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

CENTER FOR FOOD SAFETY; FOOD & WATER WATCH, INC.; PETER VAN GORDER; and ROBIN MANGINI;

Plaintiffs,

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.

Case No. 3:20-cv-00256

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

INTRODUCTION

1. The plaintiff non-profit organizations, Center for Food Safety (CFS), Food & Water Watch, Inc. (FWW); 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 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 named plaintiffs, as well as that of CFS and FWW's members, are seriously endangered by adulterated and unwholesome pork product. The named 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). Further, they are otherwise contrary to constitutional right, power, privilege, or immunity and arbitrary and capricious, an abuse of discretion, or otherwise not in accordance with law in violation of the Administrative Procedure Act (APA), 5 U.S.C. §§ 551-559, 701-706 (2018).

JURISDICTION

4. This Court has jurisdiction under 28 U.S.C. § 1331 (2018), which grants federal district courts "original jurisdiction of all civil actions arising under the . . . laws . . . of the United States,"

as well as the APA, 5 U.S.C. §§ 702 and 704, and 21 U.S.C. § 674 (2018), which establishes U.S. district court jurisdiction for all kinds of cases arising under the FMIA.

VENUE AND INTRADISTRICT ASSIGNMENT

5. Venue is proper in this Court under 28 U.S.C. § 1391 (2018) because this suit was filed in the district where Plaintiffs CFS, Peter Van Gorder, and Robin Mangini all reside, and there is no real property involved in the action. Plaintiff CFS resides in the County of San Francisco and has more than 15,500 members in Alameda, Contra Costa, Marin, Napa, San Francisco, San Mateo, and Sonoma counties. Plaintiff Robin Mangini resides in Alameda County. Peter Van Gorder resides in Sonoma County. FWW has on office in Oakland and more than 9,400 dues-paying members in Alameda, Contra Costa, Marin, Napa, San Francisco, San Mateo, and Sonoma counties.

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

PARTIES

7. Plaintiff CFS is a national, non-profit, public interest and environmental advocacy organization that works to protect human health and the environment by curbing the use of harmful food production technologies and by promoting organic and other forms of sustainable agriculture. CFS has approximately 950,000 members in the United States, with nearly 67,000 in California, including Plaintiff Robin Mangini. CFS's members were some of the hundreds of thousands of individuals that submitted public comments to the FSIS in 2018, urging the Defendants not to finalize the proposed NSIS rules.

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

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

10. Plaintiff Robin Mangini is a resident of Piedmont, California. She is a dues-paying member of FWW and a member of CFS. Before the NSIS rules became effective, she has been a regular consumer of pork, and she intended to continue consuming unadulterated USDA-inspected pork product.

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

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

13. Defendant USDA is the U.S. department that houses Defendant FSIS.

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

STATUTORY BACKGROUND

A. The Administrative Procedure Act

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

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

B. The Federal Meat Inspection Act

17. When Congress passed the FMIA in 1907 it declared that "[i]t is essential in the public interest that the health and welfare of consumers be protected by assuring that meat and meat food products distributed to them are wholesome, not adulterated, and properly marked, labeled, and packaged." 21 U.S.C. § 602. To achieve this goal, Congress authorized the Secretary of Agriculture to issue regulations "to protect the health and welfare of consumers" from "[u]nwholesome, adulterated, or misbranded meat or meat food products[.]" *Id.* The reason was that "unwholesome, adulterated, mislabeled, or deceptively packaged articles can be sold at lower prices and compete unfairly with the wholesome, not adulterated, and properly labeled and packaged articles, to the detriment of consumers and the public generally." *Id.*

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

GENERAL ALLEGATIONS

19. As detailed more fully below, this case involves a radical transformation of the federal government's food-safety inspection of swine and swine carcasses, affecting the pork product that ends up in grocery stores and restaurants around the country. Prior to the NSIS rules that are the subject of this suit, each and every swine was to first receive a mandatory government "inspection" prior to slaughter. As part of this process, federal government inspectors critically appraise animals for disease and food-safety issues. They must tag those animals with symptoms of disease so that they receive a more careful inspection, both before and after they are slaughtered separately from other animals. Federal inspectors also flag animals for residue and drug tests where necessary. Second, after slaughter, federal inspectors must critically appraise each animal's head, viscera, and

carcass on the lines where prepared. Third, federal inspectors condemn those animals and carcasses that are found to be adulterated. Finally, federal inspectors supervise the disposal of such condemned animals and carcasses.

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

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

22. This Complaint outlines how the new NSIS rules violate the FMIA and APA as follows. Section I details the comprehensive manner in which federal inspectors are required to perform their mandatory FMIA inspection duties by critically appraising all swine prior to slaughter. It also details how federal inspectors follow the FMIA's mandates to ensure that those animals showing symptoms of disease are slaughtered separately so that they receive a careful inspection when

slaughtered. Federal inspectors also condemn those animals found adulterated and supervise their disposal pursuant to the FMIA. Section II details how federal inspectors under the former, traditional inspection system followed the FMIA by critically appraising all carcasses and parts of swine after slaughter and condemning and supervising the disposal of carcasses and parts found to be adulterated. This section also details the training that allows federal inspectors to perform such critical and complicated tasks.

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

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

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

STATEMENTS OF FACT

I. ANTE-MORTEM INSPECTION UNDER THE FMIA

A. Inspection

26. 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).

27. 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").

28. Under traditional inspection, federal government 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.

29. 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.

30. 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).

31. 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).

32. 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).

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B. Suspect Animals

33. The FMIA also addresses how inspectors are required to treat animals showing symptoms of disease: "all amenable species found on [ante-mortem] inspection to show symptoms of disease shall be set apart and slaughtered separately from all other [amenable species], and when so slaughtered the carcasses . . . shall be subject to a careful examination and inspection, all as provided by the rules and regulations to be prescribed by the Secretary, as provided for in this subchapter." 21 U.S.C. § 603 (2018).

34. USDA's existing regulations require that "[a]ny livestock which, on ante-mortem inspection, do not clearly show, but are suspected of being affected with any disease or condition that . . . may cause condemnation of the carcass on post-mortem inspection, and any livestock which show, on ante-mortem inspection, any disease or condition that . . . would cause condemnation of only part of the carcass on post-mortem inspection, shall be so handled as to retain its identity as a suspect until it is given final post-mortem inspection, when the carcass shall be marked and disposed of . . . ." 9 C.F.R § 309.2(a) (2019).

35. Such animals are physically tagged with a "U.S. Suspect" tag because they are "suspected of being affected with a disease or condition which may require [their] condemnation, in whole or in part, when slaughtered, and [are] subject to further examination by an inspector to determine [their] disposal." *Id.* § 301.2.

