## BEFORE THE UNITED STATES DISTRICT COURT DISTRICT OF COLUMBIA

Farm-to-Consumer :

Legal Defense Fund, et al. : Case No. 1:08-cv-01546-RMC

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Plaintiffs : Judge Rosemary M. Collyer

:

v. :

:

**U.S. Department of Agriculture, et al.** :

:

**Defendants** :

# <u>PLAINTIFFS' MEMORANDUM IN OPPOSITION TO USDA'S MOTION TO DISMISS FIRST AMENDED COMPLAINT</u>

Plaintiffs hereby file their Memorandum in Opposition to Defendant United States

Department of Agriculture's ("USDA") Motion to Dismiss First Amended Complaint.

Dated: March 23, 2009 Respectfully submitted,

/s/ David G. Cox

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The issue in this case is whether the United States Department of Agriculture's (USDA) development and implementation of its National Animal Identification System (NAIS), in conjunction with Defendant Michigan Department of Agriculture ("MDA") is violating applicable state and federal law, and whether Plaintiffs have pled claims for which relief can be granted.

For the reasons that follow below, Plaintiffs' claims are well pled and they are entitled to relief. Consequently, USDA's motion to dismiss is not well taken and it should be denied.

### I. Introduction and Background.

USDA has described NAIS as "one of the largest systematic changes ever faced by the livestock industry." See Exhibit A, attached hereto. As set out in Plaintiffs' First Amended Complaint, USDA has taken significant steps to implement NAIS nationally and in the State of Michigan. Yet USDA continues to bypass the mandatory substantive and procedural steps required for agency action and it now seeks to avoid judicial review of its actions altogether. In essence, USDA is asking this Court to allow it to continue implementation of this massive federal program without following proper procedures or being subjected to judicial review by claiming that it has not implemented "NAIS as a whole."

In 2007, USDA issued a draft business plan (*see* USDA's 12/12/08

Administrative Record No. NAIS AR 1449, hereinafter "Draft Business Plan") and in 2008 issued a final Business Plan (Exhibit B, attached hereto, hereinafter "Final Business Plan") that contain a blue print or strategy for how it plans on implementing NAIS nationwide. In this case, USDA has acted in accordance with its Business Plans for

implementing NAIS by forcing MDA to make NAIS mandatory on Michigan cattle owners. For example, while USDA repeatedly argues it is not implementing NAIS because only one species (cattle) has been required to be tagged in Michigan, the first strategy in USDA's Business Plans is to implement NAIS on a species-by-species basis with cattle as the highest priority. *See* Draft Business Plan at pgs. 2, 15; Exhibit B at pgs. 2, 15.

The Business Plans also call for standardizing data elements by using existing disease control programs to implement NAIS, as has been done in Michigan under the guise of eradicating Tuberculosis ("TB"). *See* Draft Business Plan at pgs. 2, 30-32; Exhibit B at pgs. 3, 28-30. The Business Plans specifically recommend that USDA "integrate NAIS-compliant RFID tags in the brucellosis calfhood vaccination/ testing program and bovine tuberculosis testing." *See* Draft Business Plan at pg. 19; Exhibit B at pg. 19.

Another USDA strategy for implementing NAIS is to use automated data capture technologies in existing disease control programs "by using NAIS-compliant [radio frequency identification devices] ("RFID") devices and integrating handheld computers/readers to replace paper-based forms." *See* Draft Business Plan at pg. 33; Exhibit B at pg. 31. A final USDA strategy outlined in the Business Plans is to partner with States. *See* Draft Business Plan at pg. 36; Exhibit B at pg. 34. In other words, the piecemeal implementation of NAIS on certain species through State agreements that impact existing disease control programs is exactly the process by which USDA has admitted it is going to implement NAIS nationally.

Moreover, in entering into several Memoranda of Understanding ("MOUs") with MDA, USDA has expended funds appropriated by Congress for "the National Animal Identification System." *See, e.g.*, H.R. 2764 at p.10 (2008 Consolidated Appropriations Bill); H.R. 2744 at pg. 9 (2006 Agriculture Appropriations Bill); HR 4818 (2005 Consolidated Appropriations Bill) at pg. 10. USDA has spent a portion of these funds directly on funding MDA's implementation of NAIS and on related efforts, such as the establishment and maintenance of the federal database that holds Plaintiffs' (and many other people's) information. If USDA is not implementing NAIS as it now claims then it has misused federal funds. USDA cannot avoid judicial review of its actions simply because it has even further reaching plans for the future.

In place of meaningful process and review, USDA seeks to have this Court accept its conclusory allegations that NAIS is a low-cost, scientifically based animal disease measure. Yet USDA has wholly failed to provide any scientific studies supporting its claims, ranging from the alleged need to have 48-hour traceback to the wildly optimistic idea that NAIS would even succeed in providing such traceback. Not only has USDA failed to provide any such studies with its motion to dismiss, it has repeatedly failed to produce any documents in response to requests under the Freedom of Information Act. *See* Affidavit of Judith McGeary, Exhibit C, attached. Instead, USDA relies on unsupported statements in employees' affidavits that are devoid of any scientific analysis or data. USDA's failure to produce any studies to support NAIS merits a careful judicial review on the record.

Similarly, although USDA commissioned a cost-benefit analysis of NAIS in July 2007 it has still failed to produce any such analysis. *See* Exhibit D, attached. As early as

April 2008, Bruce Knight, the then-Undersecretary of Marketing and Regulatory Programs, informed Plaintiff Farm-to-Consumer Legal Defense Fund that USDA expected to have the draft cost-benefit analysis shortly and would produce the study publicly at the end of the summer. *See* McGeary Affidavit. That was almost a year ago, and USDA still continues to avoid a public assessment of the costs and regulatory burdens of NAIS.

While avoiding the critical issues of the scientific basis and monetary costs of the program, USDA repeatedly reassures the Court that NAIS is "technology neutral" and that it has approved several non-electronic tags for use in NAIS. What USDA fails to reveal is that at the time it signed the 2005 MOU with MDA, which included provisions for all cattle to be tagged with NAIS-compliant tags, the only form of identification that USDA had approved for cattle was electronic! In fact, USDA did not approve any visual only tags for use in NAIS until August 2008, several months after Plaintiffs sent their Notice of Intent to Sue to USDA and more than two years after MDA announced that Michigan farmers would be required to use NAIS-compliant RFID tags on all their cattle. See Exhibit E, attached.

The Plaintiffs face mandatory government requirements, i.e., the registration of their property in a federal database, the electronic tagging of their animals, and the tracing of their animals' movements. USDA has registered over half a million people's properties, including more than 21,000 properties in Michigan. *See* Exhibit F, attached. USDA has spent millions of dollars on NAIS and has budgeted millions more for 2009. It is more than time for USDA's actions to be subject to appropriate judicial review of both the procedural and substantive issues raised in Plaintiffs' First Amended Complaint.

### *II.* Plaintiffs have standing to bring their claims.

USDA's arguments on standing goes deeply into the merits of Plaintiffs' claims and USDA's version of what NAIS does and does not mandate. But standing does not require that Plaintiffs prove their case. All that standing requires is "enough fact to raise a reasonable expectation that discovery will reveal evidence of illegal [conduct]." *Bell Atlantic Corp. v. Twombly,* 550 U.S. 544, 127 Sup. Ct. 1955, 1965 (2007). According to the United States Supreme Court, "a well-pleaded complaint may proceed even if it strikes a savvy judge that actual proof of those facts is improbable, and 'that a recovery is very remote and unlikely." *Bell Atlantic Corp. v. Twombly,* 550 U.S. 544, 127 Sup. Ct. 1955, 1965 (2007) (citation omitted).

To demonstrate the likelihood of their probable recovery, Plaintiffs may establish their standing "by the submission of [their] arguments and any affidavits or other evidence appurtenant thereto at the first appropriate point in the review proceeding." *Sierra Club v. E.P.A.*, 292 F.3d 895, 900 (D.C. Cir. 2002). Consequently, this Court has jurisdiction over Plaintiffs' claims if their right to recover "will be sustained if the Constitution and laws of the United States are given one construction and will be defeated if they are given another . . . ." *Steel Co. v. Citizens for Better Environment*, 523 U.S. 83, 89, 118 S.Ct. 1003, 140 L.Ed.2d 210 (1998). *See also Verizon Maryland, Inc. v. Public Service Com'n of Maryland*, 535 U.S. 635, 642-643, 122 S.Ct. 1753 (2002).

As explained below, Plaintiffs have more than adequately pled facts to raise a reasonable expectation that they will prevail on their claims if the laws of the U.S. are construed consistent with their arguments. USDA's actions have caused Plaintiff's injuries that include not only the RFID tagging requirement that USDA's motion focuses

on, it also includes "premises identification number" requirement, or PIN. A ruling against USDA in Plaintiffs' favor would redress these injuries by ending the federal nature of NAIS and by halting the causal relationship between USDA and MDA in implementing NAIS.

- A. Plaintiffs' injuries are traceable to USDA.
  - 1. Plaintiffs' injuries include economic damages and infringement of their civil liberties due to both the RFID and PIN requirements.

