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22 **UNITED STATES DISTRICT COURT**  
23 **FOR THE NORTHERN DISTRICT OF CALIFORNIA**  
**SAN FRANCISCO DIVISION**

24 CENTER FOR FOOD SAFETY; FOOD &  
25 WATER WATCH, INC.; HUMANE FARMING  
26 ASSOCIATION; PETER VAN GORDER; and  
ROBIN MANGINI;

27 *Plaintiffs,*

Case No. 4:20-cv-00256-JSW

**FIRST AMENDED COMPLAINT  
FOR DECLARATORY  
AND INJUNCTIVE RELIEF  
(ADMINISTRATIVE  
PROCEDURE ACT CASE)**

v.

SONNY PERDUE, in his official capacity as the Secretary of the U.S. Department of Agriculture; MINDY BRASHEARS, in her official capacity as the Deputy Under Secretary for Food Safety, U.S. Dept. of Agriculture; U.S. DEPARTMENT OF AGRICULTURE; and FOOD SAFETY AND INSPECTION SERVICE;

*Defendants.*

## **INTRODUCTION**

1. The plaintiff non-profit organizations, Center for Food Safety (CFS), Food & Water Watch, Inc. (FWW); the Humane Farming Association (HFA); FWW member Peter Van Gorder; and CFS and FWW member Robin Mangini (collectively, Plaintiffs) bring this action against the above-listed Defendants (individually and collectively Defendants) for their issuance of new rules that vitiate this country's food-safety inspection system for swine in slaughter plants, effectively turning it over to the slaughter companies themselves. Defendants' New Swine Inspection System (NSIS) rules, at 84 Fed. Reg. 52300 (October 11, 2019), also lift prior limits on slaughter-line speeds, allowing plants to move swine carcasses past government inspection-program personnel (hereinafter, inspectors or Program employees) at speeds that neuter the mandatory government's critical appraisal of swine carcasses and parts. Defendants approved these dangerous regulatory rollbacks, despite the fact that contaminated pork may cause as many as 1.5 million cases of foodborne illnesses, 7,000 hospitalizations, and 200 deaths in the United States each year.

2. As a result of all of these changes—which will essentially eliminate much of the government inspection of ninety-three percent of the domestic pork supply—the health and welfare of the individual plaintiffs, as well as that of CFS, FWW, and HFA's members, are seriously endangered by adulterated and unwholesome pork product. The individual plaintiffs and the groups' members have already been forced to spend money and will continue spending money in an attempt to avoid pork from animals slaughtered in plants likely to switch to NSIS.

3. The rules cannot stand and should be permanently enjoined. They are *ultra vires* and contrary to the Federal Meat Inspection Act (FMIA or the act), 21 U.S.C. §§ 602-695 (2018).

1 Further, they are otherwise contrary to constitutional right, power, privilege, or immunity and  
2 arbitrary and capricious, an abuse of discretion, or otherwise not in accordance with law in violation  
3 of the Administrative Procedure Act (APA), 5 U.S.C. §§ 551-559, 701-706 (2018).

4 **JURISDICTION**

5 4. This Court has jurisdiction under 28 U.S.C. § 1331 (2018), which grants federal district  
6 courts “original jurisdiction of all civil actions arising under the . . . laws . . . of the United States,”  
7 as well as the APA, 5 U.S.C. §§ 702 and 704, and 21 U.S.C. § 674 (2018), which establishes U.S.  
8 district court jurisdiction for all kinds of cases arising under the FMIA.

9 **VENUE AND INTRADISTRICT ASSIGNMENT**

10 5. Venue is proper in this Court under 28 U.S.C. § 1391 (2018) because this suit was filed in  
11 the district where Plaintiffs CFS, HFA, Peter Van Gorder, and Robin Mangini all reside, and there  
12 is no real property involved in the action. Plaintiff CFS resides in the County of San Francisco and  
13 has more than 15,500 members in Alameda, Contra Costa, Marin, Napa, San Francisco, San Mateo,  
14 and Sonoma counties. Plaintiff HFA resides in the County of Marin, with roughly 40,000 members  
15 in California and 12,000 residing in in Alameda, Contra Costa, Marin, Napa, San Francisco, San  
16 Mateo, and Sonoma counties.

17 6. Plaintiff Robin Mangini resides in Alameda County. Peter Van Gorder resides in  
18 Sonoma County. FWW has on office in Oakland and more than 9,400 dues-paying members in  
19 Alameda, Contra Costa, Marin, Napa, San Francisco, San Mateo, and Sonoma counties.

20 7. This Court may issue a declaratory judgment in this case pursuant to the Declaratory  
21 Judgment Act, 28 U.S.C. §§ 2201-2202 (2018), and may grant the requested relief pursuant the  
22 APA, 5 U.S.C. § 706, 28 U.S.C. § 1651(a) (2018), the Federal Rules of Civil Procedure, and  
23 pursuant to its inherent authority as a federal district court.

24 **PARTIES**

25 8. Plaintiff CFS is a national, non-profit, public interest and environmental advocacy  
26 organization that works to protect human health and the environment by curbing the use of harmful  
27 food production technologies and by promoting organic and other forms of sustainable agriculture.

1 CFS has approximately 950,000 members in the United States, with nearly 67,000 in California,  
2 including Plaintiff Robin Mangini. CFS's members were some of the hundreds of thousands of  
3 individuals that submitted public comments to the FSIS in 2018, urging the Defendants not to  
4 finalize the proposed NSIS rules.

5 9. Plaintiff FWW is a national, non-profit, public interest, consumer advocacy organization  
6 that works to ensure safe food and clean water. FWW presently has approximately 284,000 dues-  
7 paying members in the United States, with 33,000 in California, including Plaintiffs Peter Van  
8 Gorder and Robin Mangini. Its members were some of the hundreds of thousands of individuals  
9 that submitted public comments to the Defendants in 2018, urging them not to finalize the proposed  
10 NSIS rules.

11 10. Plaintiff HFA is a national, non-profit, animal protection and consumer advocacy  
12 organization—registered since 1985 as a tax-exempt charity under §501(c)(3) of the Internal  
13 Revenue Code—that works to advance the welfare of farm animals and protect the health of  
14 Americans who consume animal products. HFA's programs focus on protecting farm animals from  
15 cruelty, protecting the public from the risks of consuming adulterated and unwholesome animal  
16 products produced in slaughterhouses, restricting the misuse of antibiotics, hormones, and other  
17 chemicals used on industrial farms, and protecting the environment from the impacts of  
18 industrialized animal farming. HFA currently has approximately 250,000 members in the United  
19 States. In 2018, HFA submitted comments to the Defendants urging against adoption of the then-  
20 proposed NSIS rules which are the subject of this lawsuit.

21 11. Plaintiff Peter Van Gorder is a resident of Sebastopol, California. He is a dues-paying  
22 member of FWW. Before the challenged NSIS rules became effective, he has been a regular  
23 consumer of pork, and he intended to continue consuming unadulterated USDA-inspected pork  
24 product.

25 12. Plaintiff Robin Mangini is a resident of Piedmont, California. She is a dues-paying  
26 member of FWW and a member of CFS. Before the NSIS rules became effective, she has been a  
27

1 regular consumer of pork, and she intended to continue consuming unadulterated USDA-inspected  
2 pork product.

3 13. Defendant Sonny Perdue is the Secretary of the U.S. Department of Agriculture (USDA)  
4 and is given authority to administer or delegate the administration of the FMIA. 21 U.S.C. §§ 621,  
5 601(a).

6 14. Defendant Dr. Mindy Brashears is Deputy Under Secretary of Food Safety for the  
7 USDA, which has been delegated the administration of the FMIA by the USDA Secretary. 7  
8 C.F.R. § 2.18(a)(1)(ii)(B) (2019).

9 15. Defendant USDA is the U.S. department that houses Defendant FSIS.

10 16. Defendant FSIS's staff and senior management wrote and approved the final NSIS rules.  
11 The agency is responsible for ensuring that the nation's commercial supply of meat, poultry, and  
12 egg products is safe, wholesome, and correctly labeled and packaged for human consumption.

### 13 **STATUTORY BACKGROUND**

#### 14 **A. The Administrative Procedure Act**

15 17. The APA governs federal agency actions, including but not limited to its rulemaking.  
16 The purpose for the APA is to improve the administration of justice by prescribing fair  
17 administrative procedure.

18 18. Under the APA, a court is empowered to hold unlawful and set aside agency action for  
19 findings and conclusions that, among other reasons, are "contrary to constitutional right, power,  
20 privilege, or immunity[,] . . . arbitrary, capricious, an abuse of discretion, or otherwise not in  
21 accordance with law[,] . . . in excess of statutory jurisdiction, authority, or limitations, or short of  
22 statutory right[,] . . . and without observance of procedure required by law." 5 U.S.C. § 706(2).

#### 23 **B. The Federal Meat Inspection Act**

24 19. When Congress passed the FMIA in 1907 it declared that "[i]t is essential in the public  
25 interest that the health and welfare of consumers be protected by assuring that meat and meat food  
26 products distributed to them are wholesome, not adulterated, and properly marked, labeled, and  
27 packaged." 21 U.S.C. § 602. To achieve this goal, Congress authorized the Secretary of

1 Agriculture to issue regulations “to protect the health and welfare of consumers” from  
2 “[u]nwholesome, adulterated, or misbranded meat or meat food products[.]” *Id.* The reason was  
3 that “unwholesome, adulterated, mislabeled, or deceptively packaged articles can be sold at lower  
4 prices and compete unfairly with the wholesome, not adulterated, and properly labeled and  
5 packaged articles, to the detriment of consumers and the public generally.” *Id.*

6 20. Regulations promulgated under the FMIA establish an exhaustive scheme (detailed  
7 further below) requiring the federal government inspection of animals, or “amenable species,”  
8 including swine, before they are slaughtered (ante-mortem) as well as inspection of the carcasses  
9 after slaughter (post-mortem). Congress was so concerned with the need for federal oversight of  
10 slaughterhouses that it made it a criminal activity to slaughter animals or prepare or sell, transport,  
11 offer for sale or transportation, or receive for transportation, in commerce, products intended for  
12 food without a federal inspection of the animals and meat and meat products as prescribed by the  
13 law. *Id.* § 610.

#### 14 **GENERAL ALLEGATIONS**

15 21. As detailed more fully below, this case involves a radical transformation of the federal  
16 government’s food-safety inspection of swine and swine carcasses, affecting the pork product that  
17 ends up in grocery stores and restaurants around the country. Prior to the NSIS rules that are the  
18 subject of this suit, each and every swine was to first receive a mandatory government “inspection”  
19 prior to slaughter. As part of this process, federal government inspectors critically appraise animals  
20 for disease and food-safety issues. They must tag those animals with symptoms of disease so that  
21 they receive a more careful inspection, both before and after they are slaughtered separately from  
22 other animals. Federal inspectors also flag animals for residue and drug tests where necessary.  
23 Second, after slaughter, federal inspectors must critically appraise each animal’s head, viscera, and  
24 carcass on the lines where prepared. Third, federal inspectors condemn those animals and carcasses  
25 that are found to be adulterated. Finally, federal inspectors supervise the disposal of such  
26 condemned animals and carcasses.

1       22. Defendants' new NSIS rules, quite to the contrary, prevent federal inspectors from  
2 performing crucial inspection activities of swine prior to slaughter and of carcasses afterwards. The  
3 new rules thus curtail the ability of federal inspectors to detect serious food-safety problems, and  
4 they expose those who consume such pork products to serious health threats. Under this new  
5 regime, it is slaughter-plant *employees* rather than federal inspectors that are charged with  
6 identifying those animals with food-safety conditions, such as septicemia, before and after  
7 slaughter. Septicemia is linked to pathogens including *Salmonella*, a serious human pathogen in  
8 contaminated pork that Defendants estimate annually sickens 69,000 people.

9       23. Likewise, after slaughter, under these new rules, plant employees without minimum  
10 education or training (an estimated average of four hours' worth, according to the Defendants' cost-  
11 benefit analysis) are now solely charged with trimming carcasses that may have problems such as  
12 bruises from drug injections (thus avoiding the detection of illegal drug use) and parts contaminated  
13 with fecal material, ingesta, or milk. Fecal matter, ingesta, and milk can contain infectious agents  
14 that can be transmitted to humans. Under- or un-trained plant employees are now charged with  
15 identifying and notifying federal inspectors when swine carcasses show serious diseases such as  
16 pork measles, a rare but fatal disease caused by a tapeworm that is transmittable to humans. The  
17 rules also preclude inspectors from preventing the release of swine infected with animal diseases,  
18 such as Foot-And-Mouth Disease and African Swine Fever, back into the animal supply, thereby  
19 substantially increasing the risk of wide-spread mortality and increased prices, threatening the  
20 health and welfare of consumers.

21       24. This Complaint outlines how the new NSIS rules violate the FMIA and APA as follows.  
22 Section I details the comprehensive manner in which federal inspectors are required to perform  
23 their mandatory FMIA inspection duties by critically appraising all swine prior to slaughter. It also  
24 details how federal inspectors follow the FMIA's mandates to ensure that those animals showing  
25 symptoms of disease are slaughtered separately so that they receive a careful inspection when  
26 slaughtered. Federal inspectors also condemn those animals found adulterated and supervise their  
27 disposal pursuant to the FMIA. Section II details how federal inspectors under the former,

1 traditional inspection system followed the FMIA by critically appraising all carcasses and parts of  
2 swine after slaughter and condemning and supervising the disposal of carcasses and parts found to  
3 be adulterated. This section also details the training that allows federal inspectors to perform such  
4 critical and complicated tasks.

5 25. Section III details how the new NSIS rules abrogate the FMIA's mandatory ante-mortem  
6 inspection, separate-slaughter, and post-mortem inspection duties. The NSIS rules prevent and  
7 preclude federal inspectors from critically appraising animals prior to slaughter, and carcasses and  
8 parts afterwards. Section IV details how the NSIS rules also eliminate the act's condemnation and  
9 disposal-supervision requirements for federal inspectors. Section V details how the Defendants  
10 have rolled back pathogen standards at the same time, despite the fact that the NSIS rules amount to  
11 a massive change in the way inspections will be carried out in swine plants.

12 26. Section VI demonstrates how the Defendants have failed to provide any adequate basis  
13 whatsoever for the NSIS rules. The chief documents upon which the Defendants have relied were  
14 prepared in response to two 2013 reports by the USDA Office of Inspector General (OIG) and U.S.  
15 Government Accountability Office (GAO). They found the pilot program for the NSIS rules  
16 lacking in oversight and usable data. This section of the Complaint painstakingly charts how the  
17 Defendants' 2014 evaluation of the pilot program and revised 2018 risk assessment demonstrate  
18 that little has changed since these two audits. Defendants' data supporting the NSIS rules remains  
19 seriously lacking. Defendants misrepresent the data that they have made public. Defendants also  
20 fail to address numerous comments including those from expert peer reviewers. This section also  
21 shows that the changes in the inspection system under NSIS will not be as protective of, much less  
22 better for food safety compared to traditional inspection. This is perhaps no surprise, as Section VII  
23 shows how the rulemaking is very much the product of Defendants' undue bias.

24 27. Last, Section VIII of this Complaint details how Plaintiffs have been, are being, and will  
25 be harmed by the NSIS rules, before ultimately presenting Plaintiffs' seven claims for relief and  
26 relief requested.

27  
28

**STATEMENTS OF FACT**

**I. ANTE-MORTEM INSPECTION UNDER THE FMIA**

**A. Inspection**

28. The FMIA plainly and simply requires the “examination and inspection of *all* amenable species” before the animals are allowed to be slaughtered. 21 U.S.C. § 603 (emphasis added).

29. An “inspection” is a critical appraisal by a federal inspector. *Am. Fed’n of Gov’t Emps. v. Glickman*, 215 F.3d 7, 11 (D.C. Cir. 2000) (*AFGE*); 21 U.S.C. § 622 (including inspectors in a list of officers and employees “of the United States authorized to perform any of the duties prescribed by this chapter”).

30. Under traditional inspection, federal inspectors perform ante-mortem inspection to remove obviously-diseased animals from the food supply prior to slaughter and to identify animals that require a more extensive post-mortem examination by a government Public Health Veterinarian (PHV). Defendants consider it the first line of defense in protecting the public from potentially harmful meat products.

31. Inspectors observe all livestock at rest and in motion. FSIS Directive 6100.1 Rev. 2 (7/24/14) (FSIS Directive 6100.1) at X(B). This allows federal inspectors to catch certain abnormal signs, such as labored breathing, which are easier to detect while the animals are at rest, and others, such as lameness, which may not be detected until the animals are in motion.

32. Inspectors are supposed to observe the overall condition of each animal, including the head—with attention to the eyes—legs, and body; the degree of alertness, mobility, and breathing; and whether there are any unusual swellings or any other abnormalities. *Id.* at X(C).

33. Inspectors are to “pass” for slaughter the livestock that do not show signs of diseases or abnormalities and thus are fit for slaughter for human consumption. *Id.* at X(D).

34. When inspectors find animals showing signs of abnormalities or diseases, they direct the establishment to set the affected animals apart into separate “U.S. Suspect” pens for further inspection by the PHV. *Id.* at X(E).



1 permission for the removal of such animal from the local, State or Federal livestock sanitary official  
2 having jurisdiction.” *Id.* § 309.2(p).

3 41. In accordance with these provisions, when inspectors find animals showing signs of  
4 abnormalities or diseases under traditional ante-mortem inspection, they direct the slaughter  
5 establishment to set the affected animals apart into separate pens, called “U.S. Suspect” pens, for  
6 further examination by the government PHV. FSIS Directive 6100.1 at X(E). Government PHVs  
7 are to examine and take the temperature (or direct establishment employees to take the  
8 temperature), as necessary, of abnormal or diseased livestock. *Id.* at XII(A). PHVs are to designate  
9 livestock as “U.S. Suspect” by applying or directing establishment employees to attach a serially  
10 numbered “U.S. Suspect” tag to livestock that:

- 11 1. Have any disease or condition that may cause the PHV to condemn the carcass or part  
12 of a carcass when inspected post-mortem; and
- 13 2. Are presented as non-ambulatory disabled.

14 *Id.* at XII(B).

15 42. Inspectors are also responsible for the detection and reporting of Foreign Animal  
16 Diseases (FADs) and reportable conditions. FSIS Directive 6000.1 Rev. 1 (8/03/06) (FSIS  
17 Directive 6000.1) at VII(A)-(B). FADs can significantly affect human health or animal production  
18 and can be costly to the livestock growers to control and eradicate, and thus also for consumers.  
19 Diseases such as classical swine fever (hog cholera), Foot-And-Mouth disease, and African Swine  
20 Influenza can cause high death rates or severe illness and production losses. This loss of  
21 productivity can increase the cost of food products obtained from those animals. Also, the  
22 quarantine required to control any disease outbreaks can stop all animal movement and trade for a  
23 significant period of time.

