Proposed Changes Booklet

to be considered at the

NPIP 43rd Biennial Conference

HYATT REGENCY BELLEVUE HOTEL

AUGUST 30 - SEPTEMBER 1, 2016

9-CFR PROPOSED CHANGES

PROPOSAL NUMBER	SUBPART	SUBPART DELEGATES	PAGE	SUBJECT OF PROPOSAL
1.	56	Combined	1	Amends indemnity amount calculation formula for determining hen's projected future egg production
2.	145, 146, 147, 56	Combined	2	Amends definition of NPIP Technical Committee
3.	145	145 Combined	3	Clarifies and explains the final determination status of Pullorum-Typhoid reactors
4.	145	145 Combined	10	Proposes a definition of Air Space
5.	145	145 Combined	11	Proposes a definition of Salmonella Serotype of Human Health Concern Profile
6.	145	145 Combined	11	Clarifies that additions to an established NPIP flock must meet all disease classifications of established flock prior to comingling
7.	145	145 Combined	12	Amends requirements for participating dealers
8.	145, 146	Combined	13	Clarifies ELISA as a screening test and AGID or PCR as a confirmatory test for Avian Influenza detection
9.	145, 146	Combined	16	Allows use of RRT-PCR for Avian Influenza surveillance by all NPIP Authorized Labs
10	145, 146	Combined	17	Allows use of RRT-PCR for Avian Influenza surveillance by all NPIP authorized labs with their State Veterinarian's approval
11.	145	145 Combined	18	Clarifies that the number of birds tested should follow Plan programs
12.	145	B	18	Amends participation requirements
13.	145	C	19	Amends participation requirements
14.	145	D	20	Amends participation requirements
15.	145	D	21	Eliminates requirement for testing for *Mycoplasma meleagridis* after initial qualifying test
16.	145	145 D, G, H	21	Updates old OIE terminology of notifiable Avian Influenza or NAI to current OIE terminology of H5/H7 AI
17.	145	E	31	Adds trachea as approved sampling site for *M. gallisepticum* and *M. synoviae* PCR testing and clarifies number of birds to be tested
18.	145	E	33	Amends Form 9-3I requirements
19.	145	G	34	Amends participation requirements
20.	145	G	35	Addition of U.S. Salmonella Monitored Classification Program
21.	145	H	36	Amends participation requirements
22.	145	H	37	Amends U.S. Salmonella Monitored Classification Program requirements
23.	145	H	40	Amends U.S. Salmonella Monitored Classification Program requirements

24.	146	B	41	Amends testing requirements for U.S. H5/H7 AI Monitored Classification Program
25.	147	Combined	42	Amends voting procedure for General Conference Committee members and alternates
26.	147	Combined	44	Amends Committee consideration of proposed changes
27.	147	Combined	45	Amends Conference consideration of proposed changes by GCC members abstaining from voting except for breaking a tie
28.	147	Combined	46	Clarifies check test proficiency requirements for Authorized Laboratories
29.	147	Combined	46	Amends requirements for Authorized Laboratories
30.	147	Combined	47	Clarifies requirements for new test submissions

PROGRAM STANDARDS PROPOSED CHANGES

PROPOSAL NUMBER	SUBPART	SUBPART DELEGATES	PAGE	SUBJECT OF PROPOSAL
1.	PS-Table of Contents	Combined	50	Proposed language change of "Subpart" to "Group" for ease of distinguishing between 9-CFR regulations and Program Standards references
2.	PS-A	Combined	52	Amends hemagglutination inhibition test procedures for Mycoplasma
3.	PS-A	Combined	59	Amends standard test procedures for Avian Influenza
4.	PS-B	Combined	62	Clarifies number of samples required for bacteriological examination of Salmonella from birds
5.	PS-B	Combined	62	Clarifies laboratory procedure recommended for the bacteriological examination of Salmonella in birds
6.	PS-C	Combined	63	Amends and updates sanitation procedures
7.	PS-D	Combined	68	Amends laboratory procedure recommended for PCR test for *Mycoplasma gallisepticum* and *M. synoviae*
8.	PS-D	Combined	69	Amends standard test procedures for use of RRT-PCR for AI testing in waterfowl
9.	PS-E	Combined	71	Establishes new Subpart E – Biosecurity Principles
10.	PS-F	145 D, G, H	74	Establishes new Subpart F – US Poultry Primary Breeder Avian Influenza Compartmentalization Program
11.	PS-D	Combined	75	Addition of new diagnostic test submissions for Mycoplasma and Salmonella

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 2016 Biennial 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 B delegates – representing multiplier egg-type chickens
Subpart C delegates – representing multiplier meat-type chickens
Subpart D delegates – representing breeding turkeys
Subpart E delegates – representing waterfowl, exhibition poultry, and game birds
Subpart F delegates – representing ostrich, emu, rhea, and cassowary
Subpart G delegates – representing primary egg-type chickens
Subpart H delegates – representing primary meat-type chickens
Subpart I delegates – representing breeding meat-type waterfowl
Subpart 6B delegates – representing commercial table-egg layers
Subpart 6C delegates – representing commercial meat-type chickens
Subpart 6D delegates – representing commercial meat-type turkeys
Subpart 6E delegates – representing commercial raised-for-release waterfowl and upland game birds

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**

§56.4 Determination of indemnity amounts.

(a) Destruction and disposal of poultry.

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

Reason: The egg industry repeatedly attempted to gain unsuccessfully an understanding from USDA/APHIS the calculator for "the appraised value should include the hen's projected future production." APHIS determined the value based on Agri-Stats and then used an arbitrary percentage discount which amounted to fractions of one cent per dozen eggs anticipated in the hen's future production.

In testimony before the Senate Agriculture, Nutrition and Forestry Committee on July 7, 2015, Ken Klippen, National Association of Egg Farmers (NAEF), explained in the questioning portion of the Senate Committee that the value of an egg-laying hen differed from meat varieties. Depreciating the value of the actual bird must be coupled with future egg production at a value consistent with the value of those eggs. Klippen also provided a model for calculating this value. In NAEF's example in determining the appraised value, including the hen's projected future production for 2015, calculations would be based on the previous 5-year average values (from year 2014 to the year 2010 in cents per dozens). The Egg Industry Center at Iowa State University in Ames, Iowa provided the average profits on a per-dozen-basis for year 2014 through 2010 as follows: 33.17 cents, 9.35 cents, .02 cents, 2.2 cents and 7.57 cents respectively for a 5-year average price per dozen at 10.46 cents per dozen. Future egg production is therefore calculated to 95 weeks of age, where each of his chickens would have produced just over 36 dozen eggs. The 5-year average profit is an average profit per dozen at 10.46 cents.

The Egg Industry Center, Iowa State University in Ames, Iowa also provided the value of the actual layer itself in 2015 is 9.51 cents per dozen. When calculating the depreciation value, using the pullet costs in cents per dozen, starting in the year 2014 and working backwards to the year 2010, that value is 9.53 cents, 10.13 cents, 10.14 cents, 9.51 cents, 8.26 cents for a hen's depreciation value average of 9.51 cents per dozen.

With the depreciation value and future egg production, egg farmers can understand the calculator for indemnity by APHIS instead of an arbitrary percentage discount from Agri-Stats.

At 20 weeks of age, the hen is most valuable. Her depreciation value is based on 9.51 cents per dozen eggs she would have produced or a value of $3.42 (9.51 x 36 dozen). Her production (36

dozen eggs) expected would have been valued at (36 x 10.46) is $3.77. Adding $3.42 to $3.77 provides a bird's true value at $7.19.

At 20 weeks, we expect federal indemnification to be $7.19 per bird. That's the peak value and will go down for each week of age before depopulation. To calculate the value based on the age of your flock, farmers universally can use the Eggs per Hen-Housed Cumulative chart provided by the Egg Industry Center. After locating the age of the flock in the left-hand column, the figures to the right are the eggs produced to that point in the age of the bird. Divide by 12 (eggs/dz) and you have your multiplier. For depreciation value, multiply the eggs/dz multiply times the average value of 9.51 cents. Then, for the future production, multiply the eggs/dz times the average price of 10.46 cents/dz. The two figures added together provide the combined depreciated value plus the future eggs produced.

Sponsor: Ken Klippen
National Association of Egg Farmers

Proposal No. 2

Delegates: **Combined**

§145.1 Definitions
§147.41 Definitions
§147.51 Definitions

NPIP Technical Committee - A committee made up of technical experts on poultry health, biosecurity, surveillance, and diagnostics. The NPIP Technical Committee will be divided into three (3) individual subcommittees (Mycoplasma, Salmonella and Avian Influenza). NPIP Technical Committee Members may serve on one or all subcommittees. The NPIP Veterinary Coordinator will serve as the NPIP Technical Committee Chairperson at the direction of the Senior Coordinator, and will evaluate membership annually. The committee consists of representatives from the poultry and egg industries, universities, and State and Federal governments and is appointed by the Senior Coordinator and approved by the General Conference Committee. The committee will evaluate proposed changes to the Provisions and Program Standards of the Plan which include but are not limited to the tests and sanitation procedures and provide recommendations to the Delegates of the National Plan Conference as to whether they are scientifically or technically sound.

§146.1 Definitions
§56.1 Definitions

NPIP Technical Committee - A committee made up of technical experts on poultry health, biosecurity, surveillance, and diagnostics. The NPIP Technical Committee will be divided into three (3) individual subcommittees (Mycoplasma, Salmonella and Avian Influenza). NPIP Technical Committee Members may serve on one or all subcommittees. The NPIP Veterinary Coordinator will serve as the NPIP Technical Committee Chairperson at the direction of the Senior Coordinator, and will evaluate membership annually. The committee consists of representatives from the poultry and egg industries, universities, and State and Federal governments and is appointed by the Senior Coordinator and approved by the General Conference Committee. The committee will evaluate proposed changes to the Provisions and Program Standards of the Plan which include but are not limited to the tests and sanitation procedures and

provide recommendations to the Delegates of the National Plan Conference as to whether they are scientifically or technically sound.

Reason: All members of the Technical Committee should have the ability to discuss and vote on all proposed tests. If a Technical Committee member is not a member of one of the subcommittees, then the member is denied the opportunity to participate in discussions about the tests prior to the biennial meeting. For many Technical Committee members, belonging to all 3 subcommittees is daunting. The Technical Committee should establish their recommendations at the biennial meeting where the Technical Committee members, the GCC, and the voting delegates are present.

Further, since the Technical Committee evaluates any proposed change as to whether they are scientifically or technically sound, therefore, all parts of the NPIP should include the definition of the committee.

Sponsors: Dr. Patricia Wakenell
Purdue University Animal Disease Diagnostic Laboratory

Dr. Dale Lauer
Minnesota Board of Animal Health

Paul Brennan
Indiana State Poultry Association

Proposal No. 3

Delegates: **145**

§145.23 Terminology and classification; flocks and products.
Participating flocks, and the eggs and chicks produced from them, which have met the respective requirements specified in this section may be designated by the following terms and the corresponding designs illustrated in §145.10:
(a) [Reserved]
(b) *U.S. Pullorum-Typhoid Clean.* A flock in which freedom from pullorum and typhoid has been demonstrated to the Official State Agency under the criteria in one of the following paragraphs (b)(1) through (4) of this section: *Provided,* That a flock qualifying by means of a blood test shall be tested within the past 12 months, except that the retesting of a participating flock which is retained for more than 12 months shall be conducted a minimum of 4 weeks after the induction of molt. (See §145.14 relating to the official blood test where applicable.)

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

§145.33 Terminology and classification; flocks and products.
Participating flocks, and the eggs and chicks produced from them, which have met the respective requirements specified in this section may be designated by the following terms and the corresponding designs illustrated in §145.10:
(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 (4) of this section: *Provided,* That a flock qualifying by means of a blood test shall

be tested within the past 12 months, except that the retesting of a participating flock which is retained for more than 12 months shall be conducted a minimum of 4 weeks after the induction of molt. (See §145.14 relating to the official blood test where applicable.)