All of the individual Plaintiffs are farmers. They are the salt of the earth and stewards of the land. They all raise livestock and they all do so in a sustainable manner. One of them lives in Pennsylvania and the others live in Michigan. Unfortunately, USDA and NAIS are destroying their pleasant agricultural way of life. *See* Attached Affidavits of Plaintiffs Dan Nolt (Exhibit G), Greg Niewendorp (Exhibit H), Robert Alexander (Exhibit I), Joe Golimbieski (Exhibits J and K), Robert Keyworth (Exhibits L and M), Glen Mast (Exhibit N), Andrew Schneider (Exhibit O) and Reverend Roseanne Wyant (Exhibit P).

For example, NAIS requires that all of the Plaintiffs incur the costs of purchasing RFIDs for all of their cattle. Not only is there a cost associated with each RFID (from \$2 to \$5 per tag), there is equipment associated with attaching the tag (a \$20 applicator), having a veterinarian issue the appropriate documents (at least \$50), and other costs. *See* Schneider Affidavit, pg. 3; Keyworth First Affidavit, Golimbieski First Affidavit. Thus, Plaintiff Andrew Schneider estimates his costs will total approximately \$5,000 to \$6,000 per year. *See* Schneider Affidavit, pg. 3. And if a tag is lost, the farmer faces yet more costs to re-tag the animal. *See* Exhibit Q (noting that getting a tag caught on baling twine on hay is a "common cause of tag loss.") Other Plaintiffs are similarly injured. This

does not even include the costs of purchasing the optical scanners and readers that are required for tracking animal movements.

Moreover, a presentation from a USDA-funded study noted that the costs of NAIS for cattle include the RFID tags, RFID technology, labor (associated with each category), animal injury, human injury, depreciation, and opportunity costs. *See* Exhibit R, slide 17. Notably, when USDA analyzed the costs for Country of Origin Labeling ("COOL") program, the agency noted that the costs would include capitol, labor, personnel training, modification of recordkeeping, loss of efficiency, and computer hardware and software. *See* 74 Fed. Reg. 2658, 2683-2685 (Jan. 15, 2009). All of the COOL costs would be imposed under NAIS, if not more, and should be accounted for.

The cost of NAIS is prohibitive and may put Plaintiffs out of business. *See* Schneider Affidavit, pg. 3, Keyworth First Affidavit, Golimbieski First Affidavit, Niewendorp Affidavit, pg. 3. In fact, dozens of other farmers in Michigan have already gone out of business because of the prohibitive cost of NAIS. *See* Schneider Affidavit, pg. 4.

Not only are Plaintiffs suffering increased economic costs in order to continue farming, they are being assigned a Premises Identification Number ("PIN") against their will, their personal information and data are also being captured against their will, and those data are being placed into a national database. *See* Alexander Affidavit, pg. 17, Nolt Affidavit, Golimbieski Second Affidavit and Keyworth Second Affidavit.

Specifically, Plaintiffs' "premises" information has been placed into a database, including their name, address, telephone number, size of farm, type of animal raised, number of animals raised, latitude and longitude coordinates. This injury occurs whether the farmer

is required to sign up his property or whether the government assigns the PIN to his property after placing his information into a database without his consent, as has happened. Consequently, Plaintiffs' private information is no longer confidential, another form of injury. *See, e.g.*, Schneider Affidavit, Keyworth Second Affidavit, Golimbieski Second Affidavit, Niewendorp Affidavit.

Moreover, although USDA repeatedly assures producers that the information under NAIS is confidential and for disease purposes only, the USDA's Privacy Act Notice for NAIS stated that a "routine use" of the information collected includes "releases related to investigations pertaining to violations of law or related to litigation" and that the information may also be released to "the appropriate agency, whether Federal, State, local, or foreign, charged with responsibility of investigating or prosecuting a violation of law or of enforcing, implementing, or complying with a statute, rule, regulation, or order," without requiring any relation to animal disease outbreaks. *See* Fed. Reg. 23412 & 23413 (Apr. 30, 2008).

The Plaintiffs have a belief in the Bible and that as humans they are endowed by their Creator with dominion and control over all the animals on earth. *See, e.g.,* Affidavits of Nolt, Niewendorp, Rev. Wyant, Golimbieski First Affidavit and Keyworth First Affidavit. They believe NAIS violates this tenet of their religion because dominion and control has now been transferred to USDA and MDA. They also believe that they are not allowed to take "the mark" of NAIS and that by subscribing to NAIS, i.e., PINs and RFIDs, they are violating this tenet of their religion as well. *See, e.g.,* Affidavits of Niewendorp, Rev. Wyant, Golimbieski First Affidavit and Keyworth First Affidavit.

In addition to the harms mentioned above, Plaintiffs Glen Mast and Robert

Alexander, who are Old Order Amish, are suffering further injury. *See* Affidavits of Mast and Alexander. For example, one tenet of their beliefs is that they must be farmers, yet the cost of complying with NAIS is prohibitive and may force these two Plaintiffs to quit farming altogether. Also, their religion eschews the use of technology, NAIS forces them to utilize technology in the form of RFIDs and scanners and computer programs. Finally, their beliefs discourage them from interfacing and co-mingling with the world, yet their private data is being communicated to a national database. In all three respects Plaintiffs Mast's and Alexander's religious beliefs are being violated. *See* Affidavits of Mast and Alexander.

Consequently, all Plaintiffs are being injured in one form or another in this case.

This is what Plaintiffs have pled in their First Amended Complaint and thus they have standing to bring this action.

USDA, however, alleges in its motion to dismiss that it is not the cause of Plaintiffs' injuries; rather it is MDA that is causing the injuries. USDA also argues that (1) NAIS does not require RFIDs, (2) NAIS is "technology neutral," and (3) other forms of identification are available. As explained below, these arguments lack merit.

2. USDA's authority under the Animal Health Protection Act excludes the intrastate regulation of animals.

Plaintiffs' injuries must be understood within the context of USDA's alleged statutory authority and its actions allegedly taken pursuant to that alleged authority.

USDA claims authority under the Animal Health Protection Act ("AHPA"), codified at 7

U.S.C. 8301 et seq., which regulates the importation, exportation, and interstate movement of animals in the U.S. *See* AHPA Sections 8303, 8304 and 8305.

The first part, importation, is governed by 7 U.S.C. 8303(a) which provides, in

part, that the Secretary of Agriculture "may prohibit or restrict (1) the importation or entry of any animal, article, or means of conveyance (2) the further movement of any animal that has strayed into the United States ... and (3) the use of any means of conveyance in connection with the importation or entry of livestock." The AHPA's provisions for export mirror the import provisions. *See* 7 U.S.C. 8304. Finally, 7 U.S.C. 8305 governs *interstate* (not intrastate) movement of animals and provides, in part, that the Secretary of Agriculture "may prohibit or restrict (1) the movement in interstate commerce of any animal, article, or means of conveyance (2) the use of any means of conveyance or facility in connection with the movement in interstate commerce of any animal or article."

In addition to the authority to regulate the importation, exportation and interstate movement of animals, other sections of the AHPA govern federal-state cooperation in the movement of animals. For example, 7 U.S.C. Section 8310(a) provides, in part, that USDA may "cooperate with other Federal agencies, States or political subdivisions of States" in the eradication of disease in animals. Further, 7 U.S.C. 8310(d) provides, in part, that USDA may "cooperate with State authorities, Indian tribe authorities, or other persons in the administration of regulations for the improvement of livestock and livestock products." Finally, 7 U.S.C. 8312(a)(3) and (4) provides, in part, that Defendant USDA may "(3) make a grant" and "(4) enter into a cooperative agreement, memorandum of understanding" with the States. Thus, the AHPA is a comprehensive program designed to utilize both state and federal resources in the eradication of animal diseases from animals that enter the county, leave the country, or move within interstate commerce.

Each State is required to cooperate with USDA in order to eliminate or minimize certain diseases in animals, for example, Tuberculosis and Brucellosis in cattle (9 CFR Parts 77 and 78), Scrapie in sheep and goats (9 CFR Part 79) and Johnes disease in domestic animals (9 CFR Part 80). Under these programs, USDA designates States as "accredited free zones" (or disease free zones) (*see, e.g.*, 9 CFR 77.7), "modified accredited advanced zones" (or MAAZ zones) (*see, e.g.*, 9 CFR 77.9) or "modified accredited zones" (or MAZ zones) (*see, e.g.*, 9 CFR 77.11). States may also be designated a combination of zones, for instance part MAZ and part MAAZ, and if this occurs the State is considered a "split-status" State. *See, e.g.*, 9 CFR 77.3 and 77.4. A State that is not accredited faces serious sanctions, such as a ban on the interstate transport of animals from that State except directly to slaughter in sealed conveyances. *See, e.g.*, 9 CFR 77.16.

USDA has promulgated regulations concerning implementation of its animal disease eradication programs at 9 CFR Parts 71, 77, 78, 79 and 80. For a State to retain its designated zone status the State *must*, among other requirements, "enter into a memorandum of understanding with APHIS in which the state agrees to adhere to any conditions for zone recognition particular to that request." *See* 9 CFR 77.4(a)(3). Plaintiffs will hereafter refer to these memoranda of understandings as "MOUs."

Thus, through the auspices of the AHPA and its implementing regulations, USDA regulates the importation, exportation and interstate movement of animals in an effort to eradicate animal disease and it does so in cooperation with the States. Significantly, the AHPA does not authorize USDA to regulate the *intrastate* movement, transport, identification or testing of animals. Yet, this is exactly what USDA is doing in this case;

it is using its authority under the AHPA to enter into MOUs with MDA to impose requirements on MDA that regulates the *intrastate* movement of animals. Moreover, USDA is using the MOUs with MDA to gather, collect and store private, personal data from properties where any cattle are located, whether or not the owner moves the cattle in interstate commerce.

