

encephalopathy (“BSE”), commonly known as Mad Cow disease. The OTM Rule is scheduled to go into effect on November 19, 2007, and Plaintiffs seek to enjoin it until the lawfulness of the OTM Rule can be reviewed in full by this Court.

Plaintiffs also ask that the Court not consolidate this Motion for Preliminary Injunction with a trial on the merits, as allowed by Fed. R. Civ. P. 65(a)(2) and D.S.D. Civ. L.R. 65.1. Plaintiffs hope to move this case along quickly to a final judgment, but because of the short amount of time before the OTM Rule goes into effect and the consequent need to prepare this motion immediately and before USDA has filed the administrative record, the briefing of this motion necessarily will only address a fraction of the arguments that Plaintiffs believe justify overturning the OTM Rule and that would be presented in a summary judgment motion.

Finally, Plaintiffs ask that, if the Court grants their request for a preliminary injunction, no security, or only a nominal amount, be required under Fed. R. Civ. P. 65(c). Because Plaintiffs are non-profit organizations and individual ranchers attempting to further the public interest and the goals of the Animal Health Protection Act, it would not be appropriate to impose other than a minimal bond requirement. Doing otherwise would effectively preclude review of USDA’s actions and would not be in the public interest. *See, e.g., Friends of the Earth v. Brinegar*, 518 F.2d 322, 323 (9th Cir. 1975); *California ex rel. Van De Kamp v. Tahoe Reg’l Planning Agency*, 766 F.2d 1319, 1325-26 (9th Cir. 1985); *Davis v. Mineta*, 302 F.3d 1104, 1126 (10th Cir. 2002). Moreover, because the defendants are government authorities that are not at risk of financial harm as a result of the preliminary injunction, there is little or no need to provide for possible compensation of an incorrectly enjoined defendant, the purpose of Rule 65(c). *See Heather K. v. City of Mallard*, 887 F. Supp. 1249, 1268 (N.D. Iowa).

Plaintiffs request, pursuant to D.S.D. Civ. L.R. 7.1, the opportunity for oral argument on this Motion for Preliminary Injunction, unless scheduling such argument will prevent the Court from ruling on this motion on or before the OTM Rule goes into effect on November 19, 2007.

MEMORANDUM

I. BACKGROUND

This is an action for judicial review, under the Administrative Procedure Act, 5 U.S.C. § 701-706, of the OTM Rule. The OTM Rule has the effect of allowing, for the first time since May of 2003, importation from Canada of live cattle born on or after March 1, 1999 and meat and other products from cattle over 30 months of age.¹ Canadian cattle in that age group are the ones most likely to have infectious levels of BSE. *See* 72 Fed. Reg. at 53,341.

BSE is a degenerative, invariably fatal neurological disorder of cattle that results from infection by an unconventional transmissible agent. BSE was not known to exist in the United States until the discovery in late 2003 of an infected cow in Washington State that had previously been imported from Canada. *See* 68 Fed. Reg. 62,386 (November 4, 2003). Eating meat products contaminated with the agent for BSE is believed to cause variant Creutzfeldt-Jakob Disease (“vCJD”) in humans, a degenerative, invariably fatal neurological disease for which there is no known cure. Both BSE and vCJD are generally thought to result from infection with a type of mis-formed protein called “prions.”

Eating BSE-contaminated bovine meat and other products is believed to have resulted in the death of over 150 people in the United Kingdom and Europe, and at least three people in the United States and one person in Canada, as well. *See* 70 Fed. Reg. at 462; 72 Fed. Reg. at

¹ Since 2005, cattle could be imported from Canada, but only for slaughter before 30 months of age, and beef could be imported only if obtained from Canadian cattle that were under 30 months of age at slaughter, under USDA’s “Minimal-Risk Region” Rule, 70 Fed. Reg. 459 (Jan. 4, 2005).

53,335; <http://www.cjd.ed.ac.uk/vcjdworld.htm> (over 200 deaths worldwide). Because of the incurable nature of this horrible, fatal disease, fears about Mad Cow Disease decimated the market for beef from the United Kingdom in the 1990s and from Canada and Japan in the 2000s.

Transmission of BSE can occur when cattle consume feed that contain bovine protein, typically meat and bone meal. This is believed to have been the primary route of BSE transmission in the past, and experts agree that the most important means of preventing the spread of BSE in cattle is limitations on cattle feed, so that healthy animals are not exposed to BSE prions through feed that contains protein from animals infected with BSE. The U.S. adopted a ban on certain animal proteins in cattle feed in 1997, and Canada adopted a similar restriction in August of 1997 (the “Canadian feed ban”). *See* 72 Fed. Reg. at 53,328. USDA relies on the Canadian feed ban for its conclusion that BSE is unlikely to be spreading in the Canadian herd, and it relies on the similar feed ban in the U.S. for its conclusion that, if BSE-infected cattle are imported from Canada, there is a negligible risk that those cattle will transmit BSE to domestic cattle. *See, e.g.*, 72 Fed. Reg. at 53,339.

Canada did not have a feed ban in place when it discovered its first case of BSE, in a cow imported from the United Kingdom, in 1993. In fact, in that way and others, Canada presents a very different potential for BSE infection than the United States. *See* Exhibit 3 Attach. 7 at 7-11. BSE has now been discovered in 11 Canadian-born cattle, including 7 since just the beginning of last year. *See* Exhibit 3 Attach. 10 at 2. Based on these data, Canadian cattle are 26 times more likely to test positive for BSE than U.S.-born cattle. *Id.* Despite USDA’s previous statements that the discovery of cattle born after the feed ban would indicate that the feed ban was ineffective or ineffectively enforced, Exhibit 3 Attach. 7 at 18, USDA concludes in the OTM Rule that Canada has had an effective feed ban since March 1, 1999 and that consequently there

is an “extremely low likelihood” that Canadian cattle were exposed to BSE after that time, even though almost half (5) of the BSE cases discovered in Canada were in cattle born after March 1, 1999, and in some cases several years after. See 72 Fed. Reg. at 53,324, 53,329-30, 53,371.