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

§145.43 Terminology and classification; flocks and products.

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

(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: *Provided,* That a flock qualifying by means of a blood test shall be tested within the past 12 months, except that the retesting of a participating flock which is retained for more than 12 months shall be conducted a minimum of 4 weeks after the induction of molt. (See §145.14 relating to the official blood test where applicable.)

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

(2) It is a multiplier breeding flock, or a breeding flock composed of progeny of a primary breeding flock which is intended solely for the production of multiplier breeding flocks, and meets the following specifications as determined by the Official State Agency and the Service:

(i) The flock is located in a State where all persons performing poultry disease diagnostic services within the State are required to report to the Official State Agency within 48 hours the source of all poultry specimens from which S. pullorum 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 multiplier breeding flock, or a breeding flock composed of progeny of a primary breeding flock which is intended solely for the production of multiplier breeding flocks, that originated from U.S. Pullorum-Typhoid Clean breeding flocks or from flocks that met equivalent requirements under official supervision, and is located in a State in which it has been determined by the Service that:

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

(ii) All turkey 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) [Reserved]
(viii) Discontinuation of any of the conditions or procedures described in paragraphs (b)(3)(i), (ii), (iii), (iv), (v), and (vi) of this section, or the occurrence of repeated outbreaks of pullorum or typhoid in turkey 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.

(4) It is a multiplier breeding flock located in a State which has been determined by the Service to be in compliance with the provisions of paragraph (b)(3) of this section and in which pullorum disease or fowl typhoid is not known to exist nor to have existed in turkey hatchery supply flocks within the State during the preceding 24 months.
(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 with <u>either</u> no reactors <u>or reactors, that upon further bacteriological examination conducted in accordance with part 147 of this subchapter, fail to demonstrate pullorum-typhoid infection</u>: *Provided*, That a bacteriological examination monitoring program acceptable to the Official State Agency and approved by the Service may be used in lieu of blood testing.

§145.53 Terminology and classification; flocks and products.

Participating flocks, and the eggs 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.):

(1) It has been officially blood tested within the past 12 months with <u>either</u> no reactors <u>or reactors, that upon further bacteriological examination conducted in accordance with part 147 of this subchapter, fail to demonstrate pullorum-typhoid infection.</u>
(2) It is a multiplier breeding flock, or a breeding flock composed of progeny of a primary breeding flock which is intended solely for the production of multiplier breeding flocks, and meets the following specifications as determined by the Official State Agency and the Service:

(i) The flock is located in a State where all persons performing poultry disease diagnostic services within the State are required to report to the Official State Agency within 48 hours the source of all poultry specimens from which S. pullorum 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 multiplier breeding flock that originated from U.S. Pullorum-Typhoid Clean breeding flocks or from flocks that met equivalent requirements under official supervision, and is located in a State in which it has been determined by the Service that:
(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) Discontinuation of any of the conditions or procedures described in paragraphs (b)(3)(i), (ii), (iii), (iv), (v), (vi), and (vii) 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.

(4) It is a multiplier breeding flock located in a State which has been determined by the Service to be in compliance with the provisions of paragraph (b)(3) of this section, and in which pullorum disease or fowl typhoid is not known to exist nor to have existed in hatchery supply flocks within the State during the preceding 24 months.

(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 either no reactors or reactors, that upon further bacteriological examination conducted in accordance with part 147 of this subchapter, fail to demonstrate pullorum-typhoid infection: *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.

§145.63 Terminology and classification; flocks and products.

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

(a) *U.S. Pullorum-Typhoid Clean.* A flock in which freedom from pullorum and typhoid has been demonstrated to the Official State Agency under the criteria in paragraph (a)(1) or (a)(2) of this section. (See §145.14(a) relating to the official blood test for pullorum-typhoid where applicable.)

(1) It has been officially blood tested within the past 12 months with either no reactors or reactors, that upon further bacteriological examination conducted in accordance with part 147 of this subchapter, fail to demonstrate pullorum-typhoid infection.

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

(i) (A) It is a multiplier or primary breeding flock of fewer than 300 birds in which a sample of 10 percent of the birds in a flock or at least 1 bird from each pen, whichever is more, has been officially tested for pullorum-typhoid within the past 12 months with either no reactors or reactors, that upon further bacteriological examination conducted in accordance with part 147 of this subchapter, fail to demonstrate pullorum-typhoid infection; or

(B) It is a multiplier or primary breeding flock of 300 birds or more in which a sample of a minimum of 30 birds has been officially tested for pullorum-typhoid within the past 12 months with either no reactors or reactors, that upon further bacteriological examination conducted in accordance with part 147 of this subchapter, fail to demonstrate pullorum-typhoid infection.

§145.73 Terminology and classification; flocks and products.

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

(a) [Reserved]

(b) *U.S. Pullorum-Typhoid Clean.* A flock in which freedom from pullorum and typhoid has been demonstrated to the Official State Agency under the criteria in paragraph (b)(1) or (b)(2) of this section: *Provided*, That a flock qualifying by means of a blood test shall be tested within the past 12 months, except that the retesting of a participating flock which is retained for more than 12

months shall be conducted a minimum of 4 weeks after the induction of molt. (See §145.14 relating to the official blood test where applicable.)

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

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

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

(ii) In the primary breeding flock, a sample of 300 birds from flocks of more than 300, and each bird in flocks of 300 or less, has been officially tested for pullorum-typhoid with either no reactors or reactors, that upon further bacteriological examination conducted in accordance with part 147 of this subchapter, fail to demonstrate pullorum-typhoid infection: *Provided,* That a bacteriological examination monitoring program acceptable to the Official State Agency and approved by the Service may be used in lieu of blood testing.

§145.83 Terminology and classification; flocks and products.

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

(a) [Reserved]

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

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

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

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

(ii) In the primary breeding flock, a sample of 300 birds from flocks of more than 300, and each bird in flocks of 300 or less, has been officially tested for pullorum-typhoid with either no reactors or reactors, that upon further bacteriological examination conducted in accordance with part 147 of this subchapter, fail to demonstrate pullorum-typhoid infection: *Provided,* That a bacteriological examination monitoring program acceptable to the Official State Agency and approved by the Service may be used in lieu of blood testing.

§145.93 Terminology and classification; flocks and products.

Participating flocks, and the eggs and baby poultry produced from them, that 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 (b)(5) 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 either no reactors or reactors, that upon further bacteriological examination conducted in accordance with part 147 of this subchapter, fail to demonstrate pullorum-typhoid infection.

(2) It is a multiplier breeding flock, or a breeding flock composed of progeny of a primary breeding flock which is intended solely for the production of multiplier breeding flocks, and meets the following specifications as determined by the Official State Agency and the Service:

(i) The flock is located in a State where all persons performing poultry disease diagnostic services within the State are required to report to the Official State Agency within 48 hours the source of all poultry specimens from which S. pullorum 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 infected wild birds, contaminated feed or waste, or birds, equipment, supplies, or personnel from flocks infected with pullorum-typhoid.

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

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

(4) It is a multiplier breeding flock located in a State which has been determined by the Service to be in compliance with the provisions of paragraph (a)(3) of this section, and in which pullorum disease or fowl typhoid is not known to exist nor to have existed in hatchery supply flocks within the State during the preceding 24 months.

(5) It is a primary breeding flock located in a State determined to be in compliance with the provisions of paragraph (a)(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 <u>either</u> no reactors <u>or reactors, that upon further bacteriological examination conducted in accordance with part 147 of this subchapter, fail to demonstrate pullorum-typhoid infection</u>: Provided, That when a flock is a primary breeding flock located in a State which has been deemed to be a U.S. Pullorum-Typhoid Clean State for the past 3 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.

Reason: Currently, the language in all 145 subparts implies that no reactors to pullorum-typhoid are allowed for qualifying purposes. The additions clarify that reactors may be found but must be further examined bacteriologically to demonstrate flock freedom from pullorum-typhoid infection.

Sponsor: Dr. Doug Waltman
Georgia Poultry Laboratory Network

Proposal No. 4

Delegates: **145**

§ 145.1 Definitions
<u>Air Space:</u> <u>A similar aged population of poultry on one farm within the same ventilated space that are maintained as a bio-secure segregated group but may be part of a larger flock (as applied to disease control).</u>

Reason: The addition of this definition of “Air Space” provides the final biosecurity barrier between poultry and the “outside” which we may use to instill the importance of the steps necessary to protect animals inside this unit and direct sampling numbers for testing appropriately. We need to instill the importance of biosecurity practices at this level to control organisms such as Avian Influenza, Mycoplasma and Salmonella.

Sponsor: Joe Schultz
Cobb-Vantress, Inc.

Proposal No. 5

Delegates: **145**

§ 145.1 Definitions
Salmonella serotypes of human health concern profile: The top three Salmonella serotypes of human health concern, possibly linked to poultry, poultry environments and their products according to the Food Safety Inspection Service (FSIS) and Centers for Disease Control (CDC). Profile is published on the NPIP website and in the NPIP Program Standards. This profile is updated annually and provided to the public.

Reason: This proposed change adds to the NPIP Part 145 general provisions a definition of Salmonella serotypes of human health concern, possibly linked to poultry, poultry environments and their products. The Service with cooperation of the Food Safety Inspection Service (FSIS) and Centers for Disease Control (CDC), shall on an annual basis communicate to the NPIP participants by way of a listing in the Program Standards or the NPIP website, the top three Salmonella serotypes of USA Human health concern which the collective agrees are possibly linked to poultry environments after review of CDC information (human health), and the annual consolidated State Salmonella serotype summaries generated from the NPIP Salmonella Monitored and Sanitation Monitored programs. Salmonella of various serotypes are found in multiple environmental areas worldwide and have been associated with colonization of most animals. In the poultry industry, we are well aware that non-poultry disease producing serotypes of this organism have at times established themselves in our populations and environments as resident bacterial organisms. While it is our desire to reduce all Salmonella serotypes to address human health concerns (some of these serotypes do have greater potential to cause disease in humans), and our ongoing NPIP efforts will continue to push this reduction, knowing the most prevalent serotypes of concern in our environments with continued real time data will assist the full poultry production process to respond in a responsible, practical and timely manner to address this concern. Having this definition and participation of our industry will show the transparency and cooperative objectives as the NPIP continues to evolve and improve the production supply of healthy and safe poultry products.

Sponsor: Joe Schultz
Cobb-Vantress, Inc.

Proposal No. 6

Delegates: **145**

§145.4 General provisions for all participants
(a) Records of purchases and sales and the identity of products handled shall be maintained in a manner satisfactory to the Official State Agency.
(b) Products, records of sales and purchase of products, and material used to advertise products shall be subject to inspection by the Official State Agency at any time.
(c) Advertising must be in accordance with the Plan, and applicable rules and regulations of the Official State Agency and the Federal Trade Commission. A participant advertising products as being of any official classification may include in his advertising reference to associated or franchised hatcheries only when such hatcheries produce the same kind of products of the same classification.

(d) Except as provided by this paragraph, participants in the Plan may not buy or receive products for any purpose from nonparticipants unless they are part of an equivalent program, as determined by the Official State Agency. Participants in the Plan may buy or receive products from flocks that are neither participants nor part of an equivalent program, for use in breeding flocks or for experimental purposes, under the following conditions only:

(1) With the permission of the Official State Agency and the concurrence of the Service; and

(2) By segregation of all birds before introduction into the breeding flock. Upon reaching sexual maturity, the segregated birds must be tested and found negative for pullorum-typhoid as well as any other disease classifications the original flock holds. The Official State Agency may require a second test at its discretion.

