

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

FOOD & WATER WATCH, INC., §
1616 P Street NW §
Suite 300 §
Washington, DC 20036; §

MARGARET SOWERWINE, §
18 East Elm St., §
Rocky Mount, NC 27804; §

and §

JANE FORAN §
94-2 Park Street §
Portland, ME 04101; §

Plaintiffs, §

v. §

Civil Action No. _____

TOM VILSACK, in his official capacity §
as the U.S. Secretary of Agriculture §
1400 Independence Ave., S.W. §
Washington, DC 20250; §

BRIAN RONHOLM, in his official §
capacity as the Deputy Under Secretary §
for Food Safety, U.S. Dept. of §
Agriculture §
1400 Independence Ave., S.W. §
Washington, DC 20250; §

ALFRED V. ALMANZA, in his official §
capacity as the Administrator of the §
Food Safety Inspection Service, U.S. §
Dept. of Agriculture §
1400 Independence Ave., S.W. §
Washington, DC 20250; §

(continued on next page) §

U.S. DEPARTMENT OF
AGRICULTURE;
1400 Independence Ave., S.W.
Washington, DC 20250;

and

FOOD SAFETY AND INSPECTION
SERVICE
1400 Independence Ave., S.W.
Washington, DC 20250;

Defendants.

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

I.

Introduction

1. Plaintiffs, Food & Water Watch, Inc. (“FWW”), Margaret Sowerwine, and Jane Foran, bring this action against the above-listed Defendants under the Poultry Products Inspection Act (“PPIA” or “the act”), 21 U.S.C. §§ 451-472 (2012), its regulations, and the Administrative Procedure Act (“APA”) 5 U.S.C. §§ 551-559, 701-706 (2012). Apparently believing that it is too onerous for poultry slaughter companies to continue to have their poultry carcasses, parts, and products pass federal government inspection requirements that have existed since the 1970s, the Defendants have finalized rules that will amount to an unprecedented elimination of inspection resources for a secret set of young chicken and turkey slaughterhouses. The rules allow such establishments to dramatically increase their slaughter line speeds, while threatening public health and introducing unwholesome poultry into interstate commerce. Plaintiffs seek to have Defendants’ rules establishing this new inspection system, the National

Poultry Inspection System (“NPIS”) enjoined and vacated because they are *ultra vires*, violating the PPIA by eliminating mandatory inspection requirements, because they were finalized without opportunity for oral presentation of views and adequate notice and opportunity for public comment, and because they are otherwise arbitrary and capricious.

II.

Jurisdiction and Venue

2. This Court has jurisdiction under 28 U.S.C. § 1331 (2012), 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 (2012) and 21 U.S.C. § 467c (2012), which provides district court jurisdiction for all kinds of cases arising under the PPIA.

3. Venue is proper in this Court under 28 U.S.C. § 1391 (2012) because this suit was filed in the district where Plaintiff FWW resides and where a substantial part of the events or omissions giving rise to the claim occurred.

4. This Court may issue a declaratory judgment in this case pursuant to the Declaratory Judgment Act, 28 U.S.C. §§ 2201-2202 (2012), and may grant the requested relief pursuant the APA, 5 U.S.C. § 706 and 28 U.S.C. § 1651(a) (2012).

III.

Parties

5. Based in Washington, DC, Plaintiff FWW is a national, non-profit, public interest, consumer advocacy organization that works to ensure safe food and clean water. FWW has been harmed by the finalization of Defendants’ NPIS rules because the organization was unable to orally present its views about the rules and advertise to its members that they would have the opportunity to orally present their views on NPIS. Moreover, FWW was not provided adequate

notice to allow it to comment on major new provisions of the rules that were finalized but never proposed or even mentioned in the proposed rules' preamble, including new line speed provisions and provisions that allow companies to opt out of NPIS. The organization's advocacy mission will be harmed by the NPIS rules. FWW will have to increase the resources that it spends on educating the public about the agency's abdication of inspection duties under NPIS, so that people are not lulled into believing that the U.S. Department of Agriculture ("USDA") inspection legend on poultry product (required for all chicken and turkey product from birds slaughtered for human food in commerce), means that the Defendants gave such a product a critical appraisal. To the extent that it will even be possible to determine which companies and establishments opt out of NPIS, FWW will also have to increase the amount of resources that it spends encouraging its members that wish to continue to eat chicken to buy poultry from such companies.

6. FWW presently has approximately 69,370 members in the United States including Plaintiffs Margaret Sowerwine and Jane Foran. Its members were some of the hundreds of thousands of consumers that submitted public comments to the FSIS in 2012, urging the agency not to finalize the proposed NPIS rules. None of FWW's members was able to provide an oral presentation of their views on the Defendants' proposed NPIS rules and none was provided sufficient notice to allow them to comment on major provisions of the final rules that were never proposed or mentioned in the proposed rules' preamble. Defendants' NPIS rules also will harm FWW's members by denying them the right to know which products that have an official inspection legend and establishment number are actually federally inspected and by deceiving them into believing that all chicken products with the USDA inspection legend will be derived from carcasses that received Defendants' critical appraisal. Members who wish to continue to

eat chicken will have to spend additional resources to seek out and purchase poultry from plants that have not adopted NPIS, if this is even possible. FWW members that have lost all confidence in USDA's inspection legend will simply avoid eating chicken altogether. Those who continue to eat chicken slaughtered in NPIS establishments will bear the burden of an increased risk of harm from purchasing and consuming adulterated and unwholesome poultry product.

7. Defendant Tom Vilsack is the Secretary of the USDA and is given authority to administer or delegate the administration of the PPIA. 21 U.S.C. §§ 463(b), 453(i) (2012).

8. Defendant Brian Ronholm is Deputy Under Secretary of Food Safety, which has been delegated the administration of the PPIA by the USDA Secretary. 7 C.F.R. § 2.18(a)(1)(ii) (2014).

9. Defendant Al Almanza is the Director of the Food Safety And Inspection Service ("FSIS"), which has been delegated the administration of the PPIA by the USDA Secretary and Under Secretary of Food Safety. 7 C.F.R. § 2.53(a)(2)(i) (2014).

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

11. Defendant FSIS's staff wrote and approved the final the NPIS 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.

IV.

STATUTORY BACKGROUND

A. The Administrative Procedure Act

12. 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.

13. The APA requires an agency conducting notice-and-comment rulemaking to publish in its notice of proposed rulemaking “either the terms or substance of the proposed rule or a description of the subjects and issues involved.” 5 U.S.C. § 553(b)(3). The final rule must be a logical outgrowth of the rule proposed.

