Pre-Conference Edition

Proposed Changes Booklet

to be considered at the

NPIP 44th Biennial Conference

FRANKLIN MARRIOTT COOL SPRINGS HOTEL

JUNE 26-28, 2018

Pre-Conference Edition

9-CFR PROPOSED CHANGES

PROPOSAL NUMBER	SUBPART	SUBPART DELEGATES	PAGE	SUBJECT OF PROPOSAL
1.	56, 145, 146, PS	Combined	**6**	Adds and amends definitions of H5/H7 LPAI (exposed) and H5/H7 LPAI (infected)
2.	56	Combined	**9**	Adds size requirements for indemnity eligibility
3.	145	Combined	**10**	Amends requirements for participating dealers
4.	145	Combined	**10**	Amends requirements for participating dealers
5.	145	Combined	**11**	Amends inspections to include all participants and amend requirements
6.	145	Combined	**11**	Proposes the addition of approved tests for Newcastle Disease Virus
7.	145, 146	Combined	**12**	Amends AGID and ELISA testing requirements for Avian Influenza
8.	145, 146	Combined	**13**	Amends stipulations for use of agent detection tests for Avian Influenza
9.	145	B	**14**	Amends U.S. Salmonella Enteritidis Clean Classification Program requirements
10.	145	C	**16**	Amends testing requirements for U.S. AI Clean Classification Program
11.	145	C	**17**	Amends testing requirements for U.S. AI Clean Classification Program
12.	145	C	**18**	Amends testing requirements for U.S. AI Clean Classification Program
13.	145	C	**19**	Proposes a new U.S. H5/H7 AI Clean Classification Program
14.	145	D	**20**	Proposes a new U.S. Newcastle Disease Virus Clean Classification Program
15.	145 146	145 E, 146 E	**24**	Establishes new Subpart J—U.S. Egg/Meat Type Game Bird & Raised for Release Game Bird Breeder Flocks and Products Program
16.	145	E	**31**	Amends U.S. H5.H7 AI Clean Classification Program
17.	145	E	**32**	Amends U.S. Salmonella Monitored Classification Program
18.	145	G	**34**	Amends U.S. Salmonella Enteritidis Clean Classification Program requirements
19.	145	G	**36**	Proposes a new U.S. Newcastle Disease Virus Clean Classification Program
20.	145	H	**40**	Amends U.S. Salmonella Enteritidis Clean Classification Program requirements
21.	145	H	**43**	Proposes a new U.S. Newcastle Disease Virus Clean Classification Program
22.	146	B	**47**	Amends U.S. H5/H7 AI Monitored requirements for pullet flocks
23.	147	Combined	**48**	Allows official delegates to represent more than one state at Biennial Conferences
24.	147	Combined	**49**	Clarifies workshop attendance requirements for trained technicians

PROGRAM STANDARDS PROPOSED CHANGES

PROPOSAL NUMBER	STANDARD	SUBPART DELEGATES	PAGE	SUBJECT OF PROPOSAL
1.	PS-A	Combined	**51**	Clarifies and amends testing protocol for Mycoplasma
2.	PS-A	Combined	**52**	Allows molecular based examination procedures to be used as a screening test for Mycoplasma
3.	PS-A	Combined	**53**	Removes specific AGID testing procedures.
4.	PS-B	Combined	**56**	Amends and clarifies isolation procedures for Salmonella
5.	PS-B	Combined	**63**	Removes outdated testing procedures for the sanitation monitored program
6.	PS-B	Combined	**64**	Updates and clarifies procedure for bacteriological examination of cull chicks and poults for salmonella
7.	PS-C	Combined	**65**	Updates and clarifies hatching egg and hatchery sanitation requirements
8.	PS-C	Combined	**66**	Updates and clarifies cleaning and disinfecting procedures
9.	PS-C	Combined	**68**	Proposes new Dealer Sanitation requirements
10.	PS-C	Combined	**69**	Updates and clarifies flock sanitation procedures
11.	PS-D	Combined	**71**	Proposes the addition of new diagnostic test submissions for Mycoplasma and Salmonella
12.	PS-E	Combined	**72**	Adds audit requirement for breeding flock premises raising more than 500 birds annually
13.	PS-F	145 D, G, H	**See Booklet**	Compartmentalization: Proposes the addition of Newcastle Disease Virus management procedures and audit checklist items
14.	PS-F	145 D, G, H	**See Booklet**	Compartmentalization: Clarifies physical requirement for an Egg Depot receiving/shipment dock
15.	PS-F	145 D, G, H	**See Booklet**	Compartmentalization: Amends and clarifies the audit guidelines and checklists
16.	PS-F	145 D, G, H	**See Booklet**	Compartmentalization: Updates and clarifies compartmentalization language

Present provisions of the National Poultry Improvement Plan are contained in the U.S. Department of Agriculture publication, "National Poultry Improvement Plan and Auxiliary Provisions," and in Title 9 CFR parts 145, 146, 147 and 56.

The detailed procedure for making changes in the Plan is described in the auxiliary provisions, sections 147.41 through 147.48. Copies of the "National Poultry Improvement Plan and Auxiliary Provisions" are available from each Official State Agency or from the National Poultry Improvement Plan staff, Animal and Plant Health Inspection Service, Veterinary Services, Suite 101, 1506 Klondike Road, Conyers, Georgia 30094 or at the NPIP website: www.poultryimprovement.org

Proposed changes and supporting statements in this publication were submitted as provided in section 147.44. They are compiled in this publication for consideration at the 2018 National Plan Conference. This publication is distributed well in advance of the conference so that participants and other interested persons may review the proposed changes and inform conference delegates of their wishes regarding the proposals.

Some proposed changes have a line drawn through a portion of the words while other portions are underscored. The line through the words indicates that they are part of the present provision but would be deleted if the proposal were adopted. The underscored words are the proposed additions to that provision.

Each State is entitled to one official delegate for each of the subparts, B, C, D, E, F, G, H and I of part 145 and B, C, D and E of part 146. Each delegate will act on proposals affecting the provisions of the program which he represents. For reference purposes, delegates are designated as follows:

subpart 145B delegates - representing egg-type chickens
subpart 145C delegates - representing meat-type chickens
subpart 145D delegates - representing turkeys
subpart 145E delegates - representing waterfowl, exhibition poultry, and game birds
subpart 145F delegates - ostrich, emu, rhea, and cassowary
subpart 145G delegates - primary egg-type chickens
subpart 145H delegates - primary meat-type chickens
subpart 145I delegates - representing meat-type waterfowl
subpart 146B delegates - commercial table-egg layers
subpart 146C delegates - commercial meat-type chickens
subpart 146D delegates - commercial meat-type turkeys
subpart 146E delegates -waterfowl, upland gamebirds

This compilation of proposed changes includes, in the margin adjacent to the section reference for each proposal, the delegate entitled to vote on the proposal. Some of the changes proposed apply equally to all participants in which case conference action will be determined by the combined vote of all delegates.

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Proposal No. 1

Delegates: **Combined**

§56.1 Definitions.

~~**H5/H7 LPAI exposed.** At risk of developing H5/H7 LPAI because of association with birds or poultry infected with H5/H7 LPAI, excrement from birds or poultry infected with H5/H7 LPAI, or other material touched by birds or poultry infected with H5/H7 LPAI, or because there is reason to believe that association has occurred with H5/H7 LPAI or vectors of H5/H7 LPAI, as determined by the Cooperating State Agency and confirmed by APHIS.~~

H5/H7 LPAI virus (exposed).

(1) Poultry will be considered to be exposed (not 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; if vaccine is used, methods should be used to distinguish vaccinated birds from birds that are both vaccinated and infected; and
   (ii) Samples collected from the flock using an agent detection test approved by the Department and the Official State Agency 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.

H5/H7 LPAI virus infection (infected).

(1) Poultry will be considered to be 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. ~~; or~~
   ~~(iii) Antibodies to the H5 or H7 subtype of the AI virus that are not a consequence of vaccination have been detected in poultry. If vaccine is used, methods should be used to distinguish vaccinated birds from birds that are both vaccinated and infected. In the case of isolated serological positive results, H5/H7 LPAI infection may be ruled out on the basis of a thorough epidemiological investigation that does not demonstrate further evidence of H5/H7 LPAI infection, as determined by the Cooperating State Agency, the Official State Agency, and APHIS.~~

(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~~, or antibodies to the H5 or H7 subtype of the AI virus have been detected~~ may only be made by the National Veterinary Services Laboratories.

§145.1 Definitions.

H5/H7 LPAI virus (exposed)

(1) Poultry will be considered to be exposed (not 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; if vaccine is used, methods should be used to distinguish vaccinated birds from birds that are both vaccinated and infected; and
   (ii) Samples collected from the flock using an agent detection test approved by the Department and the Official State Agency 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.

H5/H7 LPAI virus infection (infected)

(1) Poultry will be considered to be 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.

§146.1 Definitions.

H5/H7 LPAI virus (exposed)

(1) Poultry will be considered to be exposed (not 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; if vaccine is used, methods should be used to distinguish vaccinated birds from birds that are both vaccinated and infected; and
   (ii) Samples collected from the flock using an agent detection test approved by the Department and the Official State Agency 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.

H5/H7 LPAI virus infection (infected).

(1) Poultry will be considered to be 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. ~~; or~~
   ~~(iii) Antibodies to the H5 or H7 subtype of the AI virus that are not a consequence of vaccination have been detected in poultry. If vaccine is used, methods should be used to distinguish vaccinated birds from birds that are both vaccinated and infected. In the case of isolated serological positive results, H5/H7 LPAI infection may be ruled out on the basis of a thorough epidemiological investigation that does not demonstrate further evidence of H5/H7 LPAI infection, as determined by the Cooperating State Agency, the Official State Agency, and APHIS.~~

(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, ~~or antibodies to the H5 or H7 subtype of the AI virus have been detected~~ may only be made by the National Veterinary Services Laboratories.

Program Standards

Definitions

H5/H7 LPAI virus (exposed)

(1) Poultry will be considered to be exposed (not 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; if vaccine is used, methods should be used to distinguish vaccinated birds from birds that are both vaccinated and infected; and
   (ii) Samples collected from the flock using an agent detection test approved by the Department and the Official State Agency 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 may only be made by the National Veterinary Services Laboratories.

H5/H7 LPAI virus infection (infected)

(1) Poultry will be considered to be 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. ~~; or~~
   ~~(iii) Antibodies to the H5 or H7 subtype of the AI virus that are not a consequence of vaccination have been detected in poultry. If vaccine is used, methods should be used to distinguish vaccinated birds from birds that are both vaccinated and infected. In the case of isolated serological positive results, H5/H7 LPAI infection may be ruled out on the basis of a thorough epidemiological investigation that does not demonstrate further evidence of H5/H7 LPAI infection, as determined by APHIS.~~

(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, ~~or antibodies to the H5 or H7 subtype of the AI virus have been detected~~ may only be made by the National Veterinary Services Laboratories.

Reason: This proposed change adds the definition of H5/H7 LPAI virus infection (infected) and H5/H7 LPAI virus (exposed) to Part 145, Subpart A definitions. The addition of these definitions provides consistency to Parts 145, 146, 56 and Program Standards.

This proposed change amends the definition of H5/H7 LPAI virus infection (infected) and adds the definition of H5/H7 LPAI virus (exposed) to Part 146, Subpart A and Program Standards definitions. The amendment and addition of these definitions provides consistency to Parts 145, 146, 56 and Program Standards.

This proposed change amends the definition of H5/H7 LPAI virus infection (infected) and H5/H7 LPAI virus (exposed) to Part 56.1 definitions. Amending these definitions provides consistency with Parts 145, 146, 56 and Program Standards.

The consistency of H5/H7 LPAI virus (exposed) and H5/H7 LPAI virus infection (infected) definitions define the H5/H7 LPAI transmission risks when test results are reported from an NPIP Authorized Laboratory, NAHLN Laboratory or NVSL. Interpretation of these results by the Department, Official State Agency and Cooperating State Agency provides timely information for the H5/H7 LPAI response as outlined the State's Initial State Response and Containment Plan (ISRCP).

Sponsors: Minnesota H5/H7 LPAI Emergency Disease Management Committee (EDMC)

Proposal No. 2

Delegates: **Combined**

§56.3 Payment of indemnity.

(b) Percentage of costs eligible for indemnity.

Except for poultry that are described by the categories in paragraphs (b)(1) through (b)(3) of this section, the Administrator is authorized to pay 100 percent of the costs, as determined in accordance with §56.4, of the activities described in paragraphs (a)(1) through (a)(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 paragraphs (b)(1) through (b)(3) of this section, the Administrator is authorized to pay 25 percent of the costs of the activities described in paragraphs (a)(1) through (a)(3) of this section:

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

~~(2) The poultry are from a commercial flock or slaughter plant, but the flock or slaughter plant does not participate in the U.S. Avian Influenza Monitored program available to the commercial flock or slaughter plant in part 146 of this chapter; or~~

(2) The poultry are from:

i. A commercial table-egg laying premises with at least 75,000 birds;

ii. A meat-type chicken slaughter plan that slaughters at least 200,000 meat-type chickens in an operating week;

iii. A meat-type turkey slaughter plant that slaughters at least 2 million meat-type turkeys in a 12 month period;

iv. A commercial waterfowl and commercial upland game bird slaughter plant that slaughters at least 50,000 birds annually;

v. 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;

vi. A breeder flock premises with at least 5,000 birds. or

(3) 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.

Reason: Adding the size requirements in this section provides clarity and additional reference for indemnity eligibility. The exemption numbers are already listed in Part 146 Subparts B-E, this proposed change provides an exemption number for breeders participating in Part 145.

Sponsor: Dr. Shauna Voss, Minnesota Board of Animal Health
Dr. Dale Lauer, Minnesota Board of Animal Health
Dr. Michael Kopp, Indiana Board of Animal Health
Mr. Paul Wm. Brennan, Indiana State Poultry Association

Proposal No. 3

Delegates: **145 Combined**

§145.7 Specific provisions for participating dealers.

Dealers in ~~poultry breeding stock~~, hatching eggs, ~~or baby~~ newly-hatched poultry or started poultry shall comply with the ~~all~~ provisions in ~~this part~~ Subpart A and Program Standards that ~~which~~ apply to their operations.

Reason: This proposal closely aligns and defines the types of poultry that dealers are associated with as defined in 145.1. It will also require dealers to act in accordance with plan provisions and applicable sanitation details listed in Program Standards.

Sponsor: Dr. Dale Lauer, Minnesota Board of Animal Health

Proposal No. 4

Delegates: **145 Combined**

§145.7 Specific provisions for participating dealers.

(a) Dealers in poultry breeding stock, hatching eggs, or baby or started poultry shall comply with all provisions in ~~this part~~ Subpart A and the Program Standards that ~~which~~ apply to their operations.
(b) Dealers shall obtain, maintain and comply with licensure and importation requirements for all states where sales are conducted and where products are delivered.
(c) Dealers shall provide to each purchaser a VS Form 9-3 that correctly describes the number and the type of breeding stock, hatching eggs, or baby or started poultry at the time of shipment; the name, physical address and phone number of the purchaser, and the name, physical address and phone number of the dealer. Each VS Form 9-3 shall contain the Report Number of the original hatchery issued VS Form 9-3 listed in "Section 10. Remarks" and also be entered into the dealer's shipping and inventory records. All completed NPIP forms must be returned to the Official State Agency (OSA) within 7 days. The OSAs of the states where business is conducted may also require a weekly sales report submitted by email or fax.
(d) Dealers shall have a biosecurity plan that addresses all aspects of the business including but not limited to the poultry, housing, feed, water, equipment, vehicles and personnel.

Reason: The current language in §145.7 is very generalized and needs more details to address current issues seen with compliance matters with dealers moving poultry and eggs across multiple state lines i.e. incomplete or inaccurate records, non-compliance with state importation statutes, etc.

Sponsor: Dr. Mary Jane Lis
Connecticut Department of Agriculture

Proposal No. 5

Delegates: **145 Combined**

§145.12 Inspections.

(a) Each ~~participating~~ Plan participant ~~hatchery~~ shall be audited at least one time annually or a sufficient number of times each year to satisfy the Official State Agency that the operations ~~of the hatchery~~ are in compliance with the provisions of the Plan and Program Standards.

(b) ~~The~~ R~~r~~ecords ~~of all flocks~~ maintained ~~primarily~~ for production and distribution of hatching eggs and other products shall be made available to and examined annually by a State Inspector. Records shall include but are not limited to VS Form 9-2, "Flock Selecting and Testing Report"; VS Form 9-3, "Report of Sales of Hatching Eggs, Chicks, and Poults"; set and hatch records; egg receipts; and egg/chick orders or invoices. Records shall be maintained for 3 years. On-site inspections of flocks and premises will be conducted if the State Inspector determines that a breach of sanitation, blood testing, or other provisions has occurred for Plan programs for which the flocks have or are being qualified.

Reason: The current plan provisions only require hatcheries be audited annually, there are no auditing requirements for breeding flocks or dealers. To satisfy Official State Agencies that participants comply with plan provisions and Program Standards, this proposal will make certain adequate oversight of all plan participants is conducted at a minimum annually.

Sponsor: Dr. Shauna Voss, Minnesota Board of Animal Health
Dr. Dale Lauer, Minnesota Board of Animal Health

Proposal No. 6

Delegates: **145 Combined**

§145.14 Testing.
(e) *For Newcastle Disease Virus.* The official tests for NDV are the hemagglutination inhibition (HI) test, the enzyme-linked immunosorbent assay (ELISA) test, or a molecular based test.

Reason: The Primary Breeders propose the addition of an NDV Clean program. See corresponding proposal in Program Standards Subpart F.

Sponsor: Primary Breeder Association
Dr. Elena Behnke, Aviagen
Dr. Alberto Torres, Cobb-Vantress
Dr. Travis Schaal, Hy-Line
Dr. Dustin Burch, Aviagen Turkeys

Proposal No. 7

Delegates: **Combined**

§145.14 Testing.

(d) For Avian Influenza.

The official tests for avian influenza are described in paragraphs (d)(1) and (d)(2) of this section:

(1) Antibody detection tests-

(i) Enzyme-linked immunosorbent assay (ELISA) test.

(A) The ELISA test must be conducted using test kits approved by the Department and the Official State Agency and must be conducted in accordance with the recommendations of the producer or manufacturer.

(B) When positive ELISA samples are identified, an AGID test must be conducted within 48 hours.

(ii) ~~The a~~Agar gel immunodiffusion (AGID) test.