(e) Each participant shall be assigned a permanent approval number by the Service. This number, prefaced by the numerical code of the State, will be the official approval number of the participant and may be used on each certificate, invoice, shipping label, or other document used by the participant in the sale of his products. Each Official State Agency which requires an approval or permit number for out-of-State participants to ship into its State should honor this number. The approval number shall be withdrawn when the participant no longer qualifies for participation in the Plan.

Reason: The current language is misleading. The addition serves to clarify that, before any segregated birds can be added to an established NPIP flock, those birds must undergo appropriate testing and meet the requirements for any flock classification, not just the PT Clean classification, to which they are being added.

Sponsor: Dr. Elena Behnke
NPIP Veterinary Coordinator

Proposal No. 7

Delegates: **145**

§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 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 Official State Agency 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.

(e) The selling of *Salmonella enteritidis* (SE)-vaccinated poultry is not allowed to individuals or vendors involved with retail sales to the general public in states conducting pullorum-typhoid surveillance in exhibition and hobby flocks. If allowed by the Official State Agency of the receiving state(s), each SE-vaccinated bird must be permanently identified with a leg band or wing tag recorded in a flock vaccination record and on a sale receipt or VS Form 9-3 (listed in "Section

10. Remarks") along with a statement giving the date and the type of SE vaccine used. This documentation must be given to the new owner at the time of sale or shipment. SE-vaccinated poultry must have originated from a flock testing negative to pullorum typhoid prior to SE vaccination and documented on a VS Form 9-2 or laboratory report from a NPIP authorized laboratory.

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. Also, in the Northeast region an increasing number of pullorum-typhoid reactors have been seen with an increase use of SE vaccine in layer hens. Surplus SE vaccinated started poultry are being sold by dealers traveling throughout the Northeast in small lots or to feed stores with inaccurate documentation or no identification, making it very difficult to differentiate true pullorum-typhoid reactors from SE-vaccinated birds on serology. This also complicates state surveillance programs by having an unidentified population of SE vaccinated poultry that must be cultured to determine if they are truly positive or not, resulting in hundreds of dollars spent in time, labor and additional testing costs to find a false positive.

Sponsor: Dr. Mary Jane Lis
Connecticut Department of Agriculture

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 as the initial screening test. 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 as the primary confirmatory test on all ELISA-positive samples or ELISA positive flocks.

(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.

In addition to AGID, ~~A~~agent detection tests ~~may~~ are recommended to be used as additional confirmatory tests to detect influenza A matrix gene or protein but not to determine hemagglutinin or neuraminidase subtypes. Additional samples from the ELISA

positive flocks will be needed to run agent detection test. Samples for agent detection testing should be collected from ~~naturally occurring~~ flock mortality or clinically ill birds.

(i) The real time reverse transcriptase/polymerase chain reaction (RRT-PCR) assay.

(A) The RRT-PCR tests must be conducted using reagents approved by the Department and the Official State Agency. The RRT-PCR must be conducted using the National Veterinary Services Laboratories (NVSL) official protocol for RRT-PCR and must be conducted by personnel who have passed an NVSL proficiency test.

(B) Positive results from the RRT-PCR 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.

(ii) USDA-licensed type A influenza antigen capture immunoassay (ACIA).

(A) The USDA-licensed type A influenza ACIA 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) Chicken and turkey flocks that test positive on the ACIA must be further tested using the RRT-PCR or virus isolation. Positive results from the RRT- PCR or virus isolation 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.

(3) In case of the sample tested positive on ELISA and negative on AGID, the test results are considered "suspicious positive" and require an additional confirmatory test. The additional confirmatory test could be RRT-PCR assay if samples (swabs) are taken from the flock within 7 days from the first sample. Or the additional confirmatory test can be a second AGID test if another blood sample was taken after 7 days from the first sample. (~~3~~4) The official determination of a flock as positive for the H5 or H7 subtypes of avian influenza may be made only by NVSL.

§ 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 as the initial screening test. 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 as the primary confirmatory test on all ELISA-positive samples or ELISA positive flocks.

(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.

In addition to AGID, ~~A~~agent detection tests ~~may~~ are recommended to be used as additional confirmatory tests to detect influenza A matrix gene or protein but not to

determine hemagglutinin or neuraminidase subtypes. Additional samples from the ELISA positive flocks will be needed to run agent detection test. Samples for agent detection testing should be collected from ~~naturally occurring~~ flock mortality or clinically ill birds.

(i) The real time reverse transcriptase/polymerase chain reaction (RRT-PCR) assay.

(A) The RRT-PCR tests must be conducted using reagents approved by the Department and the Official State Agency. The RRT-PCR must be conducted using the National Veterinary Services Laboratories (NVSL) official protocol for RRT-PCR and must be conducted by personnel who have passed an NVSL proficiency test.

(B) Positive results from the RRT-PCR 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.

(ii) USDA-licensed type A influenza antigen capture immunoassay (ACIA).

(A) The USDA-licensed type A influenza ACIA 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) Chicken and turkey flocks that test positive on the ACIA must be further tested using the RRT-PCR or virus isolation. Positive results from the RRT- PCR or virus isolation must be retested by Federal Reference Laboratories using appropriate tests for confirmation. Final judgment may be based upon further sampling and appropriate tests for confirmation.

(3) In case of the sample tested positive on ELISA and negative on AGID, the test results are considered "suspicious positive" and require an additional confirmatory test. The additional confirmatory test could be RRT-PCR assay if samples (swabs) are taken from the flock within 7 days from the first sample. Or the additional confirmatory test can be a second AGID test if another blood sample was taken after 7 days from the first sample.

(~~3~~4) The official determination of a flock as positive for the H5 or H7 subtypes of avian influenza may be made only by NVSL.

Reason: The changes in the text above are proposed with the purpose of making sure that the more sensitive test (ELISA) is used as the screening test, and the more specific test (AGID) is used as the confirmatory test. The changes also encourages that additional confirmatory tests could be run with AGID. Additional confirmatory tests are particularly useful in the situation of positive ELISA but negative AGID. In this situation specific recommendations were made to use PCR or a second AGID as an additional confirmatory test.

PCR is both sensitive and specific, and could be used as a screening and as a confirmatory test. However, PCR, unlike serology, is unable to detect past infections in the flock. So, unless the infection is current and the virus is still actively circulating in the flock, PCR cannot detect the infection. For this reason, ELISA is still the preferred screening test, but PCR can be used as a confirmatory test.

These changes are intended to render the surveillance program simple and efficient in achieving the goal which is detecting any circulating H5/H7 LPAI as early as possible with the goal of preventing them from transforming into HPAI.

Sponsor: Dr. Mohamed El-Gazzar
The Ohio State University

Proposal No. 9

Delegates: **Combined**

§ 145.14 Testing

(d) For avian influenza.

(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.

(i) *The real time reverse transcriptase/polymerase chain reaction (RRT-PCR) assay.*

(A) The RRT-PCR tests must be conducted using reagents approved by the Department and the Official State Agency. The RRT-PCR must be conducted using the National Veterinary Services Laboratories (NVSL) official protocol for RRT-PCR or a test kit licensed by the Department and approved by the OSA, and must be conducted by personnel who have passed an NVSL proficiency test.

(B) Positive results from the RRT-PCR 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.

(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 this testing should be collected from naturally occurring flock mortality or clinically ill birds.

(i) *The real time reverse transcriptase/polymerase chain reaction (RRT-PCR) assay*.

(A) The RRT-PCR tests must be conducted using reagents approved by the Department and the Official State Agency. The RRT-PCR must be conducted using the National Veterinary Services Laboratories (NVSL) official protocol for RRT-PCR or a test kit licensed by the Department and approved by the OSA, and must be conducted by personnel who have passed an NVSL proficiency test.

(B) Positive results from the RRT-PCR 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: The RRT-PCR assay is the most sensitive test available to detect an active infection of a flock with Avian Influenza. An NPIP authorized lab that can satisfactorily pass a proficiency test provided by the Service using the NVSL approved protocol or federally licensed kit should be allowed to run this assay as a screening test admissible for the AI Clean program. Follow-up of a positive reaction would continue to be handled by the Department and the Official State Agency.

Sponsors: Dr. Eric Jensen
Aviagen North America

Dr. Travis Schaal
Hy-Line International

Ken Klippen
National Association of Egg Farmers

Proposal No. 10

Delegates: **Combined**

§ 145.14 Testing

(d) For avian influenza.

(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.

(i) *The real time reverse transcriptase/polymerase chain reaction (RRT-PCR) assay.*

(A) The RRT-PCR test~~s~~ must be conducted using ~~reagents approved by the Department and the Official State Agency. The RRT-PCR~~ the official RRT-PCR National Animal Health Laboratory Network (NAHLN) M gene method or a test kit licensed by the Department and approved by the Official State Agency (OSA). ~~National Veterinary Services Laboratories (NVSL) official protocol for RRT-PCR and~~ The RRT-PCR must be conducted by ~~personnel who have~~ an NPIP approved laboratory that has passed an NVSL proficiency test. Use of the RRT-PCR assay by such a laboratory must also be approved by the State Veterinarian.

(B) Positive results from the RRT-PCR 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.

(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 this testing should be collected from naturally occurring flock mortality or clinically ill birds.

(i) *The real time reverse transcriptase/polymerase chain reaction (RRT-PCR) assay.*

(A) The RRT-PCR test~~s~~ must be conducted using ~~reagents approved by the Department and the Official State Agency. The RRT-PCR~~ the official RRT-PCR National Animal Health Laboratory Network (NAHLN) M gene method or a test kit licensed by the Department and approved by the Official State Agency (OSA). ~~National Veterinary Services Laboratories (NVSL) official protocol for RRT-PCR and~~ The RRT-PCR must be conducted by ~~personnel who have~~ an NPIP approved laboratory that has passed an NVSL proficiency test. Use of the RRT-PCR assay by such a laboratory must also be approved by the State Veterinarian.

(B) Positive results from the RRT-PCR 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: The RRT-PCR assay is the most sensitive test available to detect an active infection of a flock with Avian Influenza. Any NPIP authorized lab that can satisfactorily pass a proficiency test provided by the Service should be allowed to run this assay as a screening test admissible for the AI Clean program. Follow-up of a positive reaction would continue to be handled by the Department and the Official State Agency.

Sponsor: Undine Taldo, Cobb-Vantress, Inc.

Proposal No. 11

Delegates: **145**

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

Reason: Some programs allow for testing fewer than 30 birds. This addition clarifies that the number of birds tested should follow Plan programs.

Sponsor: Dr. Doug Waltman
Georgia Poultry Laboratory Network

Proposal No. 12

Delegates: **145 B**

§ 145.22 Participation
Participating flocks of multiplier egg type chickens, and the eggs and chicks produced from them, shall comply with the applicable general provisions of subpart A of this part and the special provisions of this subpart B.
(a) Started chickens shall lose their identity under Plan terminology when not maintained by Plan participants under the conditions prescribed in §145.5(a).
(b) Hatching eggs produced by multiplier breeding flocks should be nest clean. They may be fumigated in accordance with part 147 of this subchapter or otherwise sanitized.
(c) Any nutritive material provided to chicks must be free of the avian pathogens that are officially represented in the Plan disease classifications listed in §145.10.
(d) Poultry must be protected from vectors known to be in the wild and thus must be housed in enclosed structures during brooding, rearing, grow-out or laying periods with no intentional access

to the outdoors, creatures found in the wild, raised on open range or pasture or be provided with untreated open source water such as that directly from a pond, stream or spring that wild birds or vermin have access to for usage for drinking water, as a cooling agent, or during a wash down – clean out process.