36. "Each animal required . . . to be treated as a U.S. Suspect shall be identified as such by or under the supervision of a Program employee with an official device . . . . No such device shall be removed except by a Program employee." *Id.* § 309.2(m).

37. Such animals "shall be set apart and . . . slaughtered separately from other livestock at that establishment unless disposed of as otherwise provided[.]" *Id.* § 309.2(n).

38. "When any animal identified as a U.S. Suspect is released for any purpose or reason, . . . the official identification device shall be removed only by a Program employee and he shall report his action to the area supervisor. When a suspect is to be released . . . for a purpose other than slaughter, the operator of the official establishment or the owner of the animal shall first obtain

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

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

1. Have any disease or condition that may cause the PHV to condemn the carcass or part of a carcass when inspected post-mortem; and

2. Are presented as non-ambulatory disabled.

Id. at XII(B).

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

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

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

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

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

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

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

C. The Condemnation of Animals

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

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

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

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

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

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

52. Federal inspectors may identify and tag dead animals as "U.S. Condemned." *Id.* at XIV(C). Only government PHVs may condemn live animals. *Id*.

53. "U.S. Condemned" tags are placed on:

a) Livestock that are dead or in a dying condition when offered for slaughter on the premises of the official establishment;

b) Livestock that are plainly showing on ante-mortem inspection any disease or condition that would cause the PHV to condemn the carcass when inspecting postmortem; and

c) Any swine have a temperature of 106°F or higher.

Id. at XIV(D).

54. Only government inspectors may remove U.S. Condemned tags. 9 C.F.R. § 309.13(a) (2019).

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

II. POST-MORTEM INSPECTION UNDER THE FMIA

A. Inspection

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

> For the purposes hereinbefore set forth the Secretary shall cause to be made by inspectors appointed for that purpose a postmortem examination and inspection of the carcasses and 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[.]

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

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

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

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

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

61. Under traditional inspection, there must be at least three inspection stations for market hogs, one each for the head, viscera (internal organs), and carcass. If plants increase their production, the agency increases the number of inspectors at the three stations. *Id*. § 310.1(b)(3), Table 4 (2019). The largest plants have as many as seven inspectors on the slaughter lines, with three inspectors at the head and viscera station and one at the carcass station. *Id.*

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

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

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

65. In general, when abnormalities are observed while performing post-mortem inspection, the following actions must take place: if the disease or condition of the head, organ, or carcass is localized, the inspector requests establishment employees to trim the affected tissues and the carcass is passed for food. If the disease or condition is generalized or affects the majority of the head, organ, or carcass, the carcass is retained for veterinary determination (*i.e.*, "disposition") of whether it should be condemned, with or without lab confirmation. FSIS Directive 6100.2 at Ch. VII (I)(C), (II)(F), III(C).

66. More specifically, head inspection requires observing the head and cut surfaces, including the eyes, fat, cheek muscles, and other tissues for abnormalities. *See id.* at Ch. VII (I)(A)(1). The right and left mandibular (jaw) lymph nodes are incised (cut) and observed. *See* at Ch. VII (I)(A)(2).

When abnormal conditions are observed or when the inspector has disposition questions, the inspector retains the head, viscera, and carcass for PHV disposition. *Id.* at Ch. VII (I)(C)(1). Inspectors condemn abnormal or diseased tissue and verify that the establishment trims the affected tissues if the disease or condition of the head is localized. *Id.* at Ch. VII (I)(C)(2).

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

68. Carcass inspection involves observing the back, front, and inside of the carcasses, including all cut surfaces, body cavities, and the lumbar and neck regions. *See id.* at Ch. VII (III)(A)(1)-(2). This may involve observing it in a mirror, and grasping, turning, or observing both sides of the kidneys. *See id*. If abnormal conditions are observed on but do not require veterinary disposition, the inspector can have the establishment employee properly trim the carcass. *See id.* at Ch. VII (III)(C)(2), (D). Other abnormal conditions require retention for veterinary disposition, including bruises that show signs of infection or that may indicate an injection site that would require a residue hold and test for confirmation. *See id.* at Ch. VII (III)(C)(1).

B. Condemnation and Disposal

69. Like with ante-mortem inspection, inspectors have a duty to condemn carcasses found to be adulterated: "inspectors shall label, mark, stamp, or tag as 'Inspected and condemned' all carcasses and parts thereof of animals found to be adulterated[.]" 21 U.S.C. § 604.

70. Defendants' regulations provide that "[e]ach carcass or part which is found on final inspection to be unsound, unhealthful, unwholesome, or otherwise adulterated shall be conspicuously marked, on the surface tissues thereof, by a Program employee at the time of

inspection, as 'U.S. Inspected and Condemned.'" 9 C.F.R. § 310.5 (2019). Condemned detached organs and other such parts that cannot be so marked shall be placed immediately in trucks or receptacles which shall be kept plainly marked "U.S. Condemned," in letters not less than two inches high. *Id.*

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

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

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

74. And, inspectors have a duty to supervise the destruction of "all carcasses and parts thereof thus inspected and condemned[,]" as they "shall be destroyed for food purposes by the said establishment in the presence of an inspector, and the Secretary may remove inspectors from any such establishment which fails to so destroy any such condemned carcass or part thereof . . . ." 21 U.S.C. § 604.

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

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

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

C. Training for FMIA Inspection

77. In order for inspectors to adequately perform all of these complicated inspection activities, the agency has established an intensive training program. PHVs must undergo a nine-week training program. Three weeks of this is classroom training. The other six weeks consist of three weeks spent in the plant environment with an assigned mentor and three weeks of Food Safety Regulatory Essentials training. These training topics are located here http://goo.gl/h74jzN. Other newly hired federal inspectors must undergo training covering at least 12 topics, including one on post-mortem and one on ante-mortem inspection. The training topics are located at 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 extensive training. These training topics are located at http://www.fsis.usda.gov/wps/portal/fsis/topics/inspection/workforce-training/regional-on-site-training/inspection-methods, http://www.fsis.usda.gov/wps/portal/fsis/topics/inspection/workforce-training/regional-on-site-training/export-verification, and http://www.fsis.usda.gov/wps/portal/fsis/topics/inspection/workforce-training/regional-on-site-training/Humane+Handling+of+Livestock.

III. THE LACK OF INSPECTION UNDER THE NEW SWINE INSPECTION SYSTEM

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

79. When Defendants issued the proposed rules, they also issued a Draft Compliance Guideline, titled "Compliance Guideline for Training Establishment Employees under the New Swine Slaughter Inspection System," which copies major parts of the current PHV training guide. The final guideline ("Compliance Guideline"), finalized in September, 2019, and located at

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 to slaughter plants on how to train employees to sort carcasses with condemnable conditions. Defendants have only published the guidance in English and do not plan to translate it into any other language.

