Preamble

March 11, 2022

Dear NPIP Stakeholder:

These three booklets contain the set of proposed changes to be considered at the 45th NPIP Biennial Conference to take place June 7-10, 2022. Although a little overlap does exist, in general, these three documents are organized as **Booklet (1)** the 9 CFR proposed changes for Part 145, 146, 147 and 56; **Booklet (2)** the Program Standards A-E proposed changes; and **Booklet (3)** the Program Standards F Compartmentalization Program proposed changes. As outlined in §147.44, this trio set of proposed changes serves as the *Pre-Conference Edition* and is labeled as such. You'll note that this is in draft format, where some of the formatting is subject to change, and this version will also be updated soon to include a table of contents. The edition distributed in June at the conference itself will be labeled *Conference Edition*. Throughout these proposed changes, use of * * * is utilized to denote where sections are skipped. Additionally, you may find it helpful to print some portions in color, particularly the compartmentalization proposed changes that are color-coded by sponsor. Thank you so much for your contributions to the improvement of the National Poultry Improvement Plan. We look forward to seeing you in June.

Sincerely,

Elena Behnke,
NPIP Senior Coordinator

Proposal Number 1

Delegates: **145 Combined**

§145.1 Definitions.

Hatchery. Hatchery equipment on one premises operated or controlled by any person for the production of baby poultry~~.~~, or for the purpose of incubating poultry eggs.

* * *

Multiplier breeding flock. A flock that is intended for the production of ~~hatching~~ fertile eggs used for the purpose of producing progeny for commercial egg or meat production or for other nonbreeding purposes.

* * *

Program Standards Definitions.

Hatchery
Hatchery equipment on one premises operated or controlled by any person for the production of baby poultry~~.~~, or for the purpose of incubating poultry eggs.

* * *

Multiplier breeding flock
A flock that is intended for the production of ~~hatching~~ fertile eggs used for the purpose of producing progeny for commercial egg or meat production or for other nonbreeding purposes.

Reason: Upon enrolling in the NPIP program, incubation facilities and their supply flocks, which solely produce embryos for the vaccine market, are not identified. We currently enroll in Subpart 145B, which outlines the provisions necessary for a hatchery, not an incubation facility that does not hatch any poultry of any kind. As the current standards read, we are excluded and because of this, technically out of compliance due to the definitions within the subpart we enroll in. With the two changes depicted above, I believe we have a place within the standards, and thus are able to maintain 100% compliance.

Sponsor: Samuel W. Strawser
Maple Lawn Associates Inc.

Proposal Number 2

Delegates: **145 Combined**

§ 145.1 Definitions.

Reactor. A bird that has a positive reaction to a test, required or recommended in this part or in accordance with part 147 of this subchapter, for any poultry disease for which a program has been established under the Plan. A reactor is considered suspect until additional confirmatory testing has been conducted by an authorized laboratory or Federal Reference Laboratory as outlined in §145.14.

* * *

Program Standards Definitions.

Reactor
A bird that has a positive reaction to a test required or recommended in 9 CFR part 145 or these Program Standards for any poultry disease for which a program has been established under the Plan. A reactor is considered suspect until additional confirmatory testing has been conducted by an authorized laboratory or Federal Reference Laboratory as outlined in §145.14.

Reason: Clarification is needed on what is meant by the reactor terminology. A reaction to a test does not necessarily mean the bird or flock is positive; additional confirmatory testing is needed to determine the bird or flock status. Reporting requirements for Official State Agencies also became confusing when using the reactor terminology to complete VS 9-4 forms. Per the NPIP Office, only confirmed positive birds/flocks should be reported, not reactors on screening tests.

Sponsors: Dr. Shauna Voss
Minnesota Board of Animal Health

Dr. Dale Lauer
Minnesota Board of Animal Health

Proposal Number 3

Delegates: **145 Combined**

§145.1 Definitions.

Reactor. A bird that has a positive reaction to a test, after confirmation by culture and/or molecular diagnostic testing, required or recommended in this part or in accordance with part 147 of this subchapter, for any poultry disease for which a program has been established under the Plan.

* * *

Program Standards Definitions.

Reactor
A bird that has a positive reaction to a test, after confirmation by culture and/or molecular diagnostic testing, required or recommended in 9 CFR part 145 or these Program Standards for any poultry disease for which a program has been established under the Plan.

Reason: The basis for this proposal is to provide clarification pertaining to the definition of reactor to minimize inconsistent interpretation of this word. "Reactor" should not be used to imply that screening test non-negatives are solely indicative of confirmed positive birds and/or flocks. The addition made to this definition will provide clarity to differentiate.

Sponsors: Dr. Kate Hayes
Aviagen North America

Gordon Whitbeck
Whitbeck Labs

Proposal Number 4

Delegates: **145 Combined**

§145.1 Definitions.

Specific Pathogen Free (SPF) Breeding Flock. A flock free from specified pathogens that is intended for the production of fertilized SPF eggs as outlined in the Department Veterinary Services Memorandum 800.65 and European Pharmacopoeia chapter 5.2.2. SPF eggs are primarily used for the purpose of production and quality control of vaccines.

* * *

Program Standards Definitions.

Specific Pathogen Free (SPF) Breeding Flock
A flock free from specified pathogens that is intended for the production of fertilized SPF eggs as outlined in the Department Veterinary Services Memorandum 800.65 and European Pharmacopoeia chapter 5.2.2. SPF eggs are primarily used for the purpose of production and quality control of vaccines.

Reason: A second proposal is being submitted at this time to create a new subpart (K-Special Provisions for Egg-Type SPF Breeding Flocks and Products) under part 145 under this subchapter. No definition for SPF Breeding Flocks currently exists.

Sponsors: Eduardo de Souza Pinto
President, VALO BioMedia North America, LLC

Dr. Travis Schaal
Director of GP Production & Internal Vet Services, Hy-Line International

Debra Tosto
Executive Director, Avian Vaccine Services, Charles River

Dr. Nastassja Ortega-Heinly
Director of Laboratory Operations, Charles River

Dr. Julie Helm
NPIP Official State Agent, South Carolina

Proposal Number 5

Delegates: 145 Combined

Subpart A – General Provisions.

§145.1 Definitions.

Fowl typhoid or typhoid. A disease of poultry caused by ~~Salmonella gallinarium~~ *Salmonella* Gallinarum.

* * *

Pullorum disease or pullorum. A disease of poultry caused by ~~Salmonella pullorum~~ *Salmonella* Pullorum.

* * *

§145.14 Testing.

(a) *For Pullorum-Typhoid.*

* * *

(7) When *S. ~~pullorum~~* Pullorum or *S. ~~gallinarum~~* Gallinarum organisms are isolated by an authorized laboratory from baby poultry, or from fluff samples produced by hatching eggs, the infected flock shall qualify for participation in the Plan with two consecutive negative results to an official blood test named in paragraph (a)(1) of this section. A succeeding flock must be qualified for participation in the Plan's pullorum-typhoid program with a negative result to an official blood test named in paragraph (a)(1) of this section. Testing to qualify flocks for Plan participation must include the testing of all birds in infected flocks and succeeding flocks for a 12-month period, and shall be performed or physically supervised by a State Inspector; Provided, That at the discretion of the Official State Agency, a sample of at least 500 birds, rather than all birds in the flock, may be tested by the State Inspector if it is agreed upon by the Official State Agency, the flockowner, and the Administrator. If the State Inspector determines that a primary breeding flock has been exposed to *S. ~~pullorum~~* Pullorum or *S. ~~gallinarum~~* Gallinarum,[2] the Official State Agency shall require:

(i) The taking of blood samples - performed by or in the presence of a State Inspector - from all birds on premises exposed to birds, equipment, supplies, or personnel from the primary breeding flock during the period when the State Inspector determined that exposure to *S. ~~pullorum~~* Pullorum or *S. ~~gallinarum~~* Gallinarum occurred.[2]

* * *

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[2] In making determinations of exposure, the State Inspector shall evaluate both evidence proving that exposure occurred and circumstances indicating a high probability of contacts with: infected wild birds; contaminated feed or waste; or birds, equipment, supplies, or persons from or exposed to flocks infected with *S. ~~pullorum~~* Pullorum or *S. ~~gallinarum~~ Gallinarum*.

* * *

Subpart B – Special Provisions for Multiplier Egg-Type Chicken Breeding Flocks and Products

* * *

145.23 Terminology and classification; flocks and products.

* * *

(b) ***U.S. Pullorum-Typhoid Clean.***

(1) It has been officially blood tested with either no reactors or reactors that, upon further bacteriological examination conducted in accordance with part 147 of this subchapter, fail to isolate ~~*S. pullorum*~~ S. Pullorum or ~~*S. gallinarum*~~ S. Gallinarum.
(2) It is a multiplier breeding flocks and meets the following specifications as determined by the Official State Agency and the Service:

(i) The flock is located in a State where all persons performing poultry disease diagnostic services within the State are required to report to the Official State Agency within 48 hours the source of all poultry specimens from which ~~S. pullorum~~ S. Pullorum or ~~S. gallinarum~~ S. Gallinarum is isolated.

* * *

(3) It is a multiplier breeding flock that originated from U.S. Pullorum-Typhoid Clean breeding flocks or from flocks that met equivalent requirements under official supervision, and is located in a State in which it has been determined by the Service that:

* * *

(iv) All persons performing poultry disease diagnostic services within the State are required to report to the Official State Agency within 48 hours the source of all poultry specimens from which ~~S. pullorum~~ S. Pullorum or ~~S. gallinarum~~ S. Gallinarum is isolated;

* * *

(d) ***U.S. S. Enteritidis Clean.*** This classification is intended for egg-type breeders wishing to assure their customers that the hatching eggs and chicks produced are certified free of ~~Salmonella enteritidis~~ *Salmonella* Enteritidis.

(1) A flock and the hatching eggs and chicks produced from it which have met the following requirements as determined by the Official State Agency:

(i) The flock originated from a U.S. ~~*S. enteritidis*~~ S. Enteritidis Clean flock, or meconium from the chick boxes and a sample of chicks that died within 7 days after hatching are examined bacteriologically for salmonella at an authorized laboratory. Cultures from positive samples shall be serotyped.

* * *

(2) A flock shall not be eligible for this classification if ~~*Salmonella enteritidis* ser *enteritidis*~~ *Salmonella* Enteritidis (SE) is isolated from a specimen taken from a bird in the flock. Isolation of SE from an environmental or other specimen, as described in paragraph (d)(1)(v) of this section, will require bacteriological examination for SE in an authorized laboratory, in accordance with part 147 of this subchapter, of a random sample of 60 live birds from a flock of 5,000 birds or more, or 30 live birds from a flock with fewer than 5,000 birds. If only one specimen is found positive for SE, the participant may request bacteriological examination of

a second sample, equal in size to the first sample, from the flock. If no SE is recovered from any of the specimens in the second sample, the flock will be eligible for the classification.

* * *

Note: The same/similar changes for Salmonella Pullorum/Gallinarum/Enteritidis *as listed above in Part 145 Subparts A and B (General Provisions Egg-Type Chicken Multiplier Breeding Flocks and Products) will appear in corresponding parallel parts of Part 145 Subparts C-J. Specifically, those sections will include:*

Subpart C – Special Provisions for Multiplier Meat-Type Chicken Breeding Flocks and Products

§145.33 (b)(1)
§145.33 (b)(2)(i)
§145.33 (b)(3)(iv)
§145.33 (m)
§145.33 (m)(2)
§145.33 (m)(2)(i)
§145.33 (m)(2)(iii)
§145.33 (m)(2)(iv)

Subpart D – Special Provisions for Turkey Breeding Flocks and Products

§145.43 (b)(1)
§145.43 (b)(2)(i)
§145.43 (b)(3)(iv)
§145.43 (b)(5)

Subpart E – Special Provisions for Hobbyist and Exhibition Poultry, and Raised-for-Release Waterfowl Breeding Flocks and Products

§145.53 (b)(1)
§145.53 (b)(2)(i)
§145.53 (b)(3)(iv)
§145.53 (b)(5)

Subpart F – Special Provisions for Ostrich, Emu, Rhea, and Cassowary Breeding Flocks and Products

§145.63 (a)(1)
§145.63 (a)(2)(i)(A)
§145.63 (a)(2)(i)(B)

Subpart G – Special Provisions for Primary Egg-Type Chicken Breeding Flocks and Products

§145.73 (b)(1)
§145.73 (b)(2)(i)(D)
§145.73 (b)(2)(ii)
§145.73 (d)
§145.73 (d)(2)

Subpart H – Special Provisions for Primary Meat-Type Chicken Breeding Flocks and Products

§145.83 (b)(1)
§145.83 (b)(2)(i)(D)
§145.83 (b)(2)(ii)
§145.83 (e)
§145.83 (e)(1)(i)
§145.83 (e)(2)
§145.83 (e)(6)(i)(A)
§145.83 (e)(6)(i)(B)
§145.83 (e)(6)(i)(C)
§145.83 (e)(6)(i)(D)

Subpart I – Special Provisions for Meat-Type Waterfowl Breeding Flocks and Products

§145.93 (b)(1)
§145.93 (b)(2)(i)
§145.93 (b)(3)(iv)
§145.93 (b)(5)

Subpart J – Special Provisions for Egg/Meat-Type Game Bird and Raised-for-Release Game Bird Breeding Flocks and Products

§145.103 (b)(1)
§145.103 (b)(2)(i)
§145.103 (b)(3)(iv)

* * *

Program Standards Definitions

Fowl typhoid or typhoid
A disease of poultry caused by *Salmonella* ~~*gallinarum*~~ Gallinarum.

Pullorum disease or pullorum
A disease of poultry caused by *Salmonella* ~~*pullorum*~~ Pullorum.

* * *

Standard A – Blood Testing Procedures

(1) The standard tube agglutination test[1]

* * *

(b) The antigen shall consist of representative strains of S. ~~pullorum~~ Pullorum which are of known antigenic composition, high agglutinability, but are not sensitive to negative and nonspecific sera.

* * *

(2) The rapid serum test[2]

* * *

(b) The selection and maintenance of suitable strains of S. pullorum and the composition of a satisfactory medium are described in Section 1(b) and 1(c).... strains of S. ~~pullorum~~ Pullorum.

* * *

(3) The stained antigen, rapid, whole-blood test[3]

(d) Various degrees of reaction are observed in this as in other agglutination tests. The greater the agglutinating ability of the blood, the more rapid the clumping and the larger the clumps. A positive reaction consists of a definite clumping of the antigen surrounded by clear spaces. Such reaction is easily distinguished against a white background. A somewhat weaker reaction consists of small but still clearly visible clumps of antigen surrounded by spaces only partially clear. Between this point and a negative or homogeneous smear, there sometimes occurs a very fine granulation barely visible to the naked eye; this should be disregarded in making a diagnosis. The very fine marginal clumping which may occur just before drying up is also regarded as negative. In a nonreactor, the smear remains homogeneous. (Allowance should be made for differences in the sensitiveness of different antigens and different set-ups, and therefore, a certain amount of independent, intelligent judgment must be exercised at all times. Also, the histories of the flocks require consideration. In flocks where individuals show a suspicious agglutination, it is desirable to examine representative birds bacteriologically to determine the presence or absence of S. ~~pullorum~~ Pullorum).

* * *

Standard B – Bacteriological Examination Procedure

* * *

(2) Laboratory procedure recommended for the bacteriological examination of salmonella from birds

(a) For egg- and meat-type chickens, turkeys, waterfowl, exhibition poultry, and game birds

For reactors to the pullorum-typhoid tests, if there are more than four reactors in a flock, a minimum of four reactors shall be submitted to the authorized laboratory; if the flock has four or fewer reactors all the reactors must be submitted [145.14(a)(6)(ii)]. The isolation of S. ~~*Enteritidis*~~ Enteritidis (SE) from U.S. S. Enteritidis Clean flocks will result in the submission of 60 live birds from a flock of 5,000 birds or more, or 30 live birds from a flock with fewer than 5,000 birds from multiplier eggtype chicken breeding flocks [145.23(d)(2)] or primary egg-type chicken breeding flocks [145.73(d)(2)] and 25 birds from primary meat-type chicken breeding flocks [145.83(e)(3)]. These birds should be cultured in accordance with both direct culture (paragraph (a)(1)) and selective enrichment (paragraph (a)(2)) procedures described

in this section. Provided, if there are no grossly abnormal or diseased tissues present, direct culture may be omitted. Careful aseptic technique should be used when collecting all tissue samples.

(1) Direct culture (refer to illustration 1). Grossly abnormal or diseased liver, heart, pericardial sac, spleen, lung, kidney, peritoneum, gallbladder, oviduct, misshapen ova or testes, inflamed or unabsorbed yolk sac, and other visibly pathological tissues where purulent, necrotic, or proliferative lesions are seen (including cysts, abscesses, hypopyon, and inflamed serosal surfaces) should be sampled for direct culture using either flamed wire loops or sterile swabs. Since some strains may not dependably survive and grow in certain selective media, inoculate non-selective plates (such as blood or nutrient agar) and selective plates (such as MacConkey [MAC] and brilliant green novobiocin [BGN] for suspect ~~*S. pullorum*~~ S. Pullorum or ~~*S gallinarum*~~ S. Gallinarum and MAC, BGN, and xylose-lysine-tergitol 4 [XLT 4] for SE). Refer to illustration 1 for recommended bacteriological recovery and identification procedures.[7] Proceed immediately with collection or organs and tissues for selective enrichment culture.