~~(A) The AGID test must be conducted on all ELISA-positive samples.~~

(~~B~~A) The AGID test must be conducted using reagents approved by the Department and the Official State Agency.

(~~C~~B) The AGID test for avian influenza must be conducted in accordance with ~~part 147 of this subchapter~~ Program Standard A – Blood Testing Procedures (8) Standard test procedures for avian influenza (a) agar gel immunodiffusion (AGID) test. The test can be conducted on egg yolk or blood samples. The AGID test is not recommended for use in waterfowl.

(~~D~~C) Positive tests for the AGID must be further tested by Federal Reference Laboratories using appropriate tests for confirmation. Final judgment may be based upon further sampling and appropriate tests for confirmation.

§146.13 Testing.

(b) Avian Influenza.

The official tests for avian influenza are described in paragraphs (b)(1) and (b)(2) of this section:

(1) Antibody detection tests-

(i) Enzyme-linked immunosorbent assay (ELISA) test.

(A) The ELISA test must be conducted using test kits approved by the Department and the Official State Agency and must be conducted in accordance with the recommendations of the producer or manufacturer.

(B) When positive ELISA samples are identified, an AGID test must be conducted within 48 hours.

(ii) ~~The a~~Agar gel immunodiffusion (AGID) test.

~~(A) The AGID test must be conducted on all ELISA-positive samples.~~

(~~B~~A) The AGID test must be conducted using reagents approved by the Department and the Official State Agency.

(~~C~~B) The AGID test for avian influenza must be conducted in accordance with ~~part 147 of this subchapter~~ Program Standard A – Blood Testing Procedures (8) Standard test procedures for avian influenza (a) agar gel immunodiffusion (AGID) test. The test can be conducted on egg yolk or blood samples. The AGID test is not recommended for use in waterfowl.

(~~D~~C) Positive tests for the AGID must be further tested by Federal Reference Laboratories using appropriate tests for confirmation. Final judgment may be based upon further sampling and appropriate tests for confirmation.

Reason: When samples are submitted from flocks as part of a pre-movement testing program, positive ELISA samples may not be tested via the AGID test in a timely manner to allow the flock to move. This proposal will require timely testing and reporting of AGID test results when ELISA-positive samples are identified at an NPIP Authorized Laboratory.

Sponsor: Minnesota H5/H7 LPAI Emergency Disease Management Committee (EDMC)

Proposal No. 8

Delegates: **Combined**

§145.14 Testing.
(d) For avian influenza.
The official tests for avian influenza are described in paragraphs (d)(1) and (d)(2) of this section.

(1) Antibody detection tests
  (i) Enzyme-linked immunosorbent assay (ELISA). ELISA must be conducted using test kits approved by the Department and the Official State Agency and must be conducted in accordance with the recommendations of the producer or manufacturer.
  (ii) The agar gel immunodiffusion (AGID) test.
    (A) The AGID test must be conducted on all ELISA-positive samples.
    (B) The AGID test must be conducted using reagents approved by the Department and the Official State Agency.
    (C) The AGID test for avian influenza must be conducted in accordance with part 147 of this subchapter. The test can be conducted on egg yolk or blood samples. The AGID test is not recommended for use in waterfowl.
    (D) Positive tests for the AGID must be further tested by Federal Reference Laboratories using appropriate tests for confirmation. Final judgment may be based upon further sampling and appropriate tests for confirmation.

(2) Agent detection tests. Agent detection tests may be used to detect influenza A ~~matrix gene or protein~~ but not to determine hemagglutinin or neuraminidase subtypes. Samples for agent detection testing should be collected from naturally occurring flock mortality or clinically ill birds.

§146.13 Testing.
(b) Avian influenza.
The official tests for avian influenza are described in paragraphs (b)(1) and (b)(2) of this section.

(1) Antibody detection tests-
  (i) Enzyme-linked immunosorbent assay (ELISA). ELISA must be conducted using test kits approved by the Department and the Official State Agency and must be conducted in accordance with the recommendations of the producer or manufacturer.
  (ii) The agar gel immunodiffusion (AGID) test.
    (A) The AGID test must be conducted on all ELISA-positive samples.
    (B) The AGID test must be conducted using reagents approved by the Department and the Official State Agency.
    (C) The AGID test for avian influenza must be conducted in accordance with part 147 of this subchapter. The test can be conducted on egg yolk or blood samples. The AGID test is not recommended for use in waterfowl.
    (D) Positive tests for the AGID must be further tested by Federal Reference Laboratories using appropriate tests for confirmation. Final judgment may be based upon further sampling and appropriate tests for confirmation.

(2) Agent detection tests. Agent detection tests may be used to detect influenza A ~~matrix gene or protein~~ but not to determine hemagglutinin or neuraminidase subtypes. Samples for agent detection testing should be collected from naturally occurring flock mortality or clinically ill birds.

Reason: This imposes an unnecessary technical restriction on test design and precludes the use of lateral flow antigen immunoassays which target the NP protein.

Sponsor: Dr. Erica Spackman
USDA-Agricultural Research Service

Proposal No. 9

Delegates: 145 B

§145.23 Terminology and classification; flocks and products.

(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.

(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 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 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 positive samples shall be serotyped. The authorized agent shall also collect samples every 30 days after the first sample has been collected.

~~(vi) If a Salmonella vaccine is used that causes positive reactions with pullorum-typhoid antigen, one of the following options must be utilized:~~

~~(A) Administer the vaccine after the pullorum-typhoid testing is done as described in paragraph (d)(1)(vii) of this section.~~

~~(B) If an injectable bacterin or live vaccine that does not spread is used, keep a sample of 350 birds unvaccinated and banded for identification until the flock reaches at least 4 months of age. Following negative serological and bacteriological examinations as described in paragraph (d)(1)(vii) of this section, vaccinate the banded, non-vaccinated birds.~~

~~(vii) Blood samples from 300 non-vaccinated birds as described in paragraph (d)(1)(vi) of this section shall be tested with either pullorum antigen or by a federally licensed Salmonella enteritidis enzyme-linked immunosorbent assay (ELISA) test when the flock is more than 4 months of age. All birds with positive or inconclusive reactions, up to a maximum of 25 birds, shall be submitted to an authorized laboratory and examined for the presence of group D salmonella, in accordance with part 147 of this subchapter. Cultures from positive samples shall be serotyped.~~

(~~viii~~vi) Hatching eggs are collected as quickly as possible, and their sanitation is maintained in accordance with part 147 of this subchapter.

(~~ix~~vii) Hatching eggs produced by the flock 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 ser 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) A non-vaccinated flock shall be eligible for this classification if Salmonella enteritidis (S. enteritidis ser Enteritidis) is isolated from an environmental sample collected from the flock in accordance with paragraph (d)(1)(v) of this section: Provided, That testing is conducted in accordance with paragraph (d)(1)(vii) of this section each 30 days and no positive samples are found.~~

(~~4~~3) In order for a hatchery to sell products of this classification, all products handled shall meet the requirements of the classification.

(~~5~~4) This classification may be revoked by the Official State Agency if the participant fails to follow recommended corrective measures.

Program Standard B—Bacteriological Examination Procedure

(1) Reserved

~~**(1) Laboratory procedure recommended for the bacteriological examination of egg-type and meat type breeding flocks with salmonella enteritidis positive environments.**~~

~~Birds selected for bacteriological examination from egg-type and meat-type breeding flocks positive for Salmonella enteritidis after environmental monitoring should be examined as described in Section B(2)(a) of these Program Standards, with the following exceptions and modifications allowed due to the high number of birds required for examination:~~

~~(a) Except when visibly pathological tissues are present, direct culture, Section B(2)(a)(1) of these standards, may be omitted.~~

(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

~~All reactors to the pullorum-typhoid tests, up to 25 birds, and birds from Salmonella enteritidis (SE) positive environments should be cultured in accordance with both the direct enrichment (paragraph (a)(1)) and selective enrichment (paragraph (a)(2)) procedures described in this section: Provided, if there are more than four reactors to the pullorum-typhoid tests in the flock, a minimum of four reactors as provided for in 9 CFR 145.14(a)(6)(ii) shall be submitted to the authorized laboratory for bacteriological examination. Careful aseptic technique should be used when collecting all tissue samples.~~

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 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 egg-type 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.

Reason: The pullorum-typhoid (PT) agglutination test was added to the NPIP for testing egg-type breeder flocks in the late 1980's. It first shows up in the "white book" dated August 1989 under U.S. Sanitation Monitored. When the Salmonella Enteritidis (SE) outbreak in humans associated with eggs was identified in the late 1980's there was a need to identify infected flocks that may produce contaminated eggs. Since SE is a serogroup D1 Salmonella as is S. Pullorum and S. Gallinarum, it was assumed (hoped) that the PT agglutination test would also detect SE infected flocks. Over time, results have shown that the PT agglutination test is not an effective method for the detection of SE infected flocks.

This proposal only removes the PT agglutination test from the U.S. S. Enteritidis Clean classification. It DOES NOT remove it from the U.S. Pullorum-Typhoid Clean classification. In addition to the fact that the PT agglutination test is not an effective method for detecting SE infected flocks, it causes problems for companies that are vaccinating for *Salmonella*. Also, this change resolves the confusion in Standard B(2)(a) over how many reactors to submit for culture.

Sponsor: Dr. Doug Waltman
Georgia Poultry Laboratory Network

Proposal No. 10

Delegates: **145 C**

§145.33 Terminology and classification; flocks and products.
(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 30 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

(2) ~~During each 90-day period, all multiplier spent fowl, up to a maximum of 30,~~ A sample of 11 birds must be tested ~~serologically~~ and found negative for ~~antibodies for~~ avian influenza within 21 days prior to movement to slaughter.

Reason: Approved antigen and antibody tests should be allowed to determine Avian Influenza Clean status. Approved tests, including PCR, are referenced in CFR 145.14(d). Additionally, striking the "during each 90 day period, all multiplier spent fowl, up to a maximum of 30" will make this program consistent with the language in the AI programs in 145.23 (h) and 145.73 (f).

Sponsor: Dr. Ken Opengart
Keystone Foods

Proposal No. 11

Delegates: **145 C**

§145.33 Terminology and classification; flocks and products.
(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 ~~30~~ 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;

Reason: To correct a previous omission or mistake. A total of 15 birds must be tested in each of the three options to retain the AI Clean classification. (ii) requires 30 birds to be tested, which is inconsistent with the other two options.

Sponsor: Dr. Denise Heard
USDA NPIP Senior Coordinator

Proposal No. 12

Delegates: **145 C**

§145.33 Terminology and classification; flocks and products.
(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 30 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

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

Reason: Approved antigen and antibody tests should be allowed to determine Avian Influenza Clean status. Approved tests, including PCR, are referenced in CFR 145.14(d). **THIS PROPOSAL RECEIVED INTERIM APPROVAL DURING THE 2017 GENERAL CONFERENCE COMMITTEE MEETING.**

Sponsor: Proposal was amended by the GCC during the 2017 GCC meeting and received Interim approval until the 44th NPIP Biennial Conference.

Proposal No. 13

Delegates: **145 C**

§145.33 Terminology and classification; flocks and products.
(n) 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 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

(2) During each 90-day period, all multiplier spent fowl, up to a maximum of 30, must be tested negative for H5/H7 subtypes of avian influenza within 21 days prior to movement to slaughter.

Reason: Creating a Subpart C H5/H7 specific AI Clean program similar to H5/H7 AI programs in Subpart D and Subpart E and allowing approved antibody and/or antigen testing.

Sponsor: Dr. Julie Helm
Clemson Livestock Poultry Health

Proposal No. 14

Delegates: **145 D**

§145.43 Terminology and classification; flocks and products.

(h) ***U.S. Newcastle Disease Virus 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 Newcastle Disease. It is intended to determine the presence of Newcastle Disease Virus in primary breeding turkeys through vaccination and monitoring of each participating breeding flock. A flock and the hatching eggs and poults 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 primary breeding flock that is either:

(i) Vaccinated for Newcastle Disease Virus using USDA approved vaccines and response to vaccination is serologically monitored using an approved test as described in §145.14 when more than 4 months of age and meets the criteria in §145.43(h)(2) to retain classification.

OR

(ii) Unvaccinated for Newcastle Disease Virus in which a minimum of 30 birds have tested negative to ND using an approved test as described in §145.14 when more than 4 months of age and meets criteria in §145.43(h)(3) to retain classification.

(2) To retain this classification, **for vaccinated flocks**,

(i) Vaccines for NDV must be USDA-approved vaccines manufactured with low-virulence live strains during early stages of development up to grow-out, and killed vaccines as final vaccination no later than 6 weeks prior to the onset of egg production

AND

(ii) The flock has been monitored for antibody response using approved serological tests as listed in §145.14 and the results are compatible with immunological response against ND vaccination

AND

(iii) Testing must include a minimum of 30 birds with a serologic monitoring program beginning at approximately 10 weeks of age and not longer than every 90 days thereafter.

(3) To retain this classification **for unvaccinated flocks**,

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

(ii) 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) 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.

(4) Newcastle Disease Virus must be a disease reportable to the responsible State authority (State veterinarian, etc.) by all licensed veterinarians. To accomplish this, all laboratories (private, State, and university laboratories) that perform diagnostic procedures on poultry must examine all submitted cases of unexplained respiratory disease, egg production drops, and mortality for NDV.

§145.45 Terminology and classification; compartments.

(a) U.S. H5/H7 Avian Influenza and NDV Clean Compartment.

This program is intended to be the basis from which the primary turkey 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 a primary breeding-hatchery company that is free of H5/H7 avian influenza (AI) and NDV. For the purpose of the compartment, avian influenza is defined according to the OIE Terrestrial Animal Health Code Chapter 10.4 and Newcastle Disease Virus is defined according to the OIE Terrestrial Animal Health Code Chapter 10.9. This compartment has the purpose of protecting the defined subpopulation and avoiding the introduction and spread of H5/H7 AI and NDV 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 primary breeder company will define the compartment with respect to H5/H7 AI and NDV. 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 NDV that is separate from birds and poultry outside the compartment. The Official State Agency and the Service must approve all documentation submitted to substantiate the defined compartment as adequate to qualify for epidemiological separation from other potential sources of infection of H5/H7 AI and NDV. 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. H5/H7 Avian Influenza Clean in accordance with §145.43(g) and NDV Clean in accordance with §145.43(h). 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 NDV, as described in §145.14(d) and §145.14(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 NDV- 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 primary 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 primary 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 NDV. 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 NDV.

(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 NDV, 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 primary 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:

(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 NDV. 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 NDV and the associated risk pathways in which the components of the compartment are located.

(vi) Approval or denial. Based on this 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. H5/H7 Avian Influenza and NDV Clean.

(2) Company activities for maintenance of the compartment.

(i) The primary 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. H5/H7 Avian Influenza and NDV Clean classifications, surveillance for H5/H7 AI and NDV 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 NDV in primary 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 NDV 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 will 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. H5/H7 Avian Influenza and NDV 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. H5/H7 Avian Influenza Clean program as described in §145.43(g) and NDV Clean program as described in §145.43(h) 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 primary 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 primary 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 primary 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, ~~and~~ 145.43(g), and 145.43(h).

(4) Emergency response and notification. In the case of a confirmed positive of H5/H7 AI and/or NDV 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 NDV 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 Primary Breeders propose the addition of an NDV Clean program. See corresponding proposal in Program Standards Subpart F.

Sponsor: Primary Breeder Association
Dr. Dustin Burch, Aviagen Turkeys
Dr. Elena Behnke, Aviagen
Dr. Alberto Torres, Cobb-Vantress
Dr. Travis Schaal, Hy-Line

Proposal No. 15

Delegates: **145 E, 146 E**

Subpart E—Special Provisions for Hobbyist and Exhibition ~~Waterfowl, Exhibition~~ Poultry, and ~~Game Bird~~ Raised-for-Release Waterfowl Breeding Flocks and Products

§145.51 Definitions.

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

Exhibition Poultry. Domesticated fowl which are bred for the combined purposes of meat or egg production and competitive showing.

Hobbyist Poultry. Domesticated fowl which are bred for the purpose of meat and/or egg production on a small scale as determined by the Official State Agency.

Raised-for-Release Waterfowl. Domesticated fowl that normally swim, such as ducks and geese, grown under confinement for the primary purpose of producing eggs, chicks, started, or mature birds for release on game preserves or in the wild.

~~***Game birds***. Domesticated fowl such as pheasants, partridge, quail, grouse, and guineas, but not doves and pigeons.~~

~~***Waterfowl.*** Domesticated fowl that normally swim, such as ducks and geese.~~

§145.52 Participation.

Participating flocks of hobbyist and exhibition ~~waterfowl, exhibition~~ poultry, ~~and game birds,~~ raised-for-release waterfowl, and the eggs, chicks, started, and mature ~~and baby~~ poultry produced from them shall comply with the applicable general provisions of subpart A of this part and the special provisions of this subpart E. The special provisions that apply to meat-type waterfowl flocks are found in subpart I of this part. The special provisions that apply to game bird flocks are found in subpart J of this part.

(c) It is recommended that waterfowl flocks and gallinaceous flocks ~~in open-air facilities~~ be kept separate.

(f) All participating raised-for-release waterfowl flocks, regardless of whether they are breeders or non-breeders, shall be enrolled under this part 145 subpart E.

§145.53 Terminology and classification; flocks and products.

Participating flocks, and the eggs, chicks, started, and mature ~~and baby~~ 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.

(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 one of the following paragraphs (b)(1) through (5) of this section (See §145.14 relating to the official blood test where applicable.):

(5) It is a primary breeding flock located in a State determined to be in compliance with the provisions of paragraph (b)(4) of this section, 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 within the past 12 months with no reactors: *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 when a flock is a hobbyist or ~~exhibition waterfowl or~~ exhibition poultry primary breeding flock located in a State which has been deemed to be a U.S. Pullorum-Typhoid Clean State for the past three years, and during which time no isolation of pullorum or typhoid has been made that can be traced to a source in that State, a bacteriological examination monitoring program or a serological examination monitoring program acceptable to the Official State Agency and approved by the Service may be used in lieu of annual blood testing.

(e) ***U.S. H5/H7 Avian Influenza Clean***.