USDA’s decision to lift protections that had been provided against BSE deserves particularly careful scrutiny. BSE is an invariably fatal disease, highly infectious, for which there is no cure and no vaccine. Exhibit 3 Attach. 8 ¶ 9 and Attach. 15 at 24. The BSE infectious agent is very potent and very difficult to destroy. *Id.* Attach. 8 ¶ 11. The disease is extraordinarily difficult to manage because only a tiny amount of infected tissue can infect another animal, and there are no tests available to determine whether live cattle are infected before they are imported or before they are slaughtered, and even post-mortem tests are not sensitive enough to detect BSE infection in many instances. *Id.* ¶¶ 11, 21-22; Exhibit 3 Attach. 13 at 3; 62 Fed. Reg. 65,747, 65,748; *Baur v. Veneman*, 352 F.3d 625, 639 (2d Cir. 2003). Discovery of a single BSE-infected cow in the United States, which had been imported from Canada, cost the U.S. cattle industry billions of dollars. See 72 Fed. Reg. 53,356 col. 3; Exhibit 3 ¶¶ 3-5. BSE simply is not a case where USDA’s analysis and explanation can be “close enough”; the reviewing court must give USDA’s rationale the hard look that the APA requires.

For many years, USDA has had a strict policy of prohibiting imports of cattle and beef from any country where BSE is known to exist. See 70 Fed. Reg. at 462. That policy initially was applied to Canada on May 29, 2003, 68 Fed. Reg. 31,939, after the discovery of BSE in a native-born Canadian cow. USDA has said that the most likely source of BSE infection in the United States is importation of infected animals or infected animal products, 68 Fed. Reg. 62,386 (Nov. 4, 2003), and has described this prohibition on imports as “the primary firewall” preventing BSE infection in the U.S. cattle herd. In a January 2003 report to Congress on

measures to prevent the introduction and control the spread of BSE, mandated by 2001 statute, USDA touted the longstanding policy of prohibiting imports of cattle and meat products from countries known to have BSE as an essential part of the nation's BSE protections. *See* Exhibit 3 Attach. 7 at 6 n. 13.

The principal device that USDA now claims will provide adequate protection to U.S. cattle if BSE-infected cattle are imported from Canada, the prohibition on feeding ruminant protein to other ruminants, has been in place since 1997. 70 Fed. Reg. at 466. Yet USDA has said repeatedly since then that, because of the unique nature of BSE, importation and rendering of BSE-infected cattle, followed by mis-feeding to U.S. cattle, is one of the primary risks for introduction of BSE into the United States, and a ban on imports from all countries with BSE is an essential defense.² The OTM Rule reinforces the concern that a ban on ruminant protein in ruminant feed does not completely eliminate exposure to BSE, due to cross-contamination with or mis-feeding of other animal feed in which ruminant protein is allowed, and yet abandons the “firewall” that previously protected the U.S. cattle herd and meat supply from that inevitable residual exposure. *Cf.* 72 Fed. Reg. at 56,329 col. 3 (“specific incidents of cross-contamination can, and most likely will, happen”).

The efficacy of the principal device USDA relies on in the OTM Rule to protect consumers from vCJD resulting from exposure to meat from BSE-infected Canadian cattle, “SRM removal,” has not been demonstrated directly in any scientific studies and is based on

² *See, e.g.*, 66 Fed. Reg. 52,483 Oct. 16, 2001 (“emergency” interim rule banning imports from Japan, affirmed at 67 Fed. Reg. 8181 (Feb. 22, 2002)); 63 Fed. Reg. 406 (Jan. 6, 1998); 62 Fed. Reg. 65,747, 65,748 (Dec. 16, 1997). USDA also repeatedly praised Canada's policy of banning imports of cattle from all countries where BSE is known to exist as a key measure reducing Canada's BSE risk. *See, e.g.*, 70 Fed. Reg. at 464, 467, 486; 70 Fed. Reg. 18,252, 18,254 (April 8, 2005).

numerous unverified hypotheses. *See* 72 Fed. Reg. at 3,336 cols.2-3 (“there has been no specific controlled study that clearly and unequivocally demonstrates the effectiveness of SRM restrictions on protecting public health”); Exhibit 3 Attach. 8 ¶¶ 13-16. USDA has not attempted to quantify the risk to human health of the OTM Rule and, in fact, acknowledges that the relationship between exposure to BSE-contaminated meat and risk of contracting vCJD is unknown. 72 Fed. Reg. at 53,335, col. 1; *see also* 70 Fed. Reg. 58,570, 58,587 (Oct. 6, 2005) (uncertain relationship between infectious dose for cattle and that for humans); Exhibit 3 Attach. 8 ¶¶ 13, 21 and Attach. 11 at 2.

II. LEGAL STANDARD FOR PRELIMINARY INJUNCTION

When considering whether to grant a preliminary injunction, a district court must weigh the movant’s probability of success on the merits, the threat of irreparable harm to the movant absent the injunction, the balance between the harm and the injury that the injunction’s issuance would inflict on other interested parties, and the public interest. *Dataphase Systems, Inc. v. CL Systems, Inc.*, 640 F.2d 109, 114 (8th Cir. 1981) (*en banc*). “No single factor in itself is dispositive; in each case all of the factors must be considered to determine whether on balance they weigh towards granting the injunction.” *Baker Elec. Co-op., Inc. v. Chaske*, 28 F.3d 1466, 1473 (8th Cir. 1994), quoting *Calvin Klein Cosmetics Corp. v. Lenox Labs., Inc.*, 815 F.2d 500, 503 (8th Cir. 1987); *see also United Industries Corp. v. Clorox Co.*, 140 F.3d 1175 (8th Cir. 1998).