* * *

(5) After selective enrichment, inoculate selective plates (such as MAC and BGN for ~~*S. pullorum*~~ S. Pullorum or ~~*S gallinarum*~~ S. Gallinarum and MAC, BGN, and XLT 4 for SE). Incubate the plate at 37°C ± 2°C for 20 to 24 hours. Select three to five *Salmonella*-suspect colonies from plates. Inoculate each suspect colony individually into pairs of triple sugar iron (TSI) and lysine iron agar (LIA) slants or equivalent method (i.e., inoculate TSI and LIA pair from one colony). Incubate slates at 37°C ± 2°C for 20- 24 hours. If there are no suspect colonies after 24 hours of incubation, incubate the plates an additional 24 hours before considering negative. Screen colonies by serological (i.e., serogroup) and biochemical procedures (e.g., the Analytical Profile Index for Enterobacteriaceae [API]) as shown in illustration 1.

Reason: Salmonella nomenclature has changed since the last time the NPIP provisions were updated. NPIP uses a less formal nomenclature only specifying the serotype or serovar. If spelled out *Salmonella* is italicized and may be abbreviated as "*S*." followed by the serotype. The serotype begins with a capital letter and is not italicized, for example *Salmonella* Pullorum or *S*. Pullorum. Please note in the above listing, the underlining of Pullorum, Gallinarum, and Enteritidis does NOT mean they should be underlined, but they are to replace what is struck through.

Sponsor: Dr. Doug Waltman
Georgia Poultry Laboratory Network

Proposal Number 6

Delegates: **145 Combined**

§ 145.2 Administration.

(d) The Official State Agency of any State may, except as limited by §145.3~~(e),~~ (f), adopt regulations applicable to the administration of the Plan in such State further defining the provisions of the Plan or establishing higher standards compatible with the Plan.

* * *

§ 145.3 Participation.

(e) To ensure that Plan diseases are not spread, flocks must be qualified for their intended Plan classifications before being moved into breeder production facilities.
(f) No person shall be compelled by the Official State Agency to qualify products for any of the other classifications described in §145.10 as a condition of qualification for the U.S. Pullorum-Typhoid Clean classification.

Reason: This appears to be a mistake in that 145.2(d) is clearly referencing 145.3(f) and not 145.3(e).

Sponsor: Dr. Elena Behnke
Senior Coordinator, NPIP

Proposal Number 7

Delegates: **145 Combined**

§ 145.5 Specific provisions for participating flocks.
(c) A flock shall be deemed to be a participating flock at any time only if it has qualified for the U.S. Pullorum-Typhoid Clean classification, as prescribed in Subparts B, C, D, E, F, G, H, ~~or I~~, or J of this part.

Reason: This was an oversight error from the 2018 Biennial Conference that failed to include Subpart J language in this section. The NPIP office submitted a technical amendment that has not yet been corrected or resolved. We are proposing this change to make sure the correction is made.

Sponsor: Dr. Elena Behnke
Senior Coordinator, NPIP

Proposal Number 8

Delegates: **145 Combined**

§ 145.10 Terminology and classification; flocks and products.

(b) *U.S. Pullorum-Typhoid Clean.* (See §145.23(b), §145.33(b), §145.43(b), §§145.53(b), 145.63(a), 145.73(b), 145.83(b), ~~and~~ 145.93(b), and 145.103(b).

* * *

(g) *U.S. Pullorum-Typhoid Clean State.* (See §§145.24(a), 145.34(a), 145.44(a), 145.54(a), ~~and~~ 145.94(a), and 145.104(a).

* * *

(o) *U.S. Salmonella Monitored* (See §§145.53(f), 145.73(g), 145.83(f), ~~and~~ 145.93(d), and 145.103(d).)

* * *

(t) *U.S. H5/H7 Avian Influenza Clean.* (See §§145.43(g), 145.53(e), ~~and~~ 145.93(c), and 145.103(c).)

Reason: These were oversight errors from the 2018 Biennial Conference that failed to include Subpart J in the language. The NPIP office submitted technical amendments that have not yet been corrected or resolved. We are proposing these changes to make sure the corrections are made.

Sponsor: Dr. Elena Behnke
Senior Coordinator, NPIP

Proposal Number 9

Delegates: **145 Combined**

§ 145.10 Terminology and classification; flocks and products.

(t) ***U.S. H5/H7 Avian Influenza Clean.*** (See §§ 145.43(g), 145.53(e), ~~and~~ 145.93(c)~~.~~ , and 145.103(c).)

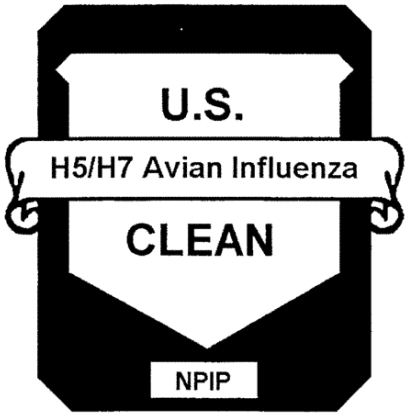

FIGURE 21

(u) ***U.S. Newcastle Disease Clean.*** (See §§145.43(h), 145.73(h), and 145.83(h).)

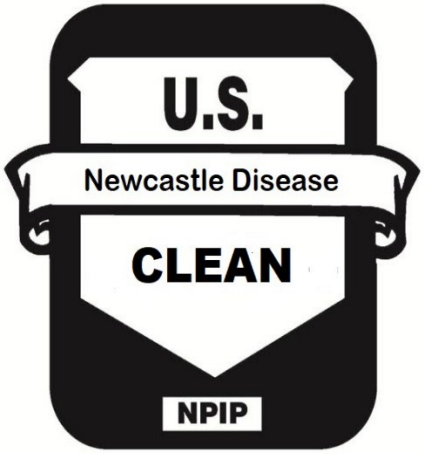

FIGURE 22

(v) ***U.S. Avian Influenza Clean Compartment.*** (See §§145.45, 145.74, and 145.84.)

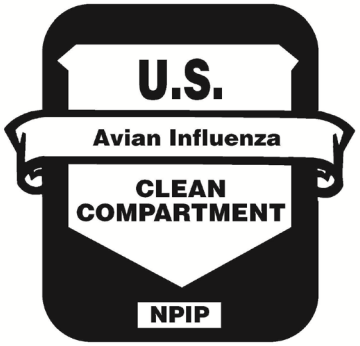

FIGURE 23

(w) ***U.S. Newcastle Disease Clean Compartment.*** (See §§145.45, 145.74, and 145.84.)

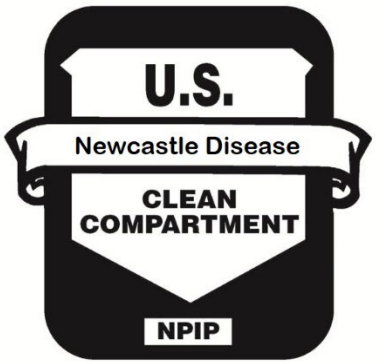

FIGURE 24

Reason: The omission of reference to Subpart J (145.103(c)) was an oversight error from the 2018 Biennial Conference, as was the unintentional omission of (u) for U.S. Newcastle Disease Clean, (v) for U.S. Avian Influenza Clean Compartment, and (w) for U.S. Newcastle Disease Clean Compartment. These changes will fix the reference to include Subpart J (145.103(c)) in the U.S. H5/H7 AI Clean program and also add Newcastle Disease Clean, AI Clean Compartment and ND Clean Compartment and affix their respective official seals.

Sponsor: Dr. Elena Behnke
Senior Coordinator, NPIP

Proposal Number 10

Delegates: **145 Combined**

§ 145.14 Testing.

Poultry must be more than 4 months of age when tested for an official classification: *Provided,* That turkey candidates under subpart D of this part may be tested at more than 12 weeks of age; game bird candidates under subpart E or subpart J of this part may be tested when more than 4 months of age or upon reaching sexual maturity, whichever comes first; and ostrich, emu, rhea, and cassowary candidates under subpart F of this part may be tested when more than 12 months of age. Samples for official tests shall be collected by an Authorized Agent, Authorized Testing Agent, or State Inspector and tested by an authorized laboratory, except that the stained antigen, rapid whole-blood test for pullorum-typhoid may be conducted by an Authorized Testing Agent or State Inspector. For Plan programs in which a representative sample may be tested in lieu of an entire flock, except the ostrich, emu, rhea, and cassowary program in §145.63(a), the minimum number tested shall be 30 birds per house, unless otherwise specified within the Plan program, with at least 1 bird taken from each pen and unit in the house. The ratio of male to female birds in representative samples of birds from meat-type chicken, waterfowl, exhibition poultry, and game bird flocks must be the same as the ratio of male to female birds in the flock. In houses containing fewer than 30 birds other than ostriches, emus, rheas, and cassowaries, all birds in the house must be tested, unless otherwise specified within the Plan program.

(a) ***For Pullorum-Typhoid.***

* * *

(5) The official blood test shall include the testing of a sample of blood from each bird in the flock: Provided, That under specified conditions (see applicable provisions of §§145.23, 145.33, 145.43, 145.53, 145.63, 145.73, 145.83, ~~and~~ 145.93, and 145.103.) the testing of a portion or sample of the birds may be used in lieu of testing each bird.

Reason: These were oversight errors from the 2018 Biennial Conference that failed to incorporate Subpart J language. The NPIP office submitted technical amendments that have not yet been corrected or resolved. We are proposing these changes to make sure the corrections are made.

Sponsor: Dr. Elena Behnke
Senior Coordinator, NPIP

Proposal Number 11

Delegates: 145 Combined

§145.14 Testing.

Poultry must be more than 4 months of age when tested for an official classification: *Provided,* That turkey candidates under subpart D of this part may be tested at more than 12 weeks of age; game bird candidates under subpart E of this part may be tested when more than 4 months of age or upon reaching sexual maturity, whichever comes first; and ostrich, emu, rhea, and cassowary candidates under subpart F of this part may be tested when more than 12 months of age. Samples for official tests shall be collected by an Authorized Agent, Authorized Testing Agent, or State Inspector and tested by an authorized laboratory, except that the stained antigen, rapid whole-blood test for pullorum-typhoid may be conducted by an Authorized Testing Agent or State Inspector. For Plan programs in which a representative sample may be tested in lieu of an entire flock, except the ostrich, emu, rhea, and cassowary program in §145.63(a), the minimum number tested shall be 30 birds per house, unless otherwise specified within the Plan program, with at least 1 bird taken from each pen and unit in the house. The ratio of male to female birds in representative samples of birds from meat-type chicken, waterfowl, exhibition poultry, and game bird flocks must be the same as the ratio of male to female birds in the flock. In houses containing fewer than 30 birds other than ostriches, emus, rheas, and cassowaries, all birds in the house must be tested, unless otherwise specified within the Plan program. The Plan defines official testing periods for participating flocks to maintain their participation status. These official testing periods for all poultry diseases in the Plan will be reported on official NPIP documents to the Official State Agency office by all laboratories (private, State and university laboratories). All testing outside these official testing periods are not part of the Plan. Reporting of diagnostic test results are reportable to the responsible State authority by all licensed veterinarians, which demonstrates that they adhere to disease control programs in which they participate.

Reason: We propose an additional section to General Provisions to clarify the reporting responsibility for diagnostic testing versus routine Plan testing.

Sponsors: Dr. Kate Hayes
Aviagen North America

Gordon Whitbeck
Whitbeck Labs

Proposal Number 12

Delegates: 145 Combined

§145.14 Testing.

Poultry must be more than 4 months of age when tested for an official classification: *Provided,* That turkey candidates under subpart D of this part may be tested at more than 12 weeks of age; game bird candidates under subpart E and subpart J of this part may be tested when more than 4 months of age or upon reaching sexual maturity, whichever comes first; and ostrich, emu, rhea, and cassowary candidates under subpart F of this part may be tested when more than 12 months of age. Samples for official tests shall be collected by an Authorized Agent, Authorized Testing Agent, or State Inspector and tested by an authorized laboratory, except that the stained antigen, rapid whole-blood test for pullorum-typhoid may be conducted by an Authorized Testing Agent or State Inspector. ~~For Plan programs in which a representative sample may be tested in lieu of an entire flock, except the ostrich, emu, rhea, and cassowary program in § 145.63(a), the minimum number tested shall be 30 birds per house, unless otherwise~~ Testing must be conducted as specified within the Subpart Plan program, with at least 1 bird ~~taken~~ tested from each pen and unit in the house and a minimum of 30 birds tested per house. The ratio of samples collected from male and ~~to~~ female birds ~~in~~ must be representative ~~samples~~ of birds throughout the house and ~~from meat-type chicken, waterfowl, exhibition poultry, and game bird flocks must be the same as the ratio of male to female birds in the~~ flock. In houses containing fewer than 30 birds other than ostriches, emus, rheas, and cassowaries, all birds in the house must be tested, unless otherwise specified within the Plan program.

(a) ***For Pullorum-Typhoid.***

(1) The official blood tests for pullorum-typhoid shall be the standard tube agglutination test, the microagglutination test, the enzyme-linked immunosorbent assay test (ELISA), or the rapid serum test for all poultry; and the stained antigen, rapid whole-blood test for all poultry except turkeys. Official blood tests must be conducted in accordance with part 147 of this subchapter and Program Standards or according to literature provided by the producer. Only antigens approved by the Department and of the polyvalent type shall be used for the rapid whole-blood and tube agglutination tests. Each serial of tube antigen shall be submitted by the antigen producer to the Department for approval upon manufacture and once a year thereafter as long as antigen from that serial continues to be made available for use. All microtest antigens and enzyme-linked immunosorbent assay reagents shall also be approved by the Department.[1]

(2) [Reserved]

(3) There shall be an interval of at least 21 days between any official blood test and any previous test with pullorum-typhoid antigen.

(4) [Reserved]

(5) The official blood test shall include the testing of a sample of blood from each bird in the flock: Provided, That under specified conditions (see applicable provisions of §§ 145.23, 145.33, 145.43, 145.53, 145.63, 145.73, 145.83, ~~and~~ 145.93, and 145.103) the testing of a portion or sample of the birds may be used in lieu of testing each bird.

(6) Poultry from flocks undergoing qualification testing for participation in the Plan that have a positive reaction to an official blood test named in paragraph (a)(1) of this section shall be evaluated for pullorum-typhoid as follows:

(i) Serum samples that react on rapid serum test or enzyme-labeled immunosorbent assay test (ELISA), or blood from birds that react on the stained antigen, rapid whole-

blood test for all birds except turkeys, shall be tested with either the standard tube agglutination test or the microagglutination test.
(ii) Reactors to the standard tube agglutination test (in dilutions of 1:50 or greater) or the microagglutination test (in dilutions of 1:40 or greater) shall be submitted to an authorized laboratory for bacteriological examination. If there are more than four reactors in a flock, a minimum of four reactors shall be submitted to the authorized laboratory; if the flock has four or fewer reactors, all of the reactors must be submitted. Bacteriological examination must be conducted in accordance with part 147 of this subchapter and Program Standards. When reactors are submitted to the authorized laboratory within 10 days of the date of reading an official blood test named in paragraph (a)(6)(i) of this section, and the bacteriological examination fails to demonstrate pullorum-typhoid infection, the Official State Agency shall presume that the flock has no pullorum-typhoid reactors.
(iii) If a flock owner does not wish to submit reactors for bacteriological examination, then the reactors shall be isolated and retested within 30 days using an official blood test named in paragraph (a)(1) of this section. If this retest is positive, additional examination of the reactors and flock will be performed in accordance with paragraph (a)(6)(ii) of this section. During this 30-day period, the flock must be maintained under a security system, specified or approved by the Official State Agency, that will prevent physical contact with other birds and assure that personnel, equipment, and supplies that could be a source of pullorum-typhoid spread are sanitized.

Reason: This section is confusing and contradicts the testing required in the individual Plan Programs (§145.23, §145.33, §145.43, §145.53, §145.73, §145.83, §145.93, and §145.103). Also, part of this proposal encompasses another proposal to add subpart J and reference to 145.103.

Sponsors: Dr. Shauna Voss
Minnesota Board of Animal Health

Dr. Dale Lauer
Minnesota Board of Animal Health

Proposal Number 13

Delegates: **145 Combined**

§ 145.14 Testing.

* * *

(a) ***For Pullorum Typhoid.***

* * *

(6) Poultry from flocks undergoing qualification testing for participation in the Plan have a positive reaction to an official blood test named in paragraph (a)(1) of this section shall be evaluated for pullorum-typhoid as follows:

(ii) Reactors to the standard tube agglutination test (in dilutions of 1:50 or greater) or the microagglutination test (in dilutions of 1:40 or greater) shall be submitted to an authorized laboratory for bacteriological examination. If there are more than four reactors in a flock, a minimum of four reactors shall be submitted to the authorized laboratory; if the flock has four or fewer reactors, all of the reactors must be submitted. Bacteriological examination must be conducted in accordance with part 147 of this subchapter. When reactors are submitted to the authorized laboratory within 10 days of the date of reading an official blood test named in paragraph (a)(6)(i) of this section, and the bacteriological examination fails to demonstrate pullorum-typhoid infection, the Official State Agency shall presume that the flock ~~has no pullorum-typhoid reactors~~ is not positive for *S.* Pullorum or *S.* Gallinarum.

Reason: By definition, a reactor is a bird that has a positive reaction to a test. Therefore these birds are still PT reactors, but are not culture positive for *S.* Pullorum or *S.* Gallinarum.