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

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

82. As detailed in the following subsections, the NSIS rules are a dramatic rollback in federal inspection. They preclude and prevent government inspectors from critically appraising animals during ante-mortem inspection and carcasses during post-mortem inspection, delegating these responsibilities to plant employees with no mandatory training or educational requirements. Plant employees are guided by nothing more than the nonbinding compliance guideline written for qualified veterinarians. The new rules prevent and preclude government inspectors from condemning adulterated animals, carcasses, and parts, and supervising the disposal of such carcasses and parts. The rules also revoke the Defendants' current standards for microbiological pathogens *E. coli* and *Salmonella*. Defendants' justification for all of these rule changes has been woefully inadequate, including the insufficient data and analysis presented in their evaluation of NSIS-pilot projects and risk assessment, both of which do not support Defendants' contentions about the new rules. Not only were Defendants' responses to public comments inadequate, but also, they completely failed to respond to comments from experts who peer reviewed the risk assessment.

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

83. The NSIS creates a new mandatory system where government inspectors are no longer responsible for the ante-mortem examination and inspection of all market hogs for visible signs of condemnable diseases or conditions while they are at rest and in motion.

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

85. Under NSIS, slaughter-plant employees are tasked with finding and removing swine with "condemnable conditions" by observing animals in motion and at rest, evaluating animals' alertness, locomotion, bodily conditions, bodily functions, and skin color. Compliance Guideline at 5, 7-8. Based on their own alleged "familiar[ity] with the behavior of normal healthy market hogs," plant employees are to look for signs of inactivity, lack of awareness, "abnormal" skin color, "irregular" respiration, frothy mouth or nasal discharges, and an inability to move, as these are signs that the animals are dying. *Id*. at 8. Plant employees are also to look for seizures, convulsions, "abnormal" gait, "difficulty" swallowing, "abnormally excited or aggressive behavior," head pressing or head tilt, as these are signs of central nervous system conditions, and must be reported to the agency as FADs. *Id.* And, plant employees are tasked with looking for high body temperatures, a loss of activity and awareness, discoloration, increased respiration, difficulty breathing, reluctance to get up from a recumbent position, and/or lameness, as these are signs the animals are febrile. *Id.*

86. In this way, plant employees supplant trained federal inspectors as the first, and often only, line of defense for preventing diseased animals from entering the food supply (and from being released to other plants and facilities where they can expose other animals to infectious or foreign animal diseases.) Having un- or under-trained slaughter-plant employees charged with "sorting" diseased animals establishes a set of screens that effectively precludes and prevents trained federal inspectors from critically appraising animals for symptoms of diseases and other significant problems in the swine supply, including the use of antibiotics and chemical residues. As a logical

corollary, the new rules screen federal inspectors from critically appraising and detaining the swine that plant employees incorrectly determine are normal and fit for slaughter.

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

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

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

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

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

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

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

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

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

94. Several indicia of condemnable conditions or diseases, including signs the animals are dying, feverish, or have central nervous system conditions, are best or only observed while the animals are in motion, as they are signs associated with abnormal body movement. These include stiffness, limpness, lameness, restlessness, staggering, circling, abnormal gait, dizziness, loss of balance, and disorientation or running into things.

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

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

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

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

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

99. Establishment employees engage in further sorting of these animals in or before the U.S. Subject pens, just as they did for those that are dying, feverish, and have central nervous system conditions. Compliance Guideline at 8. Thus, federal inspectors once again cannot observe the overall condition of each animal or check for illegal drug use. It is only after swine showing symptoms of disease have been actually presented to the inspector in a "U.S. Suspect" or "U.S. Subject" pen, that animals under NSIS receive anything that Defendants officially term an "ante-mortem inspection" from a federal government inspector. *Id.*

100. But, unlike in U.S. Suspect pens, animals placed in U.S. Subject pens do not actually receive a critical appraisal by federal inspectors, as they are not given the necessary attention when potentially affected with diseases or conditions. For example, because the animals are not tagged, government PHVs do not know what conditions necessitate the animals' segregation and what signs they should be looking for to make proper diagnoses. This is particularly crucial with animal symptoms that are intermittent or vary in severity as the condition progresses. For example, the food-safety condition Toxemia—caused by the circulation of toxins in the blood—has symptoms that include convulsions and variable temperatures, ranging from very high to subnormal, depending upon the stage of disease and ambient temperature. Government PHVs who do not

know which animals are suspected of this condition likely will not retain these animals for a long enough time or examine the animal for all Toxemia symptoms, and they may inadvertently pass animals appearing normal—simply because the symptoms are not present during the brief period of inspection in the U.S. Subject pens. Indeed, the government PHVs are not even required to take animals' temperatures in U.S. Subject pens like they would in U.S. Suspect pens when the tags and accompanying paperwork would indicate it necessary. This means that the government PHVs may not be able to identify animals with abnormal temperatures during times when there are more animals in the U.S. Subject pens.

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

102. While Defendants have not responded to Plaintiff FWW's letter and analysis detailing these findings, they have indicated that it is based on incorrect data that they provided to FWW. Defendants have refused to provide the correct information, and this is the subject of an ongoing and separate FOIA lawsuit.

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

104. On information and belief, far fewer animals are placed annually in U.S. Suspect pens in the slaughter plants that piloted the NSIS rules compared to traditional plants, regardless of whether FWW's May 2019 analysis is precise.

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

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

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

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

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

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

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

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

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

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

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

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

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

114. Defendants' NSIS rules do not require any greater post-mortem examination or inspection of the carcasses of animals that receive the limited ante-mortem inspection that is detailed above under NSIS. This is so, even though inspecting the animal prior to slaughter is critical for the detection of several conditions, including Septicemia, Toxemia, Pyemia, and Cysticercosis. These are conditions that inspectors also seek to detect in carcasses and remove during post-mortem inspection. *See infra* ¶ 117. Several symptoms of these diseases manifest themselves in the living animal and are not observable after slaughter.

115. Instead of enhancing post-mortem inspection, under NSIS all but a few federal inspectors are removed from the post-mortem slaughter lines. Federal inspectors are no longer able to demand that slaughter-plant staff remove visibly tainted carcasses from the slaughter lines, trim and reprocess them to remove such problems, and then re-inspect the carcasses to ensure that the problems have been removed. Establishments, using personnel with no approved formal training or educational qualifications, police themselves by sorting carcasses and parts, incising and palpating lymph nodes to detect the presence of animal disease, and identifying condemnable conditions or problems before carcasses are presented to online inspectors for post-mortem inspection. 84 Fed. Reg. at 52300-301, 52348. Like with ante-mortem inspection, under- or un-trained plant employees do this based on the non-binding compliance guideline that is used to identify carcasses affected with condemnable conditions. Compliance Guideline at 5; *see* 84 Fed. Reg. at 52313.