Where the threatened injury is great, a lower probability of success may still, on balance, justify granting the preliminary injunction to maintain the *status quo*. “[I]f the party seeking the preliminary injunction would suffer more harm from the denial of it than his opponent would suffer from its being granted, the injunction should be granted even if the party seeking it has no

more than a 50-50 chance of winning, and even, in some cases, if the odds are worse.” *Heather K. v. City of Mallard*, 887 F. Supp. at 1259, citing *Green River Bottling Co. v. Green River Corp.*, 997 F.2d 359, 361 (7th Cir. 1993), and *Curtis v. Thompson*, 840 F.2d 1291, 1296 (7th Cir. 1988); *Dataphase*, 640 F.2d at 113 (rejecting construction of “probability of success” to mean that movant must show a greater than 50 percent likelihood of success on the merits, “even if the balance of the other three factors strongly favored the moving party”).

III. LIKELIHOOD OF SUCCESS ON THE MERITS

As outlined in the Complaint, there are many grounds on which USDA’s promulgation of the OTM Rule was unlawful and must be reversed and remanded. For purposes of demonstrating Plaintiffs’ entitlement to a preliminary injunction so that those grounds can be considered fully by the Court, a few of those grounds are explained below.

A. Amendment of Regulations Without Public Notice and Comment

The Administrative Procedure Act (“APA”) requires federal agencies to publish a “general notice of proposed rulemaking” in the Federal Register, 5 U.S.C. § 553(b), and “give interested persons an opportunity to participate in the rule making through submission of written data, views, or arguments,” 5 U.S.C. § 553(c) (the “notice-and-comment” requirements of the APA). “Rule making,” as defined in the APA, includes not only the agency’s promulgation, but also its modification, of a rule. *See* 5 U.S. C. § 551(5) (“rule making” includes “agency process for formulating, amending, or repealing a rule”); *see also Paralyzed Veterans of America v. D.C. Arena L.P.*, 117 F.3d 579, 584 (D.C. Cir. 1997), *cert. denied*, 423 U.S. 1003 (1998) (“Under the APA, agencies are obligated to engage in notice and comment before formulating regulations, which applies as well to ‘repeals’ or ‘amendments.’” (emphasis in original)); *Shalala v. Guernsey Mem’l Hosp.*, 514 U.S. 87, 100, 115 S. Ct. 1232 (1995).

The OTM Rule amended USDA regulations without complying with APA notice-and-comment requirements. The OTM rule amends the Minimal-Risk Region Rule by deleting language in 9 C.F.R. §§ 94.19(a), (b), and (f) and 95.4(f) and (g) that prohibited importation of edible bovine products and certain bovine-derived tallow and gelatin from BSE-minimal-risk regions unless those products came from animals under 30 months of age at slaughter. 72 Fed. Reg. at 53,378. Imports of edible bovine products and certain bovine-derived tallow and gelatin from cattle 30 months of age and older had been “delayed indefinitely” after the discovery of two additional cases of BSE in Canada, one of which was born months after Canada’s partial feed ban became effective. 70 Fed. Reg. 12,112. (March 11, 2005). The 30-month cutoff was based both on the assumption that younger animals, born after Canada enacted its partial feed ban, would not have been exposed to potentially contaminated feed, and on the assumption that, since recognizable symptoms of BSE generally occur a number of years after infection, levels of BSE infectivity will be low even in infected cattle, if under 30 months of age. *See* 70 Fed. Reg. at 513.

Defendants never issued a notice of proposed rulemaking, nor did they seek public comments, on the action taken in the final OTM Rule that allows imports of edible products and tallow and gelatin from Canadian cattle that were 30 months of age or older at the time of slaughter. In the January 9, 2007 Notice of Proposed Rulemaking for the OTM Rule (attached as Exhibit 2), USDA simply made reference to the March 11, 2005 Federal Register notice that amended the regulations to prohibit imports of products from older Canadian cattle and stated that: “Removal 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.” 72 Fed. Reg. at 1125. In fact, the January 9, 2007 Notice of Proposed Rulemaking stated that USDA was not proposing to change the 30-

month restriction on imports of Canadian beef. 72 Fed. Reg. at 1123. Nor did it otherwise discuss the safety of beef and other products from Canadian cattle 30 months of age and older, and the APHIS risk assessment prepared to support the proposed OTM rule deliberately was limited to imports of live cattle, blood and blood products, and small intestines. Exhibit 3 ¶ 11.

Additionally, USDA never presented for public comment, even in the rulemaking for the January 4, 2005 Minimal-Risk Region Rule, an assessment of the risks of consuming imported beef from Canadian cattle that were 30 months of age or older at the time of slaughter. *Id.* The original proposal for the Minimal-Risk Region Rule did not allow such imports, and a March 8, 2004 notice was too vague to allow meaningful public comment, merely stating that APHIS no longer believed the 30-month restriction was necessary, because removal of SRMs and “such other measures as are necessary” were already being taken in Canada. 69 Fed. Reg. 10,633, 10,635. The “Harvard Risk Assessment” and the APHIS Risk Analysis on which USDA relied in promulgating the Minimal-Risk Region Rule did not contain an assessment of the risk of vCJD from consuming Canadian beef, other than subjective conclusions that the risks would be “small.” 70 Fed. Reg. at 505 col. 2, 506 col. 3, 507 col. 1. Moreover, the risk assessments available to the public in conjunction with the proposed Minimal-Risk Region Rule all assumed that Canadian beef imports would be limited to those from cattle under 30 months of age at slaughter. 68 Fed. Reg. at 62,391; 62,394; 62,398; 62,403-404.