As explained below, USDA is imposing requirements for: (1) PINs, (2) RFIDs, and (3) tracking of animals, all of which constitute the NAIS program. Thus, USDA is utilizing the AHPA to make NAIS mandatory in the State of Michigan.

3. USDA has implemented the Animal Health Protection Act in a manner that has caused injury to Plaintiffs.

In the case currently before this Court, USDA and MDA entered into MOUs in 2002, 2005 and 2007. *See* USDA Record Nos. TB AR 1860, 1879, 1886. In addition, USDA has authorized funding, issued several documents and plans, and has also issued agency memoranda on the subject of NAIS. When read as a whole the ostensible purpose of these MOUs, funding, documents and memoranda is the eradication of animal disease. However, as explained herein, the real purpose is to implement NAIS in the State of Michigan and across the nation.

To begin, each of the MOUs specifically state that they were all entered pursuant to the AHPA. For example, the 2002 MOU states that USDA's authority to enter into the MOU is derived from "the Organic Act of 1944, as amended, Title 21 United States Code, Section 114a" (which was subsequently repealed and is now the AHPA). The 2005 and 2007 MOUs also both specifically state that USDA's authority to enter into the MOU is the AHPA. *See* USDA's Administrative Record Nos. TB AR 1879, 1886. Thus, USDA is dictating what action needs to be taken to eradicate TB in Michigan. If MDA

did not enter into MOUs with USDA, it would lose its accreditation and face severe limitations on its ability to transport cattle interstate. *See* 9 CFR 77.16 (establishing restrictions for non-accredited States and zones); 9 CFR 77.4(a)(3) ("The State must enter into a memorandum of understanding with APHIS" to achieve or retain accredited zones).

To demonstrate that MDA is being forced to implement NAIS in the State of Michigan, here are some of the operative terms of the 2002, 2005 and 2007 MOUs:

#### (2002 MOU, Record No. TB AR 1860)

"[D]evelop, implement, and enforce scientifically-based movement restrictions and requirements including official bovine TB test requirements, prior movement permits, official intra-state health certificates to accompany movement of animals, and official identification of animals for movement between or within a Disease-Free Zone, Surveillance Zone, and an Infected Zone [zone areas within the modified accredited zone], or any combination of those zones."

Mandate "official identification" on "all domestic livestock that move from any premises" within these zones, including movement within disease-free areas within the State.

Define "official identification" as either an "eartag, tattoo, electronic identification, or other identification approved by" either USDA or MDA yet for the MAZ the "use of electronic identification would be strongly encouraged."

Mandate and "establish an inspection presence at the livestock auction markets throughout the State," and to verify "that all cattle and goats presented for sale meet bovine TB testing and official identification requirements."

USDA and MDA, to monitor enforcement of the MOU, would cooperate on "implementing an electronic identification system."

(2005 MOU, Record No. TB AR 1879)

Mandate "electronic identification and a movement permit for any cattle moved from premises" in the MAZ;

Require APHIS to provide "support for acquisition and development for electronic identification, hardware and software in accordance with the National Animal Identification System (NAIS) and USDA regulations . . . ;"

The 2005 conditions would be incorporated into a final rule to be published in the Federal Register, and MDA would agree to these "conditions for split state status for bovine TB" as defined in the final rule.

#### (2007 MOU, Record No. TB AR 1886)

Its purposes are "outlin[ing] and agree[ing] on the principles required for continuing three designations of State status \* \* \* pursuant to" 9 CFR Part 77 and the TB Uniform Methods and Rules;

Requires MDA to have the "ability to retrieve information concerning animal movements within 48 hours," and "implement and enforce a uniform, state wide certificate system to track all interstate or interzone cattle and bison movements from farm of origin to final destination;"

Requires MDA to "[u]tilize State authority to randomly intercept and inspect vehicles that are transporting livestock on public roads *within* Michigan for compliance with State and Federal split state status requirements and this MOU;" (emphasis added)

The 2007 conditions would be incorporated into a final rule to be published in the Federal Register, and that MDA would agree to these "conditions for split state status for bovine TB" as defined in the final rule.

Thus, the MOUs themselves are the clearest evidence that USDA, in cooperation with MDA, is mandating the NAIS program in the State of Michigan. Consequently, Plaintiffs' injuries are attributable to USDA as well as to MDA.

In addition to the MOUs, USDA is also using federal funds to coerce MDA to implement NAIS in the State of Michigan. For example, on July 28, 2006, MDA submitted a proposal to receive a grant of \$179,000 from USDA (the "2006 grant proposal") to implement NAIS. *See* Exhibit S, attached. MDA's purpose in receiving federal funds was to 1) register premises, issue PINs, and forward that information into the NAIS database; 2) convince the public that NAIS is a good idea; and 3) implement the electronic identification method required by the 2005 MOU. The 2006 grant proposal was re-drafted on May 7, 2007 and formally submitted to USDA on May 8, 2007. *See* Exhibit S.

In that final proposal, MDA indicated it needed federal funding to support Michigan's "movement certification program for any cattle of any age moving from one zone in Michigan to another zone in Michigan;" that "all animals being moved must be tagged;" that livestock producers "will be issued a plastic premises registration card from MDA;" and that premises registration was required in order to "allow producers to purchase RFID tags." *See* Exhibit S, pg. 71 of 90. In other words, because of USDA's agreements with MDA, Plaintiffs had to use RFIDs but before they could purchase any RFIDs they had to first register their premises and obtain a PIN.

The final grant proposal included the stipulation that "funds may only be used for the implementation and administration of premises registration in accordance with the NAIS, and support of outreach efforts pertaining to all activities that promote the NAIS implementation plan for full participation by 2009." *See* Exhibit S, pg. 68 of 90. Consequently, USDA's approval of the 2006/2007 grant proposal was clearly intended to implement NAIS in Michigan and to make NAIS requirements mandatory by 2009.

In addition to the MOUs and USDA's use of federal funds to implement NAIS in the State of Michigan, USDA has also published several documents in the Federal Register under the authority of the AHPA announcing USDA's intention to implement NAIS nationally. See *infra*, pages 26-27.

Therefore, through its MOUs with and funding of MDA under the authority of the AHPA, USDA is requiring MDA to implement NAIS at the state level. Consequently, Plaintiffs' injuries consist of both the economic costs and burdens of the required RFID tagging and the burdens of the PIN that have resulted. Accordingly, Plaintiffs' injuries are being caused by USDA.

B. Plaintiffs' injuries would be redressed by a favorable ruling from this Court.

Contrary to the misquote of USDA on page 22 of its motion to dismiss, redressability means that "it must be likely, as opposed to merely speculative, that the injury will be redressed by a favorable decision." *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 561, 112 S.Ct. 2130 (1992) (quotations and internal citation omitted). Redressability may be shown, in part, by either "attacking the separate decisions to fund particular projects allegedly causing [plaintiffs'] harm," or by challenging "specifically identifiable Government violations of law." *Id.* at 568. Significantly, the United States Supreme Court has ruled that "[w]hen the suit is one challenging the legality of government action" whereby "the plaintiff is himself an object of the action (or forgone action) at issue," then there is "ordinarily little question that the action or inaction has caused him injury, and that a judgment preventing or requiring the action will redress it." *Id.* at 561-562.

In addition, standing exists "where the challenged government action authorized conduct that would otherwise have been illegal." *Renal Physicians Ass'n v. U.S. Dept. of Health and Human Services*, 489 F.3d 1267, 1275 (D.C. Cir. 2007). Moreover, Plaintiffs "do not have to demonstrate with absolute certainty that the relief requested in their complaint will eliminate the harms they will allegedly suffer." *North Carolina Fisheries Ass'n, Inc. v. Gutierrez*, 518 F.Supp.2d 62, 82 (D.D.C. 2007). In fact, this Court must "assume for purposes of standing that an appellant will ultimately receive the relief sought . . . ." *Florida Audubon Soc. v. Bentsen*, 94 F.3d 658, 665 (D.C. Cir. 1996).

In this case, Plaintiffs have identified specific governmental actions that have caused them harm: the requirements for the use of PINs, RFIDs, or the intrastate

movement of animals. In addition, Plaintiffs have identified specific government funding of the projects that led to those injuries. Moreover, Plaintiffs have identified specific violations of law by the government, namely, USDA's issuance of the MOUs, VS memos, and other NAIS-related documents without going through proper procedures and without statutory authorization.

Plaintiffs seek a declaration that the AHPA violates several provisions of applicable law, e.g., due process because it is not rationally related to the NAIS program requirements. Plaintiffs also argue that USDA is illegally using its authority under the AHPA to enter into MOUs with MDA to incorporate illegal terms and conditions into those MOUs, i.e., terms requiring PINS, RFIDs, and animal tracking. Consequently, if this Court finds that USDA is exceeding its authority under the AHPA and that NAIS violates applicable law, Plaintiffs' injuries would be redressed. Therefore, Plaintiffs have standing to pursue their claims.

USDA, however, makes the bald statement in its motion to dismiss that even if this Court rules in Plaintiffs' favor, it would not resolve this matter because MDA could still require the use of RFIDs. In other words, USDA argues that a third party, i.e., MDA, is the cause of Plaintiffs' injuries and thus Plaintiffs' injuries are not redressable. This argument not only lacks merit, it demonstrates that USDA does not understand Plaintiffs' arguments on PINs, religious infringement and animal tracking.