116. As detailed below, by handing off inspection responsibilities to plant employees, government inspectors are prevented and precluded from critically appraising all carcasses for

conditions such as Septicemia, Cysticercosis, and feces, ingesta, and milk contamination, which pose serious threats to public health. Federal inspectors are thus not able to condemn carcasses with these problems, including those that plant employees incorrectly determine do not need to be sorted. Carcasses with these conditions are more likely to enter the food supply, as the lone federal inspectors at the head, viscera, and carcass stations cannot critically appraise animals for these condemnable conditions due to NSIS plants' increased line speeds.

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

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

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

119. In the preamble to the proposed NSIS rules, for example, Defendants stated that "[c]arcasses and parts contaminated with fecal material, ingesta, or milk or that exhibit signs of septicemia, toxemia, pyemia, or cysticercosis during post-mortem examination are likely to contain infectious agents, such as bacteria, virus, rickettsia, fungus, protozoa, or helminth [parasitic-worm] organisms, which can be transmitted to humans. For this reason, they present a food safety risk if they are permitted to enter the cooler." 83 Fed. Reg. at 4793.

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

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

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

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

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

125. Under NSIS, slaughter plant employees are charged with first examining animals for this condition outside of the federal online inspector's presence, and they are supposed to notify federal inspectors if it is detected. Federal inspectors are barred from examining the cheeks, heart, esophagus, tongue, and diaphragm by sight and making any incisions unless the employee determines it necessary. Federal inspectors are thus prevented and precluded from critically appraising all carcasses for Cysticercosis and are not able to condemn carcasses with this condition, including those that plant employees incorrectly do not sort or errantly do not flag for inspection.

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

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

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

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

Id. Attachment 2.

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

130. While Defendants have indicated that inspectors will perform twice the *offline* zero-tolerance visual verification checks for fecal matter, ingesta, and milk at NSIS plants, this does not account for the lack of *online* inspections that carcasses, viscera, and heads receive from trained federal inspectors.

131. For other conditions not specified in paragraph 117, under- or un-trained and unqualified slaughter-plant employees also must make decisions about whether the carcasses must be discarded or can merely be trimmed, based on the nature, degree, or extent of the condition, pursuant to the compliance guideline. *See* Compliance Guideline at 26. These are disposition decisions that trained federal inspectors make under traditional inspection using the same inspection tasks detailed above in paragraphs 63-68.

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

133. Instead, plants are to use the compliance guideline referenced above at paragraph 79. The guideline does not contain mandatory standards for plant employees to apply when sorting carcasses with condemnable conditions.

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

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

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

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

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

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

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

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

141. Increases in line speeds are accompanied by Defendants' plans to reduce the total number of online federal inspectors by forty percent. 84 Fed. Reg. at 52337. As Plaintiffs pointed out in

their comments, this means that instead of inspecting an average of 163 heads per hour per inspector in non-model plants (approximately 2.7 per minute), each federal inspector will be tasked with inspecting an average of 366 slaughtered animals per hour (6.1 per minute) under the new system. A mere 12.5 percent increase in line speeds results in more than a 2.25-fold reduction in average inspector time dedicated to performing a critical appraisal of hog carcasses, heads, and viscera and effectively a corresponding 2.25-fold increase in line speeds.

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

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

144. None of the data or analyses that the Defendants have relied upon in support of the final NSIS rules evaluated the effects of line speed on the production of a wholesome product or consumer illnesses. Nor have Defendants evaluated the ability of plant employees and federal inspectors to remove carcasses with condemnable conditions or for the latter to take the required residue samples for antimicrobial or other drug-use at the higher line speeds that are permitted under NSIS.

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

146. To make matters worse, only a few federal inspectors in charge can slow the line, although the criteria for this is not established or defined in the rule. 84 Fed. Reg. at 52300 (citing new 9 C.F.R. 310.26(c)).

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

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

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

150. At such line speeds, federal inspectors cannot view each and every animal's head, carcass, and viscera.

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

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

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

154. One federal inspector's comments on the proposed rules indicates that at a pilot plant, company employees personally condemned the plant's products and then attempted to sneak such carcasses past the inspector. The same inspector attested that the company had threatened plant employees with terminations if too many carcasses or carcass parts were condemned.

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

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

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

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

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

C. Plant Employee Sorters with No Mandatory Training or Education

160. Defendants have indicated that they believe that training of sorters is important to ensure that they are able to properly perform their duties, 83 Fed. Reg. at 4794, although the final rules contain no mention of the education requirement to hold these positions. Proper training and education is necessary if sorters are to make accurate decisions on how to address animal disease conditions and trim and dress defects.

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

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

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

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

165. The agency's cost-benefit analysis assumes that a HACCP training will average four hours per sorter, and that sorters will be paid slightly less for that training than the 2014 median rate for minimum-wage slaughterers and meatpackers. *See* 84 Fed. Reg. at 52324 (referencing Viator, C. et al. 2015. Costs of Food Safety Investments. Table 4–4. Training Costs for Management and 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). *See id*. at tables 2-4, 4-4.

166. Defendants' estimation of what plants would spend on training sorters is far less than what Defendants spends to train federal government inspectors.

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

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

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

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

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

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

172. The lack of required inspector condemnation and inspector-supervised disposal of sorted carcass and parts creates another avenue by which adulterated product—even that which is supposed to be removed from the slaughter plant—can end up in the food supply, both intentionally and unintentionally. *See supra* ¶¶75, 154.

V. ROLLBACKS TO PATHOGEN TESTING

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

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

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

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

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

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

178. But, as detailed below, Defendants' Hog HIMP Report does not include any such analysis. Moreover, the Hog HIMP Report's reliance on a flyspeck of data from a twenty-year pilot project, not to mention its inadequate justification for the plants it evaluated, taint Defendants' conclusions that plants opting into NSIS will perform as the pilot plants have.

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

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

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

182. Ultimately, the agency demonstrated its bias when it launched a rare, if not unprecedented, defense of their proposed rules' benefits in a press release—notwithstanding that the rules had yet to be finalized and the Defendants were supposed to be considering comments without prejudice.

A. The OIG Report

183. The Defendants have contended that a pilot project involving five market hog plants, known as the Hazard Analysis Critical Control Point Based Inspection Models Project (HIMP or

model plants) support the NSIS rules. Defendants assume that plants operating under the final NSIS rules will perform as the model plants did.