24 43. A few of the signs when observed during ante-mortem inspection pointing to a FAD  
25 include sudden lameness and the existence of central nervous system conditions. *Id.* at VI(C).

26 44. Inspectors are to deem such animals “U.S. Suspects” or “U.S. Condemned,” as  
27 appropriate, and report them to the FSIS District office if reportable or a FAD. *Id.* at VII(A)-(B).

1 45. When animals are identified as U.S. Suspect for chemical residues, the PHV is to collect  
2 required samples (of muscle, liver, and kidney) and test these animals for chemical residues during  
3 post-mortem inspection. FSIS Directive 10,800.1 Rev. 1 (3/3/14) (FSIS Directive 10,800.1) at Ch.  
4 4. I(A). Also, such testing for drug residues is required when post-mortem findings may indicate  
5 antimicrobial treatment or violative chemical use or exposure, even if the carcass and its parts have  
6 been condemned. *Id.* at Ch. 3. I(B).

7 46. Such testing is required because chemical residues and antimicrobial use can affect the  
8 plant's entire swine supply, regardless of whether an individual carcass is condemned.

9 47. Some of the pathologies and conditions that are supposed to merit the retention and  
10 testing of carcasses for chemical residues include the presence of injection sites, injury, or  
11 inflammatory conditions, even if these are not condemnable conditions. *Id.*

12 48. Under the agency's existing regulations, livestock suspected of having been treated with  
13 or exposed to any substance that may impart a biological residue which would make the edible  
14 tissues unfit for human food or otherwise adulterated shall be identified at official establishments as  
15 "U.S. Condemned." 9 C.F.R. § 309.16(a). All carcasses and edible organs and other parts thereof,  
16 in which are found any biological residues which render such articles adulterated, shall be marked  
17 as "U.S. Condemned" and disposed of in accordance with 9 C.F.R. §§ 314.1 or 314.3. *Id.* §  
18 309.16(b).

### 19 **C. The Condemnation of Animals**

20 49. In addition to the inspectors' ante-mortem-inspection duties to examine and inspect  
21 animals and ensure that suspect animals are identified as such, slaughtered separately, and given a  
22 "careful" post-mortem inspection, federal inspectors must condemn and dispose of animals that are  
23 found to be dead, dying, or diseased.

24 50. Under existing regulations, "[l]ivestock found to be dead or in a dying condition on the  
25 premises of an official establishment shall be identified as U.S. Condemned and disposed of in  
26 accordance with § 309.13." 9 C.F.R. § 309.3(a) (2019). "Livestock plainly showing on ante-  
27 mortem inspection any disease or condition that . . . would cause condemnation of their carcasses

1 on post-mortem inspection shall be identified as U.S. Condemned and disposed of in accordance  
2 with § 309.13.” *Id.* § 309.3(b)

3 51. “U.S. Condemned” means “the livestock so identified has been inspected and found to be  
4 in a dying condition, or to be affected with any other condition or disease that would require  
5 condemnation of its carcass.” *Id.* § 301.2(b).

6 52. According to FSIS directive, “[i]n accordance with 9 CFR 309.3(a)-(e), PHVs are to  
7 identify livestock as ‘U.S. Condemned’ by directing that a serially numbered metal ‘U.S.  
8 Condemned’ ear tag . . . be applied to each animal that is condemned on ante-mortem inspection.”  
9 FSIS Directive 6100.1 at XIV(A).

10 53. PHVs do not have to apply the “U.S. Condemned” tag but are to observe that the “U.S.  
11 Condemned” tag is applied by an establishment employee. *Id.* at XIV(B).

12 54. Federal inspectors may identify and tag dead animals as “U.S. Condemned.” *Id.* at  
13 XIV(C). Only government PHVs may condemn live animals. *Id.*

14 55. “U.S. Condemned” tags are placed on:

- 15 a) Livestock that are dead or in a dying condition when offered for slaughter on the  
16 premises of the official establishment;
- 17 b) Livestock that are plainly showing on ante-mortem inspection any disease or condition  
18 that would cause the PHV to condemn the carcass when inspecting postmortem; and
- 19 c) Any swine have a temperature of 106°F or higher.

20 *Id.* at XIV(D).

21 56. Only federal inspectors may remove U.S. Condemned tags. 9 C.F.R. § 309.13(a) (2019).

22 57. “Livestock identified as U.S. Condemned shall be killed by the official establishment, if  
23 not already dead.” *Id.* “Such animals shall not be taken into the official establishment to be  
24 slaughtered or dressed[.]” *Id.* “The official U.S. Condemned tag shall not be removed from, but  
25 shall remain on the carcass . . .” until it is disposed of. *Id.*

1 **II. POST-MORTEM INSPECTION UNDER THE FMIA**

2 **A. Inspection**

3 58. The FMIA similarly requires that all amenable species' carcasses receive inspection after  
4 slaughter:

5 For the purposes hereinbefore set forth the Secretary shall cause to be made by inspectors  
6 appointed for that purpose a postmortem examination and inspection of the carcasses and  
7 parts thereof of all amenable species to be prepared at any slaughtering, meat-canning,  
salting, packing, rendering, or similar establishment in any State, Territory, or the District of  
Columbia as articles of commerce which are capable of use as human food[.]

8 21 U.S.C. § 604. The FMIA defines the term "prepared" to mean "slaughtered, canned, salted,  
9 rendered, boned, cut up, or otherwise manufactured or processed." *Id.* § 601(l). Thus, when each  
10 swine is slaughtered and its carcasses and parts are prepared, it needs to be examined and inspected.

11 59. Under Defendants' still existing regulations, "[a] careful post-mortem examination and  
12 inspection shall be made of the carcasses and parts thereof of all livestock slaughtered at official  
13 establishments." 9 C.F.R. § 310.1(a) (2019).

14 60. Defendants' regulations define "carcass" as "[a]ll parts, including viscera, of any  
15 slaughtered livestock." *Id.* § 301.2 (2019).

16 61. Therefore, the FMIA and its regulations require that federal inspectors critically appraise  
17 all swine carcasses and parts, as part of the mandatory post-mortem inspection.

18 62. Defendants' inspection-system rules dictate how establishments must accommodate  
19 federal government post-mortem inspections, including setting how fast slaughter lines can operate,  
20 also known as "line speeds;" the numbers of inspection stations that establishments must set up,  
21 which dictates how many inspectors must be on each line inspecting carcasses; and the maximum  
22 number of carcasses to be inspected by each inspector, as measured by heads per hour. *See*  
23 *generally, Id.* § 310.1.

24 63. Under traditional inspection, there must be at least three inspection stations for market  
25 hogs, one each for the head, viscera (internal organs), and carcass. If plants increase their  
26 production, the agency increases the number of inspectors at the three stations. *Id.* § 310.1(b)(3),  
27  
28

1 Table 4 (2019). The largest plants have as many as seven inspectors on the slaughter lines, with  
2 three inspectors at the head and viscera station and one at the carcass station. *Id.*

3 64. These line speeds were set based on work-measurement studies that evaluated the  
4 effectiveness of inspectors under the line speeds. 47 Fed. Reg., 33673 (Aug. 4, 1982). Industrial  
5 engineers calculated the time required to complete the head-, viscera-, and carcass-inspection tasks.  
6 *Id.* Fully trained and qualified food inspectors were timed while carrying out the inspections, and  
7 these times were adjusted to allow for the observed work pace and job difficulty, other job-related  
8 activities, and other adjustments to ensure that ninety-five percent of the normal adult working-age  
9 population would be able to properly perform the work without undue stress. *Id.*

10 65. Under traditional inspection, prior to the final NSIS rules and pursuant to the FMIA,  
11 online federal inspectors organoleptically inspect (using sight, touch, and smell) each carcass's  
12 head, carcass, and viscera. FSIS Directive 6100.2. Rev. 1 (10/24/16) (FSIS Directive 6100.2) at  
13 Ch. 2 (I)(F).

14 66. Most important for the organoleptic detection of disease is the examination of the  
15 lymphatic system, which consists of vessels throughout all tissues which lead to lymph nodes.  
16 When disease, organisms, or toxins begin to spread around the animal's body, the lymph nodes are  
17 among the first tissues to become visibly affected. Septicemia is one particular food-safety hazard  
18 that is detected by palpating lymph nodes, as multiple enlarged lymph nodes are signs of this  
19 serious condition. Since these lymph nodes trap microorganisms, they also are sliced (cervical) or  
20 palpated (intestinal) to detect lesions that encapsulate Mycobacterium Tuberculosis.

21 67. In general, when abnormalities are observed while performing post-mortem inspection, the  
22 following actions must take place: if the disease or condition of the head, organ, or carcass is  
23 localized, the inspector requests establishment employees to trim the affected tissues and the carcass  
24 is passed for food.

25 68. If the disease or condition is generalized or affects the majority of the head, organ, or  
26 carcass, the carcass is retained for veterinary determination (*i.e.*, "disposition") of whether it should be  
27 condemned, with or without lab confirmation. FSIS Directive 6100.2 at Ch. VII (I)(C), (II)(F), III(C).

1 Under Defendants' regulations and a directive, "each carcass, including all detached organs and  
2 other parts, in which any lesion or other condition is found that might render the meat or any part  
3 unfit for food purposes, or otherwise adulterated" is tagged as "U.S. Retained," and the tag is not  
4 removed until final inspection. 9 C.F.R. § 310.3; FSIS Directive 6100.2 at Ch. IV (A)-(C),  
5 V(A)(1), (2).

6 69. More specifically, head inspection requires observing the head and cut surfaces, including  
7 the eyes, fat, cheek muscles, and other tissues for abnormalities. *See* FSIS Directive 6100.2 at Ch.  
8 VII (I)(A)(1). The right and left mandibular (jaw) lymph nodes are incised (cut) and observed. *See*  
9 at Ch. VII (I)(A)(2). When abnormal conditions are observed or when the inspector has disposition  
10 questions, the inspector retains the head, viscera, and carcass for PHV disposition. *Id.* at Ch. VII  
11 (I)(C)(1). Inspectors condemn abnormal or diseased tissue and verify that the establishment trims  
12 the affected tissues if the disease or condition of the head is localized. *Id.* at Ch. VII (I)(C)(2).

13 70. Viscera inspection includes observing the eviscerated carcass, viscera, and parietal (top)  
14 surface of the spleen; observing and palpating the mesenteric lymph nodes; palpating the portal  
15 lymph nodes; observing the curved surface of lungs; palpating the bronchial lymph nodes; observing  
16 the mediastinal lymph nodes; turning lungs over and observing the flat surfaces; observing the heart;  
17 observing curved surface of liver; and turning the liver over and observing the flat surface. *See id.*  
18 at Ch. VII (II)(A)(1)-(7). When abnormal conditions are observed or when the inspector has  
19 disposition questions, the inspector retains the head, viscera, and carcass for PHV disposition. *Id.* at  
20 Ch. VII (II)(F)(1)-(2). Federal inspectors condemn abnormal or diseased tissue and verify that the  
21 establishment trims the affected tissues if the disease or condition of the head is localized. *Id.*

22 71. Carcass inspection involves observing the back, front, and inside of the carcasses,  
23 including all cut surfaces, body cavities, and the lumbar and neck regions. *See id.* at Ch. VII  
24 (III)(A)(1)-(2). This may involve observing it in a mirror, and grasping, turning, or observing both  
25 sides of the kidneys. *See id.* If abnormal conditions are observed on but do not require veterinary  
26 disposition, the inspector can have the establishment employee properly trim the carcass. *See id.* at  
27 Ch. VII (III)(C)(2), (D). Other abnormal conditions require retention for veterinary disposition,  
28

1 including bruises that show signs of infection or that may indicate an injection site that would  
2 require a residue hold and test for confirmation. *See id.* at Ch. VII (III)(C)(1).

3 **B. Condemnation and Disposal**

4 72. Like with ante-mortem inspection, inspectors have a duty to condemn carcasses found to  
5 be adulterated: “inspectors shall label, mark, stamp, or tag as ‘Inspected and condemned’ all  
6 carcasses and parts thereof of animals found to be adulterated[.]” 21 U.S.C. § 604.

7 73. Defendants’ regulations provide that “[e]ach carcass or part which is found on final  
8 inspection to be unsound, unhealthful, unwholesome, or otherwise adulterated shall be  
9 conspicuously marked, on the surface tissues thereof, by a Program employee at the time of  
10 inspection, as ‘U.S. Inspected and Condemned.’” 9 C.F.R. § 310.5 (2019). Condemned detached  
11 organs and other such parts that cannot be so marked shall be placed immediately in trucks or  
12 receptacles which shall be kept plainly marked “U.S. Condemned,” in letters not less than two  
13 inches high. *Id.*

14 74. “All condemned carcasses and parts shall remain in the custody of a Program employee  
15 and shall be disposed of as required in the regulations in part 314 of this subchapter at or before the  
16 close of the day on which they are condemned.” *Id.*

17 75. Defendants’ inspectors must be able to certify that all condemned product is properly  
18 destroyed. To assure this, Defendants have deemed that security of condemned product is essential.  
19 All condemned product must be kept in custody of inspection personnel until it is destroyed for  
20 food purposes on or before the close of the day on which it was condemned.

21 76. The disposal of condemned carcasses requires an inspector to seal the rendering tank  
22 when the plant uses that method of disposal or to be present when destroyed by incineration or  
23 denaturing. *Id.* §§ 314.1(a)(1), 314.3(a) (2019).

24 77. And, inspectors have a duty to supervise the destruction of “all carcasses and parts  
25 thereof thus inspected and condemned[.]” as they “shall be destroyed for food purposes by the said  
26 establishment in the presence of an inspector, and the Secretary may remove inspectors from any  
27  
28

1 such establishment which fails to so destroy any such condemned carcass or part thereof . . . .” 21  
2 U.S.C. § 604.

3 78. This is not a mere formality, as the risks of mixing adulterated and passed product are  
4 real, especially since many swine parts are edible. In the past, Defendants have issued  
5 noncompliance reports such as the following one issued to an establishment that violated 9 C.F.R. §  
6 314.2 for its failure to properly dispose of adulterated carcasses and parts and keep them separate  
7 from edible product:

8 at approximately 0615 in the Chitterling Room, I observed the Inedible Grinder overflow  
9 guts, ingesta, and fecal material onto the floor to the bung trimming table, and table with  
10 boxes for the bungs. This Box table & Bung table is an Edible product area, and the area  
must be separated [*sic*] and protected from inedible rendering product. I applied U.S. Reject  
tag #630694334 to the area and informed that the area was rejected. . . .

11 79. In short, to protect consumers from adulterated pork, the FMIA requires federal inspectors  
12 to inspect each and every carcass and part after the swine is slaughtered, condemn all carcasses and  
13 parts found adulterated, and supervise the disposal of such carcasses and parts.

#### 14 **C. Training for FMIA Inspection**

15 80. In order for inspectors to adequately perform all of these complicated inspection  
16 activities, the agency has established an intensive training program. PHVs must undergo a nine-  
17 week training program. Three weeks of this is classroom training. The other six weeks consist of  
18 three weeks spent in the plant environment with an assigned mentor and three weeks of Food Safety  
19 Regulatory Essentials training. These training topics are located here: <http://goo.gl/h74jzN>. Other  
20 newly hired federal inspectors must undergo training covering at least twelve topics, including one  
21 on post-mortem and one on ante-mortem inspection. The training topics are located at  
22 [http://www.fsis.usda.gov/wps/portal/fsis/topics/inspection/workforce-training/regional-on-site-](http://www.fsis.usda.gov/wps/portal/fsis/topics/inspection/workforce-training/regional-on-site-training/slaughter-inspection-training)  
23 [training/slaughter-inspection-training](http://www.fsis.usda.gov/wps/portal/fsis/topics/inspection/workforce-training/regional-on-site-training/slaughter-inspection-training). More experienced Consumer Safety Inspectors have more  
24 extensive training. These training topics are located at  
25 [http://www.fsis.usda.gov/wps/portal/fsis/topics/inspection/workforce-training/regional-on-site-](http://www.fsis.usda.gov/wps/portal/fsis/topics/inspection/workforce-training/regional-on-site-training/inspection-methods)  
26 [training/inspection-methods](http://www.fsis.usda.gov/wps/portal/fsis/topics/inspection/workforce-training/inspection-methods), [http://www.fsis.usda.gov/wps/portal/fsis/topics/inspection/workforce-](http://www.fsis.usda.gov/wps/portal/fsis/topics/inspection/workforce-training/regional-on-site-training/export-verification)  
27 [training/regional-on-site-training/export-verification](http://www.fsis.usda.gov/wps/portal/fsis/topics/inspection/workforce-training/regional-on-site-training/export-verification), and

1 [http://www.fsis.usda.gov/wps/portal/fsis/topics/inspection/workforce-training/regional-on-site-](http://www.fsis.usda.gov/wps/portal/fsis/topics/inspection/workforce-training/regional-on-site-training/Humane+Handling+of+Livestock)  
2 [training/Humane+Handling+of+Livestock.](http://www.fsis.usda.gov/wps/portal/fsis/topics/inspection/workforce-training/regional-on-site-training/Humane+Handling+of+Livestock)

### 3 **III. THE LACK OF INSPECTION UNDER THE NEW SWINE INSPECTION SYSTEM**

4 81. On February 1, 2018, Defendants proposed rules implementing a new inspection system,  
5 known as NSIS, for market hogs. 83 Fed. Reg. 4780. The rules were finalized with some  
6 modifications on September 17, published in the Federal Register on October 1, and became  
7 effective on December 2, 2019. 84 Fed. Reg. 52300.

8 82. When Defendants issued the proposed rules, they also issued a Draft Compliance  
9 Guideline, titled “Compliance Guideline for Training Establishment Employees under the New  
10 Swine Slaughter Inspection System,” which copied major parts of the current PHV training guide.  
11 The final guideline (Compliance Guideline), finalized in September, 2019, and located at  
12 [https://www.fsis.usda.gov/wps/wcm/connect/887590cf-82ab-4413-835e-1e210fcad8ba/training-](https://www.fsis.usda.gov/wps/wcm/connect/887590cf-82ab-4413-835e-1e210fcad8ba/training-establishment-sorters-nsis.pdf?MOD=AJPERES)  
13 [establishment-sorters-nsis.pdf?MOD=AJPERES](https://www.fsis.usda.gov/wps/wcm/connect/887590cf-82ab-4413-835e-1e210fcad8ba/training-establishment-sorters-nsis.pdf?MOD=AJPERES), is the only guidance that the agency has provided  
14 to slaughter plants on how to train employees to sort carcasses with condemnable conditions.  
15 Defendants have only published the guidance in English and do not plan to translate it into any  
16 other language.