To begin, "standing has been found 'where the record presented substantial evidence of a causal relationship between the government policy and the third-party conduct, leaving little doubt as to causation and the likelihood of redress." *Renal Physicians Ass'n v. U.S. Dept. of Health and Human Services*, 489 F.3d at 1275 (quoting

National Wrestling Coaches Ass'n v. Department of Education, 366 F.3d 930 (D.C. Cir. 2004)). Thus, even if MDA is the immediate cause of Plaintiffs' injuries (which Plaintiffs deny), standing exists because MDA's conduct has resulted from the relationship it has with USDA, i.e., the MOUs it has entered into with and the funding it has received from USDA.

In addition, the use of RFIDs is not the sole issue in this case. The other issues in this case involve mandatory PINs, mandatory placing of personal, private information into a national database that is accessible by federal, state and private parties, and infringement of Plaintiffs' religious beliefs. The use of PINs permanently connected to individuals' real property was not part of the TB program before USDA began to implement NAIS. *See* Thornsberry Affidavit, Exhibit T. These injuries literally could not occur without USDA's involvement since USDA is the entity that assigns the PINs and holds the data in its databases. And with respect to the religious claims, the "mark" in the Book of Revelations refers to a *universal* numbering system, so there is a significant difference between the impact of a state program and a federal program. Regardless of whether MDA might choose to require RFID tagging in the absence of USDA coercion and funding, MDA *could not* cause all of the injuries complained of by Plaintiffs without USDA's involvement.

Moreover, MDA's required use of PINs, RFIDs, animal tracking and religious infringement is being forced by the MOUs it has entered into with USDA, by the funding it has received from USDA, and by the two VS Memos. MDA lacks any statutory authority to require PINs, acquire and obtain personal, private data, or to infringe on religious freedoms. Consequently, in the absence of the MOUs, of USDA's funding, and

of the VS memos, MDA would not be allowed to cause the injuries Plaintiffs are suffering. Thus, it is USDA's relationship with MDA that is causing Plaintiffs' injuries.

Therefore, a ruling by this Court that the way USDA and MDA have implemented NAIS in the State of Michigan has been illegal would redress Plaintiffs' injuries.

Consequently, USDA's argument on the issue of standing is not well taken and its motion to dismiss should be denied.

III. USDA has violated the procedural requirements of the APA because the once "voluntary" NAIS program has now become mandatory.

In count one of their First Amended Complaint, Plaintiffs' argument consists of two points. First, the 2004 interim rule and the 2007 final rule are illegal because they purport to make NAIS "voluntary" yet as subsequent events have demonstrated, NAIS has become mandatory. Second, the separate documents referenced in paragraph 229 (i) – (xix) of the First Amended Complaint constitute legislative rules for which notice and comment were not provided and which demonstrate that although purportedly "voluntary," NAIS has become a mandatory program. Consequently, USDA has violated the procedural provisions of the Administrative Procedure Act ("APA") because the mandatory nature of NAIS has not been subjected to formal notice and comment.

When determining whether the notice and comment provisions of the APA apply, a court must narrowly construe any exceptions to the notice requirement. "In any event, in light of the important policy goals of 'maximum participation and full information,' any exceptions to the APA's notice and comment requirements must be narrowly construed." *Committee for Fairness v. Kemp*, 791 F.Supp. 888, 893 (D.D.C. 1992) (quoting *American Hospital Ass'n. v. Bowen*, 834 F.2d 1037, 1044 (D.C. Cir. 1987)). This is so because the APA does not impose "arbitrary hoops through which federal

agencies must jump without reason." *Sprint Corp. v. FCC*, 315 F.3d 369, 373 (D.C. Cir. 2003). Rather, the APA's notice and comment requirement "improves the quality of agency rulemaking by exposing regulations to diverse public comment, ensures fairness to affected parties, and provides a well-developed record that enhances the quality of judicial review." *Steinhorst Associates v. Preston*, 572 F.Supp.2d 112, 119 (D.D.C. 2008).

In this case, USDA alleged in the preambles to both the 2004 interim and 2007 final rules that NAIS was "voluntary." *See* USDA Administrative Record Nos. NAIS AR 1740, 1748. However, NAIS eventually became mandatory for, as explained below, USDA continued to issue "legislative" or "substantive" rules in the form of MOUs, draft strategic plans, program standards, strategies for implementation, user guides and business plans that imposed obligations on Plaintiffs. *See* First Amended Complaint, paragraphs 113-189 and 229 (i)-(xix). Even though these subsequent documents constitute legislative rules, none of them were subjected to the APA's notice and comment provisions.

Substantive or legislative rules have been described as those "affecting individual rights and obligations" for that is the "important touchstone for distinguishing those rules that may be binding 'or have the force of law." *Chrysler Corp. v. Brown*, 441 U.S. 281, 302 (1979), citing *Morton v. Ruiz*, 415 U.S. 199, 232 (1974). Because they are binding or have the force of law, legislative or substantive rules are subject to the APA's notice and comment provisions. As stated by the D.C. Circuit in *Sprint Corp. v. FCC*, 315 F.3d 369, 374 (D.C. Cir. 2003) "when an agency changes the rules of the game ... more than a clarification has occurred. To conclude otherwise would intolerably blur the line

between when the APA notice requirement is triggered and when it is not."

Consequently, new rules "that work substantive changes in prior regulations are subject to the APA's procedures." *Id*.

According to the D.C. Circuit, a rule is legislative and subject to the APA's notice and comment provision if it either meets the criteria set out in *American Mining Congress v. Mine Safety & Health Admin.*, 995 F.2d 1106, 1108 (D.C. Cir. 1993) or if its effect is binding, as set out in *General Elec. Co. v. E.P.A.*, 290 F.3d 377 (D.C. Cir. 2002). As set out in Plaintiffs' First Amended Complaint, the USDA's actions in implementing NAIS meet both of these tests.

In *American Mining Congress*, the D.C. Circuit held that agency action constitutes a legislative rule if any of the following four criteria are met:

- (1) whether in the absence of the rule there would not be an adequate legislative basis for enforcement action or other agency action to confer benefits or ensure the performance of duties,
- (2) whether the agency has published the rule in the Code of Federal Regulations,
- (3) whether the agency has explicitly invoked its general legislative authority, or
- (4) whether the rule effectively amends a prior legislative rule.

"If any one criterion is met, the agency action is a legislative rule subject to the notice-and-comment procedures." *Steinhorst Associates v. Preston*, 572 F.Supp.2d 112, 120 (D.D.C. 2008). In this case, USDA has explicitly invoked its alleged authority under the AHPA to develop and implement NAIS so as to require PINs, RFIDs and the tracking of animal movements on an *intrastate* basis. Moreover, the draft strategic plans, program standards, strategies for implementation, user guides and business plans were all noticed in the Federal Register and referenced the AHPA as their authority. Finally, each of the draft strategic plans, program standards, strategies for implementation, user guides and business plans amends the 2004 interim rule providing for the allegedly "voluntary" use

of PINs and animal identification numbers ("AINs"). Thus, the draft strategic plans, program standards, strategies for implementation, user guides and business plans all meet the test of *American Mining*.

USDA's actions also meet the definition of a legislative rule as described by the D.C. Circuit in the case of *General Elec. Co. v. E.P.A.*, 290 F.3d 377 (D.C. Cir. 2002). In *General Electric*, the plaintiffs challenged the EPA's issuance of guidance documents, without notice or comment, concerning risk assessment techniques for PCB disposal. The EPA argued, as USDA does in this case, that its guidance documents were not subject to notice and comment or judicial review. The D.C. Circuit disagreed, stating that a document is a legislative rule if it "has binding effects on private parties or on the agency." *Id.* at 382.

The Court reasoned that "an agency pronouncement will be considered binding as a practical matter if it either appears on its face to be binding or is applied by the agency in a way that indicates it is binding." *Id.* at 383 (internal citations omitted). *See also Appalachian Power v. E.P.A.*, 208 F.3d 1015, 1023 (D.C. Cir. 2000) ("[T]he entire Guidance, from beginning to end ... reads like a ukase. It commands, it requires, it orders, it dictates. Through the Guidance, EPA has given the States their "marching orders" and EPA expects the States to fall in line. . . ."); *McLouth Steel Products Corp. v. Thomas*, 838 F.2d 1317, 1321 (D.C. Cir. 1988). As explained below, all of the documents referred to in paragraph 229 (i)-(xix) of the First Amended Complaint satisfy the *General Electric* criteria, for clearly USDA has given MDA its "marching orders" to make NAIS mandatory in the State of Michigan.

As just one example, MDA clearly understood it would lose its "split state" status

if it did not commit to implementing PINs and RFIDs on cattle in Michigan. See Exhibit U, pg. 12. This sort of behavior is precisely what the *General Electric* court stated would make a so-called "guidance document" a binding legislative rule: "A document will have practical binding effect before it is actually applied if the affected private parties are reasonably led to believe that failure to conform will bring adverse consequences, such as ... denial of an application." *General Electric*, 290 F.3d at 383. *See also Appalachian Power Co.*, 208 F.3d at 1021.