Sponsor: Dr. Doug Waltman
Georgia Poultry Laboratory Network

Proposal Number 14

Delegates: 145 Combined

§145.14 Testing.

* * *

(b) For Mycoplasma gallisepticum, M. meleagridis, and M. synoviae.

(1) The official tests for *M. gallisepticum, M. meleagridis,* and *M. synoviae* shall be the serum plate agglutination test, the hemagglutination inhibition (HI) test, the enzyme-linked immunosorbent assay (ELISA) test,[3] or a molecular based test. The HI test or molecular based test shall be used to confirm the positive results of other serological screening tests. HI titers of 1:40 or more may be interpreted as suspicious, and final judgment must be based on further samplings and/or culture of reactors. Tests must be conducted in accordance with this paragraph (b) and in accordance with part 147 of this subchapter.

(2) The serological tests shall be conducted using *M. gallisepticum*, *M. meleagridis,* or *M. synoviae* antigens approved by the Department or the Official State Agency and shall be performed in accordance with the recommendations of the producer of the antigen.

(3) When reactors to the test for which the flock was tested are submitted to a laboratory as prescribed by the Official State Agency, the final status of the flock will be determined in accordance with part 147 of this subchapter.

(4) Any drug, for which there is scientific evidence of masking the test reaction or hindering the bacteriological recovery of mycoplasma organisms, shall not be fed or administered to poultry within three weeks prior to a test or bacteriological examination upon which a Mycoplasma classification is based.

(5) The official molecular examination procedures for *M. gallisepticum* are the PCR test described in §147.30 of this subchapter and the real-time PCR test described in §147.31 of this subchapter. The official molecular examination procedure for *M. synoviae* is the PCR test described in §147.30 of this subchapter.

(6) *M. gallisepticum, M. meleagridis,* and *M. synoviae* must be diseases reportable to the responsible State authority (State veterinarian, etc.) by all licensed veterinarians. In addition, States should conduct outreach to poultry producers, especially owners of smaller flocks, regarding the importance of prompt reporting of clinical symptoms consistent with *M. gallisepticum, M. meleagridis,* and *M. synoviae.*

Reason: This proposed change is to provide clarity regarding the reporting responsibility for *Mycoplasma gallisepticum*, *M. meleagridis*, and *M. synoviae* program diseases and to establish equivalency to the wording outlined for the other program diseases.

Sponsors: Dr. Kate Hayes
Aviagen North America

Gordon Whitbeck
Whitbeck Labs

Proposal Number 15

Delegates: 145 C and D

§ 145.33 Terminology and classification; flocks and products.

Participating flocks, and the eggs and chicks produced from them, which have met the respective requirements specified in this section may be designated by the following terms and the corresponding designs illustrated in §145.10:

* * *

(d) U.S. Sanitation Monitored.
This program is intended to be the basis from which the breeding-hatching industry may conduct a program for the prevention and control of Salmonellosis. It is intended to reduce the incidence of Salmonella organisms in hatching eggs and chicks through an effective and practical sanitation program at the breeder farm and in the hatchery. This will afford other segments of the poultry industry an opportunity to reduce the incidence of Salmonella in their products.

(1) A flock and the hatching eggs and chicks produced from it which have met the following requirements as determined by the Official State Agency:

(i) The flock shall originate from a source where sanitation and management practices, as outlined in §145.33(d)(1) of this paragraph, are conducted;
(ii) The flock is maintained in accordance with part 147 of this subchapter with respect to flock sanitation, cleaning and disinfection, and Salmonella isolation, sanitation, and management;
(iii) If pelletized feed contains animal protein, the protein products shall be purchased from participants in the Animal Protein Products Industry (APPI) *Salmonella* Education/Reduction Program or the Fishmeal Inspection Program of the National Marine Fisheries Service. The protein products must have a minimum moisture content of 14.5 percent and must have been heated throughout to a minimum temperature of 190 °F. or above, or to a minimum temperature of 165 °F. for at least 20 minutes, or to a minimum temperature of 184 °F. under 70 lbs. pressure during the manufacturing process;
(iv) If mash feed contains animal protein, the protein products shall be purchased from participants in the Animal Protein Products Industry (APPI) *Salmonella* Education/Reduction Program or the Fishmeal Inspection Program of the National Marine Fisheries Service;
(v) Feed shall be stored and transported in such a manner as to prevent possible contamination;
(vi) Chicks shall be hatched in a hatchery whose sanitation is maintained in accordance with part 147 of this subchapter and sanitized or fumigated in accordance with part 147 of this subchapter;
(vii) An Authorized Agent shall take environmental samples, in accordance with part 147 of this subchapter, from each flock at 4 months of age and every 90 days thereafter. An authorized laboratory for *Salmonella* shall examine the environmental samples bacteriologically;
~~(viii) Owners of flocks found infected with a paratyphoid *Salmonella* may vaccinate these flocks with an autogenous bacterin with a potentiating agent.~~[4]

(2) The Official State Agency may monitor the effectiveness of the sanitation practices in accordance with part 147 of this subchapter.

* * *

§ 145.43 Terminology and classification; flocks and products.

Participating flocks, and the eggs and poults produced from them, which have met the respective requirements specified in this section may be designated by the following terms and the corresponding designs illustrated in §145.10:

* * *

(f) U.S. Sanitation Monitored, Turkeys.
A flock or hatchery whose owner is controlling or reducing the level of salmonella through compliance with sanitation and management practices in accordance with part 147 of this subchapter, and where the following monitoring, testing and management practices are conducted.

* * *

(4) Environmental samples shall be taken by an Authorized Agent, in accordance with part 147 of this subchapter, from each flock at 12-20 weeks of age and examined bacteriologically at an authorized laboratory for Salmonella.
~~(5) Owners of flocks found infected with a paratyphoid Salmonella may vaccinate these flocks with an autogenous bacterin with a potentiating agent.~~[5]
(6) Environmental samples shall be taken by an Authorized Agent, in accordance with part 147 of this subchapter, from each flock at 35-50 weeks of age and from each molted flock at midlay, and examined bacteriologically at an authorized laboratory for Salmonella.

Reason: The removed statement in each part is unnecessary and flawed. Paratyphoid Salmonella is not defined. The classifications of U.S. Sanitation Monitored (Subpart C) and U.S. Sanitation Monitored, Turkeys (Subpart D) deal with environmental testing so a positive result does not mean the birds are infected. Whether the birds are infected or not they can still be vaccinated.

Sponsor: Dr. Doug Waltman
Georgia Poultry Laboratory Network

Proposal Number 16

Delegates: 145 C

§ 145.33 Terminology and classification; flocks and products.

Participating flocks, and the eggs and chicks produced from them, which have met the respective requirements specified in this section may be designated by the following terms and the corresponding designs illustrated in §145.10:

* * *

(j) U.S. M. Gallisepticum Monitored.

(1) A multiplier breeding flock in which all birds or a sample of at least ~~30 birds per house~~ 60 birds per flock (30 birds per flock for single house farms) has been tested for M. gallisepticum as provided in §145.14(b) when more than 4 months of age: Provided, That to retain this classification, ~~a minimum of 30 birds per house shall be tested again at 36 to 38 weeks and at 48 to 50 weeks at a minimum: And provided further, That each 30-bird sample should come from 2 locations within the house (15 from the front half of the house and 15 from the back half of the house). A representative sample of males and females should be sampled. The samples shall be marked "male" or "female."~~ the flock will be subjected to the following:

At intervals of no more than 18 weeks after the initial testing, that 60 birds per flock (30 birds per flock for single house farms, all houses on the farm must be represented) shall be tested, provided that fewer than 60 birds from the flock may be tested at any one time if all houses are represented and a total of at least 60 birds from the flock are tested within each 18 week period. In other words, the flock is tested a minimum of 2 times during the life of the flock, once during the first 18 weeks after qualification, and the second test during the next 18 week period.

(2) A participant handling U.S. M. Gallisepticum Monitored products shall keep these products separate from other products in a manner satisfactory to the Official State Agency: Provided, That U.S. M. Gallisepticum Monitored chicks from multiplier breeding flocks shall be produced in incubators and hatchers in which only eggs from flocks qualified under parargraph (j)(1) of this section are set. Eggs from U.S. M. Gallisepticum Monitored multiplier breeding flocks shall not be set in hatchers or incubators in which eggs from U.S. M. Gallisepticum Clean primary breeding flocks qualified under §145.83(c)(1)(i) are set.
(3) U.S. M. Gallisepticum Monitored chicks shall be boxed in clean boxes and delivered in trucks that have been cleaned and disinfected in accordance with part 147 of this subchapter.

(k) U.S. M. Synoviae Monitored.

(1) A multiplier breeding flock in which all birds or a sample of at least ~~30 birds per house~~ 60 birds per flock (30 birds per flock for single house farms) has been tested for M. synoviae as provided in §145.14(b) when more than 4 months of age: Provided, That to retain this classification, ~~a minimum of 30 birds per house shall be tested again at 36 to 38 weeks and at 48 to 50 weeks at a minimum: And provided further, That each 30-bird sample should come from 2 locations within the house (15 from the front half of the house and 15 from the~~

~~back half of the house). A representative sample of males and females should be sampled. The samples shall be marked "male" or "female."~~ the flock will be subjected to the following:

At intervals of no more than 18 weeks after the initial testing, that 60 birds per flock (30 birds per flock for single house farms, all houses on the farm must be represented) shall be tested, provided that fewer than 60 birds from the flock may be tested at any one time if all houses are represented and a total of at least 60 birds from the flock are tested within each 18 week period. In other words, the flock is tested a minimum of 2 times during the life of the flock, once during the first 18 weeks after qualification, and the second test during the next 18 week period.

(2) A participant handling U.S. M. Synoviae Monitored products shall keep these products separate from other products in a manner satisfactory to the Official State Agency: Provided, That U.S. M. Synoviae Monitored chicks from multiplier breeding flocks shall be produced in incubators and hatchers in which only eggs from flocks qualified under paragraph (k)(1) of this section are set. Eggs from U.S. M. Synoviae Monitored multiplier breeding flocks shall not be set in hatchers or incubators in which eggs from U.S. M. Synoviae Clean primary breeding flocks qualified under §145.83(d)(1)(i) are set.

(3) U.S. M. Synoviae Monitored chicks shall be boxed in clean boxes and delivered in trucks that have been cleaned and disinfected in accordance with part 147 of this subchapter.

Reason: The initial goal of the MG MS Monitored classification when it was adopted in 1996 was to get integrators (that were not in the MG and MS Clean classifications) a "structured program for timely blood tests," and get them an NPIP classification for testing. Currently, it is giving the participant very narrow two (2) 2-week windows for testing. Most integrators test at least twice during the life of a breeder flock but may not fall within these testing windows. This proposal will result in the same minimum number of samplings but will give industry much more flexibility. In addition, this proposal makes the language match that of other Mycoplasma classifications, being based on flocks instead of houses, and intervals of time since qualification instead of narrow age intervals. Note that most breeder houses have 2 houses. Thirty (30) samples per house in the current system corresponds to 60 samples per flock with this proposed one. Sixty samples on a breeder farm should be adequate if all houses are represented. The guidelines of testing males and females and to test from 2 locations within each house were removed as they now seem obvious and redundant.

Sponsor: Dr. Louise Dufour Zavala
Executive Director, Georgia Poultry Laboratory Network

Proposal Number 17

Delegates: **145 C**

§ 145.33 Terminology and classification; flocks and products.

Participating flocks, and the eggs and chicks produced from them, which have met the respective requirements specified in this section may be designated by the following terms and the corresponding designs illustrated in §145.10:

* * *

(l) U.S. Avian Influenza Clean. This program is intended to be the basis from which the breeding-hatchery industry may conduct a program for the prevention and control of avian influenza. It is intended to determine the presence of avian influenza in multiplier breeding chickens through routine surveillance of each participating breeding flock. A flock and the hatching eggs and chicks produced from it will qualify for this classification when the Official State Agency determines that they have met the following requirements:

(1) It is a multiplier breeding flock in which a minimum of 30 birds have been tested negative for antibodies to avian influenza using an approved test as described in §145.14 when more than 4 months of age. To retain this classification:

(i) A sample of at least 15 birds must be tested negative at intervals of 90 days; or

(ii) A sample of fewer than 15 birds may be tested, and found to be negative, at any one time if all pens are equally represented and a total of 15 birds is tested within each 90-day period; or

(iii) The flock is tested as provided in §145.14(d) at intervals of 30 days or less and found to be negative, and a total of 15 samples are collected and tested within each 90-day period; and

<u>(iv) 15 samples are tested and found negative for avian influenza within 21 days prior to movement to slaughter regardless of the date of the previous test.</u>

~~(2) During each 90-day period, all multiplier spent fowl, up to a maximum of 30, must be tested and found negative for avian influenza within 21 days prior to movement to slaughter.~~

Reason: Following (2) to the letter means that one bird could be tested within 21 days of slaughter. The new wording ensures consistency with the rest of the testing within the classification.

Sponsor: Dr. Louise Dufour Zavala
Executive Director, Georgia Poultry Laboratory Network

Proposal Number 18

Delegates: **145 C**

§ 145.33 Terminology and classification; flocks and products.

Participating flocks, and the eggs and chicks produced from them, which have met the respective requirements specified in this section may be designated by the following terms and the corresponding designs illustrated in §145.10:

* * *

(m) U.S. Salmonella Enteritidis Monitored.
This classification is intended for multiplier meat-type breeders wishing to monitor their breeding flocks for *Salmonella enteritidis.*

* * *

(2) The following actions must be taken with respect to the test results that are generated from this *S. enteritidis* monitoring program:

(i) If *S. enteritidis* is isolated from an environmental sample collected from the flock in accordance with paragraph (m)(1)(iii) of this section, a thorough evaluation of the practices and programs associated with the sampled flock shall be conducted <u>by the company</u> with the goal of ascertaining the reason(s) for the positive finding.
~~(ii) The test results and the results of any evaluations performed in accordance with paragraph (m)(2)(i) of this section will be reported on a quarterly basis to the Official State Agency and the NPIP Senior Coordinator.~~
~~(iii) Participating broiler integrators shall combine their respective test results (and the results of any associated evaluations) to help guide their decisionmaking regarding programs and practices to implement or maintain to address *S. enteritidis.*~~
~~(iv) Aggregate data regarding the prevalence of *S. enteritidis* in participating U.S. meat-type parent breeding flocks shall be made available to the U.S. Poultry and Egg Association and the National Chicken Council.~~

(3) This classification may be revoked by the Official State Agency if the participant fails to comply with the requirements of this classification. The Official State Agency shall not revoke the participant's classification until the participant has been given an opportunity for a hearing in accordance with rules of practice adopted by the Official State Agency.

Reason: When the primary meat-type breeders (subpart H) were separated from this subpart, the U.S. S. Enteritidis Clean classification went with them. At the time, subpart C did not vote to keep it in their subpart. Later when it was determined that there was a need to collect Salmonella data, especially SE data from multiplier breeding flocks, this classification was added to the NPIP.

"This classification is intended for multiplier meat-type breeders wishing to monitor their breeding flocks for Salmonella Enteritidis." Therefore, the company should be the one to do the evaluation and determine the response. There is no need to report the results to the OSA, NPIP, NCC or anyone else. This is a monitoring program. The classification is based on testing not the results of the testing.

Sponsor: Dr. Doug Waltman
Georgia Poultry Laboratory Network

Proposal Number 19

Delegates: **145 D**

§ 145.43 Terminology and classification; flocks and products.

Participating flocks, and the eggs and poults produced from them, which have met the respective requirements specified in this section may be designated by the following terms and the corresponding designs illustrated in §145.10:

* * *

(c) U.S. M. Gallisepticum Clean.

(1) A flock maintained in accordance with part 147 of this subchapter with respect to Mycoplasma isolation, sanitation, and management, and in which no ~~reactors~~ MG positive birds are found when a random sample of at least 10 percent of the birds in the flock, or 300 birds in flocks of more than 300 and each bird in flocks of 300 or less, is tested when more than 12 weeks of age, in accordance with the procedures described in §145.14(b): *Provided,* That to retain this classification, a minimum of 30 samples from male flocks and 60 samples from female flocks shall be retested at 28-30 weeks of age and at 4-6 week intervals thereafter.

Reason: A reactor is defined as a bird that has a positive reaction to a test. Having a positive test, such as ELISA, does not disqualify a flock. A flock is disqualified when it has been confirmed to have MG. On a side note, I do not know what this reference to 10 percent of the birds in the flock refers to.

Sponsor: Dr. Doug Waltman
Georgia Poultry Laboratory Network

Proposal Number 20

Delegates: 145 D

§ 145.43 Terminology and classification; flocks and products.

Participating flocks, and the eggs and poults produced from them, which have met the respective requirements specified in this section may be designated by the following terms and the corresponding designs illustrated in §145.10:

* * *

(c) U.S. M. Gallisepcticum Clean.

(1) A flock maintained in accordance with part 147 of this subchapter with respect to Mycoplasma isolation, sanitation, and management, and in which no reactors are found when a random sample of at least 10 per cent of the birds in the flock, or 300 birds in flocks of more than 300 and each bird in flocks of 300 or less, is tested when more than 12 months of age, in accordance with the procedures described in §145.14(b): *Provided*, That to retain this classification, a minimum of 30 samples from male flocks and 60 samples from female flocks or 60 samples from mixed, male and female flocks, shall be retested at 28-30 weeks of age and at 4-6 week intervals thereafter.