17 83. Defendants expect that the new NSIS rules will be adopted by plants producing ninety-  
18 three percent of U.S. slaughtered swine and that all such plants will adopt the system within five  
19 years. 84 Fed. Reg. at 52322, 52334.

20 84. According to the final rules’ preamble, overall, when all 35 establishments that are  
21 expected to convert to NSIS do so, the agency will require 147 fewer full-time employees, a 40%  
22 reduction for swine slaughter inspection. *Id.* at 52336.

23 85. As detailed in the following subsections, the NSIS rules are a dramatic rollback in federal  
24 inspection. They preclude and prevent federal inspectors from critically appraising animals during  
25 ante-mortem inspection and carcasses during post-mortem inspection, delegating these  
26 responsibilities to plant employees with no mandatory training or educational requirements. Plant  
27 employees are guided by nothing more than the nonbinding compliance guideline written for  
28

1 qualified veterinarians. The new rules prevent and preclude federal inspectors from condemning  
2 adulterated animals, carcasses, and parts, and supervising the disposal of such carcasses and parts.  
3 The rules also revoke the Defendants' current standards for microbiological pathogens *E. coli* and  
4 *Salmonella*. Defendants' justification for all of these rule changes has been woefully inadequate,  
5 including the insufficient data and analysis presented in their evaluation of NSIS-pilot projects and  
6 risk assessment, both of which do not support Defendants' contentions about the new rules. Not  
7 only were Defendants' responses to public comments inadequate, but also, they completely failed to  
8 respond to comments from experts who peer reviewed the risk assessment.

9 **A. Federal Inspectors Prevented and Precluded from Ante-Mortem Inspection**

10 86. For plants that opt in—and Defendants project that this will be forty slaughter plants,  
11 producing ninety-three percent of the domestic pork supply—the NSIS creates a new mandatory  
12 inspection system where federal inspectors are no longer responsible for the ante-mortem  
13 examination and inspection of all market hogs for visible signs of condemnable diseases or  
14 conditions while they are at rest and in motion.

15 87. Instead, these slaughter plants are to largely police themselves, with under- or un-trained  
16 plant employees first segregating animals that appear to be abnormal, unhealthy, or have  
17 condemnable diseases or conditions from those that do not. Defendants refer to this as “sorting.”  
18 *See new 9 C.F.R § 309.19(a)*, at 84 Fed. Reg. at 52345.

19 88. Under NSIS, slaughter-plant employees are tasked with finding and removing swine with  
20 “condemnable conditions” by observing animals in motion and at rest, evaluating animals'  
21 alertness, locomotion, bodily conditions, bodily functions, and skin color. Compliance Guideline at  
22 5, 7-8. Based on their own alleged “familiar[ity] with the behavior of normal healthy market hogs,”  
23 plant employees are to look for signs of inactivity, lack of awareness, “abnormal” skin color,  
24 “irregular” respiration, frothy mouth or nasal discharges, and an inability to move, as these are signs  
25 that the animals are dying. *Id.* at 8. Plant employees are also to look for seizures, convulsions,  
26 “abnormal” gait, “difficulty” swallowing, “abnormally excited or aggressive behavior,” head  
27 pressing or head tilt, as these are signs of central nervous system conditions, and must be reported

1 to the agency as FADs. *Id.* And, plant employees are tasked with looking for high body  
2 temperatures, a loss of activity and awareness, discoloration, increased respiration, difficulty  
3 breathing, reluctance to get up from a recumbent position, and/or lameness, as these are signs the  
4 animals are febrile. *Id.*

5 89. In this way, plant employees supplant trained federal inspectors as the first, and often  
6 only, line of defense for preventing diseased animals from entering the food supply (and from being  
7 released to other plants and facilities where they can expose other animals to infectious or foreign  
8 animal diseases.) Having un- or under-trained slaughter-plant employees charged with “sorting”  
9 diseased animals establishes a set of screens that effectively precludes and prevents trained federal  
10 inspectors from critically appraising animals for symptoms of diseases and other significant  
11 problems in the swine supply, including the use of antibiotics and chemical residues. As a logical  
12 corollary, the new rules screen federal inspectors from critically appraising and detaining the swine  
13 that plant employees incorrectly determine are normal and fit for slaughter.

14 90. In practice, and as discussed in detail below, federal inspectors cannot critically appraise  
15 animals for conditions such as septicemia and toxemia, which pose a serious health threat to  
16 consumers and several symptoms of which manifest themselves in the living animal and are not  
17 observable after slaughter.

18 91. Instead of federal inspection, slaughter plants under NSIS are to develop their own  
19 written procedures for the identification, segregation, and disposition of animals suspected of  
20 having one of the condemnable generalized diseases or conditions. There is no requirement in the  
21 final NSIS rules that these written procedures be verified or approved by Defendants prior to the  
22 plants opting into NSIS.

23 **1. Federal Inspectors Prevented and Precluded from Examining and Inspecting**  
24 **Any Animals that Are Dying, Feverish, or Have Central Nervous System**  
25 **Conditions**

26 92. As a first screen, plant employees supplant the role of federal, trained inspectors in  
27 determining whether animals are dying, feverish, or have central nervous system conditions, and  
28 thus should be euthanized and discarded. 84 Fed. Reg. at 52345 (new 9 C.F.R. § 309.19(a)).

1       93. Federal inspectors cannot and do not inspect these swine that employees are charged with  
2 first observing during the sorting process. *See* FSIS, Proposed Rule: Modernization of Swine  
3 Slaughter Inspection, Webinar, April 16, 2018 (FSIS Webinar), at 13, located at  
4 [https://www.fsis.usda.gov/wps/wcm/connect/119a8a0c-8ffc-4f57-885f-](https://www.fsis.usda.gov/wps/wcm/connect/119a8a0c-8ffc-4f57-885f-9fb5422b0db3/Modernization-Swine-Slaughter-Inspection-Webinar04162018.pdf?MOD=AJPERES)  
5 [9fb5422b0db3/Modernization-Swine-Slaughter-Inspection-](https://www.fsis.usda.gov/wps/wcm/connect/119a8a0c-8ffc-4f57-885f-9fb5422b0db3/Modernization-Swine-Slaughter-Inspection-Webinar04162018.pdf?MOD=AJPERES)  
6 [Webinar04162018.pdf?MOD=AJPERES](https://www.fsis.usda.gov/wps/wcm/connect/119a8a0c-8ffc-4f57-885f-9fb5422b0db3/Modernization-Swine-Slaughter-Inspection-Webinar04162018.pdf?MOD=AJPERES). Federal inspectors are thus prevented and precluded  
7 from examining the overall condition of each animal, including the head, eyes, legs, and the body of  
8 the animal; the degree of alertness, mobility, and breathing in the animal; and whether there are any  
9 unusual swellings or any other abnormalities, which are necessary to determine whether the animals  
10 have symptoms of disease or were treated with illegal substances in order to get the animal passed  
11 by federal inspection.

12       94. Because federal inspectors cannot and do not critically appraise such animals, they are  
13 prevented and precluded from condemning any animals that plant employees incorrectly determine  
14 are fit for slaughter at this point.

15               **2. Federal Inspectors Prevented and Precluded from Inspecting and Examining**  
16               **All Animals at Rest and in Motion that Plant Employees Deem Normal**

17       95. NSIS creates a second ante-mortem inspection screen for all animals that plant employees  
18 determine are “normal and healthy” and that do not “appear to have condemnable diseases or  
19 conditions.” 83 Fed. Reg. at 4783. While federal inspectors examine all such animals at rest, they  
20 are not allowed to inspect more than five to ten percent in motion. *Id.* at 4792; 84 Fed. Reg. at  
21 52311-312. Thus, federal inspectors are precluded from inspecting ninety to ninety-five percent of  
22 animals for those abnormalities that may not be observable when the animals are at rest.

23       96. This is a deviation from how the original NSIS pilot program was designed in 1998,  
24 which had federal inspectors examine and inspect *at least* ten percent of all animals in motion.

25       97. Several indicia of condemnable conditions or diseases, including signs the animals are  
26 dying, feverish, or have central nervous system conditions, are best or only observed while the  
27 animals are in motion, as they are signs associated with abnormal body movement. These include

1 stiffness, limpness, lameness, restlessness, staggering, circling, abnormal gait, dizziness, loss of  
2 balance, and disorientation or running into things.

3 98. Other conditions that are best or that can only be observed while animals are in motion  
4 are signs of residues, including injury or inflammatory conditions such as arthritis, and signs of  
5 septicemia—one of the symptoms of which is slowed movement. Septicemia is very important to  
6 diagnose early as it can often indicate that the entire herd has multiple animals that are sick or have  
7 been exposed to the diseased animals. An early diagnosis allows producers to address other  
8 animals before the infection spreads.

9 **3. Federal Inspectors Prevented and Precluded from Examining and Inspecting**  
10 **Animals Showing Symptoms of Disease**

11 99. The NSIS rules establish a third screen preventing and precluding federal inspectors from  
12 critically appraising animals showing symptoms of disease before slaughter. Under- or un-trained  
13 employees use the FSIS-produced compliance guideline (originally written for veterinarians) to  
14 determine which animals are showing signs of fatigue and symptoms of disease, including  
15 abnormal body swellings, lameness, skin discolorations, scabs, wounds, coughing, sneezing, and  
16 abnormal body discharges (bloody urine, diarrhea, vaginal discharges, vomiting). Compliance  
17 Guideline at 9.

18 100. Plant employees place such animals and those that are not ambulatory in “U.S. Subject”  
19 pens. 83 Fed. Reg. at 4792; 84 Fed. Reg. at 52312; Compliance Guideline at 9.

20 101. Only federal inspectors may place swine in U.S. Suspect pens; plant employees are  
21 barred from doing so. FSIS Webinar at 13.

22 102. Establishment employees engage in further sorting of these animals in or before the U.S.  
23 Subject pens, just as they did for those that are dying, feverish, and have central nervous system  
24 conditions. Compliance Guideline at 8. Thus, federal inspectors once again cannot observe the  
25 overall condition of each animal or check for illegal drug use. It is only after swine showing  
26 symptoms of disease have been actually presented to the inspector in a “U.S. Suspect” or “U.S.

1 Subject” pen, that animals under NSIS receive anything that Defendants officially term an “ante-  
2 mortem inspection” from a federal inspector. *Id.*

3 103. But, unlike in U.S. Suspect pens, animals placed in U.S. Subject pens do not actually  
4 receive a critical appraisal by federal inspectors, as they are not given the necessary attention when  
5 potentially affected with diseases or conditions. For example, because the animals are not tagged,  
6 government PHVs do not know what conditions necessitate the animals’ segregation and what signs  
7 they should be looking for to make proper diagnoses. This is particularly crucial with animal  
8 symptoms that are intermittent or vary in severity as the condition progresses. For example, the  
9 food-safety condition Toxemia—caused by the circulation of toxins in the blood—has symptoms  
10 that include convulsions and variable temperatures, ranging from very high to subnormal,  
11 depending upon the stage of disease and ambient temperature. Government PHVs who do not  
12 know which animals are suspected of this condition likely will not retain these animals for a long  
13 enough time or examine the animal for all Toxemia symptoms, and they may inadvertently pass  
14 animals appearing normal—simply because the symptoms are not present during the brief period of  
15 inspection in the U.S. Subject pens. Indeed, the government PHVs are not even required to take  
16 animals’ temperatures in U.S. Subject pens like they would in U.S. Suspect pens when the tags and  
17 accompanying paperwork would indicate it necessary. This means that the government PHVs may  
18 not be able to identify animals with abnormal temperatures during times when there are more  
19 animals in the U.S. Subject pens.

20 104. As a result, under the new system, few swine are actually placed in U.S. Suspect pens.  
21 On May 23, 2019, FWW submitted an analysis to Defendants that showed that many more animals  
22 per plant were tagged as U.S. Suspect in traditional plants compared to the set of twenty-one plants  
23 of a similar volume that piloted the NSIS rules.

24 105. While Defendants have not responded to Plaintiff FWW’s letter and analysis detailing  
25 these findings, they indicated that they are based on incorrect data that they provided to FWW.  
26 Defendants first refused to provide the correct information, and this is the subject of an ongoing and  
27

1 separate Freedom of Information Act (FOIA) lawsuit, *Food & Water Watch., Inc., v. USDA et al.*,  
2 1:19-cv-03362-CRC (D.D.C. 2019).

3 106. Upon information and belief, the Defendants have intentionally attempted to conceal and  
4 have refused to release data detailing the number of animals that are segregated as U.S. Suspect in  
5 slaughter plants because it will further demonstrate that Defendants do not effectively inspect and  
6 require separate slaughter for animals showing symptoms of disease in NSIS model plants.

7 107. On February 28, 2020, pursuant to an agreement in the on-going FOIA lawsuit,  
8 Defendants released data on the number of animals and carcasses that receive PHV “dispositions,”  
9 or the outcomes of their inspections. The data also details how animals and carcasses were tagged.  
10 Two NSIS pilot and nine traditional plants reported the number of animals tagged “US Suspect” for  
11 2012 through 2015 (there were many plants, particularly NSIS-pilot plants, that did not enter this  
12 data in other years). For these traditional plants, on average, inspectors tagged 403 animals as U.S.  
13 Suspect per plant per year from 2012 to 2015. Inspectors at NSIS-pilot plants, on the other hand,  
14 *averaged thirty-nine percent fewer, tagging only 244 animals as U.S. Suspect per plant annually*  
15 *over this time period.*

16 108. This is remarkable given that Defendants have claimed that these large traditional plants  
17 already maintain voluntary programs similar to NSIS that allow plant employees to segregate  
18 animals suspected of disease. If the sole effect of these voluntary programs and NSIS were as  
19 USDA asserts, allowing plant employees to remove diseased and dying animals so that USDA  
20 veterinarians would have fewer animals to evaluate, the numbers of animals tagged as U.S. Suspect  
21 in these plants would be similar. Instead, it appears that the NSIS system has dramatically limited  
22 the number of swine that can be inspected by trained federal veterinarians, leaving their disposition  
23 in the hands of un- and under-trained plant employees.

24 109. Federal inspectors also cannot critically appraise animals that are sorted because plant  
25 employees determine which animals show signs of drug residues and diseases.

26 110. It is now the duty of un- or under-trained plant employees to identify and report FADs to  
27 inspectors. 84 Fed. Reg. at 52300. Under NSIS, those animals that are symptomatic of diseases

1 and not sorted can be moved to other facilities like farms and in-state slaughterhouses without any  
2 notification to local and federal animal health officials, unlike under traditional inspection.

3 **4. Federal Inspectors Prevented and Precluded from Ensuring that Suspect**  
4 **Animals Receive Separate Slaughter and a Careful Examination and**  
5 **Inspection Afterwards**

6 111. In addition to not receiving a critical appraisal in U.S. Subject pens, animals with  
7 diseases or conditions but passed for inspection from such pens are not tagged as “U.S. Suspect,”  
8 and need not be not slaughtered separately. FSIS Webinar at 13.

9 112. Without such tagging, the carcasses cannot retain their identity through post-mortem  
10 inspection like in traditional inspection.

11 113. Animals placed in U.S. Subject pens and passed for slaughter are not slaughtered  
12 separately from other animals.

13 114. And animals placed in U.S. Subject pens but passed for slaughter do not receive any  
14 different or additional post-mortem inspection than other animals.

15 115. In response to the contention that NSIS amounts to a dramatic rollback in ante-mortem  
16 inspection, Defendants have asserted that there is no difference between the NSIS rules and an  
17 inspection program alluded to in Defendants’ guidance termed “voluntary segregation.” *See*  
18 *Compliance Guideline 6100.1(XI)(A)*. Defendants have said that such programs have been adopted  
19 by all large slaughter plants likely to adopt NSIS.

20 116. However, there are critical differences between NSIS and the voluntary inspection  
21 programs described in Defendants’ guidance. For example, if plants do not adequately perform  
22 sorting under existing guidance, federal inspectors can simply disallow the companies’ sorting. *See*  
23 *Compliance Guideline 6100.1(XI)(C)*. On the other hand, sorting by employees is mandatory for  
24 those plants that adopt NSIS. 84 Fed. Reg. at 52345 (new 9 C.F.R. § 309.19(a)). There is no  
25 separate mechanism by which the agency can disallow the company’s segregation procedures, short  
26 of taking more formal, traditional enforcement measures. Further, under Defendants’ prior  
27 voluntary segregation program, those animals showing symptoms of disease are placed in U.S.  
28 Suspect pens, where they can receive a critical appraisal by government PHVs, *id.* at

1 6100.1(XI)(B)(4), unlike in the U.S. Subject pens under NSIS. Thus, Defendants' NSIS system  
2 differs materially from any existing voluntary segregation program that plants can opt into.

3 117. The NSIS's essential establishment of a mandatory sorting program will dramatically  
4 increase the size of the present secondary market in which animals that are disallowed into larger  
5 slaughter plants are sold at auction to small and very small plants that may not receive regular  
6 inspection by a PHV. According to FWW's analysis, employees in all NSIS-pilot plants sorted 7.6  
7 times more animals before slaughter than federal inspectors condemned from 2012 to 2018. USDA  
8 does not track where these sorted animals are sent to ensure that they do not spread infectious or  
9 foreign animal diseases to other animals or humans and—because they are not tagged—are not  
10 slaughtered elsewhere without a careful inspection by a USDA veterinarian.

11 118. In sum, the final NSIS rules creates a series of ante-mortem inspection screens that  
12 prevent and preclude federal inspectors from critically appraising swine, which are instead  
13 examined and inspected by slaughter-plant employees as part of the slaughter process. And the  
14 rules prevent federal inspectors from condemning animals that should have been condemned prior  
15 to slaughter.

16 **B. Federal Inspectors Prevented and Precluded from Post-Mortem Inspection**

17 119. Defendants' NSIS rules do not require any greater post-mortem examination or  
18 inspection of the carcasses of animals that receive the limited ante-mortem inspection that is  
19 detailed above under NSIS. This is so, even though inspecting the animal prior to slaughter is  
20 critical for the detection of several conditions, including Septicemia, Toxemia, Pyemia, and  
21 Cysticercosis. These are conditions that federal inspectors also seek to detect in carcasses and  
22 remove during post-mortem inspection. *See infra* ¶ 122. Several symptoms of these diseases  
23 manifest themselves in the living animal and are not observable after slaughter.