Reason: This proposed change will add a requirement that participants within this subpart must maintain their birds within bio-security of walled, wild bird proofed and covered buildings for their entire life and not have access to outdoors or provided open sourced untreated water to increase overall biosecurity in these segments and place more emphasis on bio-security in general as well as improve control of Salmonella serotypes of human health concern in this subpart. There are several reasons we moved commercial poultry in off the range of which disease control was paramount. We desire to protect them from disease vectors roaming the outside and should be able to market products gaining consumer confidence for the reasons we continue to do this and excluded from participation in this subpart any poultry that do not comply with this definition. While it may be "natural" to be infected with Avian Influenza from drinking pond water contaminated with wild goose or duck feces or to pick up an addition to the poultry microbiota additional strains of bacteria or parasites such as Salmonella from eating frogs and insects on the open range, it is not desirable in commercial poultry raised to produce products to feed human populations healthy protein in a predictable an economically reasonable manner. We have additional program subcategories these animals belong in. (Such as "E".) We should welcome and expand on the guidance and scientifically valid NPIP programs directed toward the improvement of Poultry in these subcategories raised in non-confinement, however at the same time we need to emphasize for the success of all of us that there truly can be no "middle ground".

Sponsor: Joe Schultz
Cobb-Vantress, Inc.

Proposal No. 13

Delegates: **145 C**

§ 145.32 Participation
Participating flocks of multiplier meat type chickens, and the eggs and chicks produced from them, shall comply with the applicable general provisions of subpart A of this part and the special provisions of this subpart C.
(a) Started chickens shall lose their identity under Plan terminology when not maintained by Plan participants under the conditions prescribed in §145.5(a).
(b) Hatching eggs produced by multiplier breeding flocks should be nest clean. They may be fumigated in accordance with part 147 of this subchapter or otherwise sanitized.
(c) Any nutritive material provided to chicks must be free of the avian pathogens that are officially represented in the Plan disease classifications listed in §145.10.
(d) Poultry must be protected from vectors known to be in the wild and thus must be housed in enclosed structures during, brooding, rearing, grow-out or laying periods with no intentional access to the outdoors, creatures found in the wild, raised on open range or pasture or be provided with untreated open source water such as that directly from a pond, stream or spring that wild birds or vermin have access to for usage for drinking water, as a cooling agent, or during a wash down – clean out process.

Reason: This proposed change will add a requirement that participants within this subpart must maintain their birds within bio-security of walled, wild bird proofed and covered buildings for their entire life and not have access to outdoors or provided open sourced untreated water to increase overall

biosecurity in these segments and place more emphasis on bio-security in general as well as improve control of Salmonella serotypes of human health concern in this subpart. There are several reasons we moved commercial poultry in off the range of which disease control was paramount. We desire to protect them from disease vectors roaming the outside and should be able to market products gaining consumer confidence for the reasons we continue to do this and excluded from participation in this subpart any poultry that do not comply with this definition. While it may be "natural" to be infected with Avian Influenza from drinking pond water contaminated with wild goose or duck feces or to pick up an addition to the poultry microbiota additional strains of bacteria or parasites such as Salmonella from eating frogs and insects on the open range, it is not desirable in commercial poultry raised to produce products to feed human populations healthy protein in a predictable an economically reasonable manner. We have additional program subcategories these animals belong in. (Such as "E".) We should welcome and expand on the guidance and scientifically valid NPIP programs directed toward the improvement of Poultry in these subcategories raised in non-confinement, however at the same time we need to emphasize for the success of all of us that there truly can be no "middle ground".

Sponsor: Joe Schultz
Cobb-Vantress, Inc.

Proposal No. 14

Delegates: **145 D**

§ 145.42 Participation
(a) Participating turkey flocks, and the eggs and poults produced from them, shall comply with the applicable general provisions of subpart A of this part and the special provisions of this subpart D.
(b) Hatching eggs should be nest clean. They may be fumigated in accordance with part 147 of this subchapter or otherwise sanitized.
(c) Any nutritive material provided to poults must be free of the avian pathogens that are officially represented in the Plan disease classifications listed in §145.10.
(d) Poultry must be protected from vectors known to be in the wild and thus must be housed in enclosed structures during, brooding, rearing, grow-out or laying periods with no intentional access to the outdoors, creatures found in the wild, raised on open range or pasture or be provided with untreated open source water such as that directly from a pond, stream or spring that wild birds or vermin have access to for usage for drinking water, as a cooling agent, or during a wash down – clean out process.

Reason: This proposed change will add a requirement that participants within this subpart must maintain their birds within bio-security of walled, wild bird proofed and covered buildings for their entire life and not have access to outdoors or provided open sourced untreated water to increase overall biosecurity in these segments and place more emphasis on bio-security in general as well as improve control of Salmonella serotypes of human health concern in this subpart. There are several reasons we moved commercial poultry in off the range of which disease control was paramount. We desire to protect them from disease vectors roaming the outside and should be able to market products gaining consumer confidence for the reasons we continue to do this and excluded from participation in this subpart any poultry that do not comply with this definition. While it may be "natural" to be infected with Avian Influenza from drinking pond water contaminated with wild goose or duck feces or to pick up an addition to the poultry microbiota additional strains of bacteria or parasites such as Salmonella from eating frogs and insects on the open range, it is not desirable in commercial poultry raised to produce products to feed human populations healthy protein in a predictable an economically reasonable manner. We have

additional program subcategories these animals belong in. (Such as “E”.) We should welcome and expand on the guidance and scientifically valid NPIP programs directed toward the improvement of Poultry in these subcategories raised in non-confinement, however at the same time we need to emphasize for the success of all of us that there truly can be no “middle ground”.

Sponsor: Joe Schultz
Cobb-Vantress, Inc.

Proposal No. 15

Delegates: **145 D**

§ 145.43. Terminology and classification; flocks and products.
(d) U.S. M. Meleagridis Clean.
(1) A flock in which freedom from M. meleagridis has been demonstrated under the following criteria:
(i) A sample of 100 birds from each flock has been tested for M. meleagridis when more than 12 weeks of age~~: Provided, That to retain this classification, a minimum of 30 samples from male flocks and 60 samples from female flocks shall be retested at 28-30 weeks of age and at 4-6 week intervals thereafter.~~

Reason: *M. meleagridis* is rarely found in US turkey breeding stock and no significant reservoir exists in commercial and non-commercial turkeys or other poultry.

Sponsor: Dr. Becky Tilley
Butterball, LLC

Proposal No. 16

Delegates: **145 D, G, H**

§145.45 Terminology and classification; compartments
(a) US H5/H7 AI 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), ~~also referred to as notifiable avian influenza (NAI)~~. For the purpose of the compartment, avian influenza is defined according to the OIE Terrestrial Animal Health Code Chapter 10.4. This compartment has the purpose of protecting the defined subpopulation and avoiding the introduction and spread of H5/H7 AI ~~NAI~~ 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. ~~NAI~~. 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 ~~NAI~~ 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 ~~NAI~~. 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). 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, as described in §145.14(d), 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-~~NAI~~ 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 ~~NAI~~. 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.

(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, 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 ~~NAI~~. 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 ~~NAI~~ 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 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 Clean classification, surveillance for H5/H7 AI ~~NAI~~ 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 ~~NAI~~ 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 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 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 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).

(4) Emergency response and notification. In the case of a confirmed positive of H5/H7 AI ~~NAI~~ 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 ~~NAI~~ 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]

§145.74 Terminology and classification; compartments

(a) U.S. Avian Influenza 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), ~~also referred to as notifiable avian influenza (NAI).~~ This compartment has the purpose of protecting the defined subpopulation and avoiding the introduction and spread of H5/H7 AI ~~NAI~~ 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 ~~NAI~~. 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 ~~NAI~~ 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 ~~NAI~~. 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). 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, as described in §145.14(d), 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 ~~NAI~~-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 ~~NAI~~. 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.

(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, 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 ~~NAI~~. 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 ~~NAI~~ 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 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 Clean classification, surveillance for H5/H7 AI ~~NAI~~ 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 ~~NAI~~ 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 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 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 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).

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

§145.84 Terminology and classification; compartments

(a) U.S. Avian Influenza 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), ~~also referred to as notifiable avian influenza (NAI).~~ This compartment has the purpose of protecting the defined subpopulation and avoiding the introduction and spread of H5/H7 AI ~~NAI~~ 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 ~~NAI~~. 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 ~~NAI~~ 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 ~~NAI~~. 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). 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, as described in §145.14(d), 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 ~~NAI~~-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 ~~NAI~~. 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.

(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, 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 ~~NAI~~. 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 ~~NAI~~ 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 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 Clean classification, surveillance for H5/H7 AI ~~NAI~~ 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 ~~NAI~~ 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 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 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 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).

(4) Emergency response and notification. In the case of a confirmed positive of H5/H7 AI ~~NAI~~ 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 ~~NAI~~ 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 terms "notifiable avian influenza" or "NAI" have been removed from the OIE Terrestrial Code and Terrestrial Manual. These changes reflect current OIE terminology more accurately.

Sponsor: Dr. Elena Behnke
NPIP Veterinary Coordinator

Proposal No. 17

Delegates: **145 E**

§ 145.53 Terminology and classification; flocks and products

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

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

(i) It is a flock in which all birds or a sample of at least 300 birds has been tested for *M. gallisepticum* as provided in § 145.14(b) when more than 4 months of age or upon reaching sexual maturity: *Provided,* That to retain this classification, a random sample of serum or egg yolk or a targeted bird sample of the trachea or choanal palatine cleft / fissure area using appropriate swabs from all the birds in the flock if flock size is less than 30, but at least 30 birds, shall be tested at intervals of not more than 90 days: *And provided further,* That a sample comprised of less than 30 birds may be tested at any one time, with the approval of the Official State Agency and the concurrence of the Service, provided that a

total of at least 30 birds or all birds in the flock if flock size is less than 30, is tested within each 90-day period; or

(ii) It is a multiplier breeding flock which originated as U.S. M. Gallisepticum Clean baby poultry from primary breeding flocks and ~~a random sample comprised of 50 percent of the birds in the flock, with a maximum of 200 birds and a minimum of 30 birds per flock or all birds in the flock if flock is less than 30 birds,~~ from which a random sample of at least 200 birds from a flock of more than 400 birds has been tested for M. gallisepticum as provided in § 145.14(b) when more than 4 months of age or upon reaching sexual maturity. For flocks of 60 to 400 birds, 50% of the birds shall be tested. For flocks of fewer than 60 birds, all birds shall be tested up to a maximum of 30 birds: *Provided,* That to retain this classification, the flock shall be subjected to one of the following procedures:

(A) At intervals of not more than 90 days, a random sample of serum or egg yolk or a targeted bird sample of the trachea or choanal palatine cleft/fissure area using appropriate swabs from all the birds in the flock if flock size is less than 30, but at least 30 birds shall be tested; or

(B) At intervals of not more than 30 days, a sample of 25 cull baby poultry produced from the flock shall be subjected to laboratory procedures acceptable to the Official State Agency and approved by the Service, for the detection and recovery of M. gallisepticum.

(2) A participant handling U.S. M. Gallisepticum Clean products shall keep these products separate from other products in a manner satisfactory to the Official State Agency: *Provided,* That U.S. M. Gallisepticum Clean baby poultry from primary breeding flocks shall be produced in incubators and hatchers in which only eggs from flocks qualified under paragraph (c)(1)(i) of this section are set.