14. Under the APA, a court is empowered to hold unlawful and set aside agency action for findings and conclusions that, among other reasons, are “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 Poultry Product Inspection Act

15. In 1957, based on findings that unwholesome, adulterated, or misbranded poultry products injure public welfare and consumers, destroy markets, and result in sundry losses to producers and processors, Congress passed the PPIA, providing Defendant USDA with the authority to protect consumer health and welfare by assuring that poultry products are wholesome, not adulterated, and properly marked, labeled, and packaged. 21 U.S.C. § 451 (2012).

16. In pursuance of this policy, the PPIA establishes a detailed scheme for the federal inspection of poultry in slaughterhouses, requiring both ante-mortem inspection activities, which take place before the poultry is slaughtered, and post-mortem inspection, which is at issue in this case and occurs after slaughter.

17. The act requires that all processed chicken and turkeys receive an inspection, stating that the “Secretary. . . shall cause to be made by inspectors post-mortem inspection of the carcass of *each bird* processed” 21 U.S.C. § 455(b) (2012) (emphasis added).

18. The PPIA’s term “[p]rocessed” includes “slaughtered,” regardless of whether the bird undergoes any other processing including canning, salting, stuffing, rendering, de-boning, or cutting up. 21 U.S.C. § 453(w) (2012).

19. An “inspector” is an employee or official of the U.S. government or of the government of any State or the District of Columbia. *Id.* § 453(k).

20. An “inspection” is a critical appraisal by a federal inspector. *AFGE v. Glickman*, 215 F.3d 7, 11 (D.C. Cir. 2000).

21. Defendants’ regulations define “carcass” as “all parts, including viscera, of any slaughtered poultry.” 9 C.F.R. § 381.1(b) (2014). Viscera are the inner organs of the bird.

22. Therefore, the PPIA requires that federal inspectors critically appraise all chicken and turkey carcasses and viscera.

23. Under Defendants’ regulations, “[a] post-mortem inspection shall be made on a bird-by-bird basis on all poultry eviscerated in every official establishment. Each carcass, or all parts comprising such carcass, must be examined by an inspector, except for parts that are not needed for inspection purposes and are not intended for human food and are condemned.” 9 C.F.R. § 381.76(a) (2013).

24. The PPIA also requires for “[a]ll poultry carcasses and parts thereof . . . found to be adulterated[,]” the federal inspector shall condemn them and they shall, “if no appeal be taken from such determination of condemnation, be destroyed for human food purposes under the supervision of an inspector[.]” 21 U.S.C. § 455(c) (2012).

25. The PPIA has one and only one exception to this condemnation provision: “carcasses, parts, and products, which may by reprocessing be made not adulterated, need not be so condemned and destroyed if so reprocessed under the supervision of an inspector and thereafter found to be not adulterated.” *Id.*

26. If an item is not found to be adulterated, Defendants are required to affix an official inspection legend on the item or on its container and the official establishment number of the establishment where the article was processed. 21 U.S.C. § 453(h)(12) (2012).

27. The official inspection legend states “Inspected for wholesomeness by U.S. Department of Agriculture.” 9 C.F.R. § 381.96 (2014). This term means that the poultry has been inspected and was found at the time of such inspection to not be adulterated. *Id.* § 381.1 (2014). Articles without such stamp are misbranded under the act. 21 U.S.C. § 453(h)(12).

28. A carcass and carcass part is adulterated under the PPIA for the following, non-exclusive, reasons:

- a) if it bears or contains any poisonous or deleterious substance which may render it injurious to health . . . ; *id.* § 453(g)(1) (2012);
- b) if it consists in whole or in part of any filthy, putrid, or decomposed substance or is for any other reason unsound, unhealthful, unwholesome, or otherwise unfit for human food; *id.* § 453(g)(3) (2012);
- c) if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health; *id.* § 453(g)(4) (2012);
- d) if it is, in whole or in part, the product of any poultry which has died otherwise than by slaughter; *id.* § 453(g)(5) (2012);

e) if any valuable constituent has been in whole or in part omitted or abstracted therefrom; or if any substance has been substituted, wholly or in part therefor; or if damage or inferiority has been concealed in any manner; or if any substance has been added thereto or mixed or packed therewith so as to increase its bulk or weight, or reduce its quality or strength, or make it appear better or of greater value than it is. *Id.* § 453(g)(8) (2012).

29. A product is misbranded if it is false or misleading in any particular. *Id.* § 453(h).

30. 21 U.S.C. § 453(c) (2012) requires an opportunity for the oral presentation of views to be accorded all interested persons when conducting rulemaking under the PPIA.

V.

GENERAL ALLEGATIONS

A. Poultry Inspection Under the PPIA

31. Defendants' inspection-system rules dictate how establishments must accommodate federal 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 birds to be inspected by each inspector per minute.

32. Prior to the NPIS rules that are the subject of the present challenge, there were four types of rules that would govern federal inspections of all slaughtered poultry other than ratites (flightless birds such as ostriches). These inspection-system rules covered the 289 federally inspected non-ratite establishments: the Streamlined Inspection System ("SIS"), the New Line

Speed Inspection System (“NELS”), the New Turkey Inspection System (“NTIS”), and Traditional Poultry Inspection System (“TPIS”).

33. The TPIS is typically employed at smaller, lower volume establishments that eviscerate carcasses by hand. 70 very small or small TPIS establishments have between one and four inspectors per line. The maximum line speeds in such facilities is between 25 and 46 young chickens and 16 and 25 turkeys per minute. These establishments only accounted for about one percent of the U.S. domestic poultry industry (excluding ratites) in 2010.

34. 194 establishments (117 SIS, 50 NELs, and 27 NTIS) made up the rest of federally inspected non-ratite poultry establishments prior to the challenged NPIS rules. They had between two and four inspectors inspecting between 70 and 140 young chickens per minute and between 21 and 51 turkeys per minute. The establishments, plus the 25 Hazard Analysis Critical Control Point Based Inspection Models Project (“HIMP”) facilities, account for 99.9 percent of the domestic young chicken and turkey market in 2010.

35. Under SIS, line speeds are limited to 35 carcasses per minute (referred to as “birds per minute” or “bpm”) per inspector.

36. Under NELs, line speeds are limited to approximately 30 bpm per inspector.

37. Under NTIS, an establishment is limited to 32 light bpm with one online inspector per line and 51 light bpm with two online inspectors per line. For heavy birds, those speeds decrease to 25 bpm and 45 bpm, respectively.