This program is intended to be the basis from which the breeding-hatchery and raised-for-release waterfowl 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~~ breeding flocks and raised-for-release waterfowl through routine surveillance of each participating ~~breeding~~ flock. A flock or premise, and the hatching

eggs, ~~and~~ chicks, started, and mature poultry produced from it, will qualify for this classification when the Official State Agency determines that it has met one of the following requirements:

(1) It is a primary or multiplier breeding flock in which a minimum of 30 birds has been tested negative to the H5 and H7 subtypes of avian influenza as provided in §145.14(d) when more than 4 months of age; *Provided*, that waterfowl flocks may test a minimum of 30 cloacal swabs for virus isolation. To retain this classification:

(i) A sample of at least 30 birds must be tested negative at intervals of ~~180~~ 90 days; or

(ii) A sample of fewer than 30 birds may be tested, and found to be negative, at any one time if all pens are equally represented and a total of 30 birds are tested within each ~~180~~90-day period.

~~(2) It is a multiplier breeding flock in which a minimum of 30 birds has been tested negative to the H5 and H7 subtypes of avian influenza as provided in §145.14(d) when more than 4 months of age; *Provided*, that waterfowl flocks may test a minimum of 30 cloacal swabs for virus isolation. To retain this classification:~~

~~(i) A sample of at least 30 birds must be tested negative at intervals of 180 days; or~~

~~(ii) A sample of fewer than 30 birds may be tested, and found to be negative, at any one time if all pens are equally represented and a total of 30 birds are tested within each 180-day period.~~

~~(3) A sample of at least 30 birds must be tested and found negative to H5/H7 avian influenza within 21 days prior to movement to slaughter.~~

(2) For participants with non-breeding flocks retained for raised-for-release or other purposes on the same premises as a breeding flock, a representative sample of at least 30 birds from the participating premise must be tested negative to the H5 and H7 subtypes of avian influenza as provided in §145.14(d) when more than 4 months of age, every 90 days.

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

§145.101 Definitions.

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

Egg/Meat-Type Bird. Birds grown under confinement for the primary purpose of producing eggs and/or meat for human consumption.

Raised-for-Release Bird. Birds grown under confinement for the primary purpose of producing eggs, chicks, started, or mature birds for release on game preserves or in the wild.

Game birds. Domesticated fowl such as pheasants, partridge, quail, grouse, and guineas, but not doves and pigeons.

Categories of Operations:

(a) Breeder. An individual or business that maintains a breeding flock for the purpose of producing eggs, chicks, started, or mature birds. A breeder that is also a hatchery and/or grower shall be categorized as a breeder.

(b) Hatchery. An individual or business that does not have a breeding flock, but hatches eggs for the purpose of producing chicks, started, or mature birds. A hatchery that is also a grower shall be categorized as a hatchery.

(c) Grower. An individual or business that does not have a breeding flock or hatchery, but raises birds for the purpose of selling started or mature birds.

(d) Dealer. An individual or business that resells eggs, chicks, started, or mature birds. Products a dealer handles are typically resold within 30 days or less.

Categories of Products:

(a) Egg. Laid by a female bird for the purpose of hatching a chick.

(b) Chick. A bird that is newly hatched from an egg.

(c) Started Bird. A bird that is between the age of a newly, hatched chick and a mature bird.

(d) Mature Bird. A bird that is fully colored and has reached the average maximum size specific to each species.

§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 J.

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

(b) Hatching eggs produced by breeding flocks shall be nest clean, fumigated, or otherwise sanitized in accordance with part 147 of this subchapter.

(c) It is recommended that gallinaceous flocks and waterfowl flocks be kept separate.

(d) 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.

(e) 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.

(f) All participating raised-for-release game bird flocks, regardless of whether they are breeders or non-breeders, shall be enrolled under this part 145 subpart J.

(g) A breeder, hatchery, or grower may also be a dealer without being categorized as a dealer. To resell products under the assigned NPIP number and avoid losing NPIP flock classifications, products must be purchased from an NPIP participant with equal or greater classifications or from a flock with equivalent or greater testing requirements under official supervision.

(h) Subject to the approval of the Service and the Official State Agencies in the importing and exporting States, participating flocks may report poultry sales to importing States by using either VS Form 9-3, "Report of Sales of Hatching Eggs, Chicks, and Poults," or by using an invoice form (9-3I) approved by the Official State Agency and the Service to identify poultry sales to clients. If the 9-3I form is used, the following information must be included on the form:

(1) The form number "9-3I", printed or stamped on the invoice;

(2) The seller name and address;

(3) The date of shipment;

(4) The invoice number;

(5) The purchaser name and address;

(6) The quantity of products sold;

(7) The NPIP hatchery approval number of the shipping hatchery;

(8) Identification of the products by bird variety or by NPIP stock code as listed in the NPIP APHIS 91-55-078 appendix; and

(9) The appropriate NPIP illustrative design in §145.10. One of the designs in §145.10(b) or (g) must be used. The following information must be provided in or near the NPIP design:

(i) The NPIP State number and NPIP approval number; and

(ii) The NPIP classification for which product is qualified (e.g., U.S. Pullorum-Typhoid Clean).

§145.103 Terminology and classification; flocks and products.

Participating flocks, and the eggs, chicks, started, and mature birds 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 one of the following paragraphs (b)(1) through (3) of this section (See §145.14 relating to the official blood test where applicable.):

(1) It has been officially blood tested within the past 12 months with no reactors.

(2) It is a started or mature bird flock that 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 or S. gallinarum is isolated;

(ii) The flock is composed entirely of birds that originated from U.S. Pullorum-Typhoid Clean breeding flocks or from flocks that met equivalent requirements under official supervision; and

(iii) The flock is located on a premises where a flock not classified as U.S. Pullorum-Typhoid Clean was located the previous year; *Provided,* That an Authorized Testing Agent must blood test up to 300 birds per flock, as described in §145.14, if the Official State Agency determines that the flock has been exposed to pullorum-typhoid. In making determinations of exposure and setting the number of birds to be blood tested, the Official State Agency shall evaluate the results of any blood tests, described in §145.14(a)(1), that were performed on an unclassified flock located on the premises during the previous year; the origins of the unclassified flock; and the probability of

contacts between the flock for which qualification is being sought and (a) infected wild birds, (b) contaminated feed or waste, or (c) birds, equipment, supplies, or personnel from flocks infected with pullorum-typhoid.

(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 within the past 12 months with no reactors: *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:

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

(ii) 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;

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

(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 or S. gallinarum is isolated;

(v) 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 the National Poultry Improvement Plan will conduct an investigation;

(vi) 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;

(vii) 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;

(viii) The flock is located in a State in which pullorum disease or fowl typhoid is not know to exist nor to have existed in hatchery supply flocks within the State during the preceding 24 months.

(ix) Discontinuation of any of the conditions or procedures described in paragraphs (b)(3)(i), (ii), (iii), (iv), (v), (vi), (vii), and (viii) 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.

(c) ***U.S. H5/H7 Avian Influenza Clean.***

This program is intended to be the basis from which the game bird 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 game bird flocks through routine surveillance of each participating flock. A flock or premise, and the hatching eggs, chicks, started, and mature birds produced from it, will qualify for this classification when the Official State Agency determines that it has met the following requirements:

(1) It is a flock in which a minimum of 30 birds has been tested negative to the H5 and H7 subtypes of avian influenza as provided in §145.14(d) when more than 4 months of age. To retain this classification:

(i) A sample of at least 30 birds must be tested negative at intervals of 90 days; or

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

(2) For participants with non-breeding flocks retained for raised-for-release or other purposes on the same premises as a breeding flock, a representative sample of at least 30 birds from the participating premise must be tested negative to the H5 and H7 subtypes of avian influenza as provided in §145.14(d) when more than 4 months of age, every 90 days.

(d) ***U.S. Salmonella Monitored.***

This program is intended to be the basis from which the game bird industry may conduct a program for the prevention and control of salmonellosis. It is intended to reduce the incidence of *Salmonella* organisms in day-old poultry through an effective and practical sanitation program in the hatchery. This will afford other segments of the poultry industry an opportunity to reduce the incidence of *Salmonella* in their products. The following requirements must be met for a flock to be of this classification:

(1) An Authorized Agent shall collect a minimum of five environmental samples, e.g., chick papers, hatching trays, and chick transfer devices, from the hatchery at least every 30 days. Testing must be performed at an authorized laboratory.

(2) To claim products are of this classification, all products shall be derived from a hatchery that meets the requirements of the classification.

(3) This classification may be revoked by the Official State Agency if the participant fails to follow recommended corrective measures.

§145.104 Terminology and classification; States.

(a) *U.S. Pullorum-Typhoid Clean State.*

(1) A State will be declared a U.S. Pullorum-Typhoid Clean State when it has been determined by the Service that:

(i) The State is in compliance with the provisions contained in §145.23(b)(3)(i) through (vii), §145.33(b)(3)(i) through (vii), §145.43(b)(3)(i) through (vi), §145.53(b)(3)(i) through (vii), §145.73(b)(2)(i), §145.83(b)(2)(i), §145.93(b)(3)(i) through (vii), and 145.103(b)(3)(i) through (ix) .

(ii) No pullorum disease or fowl typhoid is known to exist nor to have existed in hatchery supply flocks within the State during the preceding 12 months: *Provided*, That pullorum disease or fowl typhoid found within the preceding 24 months in waterfowl, exhibition poultry, and game bird breeding flocks will not prevent a State, which is otherwise eligible, from qualifying.

(2) Discontinuation of any of the conditions described in paragraph (a)(1)(i) of this section, or repeated outbreaks of pullorum or typhoid occur in hatchery supply flocks described in paragraph (a)(1)(ii) of this section, or if an infection spreads from the originating premises, the Service shall have grounds to revoke its determination that the State is entitled to this classification. 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 for a hearing in accordance with rules of practice adopted by the Administrator.

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

§146.51 Definitions.

~~Commercial upland~~ Egg/Meat-Type game birds. ~~Upland game bird pheasants, quail, or partridges~~ Domesticated fowl such as pheasants, partridge, quail, grouse, and guineas, but not doves and pigeons grown under confinement for the primary purposes of producing eggs and/or meat for human consumption.

~~Commercial~~ Egg/Meat-Type waterfowl. Domesticated ducks or geese grown under confinement for the primary purposes of producing eggs and/or meat for human consumption.

~~Commercial upland~~ Meat-Type game bird slaughter plant. A ~~commercial upland~~ meat-type game bird slaughter plant that is federally inspected or under State inspection that the U.S. Department of Agriculture's Food Safety and Inspection Service has recognized as equivalent to Federal inspection.

~~Commercial~~ Meat-Type waterfowl slaughter plant. A ~~commercial~~ meat-type waterfowl slaughter plant that is federally inspected or under State inspection that the U.S. Department of Agriculture's Food Safety and Inspection Service has recognized as equivalent to Federal inspection.

~~Raised-for-release upland game birds.~~ ~~Pheasants, quail, and partridge that are raised under confinement for release in game preserves and are not breeding stock.~~

~~Raised-for-release waterfowl.~~ ~~Waterfowl that are raised under confinement for release in game preserves and are not breeding stock.~~

Shift. The working period of a group of employees who are on duty at the same time.

§146.52 Participation.

(a) Participating ~~commercial upland~~ meat-type game bird slaughter plants, ~~commercial~~ meat-type waterfowl slaughter plants, ~~raised-for-release upland game bird premises, and raised-for-release waterfowl premises,~~ and ~~commercial upland~~ egg-type game bird and ~~commercial~~ egg-type waterfowl premises producing eggs for human consumption ~~premises~~ shall comply with the applicable general provisions of subpart A of this part and the special provisions of this subpart E.

(b) ~~Commercial waterfowl~~ Meat-type game bird slaughter plants and ~~commercial upland game bird~~ Meat-type waterfowl slaughter plants that slaughter fewer than 50,000 birds annually are exempt from the special provisions of this subpart E.

(c) ~~Raised-for-release upland game bird premises, raised-for-release waterfowl premises, and commercial upland~~ Egg-type game bird and ~~commercial~~ Egg-type waterfowl ~~producing eggs for human consumption~~ premises ~~that raise~~ with fewer than 25,000 birds ~~annually~~ are exempt from the special provisions of this subpart E.

§146.53 Terminology and classification; slaughter plants and premises.

Participating slaughter plants and 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.***

This program is intended to be the basis from which the ~~commercial waterfowl~~ egg/meat-type game bird and ~~commercial upland game bird~~ egg/meat-type waterfowl 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 ~~commercial waterfowl~~ egg/meat-type game birds and ~~commercial upland game birds~~ egg/meat-type waterfowl through routine surveillance of each participating slaughter plant or, in the case of egg-producing flocks, the regular surveillance of these flocks. A slaughter plant or flock will qualify for this classification when the Official State Agency determines that it has met one of the following requirements:

(1) It is a ~~commercial upland~~ meat-type game bird slaughter plant or ~~commercial~~ meat-type waterfowl slaughter plant where a minimum of 11 birds per shift are tested negative for the H5/H7 subtypes of avian influenza, as provided in §146.13(b), at slaughter;

(2) It is a ~~commercial upland~~ meat-type game bird slaughter plant or ~~commercial~~ meat-type waterfowl slaughter plant that only accepts ~~commercial upland~~ egg/meat-type game birds or ~~commercial~~ egg/meat-type waterfowl from flocks where a minimum of 11 birds per flock have been tested negative for the H5/H7 subtypes of avian influenza, as provided in §146.13(b), no more than 21 days prior to slaughter; ~~or~~

(3) It is a ~~commercial upland~~ meat-type game bird slaughter plant or ~~commercial~~ meat-type waterfowl slaughter plant that has an ongoing active and passive surveillance program for H5/H7 subtypes of avian influenza that is approved by the Official State Agency and the Service.

(4) It is an ~~commercial upland~~ egg-type game bird or egg-type waterfowl flock that produces eggs for human consumption where a minimum of 11 birds per flock have been tested negative to the H5/H7 subtypes of avian influenza as provided in §146.13(b) within 30 days of disposal or within a 12 month period.

(5) It is an ~~commercial upland~~ egg-type game bird or egg-type waterfowl flock that has an on-going active and passive surveillance program for H5/H7 subtypes of avian influenza that is approved by the Official State Agency and the Service.

~~**(b)** ***U.S. H5/H7 Avian Influenza Monitored***.~~

~~This program is intended to be the basis from which the raised-for-release upland game bird and raised-for-release waterfowl industries 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 through routine surveillance of each participating premises. A premises will qualify for the classification when the Official State Agency determines that a representative sample of 30 birds from the participating premises has been tested with negative results for the H5/H7 subtypes of avian influenza, as provided in §146.13(b), every 90 days.~~

Reason: The size, complexity, and uniqueness of the game bird industry has made the facilitation of NPIP provisions extremely difficult and confusing for everyone involved. The current definitions and provisions do not match the production methods and end uses for the game bird industry. As a result, there is a sufficient need to separate the game bird industry from the rest of the hobby and exhibition poultry industry.

We recommend the following changes to simplify the NPIP program and better protect each industry by clarifying where farms should be enrolled, how they should be testing, and promote the uniform application of NPIP provisions throughout the country:

(145E) Remove all references to game birds, because of the creation of subpart 145J. Use more general definitions and cleanup the language to ensure all poultry operations can be captured in 145 E. Create a definition for a hobbyist operation, since it is not currently defined.

(145J) Add 145 J to create a subpart for the game bird industry for the reasons stated above. Combine the breeding and grow out of game birds, rather than having them separate in 145E & 146E. The change will allow all game bird operations to be listed together on the NPIP website. In addition, grow out birds can become breeders when they are released or sold. Therefore, the same testing and classifications as breeder flocks should be available to grow out flocks.

Allow premises with breeders and grow out birds to be covered under one NPIP number, because breeders typically also grow out birds on the same premises. In addition, replacement breeders are usually raised with grow out birds, and spent breeders are typically reconditioned and sold with grow out birds.

Define egg/meat-type vs raised-for-release gamebirds, since it isn't done in part 145. Categorize the types of operations and products that exist in the game bird industry to provide information that allows NPIP officials to accurately register participants and enforce the proper provisions necessary to keep the industry safe.

Add "nest clean", in addition to fumigating and disinfecting, to accurately reflect egg production methods of birds that lay eggs on wire or away from litter.

Allow a breeder, hatchery, or grower, to also be a dealer without the dealer categorization to simplify the registration and record keeping process. A clear statement is provided that mandates products must be purchased from NPIP participants with equal or greater classifications to prevent a loss of classifications. It encourages everyone in the industry to belong to NPIP and test accordingly to ensure products are safer to move and more desirable.

Simplify the Pullorum-Typhoid Clean section to reflect the terminology and production methods in the game bird industry. Include started and mature birds, and define how they can be classified as PT Clean.

Increase the H5/H7 AI Clean testing requirements from 180 to 90 days to match the H5/H7 AI Monitored requirements that were in part 146 subpart E for game birds.

(146E) Update and standardize the layout, terminology, and definitions to match the other subparts within 146. Replace the term "commercial" with "egg/meat-type" to match the other subparts and eliminate confusion with the true definition of the word "commercial". Eliminate all references to grow out and raised-for-release production, since it is included in part 145. Allow grow out birds to be included with part 145 to increase the testing and classifications available to the flocks making the industry safer. It also enrolls all game bird operations together to make it much easier for NPIP officials to facilitate the program.

Sponsor: Troy L. Laudenslager, Mahantongo Game Farms
North American Gamebird Association
Dr. Nan Hanshaw, Chief Animal Health Division, PA Department of Agriculture
Dr. Eva Wallner-Pendleton, Penn State Animal Diagnostic Laboratory
Dr. Doug Anderson, GA Poultry Lab Network

Proposal No. 16

Delegates: **145 E**

§145.53 Terminology and classification; flocks and products.

(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 breeding flocks through routine surveillance of each participating breeding flock. A flock, and the hatching eggs, ~~and~~ chicks, and mature poultry produced from it, will qualify for this classification when the Official State Agency determines that it has met ~~one of~~ the following requirements:

(1) It is a primary or multiplier breeding flock in which a minimum of 30 birds has been tested negative to the H5 and H7 subtypes of avian influenza as provided in §145.14(d) when more than 4 months of age; Provided, that waterfowl flocks may test a minimum of 30 cloacal swabs for virus isolation. To retain this classification:

(i) A sample of at least 30 birds must be tested negative at intervals of ~~180~~ 90 days; **or**

(ii)A sample of fewer than 30 birds may be tested, and found to be negative, at any one time if all pens are equally represented and a total of 30 birds are tested within each ~~180~~ 90-day period.

