UNITED STATES DISTRICT COURT
DISTRICT OF SOUTH DAKOTA
NORTHERN DIVISION

RANCHERS CATTLEMEN ACTION LEGAL FUND, UNITED STOCKGROWERS OF AMERICA, *et al.*, Plaintiffs, vs. UNITED STATES DEPARTMENT OF AGRICULTURE, ANIMAL AND PLANT HEALTH INSPECTION SERVICE, and CHARLES F. CONNER, IN HIS CAPACITY AS THE ACTING SECRETARY OF AGRICULTURE, Defendants.	)	**Civ. No. 07-1023**

PLAINTIFFS' REPLY IN SUPPORT OF MOTION FOR PRELIMINARY INJUNCTION

In support of their Motion for Preliminary Injunction, Plaintiffs provided arguments, supported by reference to Department of Agriculture ("USDA") documents and declarations of representatives of Plaintiffs, which demonstrated Plaintiffs' entitlement to a preliminary injunction barring implementation of USDA's "OTM Rule," 72 Fed. Reg. 53,314 (Sept. 18, 2007). Rather than disproving those assertions, defendants USDA and Acting Secretary of Agriculture Conner (collectively, "USDA") primarily attempt to deflect judicial review of the OTM Rule by reference to USDA conclusions in, and the Ninth Circuit's review of, an earlier rule concerning imports of younger Canadian cattle and beef from younger Canadian cattle. Yet USDA itself asserted that those animals and products present much lower risk than those allowed by the OTM Rule, and that rulemaking and the resulting Ninth Circuit decisions predate many of the facts on which the Motion for Preliminary Injunction is based. When it comes to the

rulemaking that is the subject of this litigation, USDA has responded inadequately, if at all, to Plaintiffs' demonstration that there is a reasonable probability Plaintiffs will succeed in demonstrating that USDA violated the Administrative Procedure Act ("APA") and the National Environmental Policy Act.[1] Moreover, subsequent events only serve to reinforce Plaintiffs' demonstration that a preliminary injunction is needed to avoid irreparable harm, and the risk of irreparable harm, until the merits of Plaintiffs' complaint can be fully evaluated by the Court.

I. NINTH CIRCUIT DECISIONS CONCERNING THE MINIMAL-RISK REGION RULE ARE NOT CONTROLLING OR EVEN APPLICABLE TO THE OTM RULE.

On virtually every issue presented by Plaintiffs, USDA's response is merely to cite the Ninth Circuit's discussion of an earlier rule or USDA's own unsupported conclusory statements. This does not refute Plaintiffs' demonstration that they meet all the criteria for issuance of a preliminary injunction. Because USDA suggests to the Court that the Ninth Circuit has already ruled on most of the issues presented by the Plaintiffs' Motion for Preliminary Injunction ("Motion"), it is necessary at the outset of this reply to respond broadly to that implication:

In its so-called Minimal-Risk Region Rule, published January 4, 2005 at 70 Fed. Reg. 459, USDA relaxed a long-standing prohibition on imports of cattle and beef from countries known to have bovine spongiform encephalopathy ("BSE"). The Minimal-Risk Region Rule allowed importation, subject to certain restrictions, of cattle from Canada if they are slaughtered before they reach the age of 30 months. It also allowed the importation of meat from Canadian cattle of any age, but on March 11, 2005, the rule was amended to allow imports of meat only

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[1] USDA submitted a 20-page "Statement of Facts in Support of Defendants' Opposition…" which is largely an extended argument rather than a statement of facts. The rules do not provide for such a submission, and USDA did not seek the Court's authorization for argument in excess of the 25 pages provided by the Local Rules. The document largely just re-states USDA's conclusions, however, and does not contradict Plaintiffs' showing that those conclusions were inadequately explained, inconsistent with other USDA conclusions and with facts in the administrative record, illogical, and based on considerations not appropriate under the statute.

from cattle that were under 30 months of age when slaughtered. 70 Fed. Reg. 12,112. The Ninth Circuit decisions that USDA continuously cites, *Ranchers-Cattleman Action Legal Fund v. United States Dept. of Agriculture*, 415 F.3d 1078 (9thCir. 2005) ("*R-CALF II*"), and *Ranchers-Cattleman Action Legal Fund v. United States Dept. of Agriculture*, 499 F.3d 1108 (9thCir. 2007) ("*R-CALF IV*"), addressed that Minimal-Risk Region Rule.

Obviously, decisions of the Ninth Circuit are not binding on this Court, particularly where they involve a different rulemaking and different plaintiffs (except R-CALF USA itself). In fact, the opinion USDA cites most often, *R-CALF II*, 415 F.3d 1078, was not even binding on the District Court for the District of Montana, as to the merits of the challenge to the Minimal-Risk Region Rule. *See R-CALF IV*, 499 F.3d at 1114 (only "conclusions on pure issues of law" from the *R-CALF II* decision were binding on the district court, which "must apply this law to the facts anew with consideration of the evidence presented in the merits phase," and so "technically, the district court was not bound by our earlier conclusions" in *R-CALF II).*

In addition, however, in almost every instance the citations to *R-CALF II* and *R-CALF IV* that USDA offers here are not even persuasive authority—they simply are inapplicable, because they concern different facts and issues. Most obvious is the fact that they involve judicial review of a different rulemaking, and one with critical distinctions from the OTM Rule being challenged in the instant case. The Ninth Circuit placed great weight on the fact that the Minimal-Risk Region Rule it was reviewing would not allow imports of any cattle older than 30 months, because USDA assured the court that cattle that young were extremely unlikely to carry infectious levels of BSE. *See R-CALF II*, 415 F.3d at 1095. This was a key element of the "multiple, interlocking safeguards" that the Ninth Circuit relied on in upholding the Minimal-Risk Region Rule. *See id.* at 1095 ("USDA permits the importation of only a subset of

[Canadian cattle] that are extremely unlikely to have BSE—those under 30 months of age….In addition, USDA's scientific evidence suggests that Canadian cattle under 30 months of age will be far less likely to be in the advanced stages of BSE "), 1096 (risk of dissemination of BSE in the U.S. from imported cattle is addressed by the requirement that the cattle be slaughtered before they reach the age of 30 months, which "helps to ensure that BSE will not progress in any infected animals before they are slaughtered."); *see also R-CALF IV*, 499 F.3d at 1116 (evaluating "multiple, interlocking safeguards"). Thus, the validity of the OTM Rule, the very purpose of which is to abandon the protection of limiting imports to cattle and beef from cattle under 30 months of age, presents an entirely different question.[2]