38. Under all of these inspection systems, prior to the final NPIS rules and HIMP model project (discussed below) and pursuant to the PPIA, online federal government inspectors would organoleptically inspect (using sight, touch, and smell) every carcass, both the carcass exteriors

and interiors, along with its corresponding viscera at a fixed location on the slaughter line, immediately following the viscera separation, but before any trimming.

39. Under Defendants' prior regulations for all systems, "[e]ach carcass to be eviscerated shall be opened so as to expose the organs and the body cavity for proper examination by the inspector." 9 C.F.R. § 381.76(a).

40. Inspection activities for all systems would include federal inspectors pulling the carcasses' cut skin and muscle back and observing the inner surfaces of the carcasses for yellow scabbed areas that could indicate inflammatory process (severe inflammation of the dermal and subcutaneous layers of the skin); exudate in or cloudiness in air sacs (which are part of the birds lungs), which could indicate air sacculitis (inflammation of the air sacs); tissue masses or abnormal tissue, indicating tumors; and enlarged or reddened kidneys, indicating early sepsis (a disease produced by microorganisms in the blood).

41. Under Defendants' prior regulations for all systems, "[n]o viscera or any part thereof shall be removed from any poultry processed in any official establishment, except at the time of post-mortem inspection, unless their identity with the rest of the carcass is maintained in a manner satisfactory to the inspector until such inspection is made." 9 C.F.R. § 381.76(a), (b)(2)(ii)(a), (b)(3)(ii)(a), (b)(4)(i)(a), (b)(5)(i)(a) (2014).

42. In all systems, federal inspectors would examine viscera for gross enlargements of the spleen and liver, indicating leukosis (a viral infection that causes tumors); yellow or pale exudate on the hearts and lungs indicating air sacculitis; and hemorrhage, congestion, and swelling, including of the intestines, indicating sepsis.

43. Federal inspectors in all systems would inspect the viscera, the inner surfaces, and outer surfaces of carcasses for signs of septicemia because it is a disease that is manifested by a

group of clinical signs, not all of which will be present in a single carcass, and some of which are only identifiable by looking at the viscera and the inside of the carcass.

44. No matter the system, federal inspectors would not typically inspect carcass exteriors for indications of either leukosis or air sacculitis, because these are usually detected by inspecting the viscera or inside of the carcass.

45. Defendants require a nine-week training program to prepare federal Public Health Veterinarians. Three weeks of this is classroom training with a curriculum designed to cover three main categories: FSIS as a public health regulatory agency, animal dispositions/food safety, and FSIS administrative overview. 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. Their training topics are located here <http://goo.gl/h74jzN>. Other newly hired federal inspectors must undergo training covering at least 11 topics for inspectors in poultry assignments, including one on post-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>

B. Corrective Actions and Condemnations

46. Under all prior inspection systems, federal inspectors that identified defects would direct plant personnel to take appropriate corrective action if defects could be remedied through trimming and reprocessing.

47. Such reprocessing was required to be done under the supervision of federal inspectors. *See, e.g.*, 9 C.F.R. §§ 381.76(b)(3)(ii)(c), 381.76(b)(4)(i)(a), 381.76(b)(5)(i)(a) (2014).

48. When defects could not be corrected, federal inspectors would make the determination that product was to be condemned and direct the establishments to destroy the product under the inspectors' supervision. *Id.*

49. Under Defendants' regulations, "any organ or other part of a carcass which is affected by an inflammatory process shall be condemned and, if there is evidence of general systemic disturbance, the whole carcass shall be condemned." *Id.* § 381.86 (2014)

50. "Carcasses of poultry with evidence of extensive involvement of the air sacs with air sacculitis or those showing air sacculitis along with systemic changes shall be condemned." *Id.* § 381.84 (2014). Less-affected carcasses require the complete removal and condemnation of all affected tissues including the exudate. *Id.*

51. Further, "[a]ny organ or other part of a carcass which is affected by a tumor" is to be condemned and "when there is evidence of metastasis or that the general condition of the bird has been affected by the size, position, or nature of the tumor, the whole carcass shall be condemned." *Id.* § 381.87 (2014).

52. "Carcasses of poultry showing evidence of any septicemic or toxemic disease, or showing evidence of an abnormal physiologic state," must also be condemned. *Id.* § 381.83 (2014).

53. Carcasses that exhibit septicemic and toxemic conditions are likely to contain infection agents that can be transferred to humans.

54. Viscera and carcasses that are condemned are stamped “U.S. Inspected and Condemned” stamp because they may look edible. *Id.* §§ 312.6(b)(5); 381.101.

55. Condemned product must be in inspectors’ custody, meaning within sight of an inspector at all times or be placed in a secure container or room equipped with an official lock or seal until it is destroyed.

C. The New Poultry Inspection System

1. A Massive Roll-back in Federal Inspection

56. On January 27, 2012 Defendants proposed, and rules that implement a new inspection system, known as NPIS, for young chicken and turkey slaughter establishments. The final rules were published in the Federal Register on August 21, 2014 and will be effective October 20, 2014.

57. Defendants expect that the new NPIS rules will affect 219 of the 289 official non-ratite poultry establishments that receive federal inspection.

58. If 219 establishments adopt NPIS, Defendants will be able to reduce the number of online inspectors by between 663 and 770 federal inspectors.

59. Defendants expect that establishments operating under NPIS will substitute .8 staff years of their own online establishment staff that are tasked with removing adulterated and unwholesome carcasses (called “helpers and sorters”) for every one (1) staff-year of Defendants’ online inspection personnel reduced under the new NPIS rules. This means that the NPIS rules will allow a 20 percent reduction in total establishment- or federal-inspector personnel time aimed at removing adulterated carcasses from slaughter lines.

2. Slaughter Facilities, Not Federal Inspectors, Performing Inspections, Condemnations, and Reprocessing Without Any Federal Inspector Supervision

60. For establishments operating under the new system (hereinafter “NPIS establishments”), federal inspectors are no longer responsible for telling establishment staff to remove birds with visible defects from the slaughter lines or to trim and reprocess them to remove the defects. NPIS establishment personnel are responsible for removing the poultry that have visible defects and trimming and reprocessing them prior to presentation to federal inspectors.

61. Under the NPIS rules, adulterated carcasses, which are not condemned and can be reprocessed, are not reprocessed under the supervision of the inspector in NPIS establishments.

62. NPIS establishment personnel alone are responsible for condemning birds that cannot be reprocessed prior to presentation to federal inspectors.

63. NPIS establishment personnel will dispose of carcasses and their parts with condemnable conditions without the supervision of federal inspectors.