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

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

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

(i) It is a flock in which all birds or a sample of at least 300 birds has been tested for M. synoviae as provided in §145.14(b) when more than 4 months of age or upon reaching sexual maturity: *Provided,* That to retain this classification, a random sample of serum or egg yolk or a targeted bird sample of the trachea or choanal palatine cleft / fissure area using appropriate swabs (C.P. swabs) from all the birds in the flock if flock size is less than 30, but at least 30 birds, shall be tested at intervals of not more than 90 days: *And provided further,* That a sample comprised of less than 30 birds may be tested at any one time with the approval of the Official State Agency and the concurrence of the Service, provided that a total of at least 30 birds, is tested within each 90-day period; or

(ii) It is a multiplier breeding flock that originated as U.S. M. Synoviae Clean chicks from primary breeding flocks and from which a random sample ~~comprised of 50 percent of the birds in the flock, with a maximum of 200 birds and a minimum of 30 birds per flock or all birds in the flock if flock is less than 30 birds~~ of at least 200 birds from a flock of more than 400 birds has been tested for M. synoviae as provided in §145.14(b) when more than 4 months of age or upon reaching sexual maturity. For flocks of 60 to 400 birds, 50% of the birds shall be tested. For flocks of fewer than 60 birds, all birds shall be tested up to a maximum of 30 birds: *Provided,* That to retain this classification, the flock shall be subjected to one of the following procedures:

(A) At intervals of not more than 90 days, a random sample of serum or egg yolk or a targeted bird sample of the trachea or choanal palatine cleft / fissure area using appropriate swabs from all the birds in the flock if flock size is less than 30, but at least 30 birds shall be tested: *Provided*, That a sample of fewer than 30 birds may be tested at any one time, with the approval of the Official State Agency and the concurrence of the Service, provided that a total of at least 30 birds or the entire flock if flock size is less than 30, is tested each time and a total of at least 30 birds is tested within each 90-day period; or
(B) At intervals of not more than 30 days, egg yolk testing shall be conducted in accordance with part 147 of this subchapter.

(2) A participant handling U.S. M. Synoviae Clean products shall keep those products separate from other products in a manner satisfactory to the Official State Agency: Provided, That U.S. M. Synoviae Clean chicks from primary breeding flocks shall be produced in incubators and hatchers in which only eggs from flocks qualified under paragraph (d)(1)(i) or (d)(1)(ii) of this section are set.

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

References:

-Ferguson-Noel, N. and S.H. Kleven. *A laboratory manual for the Isolation and Identification of Avian Pathogens*, 6th edition. *In Press*.
-Raviv, Z. and D.H. Ley. Mycoplasma gallisepticum infection. In: *Diseases of Poultry*, 13th edition. D.E. Swayne, J.R. Glisson, L.R. McDougald, L.K. Nolan, D.L. Suarez and V.L. Nair, eds. Wiley-Blackwell, Ames, Iowa. pp 877-893. 2013.
-Kleven, S.H., and S. Levisohn. 1996. Mycoplasma infections in poultry. In: *Molecular and Diagnostic Procedures in Mycoplasmology*, Vol. II. J.G. Tully, ed. Academic Press, Inc., New York. 283-292.

Reason: We would like to request that trachea be added as a sampling site for *M. gallisepticum* and *M. synoviae* PCR testing under Subpart E. The change accepted in 2014 listed the choanal palatine cleft, but not the trachea as a sampling site. Both choanal cleft and trachea are recommended sampling sites for *M. gallisepticum* and *M. synoviae* detection by PCR and culture. We further propose that the language in 145.53 be changed to clarify the number of birds that must be sampled for *M. gallisepticum* and *M. synoviae* testing.

Sponsors: Dr. Natalie Armour
Mississippi State University

Dr. Danny Magee
Mississippi State University

Proposal No. 18

Delegates: **145 E**

§ 145.52 Participation

Participating flocks of hobbyist and exhibition waterfowl, exhibition poultry, and game birds, and the eggs 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.

(a) Started poultry 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 primary breeding flocks shall be fumigated or otherwise sanitized in accordance with part 147 of this subchapter.
(c) It is recommended that waterfowl flocks and gallinaceous flocks in open-air facilities be kept separate.
(d) 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 a hatchery invoice form (9-3I) approved by the Official State Agency and the Service to identify poultry sales to clients. If the selling hatchery uses the 9-3I form, the following information must be included on the form:

(1) The form number "9-3I", printed or stamped on the invoice;
(2) The hatchery name and address;
(3) The date of shipment;
(4) The hatchery invoice number;
(5) The purchaser name and address;
(6) The quantity of products sold;
(7) The shipping hatchery NPIP#/State
(~~7~~8) Identification of the products by bird variety or by NPIP stock code as listed in the NPIP APHIS 91-55-078 appendix; and
(~~8~~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 hatchery approval number; and
(ii) The NPIP classification for which product is qualified (e.g., U.S. Pullorum-Typhoid Clean).

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

Reason: In dealing with the 2015 outbreak of Avian Influenza at a breeder house near our facility, we had many states who were not allowing shipments of chicks from our state (Iowa), or from our location because of being in a control zone. However, we had other hatcheries drop shipping chicks for us. These drop ship hatcheries were not located in the state of Iowa, or were from hatcheries not in a control zone. By adding the shipping hatchery NPIP#/State, this allows the state receiving this form to know that the birds in the shipment came from a different location and identifies this NPIP participating location and state for them.

Sponsor: Brian Kollasch
Welp Hatchery, Inc.

Proposal No. 19

Delegates: **145 G**

§ 145.72 Participation
Participating flocks of primary egg-type chickens, and the eggs and chicks produced from them, shall comply with the applicable general provisions of subpart A of this part and the special provisions of this subpart G.
(a) Started chickens shall lose their identity under Plan terminology when not maintained by Plan participants under the conditions prescribed in §145.5(a).

(b) Hatching eggs produced by primary breeding flocks should be nest clean. They may be fumigated in accordance with part 147 of this subchapter or otherwise sanitized.
(c) Any nutritive material provided to chicks must be free of the avian pathogens that are officially represented in the Plan disease classifications listed in §145.10.
(d) Poultry must be protected from vectors known to be in the wild and thus must be housed in enclosed structures during, brooding, rearing, grow-out or laying periods with no intentional access to the outdoors, creatures found in the wild, raised on open range or pasture or be provided with untreated open source water such as that directly from a pond, stream or spring that wild birds or vermin have access to for usage for drinking water, as a cooling agent, or during a wash down – clean out process.

Reason: This proposed change will add a requirement that participants within this subpart must maintain their birds within bio-security of walled, wild bird proofed and covered buildings for their entire life and not have access to outdoors or provided open sourced untreated water to increase overall biosecurity in these segments and place more emphasis on bio-security in general as well as improve control of Salmonella serotypes of human health concern in this subpart. There are several reasons we moved commercial poultry in off the range of which disease control was paramount. We desire to protect them from disease vectors roaming the outside and should be able to market products gaining consumer confidence for the reasons we continue to do this and excluded from participation in this subpart any poultry that do not comply with this definition. While it may be "natural" to be infected with Avian Influenza from drinking pond water contaminated with wild goose or duck feces or to pick up an addition to the poultry microbiota additional strains of bacteria or parasites such as Salmonella from eating frogs and insects on the open range, it is not desirable in commercial poultry raised to produce products to feed human populations healthy protein in a predictable an economically reasonable manner. We have additional program subcategories these animals belong in. (Such as "E".) We should welcome and expand on the guidance and scientifically valid NPIP programs directed toward the improvement of Poultry in these subcategories raised in non-confinement, however at the same time we need to emphasize for the success of all of us that there truly can be no "middle ground".

Sponsor: Joe Schultz
Cobb-Vantress, Inc.

Proposal No. 20

Delegates: **145 G**

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

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

(i) The flock is maintained in accordance with part 147 of this subchapter with respect to flock sanitation, cleaning and disinfection, and Salmonella isolation, sanitation, and management;
(ii) Measures should be implemented to control Salmonella challenge through feed, feed storage, and feed transport.

(iii) Chicks shall be hatched in a hatchery whose sanitation is maintained in accordance with part 147 of this subchapter and sanitized or fumigated in accordance with part 147 of this subchapter.
(iv) An Authorized Agent shall take environmental samples from the hatchery every 30 days; i.e., meconium or chick papers. An authorized laboratory for Salmonella shall examine the samples bacteriologically;
(v) An Authorized Agent shall take environmental samples in accordance with part 147 of this subchapter from each flock at 4 months of age and every 30 days thereafter. An authorized laboratory for Salmonella shall examine the environmental samples bacteriologically. All Salmonella isolates from a flock shall be serogrouped and shall be reported to the Official State Agency on a monthly basis;
(vi) Owners of flocks may vaccinate with a paratyphoid vaccine: Provided, That a sample of 350 birds, which will be banded for identification, shall remain unvaccinated until the flock reaches at least 4 months of age to allow for the serological testing required under paragraph (g)(1)(vi) of this section.
(vii) Any flock entering the production period that is in compliance with all the requirements of §145.73(g) with no history of Salmonella isolations shall be considered "Salmonella negative" and may retain this definition as long as no environmental or bird Salmonella isolations are identified and confirmed from the flock or flock environment by sampling on 4 separate collection dates over a minimum of a 2-week period. Sampling and testing must be performed as described in paragraph (g)(1)(vi) of this section. An unconfirmed environmental Salmonella isolation shall not change this Salmonella negative status.

(2) The Official State Agency may monitor the effectiveness of the sanitation practices in accordance with part 147 of this subchapter.
(3) In order for a hatchery to sell products of paragraphs (g)(1)(i) through (g)(1)(vii) of this section, all products handled shall meet the requirements of the classification.
(4) This classification may be revoked by the Official State Agency if the participant fails to follow recommended corrective measures.

Reason: The primary egg-type breeder companies routinely monitor their flocks and chicks for all Salmonella serotypes with the goal of producing Salmonella free product. The addition of a Salmonella Monitored program for egg-type breeder companies will formalize those efforts.

Sponsor: Dr. Travis Schaal
Association of Poultry Primary Breeder Veterinarians

Proposal No. 21

Delegates: **145 H**

§ 145.82 Participation
Participating flocks of primary meat-type chickens, and the eggs and chicks produced from them, shall comply with the applicable general provisions of subpart A of this part and the special provisions of this subpart H.
(a) Started chickens shall lose their identity under Plan terminology when not maintained by Plan participants under the conditions prescribed in §145.5(a).
(b) Hatching eggs produced by primary breeding flocks should be nest clean. They may be fumigated in accordance with part 147 of this subchapter or otherwise sanitized.

(c) Any nutritive material provided to chicks must be free of the avian pathogens that are officially represented in the Plan disease classifications listed in §145.10.
(d) Poultry must be protected from vectors known to be in the wild and thus must be housed in enclosed structures during, brooding, rearing, grow-out or laying periods with no intentional access to the outdoors, creatures found in the wild, raised on open range or pasture or be provided with untreated open source water such as that directly from a pond, stream or spring that wild birds or vermin have access to for usage for drinking water, as a cooling agent, or during a wash down – clean out process.

Reason: This proposed change will add a requirement that participants within this subpart must maintain their birds within bio-security of walled, wild bird proofed and covered buildings for their entire life and not have access to outdoors or provided open sourced untreated water to increase overall biosecurity in these segments and place more emphasis on bio-security in general as well as improve control of Salmonella serotypes of human health concern in this subpart. There are several reasons we moved commercial poultry in off the range of which disease control was paramount. We desire to protect them from disease vectors roaming the outside and should be able to market products gaining consumer confidence for the reasons we continue to do this and excluded from participation in this subpart any poultry that do not comply with this definition. While it may be "natural" to be infected with Avian Influenza from drinking pond water contaminated with wild goose or duck feces or to pick up an addition to the poultry microbiota additional strains of bacteria or parasites such as Salmonella from eating frogs and insects on the open range, it is not desirable in commercial poultry raised to produce products to feed human populations healthy protein in a predictable an economically reasonable manner. We have additional program subcategories these animals belong in. (Such as "E".) We should welcome and expand on the guidance and scientifically valid NPIP programs directed toward the improvement of Poultry in these subcategories raised in non-confinement, however at the same time we need to emphasize for the success of all of us that there truly can be no "middle ground".

Sponsor: Joe Schultz
Cobb-Vantress, Inc.

Proposal No. 22

Delegates: **145 H**

§ 145.83 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 chicks through an effective and practical sanitation program at the breeder farm and in the hatchery. This will afford other segments of the poultry industry an opportunity to reduce the incidence of *Salmonella* in their products.