The Ninth Circuit relied heavily as well on USDA's representations at the time that the prevalence of BSE in Canada was 0.4 cases per million head of adult cattle and that Canada has taken measures that "ensure...that Canada's already low rate of BSE is decreasing." *R-CALF II*, 415 F.3d at 1095. In the OTM rulemaking, USDA says that, based on data that includes numerous additional BSE cases found since the Minimal-Risk Region Rule, the prevalence in the current Canadian herd is likely around 3.9 cases per million adult cattle. 72 Fed. Reg. at 53,323 col. 3. Thus, USDA now says that the prevalence of BSE in Canada is almost 10 times higher than the BSE prevalence the Ninth Circuit was considering as an essential step in the "comprehensive protections" of the Minimal-Risk Region Rule. *Cf.* 415 F.3d at 1095. Moreover, this ten-fold increase from the prevalence USDA estimated in 2004 appears to

[2] In a similar vein, the Ninth Circuit accepted USDA's decision not to require BSE testing of Canadian cattle under the Minimal-Risk Region Rule based in significant part on USDA's assertion that available tests would be ineffective to find BSE infection in cattle under 30 months of age. *See* 415 F.3d at 1100 (referring to "long incubation period" and USDA's explanation at 70 Fed. Reg. at 475-76). That obviously says nothing about whether USDA adequately explained its decision in the OTM Rule not to require testing of older cattle.

contradict the USDA assertion, adopted by the Ninth Circuit, that the rate of BSE in Canada was decreasing. *Cf. id.*

The Ninth Circuit's assessment of the Minimal-Risk Region Rule did not consider the implications of the numerous additional cases of BSE, most born after the implementation of Canada's feed ban, on the reliability of USDA's conclusion that the incidence of BSE in Canada is insignificant. *Cf.* Motion at 4-5, 15. In fact, the Ninth Circuit said that "these new incidents are certainly cause for concern," although this new information could not be considered when assessing USDA's earlier determination that was based on the information USDA had available at the time. 499 F.3d at 1117-18. Likewise, the Ninth Circuit accepted USDA's assertion that Canadian cattle were turning up with BSE, after the Canadian feed ban that supposedly stopped the spread of BSE in Canada, due to the long incubation period for BSE (*see* 415 F.3d at 1098, 499 F.3d at 1118), because that assumption was reasonable based on the information that USDA had at the time. But the six cases of BSE that have now been found in Canadian cattle born a year or more after the feed ban clearly refute USDA's assumption, and the Ninth Circuit even acknowledged that such additional BSE cases "certainly cast doubt on the effectiveness of the feed ban." 499 F.3d at 1118.[3]

In short, the Ninth Circuit's *R-CALF II* and *R-CALF IV* opinions considered very different facts than apply to the current challenge to the OTM Rule. In some instances, the *R-CALF IV* opinion even acknowledges that more recent facts, not part of the administrative record for the Minimal-Risk Region rulemaking but part of the record for the OTM Rule, are cause for concern. The Court should view USDA's liberal citation to these cases in USDA's Opposition

[3] The Ninth Circuit cases also were briefed before the U.S. Centers for Disease Control and Prevention released its analysis that Canadian cattle are 26 times more likely to test positive for BSE than U.S. cattle. *Cf.* Motion Exh. 3 ¶ 13.

Memorandum very skeptically, because in most instances the Ninth Circuit decisions are inapplicable to the facts of the OTM Rule.

II. USDA HAS NOT OVERCOME PLAINTIFFS' DEMONSTRATION OF LIKELIHOOD OF SUCCESS.

Plaintiffs demonstrated a likelihood of success on the merits by elaborating upon some of the claims made in the Complaint, any one of which would justify issuance of a preliminary injunction. Plaintiffs also noted that, under the criteria for issuance of a preliminary injunction, they need not show that it is highly likely, or even more likely than not, that they will succeed on the merits. Only a reasonable probability of success is required. *See, e.g.*, *Nolop v. Volpe*, 333 F. Supp. 1364 (D.S.D. 1971). To impose a higher standard would effectively nullify the preliminary injunction process, turning it into a decision on the merits. Also, where, as here, there is a risk of great harm (billions of dollars of damage to the U.S. beef market, risk of infection of the U.S. herd and of people contracting an invariably fatal disease), a lesser certainty of success on the merits still warrants enjoining the new regulations until they can be reviewed on the merits. *See*, *e.g*., *Hubbard Feeds, Inc. v. Animal Feed Supp.*, 182 F.3d 598 (8th Cir. 1999).

A. Failure To Comply with Notice and Comment Procedures for Expanding Imports of Beef

Plaintiffs' Motion for Preliminary Injunction cited some of the numerous decisions of the Supreme Court and other courts that an agency must go through notice-and-comment rulemaking before changing or removing a regulation, as well as before promulgating it in the first place. Motion at 8. The final OTM Rule eliminated provisions of the Code of Federal Regulations that prohibited imports of edible bovine products and certain bovine-derived tallow and gelatin from Canada, unless those products came from animals that were under 30 months of age at slaughter. Motion at 9. The January 9, 2007 Federal Register proposal for the OTM Rule referenced that

limitation and stated that "this proposed rule would not change regulations involving the importation of beef from Canada." 72 Fed. Reg. 1102, 1123 col. 3.

In spite of this unequivocal choice by USDA not to propose amendment of the regulation to eliminate the prohibition on imports of edible products from cattle 30 months of age and older at slaughter, USDA claims that it nevertheless complied with the APA because it went through notice-and-comment procedures before adopting the Minimal-Risk Region Rule.[4] Defendants' Opposition to Plaintiffs' Motion for Preliminary Injunction ("Opp. Memo") at 8-10. USDA offers no citation for its implied principle that an agency need not follow notice-and-comment procedures to remove a restriction in a regulation, if the agency could have adopted the regulation without that restriction at the time the regulation was first promulgated.