Also, the 2004 APHIS risk assessment that did address contaminated beef assumed a BSE prevalence in Canada, from the very limited test data at that time, of well under 1 in 1 million, compared to USDA’s current estimate of 3.9 per million, and assumed that Canada’s feed ban had been effective 18 months earlier (in August 1997) than USDA now assumes. 70 Fed. Reg. 512; *see also* 72 Fed. Reg. 53,323 col. 3. Thus, the public has never had an

opportunity to review and comment upon USDA's conclusion that the risk to the public of dying from vCJD as a result of consuming beef products from older Canadian cattle is acceptable (nor that the risk to others from blood transfusions from individuals who may become infected with BSE prions from consuming such products is acceptable).

USDA's failure to follow APA-required notice-and-comment procedures requires that the OTM Rule be vacated and remanded. While there are certain exceptions to the requirement for notice-and-comment procedures, none of those exceptions applies to USDA's deliberate amendment of its regulations to allow imports of beef and beef products previously considered too risky. In any event, USDA did not base its action on any of those exceptions, and so this Court could not supply that rationale to uphold USDA's action. *See Mayo v. Schiltgen*, 921 F.2d 177, 179 (8th Cir. 1990); *Downer v. U.S. By and Through U.S. Dept. of Agriculture and Soil Conservation Service*, 97 F.3d 999 (8th Cir. 1996); *Bowen v. Georgetown Univ. Hospital*, 488 U.S. 204, 212-13 (1988); *PanAmSat Corp. v. F.C.C.*, 198 F.3d 890, 897 (D.C. Cir. 1999).

B. Applying Improper Legal Standard

USDA recognizes that "incidents of cross-contamination can, and most likely will, happen...." 72 Fed. Reg. at 53,329 col. 3. Indeed, this is consistent with the conclusions of the World Organization for Animal Health ("OIE"), the Canadian Food Inspection Agency ("CFIA"), and USDA's own "International Review Team" that the only way to prevent exposure of cattle to potentially BSE-contaminated feed is to eliminate the use of meat and bone meal from cattle in any type of animal feed. *See* Exhibit 3 ¶¶ 14-15 and Attachs. 12 and 13. As a result, USDA acknowledges the likelihood that U.S. cattle will have BSE as a result of allowing imports of OTM cattle; in fact, its worst case estimate is that the OTM Rule will cause 75 new cases of BSE in U.S.-born cattle over the next 20 years. 72 Fed. Reg. at 53,347 col.1.

In short, the OTM Rule is expected, even by USDA, to result in the importation of numerous BSE-infected cattle from Canada (and infected with a strain of BSE similar to that found in the UK, unlike the two pre-feed-ban cases found in the U.S.), i.e., the “introduction” of that form of BSE into the U.S. And it is likely, even in USDA’s view, that the OTM Rule will result in the spread of BSE infection from those Canadian cattle, i.e., the “dissemination” of BSE within the United States. USDA concludes, however, that these outcomes are acceptable because it deems them “negligible” and because it predicts that these BSE cases that the United States will knowingly suffer as a result of the OTM Rule will not result in the “establishment” of BSE in the United States, meaning that BSE will not be “perpetuated in the population without the need for reintroduction from an external source,” which will lead to “eventual eradication.”³ Thus, USDA is set to allow, through the OTM Rule, imports that it believes will produce BSE infections in 2 to 75 U.S.-born cattle, lasting over a 20-year period. 72 Fed. Reg. at 1109 col. 2; 72 Fed. Reg. at 53,347 col. 1.

By substituting a new standard for regulating imports—restrictions necessary to avoid the establishment of an animal disease in the United States, rather than following Congress’ mandate that USDA take action necessary to “prevent” the “introduction into or dissemination within” the United States of animal diseases and take the steps necessary to detect, control, and eradicate animal disease, USDA acted outside of its statutory authority. *Cf.* 70 Fed. Reg. at 513 (evaluating import controls in 2005 Minimal-Risk Region rule based on whether Canadian imports “would spread the disease to other animals within the United States, in other words, whether the imported source of infectivity would generate new cases within the United States”).

³ 72 Fed. Reg. at 53,318 cols. 1-2. USDA asserts that BSE has not been “established” in Canada, despite the discovery of 11 cases of BSE since 2003 and the prediction that BSE will not be eradicated in Canada for 20 more years. *Cf. id. with* Exhibit 3 Attachs. 10 at 2; see also Exhibit 3 Attach. 13 at 2 (without new upgrades to feed ban, eradication would take decades.)

Likewise, USDA acted outside of its statutory authority when it based its restrictions on Canadian imports under the AHPA 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—objectives that are not authorized under the AHPA. *See* Exhibit 3 at 20. An agency action is arbitrary and capricious if the agency bases its decision in whole or part on the consideration of factors that are inappropriate for its statutory mandate. *See, e.g., Motor Vehicle Manufacturers Ass’n v. State Farm Automobile Insurance Co.*, 463 U.S. 29, 43, 52-56 (1983) (no deference to agency judgment when agency emphasized cost of automatic seatbelts in contrast to congressional intent that passenger safety be primary concern); *Mobil Oil Co. v. Dept. of Energy*, 610 F.2d 796, 801 (TECA 1979), *cert. denied*, 446 U.S. 937 (1980) (agency must address each statutory decisional factor “objectively”).