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

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

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

(iii) A minimum of 8 dust samples per feed mill from incoming feed ingredients shall be monitored and cultured for Salmonella on a monthly basis coming into

the mills that supply flocks in this program. Any isolates of Salmonella shall be identified as to source of sample and reported as to serotype. It is suggested that these samples include: corn, soy, wheat midds, bulking agents, and any animal byproducts or fish meal if utilized by the specific Mill manufacturing feed for birds in this category.

(iv) Processes shall be implemented in the feed milling environments to reduce the likelihood of Salmonella detected in incoming ingredients from entering the finished feed and ultimately being consumed by breeding flocks. A minimum of 8 dust samples per month from finished feed being loaded into or out of delivery vehicles shall be sampled and cultured for Salmonella monthly per feed mill that supply flocks in this program. Any isolates of Salmonella shall be identified and reported as to serotype to determine the effectiveness of Feed Milling Salmonella control interventions by the specific Mill(s).

(v) Prior to placement of a new hatch of poultry into housing units or a move of a started flock into another airspace, an Authorized Agent shall collect six environmental swab house clean out samples per airspace, in accordance with NPIP Program Standards Subpart B (3)(1) (ii), (iii), or (iv) . These samples shall be collected once the house Air Space has undergone a cleaning and disinfection process and is dry or if it is a situation where litter is to be re-used (see 2016 NPIP Program Standards proposal #6) but prior to the point birds are housed and in enough time for testing to be completed and results examined. The house clean out inspection follow up swab samples are to be examined by an authorized laboratory for Salmonella including serotype. Identification of sample source and reporting of all Salmonella serotypes isolated to the Official State Agency should be done. The following sample sites are suggested (I) Feeding system (Feed track, feed pans, feed bin boot area, feed hoppers, feed track connection joints), (II) Air System (Side curtains, Cool cell pads, Air inlets, Dark out light traps, Exhaust fans, Plenum rooms) (III) Walls and if applicable Egg collection equipment (nest pads, belts. Collection tables, (IV) Floors / Slats / Litter area (V) Rodent Bait Stations, and (VI) Water supply systems (Water filters, drinker lines, actual water collected at end of drinker lines.) If any of the top three Salmonella serotypes types of Human Health concern are detected the specific air space shall be visually re-inspected along with rewashing (if necessary), but at least re-disinfection along with re-sampling and testing as described above completed prior to re-stocking to see if the final interventions were effective.

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

(~~iv~~vii) ~~An Authorized Agent shall take environmental samples from the hatchery every 30 days; *i.e.*, meconium or chick papers. An authorized laboratory for *Salmonella* shall examine the samples bacteriologically;~~An Authorized Agent shall collect a minimum of one well soiled environmental swab sample-per hatch day, at a common point all chicks would typically pass in the hatchery process such as a chick take off belt at the point of removal from hatch baskets / trays after the last basket is worked, pedigree work stations, or a common vaccination point. This sample should be collected before the area is cleaned for the day. An authorized laboratory for *Salmonella* shall examine the daily hatchery environmental samples and identify and report any serotype(s) isolated.

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

(~~vi~~ ix) Owners of flocks may vaccinate with a paratyphoid vaccine: *Provided*, That a sample of 350 birds, which will be banded for identification, shall remain unvaccinated until the flock reaches at least 4 months of age to allow for the serological testing required under paragraph (f)(1)(~~vi~~ ix) of this section.
(~~vii~~ x) Any flock entering the production period that is in compliance with all the requirements of §145.83(f) with no history of *Salmonella* isolations shall be considered "*Salmonella* negative" and may retain this definition as long as no environmental or bird *Salmonella* isolations are identified and confirmed from the flock or flock environment by sampling on 4 separate collection dates over a minimum of a 2-week period. Sampling and testing must be performed as described in paragraph (f)(1)(~~vi~~ ix) of this section. An unconfirmed environmental *Salmonella* isolation shall not change this *Salmonella* negative status.

(2) The Official State Agency may monitor the effectiveness of the sanitation practices in accordance with part 147 of this subchapter.
(3) In order for a hatchery to sell products of paragraphs (f)(1)(i) through (f)(1)(~~vii~~ x) of this section, all products handled shall meet the requirements of the classification.
(4) This classification may be revoked by the Official State Agency if the participant fails to follow recommended corrective measures.
(5) The Authorized laboratories performing the testing in this program shall report participant results monthly to the appropriate NPIP Official State Agency (OSA). Updates to pervious months delayed serotype results shall be submitted when available. The Official State Agency will collaborate with participating Subpart members in their states to provide guidance towards improvement of results over time. The Official State Agency shall submit to the Service on an annual basis the consolidated number of flocks participating in this program in their States (Or monitored in authorized laboratories within the State), along with the incidence of and types of Salmonella detected in the State at the various program stages: Pre-housing clean out check testing, Feed Milling (Raw ingredients and finished feed), Flock Environmental testing at Pre-lay and in production cycle points, as well as the hatchery testing results in the salmonella monitoring program. The Service may report on an annual basis the consolidated success of Salmonella reduction at appropriate NPIP and other official meetings of the Agency Salmonella types of human health concern detected in Primary Meat-Type Chicken Breeding Flocks and their Products. The service may not be provided data linked to any specific enterprises as the intent of this voluntary part will not be to penalize any specific enterprise but to collectively improve Poultry biosecurity and reduce the bio-burden of Salmonella types of human health concern possibly linked to the Poultry Industry in general being transmitted down the supply system. Individual flock control is to be managed by the enterprise and State (OSA) on a cooperative basis.

Reason: This proposal amends, clarifies and adds to the primary meat type chicken breeding flock U.S. Salmonella monitored program to increase overall biosecurity in this segment and place more emphasis on control of Salmonella serotypes of human health concern in this subpart. There exist a gap in the control of Salmonella in the meat type poultry industry between the primary breeding organizations and the entry of meat chickens for processing at FSIS monitored processing plants that is perhaps not optimally being addressed currently. These practical proposed changes will provide data for the Industry to collectively work with their OSA and the Service to reduce the bio-burden of this organism in general and specifically the top three Salmonella serotypes of human health concern in the USA in the meat type chicken breeder level with the additional benefit of overall biosecurity improvement should a participant enterprise honestly and actively participate in this Subpart. As the primary breeding operations have made significant improvement over the past 15 years in Salmonella control, having ongoing and transparent information linked to introduction points of these organisms into live production systems at this level will better guide other segments of the industry where focus may be most beneficial to the final product consumed.

Sponsor: Joe Schultz
Cobb-Vantress, Inc.

Proposal No. 23

Delegates: **145 H**

§ 145.83 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 chicks through an effective and practical sanitation program at the breeder farm and in the hatchery. This will afford other segments of the poultry industry an opportunity to reduce the incidence of *Salmonella* in their products.

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

(i) The flock is maintained in accordance with part 147 of this subchapter with respect to flock sanitation, cleaning and disinfection, and Salmonella isolation, sanitation, and management;
(ii) Measures should be implemented to control Salmonella challenge through the feed, feed storage, and feed transport.
(iii) Chicks shall be hatched in a hatchery whose sanitation is maintained in accordance with part 147 of this subchapter and sanitized or fumigated in accordance with part 147 of this subchapter.
(iv) An Authorized Agent shall take environmental samples from the hatchery every 30 days; i.e., meconium or chick papers. An authorized laboratory for Salmonella shall examine the samples bacteriologically;
(v) An Authorized Agent shall take environmental samples in accordance with part 147 of this subchapter from each flock at 4 months of age and every 30 days thereafter. An authorized laboratory for *Salmonella* shall examine the environmental samples bacteriologically. All *Salmonella* isolates from a flock shall be ~~serogrouped~~ serotyped and shall be reported to the Official State Agency on a monthly basis;
(vi) Salmonella data must be reviewed by Primary Breeders on a regular basis to measure the effectiveness of their preventative efforts and to ensure the number of positive finding remain below the annual NPIP performance standard.
(vii) The annual NPIP performance standard will be established after the first year of data reporting and will continue to be adjusted annually.
(viii) Salmonella performance by each Primary Breeder will be evaluated against the annual NPIP performance standard and be made publically available quarterly on the NPIP website.
(~~vi~~ ix) Owners of flocks may vaccinate with a paratyphoid vaccine: *Provided*, That a sample of 350 birds, which will be banded for identification, shall remain unvaccinated until the flock reaches at least 4 months of age to allow for the serological testing required under paragraph (f)(1)(~~vi~~ ix) of this section.
(~~vii~~ x) Any flock entering the production period that is in compliance with all the requirements of §145.83(f) with no history of *Salmonella* isolations shall be considered "*Salmonella* negative" and may retain this definition as long as no environmental or bird *Salmonella* isolations are identified and confirmed from the flock or flock environment by sampling on 4 separate collection dates over a minimum of a 2-week period. Sampling and testing must be performed as

described in paragraph (f)(1)(~~vi~~ ix) of this section. An unconfirmed environmental *Salmonella* isolation shall not change this *Salmonella* negative status.

Reason: According to the CDC, reducing Salmonella in poultry products has been and remains an important step in decreasing the burden of foodborne illnesses in the United States. Salmonella remains one of the most common foodborne pathogens. In this country, an estimated 1.2 million illnesses annually are thought to be caused by Salmonella. The number of human salmonellosis illnesses has remained high and unchanged for decades. Importantly, illnesses due to Salmonella are often attributed to poultry. In a study published in 2013, 19% of foodborne deaths were attributed to contaminated poultry.

From 2011 through 2013, three significant outbreaks of Salmonella Heidelberg infections from poultry occurred, and some of the strains of bacteria were resistant to multiple antibiotics. Over 900 infected people were identified, and 30% to 40% of them were hospitalized. In one large outbreak, 15% of people had sepsis, a serious infection in which Salmonella leaves the intestines and enters the bloodstream. These outbreaks were traced to raw ground turkey from one producer and raw chicken from another producer.

Primary Breeders are known to play a role in the vertical transmission of *Salmonella* to broiler flocks. Therefore, in lieu of adding additional serotypes to the NPIP program or depopulating all poultry flocks found positive for Salmonella, a new additional requirement to the NPIP program is proposed.

To further reduce the incident rate of *Salmonella* in Primary Breeding stock and evaluate a Primary Breeders performance in controlling *Salmonella*, a performance standard should be set as a targeted measure to drive continual improvement within the industry. Furthermore, the State (OSA) should report to the USDA-NPIP the results of the performance of the Primary Breeder against this new performance standard, by establishments, and USDA should make this information publically available on the NPIP website.

Sponsor: Frank Yiannas
VP of Food Safety, Wal-Mart, Inc.

Proposal No. 24

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 ~~30~~21 days prior to movement; **or**

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

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

(i) It is a commercial table-egg layer flock in which a minimum of 11 birds have been tested negative to the H5/H7 subtypes of avian influenza as provided in §146.13(b) within ~~30~~21 days prior to disposal; **and either**

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

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

Reason: The maximum incubation period for Avian Influenza is approximately 21 days as defined by the OIE. This change will make the H5/H7 AI Monitored program for commercial table egg layers more consistent with the H5/H7 AI Monitored program for commercial broilers and turkeys.

Sponsor: Dr. Denise Brinson
NPIP Senior Coordinator

Proposal No. 25

Delegates: **Combined**

§147.43 General Conference Committee

(b) The regional committee members and their alternates will be elected by the official delegates of their respective regions, and the member-at-large will be elected by all official delegates. There must be at least two nominees for each position, the voting will be by secret ballot, and the results will be recorded. <u>The ballots for electing GCC members and alternates should be printed in such a way as to allow the specific selection of one nominee for member, and later one nominee for alternate from the remaining nominees.</u> At least one nominee from each region must be from an underrepresented group (minorities, women, or persons with disabilities). The process for soliciting nominations for regional committee members will include, but not be limited to: Advertisements in at least two industry journals, such as the newsletters of the American Association of Avian Pathologists, the National Chicken Council, the United Egg Producers, and the National Turkey Federation; a FEDERAL REGISTER announcement; and special inquiries for nominations from universities or colleges with minority/disability enrollments and faculty members in poultry science or veterinary science.