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

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

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

186. Among other recommendations aimed at improving the program's oversight, the OIG 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.

187. Defendants' preamble for the final NSIS rules claim Defendants addressed OIG's concerns. 84 Fed. Reg. at 52306.

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

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

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

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

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

B. The GAO Report

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

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

195. "[W]hile the pilot project is ongoing, FSIS has the opportunity to follow sound management practices by planning for and collecting key information needed to determine whether the pilot project is meeting its purpose[,]" the report found. *Id.*at 16-17. Critically, "the agency has

not aggregated and analyzed [inspector-collected] daily results to determine how the plants participating in the pilot project have performed over time." *Id.* at 17.

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

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

C. Defendants' Inadequate Hog HIMP Report and Responses to Comments

198. In response to the OIG and GAO reports detailed in paragraphs 183-197, Defendants issued its Hog HIMP Report a year later.

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

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

1. The Hog HIMP Report's Narrow Scope

201. First, Defendants have not sought to increase the number of model facilities for further study, as the Hog HIMP Report compares the performance of the same volunteer five swine plants in the pilot project with twenty-one traditional establishments not participating in the pilot.

202. All that the plants had to do to volunteer for the pilot was submit a letter. The Defendants waived these plants' line-speed limits in exchange for the submission of non-public *Salmonella* testing data.

203. Defendants have never taken any measures to ensure there was no self-selection bias amongst the model plants evaluated, despite prior GAO-report recommendations.

204. Defendants have never even detailed their basis for selecting either the five plants or the twenty-one-comparator set of traditional plants evaluated in the report.

205. The preamble to Defendants' final NSIS rules indicates that the model plants "collectively represent diversity in geography, corporate structure, management styles, product distribution patterns, and other variables. FSIS believes that the volunteer market hog slaughter establishments participating in the HIMP pilot study, viewed collectively, are typical of the broader industry." 84 Fed. Reg. at 52306.

206. Defendants have neither detailed the basis for this conclusion, nor indicated that they have performed any analysis supporting this conclusion.

207. According to Defendants' own data, the model plant produced a mean average of 3.3 million hogs per year, as of October 2011, and all of the model plants produce more than 1.8 million hogs per year. The average plant likely to switch over to NSIS (the 35 plants that Defendants used in their risk assessment and for which such data is public for that year) is about 71 percent that size. Of these plants, the average size of the more-than-one-third group of plants (14 in all), which have never been evaluated by the Defendants, produces approximately 645,000 hogs per year, with the smallest producing less than 0.2 percent (at 3,000 hogs per year) of what the smallest model plants produce. Thus, the five model plants, if nothing else, represent a group of plants that produce far more swine than the 35 plants that Defendants estimate are likely to switch over to NSIS. And, just as the GAO concluded, there is no assurance that these smaller plants will perform under NSIS as the largest plants did in the NSIS pilot.

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

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

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

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

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

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

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

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

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

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

i. No greater food-safety spot-checks

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

> the increased inspection for visible fecal material, ingesta, and milk contamination under 9 CFR 310.18. FSIS inspectors at [model] establishments inspect a sample of 24 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 . . . .

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

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

219. Moreover, the Defendants' own data from May of 2019 indicate that the agency stopped doing or recording offline verifications for 9 C.F.R. § 310.18 in model plants in 2015, 2016, and 2018. The number of reported verifications were also greatly curtailed but not eliminated in

traditional plants. Thus, Defendants cannot say that they have been and will be performing greater numbers of these spot-checks in NSIS plants under the new system.

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

221. FWW's analysis described in paragraph 101 , showed that for the PHRs applicable for all years evaluated (Fiscal Years (FY) 2014 through 2017), federal inspectors performed a statistically significantly *greater* number of such spot-checks for *more* PHR regulations in traditionally inspected plants than they did in model plants.

222. Finally, FWW's analysis described in paragraph 101 indicates that when Defendants evaluated the number of PHR verifications between CY 2012 and 2013 in its Hog HIMP Report, it likely statistically masked the differences between the numbers of PHR verification checks in model and traditional plants by pooling the data.

223. Defendants have never denied that its Hog HIMP Report suffered from the deficiencies detailed in paragraphs 221-222, and they have never addressed the comments submitted by Plaintiff FWW.

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

ii. No greater compliance with agency regulations

225. There are at least six data sets undermining Defendants' contention that model plants maintained better regulatory compliance than traditional plants.

226. First, as Plaintiffs pointed out in their comments, the Hog HIMP Report itself showed that model plants had statistically significantly more public health related NRs than the twenty-one-

comparator set of traditional plants over four years, CY 2006 through 2010. This includes large differences for violations of certain inspection procedures.

227. Consistent with Defendants general approach of selectively choosing data that supports its pre-determined conclusion, Defendants ignored this fact and simply pointed to the two years for which traditional plants had a greater number of noncompliances. 84 Fed. Reg. at 52308.

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

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

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

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

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

232. Fifth, in Plaintiff FWW's May 23, 2019, analysis (detailed above at paragraph 101), FWW evaluated more recent data and calculated that, on average, there were more noncompliances in the pilot plants from 2012 through 2018 than in the group of traditionally inspected plants that are expected to switch to NSIS.

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

234. Defendants reached the opposite conclusion for FY 2012 and 2013 for this regulation in its Hog HIMP Report by adjusting the noncompliance rate (noncompliances per verification) by a factor that accounts for an increased number of swine carcasses tested in model plants (*see* paragraph 217). Hog HIMP Report at 27. But not only does the report completely fail to disclose this, this adjustment inappropriately deflates the FS-2 noncompliance rate for model plants—as any additional swine spot-checked at model plants are supposed to *compensate* for the fact that

traditional plants have *online* inspectors that inspect every single carcass, while the model plants do not.

235. Defendants have attempted to generally respond to the fact that there have been more noncompliances in model plants than traditional plants by arguing that because government inspectors conduct "more offline inspection activities that FSIS has concluded are more effective in ensuring food safety than offline FSIS inspectors," they "have more opportunities for detecting noncompliance with regulatory requirements that are directly related to public health than inspectors do in non-HIMP traditional establishments." 84 Fed. Reg. at 52308. Regarding 9 C.F.R § 311.16(a), in particular, Defendants have indicated that inspectors do "not issue NRs for this regulation under traditional inspection because FSIS inspectors are responsible for identifying and removing food safety and non-food safety defects." *Id.*

236. Notwithstanding that inspectors do not generally conduct more offline inspection activities related to PHRs, as demonstrated above in paragraphs 220-221, Defendants' response fails to acknowledge that if model plants perform at least as well as traditional plants at producing unadulterated and wholesome product, as Defendants' contend, their noncompliance *rates* (noncompliances per inspection or verification) will be the same or better for model plants, regardless of the number of spot-checks.