The APA statutory language and case law Plaintiffs have cited give no hint that compliance with notice-and-comment procedures is required to change or remove a regulation only when the amended regulation is different from anything contemplated when the original regulation was first promulgated. *See* Motion at 8. To the contrary, they establish an unequivocal requirement: an agency must provide notice and comment before removing or amending a regulation. USDA violated that requirement when it removed the prohibition on imports of bovine products from OTM Canadian cattle contained in 9 C.F.R. §§ 94.19(a), (b), and (f) and 95.4(f) and (g), without first proposing to do so.[5] USDA's claim that the notice-and-

[4] USDA also implies that the APA may have been satisfied by an indication in the proposed OTM Rule "that the Secretary might soon decide to lift" the prohibition on imports of edible products from cattle 30 months of age and older. Opp. Memo at 10. But the portion of the proposed OTM Rule that USDA cites, 72 Fed. Reg. at 1123, col. 3, says nothing of the sort.

[5] USDA also appears to suggest that no notice was required to change these portions of the C.F.R. because the March 11, 2005 "Final rule" that included those restrictions, 70 Fed. Reg. 12,112, was not a "change in the substance of the January 2005 final rule," because it merely delayed the effective date of [an aspect of] that rule. Opp. Memo at 10. A final rule, published in the Federal Register and incorporated into the Code of Federal Regulations, delaying

comment requirement was fulfilled by a proposal issued before the restriction was imposed in the first place (and before the discovery of additional cases of BSE in younger cattle that caused the Secretary to impose the under-30-month limitation) is illogical and without legal basis.

Plaintiffs' Motion for Preliminary Injunction argued that USDA did not give the public adequate notice with respect to the proposed OTM Rule, because it did not contain any assessment of the risks of consuming imported beef from Canadian cattle that were 30 months of age or older at the time of slaughter. Motion at 10-11. USDA responds by asserting that the November 2003 proposed Minimal-Risk Region 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 (the "Harvard Risk Assessment"). Opp. Memo at 10-11. This is misleading in two ways: First, the November 2003 proposal did not address the risk from imports of OTM of beef, because the proposal was to allow imports only of beef from cattle that were under 30 months of age at slaughter. *See* 68 Fed. Reg. 62,386, 62,391. Secondly, the Harvard Risk Assessment did not assess the risk to human health of Canadian beef imports, but merely described BSE exposure under a hypothetical scenario:

> The analysis is not a complete human health risk assessment in two respects. First, we do not quantify the probability that BSE will be introduced into the U.S. Hence, all our risk estimates are conditional on hypothetical scenarios. Second, although we quantify potential human exposure to BSE-contaminated food products, we do not estimate how many people will contract variant Creutzfeldt-Jakob Disease (vCJD). We have omitted quantitative treatment of both of these issues because the available information is inadequate.

Administrative Record at AR003700. *See also* AR008426 (insufficient information at time of 2004 update to Harvard Risk Assessment to estimate the probability of BSE introduction into the U.S.). Additionally, as Plaintiffs noted, the risk assessments that USDA cites did not consider

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"indefinitely" authorization to import bovine products from cattle 30 months of age and older cannot credibly be called non-substantive. USDA offers no citation for its suggestion that no notice and comment was required to remove this type of regulatory provision.

the much higher prevalence of BSE in Canada that USDA now acknowledges (*see* p.4, *supra*) nor the fact that USDA now asserts that Canada's feed ban was effective 18 months later than USDA previously assumed. Motion at 10. USDA fails to respond to these points at all.[6]

For whatever reason, USDA decided to play "hide the ball" with the question of expanding imports of Canadian beef beyond products from cattle younger than 30 months of age. The Federal Register notice for the proposed OTM Rule said that it was not proposing to change that restriction, instead of presenting what apparently was USDA's intention: to lift age restrictions on cattle and edible products at the same time. USDA's failure to engage in notice-and-comment rulemaking before amending or repealing the OTM restriction on beef imports from Canada violated the APA and is grounds for enjoining that repeal. *See*, *e.g.*, *Utility Solid Waste Activities Group v. EPA*, 236 F.3d 749; D.C. Circ. 2001).

B. Failure To Consider Appropriate Factors

In the OTM Rule, USDA knowingly allows the introduction of BSE into the United States. Moreover, USDA acknowledges that BSE may then be disseminated in the U.S., infecting U.S.-born cattle as well. USDA's explanation to the public, at least, was that this is acceptable because BSE will not become "established" in the United States, meaning that the disease will infect U.S. cattle but ultimately will not become self-prepetuating. *See* Motion at 11-12.[7] Rather than act as necessary to prevent BSE's "introduction into or dissemination

[6] USDA's other point—that its Food Safety and Inspection Service did a risk assessment in a different rulemaking that considered risk of exposure to BSE from slaughter of cattle in the U.S. (Opp. Memo at 11-12)—hardly justifies proceeding in the subject rulemaking to allow imports of beef from older Canadian cattle without any assessment of the likelihood that U.S. citizens will contract a fatal disease as a consequence.

[7] To the extent that USDA now claims that it is preventing the "introduction" of BSE into the United States because it is unlikely that BSE, once allowed into the United States in infected cattle, will infect other cattle (*see* Opp. Memo at 13), that is both a strained interpretation of the Animal Health Protection Act's directive to prevent the "introduction into or dissemination

within" the United States as directed by the Animal Health Protection Act ("AHPA"), USDA's goal for the OTM Rule was "to promote fair trade practices, consistent with international guidelines," (*see* AR012848; *see also* AR017850), rationalizing that promoting trade in BSE-infected cattle from Canada would not result in the "establishment" of BSE infection in the domestically raised cattle herd. *See, e.g.,* 72 Fed. Reg. at 53,315-18, 53,322-23, 53,327, 53,329.

Contrary to USDA's suggestion (Opp. Memo at 12), the Ninth Circuit never considered such an argument, because in the rulemaking reviewed by the Ninth Circuit, USDA assured the court that, in part because of the 30-month limit in that rule, it was "extremely unlikely" that cattle with infectious levels of BSE would even enter the United States—an assertion USDA cannot make for the OTM Rule. *See* 415 F.3d at 1095. The Ninth Circuit's conclusion that the AHPA does not contain a requirement that "all risk of BSE entering the United States" be eliminated, *id.*, is irrelevant to the questions of whether (a) USDA can conclude that preventing the introduction into or dissemination within the United States of BSE is not necessary, because USDA wants to promote free trade in animals carrying the disease, and (b) USDA can apply a criterion of "no establishment" of an animal disease, rather than no "introduction" or "dissemination."