(2) For participants with non-breeding poultry flocks on the same breeding flock premises that are retained for raise-for-release or other purposes, a minimum of 30 birds must be tested and negative to the H5 and H7 subtypes of avian influenza as provided in §145.14(d) when more than 4 months of age; Provided, that waterfowl flocks may test a minimum of 30 cloacal swabs for virus isolation. To retain this classification:

(i) A sample of at least 30 birds must be tested negative at intervals of 90 days;

or

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

~~(2) It is a multiplier breeding flock in which a minimum of 30 birds has been tested negative to the H5 and H7 subtypes of avian influenza as provided in §145.14(d) when more than 4 months of age; Provided, that waterfowl flocks may test a minimum of 30 cloacal swabs for virus isolation. To retain this classification:~~

~~(i) A sample of at least 30 birds must be tested negative at intervals of 180 days;~~

~~**or**~~

~~(ii) A sample of fewer than 30 birds may be tested, and found to be negative, at any one time if all pens are equally represented and a total of 30 birds are tested within each 180-day period.~~

~~(3) A sample of at least 30 birds must be tested and found negative to H5/H7 avian influenza within 21 days prior to movement to slaughter.~~

Reason: To provide better credibility to these classifications, requirements for Subpart 145 E, U.S. H5/H7 Avian Influenza Clean participation (145.53) should be equivalent to or greater than the Subpart 146 E, H5/H7 Avian Influenza Monitored participation requirements.

Sponsor: Dr. Shauna Voss, Minnesota Board of Animal Health
Dr. Dale Lauer, Minnesota Board of Animal Health
Scott Meyer, Oakwood Game Farm
Michael Forsgren, Forsgren Pheasant Farm

Proposal No. 17

Delegates: **145 E**

§145.53 Terminology and classification; flocks and products.
(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 day-old poultry through an effective and practical sanitation and testing 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. The following requirements must be met for a flock or hatchery to be eligible for ~~of~~ this classification as determined by the Official State Agency:

~~(1) An Authorized Agent shall collect a minimum of five environmental samples, e.g., chick papers, hatching trays, and chick transfer devices, from the hatchery at least every 30 days. Testing must be performed at an authorized laboratory.~~

~~(2) To claim products are of this classification, all products shall be derived from a hatchery that meets the requirements of the classification.~~

~~(3) This classification may be revoked by the Official State Agency if the participant fails to follow recommended corrective measures.~~

(1) Hatcheries must be kept in a sanitary condition as applicable and as outlined in plan provisions §145.6 Specific provisions for participating hatcheries and NPIP Program Standards C.

(2) An Authorized Agent shall collect and submit to an authorized laboratory:

(i) A minimum of five samples from the hatchery at least every 30 days while in operation. These samples may include: hatchery debris, swabs from hatchers, setters, hatchery environment, hatchery equipment, sexing tables and belts, meconium, chick box papers, hatching trays, or chick transfer devices. Samples will be examined bacteriologically at an authorized laboratory for *Salmonella*; and

(ii) Environmental samples from each breeder flock in accordance with Program Standards Standard B (3)(a)(1) pre-lay (before egg production begins) and mid-lay (mid-point of scheduled egg production) when the flock is in production. Samples will be examined bacteriologically at an authorized laboratory for *Salmonella*.

(3) If *Salmonella* is identified through this testing:

(i) A qualified poultry health professional knowledgeable with the operation will be consulted and will conduct periodic on-site visits until samples at the hatchery are *Salmonella* negative.

(ii) As recommended by the poultry health professional, additional testing will be conducted to determine the source of *Salmonella.*

(iii)The participant shall provide a corrective action plan to the OSA within ten business days of the final test report. The corrective action plan shall include:

(A) Notification of the customer and chick distributor(s) of the hatchery status;

(B) Plans for cleaning and disinfection of the hatchery and/or poultry house per NPIP Program Standards C;

(C) Development of appropriate and practical *Salmonella* control measures at the breeder flock and hatchery acceptable to the OSA.

(D) A review of the breeder flock biosecurity plan to evaluate *Salmonella* control measures.

(iv) Allow OSA officials to inspect the hatchery and breeder flocks upon request to monitor compliance.

~~(2)~~ (4) To claim products are of this classification, all products shall be derived from a flock or hatchery that meets the requirements of the classification.

~~(3)~~ (5) This classification may be revoked by the Official State Agency if the participant fails to follow recommended corrective measures.

Reason: Backyard poultry flocks have increased in popularity in recent years. Poultry are well recognized as possible carriers of *Salmonella* which result in thousands of illnesses each year, with some of these illnesses resulting in human death. Between 1996 and 2017, 65 outbreaks of human *Salmonella* infections linked to live poultry from mail-order hatcheries were documented, however, these outbreaks likely underestimate the true burden of illness resulting from contact with backyard poultry. Live poultry such as chickens and ducks can be carrying *Salmonella* bacteria but appear healthy and clean, with no sign of illness, and as raising backyard flocks becomes more popular, more people are having contact with chickens and ducks – and may not understand the risk of *Salmonella* infection.

The sponsors of this proposal recognize that additional poultry dealer and retail outlet sanitation measures, public education and public awareness efforts are needed to further reduce the number of human *Salmonella* cases. This proposal is a first step in the *Salmonella* surveillance and control process. Currently the Subpart E U.S. *Salmonella* Monitored classification only requires hatchery testing which is inadequate to assess the *Salmonella* burden from

hatching eggs feeding into the hatchery. This proposal will outline a process that Subpart E participants who wish to obtain this classification can follow to reduce *Salmonella* in both breeder flocks and hatcheries.

Sponsors: Dr. Shauna Voss, Minnesota Board of Animal Health
Dr. Dale Lauer, Minnesota Board of Animal Health
Dr. Nanette Hanshaw, Pennsylvania Department of Agriculture
Dr. Doug Waltman, Georgia Poultry Laboratory Network

Proposal No. 18

Delegates: **145 G**

§145.73 Terminology and classification; flocks and products.

(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 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 positive samples shall be serotyped. The Authorized Agent shall also collect samples every 30 days after the first sample has been collected.

~~(vi) If a Salmonella vaccine is used that causes positive reactions with pullorum-typhoid antigen, one of the following options must be utilized.~~

~~(A) Administer the vaccine after the pullorum-typhoid testing is done as described in paragraph (d)(1)(vii) of this section.~~

~~(B) If an injectable bacterin or live vaccine that does not spread is used, keep a sample of 350 birds unvaccinated and banded for identification until the flock reaches at least 4 months of age. Following negative serological and bacteriological examinations as described in paragraph (d)(1)(vii) of this section, vaccinate the banded, non-vaccinated birds.~~

~~(vii) Blood samples from 300 non-vaccinated birds as described in paragraph (d)(1)(vi) of this section shall be tested with either pullorum antigen or by a federally licensed Salmonella enteritidis enzyme-linked immunosorbent assay (ELISA) test when the flock is more than 4 months of age. All birds with positive or inconclusive reactions, up to a maximum of 25 birds, shall be submitted to an authorized laboratory and examined for the presence of group D salmonella, in accordance with part 147 of this subchapter. Cultures from positive samples shall be serotyped.~~

(~~viii~~vi) Hatching eggs are collected as quickly as possible and are handled as described in §147.22 of this subchapter and are sanitized or fumigated (see §147.25 of this subchapter).

(~~ix~~vii) Hatching eggs produced by the flock 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) A non-vaccinated flock shall be eligible for this classification if SE is isolated from an environmental sample collected from the flock in accordance with paragraph (d)(1)(v) of this section: Provided, That testing is conducted in accordance with paragraph (d)(1)(vii) of this section each 30 days and no positive samples are found.~~

(~~4~~3) In order for a hatchery to sell products of this classification, all products handled shall meet the requirements of the classification.

(~~5~~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.

Program Standard B—Bacteriological Examination Procedure

(1) Reserved

~~**(1) Laboratory procedure recommended for the bacteriological examination of egg-type and meat type breeding flocks with salmonella enteritidis positive environments.**~~

~~Birds selected for bacteriological examination from egg-type and meat-type breeding flocks positive for Salmonella enteritidis after environmental monitoring should be examined as described in Section B(2)(a) of these Program Standards, with the following exceptions and modifications allowed due to the high number of birds required for examination:~~

~~(a) Except when visibly pathological tissues are present, direct culture, Section B(2)(a)(1) of these standards, may be omitted.~~

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

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

~~All reactors to the pullorum-typhoid tests, up to 25 birds, and birds from Salmonella enteritidis (SE) positive environments should be cultured in accordance with both the direct enrichment (paragraph (a)(1)) and selective enrichment (paragraph (a)(2)) procedures described in this section: Provided, if there are more than four reactors to the pullorum-typhoid tests in the flock, a minimum of four reactors as provided for in 9 CFR 145.14(a)(6)(ii) shall be submitted to the authorized laboratory for bacteriological examination. Careful aseptic technique should be used when collecting all tissue samples.~~

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 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 egg-type 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.

Reason: The pullorum-typhoid (PT) agglutination test was added to the NPIP for testing egg-type breeder flocks in the late 1980's. It first shows up in the "white book" dated August 1989 under U.S. Sanitation Monitored. When the Salmonella Enteritidis (SE) outbreak in humans associated with eggs was identified in the late 1980's there was a need to identify infected flocks that may produce contaminated eggs. Since SE is a serogroup D1 Salmonella as is S. Pullorum and S. Gallinarum, it was assumed (hoped) that the PT agglutination test would also detect SE infected flocks. Over time, results have shown that the PT agglutination test is not an effective method for the detection of SE infected flocks.

This proposal only removes the PT agglutination test from the U.S. S. Enteritidis Clean classification. It DOES NOT remove it from the U.S. Pullorum-Typhoid Clean classification. In addition to the fact that the PT agglutination test is not an effective method for detecting SE infected flocks, it causes problems for companies that are vaccinating for *Salmonella*. Also, this change resolves the confusion in Standard B(2)(a) over how many reactors to submit for culture.

Sponsor: Dr. Doug Waltman
Georgia Poultry Laboratory Network

Proposal No. 19

Delegates: **145 G**

§145.73 Terminology and classification; flocks and products.

(h) ***U.S. Newcastle Disease Virus 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 Newcastle Disease. It is intended to determine the presence of Newcastle Disease Virus in primary breeding chickens through vaccination and monitoring 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 primary breeding flock that is either:

(i) Vaccinated for Newcastle Disease Virus using USDA approved vaccines and response to vaccination is serologically monitored using an approved test as described in §145.14 when more than 4 months of age and meets the criteria in §145.73(h)(2) to retain classification.

OR

(ii) Unvaccinated for Newcastle Disease Virus in which a minimum of 30 birds have tested negative to ND using an approved test as described in §145.14 when more than 4 months of age and meets criteria in §145.73(h)(3) to retain classification.

(2) To retain this classification, **for vaccinated flocks**,

(i) Vaccines for NDV must be USDA-approved vaccines manufactured with low-virulence live strains during early stages of development up to grow-out, and killed vaccines as final vaccination no later than 6 weeks prior to the onset of egg production

AND

(ii) The flock has been monitored for antibody response using approved serological tests as listed in §145.14 and the results are compatible with immunological response against ND vaccination

AND

(iii) Testing must include a minimum of 30 birds with a serologic monitoring program beginning at approximately 10 weeks of age and not longer than every 90 days thereafter.

(3) To retain this classification **for unvaccinated flocks**,

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

(ii) 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) 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.

(4) Newcastle Disease Virus must be a disease reportable to the responsible State authority (State veterinarian, etc.) by all licensed veterinarians. To accomplish this, all laboratories (private, State, and university laboratories) that perform diagnostic procedures on poultry must examine all submitted cases of unexplained respiratory disease, egg production drops, and mortality for NDV.

§145.74 Terminology and classification; compartments.

(a) U.S. Avian Influenza and NDV Clean Compartment.

This program is intended to be the basis from which the primary 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 a primary breeding-hatchery company that is free of H5/H7 avian influenza (AI) and NDV. This compartment has the purpose of protecting the defined subpopulation and avoiding the introduction and spread of H5/H7 AI and NDV 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 primary breeder company will define the compartment with respect to H5/H7 AI and NDV. 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 NDV 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 NDV. 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 §145.73(f) and NDV Clean in accordance with §145.73(h). 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 NDV, as described in §145.14(d) and §145.14(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 NDV-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 primary 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 primary 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 NDV. 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 NDV.

(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 NDV, 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 primary 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 NDV. 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 NDV 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 NDV Clean.

(2) Company activities for maintenance of the compartment.

(i) The primary 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 NDV Clean classifications, surveillance for H5/H7 AI and NDV 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 NDV in primary 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 NDV 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 primary breeder industry;

(iii) Approval or denial of classification of compartments as U.S. Avian Influenza and NDV 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 §145.73(f) and NDV Clean program as described in §145.73(h) 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 primary 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 primary 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 primary 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, ~~and~~ 145.73(f), and 145.73(h).

(4) Emergency response and notification. In the case of a confirmed positive of H5/H7 AI and/or NDV 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 NDV 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.

Reason: The Primary Breeders propose the addition of an NDV Clean program. See corresponding proposal in Program Standards Subpart F.

Sponsor: Primary Breeder Association
Dr. Travis Schaal, Hy-Line
Dr. Elena Behnke, Aviagen
Dr. Alberto Torres, Cobb-Vantress
Dr. Dustin Burch, Aviagen Turkeys

Proposal No. 20

Delegates: 145 H

§145.83 Terminology and classification; flocks and products.

(e) U.S. S. Enteritidis Clean.

This classification is intended for primary meat-type breeders wishing to assure their customers that the chicks produced are certified free of Salmonella enteritidis.

(1) A flock and the hatching eggs and chicks produced from it shall be eligible for this classification if they meet the following requirements, as determined by the Official State Agency:

(i) The flock originated from a U.S. S. Enteritidis Clean flock, or one of the following samples has been examined bacteriologically for S. enteritidis at an authorized laboratory in accordance with part 147 of this subchapter and any group D Salmonella samples have been serotyped:

(A) A sample of chick papers, hatcher tray swabs, or fluff collected and cultured in accordance with part 147 of this subchapter; and

(B) Samples of intestinal and liver or spleen tissues from a minimum of 30 chicks that died within 7 days after hatching and have been preserved daily by freezing prior to shipment to an authorized laboratory.

(ii) The flock is maintained in compliance with isolation, sanitation, and management procedures for Salmonella in accordance with part 147 of this subchapter.

(iii) Environmental samples are collected from the flock by or under the supervision of an Authorized Agent, in accordance with part 147 of this subchapter, when the flock reaches 4 months of age and every 30 days thereafter. Once the flock is in egg production and chicks are hatching from it, the samples must include at least 4 individual test assay results every 30 days in flocks of more than 500 birds or 2 individual assays per month in flocks of 500 birds or fewer. One of these results must come from samples collected from hatched chicks at a participating hatchery derived from said flock. These individual test assays may be derived from pooled samples from the farm or hatchery in accordance with part 147 of this subchapter, but must be run as separate test assays in the laboratory. The environmental samples shall be examined bacteriologically for group D Salmonella at an authorized laboratory, and cultures from group D positive samples shall be serotyped.

~~(iv) Blood samples from 300 birds from the flock are officially tested with pullorum antigen when the flock is at least 4 months of age. All birds with positive or inconclusive reactions, up to a maximum of 25 birds, shall be submitted to an authorized laboratory and examined for the presence of group D Salmonella in accordance with part 147 of this subchapter. Cultures from group D positive samples shall be serotyped.~~

(~~v~~iv) Hatching eggs produced by the flock are collected as quickly as possible and their sanitation is maintained in accordance with part 147 of this subchapter.

(~~vi~~v) Hatching eggs produced by the flock are incubated in a hatchery whose sanitation is maintained in accordance with part 147 of this subchapter, and the hatchery must have been sanitized either by a procedure approved by the Official State Agency or by fumigation in accordance with part 147 of this subchapter.

(2) If Salmonella enteritidis serotype enteritidis (SE) is isolated from a specimen taken from a bird in the flock, except as provided in paragraph (e)(3) of this section, the flock shall not be eligible for this classification.

(3) If SE is isolated from an environmental sample collected from the flock in accordance with paragraph (e)(1)(iii) of this section, an additional environmental sampling and 25 live cull birds or fresh dead birds (if present), or other randomly selected live birds if fewer than 25 culls can be found in the flock, must be bacteriologically examined for SE in accordance with part 147 of this subchapter. If only 1 bird from the 25-bird sample is found positive for SE., the participant may request bacteriological examination of a second 25-bird sample from the flock. In addition, if the flock with the SE isolation is in egg production and eggs are under incubation, the next four consecutive hatches shall be examined bacteriologically in accordance with part 147 of this subchapter. Samples shall be collected from all of the hatching unit's chick trays and basket trays of hatching eggs, or from all chick box papers from the flock, and tested, pooling the samples into a minimum of 10 separate assays. Any followup hatchery-positive SE isolations shall result in discontinuation of subsequent hatches until the flock status is determined by bird culture. The flock will be disqualified for the U.S. S. Enteritidis Clean classification if a bird or subsequent flock environmental assay results in isolation of SE.

(4) In order for a hatchery to sell products of this classification, all products handled by the hatchery must meet the requirements of this paragraph.

(5) 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.

(6) A pedigree, experimental, great-grandparent, or grandparent flock that is removed from the U.S. S. Enteritidis Clean program may be reinstated whenever the following conditions are met:

(i) The owner attests that corrective measures have been implemented, which may include one or more of the following:

(A) Test and slaughter infected birds based on blood tests of every bird in the flock, with either pullorum antigen or by a federally licensed Salmonella enteritidis enzyme-linked immunosorbent assay (ELISA) test when the flock is more than 4 months of age.

(B) Perform other corrective actions including, but not limited to, vaccination, medication, cleaning and disinfection of houses, rodent control, and movement of uninfected birds to premises that have been determined to be environmentally negative for S. enteritidis in accordance with par 147 of this subchapter.

(C) One hundred percent of blood samples from the birds moved to the clean premises are tested negative for Salmonella pullorum and group D Salmonella. All birds with positive or inconclusive reactions, up to a maximum of 25 birds, shall be submitted to an authorized laboratory and examined for the presence of group D Salmonella, in accordance with part 147 of this subchapter. Cultures from positive samples shall be serotyped.

(D) Two consecutive environmental drag swabs taken at the clean premises collected in accordance with part 147 of this subchapter 4 weeks apart are negative for S. enteritidis.

(E) Other corrective measures at the discretion of the Official State Agency.

(ii) Following reinstatement, a flock will remain eligible for this classification if the flock is tested in accordance with paragraph (e)(1)(v) of this section every 30 days and no positive samples are found and the flock meets the requirements set forth in §145.83(e).