(2) A flock qualified as U.S. M. Gallisepticum Clean may retain the classification through its first egg-laying cycle, provided it is maintained in isolation and no evidence of *M. gallisepticum* infection is revealed. A flock which is molted following completion of an egg-laying cycle and subsequently brought back into production, shall be retested within 2 weeks prior to production, as described in paragraph (c)(1) of this section. A State inspector shall visit with the owner or manager of each flock at least once during each laying cycle to discuss and ascertain whether the flock is being maintained in accordance with part 147 of this subchapter with respect to Mycoplasma isolation, sanitation, and management. If a flock proves to be infected with *M. gallisepticum,* it shall lose this classification.

(3) In order to sell hatching eggs or poults of this classification, all hatching eggs and poults handled by the participant must be of this classification.

(d) *U.S. M. Meleagridis Clean.*

(1) A flock in which freedom from *M. meleagridis* has been demonstrated under the following criteria:

(i) A sample of 100 birds from each flock has been tested for *M. meleagridis* when more than 12 weeks of age: *Provided,* That to retain this classification, a minimum of 30 samples from male flocks and 60 samples from female flocks or 60 samples from mixed, male and female flocks, shall be retested at 28-30 weeks of age and at 4-6 week intervals thereafter.

(2)-(3) [Reserved]

(4) When reactors to the official test are found and can be identified, 10 tracheal swabs and/or vaginal or phallus swabs and their corresponding blood samples shall be submitted to a laboratory for serological and cultural examination. If reactors cannot be identified, at least 30 tracheal swabs and/or vaginal or phallus swabs and their corresponding blood samples shall be submitted. In a flock with a low reactor rate (less than 5 reactors) the reactors may be submitted to the laboratory within 10 days for serology, necropsy, and thorough bacteriological examination.

(5) If a mycoplasma is isolated, the organism must be serotyped. If *M. meleagridis* is isolated, the block shall be considered infected.

(e) *U.S. M. Synoviae Clean.*

(1) All birds, or a sample of at least 100 birds from flocks of more than 100 and each bird in flocks of 100 or less, have been tested for *M. synoviae* when more than 12 weeks of age in accordance with the procedures in §145.14(b): *Provided,* That to retain this classification a minimum of 30 samples from male flocks and 60 samples from female flocks or 60 samples from mixed, male and female flocks, shall be retested at 28-30 weeks of age and at 4-6 week intervals thereafter. It is recommended that any birds that are showing clinical signs of *M. synoviae* infection be included in samples taken.

(2) When reactors to the official test are found and can be identified, tracheal swabs and their corresponding blood samples from 10 (all if fewer than 10) reacting birds shall be submitted to an authorized laboratory for serological and cultural examination. If reactors cannot be identified, at least 30 tracheal swabs and their corresponding blood samples shall be submitted. In a flock with a low reactor rate (less than five reactors) the reactors may be submitted to the laboratory within 10 days for serology, necropsy, and thorough bacteriological examination. When reactors to the official test are found, the procedures outlined in part 147 of this subchapter will be used to determine the status of the flock.

Reason: These changes should clarify for mixed flocks.

Sponsor: Dr. Dustin Burch
Aviagen Turkeys

Proposal Number 21

Delegates: **145 D**

§ 145.43 Terminology and classification; flocks and products.

Participating flocks, and the eggs and poults produced from them, which have met the respective requirements specified in this section may be designated by the following terms and the corresponding designs illustrated in §145.10:

* * *

(d) U.S. M. Meleagridis Clean.

(1) A flock in which freedom from *M. meleagridis* has been demonstrated under the following criteria:

(i) A sample of 100 birds from each flock has been tested for *M. meleagridis* when more than 12 weeks of age~~: *Provided,* That to retain this classification, a minimum of 30 samples from male flocks and 60 samples from female flocks shall be retested at 28-30 weeks of age and at 4-6 week intervals thereafter~~.

(2)-(3) [Reserved]

Reason: *M. meleagridis* (MM) is rarely found in US turkey breeding stock and no significant reservoir exists in commercial and non-commercial turkeys or other poultry. Test if clinical signs of MM are observed (airsccculitis and skeletal deformities in progeny, decreased hatchability). Airborne transmission is of little significance after breeder turkeys reach sexual maturity (Diseases of Poultry, 14th ed., Blackwell Publishing Professional: Ames, IA. 934-935.)

Sponsor: Dr. Becky Tilley
Butterball, LLC

Proposal Number 22

Delegates: **145 D**

§ 145.43 Terminology and classification; flocks and products.

Participating flocks, and the eggs and poults produced from them, which have met the respective requirements specified in this section may be designated by the following terms and the corresponding designs illustrated in §145.10:

* * *

(d) ***U.S. M. Meleagridis Clean.***

* * *

(5) If a mycoplasma is isolated, the organism must be serotyped. If *M. meleagridis* is isolated, the ~~block~~ flock shall be considered infected.

Reason: This was an error from a long time ago. We submitted a technical amendment and were told that it had to route through the proposed changes process for correction.

Sponsor: Dr. Elena Behnke
Senior Coordinator, NPIP

Proposal Number 23

Delegates: 145 D, G, and H

§145.43 Terminology and classification; flocks and products.

Participating flocks, and the eggs and poults produced from them, which have met the respective requirements specified in this section may be designated by the following terms and the corresponding designs illustrated in §145.10:

* * *

(h) *U.S. Newcastle Disease Clean.*

* * *

(3) To retain the classification in this paragraph (h) for unvaccinated flocks:

(i) A minimum of 30 birds per flock must test negative using an approved test in §145.14 at intervals of 90 days~~;~~ or

~~(ii) A~~ a sample of fewer than 30 birds may be tested, and found negative, at any one time if all pens are equally represented and a total of 30 birds is tested within each 90-day period; and

~~(iii)~~ (ii) During each 90-day period, all primary spent fowl, up to a maximum of 30, must test negative to ND within 21 days prior to movement to slaughter.

* * *

§145.73 Terminology and classification; flocks and products.

Participating flocks, and the eggs and chicks produced from them, which have met the respective requirements specified in this section, may be designated by the following terms and the corresponding designs illustrated in §145.10:

* * *

(h) *U.S. Newcastle Disease Clean.*

* * *

(3) To retain the classification in this paragraph (h) for unvaccinated flocks:

(i) A minimum of 30 birds per flock must test negative using an approved test in §145.14 at intervals of 90 days~~;~~ or

~~(ii) A~~ a sample of fewer than 30 birds may be tested, and found negative, at any one time if all pens are equally represented and a total of 30 birds is tested within each 90-day period; and

~~(iii)~~ (ii) During each 90-day period, all primary spent fowl, up to a maximum of 30, must test negative to ND within 21 days prior to movement to slaughter.

* * *

§145.83 Terminology and classification; flocks and products.

Participating flocks, and the eggs and chicks produced from them, which have met the respective requirements specified in this section, may be designated by the following terms and the corresponding designs illustrated in §145.10:

* * *

(h) ***U.S. Newcastle Disease (ND) Clean.***

* * *

(3) To retain the classification in this paragraph (h) for unvaccinated flocks:

(i) A minimum of 30 birds per flock must test negative using an approved test in §145.14 at intervals of 90 days~~;~~ or

~~(ii) A~~ a sample of fewer than 30 birds may be tested, and found negative, at any one time if all pens are equally represented and a total of 30 birds is tested within each 90-day period; and

~~(iii)~~ (ii) During each 90-day period, all primary spent fowl, up to a maximum of 30, must test negative to ND within 21 days prior to movement to slaughter.

Reason: The punctuation presents a challenge for understanding if the choice requires iii) to be done with the participant choosing between i) and ii) or if the choice provides the option of either doing just i) by itself or doing ii) and iii) together. To fix this, the NPIP office submitted a technical amendment that has not yet been corrected or resolved. To ensure the correction is made, we are proposing to eliminate the semicolon and combine ii) with i), meaning that there is a choice between i) and ii). Then iii), which becomes ii), must be done. This punctuation change should clarify the intent.

Sponsor: Dr. Elena Behnke
Senior Coordinator, NPIP

Proposal Number 24

Delegates: **145 E**

§ 145.53 Terminology and classification; flocks and products.

Participating flocks, and the eggs, chicks, started, and mature poultry produced from them, which have met the respective requirements specified in this section may be designated by the following terms and the corresponding designs illustrated in §145.10.

*** * ***

(e) U.S. H5/H7 Avian Influenza Clean. This program is intended to be the basis from which the breeding-hatchery industry may conduct a program for the prevention and control of the H5 and H7 subtypes of avian influenza. It is intended to determine the presence of the H5 and H7 subtypes of avian influenza in hobbyist ~~or exhibition waterfowl,~~ exhibition poultry, and ~~game bird~~ raised for release waterfowl breeding flocks through routine surveillance of each participating breeding flock. A flock, and the hatching eggs and chicks produced from it, will qualify for this classification when the Official State Agency determines that it has met one of the following requirements:

Reason: Exhibition waterfowl and game birds are not included in this subsection.

Sponsor: Dr. Doug Waltman
Georgia Poultry Laboratory Network

Proposal Number 25

Delegates: **145 G**

§145.73 Terminology and classification; flocks and products.

Participating flocks, and the eggs and chicks produced from them, which have met the respective requirements specified in this section, may be designated by the following terms and the corresponding designs illustrated in §145.10:

* * *

(d) *U.S. S. Enteritidis Clean.*
This classification is intended for primary egg-type breeders wishing to assure their customers that the hatching eggs and multiplier chicks produced are certified free of Salmonella enteritidis.

(1) A flock and the hatching eggs and chicks produced from it which have met the following requirements as determined by the Official State Agency:

(i)The flock originated from a U.S. S. Enteritidis Clean flock, or meconium from the chick boxes and a sample of chicks that died within 7 days after hatching are examined bacteriologically for salmonella at an authorized laboratory. Cultures from serogroup D positive samples shall be serotyped.

Reason: It was unclear what "positive" samples referred to. The language in §145.83(e)(1) is serogroup D.

Sponsor: Dr. Doug Waltman
Georgia Poultry Laboratory Network

Proposal Number 26

Delegates: 145 G and H

§145.73 Terminology and classification; flocks and products.

Participating flocks, and the eggs and chicks produced from them, which have met the respective requirements specified in this section, may be designated by the following terms and the corresponding designs illustrated in §145.10:

* * *

(g) ***U.S. Salmonella Monitored.*** This program is intended to be the basis from which the primary egg-type breeder industry may conduct a program for the prevention and control of salmonellosis. It is intended to reduce the incidence of Salmonella organisms in hatching eggs and chicks through an effective and practical sanitation program at the breeder farm and in the hatchery. This will afford other segments of the poultry industry an opportunity to reduce the incidence of Salmonella in their products.

(1) A flock and the hatching eggs and chicks produced from it that have met the following requirements, as determined by the Official State Agency:

(i) The flock is maintained in accordance with part 147 of this subchapter with respect to flock sanitation, cleaning and disinfection, and Salmonella isolation, sanitation, and management.

(ii) Measures shall be implemented to control Salmonella challenge through feed, feed storage, and feed transport.

(iii) Chicks shall be hatched in a hatchery whose sanitation is maintained in accordance with part 147 of this subchapter and sanitized or fumigated in accordance with part 147 of this subchapter.

(iv) An Authorized Agent shall take environmental samples from the hatchery every 30 days; i.e., meconium or chick papers. An authorized laboratory for Salmonella shall examine the samples bacteriologically.

(v) An Authorized Agent shall take environmental samples in accordance with part 147 of this subchapter from each flock at 4 months of age and every 30 days thereafter. An authorized laboratory for Salmonella shall examine the environmental samples bacteriologically. All *Salmonella* isolates from a flock shall be serogrouped ~~and shall be reported to the Official State Agency on a monthly basis~~. <u>The company shall report the presence or absence of Salmonella in their flocks on a monthly basis.</u>

(vi) Owners of flocks may vaccinate with a paratyphoid vaccine: *Provided,* That a sample of 350 birds, which will be banded for identification, shall remain unvaccinated until the flock reaches at least 4 months of age to allow for the serological testing ~~required under paragraph (g)(1)(iv) of this section~~.

* * *

§145.83 Terminology and classification; flocks and products.

Participating flocks, and the eggs and chicks produced from them, which have met the respective requirements specified in this section, may be designated by the following terms and the corresponding designs illustrated in §145.10:

* * *

(f) ***U.S. Salmonella Monitored.*** This program is intended to be the basis from which the breeding-hatching industry may conduct a program for the prevention and control of salmonellosis. It is intended to reduce the incidence of Salmonella organisms in hatching eggs and chicks through an effective and practical sanitation program at the breeder farm and in the hatchery. This will afford other segments of the poultry industry an opportunity to reduce the incidence of Salmonella in their products.

(1) A flock and the hatching eggs and chicks produced from it that have met the following requirements, as determined by the Official State Agency:

(i) Measures shall be implemented to control Salmonella challenge through feed, feed storage, and feed transport.

ii) Chicks shall be hatched in a hatchery whose sanitation is maintained in accordance with part 147 of this subchapter and sanitized or fumigated in accordance with part 147 of this subchapter.

(iii) An Authorized Agent shall take environmental samples from the hatchery every 30 days; i.e., meconium or chick papers. An authorized laboratory for *Salmonella* shall examine the samples bacteriologically.

(iv) An Authorized Agent shall take environmental samples in accordance with part 147 of this subchapter from each flock at 4 months of age and every 30 days thereafter. An authorized laboratory for *Salmonella* shall examine the environmental samples bacteriologically. All *Salmonella* isolates from a flock shall be serogrouped. ~~and shall be reported to the Official State Agency on a monthly basis;~~ The company shall report the presence or absence of Salmonella in their flocks on a monthly basis.

(v) Owners of flocks may vaccinate with a paratyphoid vaccine: *Provided,* That a sample of 350 birds, which will be banded for identification, shall remain unvaccinated until the flock reaches at least 4 months of age to allow for ~~the~~ serological testing ~~required under paragraph (f)(1)(iv) of this section~~.

Reason: The OSA does not need to know what Salmonella serogroups a company has. The company would report only the presence or absence of Salmonella on a monthly basis. Also, paragraph (g)(1)(iv) in §145.73 does not deal with serological testing but hatchery environmental testing. Similarly, paragraph (f)(1)(iv) in §145.83 deals with environmental testing, not serology. The only reason to hold back 350 birds is if they will be PT tested.

Sponsor: Dr. Doug Waltman
Georgia Poultry Laboratory Network

Proposal Number 27

Delegates: **145 H**

§145.83 Terminology and classification; flocks and products.

Participating flocks, and the eggs and chicks produced from them, which have met the respective requirements specified in this section, may be designated by the following terms and the corresponding designs illustrated in §145.10:

* * *

(f) U.S. Salmonella Monitored. This program is intended to be the basis from which the breeding-hatching industry may conduct a program for the prevention and control of salmonellosis. It is intended to reduce the incidence of *Salmonella* organisms in hatching eggs and chicks through an effective and practical sanitation program at the breeder farm and in the hatchery. This will afford other segments of the poultry industry an opportunity to reduce the incidence of *Salmonella* in their products.

(1) A flock and the hatching eggs and chicks produced from it that have met the following requirements, as determined by the Official State Agency.

i) Measures shall be implemented to control *Salmonella* challenge through feed, feed storage, and feed transport.

(ii) Chicks shall be hatched in a hatchery whose sanitation is maintained in accordance with part 147 of this subchapter and sanitized or fumigated in accordance with part 147 of this subchapter.

(iii) An Authorized Agent shall take environmental samples from the hatchery every 30 days; *i.e.*, meconium or chick papers. An authorized laboratory for *Salmonella* shall examine the samples bacteriologically;

(iv) An Authorized Agent shall take environmental samples in accordance with part 147 of this subchapter from each flock at 4 months of age and every 30 days thereafter. An authorized laboratory for *Salmonella* shall examine the environmental samples bacteriologically. All *Salmonella* isolates from a flock shall be serogrouped and shall be reported to the Official State Agency on a monthly basis;

(v) Owners of flocks may vaccinate with a paratyphoid vaccine: *Provided,* That a sample of 350 birds, which will be banded for identification, shall remain unvaccinated until the flock reaches at least 4 months of age to allow for the serological testing required under paragraph (f)(1)(iv) of this section.

(vi) Any flock entering the production period that is in compliance with all the requirements of §145.83(f) with no history of *Salmonella* isolations shall be considered "*Salmonella* negative" and may retain this definition as long as no environmental or bird *Salmonella* isolations are identified and confirmed from the flock or flock environment by sampling on 4 separate collection dates over a ~~minimum~~ maximum of a ~~2~~ 4-week period. Sampling and testing must be performed as described in paragraph (f)(1)(iv) of this section. An unconfirmed environmental *Salmonella* isolation shall not change this *Salmonella* negative status.

Reason: Breeding companies have a very high requirement for providing salmonella-free product to the global poultry market. In many situations if salmonella is isolated

environmentally or from actual birds, business decisions must be made quickly regarding the supply of breeding stock used internally or for customers. With flocks in production, it is common to have hatching eggs already set in hatcheries for customer orders. If a salmonella isolation occurs, this requires timely and accurate confirmation testing to be completed, and at times less than a two-week period. Collecting four sets of confirmatory samples on four separate dates over a maximum of 4 weeks can confidently allow these business decisions to be made.

Sponsor: Kyle Traeger
Cobb-Vantress, Inc.