64. Under the NPIS rules, only one federal inspector is positioned at the end of the slaughter line, immediately before the chiller (a piece of equipment that brings the temperature of the bird down to prevent bacteria growth), and this inspector is tasked with inspection of each carcass after NPIS establishment staff have already removed the viscera from the carcass and have sorted non-complying carcasses. Another inspector is positioned offline to perform, among other tests, food safety and quality checks to verify that plant personnel have done things such as removing fecal material on carcasses.

65. Under the NPIS rules, federal online inspectors are not required to look at every carcass.

66. Under the NPIS rules, federal online inspectors in NPIS establishments are not required to touch every carcass.

67. Under the new NPIS rules, Defendants have eliminated the regulatory requirement that each carcass is to be opened so as to expose the organs and body cavity in NPIS establishments.

68. NPIS establishment personnel are responsible for inspecting and condemning viscera, which are removed prior to federal inspection under the NPIS rules. There is no regulatory requirement that federal inspectors inspect the viscera of all birds presented.

69. The NPIS rules have no provisions mandating how NPIS establishment personnel are to perform the same inspection tasks as Defendants' personnel did prior to NPIS, as detailed in paragraphs 38-55.

70. Under the NPIS rules, there are no provisions that require training or provide certification for NPIS establishments related to performing the same inspection tasks as Defendants' personnel did prior to NPIS, as detailed in paragraphs 38-55.

71. Defendants' NPIS rules have no provisions that require training or provide certification related to how NPIS establishment personnel are to determine when to condemn birds.

72. Defendants have developed a draft compliance guideline ("new compliance guideline") to assist NPIS establishments in training their staff to perform online inspection tasks. The compliance guideline was first made public after Defendants finalized the NPIS rules. Defendants will take public comment on the draft guidance until October 21, 2014.

73. The Defendants are not requiring or providing any training with the new compliance guideline.

74. Nothing in Defendants' new compliance guideline for establishments is binding on establishments.

75. Under Defendants' new compliance guideline, NPIS establishment personnel must make decisions with each carcass, called a "disposition," based on the stage of the disease process or injury existing in the live bird, and the extent to which the bird was recovering from these conditions at the time of slaughter.

76. A few examples of disposition decisions that NPIS establishment staff must make under Defendants' new compliance guideline include the following determinations:

- a) When carcasses are "severe[ly] drying out," as opposed to only "slightly" dehydrated, the birds need to be condemned;
- b) When carcasses are "excessively" contaminated with fecal matter, they should be condemned; otherwise, they can be reprocessed;
- c) When a tumor on a carcass is "very large" and "takes up too much space in the body" then the entire carcass and viscera is unwholesome, but if it is "not very large" and has not spread, it can be trimmed;
- d) When a carcass has "slightly" cloudy air sacs and a "small amount" of fluid, then establishment personnel can remove the affected tissues, but if a carcass is "extensively affected" then the entire carcass and viscera must be condemned;
- e) When the carcass has yellow, cheesy material in the vent area, these areas can be trimmed, but when the material has travelled down the breast and "most" of the carcass is affected, then the entire carcass and viscera must be condemned;

f) When there are bruises that affect “most or all of the carcass” the carcass must be condemned, but when the bruises are “localized,” then can be removed through trimming.

77. The new compliance guideline indicates that not every carcass affected with Septicemia/Toxemia will show all of the signs on the outside of the carcass and with the viscera.

3. Birds Whizzing By So Fast That No Inspection Is Possible

78. Defendants anticipate that that NPIS establishments will increase their line speeds because of the NPIS rules’ elimination of the inspection tasks that federal online inspectors are required to do under the other systems.

79. Under the NPIS rules, only one line inspector in each NPIS establishment is to inspect as many as 140 young chickens per minute, as measured at the point of federal inspection, which is approximately 2 1/3 birds per second.

80. SIS facilities did not operate at 140 bpm per inspector, but 35 carcasses per minute per inspector.

81. Allowing line speeds to increase to 140 young chickens per minute for NPIS establishments means that carcasses can pass by each individual federal inspector 4 times faster than under the prior SIS system (35 bpm) and slightly more than 4.7 times (30 bpm) faster than under the prior NELS system.

82. In part because NPIS establishment maximum line speeds of 140 bpm are the same as under the prior SIS system, Defendants do not believe that establishments’ adoption of NPIS will have adversely impacts on food safety, animal welfare, or establishment employment.

83. Defendants never received any comments indicating that maximum line speeds of 140 bpm would adequately protect food safety, animal welfare, or establishment employment.

84. Defendants determined line speeds for its prior SIS system by conducting field and work- measurement studies of online inspectors to determine the time needed for an inspector to adequately perform the SIS-inspections procedure. The studies showed that online inspectors can perform the SIS inspection procedure at overall line speeds of up to 140 bpm if each inspector is presented with up to 35 bpm.

85. Defendants never conducted field and work measurement studies of online inspectors to determine the time needed for each inspector to perform inspection at 140 bpm under NPIS.

86. Before finalizing NPIS, Defendants developed a set of pilot projects at young chicken, turkey, and hog plants to assess the removal of federal inspectors from evisceration and slaughter lines. The pilot projects are known as the Hazard Analysis Critical Control Point Based Inspection Models Project (“HIMP”). Defendants performed an analysis of certain HIMP facilities in order to support its NPIS rules (the “2011 HIMP Analysis”).

87. The non-HIMP plants that Defendants compared to HIMP plants in its 2011 HIMP Analysis had average total line speeds of 115 bpm (regardless of the number of inspectors), which is almost 18 percent slower than the maximum line speeds allowed for chickens for NPIS establishments.

88. Defendants reduced the maximum line speeds from 175 bpm in the proposed NPIS rules to 140 bpm in the final rules for NPIS establishments at least in part to more closely align with the average line speed of HIMP plants, which was 131 birds per minute.

89. Defendants believe that having facilities operate at 140 bpm will allow Defendants to assess NPIS establishments’ process controls under NPIS.

90. Defendants do not have adequate data to assess HIMP facilities’ process controls operating at line speeds as high as 140 bpm.

91. NPIS establishments will be able to operate at these increased line spends in part because of the change in required inspection activities of federal online inspectors.

92. At a rate of 140 chickens per minute, organoleptic inspection by an inspector is impossible.

93. At a rate of 140 chickens per minute per inspector, it is not possible for federal inspectors to touch every carcass.

94. At a rate of 140 chickens per minute per inspector, it is not possible for federal inspectors to smell every carcass.

95. At a rate of 140 chickens per minute per inspector, it is not possible for federal inspectors to open up every carcass so as to expose the organs and body cavity.