24 120. Instead of enhancing post-mortem inspection, under NSIS all but a few federal inspectors  
25 are removed from the post-mortem slaughter lines. Federal inspectors are no longer able to demand  
26 that slaughter-plant staff remove visibly tainted carcasses from the slaughter lines, trim and  
27 reprocess them to remove such problems, and then re-inspect the carcasses to ensure that the

1 problems have been removed. Establishments, using personnel with no approved formal training or  
2 educational qualifications, police themselves by sorting carcasses and parts, incising and palpating  
3 lymph nodes to detect the presence of animal disease, and identifying condemnable conditions or  
4 problems before carcasses are presented to online inspectors for post-mortem inspection. 84 Fed.  
5 Reg. at 52300-301, 52348. Like with ante-mortem inspection, under- or un-trained plant employees  
6 do this based on the non-binding compliance guideline that is used to identify carcasses affected  
7 with condemnable conditions. Compliance Guideline at 5; *see* 84 Fed. Reg. at 52313.

8 121. As detailed below, by handing off inspection responsibilities to plant employees, federal  
9 inspectors are prevented and precluded from critically appraising all carcasses for conditions such  
10 as Septicemia, Cysticercosis, and feces, ingesta, and milk contamination, which pose serious threats  
11 to public health. Federal inspectors are thus not able to condemn carcasses with these problems,  
12 including those that plant employees incorrectly determine do not need to be sorted. Carcasses with  
13 these conditions are more likely to enter the food supply, as the lone federal inspectors at the head,  
14 viscera, and carcass stations cannot critically appraise animals for these condemnable conditions  
15 due to NSIS plants' increased line speeds.

16 **1. Federal Inspectors Prevented and Precluded from Inspecting And**  
17 **Examining All Carcasses and Parts Evaluated by Slaughter-Plant Employees**  
18 **During Sorting**

19 122. Under NSIS, slaughter-plant employees are now charged with first “identify[ing],  
20 sort[ing], and mark[ing] for disposal market hog carcasses and all associated parts with the  
21 following food safety issues: Septicemia, Toxemia, Pyemia, Cysticercosis, Feces, Ingesta, and Milk  
22 Contamination.” *Id.* at 21; *see* 84 Fed. Reg. at 52313.

23 123. Defendants consider these conditions food safety hazards because they pose a threat to  
24 public health.

25 124. In the preamble to the proposed NSIS rules, for example, Defendants stated that  
26 “[c]arcasses and parts contaminated with fecal material, ingesta, or milk or that exhibit signs of  
27 septicemia, toxemia, pyemia, or cysticercosis during post-mortem examination are likely to contain  
28 infectious agents, such as bacteria, virus, rickettsia, fungus, protozoa, or helminth [parasitic-worm]

1 organisms, which can be transmitted to humans. For this reason, they present a food safety risk if  
2 they are permitted to enter the cooler.” 83 Fed. Reg. at 4793.

3 125. Septicemia, for example, is caused by the presence of pathogenic microorganisms and  
4 their associated toxins in the blood. Many conditions that are not considered to be a food safety  
5 hazard can lead to Septicemia. For example, pneumonia can progress and overwhelm an animal’s  
6 immune system, allowing pathogens to gain access to the carcass tissues and the animal’s vascular  
7 system and result in Septicemia.

8 126. Under traditional inspection, trained online federal inspectors determine whether  
9 carcasses show Septicemia symptoms, such as infected wounds or bruises, recent injection sites,  
10 multiple swollen lymph nodes, or fibrous adhesions, and they condemn these carcasses.

11 127. Under NSIS, under- or un-trained slaughter-plant employees are the ones who first  
12 examine animals for Septicemia, outside the presence of federal online inspectors. Plant sorters can  
13 trim bruises, although they are not supposed to do so if extensive, as well as remove injection sites,  
14 injuries, and adhesions, thus eliminating key indicia of Septicemia.

15 128. Inspectors are barred from inspecting animals until after the employees make this  
16 determination. Federal inspectors are thus prevented and precluded from giving a critical appraisal  
17 of all carcasses for Septicemia and are not able to condemn carcasses with this condition, including  
18 those that plant employees incorrectly determine need not be sorted.

19 129. As another food safety example, Cysticercosis (also called pork measles) is a condition  
20 caused by the larval form of a swine tapeworm that can be transmitted to humans. A diagnosis in  
21 the swine requires a detailed examination of the cheeks, heart, esophagus, tongue, and diaphragm,  
22 by sight and numerous incisions by a PHV.

23 130. Under NSIS, slaughter plant employees are charged with first examining animals for this  
24 condition outside of the federal online inspector’s presence, and they are supposed to notify federal  
25 inspectors if it is detected. Federal inspectors are barred from examining the cheeks, heart,  
26 esophagus, tongue, and diaphragm by sight and making any incisions unless the employee  
27 determines it necessary. Federal inspectors are thus prevented and precluded from critically  
28

1 appraising all carcasses for Cysticercosis and are not able to condemn carcasses with this condition,  
2 including those that plant employees incorrectly do not sort or errantly do not flag for inspection.

3 131. Prior to NSIS, if online federal inspectors discovered carcasses contaminated by fecal  
4 material, ingesta, or milk, they were to either stop the line or direct employees to remove the  
5 carcass from the line through a rail-out loop for trimming and reexamination. FSIS Directive  
6 6420.2 Rev. 2. Ch. II (II)(B) (12/19/19).

7 132. If federal inspectors discovered such contaminants on the head or viscera, the  
8 establishment was instructed to remove the contamination before the head or affected viscera and  
9 part could be passed. *Id.* at Ch. II (II)(E),

10 133. Defendants' compliance guideline (at 26) references FSIS Directive 6420.2, which  
11 recognizes that this determination is difficult and ultimately best performed by a PHV:

12 [T]he actual appearance of feces and ingesta reflect the diet, age of the animal, type of animal  
13 (functioning rumen; non-ruminant) and regional feeding practices. . . . [T]he PHV-[Inspector  
14 in Charge] in each official establishment is the final arbiter regarding any disputed findings  
of feces, ingesta, or milk representing zero tolerance noncompliance.

15 *Id.* Attachment 2.

16 134. Unlike under traditional inspection, under NSIS, plant employees are to examine and trim  
17 carcasses and parts for fecal matter, ingesta, and milk on the slaughter line outside of the federal  
18 online inspector's presence. Federal inspectors are barred from making such an examination until  
19 after the employees do. Federal inspectors also do not engage in examining and re-inspecting  
20 carcasses to ensure that any identified contamination has been adequately removed until the final  
21 inspection station. Federal inspectors are thus prevented and precluded from critically appraising  
22 carcasses and parts for fecal matter, ingesta, and milk in animals that plant employees incorrectly  
23 deem are free of such contaminants. Instead of federal online inspection, it is the slaughter plants  
24 themselves that create written procedures to address visible fecal material, ingesta, or milk, before  
25 FSIS post-mortem inspection.

26 135. While Defendants have indicated that inspectors will perform twice the *offline* zero-  
27 tolerance visual verification checks for fecal matter, ingesta, and milk at NSIS plants, this does not

1 account for the lack of *online* inspections that carcasses, viscera, and heads receive from trained  
2 federal inspectors.

3 136. For other conditions not specified in ¶ 122, under- or un-trained and unqualified  
4 slaughter-plant employees also must make decisions about whether the carcasses must be discarded  
5 or can merely be trimmed, based on the nature, degree, or extent of the condition, pursuant to the  
6 compliance guideline. *See* Compliance Guideline at 26. These are disposition decisions that  
7 trained federal inspectors make under traditional inspection using the same inspection tasks detailed  
8 *supra* in ¶¶ 65-71.

9 137. The NSIS rules have no provisions mandating how plant personnel make such  
10 determinations or what their minimum qualification or training must be.

11 138. Instead, plants are to use the compliance guideline referenced *supra* at ¶ 82. The  
12 guideline does not contain mandatory standards for plant employees to apply when sorting  
13 carcasses with condemnable conditions.

14 139. Federal inspectors are also barred from inspecting animals until after the employees do  
15 this sorting. Federal inspectors are thus prevented and precluded from giving a critical appraisal of  
16 all carcasses for these conditions, and they are not able to effectively condemn carcasses with these  
17 conditions, including those that plant employees incorrectly determine do not need to be sorted.

18 140. Federal inspectors are also not able to inspect carcasses and parts that that are removed  
19 by the employee from the slaughter line.

20 141. By the time carcasses reach the federal inspector in a plant operating under NSIS—after  
21 the plant employees' examination, sorting, and trimming—it can be impossible for federal  
22 inspectors to identify most disease conditions and whether there have been drugs used in treating  
23 the animals that would trigger residue sampling and testing.

## 24 **2. Federal Inspectors Prevented and Precluded from Inspecting and Examining** 25 **All Carcasses and Parts at Inspection Stations**

26 142. Nor are the three federal inspectors left at the head-, viscera-, and carcass-inspection  
27 stations able to critically appraise all carcasses and parts during post-mortem inspection.

1 143. Defendants have claimed that by removing what the Defendants term “time-intensive  
2 inspector post-mortem sorting activities,” slaughter plants supposedly will be more efficient and  
3 can thus increase their line speeds. 83 Fed. Reg. at 4784.

4 144. In fact, the NSIS rules eliminate the existing line-speed limit of 1,106 heads per hour, 84  
5 Fed. Reg. at 52314, 52345, a limit based upon the time needed to observe the spleen, liver, heart,  
6 lungs, and mediastinal lymph nodes.

7 145. Defendants estimate that plants will increase line speeds by 12.49%. 84 Fed. Reg. at  
8 52355. This is an estimated average, as line speeds may be much higher for periods of time in  
9 some plants.

10 146. Increases in line speeds are accompanied by Defendants’ plans to reduce the total number  
11 of online federal inspectors by forty percent. 84 Fed. Reg. at 52337. As Plaintiffs pointed out in  
12 their comments, this means that instead of inspecting an average of 163 heads per hour per  
13 inspector in non-model plants (approximately 2.7 per minute), each federal inspector will be tasked  
14 with inspecting an average of 366 slaughtered animals per hour (6.1 per minute) under the new  
15 system. A mere 12.5% increase in line speeds results in more than a 2.25-fold reduction in average  
16 inspector time dedicated to performing a critical appraisal of hog carcasses, heads, and viscera and  
17 effectively a corresponding 2.25-fold increase in line speeds.

18 147. In the preamble to the final NSIS rules, Defendants do not address Plaintiffs’ comment  
19 about this line-speed increase and instead merely state that model plants “do not operate at line  
20 speeds that are significantly faster than the current maximum line speeds for market hog  
21 establishments operating under traditional inspection.” 84 Fed. Reg. at 52314.

22 148. The Defendants have not done any work-measurement studies evaluating the ability of  
23 federal inspectors to perform their critical food-safety inspections with the increased line speeds  
24 allowed under NSIS.

25 149. None of the data or analyses that the Defendants have relied upon in support of the final  
26 NSIS rules evaluated the effects of line speed on the production of a wholesome product or  
27 consumer illnesses. Nor have Defendants evaluated the ability of plant employees and federal  
28

1 inspectors to remove carcasses with condemnable conditions or for the latter to take the required  
2 residue samples for antimicrobial or other drug-use at the higher line speeds that are permitted  
3 under NSIS.

4 150. Current and former federal inspectors attested in comments on the proposed rules that  
5 plant employees are discouraged from removing adulterated carcasses. In addition to the increased  
6 line speeds, this dramatically increases the burden on the remaining federal inspectors at the head-,  
7 viscera-, and carcass-inspection stations to examine and inspect carcasses and parts.

8 151. To make matters worse, only a few federal “Inspectors In Charge” can slow the line,  
9 although the criteria for this is not established or defined in the rule. 84 Fed. Reg. at 52300 (citing  
10 new 9 C.F.R. 310.26(c)).

11 152. Inspector comments submitted on the proposed rules indicated that they have been  
12 encouraged not to stop the lines for fecal contamination of carcasses and other problems.

13 153. Further, former and existing federal inspectors indicated that they were told not to do  
14 anything but look at the carcass and parts that reach the inspectors at the head, carcass, and viscera  
15 stations. This means that federal inspectors cannot and do not incise or palpate any lymph nodes  
16 and observe both sides of the kidneys, as inspectors are required to do under traditional inspection.  
17 These mandatory inspection steps, which are needed to make differential diagnosis of the fitness of  
18 the carcass for human consumption, are now supposed to be completely performed by under and  
19 un-trained plant employees with no minimum education or qualifications.

20 154. At the line speeds that will likely be adopted by plants under the final rules, slaughter-  
21 plant employees cannot properly incise and observe the cut surfaces of lymph nodes, even if they  
22 were permitted to do so.

23 155. At such line speeds, federal inspectors cannot view each and every animal’s head,  
24 carcass, and viscera.

25 156. In terms of head inspection, under NSIS, federal inspectors would have no time to incise  
26 the right and left mandibular lymph nodes if they thought it was necessary at the expected NSIS line  
27 speeds.

1 157. With the increased line speeds allowed under the NSIS rules, it would also be nearly  
2 impossible for federal inspectors to palpate and observe the mesenteric lymph nodes, the portal  
3 lymph nodes, or the bronchial lymph nodes for lesions or abnormalities, even if they thought it was  
4 necessary and were allowed to do so when performing viscera inspection.

5 158. Nor can federal inspectors visually observe all parts of the carcasses, including the back,  
6 front, and inside, all cut surfaces and body cavities for contaminants that include feces, ingesta, and  
7 milk, as the line speeds are too fast. Federal inspectors also cannot turn and observe both sides of  
8 the kidneys under NSIS at such line speeds.

9 159. According to the data that Defendants released on February 28, 2020 (detailed *supra* at ¶  
10 107), federal inspectors at the nine traditional plants that FWW evaluated tagged an average of  
11 3,797 carcasses as U.S. Retained per plant annually from 2012 to 2015. Federal inspectors at NSIS-  
12 pilot plants on average tagged as *U.S. Retained a quarter of this number, or 944 animals per plant*  
13 *per year.*

14 160. While plant employees do remove some of these carcasses through their sorting, FWW's  
15 analysis indicates that plant employees only removed .08% of them in these model plants. FWW's  
16 analysis shows that the un-or under-trained employees would have to be 98.88% accurate in their  
17 removal of adulterated carcasses in order for the 2,885 carcasses sorted per year in an average  
18 model plant to compensate for the greater number of carcasses that were tagged to receive  
19 veterinary evaluation in the average traditional plant.

20 161. In total, USDA veterinarians were able to evaluate approximately 1 in every 1,000  
21 animals slaughtered and their resulting carcasses for signs of adulteration in traditional plants  
22 (based on the average slaughter size for these plants), while these federal inspectors were only  
23 evaluating 3 in 10,000, or 3.5-fold fewer animals slaughtered, and their resulting carcasses, in the  
24 model plants.

25 162. One federal inspector's comments on the proposed rules indicates that, at a pilot plant,  
26 company employees personally condemned the plant's products and then attempted to sneak such  
27

1 carcasses past the inspector. The same inspector attested that the company had threatened plant  
2 employees with terminations if too many carcasses or carcass parts were condemned.

3 163. In response to these and other inspectors that submitted anonymous comments decrying  
4 the problems in plants piloting the new rules, Defendants have merely pointed to the data in its Hog  
5 HIMP Report (discussed below). *See* 84 Fed. Reg. at 52312.

6 164. In short, NSIS prevents and precludes Defendants' inspectors from performing the  
7 mandatory critical appraisal of all carcasses and parts of swine because these responsibilities are  
8 turned over to un- or under-trained plant personnel. Without performing such inspections, federal  
9 inspectors cannot condemn adulterated carcasses or otherwise ensure contaminated carcasses are  
10 properly trimmed, including those that plant employees incorrectly allow to pass for final  
11 inspection. Inspectors at the final head, viscera, and carcass inspection stations have no ability to  
12 critically appraise carcasses at the line speeds expected under NSIS.

13 165. As discussed further below, the Defendants have contended that any such problems can  
14 be addressed under NSIS because of an assumed increase in offline "verifications," or spot-checks,  
15 where federal inspectors verify that the plants are executing their hazard plans.

16 166. But not only do these verifications not involve the examination and inspection of every  
17 carcass, as is required under the FMIA, when these spot-checks do involve the carcass (and not the  
18 plants' paperwork), federal inspectors in offline inspection positions cannot see key signs of  
19 Septicemia, Toxemia, Pyemia, and Cysticercosis in carcasses.

20 167. Moreover, as detailed below, Defendants' conclusions about these verifications are  
21 unreasonable, and much of Defendants' data shows otherwise; in fact, NSIS plants will be worse  
22 for public health and food safety than plants operating under traditional inspection.

### 23 **C. Plant Employee Sorters with No Mandatory Training or Education**

24 168. Defendants have indicated that they believe that training of sorters is important to ensure  
25 that they are able to properly perform their duties, 83 Fed. Reg. at 4794, although the final rules  
26 contain no mention of the education requirement to hold these positions. Proper training and  
27

1 education is necessary if sorters are to make accurate decisions on how to address animal disease  
2 conditions and trim and dress defects.

3 169. The final NSIS rules require no formal training programs for plant employees to make  
4 animal- or carcass-sorting and trimming determinations. 84 Fed. Reg. at 52313.

5 170. Defendants are not mandating any specific or sorter training or certification for  
6 establishments operating under the NSIS. *Id.*

7 171. According to federal inspector comments on the proposed rule, at one pilot NSIS plant,  
8 plant employees were merely given a short orientation and a booklet illustrating various pathologies  
9 on a carcass.

10 172. The Defendants' cost-benefit analysis for the final rules assumes no additional costs for  
11 slaughter plants other than what it would cost for training production employees in plants adopting  
12 Hazard Analysis Critical Control Points (HACCP) regulation. *Id.* at 52324. In other words, the  
13 agency does not assume any specific costs for training employees on how to sort condemnable  
14 conditions or to hire qualified employees, indicating that they do not anticipate that plants will do  
15 either.

16 173. The agency's cost-benefit analysis assumes that a HACCP training will average four  
17 hours per sorter, and that sorters will be paid slightly less for that training than the 2014 median rate  
18 for minimum-wage slaughterers and meatpackers. *See* 84 Fed. Reg. at 52324 (referencing Viator,  
19 C. *et al.* 2015. Costs of Food Safety Investments. Table 4–4. Training Costs for Management and  
20 Production Employees, located at <https://www.fsis.usda.gov/wps/wcm/connect/5b165917-9db2-4f77-9aea-b8d31c1db7f1/AG-3A94K140056-Food-Safety-Costs-052015.pdf?MOD=AJPERES>).  
21 *See id.* at tables 2-4, 4-4.

22 174. Defendants' estimation of what plants would spend on training sorters is far less than  
23 what Defendants spend to train federal inspectors.