237. And, for many regulations, model plants have higher noncompliance *rates* than traditional plants. The data in Defendants' Hog HIMP Report, for example, details noncompliance *rates*. Hog HIMP Report at 22-26. While FWW's data about ten comparatively sized plants solely summed the raw numbers of non-compliances, FWW's selection of very similarly sized plants in part controlled for the number of verifications, under the general assumption that similarly sized plants receive a similar number of verifications. A more recent FWW analysis of noncompliance rates, which FWW could only perform after Defendants released data in May 2019 in response to a FOIA request, reveals that for each of the four regulations cited in paragraph 229, model plants had *twice* the total noncompliance rate from 2012 to 2016 than the similarly sized traditional plants.

238. Finally, Defendants' contention that inspectors do more spot-checks for certain regulations in model plants ignores that this is in no small part due to Defendants' assumption that

traditional plants *do not need* additional verifications for such regulations because online inspectors are responsible for ensuring contaminated carcasses do not leave slaughter lines. This means that noncompliances in model plants for regulations such as 9 C.F.R § 311.16(a) indicate a problem that is not an issue in traditional plants.

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

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

240. The Defendants have also misleadingly asserted that model plants had fewer non-food safety defects. 84 Fed. Reg. at 52303. This fails to acknowledge that Defendants do not evaluate such "Other Consumer Protection" defects in traditional plants. Hog HIMP Report at 30.

241. Moreover, the Other Consumer Protections standards that Defendants relied upon for showing that the model plants were performing as well as or better than before they were in the pilot project were created six-to-ten years earlier than the Hog HIMP Report data. In fact, a report to which the Defendants cite in their final NSIS rules' preamble for support, the *Review of the HACCP-Based Inspection Models Project by the National Alliance for Food Safety Technical Team*, criticizes a similar poultry study for only a mere two-year lag between when the baseline data were collected and when the model-system data were collected for evaluation. *See* https://www.fsis.usda.gov/OPPDE/nacmpi/Nov2002/Papers/NAFS97.pdf at 4.

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

243. Defendants also failed to disclose data showing that inspectors are testing far less product for residues in model plants, even though more testing is supposed to be a benefit of the new inspection system. Defendants have never made public an analysis prepared by its former Chief PHV at the time of the pilot that showed that model plants had a significantly lower rate of inspector-generated residue tests of animals than non-model plants in the same district. They also had a statistically significant lower rate of performing tests called Kidney Inhibition Screening tests.

This includes data showing the same trend for similar plants operated by the same company, which should have a similar quality of swine.

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

iv. No equivalent or better Salmonella verification testing positive rates

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

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

247. The risk assessment, detailed infra in paragraphs 252-304, does not compare the *Salmonella* outcomes in pilot and traditional plants. Rather, it modelled the reduced *Salmonella* incidences expected from the increased number of various *offline* verification tasks that are presumed to occur under the new rules based on the model plants, but without any evaluation of possible changes in pathogen levels at model plants from the new system's change in *online* inspections. *See* Final Risk Assessment at 27.

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

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

250. The fact that this is the only place in the Hog HIMP Report that Defendants compared the model plants to any plants other than the twenty-one-comparator set of traditional plants indicates that Defendants were cherry picking for supporting data both in this report and the risk assessment. Notwithstanding, the data show that traditional plants had much higher *Salmonella* incidences prior to evisceration than in model plants (which is prior to employee sorting in the model plants). *Id.* And traditional plants had much larger reductions in *Salmonella* incidences than did the model plants after their employees engaged in sorting. *Id.* This indicates that the employee sorting and greater amount of inspector spot-checking employed in model plants has little effect on *Salmonella* reductions.

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

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

252. The Defendants' Final Risk Assessment, which Defendants cite to for the only quantitative public-health benefits for the NSIS rules, is also fundamentally flawed. Generally, the Final Risk Assessment seeks to evaluate the relationship between an assumed increased number of off-line spot-checks at NSIS plants and the expected attributable decrease in human illness due to *Salmonella* contamination. The analysis estimates that if plants increase the number of unscheduled

and scheduled verification tasks, while decreasing scheduled-but-not-performed tasks, there would be an estimated reduction of 2,533 *Salmonella* illnesses annually, reflecting a 3.8% reduction in *Salmonella* illnesses attributable to pork products. Final Risk Assessment at 55; 84 Fed. Reg. at 52333.

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

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

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

i. The Final Risk Assessment's Circumscribed Scope

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

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

258. Again, the Defendants did not have enough *Salmonella* data from these plants from Defendants' baseline study (see paragraphs 249-250), so they had to combine the 2010 baseline study and routine verification tests outside of the study. Final Risk Assessment at 86. The combined data is similar to the baseline study discussed above in paragraph 250, in that traditional plants have more post-chill *Salmonella* incidences than model plants, but also had a *greater reduction* from pre-evisceration to post-chill compared to model plants, *id.*, thus indicating that the model inspection system does not have much an effect, if any, in reducing *Salmonella* incidences.

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

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

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

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

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

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

265. Instead of waiting for more recent *Salmonella* data to be collected, Defendants used the *Salmonella* data from carcasses from nearly ten years ago, from 2010 to 2011. Final Risk Assessment at 24. This, despite the fact that, at the time of the public comment period on the proposed NSIS rules, Defendants' exploratory testing was showing far higher *Salmonella* levels on pork products compared to the levels modeled in the risk assessment.

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

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

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

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

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

270. Although the Defendants announced that their risk assessment would be peer reviewed, they failed to conduct the review until the comment period was nearly closed in April, 2018. Adding insult to injury, the Defendants then failed to release the peer reviewers' comments until several months later. Defendants' rationale for not conducting the peer review sooner was that they were confident that the rule would not change in light of any peer review comments, and they thus did not need to wait for the peer reviewers' comments before proposing the rule. Defendants

indicated that they would reopen the comment period for the proposed rules if they made changes to the risk assessment based on peer review comments. *See* FSIS, Transcript of FSIS Webinar at 18-19, located at https://www.fsis.usda.gov/wps/wcm/connect/e7affcab-0c80-42c5-a9c3-d78d9c96e6c2/USDA-FSIS-OPACE-Swine%2BModernization-transcript%284-16-2018%29.pdf?MOD=AJPERES.

271. On September 5, 2019, Defendants posted for review a summary of peer-reviewers' comments and revised risk assessment made in response to these comments, along with a thirty-day comment period on the revised risk assessment. *See* "Response to Peer Review Comments on: Assessment of the Potential Change in Human Risk of Salmonella Illnesses Associated with Modernizing Inspection of Market Hog Slaughter Establishments" (Aug. 2018), 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 Review Comments).