96. At a rate of 140 chickens per minute per inspector, it is not possible for federal inspectors to see the insides of carcasses.

97. Under NPIS, federal online inspectors can only view the backs of chicken carcasses.

98. At a rate of 140 chickens per minute per inspector, it is not possible for federal inspectors to critically appraise the insides of carcasses.

99. At a rate of 140 birds per minute per inspector, it is not possible for federal inspectors to critically appraise the exterior of carcasses.

100. Under NPIS, only one line inspector inspects as many as 55 turkeys per minute in NPIS establishments, as measured at the point of federal inspection, which is close to one bird per second.

101. HIMP turkey plants operate at 55 bpm.

102. At a rate of 55 turkeys per minute, organoleptic inspection by an inspector is impossible.

103. At a rate of 55 turkeys per minute, it is not possible for federal inspectors to touch every carcass.

104. At a rate of 55 turkeys per minute per inspector, it is not possible for federal inspectors to smell every carcass.

105. At a rate of 55 turkeys per minute per inspector, it is not possible for federal inspectors to open up every carcass so as to expose the organs and body cavity.

106. Under NPIS, federal online inspectors can only view the backs of turkey carcasses.

107. At a rate of 55 turkeys per minute per inspector, it is not possible for federal inspectors to see the insides of carcasses.

108. At a rate of 55 turkeys per minute per inspector, it is not possible for federal inspectors to critically appraise the insides of carcasses.

109. At a rate of 55 turkeys per minute per inspector, it is not possible for federal inspectors to critically appraise the exterior of carcasses.

110. The final NPIS rules allow those 20 young chicken operations that had been allowed to operate under HIMP to run line speeds at 175 birds per minute. This will be done under the Defendants' *Salmonella* Initiative Program, that allows meat and poultry slaughter establishments to receive waivers of regulatory requirements on condition that they conduct microbial testing and share the results with the Defendants.

111. If an operation that is allowed to run under HIMP goes out of business or chooses not to operate under its waiver, Defendants will select another establishment takes its place. This means that 20 facilities will always operate under the faster HIMP-pilot line speeds.

112. At a rate of 175 birds per minute per inspector, it is not possible for federal inspectors to critically appraise the insides of carcasses.

113. At a rate of 175 birds per minute per inspector, it is not possible for federal inspectors to critically appraise the exterior of carcasses.

114. At a rate of 175 birds per minute, organoleptic inspection by an inspector is impossible.

115. At a rate of 175 birds per minute, it is not possible for federal inspectors to touch every carcass.

116. At a rate of 175 birds per minute per inspector, it is not possible for federal inspectors to smell every carcass.

117. At a rate of 175 birds per minute per inspector, it is not possible for federal inspectors to open up every carcass so as to expose the organs and body cavity.

118. Under NPIS, federal online inspectors can only view the backs of the carcasses.

119. At a rate of 175 birds per minute per inspector, it is not possible for federal inspectors to see the insides of carcasses.

120. Under all former and new systems, on-line inspectors have no authority to slow down the slaughter line. Only federal “Inspectors in Charge” have this authority.

121. Inspectors can stop the lines, but only when they observe a bird with a condemnable condition.

4. Rollbacks to Pathogenic Testing

122. Defendants’ NPIS rules revokes 9 C.F.R. 381.94(a) for all establishments besides those slaughtering ratites. This regulation required that poultry establishment test for *Escherichia coli* Biotype I (*E. coli*), and it provided criteria for which 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.

123. Defendants' NPIS rules revoke 9 C.F.R. 381.94(b) for all establishments besides those slaughtering ratites. The rule required that poultry establishment 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 Defendants to suspend inspection services.

124. Defendants' new rules allow all establishments besides those slaughtering ratites to instead develop and implement its own microbiological sampling plan, prior to carcasses entering and after carcasses exit the chiller. The establishment would be responsible for determining which microbiological organisms will best help it to monitor the effectiveness of its process control procedures.

125. Defendants did not propose or consider an alternative that would have added pathogen testing anywhere along the production line in addition to the requirement of testing before and after the carcass enters the chiller and rejected another pathogenic testing station because of its costs.

126. Defendants never proposed an alternative that would require testing prior to the carcasses entering the establishment to assess the amount of *Salmonella* and *Campylobacter* present prior to slaughter or processing.

5. Final Rules That Are Radically Different Than the Proposed Rules

127. The proposed NPIS rules were not similar to the final rules in a number of ways, including that under the proposed rules, each online inspector in NPIS establishments was to inspect as many as 175 young chickens per minute, while under the final rules online inspectors only have to inspect as many as 140 young chickens per minute.

128. The preamble to the proposed NPIS rules did not indicate that Defendants were taking comment on rules that would allow NPIS establishments to operate at different line speeds.

129. Nothing in the preamble to the proposed NPIS rules indicated that Defendants were considering final rules that would allow NPIS establishments to operate at different line speeds.

130. Defendants' proposed NPIS rules replaced the SIS, NELs, and NTIS inspection systems, meaning that establishments that used these systems have no other choice but to adopt NPIS. Establishments could not operate under their prior inspection system, unless they were operating under TPIS.

131. Nothing in the preamble to the proposed NPIS rules indicated that Defendants were taking comment on an alternative that would allow establishments that were not operating under TPIS to operate under their prior system.

132. Nothing in the preamble to Defendants' proposed NPIS rules indicated that they were considering an inspection system that allowed establishments that were not operating under TPIS to continue operating under their prior system.

133. Defendants' decision to allow establishments to keep their existing inspection system if they choose to do so under the final NPIS rules was in response to: a) an individual commenter, and b) a member of academia.

134. The individual commenter, upon which Defendants based their decision to allow companies to opt out of NPIS, addressed how the proposed rule allowed facilities to operate under either the NPIS rules or under the TPIS.

135. The academic's comment on which Defendants based their decision to allow companies to opt out of NPIS indicates that she incorrectly believed that, under the proposed NPIS rules, all establishments could keep their existing inspection system.

136. Defendants' Preliminary Regulatory Impact Analysis (PRIA) estimated that as many as 219 facilities would operate under NPIS.

137. The only change in the final NPIS rules might alter Defendants' PRIA estimate that 219 establishments will choose to operate under the NPIS rules is if fewer establishments choose to do so because of the slower line speeds in the final rules, but Defendants believe that establishments will choose the NPIS rules regardless of the line speeds.

138. Defendants estimate that that only establishments that are not likely to adopt NPIS are those 71 establishments presently operating under the TPIS, and they include 51 very small establishments that cannot absorb the costs of additional sorting activities.