Likewise, the Ninth Circuit's statement that "open borders are a default under the AHPA," even if it were binding on this Court, would not provide a justification for USDA ignoring protections "necessary to prevent" BSE's introduction into the United States just because USDA wanted to promote cross-border cattle trade.[8] Nor does it support USDA's

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within" the country of animal diseases, and an interpretation not offered during the rulemaking which therefore could not be a grounds for upholding the OTM Rule. *See, e.g., Bowen v. Georgetown Univ. Hospital*, 488 U.S. 204, 212-13 (1988).

[8] USDA describes its action as acting to restore trade "[o]nce the Secretary concluded that restrictions were not necessary…." Opp. Memo at 12 n.3. In fact, it was the other way around:

claim that the purposes of the AHPA "are to facilitate safe interstate and foreign commerce in animals and animal products, while protecting animal health as is found necessary." Opp. Memo at 24, *citing* 7 U.S.C. § 8301. USDA has it backwards: the primary purpose of the AHPA is "the prevention, detection, control, and eradication of diseases and pests of animals"; regulation of animals and articles, both domestic and imported, is listed as necessary to regulate, and eliminate burdens on, interstate and foreign commerce. *See* 7 U.S.C. §§ 8301(1), (5), 8303, 8305, 8308.

Thus, Plaintiffs have demonstrated a reasonable probability of successfully demonstrating that USDA violated the APA by applying an incorrect interpretation of its statutory duties and considering the wrong factors in assessing whether continued restrictions on imports of OTM Canadian cattle and beef are "necessary."[9] Especially where these kind of important legal questions are raised, a preliminary injunction is warranted until they can be fully briefed, argued, and considered by the Court. *See* Motion at 19-20.

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the Secretary promised to restore trade with Canada as soon as possible long before the risk from Canadian imports had been fully assessed. *See, e.g.,* Motion Exh.3 ¶ 20; *see also* AR017638, 017639, 017672 (promising to address quickly Mexico's desire to ship Canadian cattle through the U.S.). For all countries other than Canada, closed borders are the default when it comes to BSE. *See* Motion at 5-6; 9 CFR § 94.18(a)(1); *id.* § 94.18(a)(2) (banning imports from countries not known to have BSE but deemed to be at risk). Indeed, open borders are not the default under the AHPA generally: USDA regulations require a foreign country to secure USDA approval before exporting live animals or unprocessed animal products to the U.S. *See* 9 C.F.R. § 92.2.

[9] The Opposition Memo cites two 30-year-old Supreme Court cases and implies that they would allow USDA to apply whatever factors it wished, so long as the factors were not totally unrelated to the purposes of the statute. Opp. Memo at 12. USDA misrepresents those cases. *Batterson v. Francis* says that one way that an agency's discretion is limited is it cannot "adopt a regulation that bears no relationship to any recognized concept of" the subject of the statute or "that would defeat the purpose of the" statutory program, 432 U.S.416, 428 (1977), not that an agency's interpretation is authorized unless it "bears no relationship to any recognized concept" of the statutory terms. *Mourning v. Family Pub. Servs., Inc.* addressed the constraints on an agency where a statute simply gave the agency authority to "make... such rules and regulations as may be necessary to carry out the provisions of this Act," a situation not presented by the AHPA provision in question, 7 U.S.C. § 8303(a)(1). *Cf.* 411 U.S. 356, 369 (1973).

C. Failure To Consider and Respond to Comment on Effect of Differential SRM Disposal Costs

Obviously, a key factor in assessing the risk of introduction of BSE into the United States as a result of the OTM Rule is the projected number of OTM Canadian cattle that will be imported. Information submitted to USDA in public comments demonstrated that Canadian slaughterhouses face a significant cost for disposal of specified risk materials ("SRMs") for cattle slaughtered in Canada, because of a Canadian requirement, effective in the summer of 2007, that SRMs not be used in any kind of animal feed. Motion at 13-14. That creates a significant incentive for Canadian cattle to be slaughtered in the United States, where SRMs can still be used for non-ruminant animal feed. *Id*. The comments even showed that Canadian cattle producers were seeking government assistance to defray those SRM disposal costs, "to keep Canadian cattle in this country." Motion at 14.

In the materials accompanying the final OTM Rule, and now also in its Opposition Memorandum, USDA ignored the effect that this new financial incentive would have on its estimates of the number of OTM cattle that Canada will export to the United States. Instead, USDA considered only the value that SRMs would have to U.S. slaughterhouses that could sell the SRMs to animal feed producers, overlooking the SRM disposal costs that Canadian producers avoid by shipping cattle to the U.S. Opp. Memo at 13-14. USDA's failure to consider an important factor affecting the number of BSE-infected cattle that may be imported into the United States, as well as its failure to respond to public comments about this issue, constitutes an unrebutted violation of the APA. Plaintiffs therefore have demonstrated a reasonable probability of success on the merits.

D. Failure To Respond Adequately to Comments Urging Testing of OTM Cattle

Contrary to USDA's assertion (Opp. Memo at 16), Plaintiffs never alleged that USDA did not address public comments urging that OTM Canadian cattle be tested for BSE. Rather, Plaintiffs showed that USDA's reasons for refusing to require testing were non-responsive or inconsistent with the record. Motion at 17. USDA's Opposition Memo continues that approach.

An agency must provide some explanation for its position besides its *ipse dixit*. Yes, USDA said that "testing of clinically normal, apparently healthy cattle does not provide meaningful data," Opp. Memo at 17, but that statement is inconsistent with USDA's acknowledgment that testing can identify cases of BSE months before any clinical signs appear. *See* 72 Fed. Reg. at 53,339 col. 2. (Noting that there is a long incubation period during which BSE infection may be undetectable, Opp. Memo at 16, does not explain why detecting this terrible disease during the months that it is detectable by testing but not by observable symptoms is not "meaningful" (especially when USDA claims that BSE prions do not accumulate to concentrations that may infect other cattle during most of that long incubation period, *see* 72 Fed. Reg. at 53,337 col. 2).) USDA's claim that BSE testing of OTM cattle "has no basis in science and would not be effective," Opp. Memo at 16, also is inconsistent with the data from millions of cattle tested in Europe, where a significant portion of the BSE infections identified have been in cattle that had no outward signs of BSE and were tested only because those countries require blanket testing of older cattle at slaughter.[10] *See* Motion at 17; *see also*