C. Failure to Consider Differential Requirements for Waste Disposal

Comments on the proposed OTM Rule pointed out that there would be a significant economic incentive for shipment of older Canadian cattle to the U.S. for slaughter, because of differential requirements for handling the residual materials. Exhibit 3 Attach. 7 at 55-56. Because Canada now bans SRMs from all animal feed and fertilizer, while in the U.S. the wastes from slaughterhouses, including SRMs, can be used in non-ruminant animal feed and fertilizer, processing OTM cattle in Canada is substantially more costly than processing them in the United States. *Id.*; *see also* Attach. at 11-12. Not only does this waste from slaughtering OTM cattle have value in the U.S. as a protein source for animal feed, but in Canada it now often will have a negative value (i.e., disposal costs), because it cannot be used for animal feed or fertilizer. *Id.* USDA acknowledged that the value of the SRMs for animal feed when cattle are slaughtered in the United States creates an incentive for shipping older Canadian cattle to the U.S., but asserted

it was less than \$5 per animal, and not enough to change export patterns. 72 Fed. Reg. at 53,360 cols. 1-2. USDA ignored, however, the cost that SRM disposal adds if cattle are processed in Canada, which is significant (and about twice the costs that USDA did consider). See Exhibit 3 ¶¶ 9. Comments to USDA also included a Canadian news article indicating that in fact Canadian producers were seeking federal financial assistance to offset the added costs of SRM disposal under the more-stringent Canadian feed ban regulations, “in a bid to keep Canadian cattle in this country.” Exhibit 3 Attach. 17. The comments urged USDA to “assess how the new Canadian feed ban rules could result in new incentives for dumping older Canadian cattle in the U.S. market before finalizing the” proposed OTM Rule. Exhibit 3 Attach. 9 at 12.

USDA simply ignored those comments and failed to take into consideration this important factor affecting the likely numbers of Canadian cattle imports under the OTM Rule. See Exhibit 3 ¶¶ 10. An agency’s promulgation of a regulation is arbitrary and capricious if the agency failed to consider an important aspect of the issue. *Cent. S.D. Coop. Grazing Dist. v. Sec’y of the United States Dep’t of Agric.*, 266 F.3d 889, 894 (8th Cir. 2001) (quoting *Motor Vehicle Manufacturers*, 463 U.S. at 43). The potential exposure of U.S. cattle to BSE infectivity is directly proportional to the number of OTM cattle that will be imported. So too is the adverse economic impact of the OTM Rule on U.S. cattle producers. Thus, USDA’s failure to consider the impact that the new, comparatively more-stringent Canadian feed ban will have on the number of OTM cattle imported from Canada is a failure to consider a key aspect of the OTM Rule, making its promulgation arbitrary and capricious. Likewise, USDA’s failure to respond to public comments raising such an important issue violated the APA. See *Appalachian Power Co. v. EPA*, 249 F.3d 1032 (D.C. Cir. 2001), *Thompson v. Clark*, 741 F.2d 401, 408-09 (D.C. Cir. 1984) (citing *Citizens to Preserve Overland Park v. Volpe*, 401 U.S. 402, 416 (1971)); *Portland*

Cement Ass'n v. Ruckelshaus, 486 F.2d 375, 393-94 (D.C. Cir. 1973), *cert. denied* 417 U.S. 921.

D. Inconsistent Statements Purporting To Support the OTM Rule

Providing an internally inconsistent justification for a rule is another reason the agency's decision may be found arbitrary and capricious, despite the agency's expertise, since the decision therefore was "not founded on a reasoned evaluation of the relevant factors." *Defenders of Wildlife v. U.S. EPA*, 420 F.3d 946, 959 (9th Cir. 2005), *rev'd on other grounds sub nom. Nat'l Ass'n of Home Builders v. Defenders of Wildlife*, 127 S.Ct. 2518 (2007) (citations omitted); *Gen. Chem. Corp. v. United States*, 817 F.2d 844, 857 (D.C. Cir. 1987) (striking down agency action because it was "internally inconsistent and inadequately explained").

Attempting to explain away the fact that 7 of the 11 cases of BSE detected in Canadian-born cattle were discovered since the beginning of 2006 (5 of which were born after March 1, 1999), USDA claims in the preamble to the final OTM Rule that "an increased number of detections of BSE does not necessarily mean an increase in prevalence," in part because the "increased number of BSE cases have been detected in Canada as that country has increased surveillance for the disease." 72 Fed. Reg. at 53329 col. 3. But in fact, the data on BSE testing and prevalence that USDA provided to support the OTM Rule are directly at odds with USDA's assertion that Canada detected an increased number of BSE cases because CFIA increased the number of tests it performed. *See* Exhibit 3 Attach. 14 Table 2. This dramatic inconsistency undercuts USDA's key assertion that, despite the fact that more than half of the BSE cases in Canada have been detected since the beginning of last year, Canada's partial feed ban has been effective since March 1, 1999 to reduce the incidence of BSE in Canada and has produced "an extremely low likelihood 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.

Similarly, USDA refers approvingly to CFIA's claim that "surveillance results and investigations of BSE cases indicate that the feed ban in Canada has effectively reduced the spread of BSE since being implemented in 1997 . . ." 72 Fed. Reg. at 53,330 col. 2. Yet USDA makes the directly contrary admission that CFIA's surveillance results "do not provide a statistical basis for distinguishing BSE prevalence among birth year cohorts . . . In other words, the data cannot distinguish any significant difference in prevalence among animals born in different years, which would have been one way to demonstrate the effect of a feed ban (e.g., if the feed ban were implemented at the beginning of 1997, surveillance data showing a higher BSE prevalence in animals born in 1996 than in animals born in 1997 would support the effectiveness of the feed ban). *Id.* at 53,328 col. 2.

Defendant Acting Secretary Conner provided a striking example of inconsistent statements about fundamental assumptions underlying the OTM Rule in a September 24, 2007 letter to R-CALF USA. R-CALF USA had sent a letter to then Secretary of Agriculture Johanns on July 26, 2007, alleging that Canada was not testing BSE-positive birth or feed cohorts (cattle born at the same time as an animal later found to have BSE, or that were exposed to the same feed, and that are at increased risk of BSE themselves). *See* Exhibit 3 Attach. 16. Conner's September 24th reply confirms that Canada is not testing these cohorts as part of its epidemiological investigations, and he further states that Canada does not need to. *Id.* The OTM Rule, however, states just the opposite when describing Canada's BSE risk mitigation measures:

...CFIA conducts comprehensive epidemiological investigations, and one component of these investigations is to trace the feed cohorts of confirmed BSE-positive cattle, in accordance with OIE guidelines. As a result of these traces, feed cohorts that remain alive are euthanized and tested for BSE.