Moreover, there is no dispute that USDA has included Plaintiffs' properties in its NAIS premises registration database, together with all of the other individuals in Michigan whose properties have been registered. Nor is there any dispute that the PINs assigned to Plaintiffs, in violation of their religious beliefs, was generated by USDA's system. USDA has taken specific actions pursuant to the documents listed in paragraph 229 (i)-(xix) of the First Amended Complaint that have binding consequences on the Plaintiffs.

Similarly, there is no dispute that USDA's documents have legal consequences for MDA. As set out in *Section II* of this Memorandum, USDA has used the 2002, 2005 and 2007 MOUs to require MDA to make PINs, RFIDs and animal tracking mandatory in the State of Michigan. *See supra* pgs. 9-19. And regardless of the dispute over whether USDA "mandated" these provisions to MDA, there is no dispute that MDA is now under legal obligations that are based on USDA's guidance documents and memos that set out the NAIS program. These NAIS requirements are also alleged in Plaintiffs' First Amended Complaint. *See* paragraphs 118-131, 142-147, and 183-189. Because USDA's documents have binding, legal consequences, they are legislative rules subject to judicial

review. See Appalachian Power Co., 208 F.3d at 1023 ("The short of the matter is that the Guidance ... is final agency action, reflecting a settled agency position which has legal consequences both for state agencies administering their permit programs" and private individuals).

In addition, USDA's actions since the 2007 final rule continue the implementation of NAIS in a way that has binding consequences for individuals and states. For example, the 2008 Business Plan (Exhibit B, attached) describes the following:

- (1) the long-term focus of NAIS is full traceability within the cattle industries (both beef and dairy);
- (2) NAIS standards apply to the administration of disease programs;
- (3) premises registration and animal identification will be between 50% to 70% from October 2008 to March 2009, and registration and identification will be between 70% to 100% by October 2009;
- (4) registrations and identifications will be at slaughter houses, markets, auction barns, livestock dealer facilities, fairgrounds, sporting events (like horseracing), import/export facilities and veterinarian clinics.

See Exhibit B. Thus, the 2008 Business Plan constitutes USDA's blue print for implementing NAIS on a nationwide basis.

Moreover, USDA's Veterinary Services office has issued two memoranda, both numbered VS Memo No. 579.19 (one of which was "rescinded" due to public outcry), which provide, in part, that veterinarians who visit a farm will be required to obtain and record the farmer's private data and to submit that data to the federal and state governments for use in the NAIS program.

The first VS Memo 579.19, effective September 2008, announced how USDA was going to implement its Veterinary Services' "cooperative animal disease program activities," stating that its purpose is to provide guidance to "VS personnel, state cooperators, and accredited veterinarians" on how to implement the premises registration

component of NAIS. See Exhibit V, pg. 1. MDA is a "cooperating state" and all private veterinarians that do TB testing are "accredited veterinarians." *See, e.g.,* 9 CFR 77.2.

The September 2008 VS memo identified the several actions, e.g., a vaccination, a diagnostic test, an epidemiologic investigation, a routine inspection or an appraisal, that would trigger the registration of a premises and the requirement to obtain and record an individual's personal, private data. If the person responsible for the premises "chooses not to complete the form to register his/her premises" then either a State or a federal animal health official or even a private veterinarian will "collect the defined data fields" which will then "be provided to the State so the records may be added electronically to the State's premises registration system." *See* Exhibit V, pg. 2.

The September VS Memo also provided that private veterinarians who collect the data will do so "for submission to the State or Federal office in that State for interfacing with the Allocator to obtain a PIN for the premises" and that the PIN will be "provided to the appropriate databases." Exhibit V, pgs. 2, 3. The September 2008 VS memo concludes by stating that from "the date of issuance of this VS Memorandum, all PINs issued in accordance with this policy will be included in all NAIS premises registration statistical summary reports." Exhibit V, pg. 3.

The September 2008 VS Memo raised such a public outcry it was rescinded by a "second" VS Memo 579.19, issued December 2008. *See* Exhibit W, attached. The December 2008 VS Memo reiterated its policy for using PINs in administering animal disease programs under the AHPA and specifically stated that PINs will refer to "all location identifiers issued for VS disease program activities;") that all locations where VS personnel conduct disease program activities "will be identified with a standardized

PIN;" and that private veterinarians "while not directly involved in the issuance of the PIN, will collect the defined data fields on official disease program forms ... for submission to the State or Federal office in that State." *See* Exhibit W, pgs. 1, 4.

As a result of USDA's guidelines, memos, and funding, Michigan has implemented mandatory premises registration and RFID tagging for cattle. Anecdotal reports indicate that individuals in other States that have gone in for required disease testing for their horses have been registered in the NAIS database, farmers have been denied disaster relief unless they were registered, and children have been barred from State fairs if their parents' properties were not registered. *See* McGeary Affidavit. Thus, USDA's implementation of NAIS has affected individuals' legal rights and obligations around the country.

USDA has used its funding of MDA's activities, its 2008 Business Plan and its issuance of the two VS Memos to make NAIS mandatory in Michigan and to impose binding obligations on States and individuals nationwide. *See supra* pgs. 9-19. These mandatory NAIS requirements have also been alleged in Plaintiffs' First Amended Complaint at paragraphs 154-158 and 172-182 (funding), 106-112 (2008 Business Plan), and 58-71 (VS memos). Finally, Plaintiffs have gone into painstaking detail how these documents (MOUs, funding, business plan and VS memos) relate to other corollary documents published by USDA in the federal register, and how taken as a whole it becomes apparent that NAIS has moved from a voluntary program to a mandatory program.

Specifically, these corollary documents relate to a draft plan and strategy guide (USDA Record Nos. NAIS AR 494, 497), cooperative agreements with third parties

(Exhibit X, attached), a user's guide (USDA Record No. NAIS AR 1307), an animal identification number (AIN) database (Exhibit Y, attached), the draft 2007 business plan (USDA Record No. NAIS AR 1449), implementation of a record system (Exhibit Z, attached), and use of the 840 numbering system for AINs (Exhibit AA, attached). Contrary to USDA's assertion that Plaintiffs' claims are "without any supporting allegations of fact," Plaintiffs' First Amended Complaint goes into painstaking detail how each of the referenced documents specifically refer to the AHPA for their authority and how each of the documents make NAIS mandatory. *See* First Amended Complaint at paragraphs 72-75 (draft plan), 76-78 (strategies), 79-82 (cooperative agreements), 83-85 (user's guide), 86-90 (AIN database), 91-96 (draft 2007 business plan), 97-100 (records system) and 101-105 (840 numbering system rule).

In *Appalachian Power Co.*, the D.C. Circuit addressed the abuses that would arise if an agency was allowed to avoid APA's procedural safeguards by utilizing informal methods:

Law is made, without notice and comment, without public participation, and without publication in the Federal Register or the Code of Federal Regulations. With the advent of the Internet, the agency does not need these official publications to ensure widespread circulation; it can inform those affected simply by posting its new guidance or memoranda or policy statement on its website. ... The agency may also think there is another advantage – immunizing its lawmaking from judicial review.

Appalachian Power Co., 208 F.3d at 1020. This is precisely what USDA has done with NAIS. It has issued multiple documents, from its Business Plans to the 2008 memos, and registered more than half a million people's properties in a federal database, using coercive methods on both state agencies and individuals. See Exhibit F. Yet now it seeks to evade judicial review altogether, just as it has evaded APA's procedural safeguards.

Consequently, NAIS, including the 2004 and 2007 rules and all of the supporting documents identified in paragraph 229 (i)-(xix) of the First Amended Complaint, has violated the notice and comment provisions of APA because this "voluntary" program has now become mandatory. Accordingly, this argument of USDA's motion to dismiss is not well taken and it should be denied.

IV. USDA's flexibility analysis violated the Regulatory Flexibility Act because it presumed NAIS was voluntary when in fact it became mandatory over time.

In Count Two of its First Amended Complaint, Plaintiffs allege that USDA failed to perform a proper economic analysis of NAIS because USDA presumed it was voluntary when in fact it has become mandatory. The mandatory nature of this program has been explained *supra* at pages 9-19, a time period that, significantly, has spanned the issuance of the 2004 interim and 2007 final rules. *See also* First Amended Complaint, paragraphs 40-189. Because USDA has not performed a proper economic analysis on the impact NAIS is having on Plaintiffs and other farmers nationwide, USDA's motion to dismiss is not well taken and it should be denied.

When an agency violates the Regulatory Flexibility Act ("RFA"), 5 U.S.C. 601 *et seq.*, the "reviewing court may remand [the rules] to the agency for failure to comply with the RFA." *National Coalition For Marine Conservation v. Evans*, 231 F.Supp.2d 119, 142 (D.D.C. 2002). To determine whether USDA has violated its obligation under the RFA, the standard of review "is the same as that under the APA, in that a court reviews the [RFA] for arbitrary and capricious action." *Id.* If a RFA violation is found, the Court may also "[defer] the enforcement of the rule against small entities unless the court finds that continued enforcement of the rule is in the public interest." *North Carolina Fisheries Ass'n, Inc. v. Daley*, 27 F.Supp.2d 650, 656 (E.D. Va. 1998).

In this case, USDA "certified" in its 2004 interim rule that NAIS would not have any economic impact on small businesses since the program was allegedly "voluntary," and thus it chose not to conduct an interim flexibility analysis. However, USDA's decision not to conduct a flexibility analysis, which was incorporated into the 2007 final rule, was arbitrary and capricious because NAIS became a mandatory program over time that has caused Plaintiffs a significant economic hardship. As described below, USDA's presumption that NAIS was voluntary and would not have any economic impact was tantamount to no analysis at all.