[10] USDA's Opposition Memo references an article by Heim and Kihm, also cited in the OTM Rule preamble, implying that the article supports USDA's refusal to consider BSE testing as part of the OTM Rule. Opp. Memo at 17. To the contrary, the article emphasizes that: "Measures for minimizing risks for human health require the identification and elimination of infected animals before slaughter, which can only be achieved by a combination of efficient passive and active surveillance." AR017867. "Testing of all normally slaughtered cattle has the beneficial effect of removing late preclinical cases from the food chain." *Id*. In 2004, of the 691 BSE cases the

AR001740 (in the UK, eight cattle in 2004 and at least five in 2005 passed ante-mortem inspection but were found to have BSE by testing); 2006 OIE Code, at Article 3.8.4.1(2), AR017919 (cattle with BSE at "a stage at which BSE is detectable by testing before clinical signs appear" likely will be more numerous than those with clinical signs); 2006 OIE Code, at Article 3.8.4.1(4), AR017920 (recommending that countries' BSE surveillance programs include "cattle over 36 months of age at routine slaughter").[11]

It is not sufficient for USDA simply to claim that it "was fully engaged in the evaluation of this issue." Opp. Memo at 17. An agency action that is "internally inconsistent and inadequately explained" violates the APA. *Gen. Chem. Corp. v. United States*, 817 F.2d 844, 857 (D.C. Cir. 1987). Moreover, USDA continues even in this litigation to ignore entirely the public comments that requiring testing of OTM Canadian cattle, regardless of its human and animal health benefits, would mitigate some of the adverse impact on the U.S. beef market associated with co-mingling with beef from Canadian cattle more likely to have BSE.[12]

E. Huge Unexplained Inconsistencies Are Even Greater in Light of USDA's Opposition

The Motion for Preliminary Injunction provided numerous examples of statements purportedly explaining or supporting the OTM Rule are internally inconsistent, illogical, or

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European Union detected through active testing (AR017967), 166 were found in "healthy slaughtered animals." AR017974. In contrast, in countries that rely on voluntary reporting, like Canada, "disease awareness or willingness to report cases seems insufficient." AR017861.

[11] USDA's assertion that testing could be counterproductive, because "measures such as SRM removal requirements may not be sufficiently emphasized due to the perceived total reliability of the testing," Opp. Memo at 16-17, is a non-sensical, make-weight argument: SRM removal requirements should not need to be "emphasized"; they are contained in mandatory regulations enforced by USDA's Food Safety Inspection Service (FSIS). Indeed, USDA's assessment of the risk of the spread of BSE in the U.S. assumed "perfect" compliance with SRM removal procedures for that reason. *See* p. 23, *infra*.

[12] *Cf*. Motion at 17 *with* Opp. Memo at 16-17. In fact, the article USDA cites acknowledges that testing could be "a measure to restore consumer confidence." See Opp. Memo at 17.

inconsistent with facts in the record. *See* Motion at 15-19. Perhaps the most significant inconsistency is USDA's statement that Canada has had an effective feed ban, which is reducing the incidence of BSE in Canadian cattle, since March 1, 1999, despite increases in BSE cases identified in recent years and despite the fact that most BSE-infected cattle identified in the last two years were born after April 2000. *See id*. at 15; *see also* Exh. 1 to this Reply at ¶¶ 3-4.

USDA's Opposition, although it proffers multiple reasons why it was reasonable for it to ignore the plain implication of Canadian test data and conclude the opposite, really just highlights the inconsistencies and flip-flops in USDA's position. For example, although USDA now claims that it cannot evaluate the effectiveness of Canada's feed ban by examining existing BSE testing data, Opp. Memo at 15, it previously said that it could determine whether Canada's feed ban was effective based on Canadian testing data (which at the time had only shown two cases of BSE in Canadian-born cattle). In connection with the Minimal-Risk Region Rule, USDA stated that: "Cases of BSE found in animals born after the feed ban was implemented would suggest either that the feed ban was ineffective or that there were noncompliance issues." AR008322; *see also* 70 Fed. Reg. at 515 ("because the two BSE-infected animals were born before the feed ban, there is no evidence to suggest that the feed ban is ineffective"); AR008327 (BSE cases born before Canadian feed ban "do not provide any evidence of ineffectiveness"). Similarly, USDA's risk analysis accompanying that rule stated: "This factor distinguishes between regions with effective feed bans and those without them. If an animal with BSE were born after a feed ban was implemented, the observation suggests that the feed ban may not have been effectively enforced." AR008361. The Heim and Kihm article USDA relies on similarly concludes that: "The effect of the measures concerning feed can be assessed by the number of

BSE cases which occurred subsequently," AR017863, and "The effect of measures implemented can only be judged after the average BSE incubation period." AR017858."

Currently, half of all native Canadian BSE cases (6 of 12) were born subsequent to Canada's feed ban, providing empirical evidence that Canada's pre-2007 feed ban did not prevent further spread of BSE in the Canadian herd. Exh. 1 ¶ 4. USDA now estimates the BSE prevalence in Canada to be almost an order of magnitude higher than it did in 2004. *See* p. 4, *supra*. Thus, the facts do not meet USDA's own expression of the observations that would confirm an effective feed ban.[13]

USDA also offers its own recent statements that the discovery of numerous BSE cases in cattle born long after implementation of Canada's feed ban was "not unexpected." Opp. Memo at 18. But before those additional BSE cases were identified, USDA was saying something very different: As noted above, USDA said it expected there may be additional cases of BSE in cattle born before the feed ban, but that BSE cases in cattle after the feed ban would indicate a problem. USDA also quoted approvingly CFIA's prediction that the number of BSE cases in Canada would peak in 2003, approximately six years after Canada's feed ban implementation, and that the "current third generation cases would have been infected by [protein in feed] from the second generation of infectivity in 1997 and would be expected to express the disease in 2002 to 2005." AR017713-144. In fact, recent BSE test data from Canada greatly exceeded

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[13] USDA's attempt to explain how increased discoveries of BSE in Canadian cattle in the last two years are the result of increased testing, rather than inadequacies of Canada's pre-2007 feed ban, Opp. Memo at 14-15, has a fatal flaw: its reference to "the increase in testing from 1999 through 2006" fails to acknowledge that Canada has been reducing the number of cattle tested in the last two years, whereas the numbers of BSE cases detected have shot up. *See* Motion at 15. (We also now know that, contrary to USDA's statement in the OTM Rule, Canada stopped testing feed cohorts of BSE cases, which are at increased risk of BSE infection, after 2005. *See* Motion at 16 and Exh. 3 Attach. 16; *cf.* Opp. Memo at 15-16.)