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

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

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

275. Without access to the peer reviewers' comments, which substantially undermine Defendants' rationale for the NSIS rules, Defendant's response to the peer review, and the agency's

revised risk assessment (notwithstanding its inadequacies), the public was unable to fully assess the proposed rules and adequately tailor their comments on whether the rules should be finalized.

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

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

iii. Defendants' Failure to Address Peer Reviewers' and Public Comments on the Risk Assessment

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

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

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

281. FWW's comments on the revised risk assessment explained that this response was completely inadequate and that the agency should be forthright with the peer reviewer and "indicate that the risk assessment was not designed to test the hypothesis of whether [model plants]

performed better than [traditional] plants. Thus, such failings in the design of the . . . model is baked into the risk assessment and cannot be changed without collecting more data. Its power analysis in Appendix H does not address the issue that s/he raises. A failure to do so renders the entire revised risk assessment unreasonable to support the proposed NSIS rule."

282. Defendants never responded to FWW's comment in the preamble to the final NSIS rules.

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

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

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

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

287. Defendants' model did not include plant-production volume as a continuous variable.

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

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

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

> Additional information could include age of the facility, sourcing of pigs for slaughter (e.g., preferential sourcing based on *Salmonella* infection status or implemented control strategies at the farm level), slaughter line characteristics, any *Salmonella* control strategies in place at the facility (e.g., hot water decontamination of carcasses or decontamination with organic acids, and application of logistic slaughtering (i.e., separation of pigs at slaughtering based on their risk of *Salmonella* infection). The characteristics of the enrolled facilities should be compared with the rest of the industry. From this information the reader should be able to infer whether the enrolled establishments were representative of the variation in the industry and any non-enrolled facility should be able to judge whether the results apply to their 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.

Peer Review Comments at 27.

291. Defendants responded by saying that "[a]lthough having such detailed information about each establishment might provide more information on potential biases, such information was not

available. Because this risk assessment was not carried out as an experiment but rather an observational study and so [*sic*] the representativeness of the sample could not be controlled." *Id.*

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

293. Defendants never addressed FWW's comment in the preamble to the final NSIS rules.

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

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

> The only concern is how the selection of the 5 establishments for the implementation of the HIMP was conducted. Were those 5 HIMP establishments significantly different from the other 159 non-HIMP establishments **before** the FSIS initiated the voluntary HACCP-based Inspection Models Project (HIMP) in each of them? Certainly in Appendix B we can see that (as expected) there are differences in the prevalence of Salmonella in the HIMP vs non-HIMP establishments. Now, the question is, is that prevalence difference due to the 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.

Id. at 43 (emphasis in original).

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

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

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

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iv. Double Counting and Flawed Assumptions

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

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

301. In modelling the likely reductions in *Salmonella* prevalence from traditional plants switching to NSIS, Defendants apply adjustments to estimate how the verification procedures are most likely to change under the new system. The Defendants failed to explain the bases for these adjustments, however. Final Risk Assessment at 30. For example, the Defendants' model assumes that the most likely outcome is that noncompliances will increase by 10% simply by switching to the model system, when, in fact, as detailed in paragraph 231, model plants had more than 9.4 times the noncompliances, more than 10 years after the model project began. *Id*.

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

303. Defendants have presented no data supporting this assumption.

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

VII. UNDUE BIAS IN THE RULEMAKING

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

306. Defendants have repeatedly refused to release and make public the data underlying their Hog HIMP Report, for example, despite claiming in the final rules' preamble that they "made every

effort to respond to FOIA requests related to the proposed rule before the close of the comment period." 84 Fed. Reg. at 52305.

307. Plaintiff FWW has been forced to file a separate FOIA lawsuit because the agency failed to release much of the responsive information pertaining to this rulemaking for more than 21 months, even though the agency granted FWW's FOIA request for expedited processing so that it would have the records prior to the close of the NSIS comment period.

308. Finally, Defendants' contempt of public comments became readily apparent when it issued a press release in response to a *Washington Post* article about the proposed NSIS rules. *See* 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 defense of the NSIS rules, even though they were not finalized—and despite FSIS's own admission that "as a federal regulatory agency, FSIS cannot litigate or conduct rulemaking through the media." For example, Defendant FSIS claimed that "[t]he Post's decision to continue to parrot arguments that are devoid of factual and scientific evidence only serves to further the personal agenda of special interest groups that have nothing to do with ensuring food safety." The press release continued "Shame on you, Washington Post. This story earns you at least four Pinocchios."

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

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

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

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VIII. HARM TO PLAINTIFFS

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

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

314. Foodborne illness affects Plaintiffs' members' health, well-being, and finances. The new rules are intended to be adopted by enough plants that their pork products will be ubiquitous in interstate commerce. The identified individual plaintiff members of FWW and CFS have spent and plan on continuing to spend extensive time and money researching whether the products that they consume are from plants that Defendants believe are likely to switch to the new system so that they can avoid such products. And at least two FWW members regularly consume pork produced in plants that Defendants expect are likely to switch to the new system. Others will reasonably decide to avoid eating pork product altogether, depriving themselves of a product or restaurants that they enjoy. Others will not be able to avoid it because of its ubiquity in the marketplace and the absence of clear labeling disclosing which slaughter plants have adopted the new rules—especially at restaurants where purveyors often do not publicly disclose, or to have little knowledge about, where the swine are slaughtered for their pork products. This is not to mention the CFS and FWW members who will be exposed to adulterated product because they are unaware or otherwise do not know how to determine which products are from certain plants that are planning to or that have switched to the new rules by the time of purchase. Those consumers that regularly purchase and rely on pork will be harmed not only because of their exposure to adulterated or unwholesome

product, but also from increased prices resulting from disease outbreaks that are all but inevitable under the new rules.

315. In addition, the final NSIS rules injure the Plaintiff organizations by frustrating their food-safety missions, and forcing the organizations to divert organizational resources to address Defendants' NSIS rules' promulgation—resources that would otherwise be used in other organizational program areas. Plaintiff organizations are forced to take action for their members and consumers, more generally, that would not be required if Defendants were not violating the FMIA and APA. For example, FWW has spent time and money creating a webpage (https://www.foodandwaterwatch.org/news/how-can-you-tell-if-chicken-or-pork-was-actually-inspected-usda) that lets the public and its members know how to determine which products come from which particular slaughter plants and which plants are likely to switch to NSIS. And, FWW will be submitting regular FOIA requests, as it has with NPIS, to identify which plants have already switched to NSIS in order to let the public and its members know how to avoid product from these plants, if it is even possible. CFS has diverted its resources to efforts that would otherwise have been unnecessary; CFS has had to shift staff time from other efforts to protect its supporters, the public, and the environment to advocacy and raising public awareness about the inadequacies of the NSIS rules and the resultant increased risk of contaminated pork products.