Proposal Number 28

Delegates: **145 H**

§145.84 Terminology and classification; compartments.

(a) *U.S. Avian Influenza and Newcastle Disease Clean Compartment.*

* * *

(3) ***Service and Official State Agency activities for maintenance of the compartment.*** The Service will work in cooperation with the Official State Agencies to ensure the continued integrity of any recognized compartments. Activities include:

(i) Oversight of the establishment and management of compartments;

(ii) Establishment of effective partnerships between the Service, the Plan, and the primary breeder industry;

(iii) Approval or denial of classification of compartments as U.S. Avian Influenza Clean and/or ND Clean Compartments under paragraph (a)(1) of this section;

Reason: In both Subparts D and G, language about U.S. Avian Influenza Clean and ND Clean Compartments was used. The "ND Clean" part was inadvertently omitted from the new language that was passed at the 2018 Biennial Conference for Subpart H. The NPIP office submitted a technical amendment that has not yet been corrected or resolved. We are proposing these changes to make sure the correction is made. Additionally, congruent with the interim changes submitted in September 2021, the "and/or" language has been added.

Sponsor: Dr. Elena Behnke
Senior Coordinator, NPIP

Proposal Number 29

Delegates: **145 J**

§145.102 Participation.

Participating flocks of egg/meat-type game birds, raised-for-release game birds, and the products produced from them shall comply with the applicable general provisions of subpart A of this part and the special provisions of this subpart. Participation is broken into the following categories of operation and products:

* * *

(c) Products shall lose their identity under Plan terminology when not maintained by Plan participants under the conditions prescribed in §145.5(a).
(d) Hatching eggs produced by breeding flocks shall be nest clean, fumigated, or otherwise sanitized in accordance with part 147 of this subchapter.
~~(e) It is recommended that gallinaceous flocks and waterfowl flocks be kept separate.~~
~~(f)~~ (e)Any nutritive material provided to baby poultry must be free of the avian pathogens that are officially represented in the Plan disease classifications listed in §145.10.
~~(g)~~ (f) A flock of game birds that are not breeders, but are located on the same premise as game bird breeders, shall be covered under the same NPIP hatchery approval number as long as the appropriate testing requirements have been met.

Reason: Game birds as defined in Subpart J (domesticated fowl such as pheasants, partridge, quail, grouse, and guineas, but not doves and pigeons) do not include waterfowl. Waterfowl should not be located on a Subpart J premises which was part of the reason for creating Subpart J. The statement should be deleted.

Sponsors: Scott Meyer
Oakwood Game Farm

Mike Forsgren
Forsgren's Pheasant Farm

Dr. Dale Lauer
Minnesota Board of Animal Health

Dr. Shauna Voss
Minnesota Board of Animal Health

Proposal Number 30

Delegates: **145 J**

§ 145.103 Terminology and classification; flocks and products.

* * *

(b) *U.S. Pullorum-Typhoid Clean.*

* * *

(3) It is a breeding flock that originated from U.S. Pullorum-Typhoid Clean breeding flocks or from flocks that met equivalent requirements under official supervision, and in which a sample of 300 birds from flocks of more than 300, and each bird in flocks of 300 or less, has been officially tested for pullorum-typhoid with no reactors or reactors that upon bacteriologic examination fail to reveal Pullorum-Typhoid: *Provided,* That a bacteriological examination monitoring program or serological examination monitoring program for game birds acceptable to the Official State Agency and approved by the Service may be used in lieu of annual blood testing: *And provided further,* That it is located in a State in which it has been determined by the Service that:

Reason: This was a typo where Typhoid was misspelled when added to Subpart J language at the 2018 Biennial Conference. This proposed change seeks to correct the error.

Sponsor: Dr. Elena Behnke
Senior Coordinator, NPIP

Proposal Number 31

Delegates: 145 B and G

Subpart K – Special Provisions for SPF Egg-Type Chicken Breeding Flocks and Products

§145.111 Definitions.
Except where the context otherwise requires, for the purposes of this subpart the following terms shall be construed, respectively, to mean:

Chicks. Newly hatched chickens.

SPF egg-type chicken breeding flocks. Flocks that have been developed for egg production and are maintained for the principal purpose of producing SPF eggs used for the purpose of production and quality control of vaccines.

SPF Eggs. Eggs that are produced by SPF egg-type chicken breeding flocks for the purpose of production and quality control of vaccines.

SPF Products. Any materials derived from SPF egg-type chicken breeding flocks for the purpose of production and quality control of vaccines.

SPF Pullets. Birds less than 6 months of age that are hatched from SPF eggs for the purpose of production and quality control of vaccines.

Started chickens. Young chickens (chicks, pullets, cockerels, capons) which have been fed and watered and are less than 6 months of age.

§145.112 Participation.
Participating flocks of SPF egg-type chickens, and the eggs and chicks produced from them, shall comply with the applicable general provisions of subpart A of this part and the special provisions of this subpart K.

(a) Started chickens shall lose their identity under Plan terminology when not maintained by Plan participants under the conditions prescribed in §145.5(a).

(b) SPF eggs produced by breeding flocks should be nest clean. They may be fumigated in accordance with part 147 of this subchapter or otherwise sanitized.

(c) Any nutritive material provided to chicks must be free of the avian pathogens that are officially represented in the Plan disease classifications listed in §145.10.

§145.113 Terminology and classification; flocks and products.
Participating flocks, and the eggs and chicks produced from them, which have met the respective requirements specified in this section, may be designated by the following terms and the corresponding designs illustrated in §145.10:

(a) [Reserved]

(b) *U.S. Pullorum-Typhoid Clean.*

A flock in which freedom from pullorum and typhoid has been demonstrated to the Official State Agency under the criteria in paragraph (b)(1) or (b)(2) of this section: *Provided,* That a flock qualifying by means of a blood test shall be tested within the past 12 months, except that the retesting of a participating flock which is retained for more than 12 months shall be conducted a minimum of 4 weeks after the induction of molt. (See §145.14 relating to the official blood test where applicable.)

(1) It has been officially blood tested with either no reactors or reactors that, upon further bacteriological examination conducted in accordance with part 147 of this subchapter, fail to isolate *S. pullorum* or *S. gallinarum.*

(2) It is a SPF breeding flock that meets the following criteria:

(i) The SPF breeding flock is located in a State in which pullorum disease or fowl typhoid is not known to exist nor to have existed in hatchery supply flocks during the preceding 12 months and in which it has been determined by the Service that:

(A) All hatcheries within the State are qualified as "National Plan Hatcheries" or have met equivalent requirements for pullorum-typhoid control under official supervision;

(B) All hatchery supply flocks within the State are qualified as U.S. Pullorum-Typhoid Clean or have met equivalent requirements for pullorum-typhoid control under official supervision: *Provided,* That if other domesticated fowl, except waterfowl, are maintained on the same premises as the participating flock, freedom from pullorum-typhoid infection shall be demonstrated by an official blood test of each of these fowl;

(C) All shipments of products other than U.S. Pullorum-Typhoid Clean, or equivalent, into the State are prohibited;

(D) All persons performing poultry disease diagnostic services within the State are required to report to the Official State Agency within 48 hours the source of all poultry specimens from which *S. pullorum* or *S. gallinarum* is isolated;

(E) All reports of any disease outbreak involving a disease covered under the Plan are promptly followed by an investigation by the Official State Agency to determine the origin of the infection; *Provided,* That if the origin of the infection involves another State, or if there is exposure to poultry in another State from the infected flock, then officials administering the National Poultry Improvement Plan will conduct an investigation;

(F) All flocks found to be infected with pullorum or typhoid are quarantined until marketed or destroyed under the supervision of the Official State Agency, or until subsequently blood tested following the procedure for reacting flocks as contained in §145.14(a)(5), and all birds fail to demonstrate pullorum or typhoid infection;

(G) All poultry, including exhibition, exotic, and game birds, but excluding waterfowl, going to public exhibition shall come from U.S. Pullorum-Typhoid Clean or equivalent flocks, or have had a negative pullorum-typhoid test within 90 days of going to public exhibition; and

(H) Discontinuation of any of the conditions or procedures described in paragraphs (b)(2)(i)(A) through (b)(2)(i)(G) of this section, or the occurrence of repeated outbreaks of pullorum or typhoid in poultry breeding flocks within or originating within the State shall be grounds for the Service to revoke its determination that such conditions and procedures have been met or complied with. Such action shall not be taken until a thorough investigation has been made by the Service and the Official State Agency has been given an opportunity to present its views; and

(ii) In the SPF breeding flock, 2 samples of 200 birds each, taken with an interval of at least 4 weeks between the ages of 12-16 weeks and 16-20 weeks, or a single sample of 300 birds between the ages of 16-20 weeks, have been officially tested for pullorum-typhoid with either no reactors or reactors that, upon further bacteriological examination conducted in accordance with part 147 of this subchapter, fail to isolate *S. pullorum* or *S. gallinarum: Provided,* That a bacteriological examination monitoring program acceptable to the Official State Agency and approved by APHIS may be used in lieu of blood testing: *And provided further,* that samples will be equally representative of the flock.

(iii) Additionally, to retain this classification, from 20 weeks of age until not less than 4 weeks after the last sale of SPF eggs from the flock, a minimum of 50 birds at intervals of not more than 4 weeks (28 days) have been officially tested for pullorum-typhoid with either no reactors or reactors that, upon further bacteriological examination conducted in accordance with part 147 of this subchapter, fail to isolate *S. pullorum* or *S. gallinarum: Provided,* That a bacteriological examination monitoring program acceptable to the Official State Agency and approved by APHIS may be used in lieu of blood testing: *And provided further*, That a sample comprised of fewer than 50 birds may be tested at any one time, if all pens are equally represented and a total of 50 birds is tested within each 4-week (28 day) period.

(c) *U.S. M. Gallisepticum Clean.*

(1) A flock maintained in accordance with part 147 of this subchapter with respect to Mycoplasma isolation, sanitation, and management and in which freedom from *M. gallisepticum* has been demonstrated under the criteria specified in paragraph (c)(1)(i) of this section.

(i) In the SPF breeding flock, 2 samples of 200 birds each, taken with an interval of at least 4 weeks between the ages of 12-16 weeks and 16-20 weeks, or a single sample of 300 birds between the ages of 16-20 weeks, have been tested for *M. gallisepticum* as provided in §145.14(b): *Provided,* That to retain this classification, from 20 weeks of age until not less than 4 weeks after the last sale of SPF eggs from the flock, a minimum of 50 birds shall be tested at intervals of not more than 4 weeks (28 days): *And provided further*, That a sample comprised of fewer than 50 birds may be tested at any one time, if all pens are equally represented and a total of 50 birds is tested within each 4-week (28 day) period.

(ii) [Reserved]

(2) A participant handling U.S. M. Gallisepticum Clean products shall handle only products of equivalent status.

(3) U.S. M. Gallisepticum Clean chicks shall be boxed in clean boxes and delivered in trucks that have been cleaned and disinfected in accordance with part 147.

(d) *U.S. S. Enteritidis Clean.*

This classification is intended for SPF egg-type breeders wishing to assure their customers that the SPF eggs, SPF pullets, and SPF products are certified free of *Salmonella enteritidis.*

(1) A flock and the SPF eggs, SPF pullets, and SPF products produced from it which have met the following requirements, as determined by the Official State Agency:

(i) The flock originated from a U.S. S. Enteritidis Clean flock, or meconium from the chick boxes or a sample of chicks that died within 7 days after hatching are examined bacteriologically for salmonella at an authorized laboratory. Cultures from positive samples shall be serotyped.

(ii) All feed fed to the flock shall meet the following requirements:

(A) Pelletized feed shall contain either no animal protein or only animal protein products produced under the Animal Protein Products Industry (APPI) *Salmonella* Education/Reduction Program. The protein products must have a minimum moisture content of 14.5 percent and must have been heated throughout to a minimum temperature of 190 °F, or above, or to a minimum temperature of 165 °F for at least 20 minutes, or to a minimum temperature of 184 °F under 70 lbs. pressure during the manufacturing process.
(B) Mash feed may contain no animal protein other than an APPI animal protein product supplement manufactured in pellet form and crumbled: *Provided,* That mash feed may contain nonpelleted APPI animal protein product supplements if the finished feed is treated with a salmonella control product approved by the U.S. Food and Drug Administration.

(iii) Feed shall be stored and transported in such a manner as to prevent possible contamination;
(iv) The flock is maintained in accordance with part 147 of this subchapter with respect to flock sanitation, cleaning and disinfection, and Salmonella isolation, sanitation, and management. Rodents and other pests should be effectively controlled;
(v) Environmental samples shall be collected from the flock by an Authorized Agent, in accordance with part 147 of this subchapter, when the flock is 2 to 4 weeks of age. The samples shall be examined bacteriologically for group D salmonella at an authorized laboratory. Cultures from group D positive samples shall be serotyped. The Authorized Agent shall also collect samples a minimum of every 4 weeks (28 days) after the first sample has been collected.
(vi) SPF eggs are collected as quickly as possible and are handled as described in §147.21 of this subchapter and are sanitized or fumigated (see §147.21 of this subchapter).
(vii) SPF eggs produced by the flock, when used for repopulation of SPF egg-type chicken breeder flocks, are incubated in a hatchery whose sanitation is maintained in accordance with part 147 of this subchapter and sanitized either by a procedure approved by the Official State Agency or in accordance with part 147 of this subchapter.

(2) A flock shall not be eligible for this classification if *Salmonella enteritidis* serotype *enteritidis* (SE) is isolated from a specimen taken from a bird in the flock. Isolation of SE from an environmental or other specimen, as described in paragraph (d)(1)(v) of this section, will require bacteriological examination for SE in an authorized laboratory, in accordance with part 147 of this subchapter, of a random sample of 60 live birds from a flock of 5,000 birds or more, or 30 live birds from a flock with fewer than 5,000 birds. If only one specimen is found positive for SE, the participant may request bacteriological examination of a second sample, equal in size to the first sample, from the flock. If no SE is recovered from any of the specimens in the second sample, the flock will be eligible for the classification.
(3) In order for a hatchery to sell products of this classification, all products handled shall meet the requirements of the classification.
(4) This classification may be revoked by the Official State Agency if the participant fails to follow recommended corrective measures. The Official State Agency shall not revoke the participant's classification until the participant has been given an opportunity for a hearing in accordance with rules of practice adopted by the Official State Agency.

(e) *U.S. M. Synoviae Clean.*

(1) A flock maintained in accordance with part 147 of this subchapter with respect to Mycoplasma isolation, sanitation, and management and in which freedom from *M. synoviae* has been demonstrated under the criteria specified in paragraph (e)(1)(i) of this section.

(i) In the SPF breeding flock, 2 samples of 200 birds each, taken with an interval of at least 4 weeks between the ages of 12-16 weeks and 16-20 weeks, or a single sample of 300 birds between the ages of 16-20 weeks, have been tested for *M. synoviae* as provided in §145.14(b): *Provided,* That to retain this classification, from 20 weeks of age until not less than 4 weeks after the last sale of SPF eggs from the flock, a minimum of 50 birds shall be tested at intervals of not more than 4 weeks (28 days): *And provided further*, That a sample comprised of fewer than 50 birds may be tested at any one time if all pens are equally represented and a total of 50 birds is tested within each 4-week (28 day) period.

(ii) [Reserved]

(2) A participant handling U.S. M. Synoviae Clean products shall handle only products of equivalent status.

(3) U.S. M. Synoviae Clean chicks shall be boxed in clean boxes and delivered in trucks that have been cleaned and disinfected in accordance with part 147 of this subchapter.

(f) *U.S. Avian Influenza Clean.*

This program is intended to be the basis from which the breeding-hatchery industry may conduct a program for the prevention and control of avian influenza. It is intended to determine the presence of avian influenza in SPF breeding chickens through routine surveillance of each participating breeding flock. A flock and the SPF eggs and chicks produced from it will qualify for this classification when the Official State Agency determines that they have met the following requirements:

(1) It is an SPF breeding flock in which a minimum of 30 birds between the age of 16-20 weeks have been tested as provided in §145.14(d) and found negative for avian influenza. To retain this classification:

(i) From 20 weeks of age until flock depopulation, a sample of at least 10 birds shall be tested at intervals of not more than 4 weeks (28 days) as provided in §145.14(d).

(ii) Prior to flock depopulations, a sample of at least 10 birds must be tested and found negative for avian influenza within 3 weeks (21 days) prior to movement of birds off premises.

(g) *U.S. Newcastle Disease Clean.*

The program in this paragraph (g) is intended to be the basis from which the breeding-hatchery industry may conduct a program for the prevention and control of Newcastle disease. It is intended to determine the presence of Newcastle disease in SPF breeding chickens through monitoring of each participating breeding flock. A flock and the SPF eggs and chicks produced from it will qualify for the classification in this paragraph (g) when the Official State Agency determines that they have met the following requirements:

(1) It is an SPF breeding flock that is:

(i) Unvaccinated for Newcastle disease, in which a minimum of 30 birds between the age of 16-20 weeks have tested negative to ND using an approved test as described in §145.14 and meets criteria in paragraph (h)(2) of this section to retain classification.

(2) To retain the classification in this paragraph (h):

(i) From 20 weeks of age until flock depopulation, a minimum of 10 birds per flock must test negative using an approved test as described in §145.14 at intervals of not more than 4 weeks (28 days).