72 Fed. Reg. at 53,348 col. 1. When the Acting Secretary of Agriculture describes Canada's BSE risk mitigation measures in a manner directly contradicting the purported justifications

offered contemporaneously for the OTM Rule, the OTM Rule is arbitrary and capricious and must be remanded to USDA for further explanation.

E. Failure To Respond to Comments that OTM Cattle Should Be Tested

Numerous commenters asked USDA to require that OTM Canadian cattle be tested for BSE before processing, in light of their substantially increased risk of BSE infection. USDA concluded that such testing is not appropriate “at this time,” but its reasons for refusing to require testing were either non-responsive or inconsistent with the record. *See* 72 Fed. Reg. at 53,339 col. 3. USDA asserted that testing can only identify a BSE-infected cattle “a few months before the animal begins to demonstrate clinical signs,” but offered no explanation why testing that could detect this pernicious disease in such cases should not be required. *Id.* col. 2. USDA downplays the value of testing because, it asserts, most imported cattle will be less than 30 months of age, while the comments related to USDA’s proposal to allow imports of cattle 30 months of age and older, and ignoring as well the fact that the OTM Rule also authorizes and anticipates importation of vast quantities of beef from cattle that will not be under 30 months of age when slaughtered in Canada. *Id.* col. 3. USDA cites a 2003 paper that defines it “questionable” whether testing would provide “any measurable increase in consumer safety,” *id.*, but ignores more recent evidence in the record that countries in the European Union that test all OTM cattle at slaughter have frequently found BSE-infected cattle among those cattle that were not identified as displaying clinical signs (as has Canada). *See* Exhibit 3 Attach. 7 at 39-40. And USDA did not respond at all to comments that requiring testing would provide some mitigation of the adverse impact on domestic and foreign demand for U.S. beef. *Cf.* Exhibit 3 Attach. 7 at 48-50, 76-77. USDA’s failure to respond in a meaningful way to this critical issue raised by commenters renders the OTM Rule arbitrary and capricious. *See, e.g., Appalachian Power Co.*

v. *EPA*, 249 F.3d 1032, 1059, 1063 (D.C. Cir. 2001).

F. Conflict with Existing Regulations

USDA's Minimal-Risk Region Rule specifies that a BSE minimal-risk region is a region that "maintains, and...had in place prior to the detection of BSE in an indigenous ruminant, risk mitigation measures adequate to prevent widespread exposure and/or establishment of the disease." 9 C.F.R. § 94.0. The regulation also states that: "Such mitigation measures include the following: ...(iii) a ruminant-to-ruminant feed ban that is in place and is effectively enforced." *Id.* The OTM Rule, which expands the livestock and products from "minimal-risk regions" (i.e., Canada) that may be imported, acknowledges that BSE has become established in Canada, as Canada is now on at least its third generation of the disease. *See* Exhibit 3 Attach. 7 at 10-11; 72 Fed. Reg. at 53,320 col. 1; *cf. id.* at 53,318. (predicting that BSE will not become "established" in the U.S. because it will not spread without continuing inputs of infectivity from abroad). Thus, Canada by definition did not have risk mitigation measures in place, prior to the detection of its first case of BSE in native cattle in 2003, that were adequate to prevent establishment of the disease.

The Eighth Circuit has held that "[a]n agency must indeed follow its own regulations while they remain in force." *Voyageurs Region Nat. Park Ass'n v. Lujan*, 966 F.2d 424, 428 (8th Cir. 1992), *citing* *Service v. Dulles*, 354 U.S. 363, 379, 77 S.Ct. 1152, 1160, 1 L.Ed.2d 1403 (1957) (having promulgated regulations, Secretary of State could not, "so long as the Regulations remained unchanged, proceed without regard to them"); *Center for Auto Safety v. Dole*, 828 F.2d 799, 806 (D.C.Cir.1987) (recognizing "the principle that a court will require an agency to follow the legal standards contained in its own regulations despite the fact that a statute has granted the agency discretion in the matter."). USDA's continued treatment of

Canada as a minimal-risk region in the OTM Rule, while at the same time acknowledging that Canada does not meet the criteria for minimal-risk regions in 9 C.F.R. § 94.0, renders the OTM Rule arbitrary and capricious.

Similarly, USDA's statements in the preamble to the OTM Rule that beef and other products may now be imported from Canada regardless of the age of the animal from which they were obtained, e.g., 72 Fed. Reg. at 53,316, col. 1; 53,366 col. 1, are entirely inconsistent with APHIS regulations that prohibit imports of meat and meat products from Canada unless it is "derived from bovines that have been subject to a ruminant feed ban equivalent to the requirements established by the U.S. Food and Drug Administration at 21 CFR 589.200...." 9 C.F.R. § 94.19(a) (2006). See also same statement in preamble to OTM Rule, 72 Fed. Reg. at 53,366 col.1. In fact, USDA uses the existence of this requirement as a justification for not including in the OTM Rule a requirement that imported meat and meat products come from cattle born after March 1, 1999. *See id.* Yet USDA concludes, in the OTM Rule, that Canada did not have an effective feed ban until March 1, 1999. This kind of double-talk, and these purported justifications for USDA's action in the OTM Rule that are inconsistent with the existing Minimal-Risk Region regulations, render the OTM rule arbitrary and capricious.⁴

G. Plaintiffs Have Raised Important Claims About the Validity of the OTM Rule

In weighing the likelihood of success on the merits, the court is not attempting to decide whether the movant will ultimately prevail on the merits. *Glenwood Bridge, Inc. v. City of*

⁴ This confused explanation also bears on USDA's conclusions about the risk of BSE infection and the adverse economic consequences for U.S. cattle producers as a result of live cattle imports, since USDA dramatically reduced the estimate in the proposed OTM Rule of the number of OTM cattle that would be entering the United States once the ban on OTM cattle is lifted, based on its conclusion that most of the previously assumed live cattle imports would now be replaced by imports of beef from cattle of any age slaughtered in Canada. *See, e.g.,* 72 Fed. Reg. at 53,368 col. 3.