(c) Three regional members shall be elected at each Plan Conference. All members shall serve for a period of 4 years, subject to the continuation of the Committee by the Secretary of Agriculture, and may not succeed themselves: *Provided,* that an alternate member who assumed a Committee

member vacancy following mid-term would be eligible for re-election to a full term. When there is a vacancy for the member-at-large position, the General Conference Committee shall make an interim appointment and the appointee shall serve until the next Plan Conference at which time an election will be held. If a vacancy occurs due to both a regional member and alternate being unable to serve, the vacant position will be filled by an election at the earliest regularly scheduled national or regional Plan Conference, where members of the affected region have assembled.

(d) The duties and functions of the General Conference Committee shall be as follows:

(1) Advise and make recommendations to the Department on the relative importance of maintaining, at all times, adequate departmental funding for the NPIP to enable the Senior Coordinator and staff to fully administer the provisions of the Plan.

(2) Advise and make yearly recommendations to the Department with respect to the NPIP budget well in advance of the start of the budgetary process.

(3) Assist the Department in planning, organizing, and conducting the biennial National Poultry Improvement Plan Conference.

(4) Consider each proposal submitted as provided in §147.44 and make recommendations to subpart Committees and the Conference. Meet jointly with the NPIP Technical Committee and consider the technical aspects and accuracy of each proposal. Recommend whether new proposals (*i.e.*, proposals that have not been submitted as provided in §147.44) should be considered by the delegates to the Plan Conference.

(5) During the interim between Plan Conferences, represent the cooperating States in:

(i) Advising the Department with respect to administrative procedures and interpretations of the Plan provisions as contained in 9 CFR.

(ii) Assisting the Department in evaluating comments received from interested persons concerning proposed amendments to the Plan provisions.

(iii) Recommending to the Secretary of Agriculture any changes in the provisions of the Plan as may be necessitated by unforeseen conditions when postponement until the next Plan Conference would seriously impair the operation of the program. Such recommendations shall remain in effect only until confirmed or rejected by the next Plan Conference, or until rescinded by the committee.

(6) Serve as an official advisory committee for the study of problems relating to poultry health and as the need arises, to make specific recommendations to the Secretary of Agriculture concerning ways in which the Department may assist the industry in solving these problems.

(7) Serve as a direct liaison between the NPIP and the United States Animal Health Association.

(8) Advise and make recommendations to the Department regarding NPIP involvement or representation at poultry industry functions and activities as deemed necessary or advisable for the purposes of the NPIP.

Reason: Printed ballots were first used in 2014. Prior to that time the delegates from each region would vote first for their GCC member, then for the alternate. In 2014 the person with the second most votes for member became the alternate by default. This change would allow the region's delegates to vote for the GCC member, then specifically vote for the alternate from the remaining candidates.

Sponsor: Paul Brennan
Indiana State Poultry Association

Proposal No. 26

Delegates: **Combined**

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

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

(b) Each official delegate shall be appointed a voting member in one of the committees specified in paragraph (a) of this section.
(c) Since several of the proposals may be interrelated, the committees shall consider them as they may relate to others, and feel free to discuss related proposals with other committees.
(d) The committees shall make recommendations to the conference as a whole concerning each proposal. The committee report shall show any proposed change in wording and the record of the vote on each proposal, and suggest an effective date for each proposal recommended for adoption. The individual committee reports shall be submitted to the chairman of the conference, who will combine them into one report showing, in numerical sequence, the committee recommendations on each proposal. Once completed the combined committee report should be distributed electronically to delegates and alternates prior to the delegates voting on the final day of the biennial.
(e) The committee meetings shall be open to any interested person. Advocates for or against any proposal should feel free to appear before the appropriate committee and present their views.
(f) Committee chairs will abstain from voting except to break a tie.

Reason: Committee Chairs should facilitate the discussion without directing the discussion from the chair. Voting to break a tie allows the committee chair to have a vote without undue influence on the other delegates.

Distributing the combined committee report electronically to the delegates allows for more time to read the final changes and for delegates to make better informed decisions. Distributing this information swiftly will significantly speed the process on the final day of the biennial conference. The delegates' e-mail addresses should be requested with registration, thus giving NPIP staff time to establish an electronic list for distribution, well in advance of the conference.

Sponsors: Paul Brennan
Indiana State Poultry Association

Dr. Dale Lauer
Minnesota Board of Animal Health

Proposal No. 27

Delegates: **Combined**

§ 147.47 Conference consideration of proposed changes

(a) The chairman of the conference shall be a representative of the Department.

(b) At the time designated for voting on proposed changes by the official delegates, the chairman of the General Conference Committee and the four committee chairmen shall sit at the speaker's table and assist the chairman of the conference.

(c) Each committee chairman shall present the proposals which his committee approves or recommends for adoption as follows: "Mr. Chairman. The committee for Egg-type chickens recommends the adoption of Proposal No. ___, for the following reasons (stating the reasons): I move the adoption of Proposal No. ___." A second will then be called for. If the recommendation is seconded, discussion and a formal vote will follow.

(d) Each committee chairman shall present the proposals which his committee does not approve as follows: "Mr. Chairman. The Committee for Egg-type chickens does not approve Proposal No. ___." The chairman will then ask if any official delegate wishes to move for the adoption of the proposal. If moved and seconded, the proposal is subject to discussion and voted. If there is no motion for approval, or if moved but not seconded, there can be no discussion or vote.

(e) Discussion on any motion must be withheld until the motion has been properly seconded, except that the delegate making the motion is privileged, if he desires, to give reasons for his motion at the time of making it. To gain the floor for a motion or for discussion on a motion, the official delegate in the case of a motion, or anyone in case of discussion on a motion, shall rise, address the chair, give his name and State, and be recognized by the chair before proceeding further. While it is proper to accept motions only from official delegates and to limit voting only to such delegates, it is, however, equally proper to accept discussion from anyone interested. To conserve time, discussion should be pointed and limited to the pertinent features of the motion.

(f) Proposals that have not been submitted in accordance with §147.44 will be considered by the conference only with the unanimous consent of the General Conference Committee. Any such proposals must be referred to the appropriate committee for consideration before being presented for action by the conference.

(g) Voting will be by States, and each official delegate, as determined by §147.45, will be allowed one vote on each proposal pertaining to the program prescribed by the subpart which he represents.

(h) A roll call of States for a recorded vote will be used when requested by a delegate or at the discretion of the chairman.

(i) All motions on proposed changes shall be for adoption.

(j) Proposed changes shall be adopted by a majority vote of the official delegates present and voting.

(k) The conference shall be open to any interested person.

(l) GCC members shall abstain from voting except to break a tie.

Reason: GCC Members should facilitate the discussion without directing the discussion from their head table. Voting to break a tie allows the GCC member to have a vote without undue influence on the other delegates.

Sponsor: Paul Brennan
Indiana State Poultry Association

Proposal No. 28

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 ~~a regularly scheduled~~ check test for each assay that it performs.

Reason: Other poultry reference laboratories have the ability to produce valid check-tests that can be used supplementary to those produced by NVSL. Additionally, the wording "regularly scheduled" was eliminated and replaced with "the next available" to minimize confusion.

Sponsor: Dr. Elena Behnke
NPIP Veterinary Coordinator

Proposal No. 29

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. The authorized laboratory must use a regularly scheduled check test for each assay that it performs.

(b) *Trained technicians.* The testing procedures at the laboratory must be run or overseen by a laboratory technician who has attended and satisfactorily completed Service-approved laboratory workshops for Plan-specific diseases within the past 4 years. If a laboratory has more than one physical laboratory site, but operates as a single laboratory system accredited by the American Association of Laboratory Diagnosticians (AAVLD) or the American Association for Laboratory Accreditation (A2LA), at least one technician from the laboratory system must attend each required workshop; and final approval is at the discretion of the Official State Agency.

(c) *Laboratory protocol.* Official Plan assays must be performed and reported as described in the NPIP Program Standards or in accordance with other procedures approved by the Administrator in accordance with §147.53(d)(1). Assays must be performed using control reagents approved by the Plan or the reagent manufacturer.

(d) *State site visit.* The Official State Agency will conduct a site visit and recordkeeping audit at least once every two years. This will include, but may not be limited to, review of technician training records, check test proficiency, and test results. The information from the site visit and recordkeeping audit will be made available to the NPIP upon request.
(e) *Service review.* Authorized laboratories will be reviewed by the Service (NPIP staff) every 3 years. The Service's review may include, but will not necessarily be limited to, checking records, laboratory protocol, check-test proficiency, technician training, and peer review. Alternatively, and if approved by the Official State Agency, an authorized laboratory may be accredited by the American Association of Laboratory Diagnosticians (AAVLD) or the American Association for Laboratory Accreditation (A2LA). Successful accreditation by one of these two organizations assures the laboratory's accountability to a comprehensive quality management system.
(f) *Reporting.*

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

(g) *Verification.* Random samples may also be required to be submitted for verification as specified by the Official State Agency.

Reason: Accredited laboratories that operate as a system are required to conduct the same assays from the same controlled standard operating procedure (SOP), which include regular and documented monitoring for reagents, test kits, temperature requirements, equipment performance, technician training, proficiency testing, etc. Changes in NPIP requirements are immediately incorporated into system-wide SOP updates, which include mandatory, documented training by all technicians performing the test. System-wide section meetings, held on a regular basis, will be utilized to relate additional information from trainings and workshops. Meeting minutes are available for review if requested.

Successful adherence to accreditation standards required by AAVLD or A2LA provides assurances to NPIP that all laboratory technicians and procedures are held accountable to a comprehensive quality management system that fully meets the requirements for NPIP authorized laboratories, including documented check-test proficiency, technician training, and all laboratory protocols being in compliance with NPIP Program Standards.

Sponsor: Dr. Richard E. Breitmeyer
CAHFS Laboratory System – UC Davis School of Veterinary Medicine

Proposal No. 30

Delegates: Combined

§ 147.54 Approval of diagnostic test kits not licensed by the Service.

1. Diagnostic test kits that are not licensed by the Service (e.g., bacteriological culturing kits) may be approved through the following procedure:

(a) The sensitivity of the kit will be evaluated in at least three NPIP authorized laboratories by testing known positive samples, as determined by the official NPIP procedures found in the NPIP Program Standards or through other procedures approved by the Administrator. Field samples, for which the presence or absence of the target organism or analyte has been determined by the current NPIP test are the preferred samples and should be used when possible. ~~not spiked samples or pure cultures~~. Samples from a variety of field cases representing a range of low, medium and high analyte concentrations should be used. In some cases it may be necessary to utilize samples from experimentally infected animals. Spiked samples (clinical sample matrix with a known amount of pure culture added), should only be used in the event that no other sample types are available. When the use of spiked or field samples may be necessary, prior approval from the technical committee is required. Pure cultures should never be used. Additionally, labs should be selected for their experience with testing for the target organism or analyte with the current NPIP approved test. (e.g. a Salmonella test should be evaluated with NPIP authorized laboratories that test for Salmonella routinely). If certain conditions or interfering substances are known to affect the performance of the kit, appropriate samples will be included so that the magnitude and significance of the effect(s) can be evaluated.
(b) The specificity of the kit will be evaluated in at least three NPIP authorized laboratories by testing known negative samples, as determined by tests conducted in accordance with the NPIP Program Standards or other procedures approved by the Administrator in accordance with § 147.53(d)(1). If certain conditions or interfering substances are known to affect the performance of the kit, appropriate samples will be included so that the magnitude and significance of the effect(s) can be evaluated.
(c) The kit will be provided to the cooperating laboratories in its final form and include the instructions for use. The cooperating laboratories must perform the assay exactly as stated in the supplied instructions. Each laboratory must test a panel of at least 25 known positive samples. In addition, each laboratory ~~will be asked to~~ must test at least 50 known negative samples obtained from several sources, to provide a representative sampling of the general population. The cooperating laboratories must perform a current NPIP procedure or NPIP approved test on the samples alongside the test kit for comparison and must provide an outline of the method on the worksheet for diagnostic test evaluation. Reproducibility and robustness data should also be included.