FIRST CLAIM FOR RELIEF

Defendants' NSIS Violates 21 U.S.C. § 603(a) by Preventing and Precluding the Examination and Inspection of Swine Before Slaughter.

316. Plaintiffs re-allege and incorporate by reference each and every allegation set forth above in paragraphs 1 through 315 *supra* of this Complaint.

317. The FMIA provides that "the Secretary shall cause to be made, by inspectors appointed for that purpose, an examination and inspection of all amenable species before they shall be allowed to enter into any slaughtering, packing, meat-canning, rendering, or similar establishment, in which they are to be slaughtered. . . ." 21 U.S.C. § 603(a). This means that *all* such animals must receive a "critical appraisal" by a federal inspector prior to slaughter. *See AFGE v. Glickman*, 215 F.3d at 11; 21 U.S.C. § 622.

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

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

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

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

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

SECOND CLAIM FOR RELIEF

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

323. Plaintiffs re-allege and incorporate by reference each and every allegation set forth above in paragraphs 1 through 322 *supra* of this Complaint.

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

325. To ensure that animals showing symptoms of disease are slaughtered separately and receive a careful examination and inspection when slaughtered under traditional inspection, federal inspectors tag as "U.S. Suspect," all animals that they suspect are affected with any disease or

condition that may cause post-mortem condemnation of the carcass or part, per 9 C.F.R § 309.2(a) and (m). Such animals are placed in U.S. Suspect pens for a PHV inspection. And, if passed, such animals are slaughtered separately from other animals per C.F.R § 309.2(n). The tags cannot be removed except by a federal inspector and must remain on the carcasses until they receive post-mortem inspection.

326. Under NSIS, plant employees make the determination that animals are showing symptoms of disease (as detailed above, e.g., in paragraph 320), and, then, they can only place non-sorted animals showing symptoms of disease in "U.S. Subject" pens, precluding and preventing inspectors from tagging the animals and examining such animals in "U.S. Suspect" pens.

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

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

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

THIRD CLAIM FOR RELIEF

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

330. Plaintiffs re-allege and incorporate by reference each and every allegation set forth above in paragraphs 1 through 329 *supra* of this Complaint.

331. 21 U.S.C. § 604 provides that "[f]or the purposes hereinbefore set forth the Secretary shall cause to be made by inspectors appointed for that purpose a postmortem examination and inspection of the carcasses and parts thereof of all amenable species to be prepared at any slaughtering, meat-canning, salting, packing, rendering, or similar establishment . . . ." The FMIA defines the term "prepared" to mean "slaughtered, canned, salted, rendered, boned, cut up, or otherwise manufactured or processed." *Id.* § 602(*l*). Thus, when swine are slaughtered and their carcasses and parts are to be prepared, they need to be examined and inspected, i.e., receive a critical appraisal from a federal inspector. *See AFGE*, 215 F.3d at 11; 21 U.S.C. § 622.

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

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

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

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

336. Federal inspectors also cannot and do not inspect carcasses and parts sorted and removed by employees.

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

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

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

FOURTH CLAIM FOR RELIEF

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

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

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

342. Because federal inspectors cannot and do not critically appraise all carcasses and parts for abnormal conditions under NSIS due to the fact that their review has been substituted by that of plant employees, federal inspectors do not and cannot condemn those carcasses and parts that plant employees sort. Plant employees in effect condemn such carcasses and parts, precluding and preventing inspectors from doing so. Such carcasses and parts are not conspicuously marked as "U.S. Inspected and Condemned" or "U.S Condemned" as required under 21 U.S.C. § 604.

343. Accordingly, Defendants' NSIS rules violate 21 U.S.C. § 604 because inspectors are prevented and precluded from inspecting all carcasses and parts that have been sorted by plant employees, determining that they are adulterated, and condemning them by labeling, marking,

stamping, or tagging them as "inspected and condemned," and the rules should be declared *ultra vires* and set aside under 5 U.S.C. § 706(2).

FIFTH CLAIM FOR RELIEF

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

344. Plaintiffs re-allege and incorporate by reference each and every allegation set forth above in paragraphs 1 through 343 *supra* of this Complaint

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

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

347. Accordingly, Defendants' NSIS rules violate 21 U.S.C. § 604 because federal inspectors are prevented and precluded from supervising the disposal of condemned carcasses and parts, and 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).

348. Plaintiffs re-allege and incorporate by reference each and every allegation set forth above in paragraphs 1 through 347 of this Complaint.

349. Under the APA, Federal agency officials may not delegate 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).

350. 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.

351. 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' Finalizing of NSIS Is Arbitrary and Capricious, an Abuse of Discretion, and Otherwise Not in Accordance with Law, Violating 5 U.S.C. § 706(2).

352. Plaintiffs re-allege and incorporate by reference each and every allegation set forth above in paragraphs 1 through 351 *supra* of this Complaint.

353. 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.

354. 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.

355. The NSIS rules are an irrational departure from Defendants' prior practices and regulations. Defendants' NSIS rules contradict their own compliance guidelines and other materials detailing how federal inspectors are to perform the critical appraisal of animals, and carcasses and parts, as well as Defendants' existing regulations, including: 9 C.F.R. §§ 309.1(a)-(b) (requiring the ante-mortem inspection of all animals prior to slaughter); 309.2(a),(m), (n) and (p) (pertaining to inspectors' duties for the inspection, segregation, and release of animals with symptoms of disease); 309.3 (requiring inspectors to condemn dead and dying animals or those with conditions that would require condemnation on post-mortem inspection); 310.1 (requiring the careful post-mortem inspection of all carcasses and parts); 310.5 (requiring inspectors to

conspicuously mark and retain custody of condemned carcasses and parts); and 314.(a)(1) and 314.3(a) (requiring inspector supervision of disposed condemned carcasses and parts).

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

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

358. For any and all of these reasons, the NSIS rules are 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).

RELIEF REQUESTED

WHEREFORE, Plaintiffs respectfully request that this Court:

A. Declare Defendants' NSIS rules illegal as contrary to the Federal Meat Inspection Act and the Administrative Procedure Act;

B. Permanently enjoin Defendants' NSIS rules;

C. Vacate Defendants' NSIS rules;

D. Grant attorneys' fees and costs; and

E. Award any other relief the Court deems just and proper.

Respectfully submitted, this 13th day of January, 2020.

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