24 175. Defendants' response to comments in the final rules' preamble failed to address why they  
25 did not mandate specific training for employee sorters or why the cost-benefit analysis estimates so  
26 little will be spent on ensuring that employees are properly trained.  
27

1 **IV. FEDERAL INSPECTORS PREVENTED AND PRECLUDED FROM CONDEMNING**  
2 **AND SUPERVISING THE DISPOSAL OF CONDEMNED CARCASSES**

3 176. Under NSIS, federal inspectors are also prevented and precluded from being able to  
4 identify as “U.S. Condemned” those animals, carcasses, and parts that NSIS plant employees sort  
5 and dispose, and do not receive “U.S. Condemned” or “U.S Inspected and condemned” tags.

6 177. Federal inspectors are not required to verify and certify the disposal of carcasses and  
7 parts that are sorted by plant employees under NSIS, as they would under traditional inspection.

8 178. In addition, unlike in traditional inspection, federal inspectors are not required to seal  
9 rendering tanks or supervise the incineration or denaturing of carcasses and parts that are sorted by  
10 plant employees under NSIS.

11 179. Finally, NSIS plant employees can dispose of carcasses and their parts with condemnable  
12 conditions without the supervision of federal inspectors, unlike under traditional inspection.

13 180. The lack of required inspector condemnation and inspector-supervised disposal of sorted  
14 carcass and parts creates another avenue by which adulterated product—even that which is  
15 supposed to be removed from the slaughter plant—can end up in the food supply, both intentionally  
16 and unintentionally. *See supra* ¶¶ 78, 159.

17 **V. ROLLBACKS TO PATHOGEN TESTING**

18 181. Despite the fact that Defendants’ NSIS rules are a major transformation of food-safety  
19 inspection for swine and likely to have detrimental effects on public health, Defendants’ rules also  
20 revoke 9 C.F.R. § 310.25(a) for all establishments. 84 Fed. Reg. at 52301 (“This final rule rescinds  
21 the current requirement that swine establishments test carcasses for generic *E. coli*[.]”) This  
22 regulation required that establishments test for *Escherichia coli* Biotype I (*E. coli*), and it provided  
23 criteria for when an establishment’s failure to meet such criteria served as an indication that the  
24 establishment may not be maintaining process controls sufficient to prevent fecal contamination.

25 182. Defendants’ NSIS rules also revoke 9 C.F.R. § 310.25(b) for all swine slaughter  
26 establishments. *Id.* This rule required that federal inspectors test for *Salmonella*. It also provided  
27 criteria for which an establishment’s failure to meet constitutes a failure to maintain sanitary  
28 conditions and may cause a production interruption due to a suspension of inspection services.

1 183. Defendants' NSIS rules allow all swine slaughter establishments to instead develop and  
2 implement their own microbiological sampling plan, prior to carcasses entering and after carcasses  
3 exit the chiller. *Id.* The establishment would be responsible for determining which microbiological  
4 organisms will best help it to monitor the effectiveness of its process control procedures. *Id.*

5 **VI. NO VALID JUSTIFICATION FOR THE RULES AND DEFENDANTS'**  
6 **INADEQUATE RESPONSES TO COMMENTS**

7 184. Defendants have presented a number of justifications for their NSIS rules, but none are  
8 supported by Defendants' data or underlying documents, as detailed in this section. Defendants  
9 point to their report evaluating NSIS pilot plants ("Evaluation of Hazard Analysis Critical Control  
10 Point Based Inspection Models Project Inspection Models Project (HIMP) for Market Hogs" (2014)  
11 (Hog HIMP Report)). They contend that under a similar inspection system as NSIS, model plants  
12 performed just as well if not better than those under traditional inspection. But the report was  
13 issued as a response to the USDA OIG's highly critical report the year before, which had concluded  
14 (among other things) that, with little oversight, the pilot did not lead to greater food safety. Instead,  
15 the system allowed for plants to pile up the most regulatory noncompliances, even fifteen years  
16 after inception. And, despite their claimed adherence to the OIG's recommendations, Defendants  
17 ultimately ignored a key recommendation that only those plants with a strong history of regulatory  
18 compliance be allowed to remain in the program. Instead, Defendants will allow any market-hog  
19 slaughter plant to adopt NSIS upon application, regardless of its compliance history.

20 185. Defendants' Hog HIMP Report was also an attempt to respond to a GAO report that  
21 concluded that because of the limited data and voluntary nature of the pilot program, there was little  
22 assurance that plants adopting a system similar to that of the model plants would perform as well as  
23 traditional plants. GAO further stated that there needed to be an evaluation of how the model  
24 projects performed over time.

25 186. But, as detailed below, Defendants' Hog HIMP Report does not include any such  
26 analysis. Moreover, the Hog HIMP Report's reliance on a flyspeck of data from a twenty-year pilot  
27  
28

1 project, not to mention its inadequate justification for the plants it evaluated, taint Defendants’  
2 conclusions that plants opting into NSIS will perform as the pilot plants have.

3 187. Further, Defendants’ data, from both within and outside of the Hog HIMP Report, fail to  
4 demonstrate that the pilot project was ever righted and that NSIS plants will have similar or greater  
5 food safety than traditional plants. Defendants’ data show that model plants did *not*, in fact, have  
6 demonstrably greater off-line food-safety-related inspection verification checks and compliance  
7 rates with key regulations, lower demonstrable levels of non-food safety defects, or equivalent or  
8 better *Salmonella* positive rates—despite Defendants’ false and misleading claims to the contrary.

9 188. If anything, and as discussed further below, Defendants’ data show that the model plants  
10 had greater rates of regulatory non-compliances of key regulations, such as 9 C.F.R. § 310.18, and  
11 fewer numbers of public-health regulation spot-checks per plant. In truth, the pilot project portends  
12 that Defendants’ NSIS rules will result in far *worse* food safety in the thirty-five plants likely to  
13 adopt it than traditional inspection. Defendants have repeatedly ignored public comments to this  
14 effect.

15 189. The Defendants’ risk assessment (“Assessment of the Potential Change in Human Risk of  
16 *Salmonella* Illnesses Associated with Modernizing Inspection of Market Hog Slaughter  
17 Establishments,” (September 2019) (Final Risk Assessment)) shares similar problems and was  
18 roundly criticized by peer reviewers. Defendants failed to adequately respond to these criticisms,  
19 papered over the analysis’s flaws, and then refused to re-open the comment period on the proposed  
20 rules—despite the fact that these problems undercut the only stated public-health benefits for the  
21 NSIS rules. What’s more, when these and other issues were raised by commenters, Defendants  
22 ignored them or provided false or misleading responses.

23 190. Ultimately, the Defendants demonstrated their bias when they launched a rare, if not  
24 unprecedented, defense of their proposed rules’ benefits in a press release—notwithstanding that  
25 the rules had yet to be finalized and the Defendants were supposed to be considering comments  
26 without prejudice.

27  
28

1       **A. The OIG Report**

2       191. The Defendants have contended that a pilot project involving five market hog plants,  
3 known as the Hazard Analysis Critical Control Point Based Inspection Models Project (HIMP),  
4 support the NSIS rules. Defendants assume that plants operating under the final NSIS rules will  
5 perform as the model plants did.

6       192. But audits have revealed that the pilot has been plagued with problems, including that it  
7 suffered from a lack of agency oversight and resulted in little meaningful data from which to draw  
8 conclusions about the pilot program.

9       193. In May 2013, Defendant USDA's OIG released an audit of Defendants FSIS's regulation  
10 of swine slaughter plants (the OIG Report). That report contained a section on the HIMP pilot,  
11 concluding that the program lacked oversight:

- 12       • Even though FSIS announced an evaluation plan for the HIMP pilot for market hogs in  
13       1998 (63 Fed. Reg. 40381, July 29, 1998), there was never a final rule creating HIMP,  
14       raising questions about the legality of the project. OIG Report at 18-19.
- 15       • FSIS had not conducted an evaluation of the HIMP project, raising questions about the  
16       agency's oversight of the program. *Id.* at 19.
- 17       • Even though the stated goal of HIMP was an improvement in food safety, the OIG found  
18       that "3 of the 10 plants cited with the most [Noncompliance Reports (NRs) (also referred  
19       to as 'noncompliances')] from FYs 2008 to 2011 were HIMP plants. In fact, the swine  
20       plant with the most NRs during this timeframe was a HIMP plant—with nearly 50  
21       percent more NRs than the plant with the next highest number." *Id.* at 17.
- 22       • One plant was permitted to not inspect viscera manually, contrary to standard FSIS  
23       procedures. *Id.* at 18.
- 24       • FSIS did not have formal agreements with the HIMP pilot plants that outlined the food-  
25       safety objectives to be expected from the plants in exchange for the reduced inspection-  
26       staffing and unlimited line speeds. *Id.* at 18-19.

27       194. Among other recommendations aimed at improving the program's oversight, the OIG  
28 recommended that Defendants "evaluate [model] plants' noncompliance histories and allow only  
those plants with a strong history of regulatory compliance to remain in the program." OIG Report  
at 18.

1 195. Defendants' preamble to the final NSIS rules claim Defendants addressed OIG's  
2 concerns. 84 Fed. Reg. at 52306.

3 196. The same five plants remained in the program up until 2018, however, and the only one  
4 that has had its inspection withdrawn was due to a recent change in ownership.

5 197. On information and belief, Defendants took no actions specifically aimed at increasing  
6 model plants' compliance with Defendants' regulations.

7 198. Plaintiffs' comments on the proposed NSIS rules recommended that the Defendants  
8 adopt and apply rigorous criteria before plants are allowed to operate under NSIS.

9 199. Defendants failed to address this comment in the final NSIS rules' preamble.

10 200. Defendants' NSIS rules will allow any market hog slaughter plant to opt into NSIS,  
11 regardless of compliance history. 84 Fed. Reg. at 52317.

## 12 **B. The GAO Report**

13 201. In September 2013, the GAO followed the OIG in issuing a report about Defendants'  
14 regulation at swine and poultry slaughter plants, titled "More Disclosure and Data Needed to  
15 Clarify Impact of Changes to Poultry and Hog Inspections" (the GAO Report).

16 202. The GAO stated that many of the same problems plaguing Defendants' analysis of plants  
17 in a young chicken and turkey pilot project also infected the hog pilot. "In particular, FSIS did not  
18 collect comparable data from plants participating and not participating in the pilot project." GAO  
19 Report at 15-16. Because of the voluntary nature of the selection, an earlier 2001 GAO study had  
20 concluded that potential selection bias is introduced. Likewise, the 2013 GAO report related that:  
21 "information collected from the five young hog plants in the pilot project would not provide  
22 reasonable assurance that any conclusions can apply more broadly to the universe of 608 hog plants  
23 in the United States in 2012 because of the small sample size." *Id.* at 16. "FSIS officials agreed  
24 that there would be concerns regarding the strength of any conclusions based on five plants." *Id.*  
25 The GAO Report also underscored the noncompliance issues discussed in the OIG Report and the  
26 OIG's conclusion that "FSIS did not critically assess whether the pilot project had measurably  
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1 improved food safety at each participating plant because the agency did not adequately oversee the  
2 program.” *Id.*

3 203. “[W]hile the pilot project is ongoing, FSIS has the opportunity to follow sound  
4 management practices by planning for and collecting key information needed to determine whether  
5 the pilot project is meeting its purpose[,]” the report found. *Id.* at 16-17. Critically, “the agency has  
6 not aggregated and analyzed [inspector-collected] daily results to determine how the plants  
7 participating in the pilot project have performed over time.” *Id.* at 17.

8 204. Without this information, it would be impossible to determine whether NSIS rules based  
9 on the pilot project would ensure equivalent levels of food safety and quality than currently  
10 provided at traditional plants. *Id.* at 17-18.

11 205. As discussed below, however, Defendants have never evaluated how model plants have  
12 performed over time.

### 13 **C. Defendants’ Inadequate Hog HIMP Report and Responses to Comments**

14 206. In response to the OIG and GAO reports detailed in ¶¶ 191-205, Defendants issued its  
15 Hog HIMP Report a year later.

16 207. The Defendants describe the 2014 Hog HIMP Report as containing a “comprehensive  
17 analysis of data . . . that presents a thorough evaluation of the models tested[,]” and includes  
18 “analyses compar[ing] the number of offline inspection procedures, the rates of health-related  
19 regulatory non-compliances, *Salmonella* positive rates, and violative chemical residue rates.” 83  
20 Fed. Reg. at 4788, 4889.

21 208. But, as detailed below, the Hog HIMP Report fails to show that the problems that the  
22 OIG and GAO identified have been corrected, including the limited collection and presentation of  
23 data from a few volunteer model and hand-selected comparator set of traditional plants.  
24 Defendants’ data in the report and elsewhere do not show that NSIS is likely to result in equivalent,  
25 much less better, food safety than plants under traditional inspection.

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1 NSIS. And, just as the GAO concluded, there is no assurance that these smaller plants will perform  
2 under NSIS as the largest plants did in the NSIS pilot.

3 216. The preamble to the final NSIS rules indicates that Defendants chose the twenty-one  
4 plants used as a comparator set in the Hog HIMP Report because they are comparable with model  
5 market hog establishments with respect to “production volume, line speed, and days of operation,”  
6 84 Fed. Reg. at 52303, but Defendants have never made public any analysis that could support this  
7 conclusion, if it in fact was performed.

8 217. The 2014 Hog HIMP Report only evaluated data from a now-twenty-plus-year-old pilot  
9 from Calendar Years (CY) 2006-2010 and 2012-2013. Defendants have made no attempt to  
10 evaluate trends in model-plant performance since the program’s inception. Nor have Defendants  
11 evaluated more recent data from model and comparator plants.

12 218. Defendants’ response to comments in the final NSIS rules indicates that they do not  
13 believe this data to be stale because “findings from CY2006 through CY2010 and CY2012 through  
14 CY2013 were very similar.” 84 Fed. Reg. at 52307. According to Defendants, “[t]his shows that  
15 not much changed over a seven-year period, and that the model is stable[,]” and that “[n]o  
16 significant changes in swine slaughter, FSIS inspection, or related regulations have occurred since  
17 CY 2013.” *Id.*

18 219. Defendants’ statement that no “significant changes in slaughter, FSIS inspection, or  
19 related regulations have occurred since CY 2013,” indicates that the Defendants did not take any  
20 action in 2014 or since, including those actions recommended by the OIG Report, to address the  
21 fact that some of the worst performing plants were in the model program.

22 220. Contrary to Defendants’ assertions that not much has changed with FSIS inspections and  
23 regulations since CY 2013, Defendants’ Public Health Regulations (PHRs) have changed every  
24 year since 2014. These are the regulations which Defendants indicate are most directly related to  
25 protecting public health. The Defendants have used the number of agency spot-checks of, and plant  
26 compliance with these regulations as a primary way to assess the NSIS pilot. But, the Defendants  
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1 have never assessed any data except the number of 2012 PHR verifications in CY 2012-2013,  
2 despite the fact that the PHRs have changed every year since.

3 221. Finally, Defendants' own data show significant changes in slaughter plants including  
4 over CY 2006-2010 and CY 2012-2013 time period documented in the Hog HIMP Report, even  
5 changes that appear to affect the model plants differently.

6 222. As a result of such flaws, the NSIS pilot and Hog HIMP Report were not designed to, and  
7 could not produce valid data upon which the Defendants can rely in support of the NSIS rules.

8 223. Notwithstanding these bigger issues, the Defendants' own flawed data still undercut the  
9 agency's justification for the NSIS rules, as detailed in the following subsection.

10 **2. Defendants' False and Misleading Claims in Support of the NSIS rules Are**  
11 **Unsupported by the Hog HIMP Report and Defendants' Data**

12 224. Defendants draw the following five conclusions from the Hog HIMP Report in support of  
13 the final NSIS rules: compared to traditional plants, the model facilities had a) more offline food-  
14 safety related inspection verification checks; b) higher compliance with certain regulations; c) lower  
15 levels of non-food safety defects; d) lower levels of violative chemical residues; and e) equivalent  
16 or better *Salmonella* verification testing positive rates. 84 Fed. Reg. at 52307 (citing 83 Fed. Reg.  
17 at 4788). But, Defendants' data do not support these conclusions or that NSIS will be as good for  
18 or better for food safety than plants operating under traditional inspection.

19 *i. No greater food-safety spot-checks*

20 225. Defendants contend that the pilot plants received more offline spot-checks that are "more  
21 effective in ensuring food safety." *Id.* The Defendants' preamble to the NSIS final rules makes  
22 clear that that they are chiefly relying on

23 the increased inspection for visible fecal material, ingesta, and milk contamination under  
24 9 CFR 310.18. FSIS inspectors at [model] establishments inspect a sample of 24  
25 carcasses when they perform a Zero Tolerance verification task specifically for 9 CFR  
310.18, whereas FSIS inspectors at traditional market hog establishments inspect a  
sample of 11 carcasses . . . .

26 *Id.* Also important are the PHR verifications. *Id.* at 52307-308.

1       226. But regardless of whether or not this is true, Defendants ignore the fact that spot-checks  
2 by untrained employees are not a substitute for having trained federal inspectors thoroughly inspect  
3 *every* carcass. In traditional inspection, *every* carcass is inspected by online federal inspectors, and  
4 no carcass is supposed to reach the final carcass-inspection station with such material. When fecal  
5 material, ingesta, and milk contamination are found on carcasses or parts by federal inspectors, for  
6 example, those inspectors are to ensure the sanitary removal of the contamination, and carcasses are  
7 not allowed to proceed without being reconditioned and further re-inspected by inspectors.

8       227. Moreover, the Defendants' own data from May of 2019 indicate that the agency stopped  
9 doing or recording offline verifications for 9 C.F.R. § 310.18 in model plants in 2015, 2016, and  
10 2018. The number of reported verifications were also greatly curtailed but not eliminated in  
11 traditional plants. Thus, Defendants cannot say that they have been and will be performing greater  
12 numbers of these spot-checks in NSIS plants under the new system.

13       228. In terms of the other "offline food-safety related verification checks" in model plants, or  
14 the PHR spot-checks, Defendants ignored Plaintiffs' comments that inspectors' performance of  
15 2012's PHR verifications varied greatly between model and the twenty-one-comparator set of  
16 traditional plants evaluated as part of the Hog HIMP Report in CY 2012 and CY 2013. Federal  
17 inspectors performed fewer than 85% of the total spot-checks in model plants than they did in  
18 traditional plants for a large proportion of the regulations (more than 50% of them) each year.

19       229. FWW's analysis described in ¶ 104 , showed that for the PHRs applicable for all years  
20 evaluated (Fiscal Years (FY) 2014 through 2017), federal inspectors performed a statistically  
21 significantly *greater* number of such spot-checks for *more* PHRs in traditionally inspected plants  
22 than they did in NSIS model plants.