139. Defendants estimate that the total number of establishments that will not operate under NPIS will account for less than one percent of the U.S. poultry production.

140. The preamble to the final NPIS rules does not indicate that Defendants will make public the list of establishments that choose to operate under the NPIS rules, as opposed those that choose to retain their prior system.

6. No Opportunity for Oral Presentation of Views

141. On March 21, 2012, FSIS held a public meeting with its NACMPI via Web conference to discuss the January 2012 proposed NPIS rules.

142. Defendants never allowed those members of the public that were not members of the Defendants' Advisory Committee on Meat and Poultry Inspection ("NACMPI") to provide oral testimony on the proposed NPIS rules.

143. Only NACMPI members were able to provide oral testimony at the NACPI public meeting to discuss the proposed NPIS rules. Members of the public that were not on NACMPI were expressly barred from making oral comment.

144. FWW and its members are not part of NACMPI.

145. One member of the committee, Ms. Carol Tucker Foreman complained about the lack of opportunity for members of the public to make oral public comment.

146. Defendants received other comments asking for a public hearing or other opportunity for the public to orally comment on the proposed NPIS rules.

147. The preamble to Defendants' final NPIS rules do not address the requests to present oral comments on the proposed NPIS rules.

7. Inadequate 2011 HIMP Analysis and Response to Comments

148. Defendants in part based their NPIS rules on their 2011 HIMP Analysis, which compared the performance of 20 young chicken plants in the pilot project with 64 comparably sized establishments not participating in the project (also known as "Non-HIMP" establishments) and all 176 non-HIMP establishments that slaughtered chickens during the time of the study.

149. Defendants have concluded that, based on the data in it analysis, "compared to inspection at non-HIMP establishments HIMP has improved the safety of poultry products and increased overall consumer protection."

150. Defendants' 2011 HIMP Analysis did not collect data to demonstrate the relative effectiveness of plants participating and not participating in HIMP. Rather, Defendants analyzed data at both HIMP and non-HIMP facilities to evaluate compliance with certain regulatory requirements.

151. All of the 2011 HIMP Analysis’s conclusions about whether inspectors were “able to make a determination as to whether each carcass in [*sic*] not adulterated[,]” were based on data that compared the numbers and rates of carcasses that inspectors found with problems such as Septicemia, Toxemia, or visible fecal contamination that were processed and passed inspection in HIMP establishments, with the numbers and rates of carcasses with those problems, that were processed and passed inspection in non-HIMP facilities.

152. According to the 2011 HIMP Analysis, condemnation rates between HIMP and non-HIMP establishments cannot be compared because HIMP-establishment employees dispose of non-complying carcasses at many locations, both prior to and after the establishment sorting station, and birds removed prior to the evisceration line or at other locations are not consistently recorded by industry.

153. Defendants’ 2011 HIMP Analysis relied on the performance of HIMP facilities that volunteered for the demonstration project.

154. Because of the voluntary nature of the selection, a 2001 U.S. Government Accountability Office (“GAO”) study concluded that potential selection bias is introduced because such plants may be predisposed to better performance.

155. The Agency’s 2011 HIMP analysis did not create a subgroup of randomized facilities within the sample of volunteer plants as a control group, as recommended by the 2001 GAO report.

156. Defendant FSIS paid researchers from the National Alliance for Food Safety, a consortium of which the Defendant USDA’s Agricultural Research Service is a member, to review and evaluate the data from young chicken HIMP plants. Their report, titled “Review of the HACCP-based Inspection Models Project,” found that the “inability to randomly select and

require that plants participate in an expensive study of this type is indeed a limitation of the study.”

157. Defendants’ response to comments about how Defendants’ 2011 HIMP Analysis only relied upon volunteer establishments was that the selected establishments represent diversity in geography, corporate structure, management styles, number of evisceration lines, product distribution patterns, inspection system in use prior to the pilot, and other variables, but Defendants do not answer how the agency addressed any selection bias in the study.

158. Under HIMP, federal government Verification Inspectors tested 10-bird samples per hour for food safety defects.

159. Under Defendants’ final NPIS rules, there is no requirement that NPIS establishments get at least this same number of verification checks as HIMP plants did.

160. Part of the 2011 HIMP Analysis involved assessed *Salmonella* data in HIMP and non-HIMP plants.

161. Defendants’ 2011 HIMP Analysis based its conclusions for *Salmonella* on a decreasing number of samples collected at plants from 2006 to 2010. And the number of plants at which samples were taken varied each year. In August 2013, a GAO report concluded that this raised questions about the validity of Defendants’ conclusion that an inspection system based on HIMP would ensure equivalent if not better levels of food safety and quality than provided at non-HIMP plants. Defendants did not correct this issue in their 2011 HIMP analysis prior to finalizing their NPIS rules.

162. Defendants’ own *Salmonella* data from 1998 to 2007 shows that 14 of the 20 HIMP establishments evaluated had lower positive rates under non-HIMP inspection than when

they were under HIMP. The preamble to Defendants' final NPIS rules does not respond to this data.

163. The 2011 HIMP Analysis found that *Salmonella* rates are higher in HIMP chicken plants in 2009 and 2010 compared to non-HIMP comparison establishments.

164. The results of Defendants' most recent round of *Salmonella* testing released in 2013 indicate that two of the poultry plants that failed were part of the HIMP pilot – Tyson Foods Establishment P7101 located in Clarksville, Arkansas, and Golden Rod Broilers Establishment P341 located in Cullman, Alabama.

165. Part of the 2011 HIMP Analysis involved evaluating HIMP and non-HIMP facilities Noncompliance Record (“NR”) rates. An NR is a written record that documents noncompliance with Defendant FSIS regulations. An NR notifies the establishment of the noncompliance and that it should take action to remedy the situation and prevent its recurrence.

166. In the 2011 HIMP Analysis, for 5 years of data for 10 verification procedures performed by Defendant FSIS (50 combined data points which the Defendants use to compare HIMP and non-HIMP facilities), the 2011 HIMP analysis failed to show a statistically significant lower rate of health-related NRs for 41 out of 50 procedures in HIMP facilities. And in fact 3 procedures in three years showed a statistically higher health-related NR rate for HIMP plants.

167. The preamble to Defendants' final NPIS rules states that health-related NR rates at HIMP establishments were not statistically different from or were statistically lower for *all* inspection procedures considered.

168. In the 2011 HIMP Analysis, for the verification procedures that make up most of the difference in inspection activities (three times as many 030J01 verification procedures in HIMP plants compared to non-HIMP plants), there was only approximately one-half a

percentage point lower NR rate than in non-HIMP facilities averaged over the course of 5 years. This was the only health-related NR data point for which there was a large enough sample size to determine that there was a statistical difference, one way or the other, over the course of these five years.