Minneapolis, 940 F.2d 367, 371 (8th Cir. 1991); *General Mills, Inc. v. Kellogg Co.*, 824 F.2d 622 (8th Cir. 1987) (essential inquiry in weighing propriety of issuing preliminary injunction is not so much assessment of movant's probability of success on merits but whether balance of other factors tips decidedly toward movants and movant has also raised questions so serious and difficult as to call for more deliberate investigation); *Medtronic, Inc. v. Catalyst Research Corp.*, 664 F.2d 660 (8th Cir. 1981) (same). *See also O'Connor v. Peru State College*, 728 F.2d 1001, 1002 (8th Cir. 1984) (in such preliminary proceedings, "the court should avoid deciding with any degree of certainty who will succeed or not succeed."). Plaintiffs certainly have demonstrated that there is a sufficient probability that they will succeed when the merits of the case have been fully briefed, especially when the probability of success is weighed against the huge threat of irreparable harm presented by the OTM Rule, as described in the following section. At a minimum, the substantial questions raised about whether USDA has relied on inappropriate considerations in deciding to intentionally allow imports of cattle with a devastating disease, likely to result as well in that disease occurring in the U.S. herd, merit full consideration before the potentially infected cattle begin to enter the United States. *See, e.g., Magruder v. Belle Fourche Val. Water Users' Ass'n*, 219 F. 72, 82-83 (8th Cir. 1914).

IV. A PRELIMINARY INJUNCTION IS NEEDED TO AVOID IRREPARABLE HARM

That Plaintiffs will suffer irreparable harm if the OTM Rule is allowed to go into effect is clear from USDA's own description of the OTM Rule. USDA estimates that between 19 and 105 BSE-infected cattle will be imported from Canada over the next 20 years as a result of the OTM Rule, 72 Fed. Reg. at 1109 col. 2; 72 Fed. Reg. at 53,347 col. 1, with a greater than 99 percent chance that one or more BSE-infected animals will be imported. 72 Fed. Reg. 53,333, col. 2. While these estimates are understated, they still demonstrate a clear irreparable injury.

The discovery of a single BSE-infected cow in Washington State in late 2003 that had been imported from Canada caused losses to the U.S. cattle industry of \$3.4 billion in the first year. 70 Fed. Reg. 58,584, 58,587. Additionally, once BSE-infected cattle are introduced into the United States, the BSE infectious agent likely will be introduced into the U.S. animal feed supply, as well, and there is no practicable way to test feed for BSE infectivity or to eliminate the possibility of exposure of U.S. cattle to such contaminated feed. This is truly a case where there is no way to close the barn door after the horse has left the barn, a clear case of “irreparable” injury.

Although USDA optimistically opines that “the economic impact of any additional cases of BSE-infected cows imported from Canada will likely be minimal,” 72 Fed. Reg. at 53,357, col. 1, the fact is that Korea currently is not accepting any beef from the United States and numerous other countries maintain severe restrictions on imports of beef from the United States because of concerns about BSE, including restrictions specifically concerned with cattle and beef that originated in Canada. Exhibit 3 ¶¶ 3-4; *see also* 72 Fed. Reg. at 53,356, col. 3. USDA offers no credible evidence to support its counter-intuitive conclusion that the OTM rule, which even USDA admits is virtually certain to result in BSE-infected Canadian cattle merging with the U.S. cattle herd and more-risky meat from older Canadian cattle intermingling with the U.S. meat supply, will not have an adverse impact on foreign demand for U.S. beef, in light of past and current experience.

USDA itself predicts that the importation of OTM cattle from Canada may well result in a number of U.S.-born cattle becoming infected with BSE, causing the detection for the first time of BSE in domestic cattle born since the U.S. implemented its partial feed ban. This is consistent with the OIE’s very recent conclusion that the U.S. partial feed ban (which allows cattle parts,

including SRMs, to be used in non-ruminant animal feed) presents “the likelihood” of cross-contamination of cattle feed with other animal feed potentially carrying BSE infectivity. *See* Exhibit 3 Attach. 12 §§ 2.4(a) and (e).

In fact, USDA’s estimate (which Plaintiffs believe is understated, because of underestimation of the prevalence of BSE in the Canadian cattle herd and unrealistically low assumptions of imports of older Canadian cattle under the OTM Rule) is that at the 95 percent confidence level 75 U.S. cattle will become infected with BSE as a result of imports under the OTM Rule. *See* 72 Fed. Reg. at 53,347 col. 1. There is no way to test live cattle to determine if they have become infected with BSE, no assurance that they will show any outward symptoms even if they harbor substantial BSE infectivity, no medicines available to treat such infections (even if they could be detected), and no vaccines that can prevent other cattle from becoming infected. Exhibit 3 Attach. 8 ¶¶ 19, 22; *id.* Attach. 7 at 39-40, 49 (actual experience is that a large portion of cattle with detectable levels of BSE were not identified through antemortem inspection); 72 Fed. Reg. at 53,337 (likely detectable infectivity in CNS tissue occurs at 75% of the “incubation period,” the period during which there are no outward BSE symptoms of BSE).

There will also be billions of pounds of meat from Canadian cattle, including almost certainly cattle infected with BSE, entering the U.S. food supply. U.S. consumers who wish to avoid the risk of consuming such Canadian-origin beef, including members of Plaintiffs CJD Foundation and Consumer Federation of America, for example, will have no way to do so other than avoiding all beef, as the OTM Rule does not require that Canadian-origin beef be labeled as such. *See, e.g.*, Exhibit 4 (declaration of Chris Waldrop of Consumer Federation of America). These clearly are injuries for which no remedy will be available. In addition, USDA itself predicts that the OTM Rule will cause revenue losses for U.S. cow-calf producers (such as the

members of Plaintiffs Ranchers Cattlemen Action Legal Fund, United Stockgrowers of America and South Dakota Stockgrowers Association and individual cow-calf producers Schumacher, Mack, Mertz, and Nelson) of over \$66,000,000 per year, for which no compensation could be obtained from the Defendants or anyone else. *See* 72 Fed. Reg. 53,356, col. 1.