(ii) Prior to flock depopulations, a sample of at least 30 birds must be tested and found negative for ND within 3 weeks (21 days) prior to movement of birds off premises: *Provided*, That a sample comprised of fewer than 30 birds (minimum of 10 birds per week) may be tested at any one time if all pens are equally represented and a total of 30 birds is tested within the 3-week (21 day) period.

Reason: There is currently no classification for SPF egg-type chicken breeding flocks. The only federal regulatory document that currently references SPF egg type chicken breeding flocks is USDA Veterinary Services Memorandum No. 800.65, which is 5 pages in length and is intended primarily for veterinary biologics licensees, permittees, and applicants. SPF companies operate under extremely high biosecurity standards, meeting or exceeding many of the biosecurity standards employed by primary breeders; however, SPF egg-type chicken breeding flocks don't fit into any of the existing part 145 poultry classifications.

In the United States, two SPF companies produce the vast majority of SPF eggs that are used in both flu and yellow fever vaccines, and only three SPF companies in the United States produce commercial SPF eggs, which are supplied to vaccine manufacturers in the United States and exported globally for the same purpose. It is vitally important to protect the SPF breeder flocks, as USDA does not allow for the importation of SPF eggs for domestic human and animal vaccine production. If one or more of these SPF companies were to suffer a catastrophic biosecurity failure which resulted in widespread disease outbreak and flock depopulation, the resulting impact to commercial poultry companies would be devastating. There would also be an additional, significant impact to global production and supply of the human vaccines mentioned previously.

Finally, protecting SPF egg companies and their SPF breeder flocks strengthens the protection and security of all other classifications of poultry under part 145, as well as a significant amount of the downstream food supply in both the United States and many countries around the world.

Sponsors: Eduardo de Souza Pinto
VALO BioMedia North America, LLC

Dr. Travis Schaal
Director of GP Production & Internal Vet Services, Hy-Line International

Debra Tosto
Executive Director, Avian Vaccine Services, Charles River

Dr. Nastassja Ortega-Heinly
Director of Laboratory Operations, Charles River

Dr. Julie Helm
South Carolina NPIP Official State Agent

Proposal Number 32

Delegates: 145 D, G, and H

§145.114 Terminology and classification; compartments.

(a) ***U.S. Avian Influenza and/or Newcastle Disease Clean Compartment.*** This program is intended to be the basis from which the SPF egg-type chicken breeding-hatchery industry may demonstrate the existence and implementation of a program that has been approved by the Official State Agency and the Service to establish a compartment consisting of an SPF breeding-hatchery company that is free of H5/H7 avian influenza (AI) and/or Newcastle disease (ND). This compartment has the purpose of protecting the defined subpopulation and avoiding the introduction and spread of H5/H7 AI and/or ND within that subpopulation by prohibiting contact with other commercial poultry operations, other domestic and wild birds, and other intensive animal operations. The program shall consist of the following:

(1) ***Definition of the compartment.*** Based on the guidelines established by the World Organization for Animal Health (OIE) in the Terrestrial Animal Health Code and the guidelines in this paragraph (a), the SPF breeder company will define the compartment with respect to H5/H7 AI and/or ND. Specifically, the company will use a comprehensive biosecurity program to define the compartment as a subpopulation of poultry with a health status for H5/H7 AI and/or ND that is separate from birds and poultry outside the compartment. The Official State Agency and the Service must first approve all documentation submitted by the company to substantiate the defined compartment as adequate to qualify for epidemiological separation from other potential sources of infection of H5/H7 AI and/or ND. Guidelines for the definition of the compartment include:

(i) ***Definition and description of the subpopulation of birds and their health status.*** All birds included in the compartment must be U.S. Avian Influenza Clean in accordance with §145.113(f) and/or ND Clean in accordance with §145.113(g). The poultry must also be located in a State that has an initial State response and containment plan approved by APHIS under §56.10 of this chapter and that participates in the diagnostic surveillance program for H5/H7 low pathogenicity AI as described in §145.15. Within the compartment, all official tests for AI and/or ND, as described in §145.14(d) and (e), must be conducted in State or Federal laboratories or in NPIP authorized laboratories that meet the minimum standards described in §147.52 of this subchapter. In addition, the company must provide to the Service upon request any relevant historical and current H5/H7 AI and/or ND-related data for reference regarding surveillance for the disease within the compartment. Upon request, the Official State Agency may provide such data for other commercial poultry populations located in the State.

(ii) ***Description of animal identification and traceability processes.*** The SPF breeder company must also include a description of its animal identification and traceability records, including examples of Veterinary Services (VS) Form 9-5, "Report of Hatcheries, Dealers and Independent Flocks"; VS Form 9-2, "Flock Selection and Testing Report"; VS Form 9-3, "Report of Sales of Hatching Eggs, Chicks and Poults"; VS Form 9-9, " Hatchery Inspection Report"; set and hatch records; egg receipts; and egg/chick invoices for the subpopulation. Documentation must also include breed identification (NPIP stock code). The Service should ensure that an effective flock identification system and traceability system are in place.

(iii) ***Definition and description of the physical components or establishments of the defined compartment.*** The SPF breeder company must provide documentation establishing that the defined compartment is epidemiologically separated from other poultry and bird populations. The documentation must be approved by the Official State Agency and the Service as indicating adequate epidemiological separation to maintain the compartment's separate health status with respect to H5/H7 AI and/or ND. The documentation should include descriptions of:

(A) The physical and spatial factors that separate the compartment from surrounding bird populations and affect the biosecurity status of the compartment.

(B) Relevant environmental factors that may affect exposure of the birds to AI and/or ND.

(C) The functional boundary and fencing that are used to control access to the compartment.

(D) Facilities and procedures to prevent access by wild birds and to provide separation from other relevant hosts.

(E) The relevant infrastructural factors that may affect exposure to AI and/or ND, including the construction and design of buildings or physical components, cleaning and disinfection of buildings and physical components between production groups with quality assurance verification, cleaning and disinfection of equipment, and introduction of equipment or material into the compartment.

(iv) ***Definition and description of the functional relationships between components of the defined compartment.*** Functional relationships between components of the compartment include traffic movement and flow at and among premises, personnel movement at and among premises, exposure to live bird populations, and any other factors that could affect biosecurity of the compartment. All physical components of the compartment must be maintained in compliance with hygiene and biosecurity procedures for poultry SPF breeding flocks and hatcheries in accordance with part 147 of this subchapter. In addition, the company must provide a biosecurity plan for the compartment and all included components. The biosecurity plan should include but not be limited to:

(A) Requirements that company employees and contract growers limit their contact with live birds outside the compartment.

(B) An education and training program for company employees and contractors.

(C) Standard operating procedures for company employees, contractors, and outside maintenance personnel.

(D) Requirements for company employees and non-company personnel who visit any premises within the compartment.

(E) Company veterinary infrastructure to ensure flock monitoring and disease diagnosis and control measures.

(F) Policies for management of vehicles and equipment used within the compartment to connect the various premises.

(G) Farm site requirements (location, layout, and construction).

(H) Pest management program.

(I) Cleaning and disinfection process.

(J) Requirements for litter and dead bird removal and/or disposal.

(v) ***Description of other factors important for maintaining the compartment.*** The company veterinary infrastructure will assess sanitary measures, environmental risk factors, and management and husbandry practices that relate to the separation of the compartment and the health status of the birds contained within the

compartment that may affect risk of exposure to H5/H7 AI and/or ND. This assessment must include a description of internal monitoring and auditing systems (e.g., quality assurance and quality control programs) to demonstrate the effectiveness of the compartment. Upon request, the Service will provide the company with information on the epidemiology of H5/H7 AI and/or ND and the associated risk pathways in which the components of the compartment are located.
(vi) ***Approval or denial.*** Based on the documentation provided under this paragraph (a)(1), as well as any other information the Service and the Official State Agency determine to be necessary, the Service and the Official State Agency will approve or deny the classification of the compartment as U.S. Avian Influenza and/or ND Clean.

(2) ***Company activities for maintenance of the compartment.***

(i) The SPF breeder company's management of biosecurity, surveillance, and disease control efforts must be uniform and equivalent among all components that are a part of the compartment. Oversight and inspection of these management practices must be conducted by the company's licensed, accredited veterinarians.
(ii) Veterinary staff from the Official State Agency and NPIP staff will work in partnership with licensed, accredited veterinarians to train and certify auditors through Service-approved workshops. The trained auditors will conduct biosecurity and operational audits at least once every 2 years to ensure the integrity of the compartment. These audits will include evaluation of the critical control points and standard operating practices within the compartment, verification of the health status of the flock(s) contained within the compartment, and examination of the biosecurity and management system of the integrated components of the compartment.
(iii) In addition, the company must demonstrate compliance with paragraph (a)(1) of this section for remaining in the U.S. Avian Influenza and/or ND Clean classifications, surveillance for H5/H7 AI and/or ND within the compartment, and conducting tests in State or Federal laboratories or in NPIP authorized laboratories. Accredited veterinarians are responsible for the enforcement of active and passive surveillance of H5/H7 AI and/or ND in SPF breeder flocks. Baseline health status must be maintained for all flocks or subpopulations within the compartment, indicating the dates and negative results of all avian influenza and/or ND surveillance and monitoring testing, the dates and history of last disease occurrence (if any), the number of outbreaks, and the methods of disease control that were applied.
(iv) Documentation will be maintained in the company's database and will be verified as required by the Service and/or the Official State Agency.

(3) ***Service and Official State Agency activities for maintenance of the compartment.*** The Service will work in cooperation with the Official State Agencies to ensure the continued integrity of any recognized compartments. Activities include:

(i) Oversight of the establishment and management of compartments;
(ii) Establishment of effective partnerships between the Service, the Plan, and the SPF breeder industry;
(iii) Approval or denial of classification of compartments as U.S. Avian Influenza and/or ND Clean Compartments under paragraph (a)(1) of this section;
(iv) Official certification of the health status of the compartment, and commodities that may be traded from it through participation in the Plan for avian diseases, including the U.S. Avian Influenza Clean program as described in §145.113(f) and/or ND Clean program as described in §145.113(g) and diagnostic surveillance for H5/H7 low pathogenicity AI as described in §145.15;
(v) Conducting audits of compartments at least once every 2 years to:

(A) Confirm that the SPF breeding company's establishments are epidemiologically distinct and pathways for the introduction of disease into the compartment are closed through routine operational procedures; and
(B) Evaluate and assess the management and husbandry practices relating to biosecurity to determine whether they are in compliance with hygiene and biosecurity procedures for poultry SPF breeding flocks and hatcheries in accordance with part 147 of this subchapter;

(vi) Providing, upon request, model plans for management and husbandry practices relating to biosecurity in accordance with part 147 of this subchapter, risk evaluations in conjunction with the SPF breeder industry (including disease surveillance such as VS Form 9-4, "Summary of Breeding Flock Participation"), and diagnostic capability summaries and systems for initial State response and containment plans in accordance with §56.10 of this chapter; and
(vii) Publicizing and sharing compartment information with international trading partners, upon request, to establish approval and recognition of the compartment, including timeliness and accuracy of disease reporting and surveillance measures as described in §§145.15, 145.113(f), and 145.113(g).

(4) *Emergency response and notification.* In the case of a confirmed positive of H5/H7 AI and/or ND in the subpopulation of the compartment, the management of the compartment must notify the Service. The Service will immediately suspend the status of the compartment. A compartment will be eligible to resume trade with importing countries only after the compartment has adopted the necessary measures to reestablish the biosecurity level and confirm that H5/H7 AI and/or ND is not present in the compartment and the Service has reevaluated the management and biosecurity measures of the compartment and approved said compartment for trade.

(b) [Reserved]

Reason: The proposed section in this document contains terminology, definitions, descriptions, requirements and responsibilities pertaining to the Compartmentalization Program for Avian Influenza and/or Newcastle Disease and is necessary for SPF breeding companies to have a codified pathway for achieving U.S. Avian Influenza and/or Newcastle Disease Virus Clean Compartment certification.

Currently, the ability to obtain an official U.S. Avian Influenza and/or Newcastle Disease Virus Clean Compartment certificate is restricted to primary breeding companies, and SPF egg-type chicken breeding flocks do not fall under any primary breeder classifications in 9 CFR part 145. To alleviate this problem, a proposed rule change is also being submitted at this time to create *Subpart K—Special Provisions for SPF Egg-Type Chicken Breeding Flocks and Products* under 9 CFR part 145. There is an additional proposal being submitted at this time to include SPF breeders in the NPIP Program Standards, Subpart F – Compartmentalization.

The only federal regulatory document that currently references SPF egg type chicken breeding flocks is USDA Veterinary Services Memorandum No. 800.65, which is 5 pages in length and is intended primarily for veterinary biologics licensees, permittees, and applicants. SPF companies operate under extremely high biosecurity standards, meeting or exceeding many of the biosecurity standards employed by

primary breeders; however, SPF egg companies aren't eligible to apply for compartmentalization at this time.

In the United States, two SPF companies produce the vast majority of SPF eggs that are used in both flu and yellow fever vaccines, and only three SPF companies in the United States produce commercial SPF eggs, which are supplied to vaccine manufacturers in the United States and exported globally for the same purpose. It is vitally important to protect the SPF breeder flocks, as USDA does not allow for the importation of SPF eggs for domestic human and animal vaccine production. If one or more of these SPF companies were to suffer a catastrophic biosecurity failure which resulted in widespread disease outbreak and flock depopulation, the resulting impact to commercial poultry companies globally would be devastating. There would also be an additional, significant impact to global production and supply of the human vaccines mentioned previously.

Finally, protecting SPF egg companies and their SPF breeder flocks strengthens the protection and security of all other classifications of poultry under part 145, global poultry producers, as well as a significant amount of the downstream food supply in both the United States and many countries around the world.

Sponsors: Eduardo de Souza Pinto
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Dr. Travis Schaal
Director of GP Production & Internal Vet Services, Hy-Line International

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Executive Director, Avian Vaccine Services, Charles River

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Director of Laboratory Operations, Charles River

Dr. Julie Helm
South Carolina NPIP Official State Agent

Proposal Number 33

Delegates: **146 E**

§146 Table of Contents
Subpart E – Special Provisions for ~~Commercial Upland~~ Egg/Meat-Type Game Birds, ~~Commercial~~ Egg/Meat-Type Waterfowl, ~~Raised-for-Release Upland Game Birds, and~~ ~~Raised-for-Release Waterfowl~~ Meat-Type Game Bird Slaughter Plants, and Meat-Type Waterfowl Slaughter Plants

146.51-146.53

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§146.51 Subpart E – Special Provisions for Egg / Meat-Type ~~Commercial Upland~~ Game Birds, Egg / Meat-Type ~~Commercial~~ Waterfowl, ~~Raised-for-Release Upland Game Birds, and Raised-for-Release Waterfowl~~ Meat-Type Game Bird Slaughter Plants, and Meat-Type Waterfowl Slaughter Plants

146.51 Definitions.
146.52 Participation.
146.53 Terminology and classification; slaughter plants and premises.

Reason: These were errors that were incorporated incorrectly from the language submitted for the 2018 Biennial Conference. The NPIP office submitted technical amendments that have not yet been corrected or resolved. We are proposing these changes to make sure the correction is made.

Sponsor: Dr. Elena Behnke
Senior Coordinator, NPIP

Proposal Number 34

Delegates: 146 Combined

§146.3 Participation.

(a) Any commercial table-egg layer pullet flock, table-egg producer, ~~raised-for-release upland game bird premises, and raised-for-release waterfowl premises and any commercial upland game bird, commercial waterfowl~~, egg/meat-type game bird, egg/meat-type waterfowl, meat-type chicken or meat-type turkey slaughter plant, including its affiliated flocks, may participate in the Plan when the producer or plant has demonstrated, to the satisfaction of the Official State Agency, that its facilities, personnel, and practices are adequate for carrying out the relevant special provisions of this part and has signed an agreement with the Official State Agency to comply with the relevant special provisions of this part.

(b) Each participant shall comply with the Plan throughout the operating year, or until released by the Official State Agency.

(c) A participating slaughter plant shall participate with all of the ~~commercial upland~~ egg/meat-type game bird, ~~commercial~~ egg/meat-type waterfowl, meat-type chicken, spent fowl, and/or meat-type turkey flocks that are processed at the facility, including affiliated flocks. Affiliated flocks must participate through a written agreement with a participating slaughter plant that is approved by the Official State Agency.

Reason: Part (c) was an error that was incorporated incorrectly from the language submitted for the 2018 Biennial Conference. The NPIP office submitted technical amendments that have not yet been corrected or resolved. We are proposing this change in (c) to make sure the corrections are made. Part (a) had failed to incorporate the word "egg" before meat-type so this amendment in (a) should make the language parallel with part (c).

Sponsor: Dr. Elena Behnke
Senior Coordinator, NPIP

Proposal Number 35

Delegates: **146 Combined**

§146.6 Specific provisions for participating slaughter plants.

(a) Only ~~commercial upland~~ meat-type game bird, ~~commercial~~ meat-type waterfowl, meat-type chicken, and meat-type turkey slaughter plants that are under continuous inspection by the Food Safety and Inspection Service of the Department or under State inspection that the Food Safety and Inspection Service has recognized as equivalent to Federal inspection may participate in the Plan.

(b) To participate in the Plan, meat-type chicken, meat-type turkey, and ~~commercial upland~~ meat-type game bird and ~~commercial~~ meat-type waterfowl slaughter plants must follow the relevant special provisions in §§146.33(a), 146.43(a), and 146.53(a), respectively, for sample collection and flock monitoring, unless they are exempted from the special provisions under §§146.32(b), 146.42(b), or 146.52(b), respectively.