In the case of *North Carolina Fisheries Ass'n, Inc. v. Daley*, 27 F.Supp.2d 650 (E.D. Va. 1998), the issue was whether the Secretary of Commerce was arbitrary and capricious in his failure to consider the economic impact that fishing quotas would have on small businesses. In that case, the Court found that "the Secretary of Commerce acted arbitrarily and capriciously in failing to give any meaningful consideration to the economic impact of the 1997 quota regulations on North Carolina fishing communities." *Id.* at 652.

In *North Carolina Fisheries*, the Secretary used the same fishing quota for 1997 that he had previously used for 1996 and concluded that because the quota was the same for both years there would not be any significant economic impact. Hence, no flexibility analysis was conducted under the RFA. The Court was not persuaded by this argument and rejected it, stating that there was nothing in the administrative "record whatsoever showing that the federal government did any comparison between conditions in 1996 and 1997. A simple conclusory statement that, because the quota was the same in 1997 as it was in 1996, there would be no significant impact, is not an analysis." *Id.* at 652-653.

Thus, the rule was remanded back to the Secretary. Similarly, USDA wholly failed to address the changes in the program's implementation between 2004 and 2007 and beyond.

In Southern Offshore Fishing Ass'n v. Daley, 995 F.Supp. 1411 (M.D. Fla. 1998), the issue again was whether the Secretary of Commerce had acted arbitrarily by issuing new fishing quotas for sharks without performing an adequate flexibility analysis. The Draft Analysis stated, with what the Court characterized as "suspiciously cryptic terms," that "shark fishermen are nimble and adaptive in their fishing operations (that is, they pursue sharks in the season as well as other fish and at other times) and that the shark fishing season was historically too brief to permit a prudent fisherman to rely exclusively on annual revenue from shark fishing." *Id.* at 1434. Because of this "nimble adaptiveness" and "prudence" of shark fishermen, the Secretary concluded that no economic hardship would result and issued a final analysis "on the basis that shark fishermen can effortlessly transfer their fishing efforts to other fish stocks for which they might have (or may obtain) permits." *Id.* at 1435.

Needless to say, the Court rejected this analysis. "One can no more readily change a bass boat to a flats boat than change directed shark fishing paraphernalia to equipment for profitable tuna fishing. To suggest otherwise is to transgress the knowledge and common sense that are insinuated into reality; it is a contrivance that imports arrogance." *Id.* at 1436. Thus, the rule was remanded to the Secretary.

Plaintiffs' case is similar. USDA's opinion, stated in both the 2004 interim and 2007 final rules, that the NAIS program was voluntary and would not cause any significant economic impact on small farmers was likewise "not an analysis" and was a

self-serving statement that constituted nothing more than "a contrivance that imports arrogance." *See North Carolina Fisheries Ass'n, Inc. v. Daley*, 27 F.Supp.2d at 653; *Southern Offshore Fishing Ass'n v. Daley*, 995 F.Supp. at 1436.

USDA's opinion that NAIS would not have a significant economic impact on small farmers was wrong. USDA's actions have led to the mandatory implementation of NAIS requirements (specifically, the use of PINs and AINs that were authorized under the 2004 and 2007 rules) on Plaintiffs, causing a substantial economic impact on Plaintiffs and other individuals and small businesses in Michigan. *See* Affidavits of Schnieder, Keyworth First, Golimbieski First, and Niewendorp. Specifically, from 2004 to 2007, USDA took the following steps to make NAIS mandatory nationwide:

- 1. On May 6, 2005, USDA announced in the Federal Register that it had issued three documents, one of which was identified as a "Draft Strategic Plan" ("Draft Plan") and a second identified as a "Draft Program Standards" ("Draft Standards"). USDA stated that these two documents would set out its three-step plan for NAIS and that the program would become mandatory after an initial voluntary period; (See First Amended Complaint, paragraphs 72-73) (See also USDA Record Nos. NAIS AR 494, 497)
- 2. In April 2006, USDA issued a "Strategies for Implementation of NAIS," ("2006 Strategies") which alleged that although NAIS was voluntary at the federal level USDA's goal was 100% participation within three years, or by 2009; (See First Amended Complaint, paragraph 76) (See also USDA Record No. NAIS AR 655)
- 3. On July 28, 2006, USDA published in the federal register an announcement of the availability of "a revised cooperative agreement that [private] organizations may enter into" with USDA in order to "participate in the animal tracking database component" of NAIS. The purpose of the private cooperative agreements was to "facilitate the integration of private and State animal tracking databases into the NAIS. . . ;" (See First Amended Complaint, paragraphs 79-80) (See also Exhibit X, attached)
- 4. In November 2006, USDA issued a NAIS "User Guide" which again stated that NAIS was voluntary at the federal level but was quiet on numerical goals for participation. However, a concurrently issued announcement of funding for state implementation of NAIS still called for States to implement NAIS on the original timeline; (See First Amended Complaint, paragraph 83) (See also USDA Record No. NAIS AR 1307)

- 5. On February 28, 2007, USDA published a notice in the federal register that it would be conducting public meetings to discuss "the implementation of private/State animal identification number device distribution databases" for the AIN component of NAIS." The February 2007 notice also stated that the third component of NAIS, "animal tracking, is currently under development by APHIS and its State and industry partners. Industry, through private systems, and States will manage the animal tracking databases ... that maintain the movement records of animals." Finally, the February 2007 notice stated that "APHIS will continue to approve identification devices for official use in the NAIS" and that producers "will continue to need" to obtain a PIN before it can "obtain AIN tags;" (See First Amended Complaint, paragraphs 86-88) (See also Exhibit Y, attached)
- 6. On December 19, 2007, USDA issued a Business Plan that provided detailed "strategies and actions" to implement NAIS, including "a comprehensive animal-disease traceability infrastructure." The Business Plan also detailed all of the final agency actions that USDA/APHIS has taken, is currently taking, or will soon take to implement NAIS. Finally, the 2007 Business Plan stated the following: (a) "USDA will . . . implement immediate short term strategies, as outlined in this business plan;" (b) "Beginning with fiscal year 2008, this draft business plan will uniquely serve as a blueprint for the development of work plans associated with NAIS implementation cooperative agreement funding;" (c) "Each State, Tribe or Territory will be required to evaluate, describe, and identify animal disease traceability within their State, Tribe or Territory" and (d) "USDA will take steps to standardize data elements in existing programs. . . ." (See First Amended Complaint, paragraphs 91-94) (See also USDA Record No. NAIS AR 1449)

In addition to the steps identified above, Plaintiff has already explained how USDA through MOUs, financial aid, other documents and VS Memos, has made NAIS mandatory on all cattle owners in the State of Michigan. *See supra*, pages 9-19. Consequently, USDA violated RFA because it failed to conduct a proper flexibility analysis of the economic impact that NAIS would have because it believed NAIS was voluntary and would not cause any economic impact on small farmers.

USDA argues on page 30 of its motion to dismiss that the RFA does not apply to "the NAIS guidance documents, the MOUs, and the other documents" that Plaintiffs reference in their First Amended Complaint because those other documents do not constitute "legislative rules." However, Plaintiffs have already responded to this

argument. *See supra* pages 19-28. Because these other documents constitute legislative rules they should have been subjected to a flexibility analysis under the RFA. Since they were not so subjected, USDA violated the RFA.

Accordingly, USDA violated the RFA by failing to conduct a flexibility analysis.

USDA's assertion that NAIS was voluntary does not excuse it from complying with the RFA when its actions imposed mandatory requirements on Plaintiffs. Consequently, USDA's motion to dismiss is not well taken and it should be denied.

V. Each of USDA's actions violate the substantive provisions of the APA because none of them are rationally related to the health of animals or are authorized under the AHPA.

USDA argues on page 33 of its motion that the validity of its actions in this case "will be sustained so long as it is reasonably related to the purposes of the enabling legislation" under which it acted, i.e, the AHPA. For this proposition USDA cites the case of *Mourning v. Family Publ'ns Serv., Inc.*, 411 U.S. 356, 369 (1973). However, *Mourning* was limited by the United States Supreme Court in *Ragsdale v. Wolverine* World Wide, Inc., 535 U.S. 81, 122 S.Ct. 1155 (2002). The Ragsdale Court noted that despite the broad language of *Mourning* the "crucial distinction" in determining whether an agency's "rule" exceeds its authority is whether the agency's rule can in fact be "enforced through the statute's pre-existing remedial scheme and in a manner consistent with it." *Id.* at 92.

The D.C. Circuit has also disagreed with the argument that *Mourning* grants such virtually unlimited authority to agencies. As stated by the D.C. Circuit in *Colorado River Indian Tribes v. National Indian Gaming Com'n.*, 466 F.3d 134, 139 (D.C. Cir. 2006), "*Mourning v. Family Publications Service, Inc.*, the Commission tells us, states a canon

of statutory interpretation for general rulemaking provisions such as this--regulations promulgated pursuant to such statutes are valid so long as they are 'reasonably related to the purposes of the enabling legislation.' Judge Bates rejected this argument and so do we." (Internal citations omitted.) Thus, USDA cites to the wrong standard in its motion.