Plaintiffs have no adequate remedy at law. No monetary damages are available against the United States (or anyone else) to redress Plaintiffs' expected injuries. *See Baker Elec. Co-op*, 28 F.3d at 1473; *Entergy, Arkansas, Inc. v. Nebraska*, 210 F.3d 887 (8th Cir. 2000). Moreover, even if monetary damages were available, they could not compensate for the increased risk to the health and reputation of the U.S. cattle herd and to U.S. consumers that will result from allowing imports of Canadian OTM cattle and beef from OTM cattle.

V. BALANCE OF HARM BETWEEN PLAINTIFFS AND OTHER INTERESTED PARTIES

The balance of harm analysis required by *Dataphase* and its progeny examines the adverse effects that granting or denying the injunction would have on the parties to the dispute and upon other interested parties, including the public. *Dataphase*, 640 F.2d at 114. Courts examine the threat to each of the parties' rights from granting or denying the injunction and the potential economic harm to each of the parties and to interested third parties. *Baker Elec. Co-op*, 28 F.3d at 1473.

There is no "right" to import cattle or beef into the United States. *Cf. id.* That importation is prohibited by long-standing USDA regulations. *See* pp. 5-6, *supra*. The rule to be enjoined is an exception to a general prohibition in USDA regulations of any imports from countries known or believed to have BSE, issued pursuant to a specific congressional authorization to restrict imports when necessary to prevent the introduction into or dissemination within the United States of animal diseases. Neither Canadian ranchers and slaughterhouses, nor

U.S. meatpackers that would like to import cheap, older Canadian cattle and meat from older Canadian cattle, can claim hardship from an injunction that would merely delay implementing an exception in their favor from generally applicable rules that have now been in place for many years. *See Heather K. v. City of Mallard*, 847 F. Supp. at 1261. Certainly there would be no lasting, irreversible adverse effect of an injunction comparable to the potentially devastating, long-lasting effects of importing BSE-infected cattle into the United States and thereby allowing the introduction and dissemination of BSE in the United States.

VI. THE PUBLIC INTEREST FAVORS GRANTING A PRELIMINARY INJUNCTION

In considering the last and most general of the *Dataphase* factors, whether granting the injunction is in the public interest, courts have looked, among other things, to expressions of the public interest contained in the relevant statutes. *See, e.g., Heather K. v. City of Mallard*, 847 F. Supp. at 1263-67. In this case, the statute the OTM Rule is issued under, the Animal Health Protection Act, 7 U.S.C. §§ 8301 *et seq.* (“AHPA”), evidences a strong public interest in the detection, control, and eradication of diseases of livestock. It authorizes the Secretary of Agriculture to “prohibit or restrict...the importation or entry” of animals or products “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.” *Id.* at § 8303(a)(3). It also contains congressional findings that “the prevention, detection, control, and eradication of diseases and pests of animals are essential to protect,” *inter alia*, animal health, the health and welfare of the people of the United States, and “the economic interests of the livestock and related industries of the United States.” *Id.* at § 8301(1). Congress deemed regulation of imports “necessary...to protect the agriculture, environment, economy, and health and welfare of the people of the United States.” *Id.* at § 8301(5)(B).

In addition, the Meat Inspection Act, 21 U.S.C. §§ 601 *et seq.*, which authorizes USDA measures to inspect and regulate live cattle, meat and other products, and animal carcasses, is premised on the congressional finding that: “It is essential in the public interest that the health and welfare of consumers be protected by assuring that meat and meat food products distributed to them are wholesome, not adulterated, and properly marked, labeled, and packaged.” 21 U.S.C. § 602. Congress also provided an indication of congressional intent with respect to BSE in particular in the Animal Disease Risk Assessment, Prevention, and Control Act of 2001, P.L. 107-9, a statute requiring planning and reporting by USDA and other government agencies to coordinate actions to prevent an outbreak of BSE and foot-and-mouth disease in the United States, finding *inter alia* that “the potential introduction of [BSE and related] diseases into the United States would cause devastating financial losses to...the agriculture industry and other economic sectors.” *Id.* at § 3 (emphasis added); see also Exhibit 3 App. 7 at 5-6.

These statutes make it clear that the public interest lies in preventing the knowing importation of BSE-infected cattle and potentially infected beef until the Court has had an opportunity to review thoroughly the OTM Rule and USDA’s justification for it. Also, more generally, the public interest favors enjoining safety risks. *See, e.g., Sanborn Mfg. v. CampbellHausfeld/Scott Fetzer Co.*, 997 F.2d 484,490 (8th Cir. 1993). USDA’s predictions that the OTM Rule would provide limited benefit to some feedlot operators and meatpackers are insufficient to counteract the interest of millions of Americans in assuring that the health of the U.S. cattle herd and the safety of the U.S. meat supply is not threatened by foreign imports. *Cf.* 72 Fed. Reg. at 53,371.

Dated: November 1, 2007

Respectfully submitted,

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* Motions for admission pro hac vice have been submitted.

CERTIFICATE OF SERVICE

I I hereby certify that, on November 1, 2007, I caused the foregoing Motion for Preliminary Injunction, along with the supporting exhibits and declarations, to be served on the defendants by filing these documents pursuant to this Court's Case Management/Electronic Case Filing Administrative Procedures, and also by causing a copy to be hand-delivered on this date to the office of the Department of Justice trial attorney who will be representing the Department of Agriculture and Acting Secretary of Agriculture Conner..

/s/ Thomas P. Tonner
Thomas P. Tonner