Program Standard B—Bacteriological Examination Procedure

(1) Reserved

~~**(1) Laboratory procedure recommended for the bacteriological examination of egg-type and meat type breeding flocks with salmonella enteritidis positive environments.**~~

~~Birds selected for bacteriological examination from egg-type and meat-type breeding flocks positive for Salmonella enteritidis after environmental monitoring should be examined as described in Section B(2)(a) of these Program Standards, with the following exceptions and modifications allowed due to the high number of birds required for examination:~~

~~(a) Except when visibly pathological tissues are present, direct culture, Section B(2)(a)(1) of these standards, may be omitted.~~

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

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

~~All reactors to the pullorum-typhoid tests, up to 25 birds, and birds from Salmonella enteritidis (SE) positive environments should be cultured in accordance with both the direct enrichment (paragraph (a)(1)) and selective enrichment (paragraph (a)(2)) procedures described in this section: Provided, if there are more than four reactors to the pullorum-typhoid tests in the flock, a minimum of four reactors as provided for in 9 CFR 145.14(a)(6)(ii) shall be submitted to the authorized laboratory for bacteriological examination. Careful aseptic technique should be used when collecting all tissue samples.~~

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 from U.S. S. Enteritidis Clean flocks will result in the submission of 60 birds from multiplier egg-type 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.

Reason: The pullorum-typhoid (PT) agglutination test was added to the NPIP for testing egg-type breeder flocks in the late 1980's. It first shows up in the "white book" dated August 1989 under U.S. Sanitation Monitored. When the Salmonella Enteritidis (SE) outbreak in humans associated with eggs was identified in the late 1980's there was a need to identify infected flocks that may produce contaminated eggs. Since SE is a serogroup D1 Salmonella as is

S. Pullorum and S. Gallinarum, it was assumed (hoped) that the PT agglutination test would also detect SE infected flocks. Over time, results have shown that the PT agglutination test is not an effective method for the detection of SE infected flocks.

This proposal only removes the PT agglutination test from the U.S. S. Enteritidis Clean classification. It DOES NOT remove it from the U.S. Pullorum-Typhoid Clean classification. In addition to the fact that the PT agglutination test is not an effective method for detecting SE infected flocks, it causes problems for companies that are vaccinating for *Salmonella*. Also, this change resolves the confusion in Standard B(2)(a) over how many reactors to submit for culture.

Sponsor: Dr. Doug Waltman
Georgia Poultry Laboratory Network

Proposal No. 21

Delegates: **145 H**

§145.83 Terminology and classification; flocks and products.

(h) ***U.S. Newcastle Disease Virus 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 Newcastle Disease. It is intended to determine the presence of Newcastle Disease Virus in primary breeding chickens through vaccination and monitoring 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 primary breeding flock that is either:

(i) Vaccinated for Newcastle Disease Virus using USDA approved vaccines and response to vaccination is serologically monitored using an approved test as described in §145.14 when more than 4 months of age and meets the criteria in §145.83(h)(2) to retain classification.

OR

(ii) Unvaccinated for Newcastle Disease Virus in which a minimum of 30 birds have tested negative to ND using an approved test as described in §145.14 when more than 4 months of age and meets criteria in §145.83(h)(3) to retain classification.

(2) To retain this classification, **for vaccinated flocks**,

(i) Vaccines for NDV must be USDA-approved vaccines manufactured with low-virulence live strains during early stages of development up to grow-out, and killed vaccines as final vaccination no later than 6 weeks prior to the onset of egg production

AND

(ii) The flock has been monitored for antibody response using approved serological tests as listed in §145.14 and the results are compatible with immunological response against ND vaccination

AND

(iii) Testing must include a minimum of 30 birds with a serologic monitoring program beginning at approximately 10 weeks of age and not longer than every 90 days thereafter.

(3) To retain this classification **for unvaccinated flocks**,

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

OR

(ii) 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) 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.

(4) Newcastle Disease Virus must be a disease reportable to the responsible State authority (State veterinarian, etc.) by all licensed veterinarians. To accomplish this, all laboratories (private, State, and university laboratories) that perform diagnostic procedures on poultry must examine all submitted cases of unexplained respiratory disease, egg production drops, and mortality for NDV.

§145.84 Terminology and classification; compartments

(a) U.S. Avian Influenza and NDV Clean Compartment

This program is intended to be the basis from which the primary meat-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 a primary breeding-hatchery company that is free of H5/H7 avian influenza (AI) and NDV. This compartment has the purpose of protecting the defined subpopulation and avoiding the introduction and spread of H5/H7 AI and NDV 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 primary breeder company will define the compartment with respect to H5/H7 AI and NDV. 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 NDV 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 NDV. 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 §145.83(g) and NDV Clean in accordance with §145.83(h). 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 NDV, as described in §145.14(d) and §145.14(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 NDV-related data for reference regarding surveillance for the disease and the health status of 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 primary 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 primary 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 NDV. 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 NDV.

(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 NDV, 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 primary 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 NDV. 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 NDV 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 NDV Clean.

(2) Company activities for maintenance of the compartment.

(i) The primary 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 NDV Clean classifications, surveillance for H5/H7 AI and NDV 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 NDV in primary 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 NDV 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 primary breeder industry;

(iii) Approval or denial of classification of compartments as U.S. Avian Influenza and NDV 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 §145.83(g) and NDV Clean Program as described in §145.83(h) 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 primary 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 primary 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 primary 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, ~~and~~ 145.83(g), and 145.83(h).

(4) Emergency response and notification. In the case of a confirmed positive of H5/H7 AI and/or NDV 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 would 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 NDV 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.

Reason: The Primary Breeders propose the addition of an NDV Clean program. See corresponding proposal in Program Standards Subpart F.

Sponsor: Primary Breeder Association
Dr. Elena Behnke, Aviagen
Dr. Alberto Torres, Cobb-Vantress
Dr. Travis Schaal, Hy-Line
Dr. Dustin Burch, Aviagen Turkeys

Proposal No. 22

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 negative to the H5/H7 subtypes of avian influenza as provided in §146.13(b) within 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.

(iii) Pullet flocks of 75,000 or more birds located on a participating table egg layer premises may be enrolled under the same NPIP number as the layer flock;

(iv) If a premises owner grows pullets for multiple owners, and has the housing capacity of 75,000 or more pullets, that grower should be enrolled as the NPIP participant and an NPIP number should be assigned to that grower;

Reason: The additional language regarding enrollment of pullet flocks would help reduce confusion for participants.

Sponsor: Ron Ballew, Hillandale-Gettysburg LP
Dr. Nan Hanshaw, PA Dept. of Agriculture

Proposal No. 23

Delegates: **Combined**

§147.45 Official delegates.

Each cooperating State shall be entitled to one official delegate for each of the programs prescribed in parts 145 and 146 of this chapter in which it has one or more participants at the time of the Conference. The official delegates shall be elected by a representative group of participating industry members and be certified by the Official State Agency. It is recommended but not required that the official delegates be Plan participants. With the approval of the Official State Agencies, individuals may be allowed to be an official delegate for multiple States in which that delegate has flocks or is a plan participant. Each official delegate shall endeavor to obtain, prior to the Conference, the recommendations of industry members of his State with respect to each proposed change.

Reason: This proposal is to provide a more clear allowance for representation of a single delegate in multiple states in which that delegate has participation. For the 2016 NPIP Biennial meeting several participating companies with operations in several states were contacted by multiple states to represent their subsections. Several industry individuals obtained approval from the respective OSA's in each state to have that one individual vote for the applicable subpart in each of the states thus having multiple votes. However it was disallowed based on unknown reasons not contained in the above CFR section in 147.45 stating that multiple votes for multiple states by a single person was not allowed. This is contradictory to what already occurs routinely within a state with little participation in which an OSA holds multiple votes for subsections with no industry participants in attendance. The concern expressed by some is that they don't want to get in a situation where company X with operations in multiple states "controls votes" with a single person. Although this is understandable, all that company X has to do is send additional people to each individually vote for each separate state. All that this does is increase the costs to both the company and NPIP for dinners and meeting space arrangements associated with getting these additional voting members to the Biennial meeting. Ultimately it will still be up to the OSA's to make sure they get the right people that will accurately represent their entire industry/subpart fairly no matter if multiple votes is allowed or not. The last sentence of section 147.45 states this requirement for the delegate to seek out the recommendations of industry members of that state prior to the meeting. For some subsections, for example turkey breeders, there just aren't a lot of choices for many states for delegate participation from different companies due to consolidation, so multi-state representation by a single individual would be a justifiable allowance and is often requested by the OSA's of that state. The proposed wording above also provides the restriction such that a delegate is only allowed to represent multiple states if they have flocks or participation in that state as to not allow nefarious representation in states with no active stake or participation in by that delegate.

Sponsors: Dr. Ben Wileman, Select Genetics
Dr. Kabel Robbins, Butterball
Dr. Brian Wooming, Cargill
Mr. Bill Pittenger, Missouri Department of Agriculture
Dr. Katie Schlist, Forsman Farms
Dr. Rosemary Marusak, Daybreak Foods
Dr. Travis Schaal, Hy-Line International
Dr. Carrie Cremers, Pilgrim's Pride

Proposal No. 24

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.

(a) *Check-test proficiency.* The NPIP will serve as the lead agency for the coordination of available check tests from the National Veterinary Services Laboratories. Further, the NPIP may approve and authorize additional laboratories to produce and distribute a check test as needed. The authorized laboratory must use the next available check test for each assay that it performs.

(b) *Trained technicians.* ~~The~~ ~~t~~ Testing procedures at ~~the~~ all authorized ~~laboratory~~ laboratories must be run or overseen by a laboratory technician who every 4 years has attended, and satisfactorily completed, Service-approved laboratory workshops for Plan-specific diseases. ~~within the past 4 years.~~

Reason: By removing the word "within" and substituting "every", the proposed change to paragraph (b) clears up any confusion that might arise as to the timing of when a laboratory technician is required to attend a Service-approved laboratory workshop. This change makes clear that a workshop for an individual Plan disease must be attended by a laboratory technician at 4-year intervals, rather than any time during a 4-year span. Additionally, including the word "authorized" allows for consistency with other paragraphs in the section.

Sponsor: Monica Della Maggiore
California Poultry Federation

NPIP Program Standards Proposed Changes

Program Standards - Proposal No. 1

Delegates: **Combined**

Standard A – Blood Testing Procedures

(5) Procedure for determining the status of flocks reacting to tests for Mycoplasma gallisepticum, Mycoplasma synoviae, and Mycoplasma meleagridis.
Procedures for isolation and identification of Mycoplasma may be found in A Laboratory Manual for the Isolation, Identification and Characterization of Avian Pathogens, published by the American Association of Avian Pathologists; Avian Mycoplasmosis (Mycoplasma gallisepticum), Manual of Diagnostic Tests and Vaccines for Terrestrial Animals, Fifth Ed., Office International des Epizooties, pp 842–855, 2004; and Program Standards, Standard B sections (6) and (7).

(a) Determining flock Mycoplasma status

(a) The status of a flock for Mycoplasma shall be determined according to the following criteria:

(1) If the enzyme-labeled immunosorbent assay (ELISA), official molecular examination procedure, or serum plate test is negative, the flock qualifies for the classification for which it was tested.

(2) If the ELISA or serum plate test is positive, the hemagglutination inhibition (HI) test or a molecular examination procedure shall be conducted: Provided, for the molecular examination procedure the appropriate antigen detection samples from a minimum of 30 clinically affected birds are tested. And ~~P~~provided, for the HI test, that if more than 50 percent of the samples are positive for M. gallisepticum, M. meleagridis, or M. synoviae, the HI test shall be conducted on 10 percent of the positive samples or 25 positive samples, whichever is greater. HI titers of 1:40 or more may be interpreted as suspicious and appropriate antigen detection samples should be taken promptly (within ~~7~~ 10 days of the original sampling) from 30 clinically affected birds and examined by an approved cultural technique individually, or pooled (up to 5 swabs per test) and used in a molecular examination procedure or in vivo bioassay.

(3) If the in vivo bioassay, molecular examination procedure, or culture procedure is negative, the Official State Agency may qualify the flock for the classification for which it was tested. In the event of contaminated cultures, the molecular examination technique must be used to make a final determination.

(4) If the in vivo bioassay, molecular examination procedure, or culture procedure is positive, the flock will be considered infected.

Reason: Clarification of the sampling required if molecular examination procedure is selected as the confirmatory test. As well, it can be logistically challenging if suspect sera must be sent over a weekend to obtain HI results and be able to collect swabs for PCR within 7 days on occasion.

Sponsor: Dr. Eric Jensen
Aviagen North America

Delegates: **Combined**

Standard A—Blood Testing Procedures

(6) Standard test procedures for mycoplasma.[5]
The serum plate agglutination test and the enzyme-linked immunosorbent assay (ELISA) test should be considered basic screening tests for mycoplasma antibodies. Alternatively, an approved molecular examination procedure may be used alone or in conjunction with serology as a screening test for mycoplasma. The test selected will depend on preference, laboratory facilities, and availability of antigen. These ~~two~~ tests, though quite accurate, determine flock status rather than individual bird status, since occasional reactions are nonspecific. Under normal circumstances, the rate of such nonspecific reactions is low. Nonspecific reactions may occasionally be high, particularly after the use of erysipelas bacterin in turkeys and where mycoplasma antibodies are present for closely related mycoplasma other than for the species being tested. The hemagglutination inhibition (HI) test is too cumbersome for routine screening use. Positive reactions are extremely accurate, however, and are useful in evaluating serum samples that react with the ELISA and/or plate antigens. The test should be conducted with 4 HA units. Titers of 1:80 or greater for both chicken and turkey sera are considered positive, while a 1:40 titer would be suspicious and additional tests should be required.

Reason: Clarification that, in addition to SPA and ELISA, a molecular examination procedure may be used to screen flocks for mycoplasma.

Sponsor: Dr. Eric Jensen
Aviagen North America

Delegates: **Combined**

Standard A – Blood Testing Procedures

(8) Standard test procedures for avian influenza

(a) The agar gel immunodiffusion (AGID) test should be considered the basic screening test for antibodies to Type A influenza viruses. The AGID test is used to detect circulating antibodies to Type A influenza group-specific antigens, namely the ribonucleoprotein (RNP) and matrix (M) proteins. Therefore, this test will detect antibodies to all influenza A viruses, regardless of subtype. The AGID test can also be used as a group-specific test to identify isolates as Type A influenza viruses. The method used is similar to that described by Beard.[6] The basis for the AGID test is the concurrent migration of antigen and antibodies toward each other through an agar gel matrix. When the antigen and specific antibodies come in contact, they combine to form a precipitate that is trapped in the gel matrix and produces a visible line. The precipitin line forms where the concentration of antigen and antibodies is optimum. Differences in the relative concentration of the antigen or antibodies will shift the location of the line towards the well with the lowest concentration or result in the absence of a precipitin line. Electrolyte concentration, pH, temperature, and other variables also affect precipitate formation.

(1) The testing procedure outlined in NVSL SOP-AV-0045 (Avian Influenza Agar Gel Immunodiffusion Test to Detect Antibodies to Type A Influenza Virus) should be followed. Document requests should be submitted to NVSL by e-mail at nvsl.dvl.avian@aphis.usda.gov.

~~(1) *Materials needed.*~~

~~(i) Refrigerator (4 °C).~~
~~(ii) Freezer (−20 °C).~~
~~(iii) Incubator or airtight container for room temperature (approximately 25 °C) incubations.~~
~~(iv) Autoclave.~~
~~(v) Hot plate/stirrer and magnetic stir bar (optional).~~
~~(vi) Vacuum pump.~~
~~(vii) Microscope illuminator or other appropriate light source for viewing results.~~
~~(viii) Immunodiffusion template cutter, seven-well pattern (a center well surrounded by six evenly spaced wells). Wells are 5.3 mm in diameter and 2.4 mm apart.~~
~~(ix) Top loading balance (capable of measuring 0.1 gm differences).~~
~~(x) Pipetting device capable of delivering 50µl portions.~~
~~(xi) Common laboratory supplies and glassware—Erlenmeyer flasks, graduated cylinders, pipettes, 100 × 15 mm or 60 × 15 mm petri dishes, flexible vacuum tubing, side-arm flask (500 mL or larger), and a 12- or 14-gauge blunt-ended cannula.~~

~~(2) *Reagents needed.*~~

~~(i) Phosphate buffered saline (PBS), 0.01M, pH 7.2 (NVSL media #30054 or equivalent).~~
~~(ii) Agarose (Type II Medium grade, Sigma Chemical Co. Cat.# A—6877 or equivalent).~~
~~(iii) Avian influenza AGID antigen and positive control antiserum approved by the Department and the Official State Agency.~~
~~(iv) Strong positive, weak positive, and negative control antisera approved by the Department and the Official State Agency (negative control antisera optional).~~

~~(3) *Preparing the avian influenza AGID agar.*~~

~~(i) Weigh 9 gm of agarose and 80 gm of NaCl and add to 1 liter of PBS (0.01 M, pH 7.2) in a 2 liter Erlenmeyer flask.~~
~~(ii) To mix the agar, either:~~
~~(A) Autoclave the mixture for 10 minutes and mix the contents by swirling after removing from the autoclave to ensure a homogeneous mixture of ingredients; or~~
~~(B) Dissolve the mixture by bringing to a boil on a hot plate using a magnetic stir bar to mix the contents in the flask while heating. After boiling, allow the agar to cool at room temperature (approximately 25°C) for 10 to 15 minutes before dispensing into petri plates.~~
~~(iii) Agar can be dispensed into small quantities (daily working volumes) and stored in airtight containers at 4°C for several weeks, and melted and dispensed into plates as needed.~~
~~**Note:** Do not use agar if microbial contamination or precipitate is observed.~~

~~(4) *Performing the AGID—*~~

~~(i) *Detection of serum antibodies.*~~

(A) Dispense 15 to 17 mL of melted agar into a 100 × 15 mm petri plate or 5 to 6 mL agar into a 60 × 15 mm petri plate using a 25 mL pipette. The agar thickness should be approximately 2.8 mm.

(B) Allow plates to cool in a relatively dust-free environment with the lids off to permit the escape of water vapor. The lids should be left off for at least 15 minutes, but not longer than 30 minutes, as electrolyte concentration of the agar may change due to evaporation and adversely affect formation of precipitin lines.

Note: Plates should be used within 24 hours after they are poured.

(C) Record the sample identification, reagent lot numbers, test date, and identification of personnel performing and reading the test.