23       230. Finally, FWW's analysis described in ¶ 104 indicates that when Defendants evaluated the  
24 number of PHR verifications between CY 2012 and 2013 in its Hog HIMP Report, it likely  
25 statistically masked the differences between the numbers of PHR verification checks in model and  
26 traditional plants by pooling the data.

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1 231. Defendants have never denied that its Hog HIMP Report suffered from the deficiencies  
2 detailed in ¶¶ 229-230, and they have never addressed the comments submitted by Plaintiff FWW.

3 232. Thus, Defendants are wrong in saying that “offline inspectors in HIMP establishments  
4 perform more offline inspection activities that FSIS has concluded are more effective in ensuring  
5 food safety than offline FSIS inspectors perform in non-HIMP establishments operating under the  
6 traditional inspection system.” 84 Fed. Reg. at 52308.

7 *ii. No greater compliance with agency regulations*

8 233. There are at least six data sets undermining Defendants’ contention that model plants  
9 maintained better regulatory compliance than traditional plants.

10 234. First, as Plaintiffs pointed out in their comments, the Hog HIMP Report itself showed  
11 that model plants had statistically significantly more public-health-related NRs than the twenty-one-  
12 comparator set of traditional plants over five years, CYs 2006-2010. This includes large differences  
13 for violations of certain inspection procedures.

14 235. Consistent with Defendants’ general approach of selectively choosing data that supports  
15 its pre-determined conclusion, in the final rules’ preamble, Defendants ignored this fact and simply  
16 pointed to the two years for which traditional plants had a greater number of noncompliances. 84  
17 Fed. Reg. at 52308.

18 236. Second, while the Hog HIMP Report details that the total noncompliances for certain  
19 PHR violations were lower in CYs 2012 and 2013 for model plants, Plaintiffs’ comments pointed  
20 out that model plants had a dramatic and statistically significant higher noncompliance rate for  
21 certain regulations such as 9 C.F.R § 417.3(a)(2). This regulation is a measure of whether the plant  
22 is maintaining control over a critical control point in the plant. Model plants had an eleven-fold and  
23 three-fold higher rate of violating this regulation in CYs 2012 and 2013, respectively. Plaintiffs  
24 commented that the fact that, for two years, model plants had a higher noncompliance rate for this  
25 regulation shows that the model plants were not adhering to their food safety plans and, thus, that  
26 these plants were out of control far more frequently than in the ostensibly comparable traditional  
27 plants. Defendants ignored this comment in the response to comments in the final rules’ preamble.

1       237. Third, Plaintiff FWW submitted additional noncompliance data with its comments on the  
2 proposed rules that FWW had compiled by examining noncompliance reports filed from 2012  
3 through 2016 in the five model plants and five traditional plants that slaughtered a comparable  
4 number of hogs. FWW's analysis showed that regulatory violations for which there were 200 or  
5 more citations showed that the model plants received:

- 6       • 84% of the non-compliance reports that were filed for problems with food safety plans [9  
7 C.F.R § 417.2(c)(4)];
- 8       • 73% of the reports that were filed for carcass contamination with feces, bile, hair or dirt  
9 [9 C.F.R § 310.18(a)];
- 10      • 65% of the reports that were filed for general carcass contamination [9 C.F.R § 310.18];  
11      and
- 12      • 61% of the reports that were filed for equipment sanitation [9 C.F.R § 416.3(a)].

13       238. FWW's analysis also showed that that there were thirty-two instances in which the  
14 federal inspector discovered that a plant employee failed to identify a carcass so infected that  
15 consumption of the meat could cause food poisoning in violation of regulation 9 C.F.R § 311.16(a).  
16 All of these violations occurred in the pilot plants.

17       239. Fourth, Plaintiffs' comments explained that Defendants' own risk assessment showed  
18 that model plants had 9.4-times more NRs than all traditional plants for all regulations. The risk  
19 assessment found that such NRs are the strongest and a statistically significant indicator of human  
20 illnesses related to consuming contaminated pork. *See* Final Risk Assessment at 54, 91. Instead of  
21 specifically addressing this strong evidence that plants under NSIS will have more noncompliances,  
22 Defendants just choose to ignore it, stating that they do not believe that different allocation of  
23 inspection resources can alter plants' noncompliance rates—notwithstanding the significant  
24 differences between those in model and traditional plants. 84 Fed. Reg. at 52309.

25       240. Fifth, in Plaintiff FWW's May 23, 2019, analysis (detailed *supra* at ¶ 104), FWW  
26 evaluated more recent data and calculated that, on average, there were more noncompliances in the  
27

1 pilot plants from 2012 through 2018 than in the group of traditionally inspected plants that are  
2 expected to switch to NSIS.

3 241. Sixth, according to an FWW analysis based on data obtained in a FOIA request, model  
4 plants have a statistically greater noncompliance rate for 9 C.F.R. § 310.18 (also known as a FS-2  
5 standard) for FYs 2012 through 2014. The agency has zero tolerance for this standard, meaning  
6 that no contaminated product is deemed acceptable. This demonstrates that model plants are  
7 allowing more contaminated carcasses to the final inspection station than traditional plants.

8 242. Defendants reached the opposite conclusion for FYs 2012 and 2013 for this regulation in  
9 its Hog HIMP Report by adjusting the noncompliance rate (noncompliances per verification) by a  
10 factor that accounts for an increased number of swine carcasses tested in model plants (*see* ¶ 225).  
11 Hog HIMP Report at 27. But not only does the report completely fail to disclose this, this  
12 adjustment inappropriately deflates the FS-2 noncompliance rate for model plants—as any  
13 additional swine spot-checked at model plants are supposed to *compensate* for the fact that  
14 traditional plants have *online* inspectors that inspect every single carcass, while the model plants do  
15 not.

16 243. Defendants have attempted to generally respond to the fact that there have been more  
17 noncompliances in model plants than traditional plants by arguing that it is because federal  
18 inspectors in model plants conduct “more offline inspection activities that FSIS has concluded are  
19 more effective in ensuring food safety than offline FSIS inspectors[.]” 84 Fed. Reg. at 52308. So,  
20 inspectors in these plants “have more opportunities for detecting noncompliance with regulatory  
21 requirements that are directly related to public health than inspectors do in non-HIMP traditional  
22 establishments.” *Id.* Regarding 9 C.F.R § 311.16(a), in particular, Defendants have indicated that  
23 inspectors do “not issue NRs for this regulation under traditional inspection because FSIS  
24 inspectors are responsible for identifying and removing food safety and non-food safety defects.”  
25 *Id.*

26 244. Notwithstanding that inspectors do not generally conduct more offline inspection  
27 activities related to PHRs, as demonstrated *supra* in ¶¶ 228-229, Defendants’ response fails to  
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1 acknowledge that if model plants perform at least as well as traditional plants at producing  
2 unadulterated and wholesome product, as Defendants' contend, their noncompliance *rates*  
3 (noncompliances per inspection or verification) will be the same or better for model plants,  
4 regardless of the number of spot-checks.

5 245. And, for many regulations, model plants have higher noncompliance *rates* than  
6 traditional plants. The data in Defendants' Hog HIMP Report, for example, details noncompliance  
7 *rates*. Hog HIMP Report at 22-26. While FWW's data about ten comparatively-sized plants solely  
8 summed the raw numbers of non-compliances, FWW's selection of similarly-sized plants in part  
9 controlled for the number of verifications, under the general assumption that similarly-sized plants  
10 receive a similar number of verifications. A more recent FWW analysis of noncompliance rates,  
11 which FWW could only perform after Defendants released data in May 2019 in response to a FOIA  
12 request, reveals that for each of the four regulations cited in ¶ 237, model plants had *twice* the total  
13 noncompliance rate from 2012 to 2016 than the similarly-sized traditional plants.

14 246. Finally, Defendants' contention that inspectors do more spot-checks for certain  
15 regulations in model plants ignores that this is in no small part due to Defendants' assumption that  
16 traditional plants *do not need* additional verifications for such regulations because online inspectors  
17 are responsible for ensuring contaminated carcasses do not leave slaughter lines. This means that  
18 noncompliances in model plants for regulations such as 9 C.F.R. § 311.16(a) indicate a problem that  
19 is not an issue in traditional plants.

20 247. In short, Defendants cannot rely on greater regulatory compliance rates at model plants as  
21 a justification for the final NSIS rules.

22 *iii. No lesser levels of non-food-safety defects or lower violative levels of*  
23 *chemical residues*

24 248. The Defendants have also misleadingly asserted that model plants had fewer non-food  
25 safety defects. 84 Fed. Reg. at 52303. This fails to acknowledge that Defendants do not evaluate  
26 such "Other Consumer Protection" defects in traditional plants. Hog HIMP Report at 30.  
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1       249. Moreover, the Other Consumer Protections standards that Defendants relied upon for  
2 showing that the model plants were performing as well as or better than before they were in the  
3 pilot project were created six-to-ten years earlier than the Hog HIMP Report data. In fact, a report  
4 to which the Defendants cite in their final NSIS rules' preamble for support, the *Review of the*  
5 *HACCP-Based Inspection Models Project by the National Alliance for Food Safety Technical*  
6 *Team*, criticizes a similar poultry study for only a mere two-year lag between when the baseline  
7 data were collected and when the model-system data were collected for evaluation. *See*  
8 <https://www.fsis.usda.gov/OPPDE/nacmpi/Nov2002/Papers/NAFS97.pdf> at 4.

9       250. As for Defendants' claims of lower violative residues, Defendants failed to mention that  
10 for four years, 2006 to 2010, the differences in violative chemical residues between model and  
11 traditional plants were not statistically significant. Hog HIMP Report at 33.

12       251. Defendants also failed to disclose data showing that inspectors are testing far less product  
13 for residues in model plants, even though more testing is supposed to be a benefit of the new  
14 inspection system. Defendants have never made public an analysis prepared by its former Chief  
15 PHV at the time of the pilot that showed that model plants had a significantly lower rate of  
16 inspector-generated residue tests of animals than non-model plants in the same district. They also  
17 had a statistically significant lower rate of performing tests called Kidney Inhibition Screening tests.  
18 This includes data showing the same trend for similar plants operated by the same company, which  
19 should have a similar quality of swine.

20       252. Data released by Defendants in response to FWW's FOIA request after the close of the  
21 comment period indicates that traditional plants had an average of four-times more inspector-  
22 generated residue samples than model plants.

23                   *iv. No equivalent or better Salmonella verification testing positive rates*

24       253. Finally, and despite statements in the final NSIS rules' preamble suggesting otherwise,  
25 Defendants can point to nothing, including in their Hog HIMP Report and risk assessment, that  
26 indicate that slaughter plants' adoption of NSIS will reduce the levels of pathogens in swine.  
27

1       254. Defendants' Hog HIMP Report found no statistically significant differences in  
2 *Salmonella* rates between CYs 2006 and 2010 between model and non-model plants. Hog HIMP  
3 Report at 31. Another study, Defendants' 2010 baseline study, likewise found no statistically  
4 significant differences in *Salmonella* prevalence between the model and similarly sized traditional  
5 plants. *Id.* at 31-32. This means that there is not enough evidence to conclude that any differences  
6 are anything but statistical noise.

7       255. The risk assessment, detailed *infra* in ¶¶ 260-312, does not compare the *Salmonella*  
8 outcomes in pilot and traditional plants. Rather, it modelled the reduced *Salmonella* incidences  
9 expected from the increased number of various *offline* verification tasks that are presumed to occur  
10 under the new rules based on the model plants, but without any evaluation of possible changes in  
11 pathogen levels at model plants from the new system's change in *online* inspections. *See* Final Risk  
12 Assessment at 27.

13       256. As demonstrated in Plaintiffs' comments on the proposed NSIS rules, the performance of  
14 poultry-slaughter plants under the similar New Poultry Inspection System (NPIS) rules, adopted by  
15 Defendants in 2014, has not demonstrated the *Salmonella* reductions that Defendants' risk  
16 assessment predicted for plants operating under those rules.

17       257. The only statistically significant difference in *Salmonella* test results to which the  
18 Defendants can point are between a group of 147 traditional plants and the five NSIS model plants  
19 in the Defendants' 2010 baseline study. Hog HIMP Report at 32.

20       258. The fact that this is the only place in the Hog HIMP Report that Defendants compared the  
21 model plants to any plants other than the twenty-one-comparator set of traditional plants indicates  
22 that Defendants were cherry-picking for supporting data both in this report and the risk assessment.  
23 Notwithstanding, the data show that traditional plants had much higher *Salmonella* incidences prior  
24 to evisceration than in model plants (which is prior to employee sorting in the model plants). *Id.*  
25 And traditional plants had much larger reductions in *Salmonella* incidences than did the model  
26 plants after their employees engaged in sorting. *Id.* This indicates that the employee sorting and  
27

1 greater amount of inspector spot-checking employed in model plants has little effect on *Salmonella*  
2 reductions.

3 259. In sum, Defendants have produced a very flawed evaluation of the small sample of five  
4 volunteer model plants (all of which are substantially larger than most of the other plants that the  
5 agency indicates will adopt NSIS), and twenty-one hand-selected comparator set of traditional  
6 plants. Whether it is the number of food-safety-related spot-checks, compliance with regulations,  
7 rates of non-food safety defects or violative residues, or positive *Salmonella* verification tests,  
8 Defendants' misleading or otherwise inadequate analysis does not indicate that the model plants  
9 provide equivalent, much less better, public-health protection than under the traditional inspection  
10 system. Indeed, the model plants' higher rates of regulatory non-compliances of key regulations,  
11 such as 9 C.F.R. § 310.18, greater number of total non-compliances per plant, and fewer number of  
12 public-health regulation spot-checks per plant all indicate that the NSIS rules will provide for *worse*  
13 protection than under traditional inspection. Defendants have refused to acknowledge these flaws  
14 and address these serious concerns, instead simply ignoring public comments or providing false and  
15 misleading responses in the final NSIS rules' preamble.

### 16 **3. Defendants' Inadequate Final Risk Assessment and Responses to Comments**

17 260. The Defendants' Final Risk Assessment, which Defendants cite to for the only  
18 quantitative public-health benefits for the NSIS rules, is also fundamentally flawed. Generally, the  
19 Final Risk Assessment seeks to evaluate the relationship between an assumed increased number of  
20 off-line spot-checks at NSIS plants and the expected attributable decrease in human illness due to  
21 *Salmonella* contamination. The analysis estimates that if plants increase the number of unscheduled  
22 and scheduled verification tasks, while decreasing scheduled-but-not-performed tasks, there would  
23 be an estimated reduction of 2,533 *Salmonella* illnesses annually, reflecting a 3.8% reduction in  
24 *Salmonella* illnesses attributable to pork products. Final Risk Assessment at 55; 84 Fed. Reg. at  
25 52333.

26 261. But the Final Risk Assessment has serious flaws. First, it is limited in scope, including  
27 its use of stale and sparse data of one pathogen from only five model plants.

1       262. Second, the peer review process of the assessment was not transparent, nor did it result in  
2 a more sound evaluation. After the close of the comment period on the proposed rules, it was  
3 revealed that a set of expert peer-reviewers had raised serious concerns about the fundamental flaws  
4 in the risk assessment. Defendants refused to reopen the comment period on the proposed rules  
5 after making a large number of changes to the document, contrary to their prior statements that they  
6 would. According to the Defendants, the peer reviewers' comments did not alter the risk  
7 assessment's conclusions. But this simply reflects the Defendants' resolve in ignoring the peer  
8 reviewers' critiques that questioned the very validity of the risk assessment—as many of  
9 Defendants' changes to the risk assessment merely papered over peer reviewers' critiques. Because  
10 of the failure to reopen the comment period, the public did not have the peer reviewers' comments  
11 to inform and tailor its own comments.

12       263. Third, the Defendants did not and could not address the risk assessments' fundamental  
13 flaws that include double-counting and other faulty assumptions. Perhaps its most glaringly  
14 problematic assumption is that the inspection system employed by the plant is a more important  
15 predictor of *Salmonella* prevalence than plant volume and Defendants' refusal to take this into  
16 consideration with its modelling.

17                   *i. The Final Risk Assessment's Circumscribed Scope*

18       264. The Final Risk Assessment attempts to model what will occur at 35 traditional plants that  
19 are likely to adopt NSIS, based on the inspection activities and the results of *Salmonella* testing  
20 from 159 traditional and 5 model plants from 2010 to 2011. Final Risk Assessment at 15-16.

21       265. The five model plants listed are the same volunteer plants that the Defendants evaluated  
22 as part of the Hog HIMP Report.

23       266. Again, the Defendants did not have enough *Salmonella* data from these plants from  
24 Defendants' baseline study (see ¶¶ 257-258), so they had to combine the 2010 baseline study and  
25 routine verification tests outside of the study. Final Risk Assessment at 86. The combined data is  
26 similar to the baseline study discussed *supra* in ¶ 258, in that traditional plants have more post-chill  
27 *Salmonella* incidences than model plants, but also had a *greater reduction* from pre-evisceration to

1 post-chill compared to model plants, *id.*, thus indicating that the model inspection system does not  
2 have much an effect, if any, in reducing *Salmonella* incidences.

3 267. On information and belief, the Final Risk Assessment does not report all of the  
4 *Salmonella* data from the baseline study, raising questions about whether certain data was excluded  
5 because it did not support Defendants' conclusions.

6 268. The list of thirty-five plants that the Defendants used for the risk assessment model  
7 inexplicably has a few different plants than the list of plants that Defendants have indicated are  
8 likely to switch over and used in the agency's cost-benefit analysis and Regulatory Impact  
9 Analysis, again raising questions about its findings.

10 269. Like with the Hog HIMP Report, the Defendants have never explained the basis for its  
11 selection of thirty-five plants that it used in the risk assessment's model.

12 270. Defendants' Final Risk Assessment did not compare the likely impacts on traditional  
13 plants switching to NSIS versus not switching. Defendants instead chose to model possible  
14 *Salmonella* illness reduction as a result of plants employing those offline verification procedures  
15 they assume are likely to occur under NSIS. Final Risk Assessment at 27, 29-30. For example,  
16 Defendants' Final Risk Assessment did not evaluate what the decrease in *online* inspection would  
17 do to the attributable rate of human illness due to *Salmonella*. *Id.* Nor does Defendants' Final Risk  
18 Assessment evaluate what the increase in line speeds would do to the attributable rate of human  
19 illness. *Id.* at 39.

20 271. Defendants' risk assessment only modeled the effects of human illness due to one  
21 pathogen, *Salmonella*. Defendants chose this pathogen, despite the fact that Defendants had  
22 discontinued collecting *Salmonella* verification samples for carcasses in market hog slaughter  
23 classes in July 2011 due to Defendants' perception of a low rate of *Salmonella* in carcasses.