The proper analysis was laid down in *Colorado River*: "An agency's general rulemaking authority does not mean that the specific rule the agency promulgates is a valid exercise of that authority." *Id.* Whenever an agency does take an action, it is "bound, not only by the ultimate purposes Congress has selected, but by the means it has deemed appropriate, and prescribed, for the pursuit of those purposes." *Id.* at 139-140 (citing and quoting *MCI Telecomms. Corp. v. AT & T*, 512 U.S. 218, 231 n. 4, 114 S.Ct. 2223, 129 L.Ed.2d 182 (1994)). Thus, for USDA to defeat Plaintiffs' third claim, the AHPA must authorize MOUs that impose NAIS conditions on an *intrastate* basis and NAIS must be rationally related to animal health. As described below, neither of these elements is met.

Plaintiffs allege in Count Three of their First Amended Complaint that the AHPA deals with the importation, exportation and interstate movement of animals, yet USDA is imposing requirements on MDA that have to do with the *intrastate* movement and regulation of animals. Thus, USDA has exceeded its authority under the AHPA and thus has violated the substantive provisions of the APA.

For example, Plaintiffs allege at paragraph 124 of their First Amended Complaint that "the 2002 MOU required MDA to mandate 'official identification' on 'all domestic livestock that move from any premises' within these zones, including movement within disease-free areas within the State." At paragraph 143, Plaintiffs allege that "the 2005

MOU now required MDA to mandate "electronic identification and a movement permit for any cattle moved from premises in the Modified Accredited Zone."

Plaintiffs also allege in their third claim that there is no rational relationship between any of the NAIS requirements and the AHPA, i.e., placing an RFID in the ear of a cow will not make the cow healthier; requiring a farmer to obtain a PIN will not make the cow healthier either; or giving MDA hundreds of thousands of dollars to implement and staff such a program will not make cows healthier. *See, e.g.*, attached Affidavits of Veterinarians Melvin Massey (Exhibit BB), Glen Dupree (Exhibit CC) and Don McLeod (Exhibit DD). Moreover, MDA's State Veterinarian Steve Halstead has admitted that use of RFIDs will not eradicate TB. *See* Schneider Affidavit, pg. 2. For these reasons, each of the NAIS requirements violates the substantive provisions of the APA because the conduct involved (RFIDs, PINs, AINs, animal tracking) is not rationally related to the interest allegedly being protected (animal health).

Plaintiffs allege in paragraph 261 of their First Amended Complaint that "USDA has failed to provide a rational relationship between any of the documents identified in paragraph 229 [of the complaint] and the control and eradication of animal disease under the AHPA." In that same paragraph, Plaintiffs also allege that "USDA has failed to show any rational basis for applying a universal NAIS program to geographic areas where particular diseases are not found or for applying NAIS requirements to every livestock producer in the state when the AHPA authorizes the regulation of animal movements only 'between states' or when being 'imported' or 'exported." Thus, Plaintiffs have explained the basis of their substantive APA violation claim.

Accordingly, Plaintiffs have alleged that there is no rational relationship between

NAIS and animal safety, and that USDA is using its authority under the AHPA to impose intrastate requirements on the movement of animals within Michigan. For these reasons, USDA has violated the substantive provisions of the APA.

USDA, however, re-characterizes Plaintiffs' substantive APA claims to buttress its weak argument. For example, USDA has a caption on page 31 entitled "In Challenging the NAIS System *as a Whole*, Plaintiffs Fail to State a Claim Upon which Relief can be Granted Under the APA." (Emphasis added.) However, Plaintiffs are not challenging the NAIS program as a whole. *See, e.g.*, First Amended Complaint, paragraph 229 (i)-(xix). Instead, Plaintiffs are challenging each of the NAIS components, although by default the program as a whole is illegal.

USDA continues this pattern on page 32 when it first states "neither the final rule nor the guidance documents require the use of RFID tags for cattle located in Michigan" (emphasis added) and then insinuates that none "of the NAIS guidance documents issued by the USDA is targeted to the movement of livestock from one premises to another within Michigan." (Emphasis added). While it may be true that the 2007 final rule and the guidance documents (identified supra, page 26) themselves do not specifically refer to MDA, the MOUs and the funding MDA has received in this case do indeed refer to the required RFIDs and to animal tracking from one premises to another in Michigan. See, e.g., First Amended Complaint, paragraphs 118-131, 142-147, 183-189, 154-158, 172-182. Moreover, Plaintiffs' argument is more than RFIDs and animal tracking; it is also about PINs and religious infringement. Thus, USDA is not forthcoming in this portion of its argument when it refers only to RFIDs, the 2007 final rule, and some of the guidance documents.

On page 33 of its motion, USDA mixes apples and oranges when it argues that the MOUs it entered into with MDA "were not issued as part of the USDA's development of the NAIS system" and that it is "expressly authorized to enter into such memorandums and to make such grants." Plaintiffs concede that USDA has the authority to enter into MOUs with MDA under the AHPA, but that does not mean that USDA is authorized to put any provision it likes into the MOUs. For example, the AHPA does not authorize the imposition of NAIS requirements in any MOU (with *any* State) that apply only to intrastate activities, i.e., terms and conditions that impose RFIDs, PINs, AINs or animal tracking *within* a state.

Although each of the MOUs themselves specifically state they were issued under the authority of the AHPA, there is nothing in the AHPA that authorizes USDA to include terms and conditions in any MOU that regulates the *intrastate* movement of animals, let alone requiring the use of PINs, AINs, RFIDs and the tracking of animal movements *intrastate*. If there were such authority USDA would have cited to it. USDA's failure to cite to such authority is telling.

USDA claims in general terms that the AHPA authorizes it to implement NAIS. However, the only reference in the AHPA that allows USDA to implement NAIS is Section 8308, which states: "The Secretary may carry out operations and measures to detect, control, or eradicate any pest or disease of livestock (including the drawing of blood and diagnostic testing of animals), including animals at a slaughterhouse, stockyard, or other point of concentration." 7 U.S.C. 8308(a). This section also provides that USDA "shall compensate industry participants and State agencies that cooperate with the Secretary in carrying out operations and measures under subsection (a) for 100

percent of eligible cost relating to cooperative programs involving Federal, State, and industry participants to control diseases of low pathogenicity in accordance with regulations issued by the Secretary." 7 U.S.C. 8303(b)(2). Significantly, nothing in Section 8308 or in any other section of the AHPA authorizes USDA to impose a general program of *intrastate* tracking at individuals' expense.

Because the AHPA does not authorize a MOU to include NAIS terms on an *intrastate* basis, and because NAIS has nothing to do with the health of animals, USDA has exceeded its authority under the AHPA and has violated the substantive provisions of the APA. Consequently, USDA's motion to dismiss is not well taken and it should be denied.

VI. Plaintiffs' NEPA claim is valid because they are challenging individual, specific actions of USDA and because no NEPA analysis was performed, whether for the impact of RFIDs, of PINs, of tracking of animal movement or of religious infringement.

In order to demonstrate standing under the APA for violating the procedural requirements of NEPA, "a private individual must be 'adversely affected or aggrieved ... within the meaning' of NEPA by some final agency action." *Florida Audubon Soc. v. Bentsen*, 94 F.3d 658, 665 (D.C. Cir. 1996) (quoting *Lujan v. National Wildlife Federation*, 497 U.S. 871, 882-883, 110 S.Ct. at 3185, 3186 (1990)). In other words, "a procedural-rights plaintiff must show not only that the defendant's acts omitted some procedural requirement, but also that it is substantially probable that the procedural breach will cause the essential injury to the plaintiff's own interest." *Florida Audubon Soc. v. Bentsen*, 94 F.3d 658, 664-665 (D.C. Cir. 1996).

To demonstrate the sufficiency of their injury, Plaintiffs "must show that the omission or insufficiency of an EIS may cause [USDA] to overlook the creation of a

demonstrable risk not previously measurable (or the demonstrable increase of an existing risk) of serious environmental impacts that imperil [Plaintiffs'] particularized interest." *Id.* at 666. In other words, Plaintiffs do not have to prove that specific environmental impacts will occur, only that the agency's failure to review its action could cause it to overlook a demonstrable *risk* of environmental impacts. Moreover, because Plaintiffs are the object of USDA's failure to conduct an EIS and "they are the object of the action (or forgone action) at issue," there is "ordinarily little question that the action or inaction has caused [Plaintiffs] injury, and that a judgment preventing or requiring the action will redress it." *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 561-562, 112 S.Ct. 2130 (1992).

The injury under NEPA, however, need not be merely aesthetic or environmental, it can be economic as well. The D.C. Circuit has long recognized that "a party is not precluded from asserting cognizable injury to environmental values because his 'real' or 'obvious' interest may be viewed as monetary. It is established in this circuit that a party is not 'disqualif(ied)' from asserting a legal claim under NEPA because the 'impetus' behind the NEPA claim may be economic." *Realty Income Trust v. Eckerd*, 564 F.2d 447, 452 (D.C. Cir. 1977). *See also National Ass'n of Home Builders v. U.S. Army Corps of Engineers*, 417 F.3d 1272, 1287 (D.C. Cir. 2005). Indeed, parties that are "'motivated by purely commercial interests routinely satisfy the zone of interests test,' we have said, as '[c]ongruence of interests, rather than identity of interests, is the benchmark."

\*\*National Ass'n of Home Builders v. U.S. Army Corps of Engineers, 417 F.3d at 1287. See also Amgen, Inc. v. Smith, 357 F.3d 103, 109 (D.C. Cir. 2004) ("Parties motivated by purely commercial interests routinely satisfy the zone of interests test under this court's precedents.").