Reason: These were errors that were incorporated incorrectly from the language submitted for the 2018 Biennial Conference. The NPIP office submitted technical amendments that have not yet been corrected or resolved. We are proposing these changes to make sure the corrections are made.

Sponsor: Dr. Elena Behnke
Senior Coordinator, NPIP

Proposal Number 36

Delegates: **146 Combined**

§146.9 Terminology and classification; flocks, products and States.

Participating flocks, products produced from them, and States that have met the requirements of a classification in this part may be designated by the corresponding illustrative design in this section.

(a) ***U.S. H5/H7 Avian Influenza Monitored.*** (See §§ 146.23(a), 146.33(a), 146.43(a) and 146.53 (a) ~~and (b)~~.)

Reason: There is not a 146.53(b). It's reserved.

Sponsor: Dr. Doug Waltman
Georgia Poultry Laboratory Network

Proposal Number 37

Delegates: 146 B

§146.23 Terminology and classification; flocks and products.

Participating flocks which have met the respective requirements specified in this section may be designated by the following terms and the corresponding designs illustrated in §146.9 of this part:

(a) ***U.S. H5/H7 Avian Influenza Monitored*** -

(1) ***Table-egg layer pullet flocks.*** This program is intended to be the basis from which the table-egg layer industry may conduct a program to monitor for the H5/H7 subtypes of avian influenza. It is intended to determine the presence of the H5/H7 subtypes of avian influenza in table-egg layer pullets through routine surveillance of each participating commercial table-egg layer pullet flock. A flock will qualify for this classification when the Official State Agency determines that it has met one of the following requirements:

(i) It is a commercial table-egg layer pullet flock in which a minimum of 11 birds have been tested and are virus negative to the H5/H7 subtypes of avian influenza as determined by the Official State Agency and as provided in §146.13(b) within 14 ~~21~~ days prior to movement; or

(ii) It is a commercial table-egg layer pullet flock that has an ongoing active and diagnostic surveillance program for the H5/H7 subtypes of avian influenza in which the number of birds tested is equivalent to the number required in paragraph (a)(1)(i) of this section and that is approved by the Official State Agency and the Service.

(2) ***Table-egg layer flocks.*** This program is intended to be the basis from which the table-egg layer industry may conduct a program to monitor for the H5/H7 subtypes of avian influenza. It is intended to determine the presence of the H5/H7 subtypes of avian influenza in table-egg layer through routine surveillance of each participating commercial table-egg layer flock. A flock will qualify for this classification when the Official State Agency determines that it has met the following requirements:

(i) It is a commercial table-egg layer flock in which a minimum of 11 birds have been tested and are virus negative to the H5/H7 subtypes of avian influenza as determined by the Official State Agency and as provided in §146.13(b) within 14 ~~21~~ days prior to disposal; and either

(ii) It is a commercial table-egg layer flock in which a minimum of 11 birds have been tested negative for the H5/H7 subtypes of avian influenza as provided in §146.13(b) within a 12-month period; or

(iii) It is a commercial table-egg layer flock that has an ongoing active and diagnostic surveillance program for the H5/H7 subtypes of avian influenza in which the number of birds tested is equivalent to the number required in paragraph (a)(2)(i) or paragraph (a)(2)(ii) of this section and that is approved by the Official State Agency and the Service.

(b) [Reserved]

Reason: This change provides assurances that table-egg layer pullets or table-egg chickens moved off a premises are H5/H7 virus negative.

Sponsors: Dr. Jill Nezworski
Blue House Veterinary

Caitlin McKenzie
Daybreak Foods

Dr. Dale Lauer
Minnesota Board of Animal Health

Dr. Shauna Voss
Minnesota Board of Animal Health

Proposal Number 38

Delegates: **Combined**

§147.46 Committee consideration of proposed changes.
(a) The following committees shall be established to give preliminary consideration to the proposed changes falling in their respective fields:

(1) Egg-type breeding chickens.
(2) Meat-type breeding chickens.
(3) Breeding turkeys.
(4) Breeding waterfowl, exhibition poultry, and breeding game birds.
(5) Breeding ostriches, emus, rheas, and cassowaries.
(6) Egg-type commercial chickens.
(7) Meat-type commercial chickens.
(8) Meat-type commercial turkeys.
(9) ~~Commercial upland game birds and waterfowl and raised for release upland game birds and waterfowl.~~ Egg/meat-type game birds and waterfowl.

Reason: This was an oversight error that failed to incorporate the new language that was passed at the 2018 Biennial Conference. We are proposing these changes to make this section congruent with 145 and 146.

Sponsor: Dr. Elena Behnke
Senior Coordinator, NPIP

Proposal Number 39

Delegates: **Combined**

§147.52 Authorized Laboratories.
These minimum requirements are intended to be the basis on which an authorized laboratory of the Plan can be evaluated to ensure that official Plan assays are performed in accordance with the NPIP Program Standards or other procedures approved by the Administrator in accordance with §147.53(d)(1) and reported as described in paragraph (f) of this section. A satisfactory evaluation will result in the laboratory being recognized by the NPIP office of the Service as an authorized laboratory qualified to perform the assays provided for in this part.

* * *

(f) **Reporting.**

(1) A memorandum of understanding or other means shall be used to establish testing and reporting criteria to the Official State Agency, including criteria that provide for reporting H5 and H7 low pathogenic avian influenza directly to the Service.
(2) All *Salmonella pullorum* and *Mycoplasma* Plan disease ~~reactors~~ positive flocks confirmed by culture and/or molecular diagnostic testing must be reported to the Official State Agency within 48 hours.

Reason: A reactor is defined as a positive test result. Within the NPIP many of our screening tests must be confirmed with further testing. Screening tests are typically subject to false positive results, which necessitates the confirmation. The basis for this proposal is to provide clarification pertaining to the definition of "reporting" to minimize inconsistent interpretation of this word. "Reporting" should not be used to imply that screening test non-negative results must be reported to the Official State Agency within 48 hours. Reporting all reactors within 48 hours is an unnecessary and burdensome request of our laboratories. Only non-negative results confirmed by culture and/or molecular diagnostic testing and signifying bird and/or flock infection, must be reported to the Official State Agency within 48 hours. Therefore, it is not the reactors that should be reported within 48 hours, but rather the confirmed positive flocks.

Additionally, other parts of the provisions support this stance. Take, for example, **145.23(b)(2)(i)** as well as similar sections in Subparts C, D, E, etc.: *The flock is located in a State where all persons performing poultry disease diagnostic services within the State are required to report to the Official State Agency within 48 hours the source of all poultry specimens from which S. pullorum or S. gallinarum is isolated.* This statement means that the reporting is for cases in which an isolation has been confirmed, not in which a reactor is present.

Sponsors: Dr. Doug Waltman
Georgia Poultry Laboratory Network

Dr. Kate Hayes
Aviagen North America

Gordon Whitbeck
Whitbeck Labs

Proposal Number 40

Delegates: Combined

§56.1 Definitions.

Administrator. The Administrator, Animal and Plant Health Inspection Service, or any other employee of the Animal and Plant Health Inspection Service delegated to act in the Administrator's stead.

Animal and Plant Health Inspection Service (APHIS). The Animal and Plant Health Inspection Service of the U.S. Department of Agriculture.

Breeding flock. A flock that is composed of stock that has been developed for commercial egg or meat production and is maintained for the principal purpose of producing progeny for the ultimate production of eggs or meat for human consumption.

Classification. A designation earned by participation in a Plan program.

Cleaning. The removal of gross contamination, organic material, and debris from the premises or respective structures, via mechanical means like sweeping (dry cleaning) and/or the use of water and soap or detergent (wet cleaning), in order to minimize organic material to prepare for effective disinfection.

Commercial flock or slaughter plant. A commercial poultry flock or slaughter plant that is required because of its size to participate in the special provisions in part 146 of this chapter in order to participate in the Plan.

Compensation. In the case of H5/H7 LPAI detection, compensation specifically refers to reimbursement for the activities associated with the depopulation of infected or exposed poultry, including the disposal of contaminated carcasses and materials and the cleaning and disinfection of premises, conveyances, and materials that came into contact with infected or exposed poultry. In the case of contaminated materials, if the cost of cleaning and disinfection would exceed the value of the materials, or cleaning and disinfection would be impracticable for any reason, APHIS' Veterinary Services will base compensation on the fair market value (depreciated value) of those materials. Compensation does not include payment for depopulated birds or eggs destroyed (see definition of *Indemnity* in this section).

Cooperating State Agency. Any State authority recognized by the Department to cooperate in the administration of the provisions of this part 56. This may include the State animal health authority or the Official State Agency.

Department. The U.S. Department of Agriculture.

Disinfection. Methods used on surfaces to destroy or eliminate H5/H7 LPAI virus through physical (*e.g.,* heat) or chemical (*e.g.,* disinfectant) means. A combination of methods may be required.

Domesticated. Propagated and maintained under the control of a person.

Flock plan. A written flock management agreement developed by APHIS and the Official State Agency with input from the flock owner and other affected parties. A flock plan sets out the steps to

be taken to eradicate H5/H7 LPAI from a positive flock, or to prevent introduction of H5/H7 LPAI into another flock. A flock plan shall include, but is not necessarily limited to, poultry and poultry product movement and geographically appropriate infected and control/monitoring zones. Control measures in the flock plan should include detailed plans for safe handling of conveyances, containers, and other associated materials that could serve as fomites; disposal of flocks; cleaning and disinfection; downtime; and repopulation.

H5/H7 low pathogenic avian influenza (LPAI). An infection of poultry caused by an influenza A virus of H5 or H7 subtype that has an intravenous pathogenicity index in 6-week-old chickens less than or equal to 1.2 or causes less than 75 percent mortality in 4- to 8-week-old chickens infected intravenously, or an infection with influenza A viruses of H5 or H7 subtype with a cleavage site that is not consistent with a previously identified highly pathogenic avian influenza virus.

H5/H7 LPAI virus actively infected (infectious).

(1) Poultry will be considered to be actively infected with H5/H7 LPAI for the purposes of this part if:

(i) H5/H7 LPAI virus has been isolated and identified as such from poultry; or

(ii) Viral antigen or viral RNA specific to the H5 or H7 subtype of AI virus has been detected in poultry.

(2) The official determination that H5/H7 LPAI virus has been isolated and identified, or viral antigen or viral RNA specific to the H5 or H7 subtype of AI virus has been detected, may only be made by the National Veterinary Services Laboratories.

H5/H7 LPAI virus exposed (non-infectious).

(1) Poultry will be considered to be exposed (non-infectious) to H5/H7 LPAI for the purposes of this part if:

(i) Antibodies to the H5 or H7 subtype of the AI virus that are not a consequence of vaccination have been detected in poultry; and

(ii) Samples collected from the flock using real-time reverse transcription polymerase chain reaction (RT-PCR) or virus isolation are determined to be not infectious for H5/H7 LPAI.

(2) The official determination that H5/H7 LPAI virus exposure has occurred is by the identification of antibodies to the H5 or H7 subtype of AI virus detected and may only be made by the National Veterinary Services Laboratories.

Indemnity. Payments representing the fair market value of destroyed birds and eggs. Indemnity does not include reimbursements for depopulation, disposal, destroyed materials, or cleaning and disinfection (virus elimination) activities; these activities are covered under compensation (see definition of *Compensation* in this section).

Mortgage. Any mortgage, lien, or other security or beneficial interest held by any person other than the one claiming indemnity for the destruction of poultry or eggs due to H5/H7 LPAI.

NPIP Program Standards. A document that contains tests and sanitation procedures approved by the Administrator under 9 CFR 147.53.

Official appraiser (APHIS official appraiser, State official appraiser). A person authorized by APHIS to appraise poultry for the purposes of this part. A State official appraiser is selected by a State and authorized by APHIS.

Official State Agency. The State authority recognized by the Department to cooperate in the administration of the Plan.

Plan. The provisions of the National Poultry Improvement Plan contained in parts 145, 146, and 147 of this chapter.

Poultry. Domesticated fowl, including chickens, turkeys, ostriches, emus, rheas, cassowaries, waterfowl, and game birds, except doves and pigeons, which are bred for the primary purpose of producing eggs or meat.

Secretary. The Secretary of the United States Department of Agriculture, or any officer or employee of the Department delegated to act in the Secretary's stead.
State. Any of the States, the District of Columbia, the Commonwealth of Puerto Rico, Guam, the Commonwealth of the Northern Mariana Islands, the Virgin Islands of the United States, or any territory or possession of the United States.

Table-egg layer. A domesticated chicken grown for the primary purpose of producing eggs for human consumption.

United States. All of the States.

Virus elimination (VE). Cleaning and disinfection or other measures conducted to destroy or eliminate all AI virus on the ~~an affected~~ premises as cost effectively as possible.

§56.2 Cooperation with States.

(a) The Administrator has been delegated the authority to cooperate with Cooperating State Agencies in the eradication of H5/H7 LPAI. This cooperation may include, but is not necessarily limited to, the following activities:

(1) Payment to Cooperating State Agencies for surveillance and monitoring associated with poultry that have been infected with or exposed to H5/H7 LPAI;
(2) Transfer of vaccine for H5/H7 LPAI to Cooperating State Agencies if provided for in the initial State response and containment plan approved by APHIS under §56.10; and
(3) Payment for vaccine administration by Cooperating State Agencies, if provided for in the initial State response and containment plan approved by APHIS under §56.10.

(b)

(1) Any payment made to a State or an Official State Agency for the activities listed in paragraphs (a)(1) and (a)(3) of this section must be made through a cooperative agreement between the Cooperating State Agency and APHIS. The payment for which the Cooperating State Agency is eligible will be determined in the cooperative agreement.

(i) For any Cooperating State Agency that participates in the National Poultry Improvement Plan diagnostic surveillance program for H5/H7 LPAI, as described in §146.14 of this chapter, and has an initial State response and containment plan for H5/H7 LPAI that is approved by APHIS, as described in §56.10 of this part, the cooperative agreement will provide that the Cooperating State Agency is eligible for payment of 100 percent of the costs of surveillance and monitoring and 100 percent of the costs of vaccine administration, as determined in the cooperative agreement.
(ii) For any Cooperating State Agency that does not meet the criteria in paragraph (b)(1)(i) of this section, the cooperative agreement will provide that the Cooperating State Agency is eligible for payment of 25 percent of the costs of surveillance and monitoring and 25 percent of the costs of vaccine administration, as determined in the cooperative agreement.

(2) Transfer of vaccine under paragraph (a)(2) of this section must be accomplished through a cooperative agreement between the Cooperating State Agency and APHIS.

(c) Cooperating State Agencies will be responsible for making the determination to request Federal assistance under this part in the event of an outbreak of H5/H7 LPAI.

§56.3 Payment of indemnity and/or compensation.

(a) *Activities eligible for indemnity and/or compensation.* The Administrator may pay indemnity and/or compensation for the activities listed in this paragraph (a), as provided in paragraph (b) of this section:

(1) Destruction and disposal of poultry that were infected with or exposed to H5/H7 LPAI;
(2) Destruction of any eggs destroyed during testing of poultry for H5/H7 LPAI during an outbreak of H5/H7 LPAI; and
(3) Virus elimination (VE) measures taken ~~Cleaning and disinfection~~ on~~f~~ premises, conveyances, and materials that came into contact with poultry that were infected with or exposed to H5/H7 LPAI; or, in the case of materials, if the cost of the VE measures ~~cleaning and disinfection~~ would exceed the value of the materials or the VE measures ~~cleaning and disinfection~~ would be impracticable for any reason, the destruction and disposal of the materials.

(b) *Percentage of costs eligible for indemnity and/or compensation.* ~~Except for poultry that are described by the categories in this paragraph (b), the Administrator is authorized to pay 100 percent of the costs and/or compensation, as determined in accordance with § 56.4, of the activities described in paragraphs (a)(1) through (3) of this section, regardless of whether the infected or exposed poultry participate in the Plan. For infected or exposed poultry that are described by the categories in this paragraph (b), the Administrator is authorized to pay 25 percent of the costs of the activities described in paragraphs (a)(1) through (3) of this section.~~

~~(1)~~ (1) The Administrator is authorized to pay 100 percent of the costs and/or compensation, as determined in accordance with §56.4, of the activities described in paragraphs (a)(1) through (3) of this section, for flocks that participate in the Plan, if:

~~(i) The poultry are from a breeding flock, commercial flock, or slaughter plant that participates in any Plan program in part 145 or 146 of this chapter but that does not participate in the U.S. Avian Influenza Clean, U.S. H5/H7 Avian Influenza Clean, or U.S. H5/H7 Avian Influenza Monitored program of the Plan available to the flock in part 145 or 146 of this chapter; and~~

~~(ii)~~ (i) The poultry are from:

(A) A commercial table-egg laying premises with at least 75,000 birds~~;~~ or
(B) A meat-type chicken slaughter plant that slaughters at least 200,000 meat-type chickens in an operating week~~;~~ or
(C) A meat-type turkey slaughter plant that slaughters at least 2 million meat-type turkeys in a 12-month period~~;~~ or
(D) A commercial waterfowl and commercial upland game bird slaughter plant that slaughters at least 50,000 birds annually~~;~~ or
(E) A raised-for-release upland game bird premises, raised-for-release waterfowl premises, and commercial upland game bird or commercial waterfowl producing eggs for human consumption premises that raise at least 25,000 birds annually~~;~~ or
(F) A breeder flock premises with at least 5,000 birds~~.~~; and

ii) The breeding flock, commercial flock, or slaughter plant participates in the U.S. Avian Influenza Clean, U.S. H5/H7 Avian Influenza Clean, or U.S. H5/H7 Avian

Influenza Monitored program of the Plan available to the flock in part 145 or 146 of this chapter; and

iii) The owner of the poultry or eggs and, if applicable, any party that enters into a contract with the owner to grow or care for the poultry or eggs, had in place and was following a biosecurity plan that meets the requirements of the NPIP Program Standards – Standard E – Biosecurity Principles and has been audited by the Official State Agency to ensure that the biosecurity plan is in compliance at the time of detection of H5/H7 LPAI; or

iv) The flock does not meet the size requirements as described above, regardless of whether the infected or exposed poultry participate in the Plan.