those expectations, with the highest year so far occurring in 2006 (five cases detected), and the three cases detected in 2007 suggest that Canada may now be into its fourth generation of BSE.[14]

III. PLAINTIFFS' NOTICE OF SUPPLEMENTAL AUTHORITY DEMONSTRATES LIKELIHOOD OF SUCCESS ON THE NEPA CLAIM.

On November 20, 2007, Plaintiffs filed a notice of supplemental authority, bringing the Court's attention to *Center for Biological Diversity v. National Highway Traffic Safety Administration*, 508 F.3d 508, (9th Cir. No. 06-71891, Nov. 15, 2007). That decision, issued after Plaintiffs' Motion for Preliminary Injunction, further demonstrates Plaintiffs' reasonable probability of success on the merits of Count 4 of the Complaint. Plaintiffs assert that USDA violated the National Environmental Policy Act ("NEPA") when it refused to assess the impact of increased emissions of greenhouse gases and other air pollutants resulting from the OTM Rule, in part because USDA asserted that those increased emissions would be small compared to other emissions. Complaint ¶¶ 70, 71. USDA summarily dismissed those increased emissions as insignificant because total heavy truck traffic from Canada would increase 0.05 to 0.16 percent. 72 Reg. at 53,360-61. In *Center for Biological Diversity*, the Ninth Circuit rejected an almost identical conclusion that incremental greenhouse gas emissions from light trucks were insignificant because they constituted only 0.2 percent of total greenhouse gas emissions from light trucks. *See* 508 F.3d at 548-50.

USDA has not responded to this demonstration of Plaintiffs' likelihood of success on the NEPA count, offering two reasons. Opp. Memo at 3 n.1. First, USDA asserts that Plaintiffs'

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[14] These test data also make it impossible to understand USDA's protestation that Canada, despite now having three or four generations of BSE-infected cattle, "does not have 'widespread exposure and/or an establishment' of BSE," Opp. Memo at 19 (emphasis in original), when USDA has said a disease becomes "established" if it is propagating without outside sources of infection. *See* 72 Fed. Reg. at 53,318. For the same reason, USDA's claim that Canada still meets the criteria for a Minimal-Risk Region because, it asserts, BSE has not become established in Canada, must fail. *Cf*. Opp. Memo at 18-19; Motion at 18-19.

notice of supplemental authority should have been "addressed by a motion with supporting papers" under the Court's Standard Operating Procedures ¶ 18. A letter attaching the supplemental authority is the standard way of presenting such subsequently available information, however, and USDA offers no justification for its assertion that Plaintiffs should have presented this information by motion, nor that USDA can ignore supplemental authority provided to the Court by letter. *See* Fed. R. App. P. 28(j).

Secondly, USDA asserts it can ignore the supplemental authority because NEPA issues were not mentioned in Plaintiffs' Motions for Preliminary Injunction and for a Temporary Restraining Order. The Motion for Preliminary Injunction explained specifically "a few of" the "many grounds on which USDA's promulgation of the OTM Rule was unlawful," as "outlined in the Complaint." Motion at 8. When the Ninth Circuit later issued an opinion directly on point as to one of the grounds outlined in the Complaint, it was entirely appropriate for Plaintiffs to bring the opinion to the Court's attention as another example of Plaintiffs' likelihood of succeeding on the merits of their Complaint. USDA's failure to conduct an adequate analysis of the environmental impacts of the proposed OTM Rule under NEPA justifies a stay of the OTM Rule. *See, e.g.*, *Idaho Sporting Congress, Inc. v. Alexander*, 222 F.3d 562, 569 (9th Cir. 2000).[15]

IV. SERIOUS, IRREPARABLE HARM FROM THE OTM RULE HAS OCCURRED AND IS THREATENED.

USDA responds to Plaintiffs' demonstration that they meet the "irreparable harm" criterion for a preliminary injunction largely just by repeating USDA's own conclusions that there is negligible risk of the "establishment" of BSE in the U.S. cattle herd or of U.S. beef consumers contracting vCJD. Those conclusions are not supported by the record and in a

[15] USDA may again claim that *R-CALF II* disposes of the NEPA claim. But *R-CALF II* merely found a lack of standing to pursue specific objections under NEPA to a different rule. *See* 415 F.3d at 1103-1104. Here we have different plaintiffs and allegations supporting standing.

number of cases are absurd on their face.[16] Even since the Motion for Preliminary Injunction was filed, Canada has reported yet another case of BSE in an Alberta cow. *See* Exh. 1 ¶ 2. In the meantime, older Canadian cattle have been streaming into the U.S. at an annualized rate of between 150,000 and 200,000 head per year.[17]

For reasons noted in Plaintiffs' Motion for Preliminary Injunction and in this reply, USDA's assertions about the insignificant risk of U.S. cattle contracting BSE or U.S. consumers contracting vCJD are not supported by the available data. But even if those risks were insignificant, that would not in any way mean that Plaintiffs have failed to show irreparable harm if the OTM Rule is not enjoined, as those are not the only types of irreparable harm presented.

A. Harm to the Demand for U.S. Beef

USDA says that the prevalence of BSE in the current Canadian adult cattle population is likely 3.9 cases per million head. 72 Fed. Reg. at 53,323 col. 3. Given that this is the average prevalence for all adult cattle, and USDA believes that Canada's feed ban makes BSE less likely in cattle born in recent years, the prevalence in Canadian cattle over 30 months of age should be even higher. Canada in the last few years has detected 11 cases of BSE out of less than 200,000 head tested. *See* Exh. 1 ¶¶ 2-3. Just those BSE-infected cattle that subsequently were identified by testing represented about 2 cases per million head in late 2004. *See id.* ¶ 5. Clearly the

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[16] For example, USDA says that there are "effective feed bans in place in the United States and Canada which prevent cattle from becoming infected at all," Opp. Memo at 21, ignoring the fact that 6 Canadian cattle found to have BSE were born after Canada's feed ban supposedly prevented them from becoming infected. *See* pp. 15-17, *supra*. And USDA repeats the misleading assertion that no cases of vCJD associated with eating Canadian beef have been identified, when, with an estimated average incubation time of over 16 years, 72 Fed. Reg. at 53,337, col. 1, no cases of vCJD could have been identified yet from consuming any of the native Canadian cattle found to have infectious levels of BSE, nor of any Canadian cattle since BSE is first known to have been introduced in Canada from a UK cow in 1993. See Exh. 1 ¶ 3.