(D) Using the template, cut the agar after it has hardened. Up to seven template patterns can be cut in a 100×15 mm plate and two patterns can be cut in a 60×15 mm plate.

(E) Remove the agar plugs by aspiration with a 12- to 14- gauge cannula connected to a side arm flask with a piece of silicone or rubber tubing that is connected to a vacuum pump with tubing. Adjust the vacuum so that the agar surrounding the wells is not disturbed when removing the plugs.

(F) To prepare the wells, place 50 µl of avian influenza AGID antigen in the center well using a micropipette with an attached pipette tip. Place 50 µl AI AGID positive control antiserum in each of three alternate peripheral wells, and add 50 µl per well of test sera in the three remaining wells. This arrangement provides a positive control line on each side of the test serum, thus providing for the development of lines of identity on both sides of each test serum (see figure 1).

Note: A pattern can be included with positive, weak positive, and negative reference serum in the test sera wells to aid in the interpretation of results (*see* figure 2).

(G) Cover each plate after filling all wells and allow the plates to incubate for 24 hours at room temperature (approximately 25 °C) in a closed chamber to prevent evaporation. Humidity should be provided by placing a damp paper towel in the incubation chamber.

Note: Temperature changes during migration may lead to artifacts.

(ii) *Interpretation of test results.*

(A) Remove the lid and examine reactions from above by placing the plate(s) over a black background, and illuminate the plate with a light source directed at an angle from below. A microscope illuminator works well and allows for varying intensities of light and positions.

(B) The type of reaction will vary with the concentration of antibody in the sample being tested. The positive control serum line is the basis for reading the test. If the line is not distinct, the test is not valid and must be repeated. The following types of reactions are observed (see figure 3):

(*1*) *Negative reaction.* The control lines continue into the test sample well without bending or with a slight bend away from the antigen well and toward the positive control serum well.

(*2*) *Positive reaction.* The control lines join with, and form a continuous line (line of identity) with, the line between the test serum and antigen. The location of the line will depend on the concentration of antibodies in the test serum. Weakly positive samples may not produce a complete line between the antigen and test serum but may only cause the tip or end of the control line to bend inward toward the test well.

(*3*) *Non-specific lines.* These lines occasionally are observed between the antigen and test serum well. The control lines will pass through the non-specific line and continue on into the test serum well. The non-specific line does not form a continuous line with positive control lines.

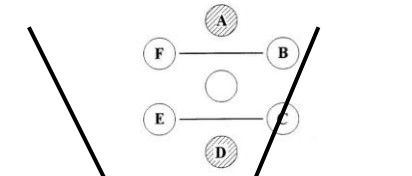


FIGURE 1.—*Immunodiffusion test that uses AI AGID antigen in the center well; AI-positive control serum in wells A and D; and AI-negative test serum in wells B, C, E, and F.*

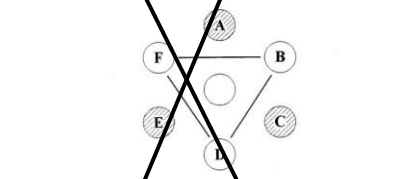


FIGURE 2.—*Immunodiffusion test that has AI AGID antigen in the center well; AI-positive control serum in wells A, C, and E; and AI-negative test serum in wells B, D, and F.*

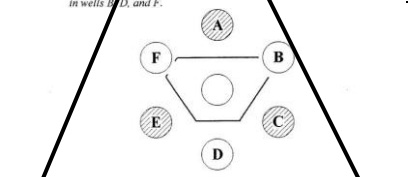


FIGURE 3.—*Immunodiffusion test that has AI AGID antigen in the center well; AI-positive control serum in wells A, C, and E; AI-negative test serum in well B; AI-positive test serum in well D; and weak positive test serum in well F.*

6 Beard, C.W. Demonstration of type-specific influenza antibody in mammalian and avian sera by immunodiffusion. Bull. Wld. Hlth. Org. 42:779–785. 1970.

Reason: Due to inconsistencies noted between the 9CFR and other written procedures for AI AGID, NVSL conducted a method evaluation and discovered opportunities to optimize the assay. While the procedure as written in the 9CFR is not incorrect, the details included in the updated NVSL SOP-AV-0045 improve the overall accuracy and interpretation of the assay. Additionally, as advances in technology continue future updates may be needed.

Sponsor: Dr. Mia Torchetti, Mary Lea Killian, Terra Jenson
USDA APHIS National Veterinary Services Laboratory (NVSL)

Delegates: **Combined**

Standard B - Bacteriological Examination Procedures

(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

(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* or *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 of organs and tissues for selective enrichment culture.

(2) Selective enrichment culture (refer to illustration 1). Collect and culture organ samples separately from intestinal samples, with intestinal tissues collected last to prevent cross-contamination. Samples from the following organs or sites should be collected for culture in selective enrichment broth:

(i) Heart (apex, pericardial sac, and contents if present);

(ii) Liver (portions exhibiting lesions or, in grossly normal organs, the drained gallbladder and adjacent liver tissues);

(iii) Ovary-Testes (entire inactive ovary or testes, but if ovary is active, include any atypical ova);

(iv) Oviduct (if active, include any debris and dehydrated ova);

(v) Kidneys and spleen; and

(vi) Other visibly pathological sites where purulent, necrotic, or proliferative lesions are seen.

(3) From each bird, aseptically collect up to 10 to 15 grams of each organ or site listed in paragraph (a)(2) of this section. Mince, grind, or blend and place in a sterile plastic bag. All the organs or sites listed in paragraph (a)(2) of this section from the same bird may be pooled into one bag. Do not pool samples from more than one bird. Add sufficient tetrathionate enrichment broth to give a 1:10 (sample to enrichment) ratio. Incubate the sample at 37°C ~~or 42.0° C~~ for 20 to 24 hours. Follow the procedure outlined in illustration 1 for the isolation and identification of *Salmonella*.

(4) From each bird, aseptically collect 10 to 15 grams of each of the following parts of the digestive tract: Crop wall, duodenum, jejunum (including remnant of yolk sac), both ceca, cecal tonsils, and rectum-cloaca. Mince, grind, or blend tissues and pool them into a sterile plastic bag. Do not pool tissues from different birds into the same sample. Add sufficient tetrathionate enrichment broth to give a 1:10 (sample to enrichment) ratio. Incubate the sample at 37°C or 42°C for 20 to 24 hours. Follow the procedure outlined in illustration 1 for the isolation and identification of *Salmonella*.

(5) After selective enrichment, inoculate selective plates (such as MAC and BGN for *S*. Pullorum or *S*. Gallinarum and MAC, BGN, and XLT4~~)~~ for SE). Incubate the plate at 37°C for 20 to 24 hours. Inoculate three to five *Salmonella*-suspect colonies from plates into triple sugar iron (TSI) and lysine iron agar (LIA) slants or equivalent method. Incubate slants at 37°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.

(6) If the initial selective enrichment is negative [Section B(2)(a)(5)] for *Salmonella*, a delayed secondary enrichment (DSE) procedure is used. Leave the tetrathionate-enriched sample at room temperature for 5 to 7 days. Transfer 1 mL of the culture into a tube containing 10 mL of fresh tetrathionate enrichment broth, incubate at 37°C for 20 to 24 hours, and plate as in Section B(2)(a)(5).

(7) Serogroup all isolates identified as salmonellae and serotype all serogroup D1 isolates. ~~Phage-type all SE isolates.~~

(3) Procedures for collection, isolation, and identification of Salmonella from house environmental samples, cloacal swabs, and hatchery samples.

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

(1) *Poultry house environmental samples.*

(ii) Drag swabs (DS).

(A) Preparation. DS may be purchased commercially or be user prepared. One suggested method of making the DS assemblies is as follows: A sterile gauze pad is folded in half and a 2-foot long (60cm) piece of twine is securely attached to the folded pad using a paper clip, staple, or similar device. A second sterile gauze pad is similarly fastened to a 5-foot (150 cm) long piece of twine. The shorter piece of twine is then tied to the longer piece producing a DS sample set of two swabs arranged in a Y-shaped configuration. Alternatively, two separate DS samplers may be prepared. The twine is wrapped around the swabs, and the swabs moistened with double-strength skim milk (DSSM) or BPW. The moistened swabs are placed in an instrument package. The sterilized swabs contained in the instrument pack may be frozen (to prevent drying) until use.

(B) Procedure. At the farm the thawed DS assemblies are unraveled and the ends of the twine held in gloved hands. The swabs are dragged across the environmental surfaces of the house for 15 minutes or the length of the house (down and back). One set of swabs (two individual pads) is dragged across the center of the house floor and another set of swabs (two individual pads) is dragged across the inside perimeter of the house floor. The four pads are individually placed in labeled, sterile bags. If necessary to prevent drying out, additional DSSM (evaporated skim milk) or BPW may be added to the bags. The bags should be protected from excessive heat and submitted as soon as possible to the authorized laboratory for testing. If samples are to be processed within 48 hours after collection at the farm, the drag swab assemblies may be stored in BPW. Samples to be processed after 48 hours and before 5 days, must be pre- moistened with DSSM. If the samples cannot be submitted to the laboratory the same day, they should be stored 2°- ~~4~~8°C or placed in a cooler with ice or ice packs (do not freeze) for no more than 5 days before culturing.

(iii) Shoe cover swabs (Boot swabs).

Absorbable fabric shoe covers involve the exposure of the bottom surface of shoe covers to the surface of floor litter and slat areas. Wearing clean gloves, place the shoe covers over footwear that is only worn inside the poultry house. This can be footwear dedicated to the facility or disposable overshoes. Each pair of shoe covers should be worn while walking at a normal pace over a distance of 1,000 feet (305 meters). For flocks with fewer than 500 breeders, at least 1 pair of shoe covers should be worn to sample the floor of the bird area. For flocks with 500 or more breeders, at least 2 pairs of shoe covers should be worn to sample the floor of the bird area. After sampling, place each shoe cover in a sterile container with 30 ml of double strength skim milk, unless pre-moistened swabs (BPW) are used. Seal the sterile containers and promptly refrigerate them at 2° to ~~4~~ 8°C or place in a cooler with ice or ice packs. Do not freeze. If shoe cover swab samples are to be processed within 48 hours after collection, the shoe cover swab samples may be pre-moistened with BPW. Samples to be processed after 48 hours and before 5 days must be pre-moistened with DSSM. All samples are to be placed in a cooler with ice or ice packs for transport and refrigeration at $2^{o} – 8^{o}$ C in the period prior to the addition of the pre-enrichment broth. Samples should be stored at refrigerator temperatures of 2° to ~~4~~ 8°C no more than 5 days before culturing.

(iv) Nest box or egg belt swabs as alternative sampling source

(A) Two sterile pre-moistened (ex. DSSM or BPW) gauze pads or sponges are swabbed inside approximately 10 percent of the nest boxes. Each swab or sponge is placed into a separate sterile bag and submitted to the authorized laboratory.

(B) Two sterile pre-moistened (ex. DSSM or BPW) gauze pads or sponges are used to swab the egg belts. At least 30 feet of belt material is swabbed with each swab. Each swab is placed into a separate sterile bag and submitted to the authorized laboratory.

(C)If nest box or egg belt swab samples are to be processed within 48 hours after collection, the nest box or egg belt swab samples may be pre-moistened with BPW. Samples to be processed after 48 hours and before 5 days must be pre-moistened with DSSM. All samples are to be placed in a cooler with ice or ice packs for transport and refrigeration at 2° – 8° C in the period prior to the addition of the pre- enrichment broth.

(2) Cloacal swabs. Cloacal swabs for bacteriological examination shall be taken from each bird in the flock or from a minimum of 500 birds in accordance with the procedure described this section. A sterile cotton-tipped applicator or swab is inserted into the cloaca and rectum of the bird in such a manner to ensure the collection of fecal material. The applicator may be broken off in to a sterile tube. The cloacal swabs may be combined in multiples of five or in combinations specified by the authorized laboratory.

(3) Hatchery samples. Hatchery-related samples, such as chick box papers, meconium, and fluff may be examined for the presence of Salmonella to indicate the transfer of Salmonella from parent to offspring.

(i) Chick box papers. Chick box paper samples may be collected by an authorized agent according to paragraph (a)(3)(i)(A) of this section or may be submitted directly to an authorized laboratory for testing according to paragraph (a)(3)(~~ii~~ i)(B) of this section. It is important to remove the paper from the chick box before the box is placed in the brooding house.

(A) Instructions for sampling chick box papers. One chick box paper is collected for every 10 boxes of chicks placed in a house. With sanitized and gloved hands, lay out the papers on a clean, disinfected surface. Saturate a sterile gauze pad or sponge with DSSM or BPW and swab the surface of 5 chick box papers. The pad should be rubbed over approximately 75 percent of each paper with sufficient pressure to remove any dried meconium. Addition of more DSSM or BPW may facilitate sampling. The process is repeated with a second swab and the other five chick box papers. Both swabs may be added to a single sterile, labeled plastic bag and submitted to the authorized laboratory. If chick box paper samples are to be processed within 48 hours after collection, the chick box paper samples may be pre-moistened with BPW. Samples to be processed after 48 hours and before 5 days must be pre-moistened with DSSM. All samples are to be placed in a cooler with ice or ice packs for transport and refrigeration at 2° – 8° C in the period prior to the addition of the pre-enrichment broth. Promptly refrigerate the Whirl-Pak bags containing the samples and transport them, on ice or otherwise refrigerated, to a laboratory to be cultured within 5 days of collection.

~~(ii) The Plan participant may send chick box papers directly to a laboratory, where samples may be collected as described in paragraph (a)(3)(i)(A) of this section. To send chick box papers directly to a laboratory:~~

~~(A) Collect 1 chick box paper for each 10 boxes of chicks placed in a house and place the chick papers immediately into large plastic bags and label and seal the bags.~~

~~(B) Place the plastic bags containing the chick box papers in a clean box and transport them within 48 hours to a laboratory. The plastic bags do not require refrigeration.~~

(B) Instructions for sending chick box papers directly to the laboratory. With sanitized or gloved hands collect 1 chick box paper for each 10 boxes of chicks placed in a house. Place the chick papers immediately into large clean plastic bags, label and seal the bags. Transport them to the laboratory within 48 hours. The plastic bags do not require refrigeration.

(~~iii~~ ii) Chick meconium. After collection, the container of meconium is mixed to obtain a uniform consistency. In the laboratory, a 25-gram sample will be removed for bacteriological examination.

(~~iv~~ iii) Fluff. Fluff samples may be collected from the floor of the hatchery or from the tray following hatching. The fluff sample may be collected by either swabbing the floor or tray with a pre-moistened gauze pad or sponge or by placing fluff material directly into a sterile bag.

b) Isolation and identification of Salmonella.

There are two enrichment procedures approved for the isolation of *Salmonella* from environmental samples as described in this section (See Illustration 2). Alternatively, approved rapid methods may be used to

detect the presence of *Salmonella*. Provided, positive samples must be confirmed by culture~~which must then be isolated~~.

(1) Direct tetrathionate (TT) enrichment followed by Modified Semisolid Rappaport-Vassialidis (MSRV) enrichment (Illustration 2).

(i) Fresh Tetrathionate enrichment broth is added to the sample to give a 1:10 (sample to enrichment) ratio. Incubate the samples at 37°C or 42°C for 20 to 24 hours.

(ii) After incubation, transfer approximately 100 microliters (3 drops) of the enriched culture into (subsurface) an MSRV plate. Incubate the plate right side up at 42°C for 24 hours.

(iii) Observe the MSRV plate for growth migrating from the point of inoculation. If present, insert a sterile loop into the outer edge of the zone of growth and inoculate selective agar plates, such as BGN and XLT4.

(iv) If no zone of growth is present, incubate the MSRV plate at 42°C for another 24 hours. Observe the MSRV plate for growth migrating from the point of inoculation. If growth is present, insert a sterile loop into the outer edge of the zone of growth and inoculate selective agar plates, such as BGN and XLT4. If still no zone, insert the loop into the point of inoculation and inoculate selective agar plates. This ensures that weakly or non-motile strains of *Salmonella* will not be missed.

(v) Incubate the selective agar plates at 37°C for 20 to 24 hours. Observe the plates for *Salmonella* suspect colonies. Screen three to five colonies by inoculating them individually into triple sugar iron agar (TSI) and lysine iron agar (LIA) slants or equivalent method. Incubate the slants at 37°C for 20 to 24 hours. Screen the colonies by serological (i.e., serogroup) or biochemical (e.g. API) procedures as shown in Illustration 2.

(vi) Serogroup all isolates identified as *Salmonella* and serotype all serogroup D isolates. ~~Phage type one SE isolate per flock per submission~~.

(2) Pre-enrichment followed by selective enrichment. (Illustration 2.)