(2) The Administrator is authorized to pay 25 percent of the costs and/or compensation, as determined in accordance with 56.4, of the activities described in paragraphs (a)(1) through (3) of this section, for flocks that:

(i) Do not meet the conditions described in paragraph (b)(1); or

~~(2)~~ (ii) The poultry are located in a State that does not participate in the diagnostic surveillance program for H5/H7 LPAI, as described in §146.14 of this chapter, or that does not have an initial State response and containment plan for H5/H7 LPAI that is approved by APHIS under §56.10, unless such poultry participate in the Plan with another State that does participate in the diagnostic surveillance program for H5/H7 LPAI, as described in §146.14 of this chapter, and has an initial State response and containment plan for H5/H7 LPAI that is approved by APHIS under §56.10.

(c) *Other sources of payment.* If the recipient of indemnity and/or compensation for any of the activities listed in paragraphs (a)(1) through (3) of this section also receives payment for any of those activities from a State or from other sources, the indemnity and/or compensation provided under this part may be reduced by the total amount of payment received from the State or other sources to the extent that total payments do not exceed 100 percent of total reimbursable indemnity and/or compensation amounts.

§56.4 Determination of indemnity and/or compensation amounts.

(a) *Destruction and disposal of poultry.*

(1) Indemnity for the destruction of poultry and/or eggs infected with or exposed to H5/H7 LPAI will be based on the fair market value of the poultry and/or eggs, as determined by an appraisal. Poultry infected with or exposed to H5/H7 LPAI that are removed by APHIS or a Cooperating State Agency from a flock will be appraised by an APHIS official appraiser and a State official appraiser jointly, or, if APHIS and State authorities agree, by either an APHIS official appraiser or a State official appraiser alone. For laying hens, the appraised value should include the hen's projected future egg production. Appraisals of poultry must be reported on forms furnished by APHIS and signed by the appraisers and must be signed by the owners of the poultry to indicate agreement with the appraisal amount. Appraisals of poultry must be signed by the owners of the poultry prior to the destruction of the poultry, unless the owners, APHIS, and the Cooperating State Agency agree that the poultry may be destroyed immediately. Reports of appraisals must show the number of birds and the value per head.

(2) Compensation for disposal of poultry and/or eggs infected with or exposed to H5/H7 LPAI will be based on receipts or other documentation maintained by the claimant verifying expenditures for disposal activities authorized by this part. Any disposal of poultry infected with or exposed to H5/H7 LPAI for which compensation is requested must be performed under a compliance agreement between the claimant and APHIS. APHIS will review claims for compensation for disposal to ensure that all expenditures relate directly to activities described in §56.5 and in the initial State response and containment plan described in

§56.10. If disposal is performed by the Cooperating State Agency, APHIS will compensate the Cooperating State Agency for disposal under a cooperative agreement.
(3) The destruction and disposal of the poultry and/or eggs must be conducted in accordance with the initial State response and containment plan for H5/H7 LPAI, as described in §56.10.

(b) *Cleaning and disinfection (virus elimination).*
(1) Compensation for cleaning and disinfection (virus elimination) of premises, conveyances, and materials that came into contact with poultry that are infected with or exposed to H5/H7 LPAI will be determined using the current APHIS flat-rate virus elimination (VE) calculator in effect at the time of the infection, except in instances when the claimant and APHIS jointly agree the VE calculator is not applicable to the premises type.
(2) For premises types for which a flat-rate VE calculator is not applicable, reimbursement will be based on receipts or other documentation maintained by the claimant verifying expenditures for cleaning and disinfection (virus elimination) activities authorized by this part. Any cleaning and disinfection (virus elimination) of premises, conveyances, and materials for which compensation is requested must be performed under a compliance agreement between the claimant, the Cooperating State Agency, and APHIS. APHIS will review claims for compensation for cleaning and disinfection (virus elimination) to ensure that all expenditures relate directly to activities described in §56.5 and in the initial State response and containment plan described in §56.10.
(i) In the case of materials, if the cost of cleaning and disinfection (virus elimination) would exceed the value of the materials or cleaning and disinfection (virus elimination) would be impracticable for any reason, compensation for the destruction of the materials will be based on the fair market value (depreciated value) of those materials, as determined by an appraisal. Materials will be appraised by an APHIS official appraiser. Compensation for disposal of the materials will be based on receipts or other documentation maintained by the claimant verifying expenditures for disposal activities authorized by this part. Appraisals of materials must be reported on forms furnished by APHIS and must be signed by the appraisers and by the owners of the materials to indicate agreement with the appraisal amount. Appraisals of materials must be signed and received by APHIS prior to the disassembly or destruction of the materials, unless the owners, APHIS, and the Cooperating State Agency agree in writing that the materials may be disassembled and/or destroyed immediately. Any disposal of materials for which compensation is requested must be performed under a compliance agreement between the claimant, the Cooperating State Agency, and APHIS. APHIS will review claims for compensation for disposal to ensure that all expenditures relate directly to activities described in §56.5 and in the initial State response and containment plan described in §56.10.
(ii) [Reserved]

(c) *Requirements for compliance agreements.* The compliance agreement is a comprehensive document that describes the depopulation, disposal, and cleaning and disinfection plans for poultry that were infected with or exposed to H5/H7 LPAI, or a premises that contained such poultry. The compliance agreement must set out cost estimates that include labor, materials, supplies, equipment, personal protective equipment, and any additional information deemed necessary by APHIS. A compliance agreement is comparable to a statement of work and must indicate what tasks will be completed, who will be responsible for each task, and how much the work is expected to cost. A compliance agreement may also be referred to as a detailed financial plan. Once work associated with the compliance agreement is completed, receipts and documentation detailing the activities specified in the agreement should be forwarded to APHIS for review, approval, and final payment.

This documentation should be submitted to APHIS no later than 30 days after the quarantine release of the affected or exposed premises.

§56.5 Destruction and disposal of poultry and cleaning and disinfection (virus elimination of premises, conveyances, and materials.

(a) *Destruction of poultry.* Poultry that are infected with or exposed to H5/H7 LPAI may be required to be destroyed at the discretion of the Cooperating State Agency and APHIS and in accordance with the initial State response and containment plan described in §56.10. The Cooperating State Agency and APHIS will select a method to use for the destruction of such poultry based on the following factors:

(1) The species, size, and number of the poultry to be destroyed;
(2) The environment in which the poultry are maintained;
(3) The risk to human health or safety of the method used;
(4) Whether the method requires specialized equipment or training;
(5) The risk that the method poses of spreading the H5/H7 LPAI virus;
(6) Any hazard the method could pose to the environment;
(7) The degree of bird control and restraint required to administer the destruction method;
(8) The speed with which destruction must be conducted; and
(9) Consistency of the method with humane euthanasia guidelines.

(b) *Disposal of poultry.* Carcasses of poultry that have died from H5/H7 LPAI infection or poultry that have been humanely slaughtered to fulfill depopulation requirements must be disposed of promptly and efficiently in accordance with the initial State response and containment plan described in §56.10 to prevent the spread of H5/H7 LPAI infection. Disposal methods will be selected by the Cooperating State Agency and APHIS and may include one or more of the following: Burial, incineration, composting, or rendering. Regardless of the method used, strict biosecurity procedures must be implemented and enforced for all personnel and vehicular movement into and out of the area in accordance with the initial State response and containment plan to prevent dissemination of the H5/H7 LPAI virus.

(c) *Controlled marketing.*

(1) At the discretion of the Cooperating State Agency and APHIS, poultry that has been infected with or exposed to H5/H7 LPAI may be allowed to move for controlled marketing and maintain their current National Poultry Improvement Plan (NPIP) certifications in accordance with the initial State response and containment plan described in §56.10 and in accordance with the following requirements:

(i) Poultry infected with or exposed to H5/H7 LPAI must not be transported to a market for controlled marketing until approved by the Cooperating State Agency in accordance with the initial State response and containment plan described in §56.10.
(ii) Poultry will be monitored daily for the development of clinical signs suggestive of H5/H7 LPAI with scheduled flock observation, tracking, and recording flock(s) mortality, taking action as directed by the Official State Agency.
(iii) Within 7 days prior to slaughter, each flock to be moved for controlled marketing must be tested for H5/H7 LPAI using a test approved by the Cooperating State Agency and found to be free of the virus.
(iv~~ii~~) Routes to slaughter must avoid other commercial poultry operations whenever possible. All load-out equipment, trailers, and trucks used on the premises that have housed poultry that were infected with or exposed to H5/H7 LPAI must undergo virus elimination procedures ~~be cleaned and disinfected~~ and not enter other poultry premises or facilities for 48 hours after the virus elimination procedures have been completed ~~removing such poultry from their premises~~.

(iv) Flocks moved for controlled marketing must be the last poultry marketed during the week they are marketed.

(2) Poultry moved for controlled marketing will not be eligible for indemnity under §56.3. However, any costs related to cleaning and disinfection (virus elimination) of premises, conveyances, and materials that came into contact with poultry that are moved for controlled marketing will be eligible for compensation under §56.3.

(d) *Cleaning and disinfection (virus elimination) of premises, conveyances, and materials.* Premises, conveyances, and materials that came into contact with poultry infected with or exposed to H5/H7 LPAI must be cleaned and disinfected; *Provided,* that materials for which the cost of cleaning and disinfection would exceed the value of the materials or for which cleaning and disinfection would be impracticable for any reason may be destroyed and disposed. Cleaning and disinfection must be performed in accordance with the initial State response and containment plan described in §56.10, which must be approved by APHIS. Cleaning and disinfection must also be performed in accordance with any applicable State and local environmental regulations.

§56.6 Presentation of claims for indemnity and/or compensation.

Claims for the following must be documented on a form furnished by APHIS and presented to an APHIS employee or the State representative authorized to accept the claims:
(a) Indemnity for the value of poultry to be destroyed due to infection with or exposure to H5/H7 LPAI;

(b) Indemnity for the value of eggs to be destroyed due to infection or exposure to H5/H7 LPAI; and

(c) Compensation for the cost of cleaning and disinfection (virus elimination) of premises, conveyances, and materials that came into contact with poultry infected with or exposed to H5/H7 LPAI, or, in the case of materials, if the cost of cleaning and disinfection (virus elimination) would exceed the value of the materials or cleaning and disinfection (virus elimination) would be impracticable for any reason, the cost of destruction and disposal for the materials.

§56.7 Mortgage against poultry or eggs.

When poultry or eggs have been destroyed under this part, any claim for indemnity must be presented on forms furnished by APHIS. The owner of the poultry or eggs must certify on the forms that the poultry or eggs covered are, or are not, subject to any mortgage as defined in this part. If the owner states there is a mortgage, the owner and each person holding a mortgage on the poultry or eggs must sign the APHIS-furnished form, consenting to the payment of indemnity to the person specified on the form.

§56.8 Conditions for payment.

(a) When poultry or eggs have been destroyed pursuant to this part, the Administrator shall pay claims to any party with which the owner of the poultry or eggs has entered into a contract for the growing or care of the poultry or eggs. The indemnity the Administrator shall pay to such a party or parties shall be determined as follows:

(1) Divide the value of the contract the owner of the poultry or eggs entered into with another party for the growing and care of the poultry or eggs in dollars by the duration of the contract as it was signed prior to the H5/H7 LPAI outbreak in days;

(2) Multiply this figure by the time in days between the date the other party began to provide services relating to the destroyed poultry or eggs under the contract and the date the poultry or eggs were destroyed due to H5/H7 LPAI.

(b)

(1) If indemnity for the destroyed poultry or eggs is being provided for 100 percent of eligible costs under §56.3(b), the Administrator may pay contractors eligible for indemnity under this section 100 percent of the amount determined in paragraph (a) of this section.
(2) If indemnity for the destroyed poultry or eggs is being provided for 25 percent of eligible costs under §56.3(b), the Administrator may pay contractors eligible for indemnity under this section 25 percent of the amount determined in paragraph (a) of this section.

(c) If a contractor receiving indemnity under this section has received any payment under his or her contract from the owner of the poultry or eggs at the time the poultry or eggs are destroyed, the amount of indemnity for which the contract grower is eligible will be reduced by the amount of the payment the contract grower has already received.

(d) If indemnity is paid to a contractor under this section, the owner of the poultry or eggs will be eligible to receive the difference between the indemnity paid to the growers and the total amount of indemnity that may be paid for the poultry or eggs.

(e) In the event that determination of indemnity to a party with which the owner of destroyed poultry or eggs has entered into a contract for the growing or care of the poultry or eggs using the method described in paragraph (a) of this section is determined to be impractical or inappropriate, APHIS may use any other method that the Administrator deems appropriate to make that determination.

§56.9 Claims not allowed.

(a) The Department will not allow claims arising out of the destruction of poultry unless the poultry have been appraised as prescribed in this part and the owners have signed the appraisal form indicating agreement with the appraisal amount as required by §56.4(a).

(b) The Department will not allow claims arising out of the destruction of poultry unless the owners have signed a written agreement with APHIS in which they agree that if they maintain poultry in the future on the premises used for poultry for which indemnity and/or compensation is paid, they will maintain the poultry in accordance with a plan set forth by the Cooperating State Agency and will not introduce poultry onto the premises until after the date specified by the Cooperating State Agency. Persons who do not maintain their poultry and premises in accordance with this written agreement will not be eligible to receive indemnity and/or compensation under this part.

(c) The Department will not allow claims arising out of the destruction of poultry unless the poultry have been moved or handled by the owner in accordance with an agreement for the control and eradication of H5/H7 LPAI and in accordance with part 56, for any progeny of any poultry unless the poultry have been moved or handled by the owner in accordance with an agreement for the control and eradication of H5/H7 LPAI and in accordance with part 56, or for any poultry that become or have become infected with or exposed to H5/H7 LPAI because of actions not in accordance with an agreement for the control and eradication of H5/H7 LPAI or a violation of this part.

§56.10 Initial State response and containment plan.

(a) In order for poultry owners within a State to be eligible for indemnity and/or compensation for 100 percent of eligible costs under §56.3(b), the State in which the poultry participate in the Plan must have in place an initial State response and containment plan that has been approved by APHIS. The initial State response and containment plan must be developed by the Official State Agency. In States where the Official State Agency is different than the Cooperating State Agency, the

Cooperating State Agency must also participate in the development of the plan. The plan must be administered by the Cooperating State Agency of the relevant State. This plan must include:

(1) Provisions for a standing emergency disease management committee, regular meetings, and exercises, including coordination with any tribal governments that may be affected;
(2) A ~~minimum~~ biosecurity plan for poultry owners based on their flock size as stated in §56.3 and, if applicable, any party that enters into a contract with the owner to grow or care for the poultry or eggs, had in place and was following a biosecurity plan that has been audited by the Official State Agency to ensure that the biosecurity plan is in compliance with the NPIP Biosecurity Principles ~~followed by all poultry producers~~;
(3) Provisions for adequate diagnostic resources;
(4) Detailed, specific procedures for initial handling and investigation of suspected cases of H5/H7 LPAI;
(5) Detailed, specific procedures for reporting test results to APHIS. These procedures must be developed after appropriate consultation with poultry producers in the State and must provide for the reporting only of confirmed cases of H5/H7 LPAI in accordance with §146.13 of this chapter;
(6) Detailed, strict quarantine measures for presumptive and confirmed index cases;
(7) Provisions for developing flock plans for infected and exposed flocks;
(8) Detailed plans for disposal of infected flocks, including preexisting agreements with regulatory agencies and detailed plans for carcass disposal, disposal sites, and resources for conducting disposal, and detailed plans for disposal of materials that come into contact with poultry infected with or exposed to H5/H7 LPAI;
(9) Detailed plans for cleaning and disinfection (virus elimination) of premises, repopulation, and monitoring after repopulation;
(10) Provisions for appropriate control/monitoring zones, contact surveys, and movement restrictions;
(11) Provisions for monitoring activities in control zones;
(12) If vaccination is considered as an option, a written plan for use in place with proper controls and provisions for APHIS approval of any use of vaccine;
(13) Plans for H5/H7 LPAI-negative flocks that provide for quarantine, testing, and controlled marketing; and
(14) Public awareness and education programs regarding avian influenza.

(b) If a State is designated a U.S. Avian Influenza Monitored State, Layers under §146.24(a) of this chapter or a U.S. Avian Influenza Monitored State, Turkeys under §146.44(a) of this chapter, it will lose that status during any outbreak of H5/H7 LPAI and for 90 days after the destruction and disposal of all infected or exposed birds and cleaning and disinfection of all affected premises are completed.

Reason: Making changes to Part 56 provides clarity for indemnity and compensation payments during an H5/H7 LPAI response.

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