[17] *See* Exh. 1 ¶¶ 6-7. This contrasts to USDA's estimate that 2008 imports of older Canadian cattle—a key element of the assessment of the risk of BSE from the OTM Rule—would be only 75,000 head. 72 Fed. Reg. at 53,368 and 53,369 Table C.

importation of older Canadian cattle under the OTM rule, which currently is running at 3000-4000 head a week (Exh. 1 ¶ 6), is likely to result in BSE-infected cattle entering the country. The OTM Rule preamble acknowledged as much. *See* Motion at 20. *See also* AR016888-90 (using estimate of BSE prevalence in current Canadian herd that USDA deems most likely, 72 Fed. Reg. 53,323 col. 3, USDA Sept. 2007 Revised Risk Assessment predicts "less than 6" (5.37) BSE-infected cattle would be imported in the first year).[18]

USDA asserts that this does not present the potential for irreparable harm, however, because safeguards required by USDA regulations will prevent BSE infectivity from reaching U.S. cattle. Opp. Memo at 20-22. But the cow imported from Canada that was found to have BSE in Washington State in late 2003 was subject to the 1997 U.S. feed ban and all potentially infectious tissues were landfilled (AR0190852-53), nor was her existence evidence of any BSE contamination in U.S. animal feed, since she was around four years of age before entering the U.S. It was the mere existence of a BSE-infected animal in the United States that tainted the perception of the U.S. beef supply in a way that cost billions of dollars and that even now substantially restricts U.S. beef exports. *See* Motion at 5, 21.

USDA attempts to dismiss the relevance of lost exports by asserting: "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

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[18] USDA repeatedly claims that Plaintiffs base their claims of irreparable harm on outcomes USDA predicts only under unrealistic, pessimistic assumptions. *See*, *e.g.*, Opp. Memo at 13, 20-21. But USDA's explanation for using lower assumptions of BSE prevalence when assessing BSE risks over the next 20 years, *see* 72 Fed. Reg. at 53,335, do not apply to the risk of importing BSE-infected cattle in the current year—the only thing relevant for preliminary injunction purposes. There, USDA admits that a prevalence of at least 3.9 cases per million head is the most likely to be true. 73 Fed. Reg. at 53,323 col. 3; *see also* 53,319 (recent cases support a higher prevalence, but still within 3-8 confidence ban). Using that higher prevalence USDA estimates 5.37 infected cattle will be imported in the first year of the OTM Rule. AR016890

mutually beneficial trade while maintaining the safety of the beef supply.'" Opp. Memo at 22, *quoting* 72 Fed. Reg. at 53,336. In contrast to these platitudes, the USDA Economic Research Service (ERS) predicts that "it may take years for U.S. exports to Japan and South Korea to return to earlier levels" after the loss caused by the discovery of BSE in Washington State. AR017940. The ERS also acknowledges that: "Lingering questions about the safety of U.S. beef remain in the minds of some Japanese consumers, as reflected in a number of consumer surveys." AR017938, AR017939. *see also* 72 Fed. Reg. at 53,356 col. 3 (principal Asian markets "remain largely restricted").[19] The assertion in USDA's Opposition Memo at 23 that "there is no reason to think that OTM imports would affect exports" is directly at odds with recent experience and simply ignores Plaintiffs' demonstration that many export markets specifically prohibit U.S. shipments of meat derived from Canadian cattle or from cattle over 30 months of age. Motion at 21. USDA's unsupported conclusions, at odds with actual experience and its own experts' opinions, do not refute Plaintiffs' demonstration that importing older Canadian cattle, some of which are expected to have BSE, presents an imminent risk of substantial irreparable harm to U.S. cattle and beef markets.

B. Harm to U.S. Cattle Producers from Imports of Cheap Cattle and Beef

USDA cannot avoid its own estimates that the OTM Rule will cost U.S. cattle producers, including some of the Plaintiffs, a whopping $66 million per year, because of the effect of bringing cheap Canadian cattle and beef, for which there is little market outside Canada, into the

[19] USDA also acknowledged the reality of the potential impact that an incident involving something like BSE could have on domestic and foreign demand for U.S. products, in a recent proposal to renew its listing of BSE as one of the "select agents" deserving of special protections under the Agricultural Bioterrorism Protection Act of 2002, Pub. L. 107-188: "Past food safety incidents have shown that consumer perception (both domestic and international) about the safety of an implicated food product and about the producing country or sector's ability to produce safe food can be slow to recover and can have a lasting influence on food demand and global trade." 72 Fed. Reg. 49,231, 49234 col. 2 (August 28, 2007).

United States. *See* Motion at 23. So USDA simply dismisses this irreparable harm as not "great" and only "incremental." Opp. Memo at 23. This is neither a legal defense nor a logical one. USDA's own projections (not Plaintiffs' "alarmist predictions," *id.*) show a significant, immediate, irreparable harm to U.S. cattle producers from the OTM Rule. That cost to U.S. producers alone is irreparable harm justifying a preliminary injunction. Motion at 23.

C. Harm to U.S. Consumers Who Wish To Avoid Meat from Countries with BSE

USDA predicted a slight economic benefit to U.S. consumers as a result of allowing imports of OTM cattle. 72 Fed. Reg. at 53,353 col. 2 (estimated increase in "consumer surplus" of 1 to 1.3 percent). But USDA has ignored entirely the effect of the OTM Rule on U.S. consumers who do not want to expose themselves to meat that has a higher risk of BSE (something the U.S. Centers for Disease Control suggests they may want to do when traveling abroad). *See* Motion Exh. 4 (declaration of Chris Waldrop of Consumer Federation of America); *cf.* Opp. Memo at 20-25. By allowing imports of cattle, and meat from cattle, that are at least 26 times more likely to test positive for BSE than domestic cattle, and then by refusing to require that meat derived from such cattle be identified through labeling, USDA is currently subjecting consumers, whom Plaintiffs represent, to irreparable harm. That harm is ongoing and exists regardless of USDA's assurance that the risk of contracting vCJD from that meat is "negligible."