As Plaintiffs have explained, they are farmers and stewards of the land. They are the ones being regulated by NAIS, the ones that are supposed to obtain PINs for themselves, RFIDs for their cattle, and to track the movement of all their cattle. They are the ones whose private, personal data is being captured and transferred to a national database accessible by federal, State and private third parties. They are the ones whose religious freedoms are being infringed upon and, for Plaintiffs Alexander and Mast, their Old Order Amish tenets are also being violated. Thus, Plaintiffs are not only suffering economic injury, they are losing the privacy of their personal information and their agricultural way of life.

USDA's failure to perform any environmental impact statement or an environmental assessment means that USDA has failed to understand the environmental, social, and economic impacts NAIS is having on these Plaintiffs. This failure constitutes a procedural violation of NEPA for which Plaintiffs have standing to assert a claim. Therefore, USDA's motion to dismiss is not well taken and it should be denied.

Moreover, the impact on Plaintiffs as individuals has a direct impact on the environment. As farmers, Plaintiffs' daily actions impact the environment, from the preservation of topsoil to the cleanliness of surface water. *See, e.g.*, Goliembieski and Keyworth First Affidavits. The impact of NAIS, in particular the burdens placed on small farmers, has a direct impact on the use of agricultural lands.

USDA, however, argues that Plaintiffs' NEPA claim should fail because (1)

Plaintiffs challenge NAIS as a whole, and (2) USDA is not requiring the use of RFIDs in the State of Michigan. Both of these arguments lack merit.

To begin, Plaintiffs allege in their First Amended Complaint that USDA engaged

in several different actions, each of which constitutes "major federal action" for purposes of NEPA. See First Amended Complaint, paragraphs 52, 56, 64, 70, 74 (two actions), 77, 81 (multiple actions), 84, 89, 95, 99, 104, 111, 129, 145, 175, 187. Thus, Plaintiffs have challenged each of these actions, separately and individually. If this means that Plaintiffs are also challenging "NAIS as a whole" then that is the logical result of challenging each individual action on its own merits. In any event, USDA failed to perform any type of environmental study for any of these individual actions.

With respect to USDA's second argument, as explained *supra* at pages 9-19, USDA has indeed required the use of RFIDs in the State of Michigan or else it will revoke Michigan's "split state" status. *See* Exhibit U, pg. 12. Thus, USDA was required to perform the requisite environmental study prior to imposing this requirement on MDA. USDA's failure to do so results in a procedural violation of NEPA, for which Plaintiffs have stated a claim.

Moreover, Plaintiffs are alleging more than just the use of RFIDs in their First

Amended Complaint. They are also alleging loss of their personal, private data and are
alleging the infringement of their religious beliefs. USDA did not address either of these
arguments in its motion to dismiss. Because Plaintiffs' injuries are more than the
"economic" cost of purchasing and installing RFIDs, USDA was required to perform
some type of environmental study in order to comply with the procedural requirements of
NAIS.

Thus, USDA's motion to dismiss is not well taken and it should be denied.

VII. USDA violated RFRA because it has coerced and exerted significant influence over MDA's implementation of NAIS in Michigan.

Government is required to accommodate religious freedoms when it "itself, directly or indirectly, places a burden on religious exercise." *United Christian Scientists v. First Church of Christ, Scientist*, 829 F.2d 1152, 1166, n. 67 (D.C. Cir. 1987) (citation omitted). In analyzing whether USDA has violated the Religious Freedom Restoration Act ("RFRA"), 42 U.S.C. 2000bb-1 *et seq.*, the Court should begin its analysis "by identifying 'the specific conduct of which the plaintiff complains." *Am. Mfrs. Mut. Ins. Co. v. Sullivan*, 526 U.S. 40, 51, 119 S.Ct. 977 (1999) (quoting *Blum v. Yaretsky*, 457 U.S. 991,1004, 102 S.Ct. 2777 (1982)). If the conduct is that of a third party, the Court should then determine whether the federal agency has merely approved or acquiesced in a third party's conduct or whether the government has "exercised coercive power or has provided such significant encouragement, either overt or covert, that the choice must in law be deemed to be that of the [federal agency]." *Blum*, 457 U.S. at 1004, 102 S.Ct. 2777. *See also Village of Bensenville v. Federal Aviation Admin.*, 457 F.3d 52, 64 (D.C. Cir. 2006).

In this case, Plaintiffs complain of USDA's imposition of NAIS in the State of Michigan, a program that creates a substantial burden on Plaintiffs' religious beliefs. As alleged in their First Amended Complaint, NAIS burdens Plaintiffs' religious faiths by forcing them to accept technology, forcing them to interact with the world, threatens their existence as farmers, makes them take the "mark" of the beast, and deprives them of their dominion over animals. *See* First Amended Complaint, paragraphs 8-13, 15, 329-335.

As stated previously, USDA is causing Plaintiffs' injuries and is far more than a mere bystander in the implementation of NAIS in the State of Michigan. To the contrary, USDA has coerced and "provided such significant encouragement" to MDA that NAIS in

the State of Michigan is actually the action of USDA. *Blum*, 457 U.S. at 1004. Specifically, NAIS has been imposed on MDA via the use of the MOUs, the funding of MDA's NAIS program, the VS Memos and by assorted documents issued by USDA. *See supra*, pages 9-19. Thus, just as USDA's standing argument should fail because USDA is the cause of Plaintiffs' injuries, USDA's RFRA argument should fail for the same reason.

Moreover, USDA undisputedly plays a direct causal role not only in the assignment of *national* PINs to the Plaintiffs' property and their animals, but also in the holding of Plaintiffs' data in a *national* database. By definition, these infringements on the Plaintiffs' religious beliefs could not occur without federal government involvement.

In addition, there is no rational relationship between NAIS and the eradication of animal diseases. *See supra*, pages 33-38. Specifically, placing an RFID in an animal's ear will not make it less susceptible or more immune to a disease; neither will mandating a PIN for each Plaintiff eradicate disease. Moreover, as admitted in the 2004 interim rule, existing disease animal programs have nearly eradicated all TB in the State of Michigan because TB in Michigan is being caused by wild animals. Thus, NAIS is not the least stringent means of continuing this decline in animal disease in Michigan.

Consequently, the actions that are infringing on Plaintiffs' religious beliefs are the actions of both USDA and MDA. Therefore, USDA has violated the RFRA and its motion to dismiss is not well taken and it should be denied.

VIII. USDA has violated due process because the mandatory NAIS program as implemented in Michigan is different than the voluntary NAIS program that was noticed for comment.

USDA argues that it has not violated due process by yet again arguing that the NAIS requirements come not from it, but from MDA. USDA also argues that the 2007 final rule was subjected to notice and comment and that the rest of the NAIS documents are guidance documents, not legislative rules. All of these arguments have been dealt with previously and none of them have any merit.

With respect to USDA's argument that it is MDA, not USDA, who is requiring NAIS, that argument has been addressed *supra* at pages 9-19. Due to the MOUs, USDA's funding of MDA's NAIS program, the USDA VS Memos and the other USDA documents published in the Federal Register (identified *supra*, pages 26-27), it is apparent that USDA has imposed NAIS on MDA under the guise of TB eradication. Consequently, USDA was required to comply with the Fifth Amendment's due process safeguards.

With respect to USDA's argument that the 2007 final rule was subjected to notice and comment, that argument has also been addressed *supra* at pages 28-33. Specifically, the 2007 final rule claims that NAIS is "voluntary" when it is not. Thus, the mandatory nature of NAIS is not a "logical outgrowth" of the voluntary program that was noticed for public comment. See *National Min. Ass'n v. Mine Safety and Health Admin.*, 116 F.3d 520, 531 (D.C. Cir. 1997) ("No further notice and comment is required if a regulation is a "logical outgrowth" of the proposed rule."). *See also American Water Works Ass'n v. EPA*, 40 F.3d 1266, 1274 (D.C. Cir. 1994); *Anne Arundel County v. EPA*, 963 F.2d 412, 418 (D.C. Cir. 1992).

With respect to USDA's argument that all of the subsequent documents are "guidance" and not "legislative" rules, that argument has also been addressed. See *supra*,

pages 19-28. Because those subsequent documents impose mandatory requirements and

legal obligations, they should be construed as legislative and subjected to the APA's

notice and comment requirement. See General Elec. Co. v. E.P.A., 290 F.3d 377 (D.C.

Cir. 2002); Appalachian Power v. E.P.A., 208 F.3d 1015, 1023 (D.C. Cir. 2000);

McLouth Steel Products Corp. v. Thomas, 838 F.2d 1317, 1321 (D.C. Cir. 1988). The

fact that the subsequent documents were not subjected to notice and comment renders

them due process violations.

Consequently, USDA has violated the Due Process clause. Therefore, USDA's

motion to dismiss is not well taken and it should be denied.

IX. Conclusion.

For these reasons, USDA's motion to dismiss is not well taken and it should be

denied

Dated: March 23, 2009

Respectfully submitted,

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## CERTIFICATE OF SERVICE

I hereby certify that on March 23, 2009, I electronically filed PLAINTIFFS' REPLY TO DEFENDANT USDA'S OPPOSITION TO PLAINTIFFS' MOTION FOR LEAVE TO FILE FIRST AMENDED COMPLAINT with the Clerk of the Court using the CM/ECF system, which will send notification of such filing to the following:

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