169. In the 2011 HIMP Analysis, fecal NR rates were less than 1 percentage point lower at HIMP facilities than non-HIMP establishments.

170. Part of the 2011 HIMP Analysis involved evaluating the HIMP and non-HIMP facilities against food safety and quality performance standards that were developed for the HIMP facilities to meet. Defendants set the performance standard for food safety defects, which include contamination with fecal material, as an example, at zero. Defendants set performance standards for food quality, such as bruises at various levels, depending on the bird species and the defect.

171. The 2013 GAO report concluded that a major limitation of the 2011 HIMP Analysis's conclusions that young HIMP chicken facilities were meeting food safety and quality performance standards was that it was based on two-year snapshots of data that varied depending on whether the standards were for food safety or food quality. The report concluded that the 2011 HIMP Analysis may not be indicative of plants' performance over time.

172. Defendants did not include larger data sets than the two-year snapshots for the 2011 HIMP Analysis of food safety and quality performance standards because of the additional work it would have taken to enter the data from paper forms into a computer database.

173. Defendants believe that their 2011 HIMP Analysis supports the NPIS rules for turkey establishments.

174. Defendants have not prepared a report evaluating HIMP at young turkey plants, because data at the five turkey HIMP plants provided limited information due to small sample sizes.

175. Defendants' protocols for testing chicken and turkey carcasses for the *Salmonella* and *Camplobacter* pathogens are different, affecting the results of the testing, and the microbial data cannot be compared between the chicken and turkeys.

176. The food quality performance standards in HIMP facilities for young chicken and turkey establishments differ by as much as 0.5 to 16%.

177. An FWW analysis of the data for 14 HIMP plants found that out of 229 NRs filed from March to August 2011, 208 (90 percent) were for visible fecal contamination that was missed by company employees.

178. An FWW analysis previously submitted to the agency details that for 11 of the 20 HIMP plants from March to August 2011, establishment personnel missed more than 30 percent of conditions on chickens that includes blisters, bruises, external mutilation, fractures, sores, and scabs, and 60 percent of dressing defects such as the presence of feathers, oil glands, trachea. The same analysis found that the company employees missed 30 percent of conditions on turkeys that includes blisters, bruises, external mutilation, fractures, sores, and scabs, and 87 percent of dressing defects such as the presence of feathers, oil glands, trachea. Defendants' do not address these comments in the preamble to their final NPIS rules.

8. Inadequate Risk Analysis and Response to Comments

179. Defendants also conducted a risk analysis in 2011 that attempted to evaluate the relationship between the increased off-line inspection tasks expected under NPIS and the

expected attributable decrease in the *Campylobacter* and *Salmonella* pathogen contamination and rate of human illness.

180. The risk analysis concluded that there are ambiguous expected results with *Campylobacter* in their model that examined the results of the increase in indiscriminate offline inspection activities (that is, there is an increase in inspection activities, but there is no assumption of how Defendants FSIS might emphasize or de-emphasize certain inspection activities) with the possibility of increased illnesses occurring under some scenarios. This model predicts an increase in 170 annual *Campylobacter* illnesses (0.1% of illnesses attributable to young chicken and turkey establishments.)

181. The risk analysis's assumptions about discriminate inspection activities (that is, where there is an assumed increase in surprise inspection activities that are not scheduled ahead of time) were based on activities scheduled under the Defendants' Performance Based Inspection System ("PBIS"), which provides inspection personnel the frequencies with which to perform verification tasks and the relative priorities of those tasks.

182. Since the time of this risk analysis, the number of pre-operational sanitation procedures that federal inspectors conduct on a monthly basis under Defendants' new inspection-scheduling program, the Public Health Inspection System ("PHIS") was reduced to accommodate other inspection procedures. Defendants did not alter their risk analysis or collect more data to address the limitation in the study.

183. Defendants' risk analysis only evaluated what an increase in offline inspection resources would do to the estimated attributable rate of human illness.

184. Defendants' risk analysis did not evaluate what the decrease in online inspection tasks would do to the attributable rate of human illness.

185. Defendants' risk analysis did not evaluate the increase in line speeds would do to attributable rate of human illness.

186. The preamble to the Defendants' proposed NPIS rules includes a discussion of its risk analysis, which has an analysis of alternatives to NPIS, but this discussion does not include any alternative that increases the offline inspection resources without decreasing the online inspections.

VI.

First Claim for Relief

Defendants' NPIS Violates 21 U.S.C. § 455(c) by Allowing Young Chicken and Turkey Carcasses to be Condemned By NPIS Establishment Staff.

187. Plaintiffs re-allege and incorporate by reference each and every allegation set forth above in paragraphs 1- 186 of this Complaint.

188. The PPIA requires Federal Inspectors to condemn all “[a]ll poultry carcasses and parts thereof . . . found to be adulterated[,]” and “if no appeal [is] taken from such determination of condemnation,” such carcasses and parts are to “be destroyed for human food purposes under the supervision of an inspector” provided the product cannot be reprocessed. 21 U.S.C. § 455(c).

189. Under NPIS, poultry carcasses and parts that are adulterated and cannot be reprocessed are condemned by NPIS establishment personnel, not by federal inspectors.

190. Accordingly, Defendants' NPIS rules violate 21 U.S.C. § 455(c), as federal inspectors do not condemn all poultry carcasses found to be adulterated, and the rules should be declared illegal and set aside pursuant to the APA, 5 U.S.C. § 706(2).

Second Claim for Relief

Defendants' NPIS Violates 21 U.S.C. § 455(c) by Allowing Young Chicken and Turkey Carcasses to be Reprocessed by NPIS Establishment Staff Without Inspector Supervision.

191. Plaintiffs re-allege and incorporate by reference each and every allegation set forth above in paragraphs 1-190 of this Complaint.

192. The PPIA provides that “carcasses, parts, and products, which may by reprocessing be made not adulterated, need not be so condemned and destroyed if so reprocessed under the supervision of an inspector and thereafter found to be not adulterated.” 21 U.S.C. § 455(c).

193. Under Defendants NPIS rules, NPIS establishments are allowed to reprocess adulterated carcasses, parts, and products outside of the supervision of federal inspectors.

194. Accordingly, Defendants’ NPIS rules violate 21 U.S.C. § 455(c), as carcasses are reprocessed outside the supervision of federal inspectors, and the rules should be declared illegal and set aside pursuant to the APA, 5 U.S.C. § 706(2).