D. Risk of BSE for U.S. Cattle and of vCJD for U.S. Consumers

The assertions in USDA's Opposition Memo that imports of OTM cattle and beef under the OTM rule present "no threat of irreparable harm" to the health of U.S. consumers and the health of U.S. cattle are based on inaccurate descriptions of the analyses USDA relied upon. For example, with respect to the risk of humans contracting vCJD from BSE-infected meat, USDA repeatedly says that the "FSIS's updated risk assessment" prepared in conjunction with FSIS

SRM removal regulations found that "the potential for human exposure to BSE would be almost completely eliminated" as a result of SRM removal requirements. Opp. Memo at 21; *id*. at 7. (The risk assessment USDA did for the OTM Rule itself "specifically examines animal health, not human health." 72 Fed. Reg. at 53,340, col. 2.) But the citations provided in the Opposition Memo for the most part do not even relate to the FSIS risk assessment. The statements from the FSIS preamble that do relate to the FSIS risk assessment, and the risk assessment itself, show that FSIS concluded the risk of BSE exposure would be almost completely eliminated by SRM removal requirements only if compliance is "perfect" (72 Fed. Reg. at 38,726, col. 1; AR017086), and only if SRMs are removed from carcasses used both for human food and for animal feed (72 Fed. Reg. at 38,724 -26 and AR017086), the latter of which is not required in the United States, *see* Motion at 6, 11. In fact, reducing assumed compliance with SRM removal requirements from 100 percent to 99 percent more than quadrupled predicted human exposure to BSE infectivity. *Cf.* AR017464, AR017467 (exposure increases from 20 to 83).

As for the risk to U.S. cattle, USDA denies that U.S. cattle will be exposed to BSE from imported Canadian cattle, ignoring statements, by the OIE and by the same Heim and Kihm article it relies on elsewhere, that the partial feed ban in the United States still allows substantial risk of exposure to BSE. This is because U.S. regulations allow SRMs to be used in animal feed designated for non-ruminants, with resulting cross-contamination of ruminant feed and mis-feeding. *See* Motion at 6, 11 and Exh. 3 Attach. 12; AR017861 ("Even when no MBM is included in ruminant feed, the agent may still be recycled through cross-contamination and cross-feeding."); AR017863-64 (if SRMs "are processed for further use in animal feed, there is a high risk of amplification of the BSE agent." *Id.* at AR017863.). USDA's assertion that the exposure of U.S. cattle to BSE-infected tissues from OTM Canadian cattle imports will be

insignificant is irresponsible in light of the fact that the CFIA, consistent with the conclusions of the OIE and Heim and Kihm, has found that the majority of BSE cases detected in the Canadian herd are the result of such cross-contamination or mis-feeding. *See* Motion Exh. 3 ¶ 15.

V. USDA FAILS TO SHOW THAT THE BALANCE OF HARMS OR PUBLIC INTEREST JUSTIFIES ALLOWING IRREPARABLE HARM TO PLAINTIFFS PENDING REVIEW OF THE OTM RULE ON THE MERITS.

USDA's arguments that issuing a preliminary injunction to suspend the irreparable harm to Plaintiffs resulting from the OTM Rule would not be in the public interest and would not reflect a proper balancing of the harms to the parties are tautological: Because Congress intended for USDA to implement the AHPA and decide whether restrictions on imports are necessary to protect domestic livestock, it is in the public interest to allow USDA to do so unrestrained, the argument goes. That logic obviously begs the question presented by the merits; and, if it were an appropriate application of the balance of harms and public interest criteria, no preliminary injunction would ever be issued to stay the implementation of a challenged government action.

Plaintiffs' Motion for Preliminary Injunction presented numerous indications of congressional intent that protection of U.S. livestock and U.S. agricultural markets and protection of U.S. consumers, including specifically protection from BSE, is a crucial U.S. policy goal. *See* Motion at 24-25. (Contrary to USDA's assertion, Opp. Memo at 25 n.7, the Court need not look to the goals of the AHPA alone in assessing where the public interest lies.) Plaintiffs also noted the general principle that the public interest favors enjoining a regulation that increases risks to public health and safety until such risks can be subject to judicial review. Motion at 25, *citing Sanborn Mfg, v. CampbellHausfeld/Scott Fetzer Co.*, 997 F.2d 484, 490 (8th Cir. 1993). USDA's self-serving assertions equating the public interest with leaving USDA's

decisionmaking unquestioned do not contradict those indications that granting a preliminary injunction is in the public interest.

USDA asserts that the balance of harms "favors the benefits certain to be gained by the implementation of the OTM Rule" but fails to identify what those certain benefits are. Opp. Memo at 24. While it is clear how the OTM Rule benefits the Canadians (and also, the record discloses, the Mexicans wishing to ship Canadian cattle through the U.S., *see* n. 8, *supra*), that kind of benefit should be given little or no weight by a U.S. court considering whether to grant Plaintiffs a preliminary injunction. USDA's speculation that allowing imports of undesirable older Canadian cattle and beef will help promote exports from the U.S. certainly does not describe a "certain" benefit. And any relatively slight net economic benefit predicted from access to cheap Canadian OTM cattle and beef could—based on actual experience—be wiped out rapidly if another BSE-infected cow dies in the United States.

VI. CONCLUSION

USDA's opposition to Plaintiffs' Motion for Preliminary Injunction for the most part repeats USDA's assertions in the OTM Rule rather than engaging directly Plaintiffs' demonstration that there is a reasonable probability they will succeed on a number of their challenges to the OTM Rule, and that an injunction is appropriate to prevent ongoing and threatened irreparable harm to Plaintiffs until the Court can review thoroughly the merits of Plaintiffs' claims. Accordingly, for the reasons set for in the Motion for Preliminary Injunction, it should be granted.

Dated: January 9, 2008

Respectfully submitted,

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CERTIFICATE OF SERVICE

I I hereby certify that, on January 9, 2008, I caused the foregoing Plaintiffs' Reply in Support of Motion for Preliminary Injunction, along with the supporting declaration and exhibits, to be served on the defendants by filing these documents pursuant to this Court's Case Management/Electronic Case Filing Administrative Procedures.

_/s/ Thomas P. Tonner______
Thomas P. Tonner