikely that BSE-infected tissue would ever reach the human food supply in the United States and lead to vCJD. The possibility that this

might occur and endanger people in the next few months, while this case proceeds to summary judgment based on the existing administrative record, is infinitesimal. There are effective feed bans in place in the United States and Canada which prevent cattle from becoming infected at all. 72 Fed. Reg. at 53,328, 53,352. If they do, SRMs, the repositories of BSE, must be removed at slaughter, so the infectivity would never reach beyond slaughterhouse walls, and the potential for human exposure to BSE would be almost completely eliminated, as found by FSIS's updated risk assessment. Id. at 53,316, 53,328, 53,335-36; id. at 38,700, 38,724-26. Import restrictions in the United States and Canada prevent high-risk ruminants from entering either country. Id. at 53,314. The September 2007 rule introduces an additional safeguard—only OTM Canadian cattle born after the effective implementation of the Canadian feed ban (March 1, 1999) may be imported to the United States. Id. at 53,328. Finally, an active, targeted comprehensive surveillance program is in place in both countries to detect BSE and ensure that all mitigation measures are effective. Id. at 53,322, 53,351. Only if every one of these measures failed could a case of vCJD develop. This possibility is not only extremely remote, it is not remotely imminent.

Examining RCALF's previous motion for preliminary injunction against the January 2005 rule, the Ninth Circuit found the facts belied any imminent threat of vCJD and agreed with APHIS that measures inside Canada and the United States minimized the risk that BSE would enter the human food supply. See RCALF, 415 F.3d at 1096. The Ninth Circuit rejected RCALF's allegations of irreparable harm to human health, endorsing the existing regulatory system, "with its numerous overlapping and complementary safeguards," in combination with the apparent "substantial species barrier that prevents BSE from easily infecting humans." Id. Plaintiffs offer no new evidence or argument that would lead this Court to conclude that, in light of the extensive prophylactic measures in place in Canada and the United States, a BSE-infected cow will imminently cross the border, contaminate animal or human food, and cause a case of vCJD.

B. No Threat of Imminent Irreparable Harm to U.S. Cattle Herd Health Exists

The same interlocking regulatory system that protects U.S. consumer health serves to protect the health of the U.S. cattle herd; plaintiffs' claim to the contrary ignores both sound science and the law. Before publishing the proposed OTM Rule, APHIS evaluated the animal health risk to the United States of BSE, i.e., the likelihood of establishment and the potential impacts of cases that may occur even without establishment, as a result of importing OTM cattle. 72 Fed. Reg. at 53,315. The assessment concluded that the BSE risk to the United States, for the next 20 years, is negligible. Id.; see also RCALF, 415 F.3d at 1104 ("any increased risk to human and animal health created by the [previous] Final Rule is negligible"). Of course, the question before this Court is not what might happen over the next 20 years, but whether the Final OTM Rule will result in harm that is of "such imminence that there is a clear and present need for equitable relief," Iowa Utilities, 109 F.3d at 425, prior to this Court's decision on the merits. Clearly, it will not.

C. No Threat of Irreparable Harm to U.S. Beef Industry Exists

Plaintiffs' claim of imminent economic harm to the U.S. beef industry, which is based on speculation and a misplaced sense of entitlement, can be separated into two concerns: (1) a loss of international confidence and related foreign market effects, and (2) financial losses due to an alleged flood of cheap OTM cattle from Canada. Pl. Br. at 21, 22-23. APHIS considered the first concern and concluded the Rule would "have little effect on U.S. beef export markets." 72 Fed. Reg. at 53,337. Although the first BSE discovery in the United States resulted in major restrictions on U.S. beef exports, "[t]rade impacts tend to decline over time as exporting and importing countries find ways to resume mutually beneficial trade while maintaining the safety of the beef supply." Id. at 53,336. In fact, U.S. beef exports have rebounded significantly since a 2004 drop, and over half the countries that banned U.S. beef after the 2003 detection of BSE in Washington State – including the

largest U.S. export market, Japan [5] – have resumed U.S. imports. Id. at 53,357. This rebound has taken place despite resumed Canadian UTM cattle importation in July 2005 under the January 2005 rule, and there is no reason to think that OTM imports would affect exports.[6] Further, OIE's classification of both Canada and the United States as BSE controlled risk regions,"is expected to help the beef industries in both [countries] to expand their access to export markets." Id. There is no indication that importing OTM Canadian cattle will cause imminent harm to U.S. exports.

As to the second concern, APHIS acknowledged that, in the short term, resumed imports of OTM Canadian cattle could reduce the revenues of U.S. producers. 72 Fed. Reg. at 53,356. However, given that Canadian boneless beef has been imported continuously since August 2003, RCALF, 499 F.3d at 1112, and UTM Canadian cattle since July 2005, id. at 1113, the notion that the importation of OTM Canadian cattle will devastate domestic producers or even cause them "great" harm is far-fetched. This is especially true since the OTM Rule represents only an incremental expansion of existing trade. See n. 6, supra. The Ninth Circuit rejected similar alarmist predictions by RCALF regarding the January 2005 rule, RCALF, 415 F.3d at 1105, and, as noted above, recent experience with U.S. trading partners has proven them wrong. At bottom, plaintiffs' alleged economic injuries are founded on the mistaken view that their advantage in the domestic beef market since the interim halt to importations in May 2003 is an entitlement rather than a windfall. The AHPA offers them no such guarantee.