Third Claim for Relief

Defendants’ NPIS Violates 21 U.S.C. § 455(b) because Each Young Chicken and Turkey Carcass Will Not Receive a Post-Mortem Inspection in NPIS Establishments.

195. Plaintiffs re-allege and incorporate by reference each and every allegation set forth above in paragraphs 1-194 of this Complaint.

196. The PPIA requires that each carcass of each chicken and turkey processed receive a post-mortem inspection, which is a critical appraisal by an employee or official of the U.S. government or of the government of any State or the District of Columbia. 21 U.S.C. §§ 455(b), 453(k).

197. NPIS does not allow for federal inspectors to critically appraise each young chicken and turkey carcass processed in NPIS establishments including because establishment

staff remove viscera and reprocess and condemn noncomplying carcasses, and because federal inspectors are not required to – and, because of line speeds, they are unable to – touch, smell, and open up every carcass presented for inspection and are only able to see the exterior backsides of such carcasses.

198. Such increased line speeds prevent federal inspectors from critically appraising the exterior backsides of carcasses.

199. Accordingly, Defendants’ NPIS rules violate 21 U.S.C. § 455(b) by not allowing federal inspectors to critically appraise each chicken and turkey carcass processed, and the rules should be declared illegal and set aside pursuant to the APA, 5 U.S.C. § 706(2).

Fourth Claim for Relief

Defendants’ Attachment of Their Official Inspection to Products From NPIS Establishments Renders Them False and Misleading Violating 21 U.S.C. § 453(h).

200. Plaintiffs re-allege and incorporate by reference each and every allegation set forth above in paragraphs 1-199 of this Complaint

201. 21 U.S.C. § 455(h) makes product misbranded if it is false or misleading in any particular.

202. Under Defendants’ NPIS rules, items that are not found to be adulterated will bear an official inspection legend on the item or on its container stating “Inspected for wholesomeness by U.S. Department of Agriculture.” 9 C.F.R. § 381.96 (2014). This term means that the poultry has been inspected and was found at the time of such inspection to be not adulterated. *Id.* § 381.1. Articles without such stamp are misbranded under the act. 21 U.S.C. § 453(h)(12).

203. Under Defendants' final NPIS rules, products derived from chicken and turkey carcasses slaughtered in NPIS establishments do not receive a critical appraisal and thus have not been inspected.

204. Accordingly, Defendants' NPIS rules violate 21 U.S.C. § 453(b) by falsely and misleadingly allowing the inspection label to be affixed to poultry product that has not been inspected by the Defendants, and the rules should be declared illegal and set aside pursuant to the APA, 5 U.S.C. § 706(2).

Fifth Claim for Relief

Defendants' NPIS Violates 21 U.S.C. § 455(b) and 9 C.F.R § 381.1 Because Each Chicken and Turkey Viscera Will Not Receive Federal Inspection.

205. Plaintiffs re-allege and incorporate by reference each and every allegation set forth above in paragraphs 1-204 of this Complaint.

206. The PPIA provides that the "Secretary. . . shall cause to be made by inspectors post-mortem inspection of the *carcass* of each bird processed" 21 U.S.C. § 455(b) (emphasis added).

207. 9 C.F.R. § 381.1 defines "carcass" as "all parts, including viscera, of any slaughtered poultry."

208. Under NPIS, viscera in NPIS establishments will be removed prior to federal inspection, so that federal inspectors will not inspect the viscera of each bird processed.

209. Accordingly, Defendants' NPIS rules violate 21 U.S.C. § 455(b) and 9 C.F.R § 381, as inspectors are prevented from inspecting each chicken and turkey's viscera in NPIS establishments, and the rules should be declared illegal and set aside pursuant to the APA, 5 U.S.C. § 706(2).

Sixth Claim for Relief

Defendants' Failure to Provide an Opportunity for Oral Presentation of Views Violated 21 U.S.C. § 463(c).

210. Plaintiffs re-allege and incorporate by reference each and every allegation set forth above in paragraphs 1-209 of this Complaint.

211. 21 U.S.C. § 463(c) requires an opportunity for the oral presentation of views to be accorded all interested persons when conducting rulemaking under the PPIA.

212. Defendants held no public hearings and afforded no opportunity for the presentation of views on its NPIS rulemakings, despite a number of requests.

213. Therefore, Defendants' failure to allow the oral presentation of views violates 21 U.S.C. § 463(c) and their NPIS rules should be declared illegal and set aside the APA, 5 U.S.C. § 706(2).

Seventh Claim for Relief

Defendants' Failed to Provide Adequate Opportunity for Notice and Comment Violating 5 U.S.C. §§ 553(b)(3)

214. The APA requires an agency conducting notice-and-comment rulemaking to publish "either the terms or substance of the proposed rule or a description of the subjects and issues involved" in its notice of proposed rulemaking. 5 U.S.C. § 553(b)(3).

215. In their notice of proposed rulemaking, Defendants never published as proposed rules, nor described that they were considering, major provisions of what would become their final NPIS rules, including NPIS establishment maximum lines speeds of 140 bpm and that all establishments would be able to opt out of the NPIS rules and operate under their prior inspections system rules.

216. The final NPIS rules are not a logical outgrowth of the rules that Defendants proposed.

217. Accordingly, Defendants' final NPIS rules violate 5 U.S.C. §§ 553(b)(3), and they should be declared illegal and set aside under the APA, 5 U.S.C. § 706(2).

Eighth Claim for Relief

Defendants' NPIS is Arbitrary and Capricious, Violating 5 U.S.C. § 706(2).

218. Plaintiffs re-allege and incorporate by reference each and every allegation set forth above in paragraphs 1- 217 of this Complaint.

219. Defendant' approval of their NPIS rules is arbitrary and capricious and an abuse of discretion, including because Defendants relied on inappropriate factors which Congress has not intended them to consider under the PPIA, and they entirely failed to consider an important aspects related to preventing adulterated and misbranded carcasses from entering commerce, offered explanations for its NPIS rules counter to the evidence before the agency, and offered implausible and inadequate responses to public comments.

220. Accordingly, Defendants violated 5 U.S.C. § 706(2), and their final NPIS rules should be declared illegal and set aside.

VII.

Relief Requested

WHEREFORE, Plaintiff respectfully requests that this Court:

- A. Declare Defendants' NPIS rules illegal;
- B. Temporarily and permanently enjoy Defendants' NPIS rules from taking effect;

- C. Vacate Defendants' NPIS rules;
- D. Grant attorneys' fees and costs; and
- E. Award any other relief the Court deems just and proper.

Respectfully submitted,

/s/

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