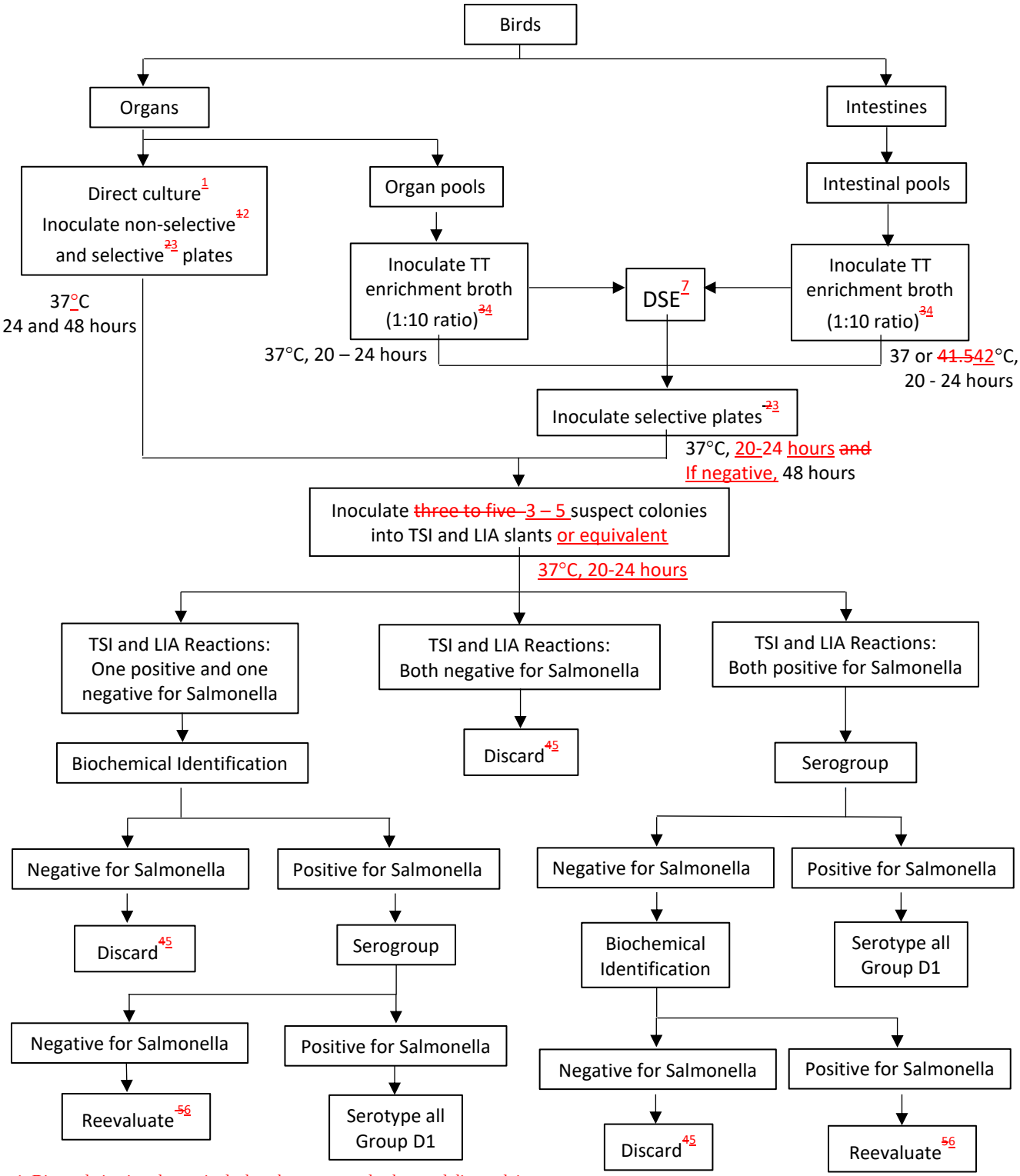
(i) Pre-enrichment broth (e.g. buffered peptone water, BPW) is added to the sample to give a 1:10 (sample to enrichment) ratio. Incubate the sample at 37°C for 20 to 24 hours.

(ii) Transfer 1 ml of the pre-enriched sample into a tube containing 10 ml of tetrathionate enrichment broth and transfer 0.1 ml into either a tube containing 10 ml of Rappaport-Vassiliadis (RV) enrichment broth or into a MSRV plate. Incubate at 42°C for 20 to 24 hours.

(iii) After incubation, inoculate the ~~tetrathionate~~ TT and RV enrichments onto separate selective agar plates, such as BGN and XLT4. If the MSRV media was inoculated, then follow the steps in (1)(iii) and (1)(iv).

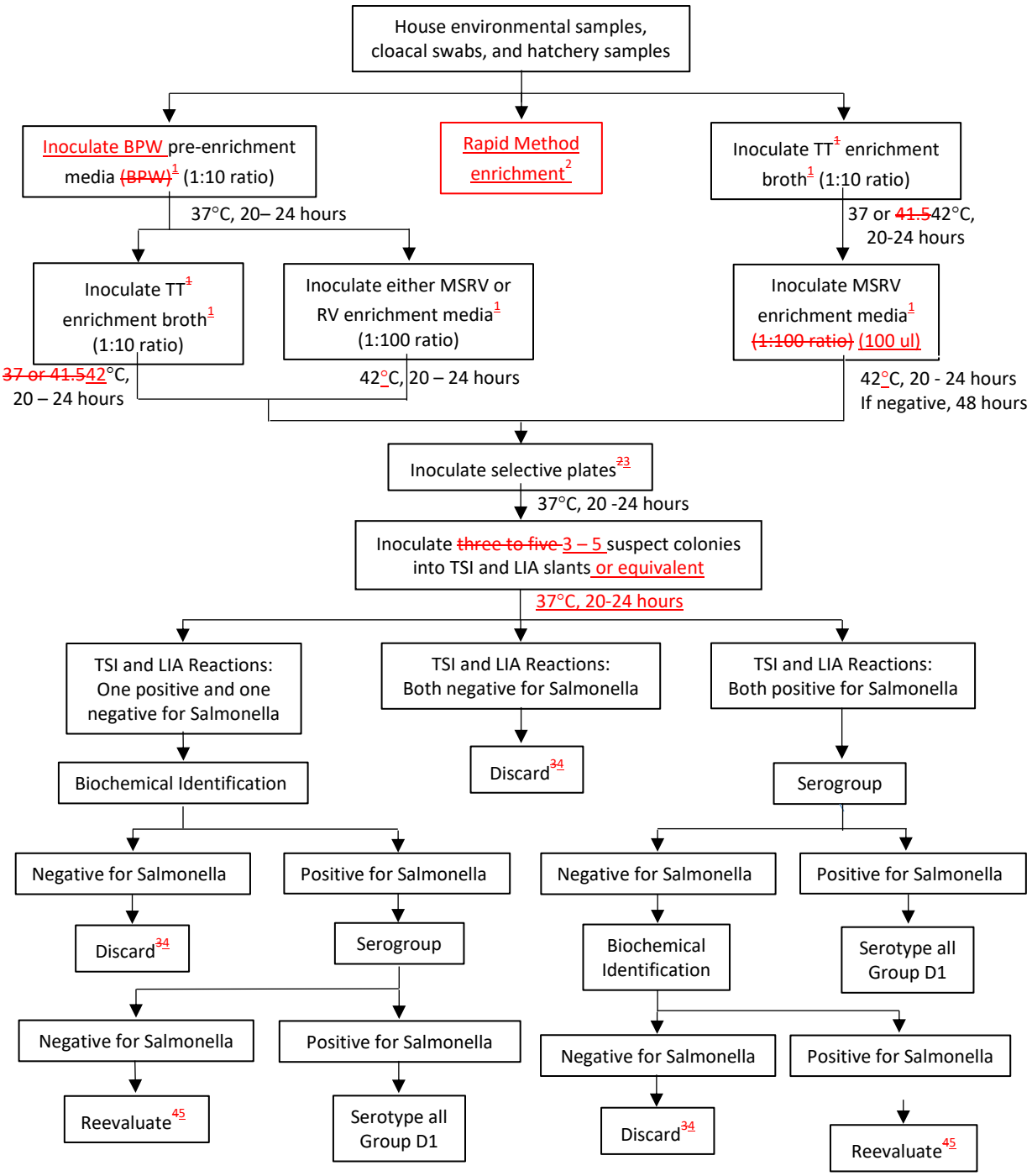
(iv) Screen the selective agar plates for *Salmonella* as described in (1)(v) and (1)(vi).

Illustration 1. Procedure for culturing Pullorum-Typhoid reactors and birds from SE positive environments.



1. Direct plating is only required when there are grossly abnormal diseased tissues or organs present.
~~1~~2.Non-selective plates, such as blood or nutrient agar.
~~2~~3. Selective plates, such as MacConkey (MAC) and Brilliant Green Novobiocin (BGN) for pullorum-typhoid reactors and ~~MacConkey~~MAC, BGN and~~/or~~ xy~~lose-lysine tergitol 4 (XLT 4) for SE.~~
~~3~~4. Tetrathionate enrichment broth.
~~4~~5.Reevaluate if epidemiologic, necropsy or other information indicates the presence of an unusual strain of Salmonella.
~~5~~6. If biochemical identification and serogroup procedures results are inconclusive restreak original colony onto non-selective plating media to check for purity. Repeat biochemical and serology tests.
7.If initial selective enrichment is negative, use Delayed Secondary Enrichment (DSE): Hold TT-enriched sample at room temperature for 5-7 days, then transfer 1 mL of the sample into 10 mL TT. Incubate at 37°C for 20-24 hours.

Illustration 2. Two approved culture procedures for house environmental samples, cloacal swabs and hatchery samples



1. Buffered Peptone Water (BPW), Tetrathionate (TT) enrichment broth, ~~e.g.,~~ Rappaport-Vassiliades (RV) or modified semisolid Rappaport-Vassiliades media (MSRV).

2. Rapid method enrichments that are different from BPW and TT refer to manufacturers protocols.

~~2~~3.Selective plates, such as Brilliant Green with Novobiocin (BGN) ~~or~~ and Xylose-Lysine Tergitol 4 (XLT 4).

~~3~~4.Reevaluate if epidemiologic, necropsy, or other information indicates the presence of an unusual strain of Salmonella.

~~4~~5.If biochemical identification and serogroup procedures are inconclusive, restreak original colony onto non-selective plating media to check for purity. Repeat biochemical and serology tests.

Reason: This proposal attempts to clean-up and clarify the isolation procedures for Salmonella and to ensure that Illustrations 1 and 2 agree with the written text in Standards B(2) and B(3). We removed the requirement for phage typing and clarified sampling of chick box papers. We widened the temperature range for refrigeration of samples from 2°-4°C to 2°-8°C to facilitate compliance with the standards set forth by laboratory accreditation bodies.

To allow for Buffered Peptone Water (BPW) to be used as an acceptable media to pre-moisten drag swabs, shoe cover, and chick liner paper samples for samples to be cultured within 48 hours of collection. To ensure that environmental samples are stored under refrigeration during transport and storage, added requirements for transporting environmental samples in a cooler with ice or ice packs for transport and refrigeration for storage. The coolers with ice or ice packs will avoid extreme temperatures and potential overgrowth of bacteria.

Sponsor: Dr. Doug Waltman, Georgia Poultry Laboratory Network
Dr. Carolyn Miller, Aviagen, Inc.

Delegates: **Combined**

Standard B – Bacteriological Examination Procedures

~~**(4) Procedure for bacteriological culturing of eggshells for colon bacilli organisms**~~

~~Proper precautions to avoid environmental contamination of the samples during the collection and laboratory process, and proper handling of the samples following collection are essential. Each State Inspector involved in eggshell culture activities must receive instruction in the necessary sanitation procedures, sampling procedures, and sample handling by the authorized laboratory involved. The Official State Agency will maintain a record showing that the required instruction was given to each State Inspector.~~

~~(a) Sample selection. Forty eggs in the top flats of each of three randomly selected cases of sanitized eggs from each flock will be used for each sampling.~~

~~(b) Swab procedure. A 2.5 centimeter diameter circular area of the large end of each of the eggs will be rubbed with a sterile swab previously moistened with sterile lactose broth or other suitable liquid media provided by the authorized laboratory. One swab will be used for five eggs, and four swabs will be pooled to each sterile, capped tube provided by the authorized laboratory.~~

~~(1) From the tube containing four swabs and lactose broth or other suitable media, 1 ml. will be transferred to 10 ml. lactose in a fermentation tube.~~

~~(2) Incubate at 37 °C for 48 hours. The presence of acid, and gas in the amount of 10 percent or more after 24 and 48 hours of incubation, provides a presumptive conclusion of the presence of colon bacilli organisms.~~

Standard B – Bacteriological Examination Procedures

~~**(5) Procedures to determine status and effectiveness of sanitation monitored program**~~

~~The following monitoring procedures [8] may be applied at the discretion of the Official State Agency:~~

~~(a) Monitor effectiveness of sanitation program~~

~~(1) Culture the surface of cased eggs periodically for fecal contaminating organisms as described in Section B(4).~~

~~(2) Culture a sample of dead-in-shell eggs periodically from each breeding flock for coliforms. Such eggs should also be cultured for the dependable recovery of salmonellae. Culturing for the dependable recovery of salmonellae should include the use of:~~

~~(i) Preenrichment broths supplemented with 35 mg ferrous sulfate per 1,000 ml preenrichment to block iron-binding, Salmonella-inhibiting effects of egg conalbumin; and~~

~~(ii) Tetrathionate-selective enrichment broths, competitor-controlling plating media (XLT4, BGN, etc.), delayed secondary enrichment procedures, and colony-lift assays detailed in paragraph (a)(5) and illustration 2 of these Program Standards.~~

~~[8] Laboratory procedures for monitoring operations proposed here are described in the following two publications: Isolation and Identification of Avian Pathogens, American Association of Avian Pathologists, University of Pennsylvania, New Bolton Center, Kennett Square, Pennsylvania 19348–1692, 1980, and Culture Methods for the Detection of Animal Salmonellosis and Arizonosis, Iowa State University Press, Ames, Iowa 50010, 1976.~~

Reason: These procedures are historic (present in white book dated June 1985) in nature and are no longer used for "determining status and effectiveness of sanitation monitored program".

Sponsor: Dr. Doug Waltman
Georgia Poultry Laboratory Network

Program Standards - Proposal No. 6

Delegates: **Combined**

Standard B – Bacteriological Examination Procedures

(8) Laboratory procedure recommended for the bacteriological examination of cull chicks and poults for *Salmonella*.

(a) For cull chicks, from 25 randomly selected 1- to 5-day-old chicks that have not been placed in a brooding house, prepare 5 organ pools, 5 yolk pools, and 5 intestinal tissue pools as follows. For poults, from a sample of 10 poults that died within 10 days after hatching, prepare organ pools, yolk pools, and intestinal pools as follows:

(1) Organ pool: From each of five chicks or two poults, composite and mince 1- to 2-gram samples of heart, lung, liver, and spleen tissues. Include the proximal wall of the bursa of Fabricius for chicks only.

(2) Yolk pool: From each of five chicks or two poults, composite and mince 1- to 2-gram samples of the unabsorbed yolk sac or, if the yolk sac is essentially absent, the entire yolk stalk remnant.

(3) Intestinal pool: From each of five chicks or two poults, composite and mince approximately 0.5 cm^2 sections of the crop wall and 5-mm-long sections of the duodenum, cecum, and ileocecal junction.

(b) Transfer each pool to tetrathionate selective enrichment broth (Hajna or Mueller-Kauffmann) at a ratio of 1 part tissue pool to 10 parts broth.

(c) For cull chicks, repeat the steps in paragraphs (a) and (b) of this section for each 5-chick group until 25 chicks have been examined, producing a total of 15 pools (5 organ, 5 yolk, and 5 intestinal). For poults, repeat the steps in paragraphs (a) and (b) of this section for each two-poult group until all the poults in the sample have been examined.

(d) Culture the tetrathionate pools as outlined for selective enrichment in illustration ~~2~~ 1 of these Standards. Incubate the organ and yolk pools for 24 hours at 37 °C and the intestinal pools at ~~41.5~~ 42°C. Plate as described in illustration ~~2~~ 1 of these Standards and examine after both 24 and 48 hours of incubation. Confirm suspect colonies as described. Further culture all Salmonella-negative tetrathionate broths by delayed secondary enrichment procedures described for ~~environmental,~~ organ~~,~~ and intestinal samples in illustration ~~2~~ 1. ~~A colony lift assay may also be used as a supplement to TSI and LI agar picks of suspect colonies.~~

Reason: This section currently is in Standard B, but is located after Mycoplasma methods. I would suggest moving this section into the section of Standard B that deals with *Salmonella*, for example before Standard B(4). Additionally, some modifications are proposed to clarify and update the procedure.

Sponsor: Dr. Doug Waltman
Georgia Poultry Laboratory Network

Delegates: **Combined**

Standard C—Sanitation Procedures

(2) Hatching egg sanitation.

Hatching eggs should be collected from the nests at frequent intervals. ~~and, to aid in the prevention of contamination with disease-causing organisms, the~~ The following practices should be observed:

(a) Cleaned and disinfected containers, such as egg flats, should be used in collecting the nest eggs for hatching and should be disinfected using products that are known to be effective against program diseases and/or are registered by the U.S. Environmental Protection Agency as effective against program diseases. Egg handlers should thoroughly wash their hands with soap and water before and after egg collection. Clean outer garments should be worn.

(b) Dirty eggs should not be used for hatching purposes and should be collected in a separate container from the nest eggs. Slightly soiled nest eggs may be gently dry cleaned by hand.

(c) Hatching eggs should be stored in a designated egg room under conditions that will minimize egg sweating. The egg room walls, ceiling, floor, door, heater, and humidifier should be cleaned and disinfected after every egg pickup. Cleaning and disinfection procedures should be as outlined in Section C(4) of these Program Standards.

(d) The egg processing area should be cleaned and disinfected daily.

(e) Effective rodent and insect control programs should be implemented.

(f) The egg processing building or area should be designed, located, and constructed of such materials as to ensure that proper egg sanitation procedures can be carried out, and that the building itself can be easily, effectively, and routinely sanitized.

(g) All vehicles used for transporting hatching eggs ~~or chicks or poults~~ should be cleaned and disinfected after use. Cleaning and disinfection procedures should be as outlined in Section C(4).

(h) Egg collection belts, tables, nest box pads and other egg collection equipment should be cleared of fecal material and managed on a regular basis to facilitate clean eggs.

(3) Hatchery sanitation.

An effective program for the prevention and control of *Salmonella* and other infections should include the following measures:

(a) An effective hatchery sanitation program should be designed and implemented.

(b) The hatchery building should be arranged so that separate rooms are provided for each of the four operations: Egg receiving, incubation and hatching, chick/poult processing, and egg tray and hatching basket washing. Traffic and airflow patterns in the hatchery should be from clean areas to dirty areas (*i.e.*, from egg room to chick/poult processing rooms) and should avoid tracking from dirty areas back into clean areas.

(c) The hatchery rooms, and tables, racks, and other equipment in them should be thoroughly cleaned and disinfected frequently. All hatchery wastes and offal should be ~~burned~~ appropriately managed and disposed of to prevent contamination of subsequent hatches. ~~or otherwise properly disposed of, and the containers~~ The equipment used to remove such materials should be cleaned and sanitized ~~after each use~~.

(d) The hatching compartments of hatchers ~~incubators~~, including the hatching trays, should be thoroughly cleaned and disinfected after each hatch.

(e) Only visually clean eggs should be used for hatching purposes.

(f) Only new or cleaned and disinfected egg cases should be used for transportation of hatching eggs. Soiled egg case fillers should be destroyed.

(g) Day-old chicks, poults, or other newly hatched poultry should be distributed in cleaned, or new boxes and new chick, or poult papers. All crates, lifting equipment, and vehicles used for transporting birds should be cleaned and disinfected after each use.

Reason: This proposal will update hatchery sanitation practices in Subpart C(2) Hatching egg sanitation and Subpart C(3) Hatchery sanitation that are currently employed by NPIP Participants. The proposed changes will allow flexibility for industry practices that are and have been commonly employed for many years.