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[5] Further undercutting plaintiffs' allegations of irreparable harm, "[t]he joint U.S.-Japan press statement for resuming trade in beef and beef products after market closures in response to finding BSE in the United States noted that the United States has a 'robust' food safety system, and stated that 'identification of a few additional BSE cases will not result in market closures and disruption of beef patterns without scientific foundations.'" 72 Fed. Reg. at 53,357.

[6] That is especially so since USDA projects that 88 percent or more of cattle to be imported under the new rule will still be less than thirty months of age, and so would have been eligible for import even under the January 2005 rule; only 12 percent or so of the Canadian cattle to be imported under the OTM Rule will be older than 30 months. 72 Fed. Reg. at 53,333, col. 2, n.8.

III. THE BALANCE OF HARMS FAVORS DENYING A PRELIMINARY INJUNCTION

Plaintiffs offer no valid reason why imports of OTM Canadian cattle and beef products should not be resumed under the rule. Their arguments contradict overwhelming scientific evidence and economic analyses that show a resumption of imports would be safe and result in a net gain for the U.S. economy. An economic analysis prepared by USDA shows benefits to consumers and many sectors of the economy. 72 Fed. Reg. at 53,352-60, 53,366-73; id. at 1114-25. The harms plaintiffs allege are speculative at best, as shown by experience under the existing rule. Given the entirely speculative, if not dubious, nature of the harms foreseen by plaintiffs, the balance weighs in favor of the benefits certain to be gained by the implementation of the OTM Rule. Furthermore, to prevent USDA from opening the borders under a rule adopted only after the most careful and thorough consideration would prevent defendants from discharging their proper obligations and disserve the public interest in the process. For this reason, too, the balance of hardships tips clearly against an injunction.

IV. THE PUBLIC INTEREST FAVORS DENYING A PRELIMINARY INJUNCTION

The public interest lies in ensuring that the broad purposes of the AHPA are carried out as Congress intended. Those purposes are to facilitate safe interstate and foreign commerce in animals and animal products, while protecting animal health as is found necessary. 7 U.S.C. § 8301. The AHPA does not authorize trade restrictions to maximize profits for any business sector. Thus, "open borders are [the] default under the AHPA," RCALF, 415 F.3d at 1095, and now that the Secretary has determined, based on overwhelming evidence, that a ban on imports of OTM cattle and beef is no longer necessary to protect animal (or human) health, the public interest as embodied in the AHPA favors implementation of the OTM Rule.

Opening U.S. borders to allow imports of OTM Canadian cattle is consistent with the purposes of the AHPA and its provisions. The OTM Rule protects both human and animal health,

and it benefits not only private consumers, but also all sectors of the livestock and beef industry. 72 Fed. Reg. at 53,352-60, 53,366-73; id. at 1114-25. The rule further advances a science-based regulatory program which may hasten the opening of foreign markets to U.S. cattle and beef, thereby benefitting the domestic livestock and beef industry in the long term. Id. at at 53,352-60, 53,366-73; id. at 1114-25. Similarly, APHIS upheld the public interest and complied with the Congressional intent underlying the AHPA by putting in place all of the extensive aforementioned measures to protect animal health in the United States and to prevent the introduction into and dissemination within the United States of BSE. 7 U.S.C. § 8303. At all times, the public interest was of paramount importance to APHIS.[7/] The OTM Rule reflects this prioritization, and should take effect.

CONCLUSION

For the above reasons, Plaintiffs' Motion for Preliminary Injunction should be denied.

Dated: Nov. 21, 2007

Respectfully submitted,

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[7/] Plaintiffs' reliance on the Federal Meat Inspection Act ("FMIA") is misplaced. Pl. Brief at 25. The FMIA reflects the manifest public interest in preventing adulteration of food, but advances that interest by authorizing USDA to impose food safety and inspection requirements, not trade restrictions. USDA has already vindicated the interests underlying the FMIA, so far as BSE is concerned, by imposing SRM rules that prevent human exposure to the disease. That being so, the policies underlying the FMIA provide no warrant to enjoin implementation of the OTM Rule.

CERTIFICATE OF SERVICE

I hereby certify that on November 21, 2007, I caused the foregoing Defendants' Opposition to Plaintiffs' Motion for Preliminary Injunction to be served on plaintiffs by filing it pursuant to this Court's Case Management/Electronic Case Filing Administrative Procedures. Copies were also sent by first-class mail, postage prepaid, to plaintiffs' counsel at the following addresses:

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