24 272. In part, *Salmonella* was evaluated because of high levels of *Salmonella* found in recent  
25 exploratory sampling, which was launched in 2015. Final Risk Assessment at 10.

26 273. Instead of waiting for more recent *Salmonella* data to be collected, Defendants used the  
27 *Salmonella* data from carcasses from nearly ten years ago, from 2010 to 2011. Final Risk

1 Assessment at 24. This, despite the fact that, at the time of the public comment period on the  
2 proposed NSIS rules, Defendants' exploratory testing was showing far higher *Salmonella* levels on  
3 pork products compared to the levels modeled in the risk assessment.

4 274. In its response to comments on the final NSIS rules, Defendants claim that they would  
5 not find this exploratory sampling data to be helpful for evaluating process control in slaughter  
6 plants because of the cross-contamination involved in processing plants that purchase primal cuts  
7 from multiple slaughter plants. 84 Fed. Reg. at 52311.

8 275. This response ignores the fact that commenters had cited a 2005 survey of the meat  
9 industry that found that "[m]ore than 80 percent of meat plants also perform processing activities."

10 276. All of the thirty-five plants that Defendants believe will adopt NSIS also process meat in  
11 addition to slaughtering swine.

12 277. Defendants chose not to include other microbiological contaminants or other public  
13 health issues as part of its risk assessment, despite commenters' request that they be included to  
14 ensure a more robust assessment. Defendants have provided no reason for excluding other  
15 microbiological contaminants or public health issues, except to say that *Salmonella* was an indicator  
16 for *Yersinia enterocolitica* and that it did not include swine influenza because it is not pathogenic.  
17 84 Fed. Reg. at 52311.

18 *ii. The Lack of Transparency in the Peer-Review Process*

19 278. Although the Defendants announced that their risk assessment would be peer reviewed,  
20 they failed to conduct the review until the comment period was nearly closed in April 2018.  
21 Adding insult to injury, the Defendants then failed to release the peer reviewers' comments until  
22 several months later. Defendants' rationale for not conducting the peer review sooner was that they  
23 were confident that the rule would not change in light of any peer review comments, and they thus  
24 did not need to wait for the peer reviewers' comments before proposing the rule. Defendants  
25 indicated that they would reopen the comment period for the proposed rules if they made changes to  
26 the risk assessment based on peer review comments. *See* FSIS, Transcript of FSIS Webinar at 18-  
27 19, located at <https://www.fsis.usda.gov/wps/wcm/connect/e7affcab-0c80-42c5-a9c3->

1 d78d9c96e6c2/USDA-FSIS-OPACE-Swine%2BModernization-transcript%284-16-  
2 2018%29.pdf?MOD=AJPERES.

3 279. On September 5, 2019, Defendants posted for review a summary of peer-reviewers'  
4 comments and revised risk assessment made in response to these comments, along with a thirty-day  
5 comment period on the revised risk assessment. *See* "Response to Peer Review Comments on:  
6 Assessment of the Potential Change in Human Risk of Salmonella Illnesses Associated with  
7 Modernizing Inspection of Market Hog Slaughter Establishments" (Aug. 2018),  
8 [https://www.fsis.usda.gov/wps/wcm/connect/eeaf2769-92ef-4639-a653-ecbe5364252d/Response-](https://www.fsis.usda.gov/wps/wcm/connect/eeaf2769-92ef-4639-a653-ecbe5364252d/Response-to-Peer-Review-CommentsMarket-Hog-Risk-Assessment-080318.pdf?MOD=AJPERES)  
9 [to-Peer-Review-CommentsMarket-Hog-Risk-Assessment-080318.pdf?MOD=AJPERES](https://www.fsis.usda.gov/wps/wcm/connect/eeaf2769-92ef-4639-a653-ecbe5364252d/Response-to-Peer-Review-CommentsMarket-Hog-Risk-Assessment-080318.pdf?MOD=AJPERES). (Peer  
10 Review Comments).

11 280. As discussed below, peer reviewers questioned the very validity of the model project and  
12 pointed out fundamental problems with the risk assessment's modeling.

13 281. A separate analysis of the number of changes in the risk assessment reveals that more  
14 than 4,900 changes were made to the risk assessment in light of the peer reviewers' comments, of  
15 which approximately sixty percent were substantive. (As discussed below, however, Defendants  
16 did not and could not address many of the peer reviewers' more fundamental concerns.)

17 282. Notwithstanding the extensive peer-reviewer critiques and resulting changes to the risk  
18 assessment, Defendants refused to reopen the comment period on the proposed rules because  
19 "neither the peer review comments nor the revisions to the risk assessment made in response to  
20 those comments, produced changes to the assessment's conclusions that would require  
21 modifications to the proposed rule." FSIS, Constituent Update Special Alert - August 6, 2018,  
22 [https://www.fsis.usda.gov/wps/portal/fsis/newsroom/meetings/newsletters/constituent-](https://www.fsis.usda.gov/wps/portal/fsis/newsroom/meetings/newsletters/constituent-updates/archive/2018/ConstUpdate080618)  
23 [updates/archive/2018/ConstUpdate080618](https://www.fsis.usda.gov/wps/portal/fsis/newsroom/meetings/newsletters/constituent-updates/archive/2018/ConstUpdate080618).

24 283. Without access to the peer reviewers' comments, which substantially undermine  
25 Defendants' rationale for the NSIS rules, Defendant's response to the peer review, and the agency's  
26 revised risk assessment (notwithstanding its inadequacies), the public was unable to fully assess the  
27 proposed rules and adequately tailor their comments on whether the rules should be finalized.

1       284. Defendants did not announce the availability of the peer-review comments and revised  
2 risk assessment for public comment in the *Federal Register*. Instead, Defendants simply posted the  
3 revised risk assessment on the FSIS website. The revised risk assessment received just five public  
4 comments.

5       285. Plaintiff FWW submitted a letter requesting an extension of the comment period on the  
6 revised risk assessment but was denied on the grounds that “neither the peer review comments, nor  
7 the revisions to the risk assessment made in response to those comments, produced major changes  
8 to the assessment’s conclusions.” Letter from Roberta Wagner to Wenonah Hauter (Sept. 5, 2018).

9                   *iii. Defendants’ Failure to Address Peer Reviewers’ and Public Comments on*  
10                   *the Risk Assessment*

11       286. In September 2018, FWW submitted comments on the revised risk assessment indicating  
12 that Defendants had failed to even minimally address some of the concerns of the peer reviewers as  
13 well as respond to the organization’s questions related to that analysis—rendering the revised risk  
14 assessment inadequate to support the NSIS rules.

15       287. One peer reviewer had questioned the design of the study, indicating that with only five  
16 model plants, there are essentially only five observations: “. . . [i]f other non-measured factors play  
17 a part (like discipline, building work conditions) then the model does not have enough data points  
18 to have such unknown factors average out.” Peer Review Comments at 10. The peer reviewer also  
19 commented that plants have been using the model inspection system for many years, and “there are  
20 no data that could be used to compare the same plant’s contamination post-chilling with and  
21 without HIMP—which would have been ideal.” *Id.*

22       288. Defendants responded to this peer reviewer’s comment by saying it had done additional  
23 power analyses in Appendix H and that the sample size is large enough to detect differences. *Id.*

24       289. FWW’s comments on the revised risk assessment explained that this response was  
25 completely inadequate and that the agency should be forthright with the peer reviewer and “indicate  
26 that the risk assessment was not designed to test the hypothesis of whether [model plants]  
27 performed better than [traditional] plants. Thus, such failings in the design of the . . . model is

1 baked into the risk assessment and cannot be changed without collecting more data. Its power  
2 analysis in Appendix H does not address the issue that s/he raises. A failure to do so renders the  
3 entire revised risk assessment unreasonable to support the proposed NSIS rule.”

4 290. Defendants never responded to FWW’s comment in the preamble to the final NSIS rules.

5 291. The same peer reviewer also indicated that the data did not seem to show a relationship  
6 between the type of plant (model or traditional) and a reduction in *Salmonella*. *Id.* at 17-22. Plant  
7 volume seemed to be a much stronger predictor of *Salmonella* prevalence that was not accounted  
8 for in the model. *Id.* at 22. The reviewer pointed out that one model plant had much lower pre-  
9 evisceration and post-evisceration *Salmonella* rates than other model plants, raising the question of  
10 how much the employment of the model inspection system had to do with reductions in *Salmonella*.  
11 *Id.* The reviewer “conclude[d] that the regression model assumption that there is a relationship  
12 between [model plant] inspection activities and post-chill prevalence of *Salmonella* contamination  
13 has not been established. In my view, this makes the risk assessment model invalid.” *Id.* Another  
14 peer reviewer also criticized the lack of controlling for confounders. *Id.* at 45.

15 292. Defendants responded to the peer reviewers’ comments about plant volume by pointing  
16 to additional analyses in its revised risk analysis. But the revised risk assessment did not include  
17 any analysis on why plant volume as a continuous variable should be excluded from the model.

18 293. FWW raised this issue in an email prior to the close of the comment period on the revised  
19 risk assessment. The Defendants responded by saying that that there is a significant linear  
20 correlation between plant volume and the number of inspectors at plants, which is captured in the  
21 agency’s model regression. But when FWW responded by pointing out that the peer reviewer had  
22 indicated that this was not the same as modeling production volume, Defendants indicated that  
23 FWW should include this issue in its comments. FWW did.

24 294. Defendants did not address these issues in its final response to comments in the preamble  
25 to its final NSIS rule.

26 295. Defendants’ model did not include plant-production volume as a continuous variable.  
27  
28

1       296. The Defendants' failure to evaluate whether plant-production volume is a better predictor  
2 of post-chill *Salmonella* prevalence than the type of inspection procedure means that the  
3 Defendants' model does not accurately predict the likely *Salmonella* prevalence and illnesses from  
4 the substantial number of smaller-volume traditional plants that Defendants predict will switch to  
5 the NSIS system.

6       297. This is supported by an FWW analysis indicating that the mostly smaller-volume group  
7 of fourteen non-model plants that are likely to adopt NSIS have a significantly larger *Salmonella*  
8 post-chill prevalence rate compared to the twenty-one mostly larger-volume non-model plants  
9 likely to switch over. This indicates that the smaller-volume plants most likely to switch to NSIS  
10 may perform worse than the larger-volume plants. Defendants have never made public any  
11 evaluation of the performance of more than fourteen traditional plants that they project are likely to  
12 switch over to NSIS but were not amongst the twenty-one evaluated in the Hog HIMP Report.

13       298. Two other peer reviewers commented that the agency should provide the characteristics  
14 of the model plants in order to better assess the general applicability of the results. One of these  
15 reviewers also indicated that there was uncertainty due to selection bias:

16       Additional information could include age of the facility, sourcing of pigs for slaughter (e.g.,  
17 preferential sourcing based on *Salmonella* infection status or implemented control strategies  
18 at the farm level), slaughter line characteristics, any *Salmonella* control strategies in place at  
19 the facility (e.g., hot water decontamination of carcasses or decontamination with organic  
20 acids, and application of logistic slaughtering (i.e., separation of pigs at slaughtering based  
21 on their risk of *Salmonella* infection). The characteristics of the enrolled facilities should be  
22 compared with the rest of the industry. From this information the reader should be able to  
23 infer whether the enrolled establishments were representative of the variation in the industry  
24 and any non-enrolled facility should be able to judge whether the results apply to their  
25 facility or not. It is impossible to control for the presence of selection bias at the analysis  
stage (stage 1); this bias is controlled at the study design stage (i.e., enrollment of facilities).  
However, the stage 1 results should be discussed in the context of any evidence for or against  
the presence of selection bias. If the characteristics of the enrolled facilities are representative  
of the industry that would reduce the uncertainty around the results. If there is evidence of  
selection bias, that limitation and the likely direction of bias (i.e., under- or over-estimation  
of the measures of association) should be discussed.

26 Peer Review Comments at 27.

1 299. Defendants responded by saying that “[a]lthough having such detailed information about  
2 each establishment might provide more information on potential biases, such information was not  
3 available. Because this risk assessment was not carried out as an experiment but rather an  
4 observational study and so [*sic*] the representativeness of the sample could not be controlled.” *Id.*

5 300. In its comment on the revised risk assessment, FWW pointed out that this information  
6 could be easily collected, as more information was collected about poultry plants prior to a similar  
7 NPIS rulemaking now applicable to young chicken and poultry slaughter plants.

8 301. Defendants never addressed FWW’s comment in the preamble to the final NSIS rules.

9 302. If nothing else, Defendants have information on the microbiological control strategies at  
10 market hog slaughter plants at the time that the *Salmonella* data was collected that was used in the  
11 risk assessment.

12 303. One peer reviewer critiqued the analysis for not demonstrating that the lower level of  
13 *Salmonella* prevalence in the model plants was related to the pilot as opposed to other possible  
14 characteristics of the plant:

15 The only concern is how the selection of the 5 establishments for the implementation of the  
16 HIMP was conducted. Were those 5 HIMP establishments significantly different from the  
17 other 159 non-HIMP establishments **before** the FSIS initiated the voluntary HACCP-based  
18 Inspection Models Project (HIMP) in each of them? Certainly in Appendix B we can see  
19 that (as expected) there are differences in the prevalence of *Salmonella* in the HIMP vs non-  
20 HIMP establishments. Now, the question is, is that prevalence difference due to the  
21 implementation of the HIMP or is this something that may have been observed even before  
the implementation of HIMP just due to the nature and specific characteristics of those  
particular 5 establishments. It will be great (if possible) to present some tables similar to the  
ones in Appendix B of the historical info of those 5 establishments **before** the actual  
implementation of the HIMP protocols to actually address this question/concern.

22 *Id.* at 43 (emphasis in original).

23 304. FWW commented on how Defendants’ response to this comment, by referring to the Hog  
24 HIMP Report, was inappropriate given that this report presented no historical *Salmonella* data from  
25 model plants prior to their joining the pilot.

26 305. The Defendants failed to address these comments in the preamble to the final NSIS rules.

1 306. None of the *Salmonella* data in the Defendants' Hog HIMP Report pre-date the data  
2 presented in the risk assessment, so Defendants did not address the peer reviewer's issues by  
3 referring him or her to the Hog HIMP Report for historical data.

4 *iv. Double Counting and Flawed Assumptions*

5 307. There are other serious problems with the Defendants' Final Risk Assessment, including  
6 double counting and flawed assumptions.

7 308. Defendants modeled the effects in *Salmonella* reduction from an increase in "scheduled  
8 performed" tasks, as added to a decrease in "scheduled not performed" tasks projected to occur in  
9 NSIS plants, even though the latter is just the logical result of the former and should not result in  
10 any additional reductions in *Salmonella* incidences.

11 309. In modelling the likely reductions in *Salmonella* prevalence from traditional plants  
12 switching to NSIS, Defendants apply adjustments to estimate how the verification procedures are  
13 most likely to change under the new system. The Defendants failed to explain the bases for these  
14 adjustments, however. Final Risk Assessment at 30. For example, the Defendants' model assumes  
15 that the most likely outcome is that noncompliances will increase by 10% simply by switching to  
16 the model system, when, in fact, as detailed in ¶ 239, model plants had more than 9.4 times the  
17 noncompliances, more than 10 years after the model project began. *Id.*

18 310. Defendants' analysis "assumed that noncompliance records may initially increase with  
19 more offline inspectors in slaughter establishments, but, in the long run, may decrease because such  
20 establishments would attain appropriate process control." *Id.* at 82.

21 311. Defendants have presented no data supporting this assumption.

22 312. Defendants claim these adjustments were based in part on the risk assessment for the  
23 NPIS, but they failed to show that presumed allocations of inspection tasks actually occurred in  
24 poultry plants operating under NPIS, which was finalized in 2014, and what the effects on  
25 *Salmonella* incidences have been. *Id.* at 49-50.

1 **VII. UNDUE BIAS IN THE RULEMAKING**

2 313. Finally, if the above does not sufficiently demonstrate how the Defendants' bases for the  
3 final NSIS rules are fundamentally flawed, Defendants demonstrated undue bias by prejudging both  
4 the facts and the law in promulgating the final NSIS rules.

5 314. Defendants have repeatedly refused to release and make public the data underlying their  
6 Hog HIMP Report, for example, despite claiming in the final rules' preamble that they "made every  
7 effort to respond to FOIA requests related to the proposed rule before the close of the comment  
8 period." 84 Fed. Reg. at 52305.

9 315. Plaintiff FWW has been forced to file a separate FOIA lawsuit because the agency failed  
10 to release much of the responsive information pertaining to this rulemaking for more than twenty-  
11 one months, even though the agency granted FWW's FOIA request for expedited processing so that  
12 it would have the records prior to the close of the NSIS comment period. Defendants only started  
13 releasing data per agreement with FWW on February 28, 2020.

14 316. Recently, the Defendants have denied several FOIA requests by FWW and others,  
15 refusing to release agency records detailing the identities of plants seeking to switch to NSIS.

16 317. Finally, Defendants' contempt for public comments became readily apparent when it  
17 issued a press release in response to a *Washington Post* article about the proposed NSIS rules. *See*  
18 [https://www.fsis.usda.gov/wps/portal/fsis/newsroom/news-releases-statements-transcripts/news-](https://www.fsis.usda.gov/wps/portal/fsis/newsroom/news-releases-statements-transcripts/news-release-archives-by-year/archive/2019/nr-040819-01)  
19 [release-archives-by-year/archive/2019/nr-040819-01](https://www.fsis.usda.gov/wps/portal/fsis/newsroom/news-releases-statements-transcripts/news-release-archives-by-year/archive/2019/nr-040819-01). It was a bellicose critique of the article and  
20 defense of the NSIS rules, even though they were not finalized—and despite FSIS's own admission  
21 that "as a federal regulatory agency, FSIS cannot litigate or conduct rulemaking through the  
22 media." For example, Defendant FSIS claimed that "[t]he Post's decision to continue to parrot  
23 arguments that are devoid of factual and scientific evidence only serves to further the personal  
24 agenda of special interest groups that have nothing to do with ensuring food safety." The press  
25 release continued "Shame on you, Washington Post. This story earns you at least four Pinocchios."  
26  
27  
28

1 318. Defendants thus made apparent their belief that substantive critiques of the proposed  
2 NSIS rules were without merit, had nothing to do with food safety, and that the groups advancing  
3 such critiques are simply “special interest groups.”

4 319. The Defendants also distorted the nature of their rules in the press release. For example,  
5 they misleadingly contended slaughter-plant sorting under NSIS was different than “inspection,”  
6 and “condemnation,” even though, as demonstrated above, they both involve the identifying and  
7 removal of animals and carcasses with condemnable conditions. Defendants also falsely claim that  
8 “[i]f the proposed rule becomes final, USDA will follow the same ante-mortem inspection  
9 procedures in traditional and NSIS establishments.”