Sponsors: Dr. Michelle Kromm, Jennie-O Turkey Store
Dr. Bernie Beckman, Dr. Travis Schaal, Hy-Line International
Dr. Rosemary Marusak, Daybreak Foods
Dr. Katie Schlist, Forsman Farms
Dr. Dale Lauer, Minnesota Board of Animal Health

Delegates: **Combined**

Standard C—Sanitation Procedures

(4) Cleaning and disinfecting

The following procedures are recommended:

(a) ~~In the~~ ~~p~~Poultry houses:

(1) Remove all ~~live "escaped" and dead~~ birds from the building. Blow dust from equipment and other exposed surfaces. Empty the residual feed from the feed system and feed pans and remove it from the building. As appropriate, ~~D~~disassemble feeding equipment and dump and scrape as needed to remove ~~any and all~~ feed cake and residue. Clean up spilled feed around the ~~tank~~ bulk feed bins and physically clean out ~~the tank~~ if possible. After dry cleaning of the inside of feed bins to remove any residual build-up of feed it may be beneficial to ~~R~~rinse down and wash out the inside of the feed ~~tank~~ bins to decontaminate the surfaces and allow to completely dry.

(2) The company and/or site specific biosecurity plan will detail the appropriate insect and rodent control.

(~~2~~ 3) If litter is to be removed, r~~R~~emove all litter and manure ~~droppings~~ to an isolated area where there is no opportunity for dissemination of any program ~~infectious~~ disease organisms that may be present. ~~Housing where poultry infected with a mycoplasmal disease were kept should remain closed for 7 days before removal of the litter.~~

(~~3~~ 4) When indicated for control of a program disease, a wash down using clean water should be used, avoiding untreated pond or stream water. ~~Wash down~~ Washing the entire inside surfaces of the building and all the installed equipment such as curtains, ventilation ducts and openings, light traps and openings, fans, fan housings and shutters, feeding equipment, watering equipment, etc. shall be performed. Use ~~high~~ appropriate pressure and ~~high~~ volume of water ~~spray (for example 200 pounds per square inch and 10 gallons per minute or more) to soak into and remove the dirt~~ to decontaminate the building. ~~Scrub the walls, floors, and equipment with a hot soapy water solution. Rinse to remove soap.~~ Pay specific attention to the area linking of side walls with building floors and or stem walls to remove all accumulated organic material. Make sure to close up any drain caps and doorways when building is not actively being worked on at all times during the cleaning process. Make sure any chemical cleaning and disinfecting agents used in the cleaning process are agents known to be effective against program diseases and/or are registered by the Environmental Protection Agency as effective against program diseases.

(5) Perform any mechanical or physical maintenance on buildings and/or equipment necessary including patching up any wild bird or obvious rodent entry points.

(~~4~~ 6) After washing is complete, ~~S~~spray with a disinfectant ~~which~~ that is known to be effective against program diseases and/or is registered by the Environmental Protection Agency as effective against program diseases, applying ~~as germicidal, fungicidal, pseudomonocidal, and tuberculocidal,~~ in accordance with the specifications for use, as shown on the label of such disinfectant.

(7) Make sure any building end pad areas are completely cleaned and free of organic material from the previous flock prior to adding new bedding or other supplies, birds, or equipment.

(b) In the hatchers and hatchery rooms:

(1) Use cleaning agents and sanitizers that are known to be effective against program diseases and/or are registered by the U.S. Environmental Protection Agency as effective against program diseases. ~~as germicidal, fungicidal, pseudomonocidal, and tuberculocidal~~. Use manufacturer's recommended dilution rates. Remove loose organic debris. ~~by sweeping, scraping, vacuuming, brushing, or scrubbing, or by hosing surface with high pressure water (for example 200 pounds per square inch and 10 gallons per minute or more)~~. Remove trays and all controls and fans for separate cleaning. Use hot water (minimum water temperature of 140 °F) for cleaning hatching trays and chick separator equipment. Thoroughly wet the ceiling, walls, and floors ~~with a stream of water~~, then scrub with a ~~hard bristle~~ brush. Use a cleaner/sanitizer that can penetrate protein and fatty deposits. Allow the appropriate contact time per the manufacturer's recommendations ~~chemical to cling to treated surfaces at least 10 minutes before rinsing off~~. Manually scrub any remaining deposits of organic material until they are removed. Rinse until there is no longer any deposit on the walls, particularly near the fan opening~~, and apply disinfectant~~. Use a clean and sanitized squeegee to remove excess water, working down from ceilings to walls to floors, ~~and~~ being careful not to recontaminate cleaned areas. Apply disinfectant per the manufacturer's recommendations.

(2) Replace the cleaned fans and controls. Replace the trays, ~~preferably still wet from cleaning,~~ and

bring the incubator to normal operating temperature.

(3) The hatcher should be ~~fumigated (see Section C(5)) or otherwise~~ disinfected before transferring the eggs.

(4) If the same machine is used for incubating and hatching, the entire machine should be cleaned after each hatch. A vacuum cleaner should be used to remove dust and down from the egg trays; then the entire machine should be vacuumed, mopped, and ~~fumigated (see Section C(5)) or otherwise~~ sanitized.

(c) The egg and chick/poult delivery truck drivers and helpers should use the following good biosecurity practices while picking up eggs or delivering chicks or poults:

~~(1) Spray truck tires thoroughly with disinfectant before leaving the main road and entering the farm driveway.~~

(~~2~~ 1) ~~Put on sturdy, disposable plastic boots or clean rubber boots before getting out of the truck cab. Put on a clean smock or coveralls and a hairnet before entering the poultry house.~~ Personnel that are entering egg rooms, or poultry ready facilities should take precautions, including washing of and or sanitation of hands, and wearing of premises specific clothing and footwear according to the company and/or site specific biosecurity plan.

(~~3~~ 2) After loading eggs or unloading chicks or poults, remove the dirty premises specific clothing and footwear (to leave at the facility), or ~~smock or coveralls and~~ place into a plastic garbage bag before loading in the truck. Be sure to keep clean clothing and footwear ~~coveralls~~ separate from dirty ones. Remove hairnet and disposable boots (if applicable) and discard at the farm.

~~(4) Reenter the cab of the truck and remove boots before placing feet onto floorboards. Remove hairnet and leave with disposable boots on farm.~~

(~~5~~ 3) Sanitize hands using appropriate hand sanitizer.

(~~6~~ 4) Re-enter the truck to ~~R~~return to the hatchery or go to the next farm and repeat the process.

Reason: This proposal will update poultry house and hatchery sanitation practices in Subpart C(4) Cleaning and disinfection that are commonly employed by NPIP Participants. The proposed changes will allow flexibility for some industry practices that are and have been commonly employed for many years.

Sponsors: Dr. Michelle Kromm, Jennie-O Turkey Store
Dr. Bernie Beckman, Dr. Travis Schaal, Hy-Line International
Dr. Rosemary Marusak, Daybreak Foods
Dr. Katie Schlist, Forsman Farms
Dr. Dale Lauer, Minnesota Board of Animal Health

Program Standards Proposal No. 9

Delegates: **Combined**

Standard C – Sanitation Procedures

(9) Dealer sanitation

As applicable, a recommended program for control of *Salmonella* and other program diseases:

(a) Hatching eggs

(1) Accept hatching eggs from NPIP participants that follow the appropriate sanitation procedures outlined in Program Standards, Standards C – Sanitation Procedures.

(2) Prior to movement refer to and follow the company and/or site specific biosecurity plan.

(b) Newly hatched poultry

(1) Provide a pen location that can be cleaned and sanitized on a regular basis, in a manner acceptable to the Official State Agency.

(2) Provide adequate clean bedding that is removed on a regular basis in a manner acceptable to the Official State Agency.

(3) Provide an adequate heat source with ventilation managed to optimize the well-being of the newly hatched poultry.

(4) Provide sufficient feed and water in containers that are cleaned and sanitized on a regular basis, in a manner acceptable to the Official State Agency.

(5) Maintain a physical barrier to prevent people from having direct contact with the newly hatched poultry.

(6) Make available a wash station or hand sanitizer nearby the poultry display areas.

(7) Provide information to customers about preventative public health measures regarding *Salmonella* in live poultry.

(c) Started poultry

(1) Accept poultry from NPIP Participants that have followed the appropriate sanitation procedures detailed in Program Standards, Standards C – Sanitation Procedures.

(2) Prior to movement refer to and follow the company and/or site specific biosecurity plan.

Reason: This proposal will create a new Dealer sanitation standard that can be recommended, followed and used for the control of *Salmonella* and other program diseases.

Sponsor: Dr. Dale Lauer, Minnesota Board of Animal Health

Delegates: **Combined**

Standard C—Sanitation Procedures

(1) Flock sanitation.

To aid in the maintenance of healthy flocks, the following procedures should be practiced:

(a) ~~Baby poultry~~ Poultry should be started in a ~~clean brooder~~ house managed to reduce or eliminate exposure to program organisms.~~and~~ Flocks should be housed ~~maintained~~ in ~~constant~~ physical isolation from older birds and other animals. Personnel that are ~~in contact with older birds and other animals~~ crossing the Line of Separation (LOS) should take precautions, including ~~disinfection of footwear and change of outer clothing~~ washing and or sanitation of hands, and wearing premises specific clothing and footwear. ~~to prevent the introduction of infection through droppings that may adhere to the shoes, clothing, or hands. (See Section C(4)(a).)~~

(b) ~~Range used for growing young stock should not have been used for poultry the preceding year.~~ Where ~~broods~~ flocks of different ages must be kept on the same farm, there should be complete depopulation ~~of brooder houses and other premises~~ following ~~infection~~ contamination of such premises by any ~~contagious~~ program disease that causes the existence of a carrier population or a reservoir in the environment.

(c) Poultry houses ~~should~~ shall be ~~screened and~~ proofed against free-flying wild birds~~.~~ with ~~An~~ active rodent ~~eradication campaign~~ and insect vector eradication /control programs as defined in the company and/or site specific biosecurity plan. ~~is an essential part of the general sanitation program.~~ The area adjacent to the poultry house ~~should~~ shall be kept free from accumulated manure, rubbish, and unnecessary equipment. Vegetation surrounding all poultry housing shall be excluded from or minimized in amount for at least three feet distance to facilitate control of vermin. Dogs, cats, sheep, cattle, horses, and swine should not cross the Line of Separation (LOS). ~~never have access to poultry operations.~~ Visitors should not be admitted to poultry areas, and authorized personnel should take the necessary precautions to prevent the introduction of program disease in accordance with the company and/or site specific biosecurity plan.

(d) ~~Poultry houses and equipment should be thoroughly cleaned and disinfected prior to use for a new lot of birds. (See Section C(4)(a).) Feed and water containers should be situated where they cannot be contaminated by droppings and should be frequently cleaned and disinfected. Dropping boards or pits should be constructed so birds do not have access to the droppings.~~ Prior to the placement of a new flock, the company and/or site specific biosecurity plan should detail the procedures in place to minimize the risk of program disease introduction and transmission from premises sanitation, feed, replacement litter and water supplies.

(e) ~~Replacement breeders shall be housed at the proper density consistent with the type of building and locality and which will allow the litter to be maintained in a dry condition. Frequent stirring of the litter may be necessary to reduce excess moisture and prevent surface accumulation of droppings. Slat or wire floors should be constructed so as to permit free passage of droppings and to prevent the birds from coming in contact with the droppings. Nesting areas should be kept clean and, where appropriate, filled with clean nesting material.~~ Management of ventilation systems should be done in a manner to optimize moisture removal and reduce excess moisture, dust and ammonia. Nesting areas should be kept clean, dry and free of fecal material.

(f) When an outbreak of a program disease occurs in a flock, every effort should be made to identify the causative agent. ~~dead or sick birds should be taken, by private carrier, to a diagnostic laboratory for complete examination. All~~ Salmonella cultures isolated should be typed ~~serologically,~~ as appropriate to determine specific control measures. ~~and complete records maintained by the laboratory as to types recovered from each flock within an area. Records on isolations and serological types should be made available to Official State Agencies or other animal disease control regulatory agencies in the respective States for followup of foci of infection. Such information is necessary for the development of an effective Salmonella control program.~~

(g) ~~Introduction~~ Placement of started or mature birds should be ~~avoided~~ managed to reduce the ~~possible hazard of introducing~~ introduction of program ~~infectious~~ diseases. ~~If~~ When birds are to be placed ~~introduced~~, the health status of ~~both the flock and~~ the newly placed ~~introduced~~ birds should be evaluated with recent test results for applicable plan disease agents prior to movement.

(h) In ~~rearing broiler or replacement~~ all poultry stock, a sound and adequate immunization program, as advised by a poultry health professional, should be adopted. ~~Since different geographic areas may require certain specific recommendations, the program recommended by the State experiment station or other State agencies should be followed.~~

(i) Feed~~, pelleted by heat process,~~ should be ~~fed to all age groups~~ produced and treated to prevent transmission of program organisms by heating or approved chemical treatment. ~~Proper feed pelleting procedures can destroy many disease producing organisms contaminating feedstuffs.~~

Reason: This proposal will update flock sanitation practices in Subpart C (1), flock sanitation measures commonly employed by NPIP Participants. The proposed changes will allow flexibility for industry practices that are and have been used for many years.

Sponsors: Dr. Michelle Kromm, Jennie-O Turkey Store
Dr. Bernie Beckman, Dr. Travis Schaal, Hy-Line International
Dr. Rosemary Marusak, Daybreak Foods
Dr. Katie Schlist, Forsman Farms
Dr. Dale Lauer, Minnesota Board of Animal Health

Delegates: **Combined**

Standard D—Molecular Examination Procedures

(7) Approved tests

The following diagnostic test kits that are not licensed by the Service (e.g., bacteriological culturing kits) are approved for use in the NPIP:

1. Rapid Chek©Select TMSalmonella Test Kit, Romer Labs, Inc., Newark, DE 19713.
2. ADIAFOOD Rapid Pathogen Detection System for *Salmonella* spp., AES Chemunex Canada. Laval, QC (Canada) H7L4S3.
3. DuPont Qualicon BAX Polymerase Chain Reaction (PCR)-based assay for *Salmonella* 1 and 2 DuPont Qualicon, Wilmington, DE 19810.
4. Applied Biosystems TaqMan® *Salmonella* Enteritidis Real-Time PCR assay for the detection of *Salmonella* Enteritidis. Life Technologies Corporation. Foster City, CA 94404.
5. IDEXX MG/MS RT-PCR.
6. MicroSEQ Salmonella Species Detection Kit, Life Technologies Corporation, Austin, TX.
7. ANSR Salmonella Test, Neogen Corporation, Lansing, MI 48912.
8. Reveal 2.0 Group D1 Salmonella (Including SE) Kit, Neogen, Neogen Corporation, Lansing, MI 48912.
9. DNAble Salmonella Detection Kit, EnviroLogix, Inc., Portland, Maine 04103.
10. Bactotype MG/MS Kit, QIAGEN, Germantown, Maryland, 20874.
11. IDEXX RealPCR MG DNA reagents-IDEXX Laboratories, Inc. Westbrook, ME 04092.
12. IDEXX RealPCR MS DNA reagents-IDEXX Laboratories, Inc. Westbrook, ME 04092.
13. IDEXX RealPCR MG-MS Multiplex DNA reagents-IDEXX Laboratories, Inc. Westbrook, ME 04092.
14. Poultry Check MP MS-MG Test Kit-Biovet, Inc. St. Hyacinthe, Quebec J2S 8W2 Canada.
15. Thermo Fisher Scientific MG/MS Reagents-Thermo Fisher Scientific, Life Sciences Solutions, Austin, TX 78744.
16. Qiagen *mericon* ® Salmonella spp. real-time PCR kit-Qiagen, Germantown, MD 20874.
17. IDEXX RealPCR Salmonella DNA spp. DNA reagents- IDEXX Laboratories, Inc. Westbrook, ME 04092.
18. BioChek Salmonella Species PCR-BioChek, 3 Southgate Rd. Scarborough, ME 04074.
19. BioChek MgMs qPCR test-BioChek, 3 Southgate Rd. Scarborough, ME 04074.

Program Standards Proposal No. 12

Delegates: **Combined**

Standard E – Biosecurity Principles

Based on the flock size as stated in the 9 CFR 53.10, and including breeding flock premises where greater than 500 birds are raised annually, the following minimum management practices and principles are designed to prevent the introduction and spread of infectious diseases.

(14) Auditing

Auditing of the biosecurity principles is based on flock size as outlined in 9 CFR 53.10, and shall include breeding flock premises where greater than 500 birds are raised annually. Audits shall be conducted at least once every two years or a sufficient number of times during that period by the Official State Agency to ensure the participant is in compliance. Each audit shall require the biosecurity plan's training materials, documentation of implementation of the NPIP Biosecurity Principles, corrective actions taken, and the Biosecurity Coordinator's annual review to be audited for completeness and compliance with the NPIP Biosecurity Principles. An audit summary report containing satisfactory and unsatisfactory audits will be provided to the NPIP National Office by the OSAs.

Those participants who failed the initial document audit conducted by the NPIP OSA may elect to have a check audit performed by a team appointed by National NPIP Office including: an APHIS poultry subject matter expert, the OSA, and a licensed, accredited poultry veterinarian familiar with that type of operation. If these participants seek to be reinstated as being in compliance with the Biosecurity Principles by the NPIP OSA, they must demonstrate that corrective actions were taken following the audit by the team appointed by NPIP.

Reason: There are several reasons supporting these changes to the program standards. The original intention of the biosecurity principles was to increase the minimum biosecurity requirements for all commercial industry, including breeding complexes. The current language, referencing section 53.10 of the 9 CFR, unintentionally exempts all breeding complexes from the auditing requirement. While most companies have no issues complying across the board with the audits, some OSAs have already reported push back on the auditing requirement from a few companies, thus prompting the need to revisit the language. If we are going to hold the poultry industry to a specific standard, especially when indemnity funds can potentially become involved, then all aspects of commercial production should be held to that standard equally. Additionally, as recent HPAI outbreaks have demonstrated, there is a larger risk for long-lived birds to contract Avian Influenza, thus it's counterintuitive to only be auditing the biosecurity program of broiler complexes, and not the parent stock. All birds are at risk for contracting avian diseases, therefore all aspects of commercial industry should adhere to the same standard, and would benefit from these biosecurity principles. Finally, one would expect the breeding stock of commercial broilers and turkeys to have higher biosecurity standards than their progeny as typical industry practice, thus this change should not create an increased burden.

Sponsor: Dr. Melissa Yates
Arkansas Livestock and Poultry Commission