10 320. Thus, Defendants’ press release made clear that they had already reached a conclusion on  
11 the validity of their proposed rules and were intent on defending these conclusions in the media.

#### 12 **VIII. HARM TO PLAINTIFFS**

13 321. The interests of Plaintiffs, organizationally and through their hundreds of thousands of  
14 members, have been, are being, and will be adversely affected by Defendants’ implementation of  
15 the final NSIS rules.

16 322. In particular, the final NSIS rules injure Plaintiff organizations by putting their members’  
17 health and safety in increased jeopardy, through the risk of contracting foodborne illness.  
18 Contaminated pork may already cause as many as 1.5 million cases of foodborne illnesses, 7,000  
19 hospitalizations, and 200 deaths in the United States each year. With slaughter plant employees  
20 replacing federal inspectors both before and after slaughter and no limits on line speeds, Congress’s  
21 command that Defendants “protect the health and welfare of consumers” is thwarted and Plaintiffs’  
22 members are put at a greater risk of contracting foodborne illnesses. *See* 21 U.S.C. § 602.

23 323. Foodborne illness affects the Plaintiff-members’ health, well-being, and finances. The  
24 new rules are intended to be adopted by enough plants that their pork products will be ubiquitous in  
25 interstate commerce. Indeed, at least two of FWW members have regularly consumed pork  
26 produced in plants that Defendants expect are likely to switch to the new system. FWW, CFS, and  
27 HFA members will not be able to avoid pork from de-regulated plants because of its ubiquity in the

1 marketplace and the absence of clear labeling disclosing which slaughter plants have adopted the  
2 new rules—especially at restaurants where purveyors often do not publicly disclose, or have little  
3 knowledge about, where the swine are slaughtered for their pork products. For example, Marian  
4 Lapp, a 74-year-old resident of Virginia and dues-paying member of HFA, has been a regular  
5 consumer of pork for many years—in her home, in the homes of her friends, and in restaurants.  
6 Gordon Levenbach, a 76-year-old resident of North Carolina and dues-paying member of HFA,  
7 likewise has regularly consumed pork for many years in his home and in restaurants. Both intend to  
8 continue consuming pork, and for that reason they are at an increased risk of food-borne illness  
9 when they consume pork that is processed according to the less-rigorous federal-oversight standards  
10 embodied in the NSIS. Other CFS and FWW members, including the identified individual  
11 Plaintiffs have already spent extensive time and money trying to research whether the products that  
12 they consume are from plants that Defendants believe are likely to switch to the new system, in the  
13 hopes that they might be able to avoid such products. Some of CFS and FWW members have  
14 reasonably decided to reduce their consumption of pork or avoid eating it altogether, depriving  
15 themselves of a product or restaurants that they enjoy.

16 324. What’s more, Defendants have initially indicated that they will not make public the  
17 identities of plants that have requested to switch over to NSIS. It is not clear whether they will  
18 make public the names of those that have already switched over. Defendants have informed at least  
19 one processing plant that it cannot alter its label to inform customers that its product is slaughtered  
20 under traditional inspection. Moreover, because of the new system, consumers will be purchasing  
21 and eating product that was sorted at NSIS plants and then sold on the secondary market without a  
22 PHV inspection. All of this means that it will be impossible for consumers to actually know  
23 whether the pork products they purchase come from plants that have switched over to NSIS, and  
24 protect themselves and their families from product that did not receive full federal inspection.  
25 Those who regularly consume pork will be harmed not only because of their exposure to  
26 adulterated or unwholesome product, but also from increased prices resulting from disease  
27 outbreaks that are all but inevitable under the new rules.



1 a “critical appraisal” by a federal inspector prior to slaughter. *See AFGE v. Glickman*, 215 F.3d at  
2 11; 21 U.S.C. § 622.

3 328. Under traditional inspection, federal government inspectors critically appraise all swine  
4 prior to slaughter, including by inspecting all animals, both when they are at rest and in motion.

5 329. The NSIS rules, to the contrary, establish a set of screens that effectively prevent and  
6 preclude inspectors from critically appraising all animals prior to slaughter.

7 330. First, plant employees are effectively charged with performing the inspection of swine by  
8 determining which swine are dying, feverish, or have central nervous system conditions, and which  
9 appear “normal and healthy” and can proceed to slaughter. Federal inspectors under NSIS cannot  
10 inspect and condemn livestock for condemnable conditions at this point because their review has  
11 been substituted by that of plant employees.

12 331. Then, as a second screen, federal inspectors in NSIS plants are barred from inspecting 90  
13 to 95 percent of the supposed “normal and healthy” animals while they are in motion, thus  
14 preventing and precluding federal inspectors from critically appraising the animals for  
15 abnormalities that only or can best be observed during movement.

16 332. Accordingly, Defendants’ NSIS rules violate 21 U.S.C. § 603(a) as federal inspectors  
17 cannot and do not critically appraise all animals offered for slaughter, and the rules should be  
18 declared *ultra vires* and set aside under 5 U.S.C. § 706(2).

### 19 **SECOND CLAIM FOR RELIEF**

#### 20 **Defendants’ NSIS Violates 21 U.S.C. § 603(a) by Preventing and Precluding the Inspection 21 and Separate Slaughter of Swine Showing Symptoms of Disease and Careful Examination and 22 Inspection When Slaughtered.**

23 333. Plaintiffs re-allege and incorporate by reference each and every allegation set forth in ¶¶  
24 1 through 332 *supra* of this Complaint.

25 334. FMIA § 603(a) further provides that “all amenable species found on such inspection to  
26 show symptoms of disease shall be set apart and slaughtered separately from all other [amenable  
27 species], and when so slaughtered the carcasses . . . shall be subject to a careful examination and  
28 inspection[.]”

1       335. To ensure that animals showing symptoms of disease are slaughtered separately and  
2 receive a careful examination and inspection when slaughtered under traditional inspection, federal  
3 inspectors tag as “U.S. Suspect,” all animals that they suspect are affected with any disease or  
4 condition that may cause post-mortem condemnation of the carcass or part, per 9 C.F.R § 309.2(a)  
5 and (m). Such animals are placed in U.S. Suspect pens for a PHV inspection. And, if passed, such  
6 animals are slaughtered separately from other animals per 9 C.F.R § 309.2(n). The tags cannot be  
7 removed except by a federal inspector and must remain on the carcasses until they receive post-  
8 mortem inspection.

9       336. Under NSIS, plant employees make the determination that animals are showing  
10 symptoms of disease (as detailed *supra*, e.g., in ¶ 330), and, then, they can only place non-sorted  
11 animals showing symptoms of disease in “U.S. Subject” pens, precluding and preventing inspectors  
12 from tagging the animals and examining such animals in “U.S. Suspect” pens.

13       337. Animals in U.S. Subject pens do not receive a critical appraisal by inspectors because  
14 animals that show symptoms of FADs and signs of drug residues can be sorted without any  
15 inspection. Further, animals are not given the critical appraisal needed for those showing signs of  
16 disease because PHVs must inspect the animals without being provided any basis for the animals’  
17 segregation, allowing them to inadvertently pass for slaughter those diseased animals that appear  
18 normal, simply because symptoms are not present during the brief inspection. PHVs are not even  
19 required to take animals’ temperatures in U.S. Subject pens, thus allowing inspectors to miss those  
20 with abnormal temperatures, especially during times when there are more animals in the U.S.  
21 Subject pens.

22       338. Under NSIS, animals that are passed for slaughter by federal inspectors from U.S.  
23 Subject pens are neither tagged to retain their identity as suspected of disease, nor slaughtered  
24 separately from other animals, and their carcasses receive no more attention from federal inspectors  
25 during post-mortem inspection than other animals not suspected of disease. Such carcasses are also  
26 not subject to residue testing.

1 339. Accordingly, Defendants' NSIS rules violate 21 U.S.C. § 603(a), as federal inspectors  
2 cannot and do not critically appraise swine showing symptoms of disease, set such animals apart for  
3 separate slaughter, and tag them so that their carcasses can receive a careful post-mortem  
4 inspection. The NSIS rules should be declared *ultra vires* and set aside under 5 U.S.C. § 706(2).

5 **THIRD CLAIM FOR RELIEF**

6 **Defendants' NSIS Violates 21 U.S.C. § 604 by Preventing and Precluding the Examination  
and Inspection of Swine Carcasses and Parts After Slaughter.**

7 340. Plaintiffs re-allege and incorporate by reference each and every allegation set forth in ¶ 1  
8 through 339 *supra* of this Complaint.

9 341. 21 U.S.C. § 604 provides that “[f]or the purposes hereinbefore set forth the Secretary  
10 shall cause to be made by inspectors appointed for that purpose a postmortem examination and  
11 inspection of the carcasses and parts thereof of all amenable species to be prepared at any  
12 slaughtering, meat-canning, salting, packing, rendering, or similar establishment . . . .” The FMIA  
13 defines the term “prepared” to mean “slaughtered, canned, salted, rendered, boned, cut up, or  
14 otherwise manufactured or processed.” *Id.* § 601 . Thus, when swine are slaughtered and their  
15 carcasses and parts are to be prepared, they need to be examined and inspected, i.e., receive a  
16 critical appraisal from a federal inspector. *See AFGE*, 215 F.3d at 11; 21 U.S.C. § 622.

17 342. Under traditional inspection, federal inspectors must give a careful post-mortem  
18 examination of the carcasses and parts thereof of all livestock slaughtered at official establishments,  
19 per 9 C.F.R. § 310.1(a). Online federal inspectors are required to critically appraise each and every  
20 carcass to determine whether they are contaminated or show signs of disease, including those that  
21 are considered serious food-safety issues. And they must condemn these carcasses.

22 343. Under NSIS, slaughter-plant employees, outside the presence of federal online inspectors,  
23 are charged with first examining carcasses and parts for food safety diseases and other problems,  
24 including by incising and palpating lymph nodes.

25 344. Plant employees are effectively charged with performing the inspections of carcasses and  
26 parts and determining whether visibly tainted carcasses should be removed from the slaughter lines  
27 or trimmed and reprocessed.

1 345. Federal inspectors are barred from inspecting animals until after the plant employees do  
2 this sorting. Because federal inspectors' review has been substituted by that of plant employees,  
3 federal inspectors are prevented and precluded at this point from critically appraising and  
4 condemning all carcasses with condemnable conditions such a Septicemia, Cysticercosis, fecal  
5 matter, ingesta, and milk, including those carcasses that plant employees incorrectly fail to sort.

6 346. Federal inspectors also cannot and do not inspect carcasses and parts sorted and removed  
7 by employees.

8 347. Moreover, plant employee trimming of carcasses prevents and precludes inspectors from  
9 being able to perform subsequent critical appraisals at the head, viscera, and carcass stations,  
10 because it is impossible for the federal inspectors to identify most disease conditions and whether  
11 there have been drugs used in treating this animal that would trigger residue sampling and testing.

12 348. Finally, without line-speed limits, federal inspectors cannot critically appraise all  
13 carcasses and parts at their designated stations including by incising specific lymph nodes and  
14 observing the back, front, and inside of the carcasses, including all cut surfaces and body cavities.  
15 Inspectors also cannot turn and observe both sides of the kidneys.

16 349. Accordingly, Defendants' NSIS rules violate 21 U.S.C. § 604 as federal inspectors cannot  
17 and do not critically appraise all carcasses and parts after slaughter; and the rules should be declared  
18 *ultra vires* and set aside under 5 U.S.C. § 706(2).

19 **FOURTH CLAIM FOR RELIEF**

20 **Defendants' NSIS Violates 21 U.S.C. § 604 by Preventing and Precluding Condemnations of  
21 Adulterated Carcasses and Parts.**

22 350. Plaintiffs re-allege and incorporate by reference each and every allegation set forth in ¶¶  
23 1 through 349 *supra* of this Complaint.

24 351. Under 21 U.S.C. § 604, "inspectors shall label, mark, stamp, or tag as 'Inspected and  
25 condemned' all carcasses and parts thereof of animals found to be adulterated[.]"

26 352. Because federal inspectors cannot and do not critically appraise all carcasses and parts for  
27 abnormal conditions under NSIS due to the fact that their review has been substituted by that of  
28 plant employees, federal inspectors do not and cannot condemn those carcasses and parts that plant

1 employees sort. Plant employees in effect condemn such carcasses and parts, precluding and  
2 preventing federal inspectors from doing so. Such carcasses and parts are not conspicuously  
3 marked as “U.S. Inspected and Condemned” or “U.S Condemned” as required under 21 U.S.C. §  
4 604.

5 353. Accordingly, Defendants’ NSIS rules violate 21 U.S.C. § 604 because inspectors are  
6 prevented and precluded from inspecting all carcasses and parts that have been sorted by plant  
7 employees, determining that they are adulterated, and condemning them by labeling, marking,  
8 stamping, or tagging them as “inspected and condemned,” and the rules should be declared *ultra*  
9 *vires* and set aside under 5 U.S.C. § 706(2).

10 **FIFTH CLAIM FOR RELIEF**

11 **Defendants’ NSIS Violates 21 U.S.C. § 604 by Preventing and Precluding Federal Inspector  
Supervision of Slaughter-Plant Carcasses-and-Part Disposal.**

12 354. Plaintiffs re-allege and incorporate by reference each and every allegation set forth in ¶¶  
13 1 through 353 *supra* of this Complaint

14 355. Under FMIA § 604, federal inspectors have a duty to supervise the destruction of “all  
15 carcasses and parts thereof thus inspected and condemned[,]” as they are to “be destroyed for food  
16 purposes by the said establishment in the presence of an inspector, and the Secretary may remove  
17 inspectors from any such establishment which fails to so destroy any such condemned carcass or  
18 part thereof[.]” 21 U.S.C. § 604.

19 356. Because federal inspectors cannot and do not critically appraise all carcasses and parts for  
20 abnormal conditions under NSIS, as their review has been substituted by that of plant employees,  
21 federal inspectors cannot condemn sorted carcasses. Plant employees in effect condemn such  
22 carcasses and parts. Such carcasses and parts do not remain in the custody of the federal inspectors.  
23 Federal inspectors do not supervise the disposal of such carcasses and parts, and their destruction  
24 for food purposes is not done by the establishment in the presence of federal inspectors.

25 357. Accordingly, Defendants’ NSIS rules violate 21 U.S.C. § 604 because federal inspectors  
26 are prevented and precluded from supervising the disposal of condemned carcasses and parts, and  
27 the rules should be declared *ultra vires* and set aside under 5 U.S.C. § 706(2).

**SIXTH CLAIM FOR RELIEF**

**Defendants’ NSIS Is an Unlawful Sub-Delegation of Inspection Authority to the Slaughter Companies, Violating 5 U.S.C. § 706(2).**

358. Plaintiffs re-allege and incorporate by reference each and every allegation set forth in ¶¶ 1 through 357 *supra* of this Complaint.

359. Under the APA, Federal agency officials may not delegate regulatory responsibilities to private parties absent affirmative evidence of authority to do so. *See United States Telecom Ass’n v. FCC*, 359 F.3d 554, 566 (D.C. Cir. 2004).

360. Defendants’ NSIS rules violate the APA because the Defendants—without Congressional authority—effectively subdelegate their mandatory obligations to: 1) inspect all animals prior to slaughter and all carcasses and parts afterwards; 2) ensure that animals suspected of disease are slaughtered separately and receive a careful examination and inspection when slaughtered; 3) condemn all adulterated carcasses and parts; and 4) supervise the disposal of condemned carcasses and parts.

361. Accordingly, Defendants’ NSIS rules are *ultra vires*; contrary to constitutional right, power, privilege, or immunity; or arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law, and they should be declared unlawful and set aside under 5 U.S.C. § 706(2).

**SEVENTH CLAIM FOR RELIEF**

**Defendants’ Promulgation of NSIS Is Arbitrary and Capricious, an Abuse of Discretion, and Otherwise Not in Accordance with Law, Violating 5 U.S.C. § 706(2).**

362. Plaintiffs re-allege and incorporate by reference each and every allegation set forth in ¶¶ 1 through 361 *supra* of this Complaint.

363. Defendants have dramatically curtailed federal inspection of animals before slaughter and carcasses afterwards, contrary to the language and purposes for the FMIA and as embodied by Defendants’ existing regulations.

364. Defendants failed to consider important aspects related to preventing adulterated and unwholesome pork from entering commerce, including such issues as the effects of line speeds on inspection and public health.

1 365. The NSIS rules are an irrational departure from Defendants' prior practices and  
2 regulations. Defendants' NSIS rules contradict their own compliance guidelines and other  
3 materials detailing how federal inspectors are to perform the critical appraisal of animals, and  
4 carcasses and parts, as well as Defendants' existing regulations, including: 9 C.F.R. §§ 309.1(a)-(b)  
5 (requiring the ante-mortem inspection of all animals prior to slaughter); 309.2(a),(m), (n) and (p)  
6 (pertaining to inspectors' duties for the inspection, segregation, and release of animals with  
7 symptoms of disease); 309.3 (requiring inspectors to condemn dead and dying animals or those  
8 with conditions that would require condemnation on post-mortem inspection); 310.1 (requiring the  
9 careful post-mortem inspection of all carcasses and parts); 310.5 (requiring inspectors to  
10 conspicuously mark and retain custody of condemned carcasses and parts); and 314.(a)(1) and  
11 314.3(a) (requiring inspector supervision of disposed condemned carcasses and parts).

12 366. Defendants have failed to provide the public with the opportunity to comment on the  
13 proposed rules in light of the peer reviewers' critiques of the Final Risk Assessment.

14 367. Defendants' explanations for their NSIS rules run counter to the evidence that was  
15 before the agency, demonstrate extreme bias and otherwise fail to adequately consider public  
16 comments, and offer implausible and inadequate responses to public comments.

17 368. For any and all of these reasons, the NSIS rules are arbitrary, capricious, an abuse of  
18 discretion, or otherwise not in accordance with law, and they should be declared unlawful and set  
19 aside under 5 U.S.C. § 706(2).

20 **RELIEF REQUESTED**

21 WHEREFORE, Plaintiffs respectfully request that this Court:

- 22 A. Declare Defendants' NSIS rules illegal as contrary to the Federal Meat Inspection Act
- 23 and the Administrative Procedure Act;
- 24 B. Permanently enjoin Defendants' NSIS rules;
- 25 C. Vacate Defendants' NSIS rules;
- 26 D. Grant attorneys' fees and costs; and
- 27 E. Award any other relief the Court deems just and proper.

1  
2 Respectfully submitted, this 6th day of April, 2020.

3  
4 /s/ Ryan D. Talbott

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(Admitted *Pro Hac Vice* on Jan. 28, 2020)

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