Special Considerations
Salmonella. It may be difficult to find naturally-contaminated positive samples for serotype-specific assays. The use of spiked samples should be avoided. A last resort should be the use of experimentally produced samples, such as bird inoculation and environmental testing. The importance of naturally-contaminated samples comes from the fact that these are wild (non-lab adapted) isolates, present in various levels competing with other organisms in the samples and may or may not be sub-lethally injured.
Mycoplasma. Finding sufficient field positive mycoplasmas (MG, MS and MM) may be difficult, but it is important to test them. Testing naturally contaminated samples provides for detection of various levels of the target organism within the background flora of the tissue. It may also provide opportunities for testing of various strains, including vaccine strains that may be present.
Avian Influenza. It will be important to select laboratories that are equipped and experienced or authorized for handling AIV. Avian influenza samples may not be available and may require experimentally infecting birds.
Molecular-based testing. Testing of field samples is preferred. In the event that field samples cannot be obtained, the use of experimentally produced samples such as bird inoculation and environmental testing should be used. The use of spike samples should be avoided. The production of DNA from a panel of isolates may be sufficient to evaluate molecular based tests. The panel of isolates must include target and non-target strains and may also represent different detection levels and mixed cultures. The party submitting the test for approval must recommend a specific extraction method to be used with the

molecular test. NPIP approved laboratories may use an alternative extraction method if they can show equivalency to the recommended extraction method.
(d) Cooperating laboratories will submit to the kit manufacturer all compiled output ~~raw~~ data regarding the assay response. Each sample tested will be reported as positive or negative, and the official NPIP procedure used to classify the sample must be submitted in addition to the assay response value. A completed worksheet for diagnostic test evaluation is required to be submitted with the compiled output ~~raw~~ data and may be obtained by contacting the NPIP Senior Coordinator. Compiled output ~~Raw~~ data and the completed worksheet for diagnostic test evaluation must be submitted to the NPIP Senior Coordinator four months prior to the next scheduled General Conference Committee meeting, which is when approval will be sought.
(e) The findings of the cooperating laboratories will be evaluated by the NPIP technical committee, and the technical committee will make a majority recommendation whether to approve the test kit to the General Conference Committee at the next scheduled General Conference Committee meeting. If the technical committee recommends approval, the final approval will be granted in accordance with the procedures described in §§ 147.46, 147.47, and 147.48.
(f) Diagnostic test kits that are not licensed by the Service (e.g., bacteriological culturing kits) and that have been approved for use in the NPIP in accordance with this section are listed in the NPIP Program Standards:

2. Approved tests modification and removal

(a) The specific data required for modifications of previously approved tests will be taken on a case by case basis by the technical committee.
(b) If the technical committee determines that only additional field data is needed at the time of submission for a modification of a previously approved test, allow for a conditional approval for 60 days for data collection side-by-side with a current test. The submitting party must provide complete protocol and study design, including criteria for pass/fail to the technical committee. The technical committee must review the data prior to final approval. This would only apply to the specific situation where a modified test needs additional field data with poultry to be approved.
(c) Approved diagnostic tests may be removed from the Plan by submission of a proposed change from a participant, official state agency, the Department, or other interested person or industry organization. The data in support of removing an approved test will be compiled and evaluated by the NPIP technical committee, and the technical committee will make a majority recommendation whether to remove the test kit to the General Conference Committee at the next scheduled General Conference Committee meeting. If the technical committee recommends removal, the final decision to remove the test will be granted in accordance with the procedures described in §§ 147.46, 147.47, and 147.48.

Reason: The changes above clarify the new test submissions process for review.

Sponsor: NPIP Technical Committee

Delegates: **Combined**

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Reason: The Title 9-Code of Federal Regulations Parts 145-147 utilizes the word “Subpart” to classify categories of regulations. Using this same language, “Subpart,” in the Program Standards Document has become very confusing to readers. In order to make thing simpler, we propose changing “Subpart” to “Group” only in the Program Standards Document.

Sponsor: Dr. Denise Brinson
NPIP Senior Coordinator

Delegates: **Combined**

Subpart A—Blood Testing Procedures

(6) Standard test procedures for mycoplasma.[5]

(b) Hemagglutination Inhibition (HI) test. The mycoplasma HI test is conducted by the constant-antigen, decreasing-serum method. This method requires using a 4-hemagglutination (HA) unit of diluted antigen. Differences in the number of HA units used will change the titers of positive sera markedly. Standard HA antigens for *Mycoplasma gallisepticum*, *M. synoviae*, and *M. meleagridis* are available from NVSL. The antigen has been titrated and diluted to approximately 1:640. The HA titration of each sample should be checked as described in paragraphs (b)(2)(ii) or (b)(3)(ii) on initial use or after long storage. To maintain HA activity, the undiluted HA antigen should be stored ~~at 60° to 70°C.~~ between -75 ^{0} C and -55 ^{0} C, or manufacturer's storage recommendations.

(1) Preparations of materials.

(i) Prepare phosphate-buffered saline (PBS) as follows:

	Grams
Sodium hydroxide (C.P.)	0.15
Sodium chloride (C.P.)	8.5
Potassium dihydrogen phosphate (KH_2PO_4) (C.P.)	0.68
Distilled water to make 1,000 ml	

The pH of the PBS will be 7.1–7.2 if all reagents are accurately measured.

(ii) Collect the turkey or chicken red blood cells (RBC's) in heparin (1,000 units per mL) or Alsever's solution which has been prepared as follows:

	Grams
Sodium citrate	8.0
Sodium chloride	4.2
Dextrose	20.5
Distilled water to make 1,000 ml	

The sodium citrate and sodium chloride are dissolved in 800 ml distilled water and sterilized at 15 lbs. pressure for 15 minutes. Dissolve the dextrose in 200 ml distilled water, sterilize by Seitz or other type of filtration and then add aseptically to the sterile sodium citrate and sodium chloride solution.

(iii) From turkeys or chickens known to be free of the mycoplasma being tested, withdraw sufficient blood with a syringe containing

heparin (approximately 0.2 mL heparin (1,000 units per mL) per 10 mL of blood) or Alsever's solution to give a ratio of 1 part blood to 5 parts Alsever's solution (e.g., 8 ml blood in 40 ml of Alsever's solution). Centrifuge the blood suspension at 1,000 rpm for 10 minutes and remove or supernatant with a pipette.

(iv) Wash the RBCs two times in 10 or more parts of Alsever's solution or buffered saline, centrifuging after each washing. Centrifugation is at 1,000 rpm for 10 minutes. The supernatant fluid is removed and the RBC deposit resuspended to give a 25 percent suspension of packed RBC's in Alsever's solution or buffered saline. (In testing either chicken or turkey sera, the homologous RBC system must be used; *i.e.* , use chicken cells when testing chicken serum and turkey cells when testing turkey serum.) If this suspension is kept refrigerated, it should keep for 7 or 8 days after the blood has been collected.

(v) For the test, 2 ml of the 25 percent RBCs is added to 98 ml of buffered saline to make a 0.~~25~~5 percent RBC suspension.

~~(2) Procedure No. 1.~~

~~*(i) Materials needed*~~

~~(A) Microtiter equipment (minimal); *i.e.*, microplates, microdiluters, micropipettes, go-no-go diluter delivery tester, (0.05 ml).~~

~~(B) Phosphate-buffered saline (PBS).~~

~~(C)Reagents from NVSL; *i.e.*, HA antigen and negative and positive titered sera for the mycoplasma to be tested.~~

~~(D) Homologous red blood cells (RBCs) suspension 0.5 percent (2 ml of 25 percent RBCs to 98 ml of PBS) obtained from birds free of the mycoplasma to be tested. (See paragraphs (d)(1)(ii) through (v) of this section for preparation of RBCs.)~~

~~(ii) Hemagglutination (HA) antigen titration.~~

~~(A) (Mark off two rows of 10 wells each for antigen titer (HA is done in duplicate)~~

~~(B) Mark last well in each row for cell controls.~~

~~(C) Prepare in small test tube (12×75 mm) a starting dilution of antigen by combining 0.1 ml antigen with 0.9 ml PBS. This is a 1:10 dilution.~~

~~(D) Add 0.05 ml PBS to all wells, including cell controls.~~

~~(E) Add 0.05 ml antigen (1:10 dilution) with diluters to the first well in both rows, mix thoroughly, transfer diluter to second well of each row and mix, continuing through the 10th well of each row. With mixture in diluter from last well, check diluter on go-no-go card, then place diluter in distilled water. If diluter checks out, antigen dilution will be 1:20, 1:40, 1:80, 1:160, 1:320, 1:640, 1:1280, 1:2560, 1:5120.~~

~~Table 1—Sample Results of HI Tests~~

~~[Tube and Serum Dilution]~~

	1	2	3	4	5	6	7	8	9	10
	1:5	1:10	1:20	1:40	1:80	1:160	1:320	1:640	1:1280	1:2560
Serum A (HI neg.)	−	+	+	+	+	+	+	+	+	+
Serum B (HI 1:40)	−	−	−	−	+	+	+	+	+	+
Serum C (HI 1:160)	−	−	−	−	−	−	+	+	+	+
Serum D (HI 1:20)	−	−	−	+	+	+	+	+	+	+

+, HA; −, no HA or HI

(F) Add 0.05 ml of 0.5 percent RBC suspension to all wells using a 0.05 dropper.

(G) Seal plate (if plate is to be held over 2 hours); shake and allow to stand at room temperature until cells in cell control gather in compact button. The titer is the highest dilution in which agglutination is complete. The dilution contains 1 HA unit in 0.05 ml.

(H) Prepare a dilution of antigen which contains 8 HA units in 0.05 ml. Example: if the antigen titer is 1:640, then that dilution contains 1 HA unit per 0.05 ml. Then 640÷8=80, or a dilution of 1:80 containing 8 HA units. Or 640÷4=160, a dilution of 1:160 containing 4 HA units per 0.05 ml.

(iii) HI test.

(A) Prepare two dilutions of antigen, one containing 8 HA units per 0.05 ml and one containing 4 HA units per 0.05 ml. The 4-unit antigen can be prepared from the 8-unit antigen by mixing with equal parts of PBS.

(B) Mark off one row of 8 wells for each test.

(C) Prepare a 1:5 dilution of each sera to be tested in a small test tube (12×75 mm): 0.1 ml serum plus 0.4 ml PBS or 0.05 ml serum plus 0.20 ml PBS.

(D) Add 0.05 ml PBS with the 0.05 ml dropper to the first well in each row.

(E) Add 0.05 ml of 8 unit antigen to well 2 in each row.

(F) Add 0.05 ml of 4 unit antigen to well 3 through 8 for each row.

(G) For each serum to be tested, load 0.05 ml diluter with 1:5 dilution as prepared in paragraph (iii) above and place in first well of row.

(H) Mix well and transfer loaded diluter to well 2. Continue serial twofold dilutions through well number 8.

(I) Well 1 (serum dilution of 1:10) is serum control. Well 2=1:20 dilution; well 3=1:40 dilution; well 4=1:80 dilution; well 5=1:160 dilution; well 6=1:320 dilution; well 7=1:640 dilution; and well 8=1:1280 dilution.

(J)Antigen control.

(1) Mark off 6 wells for antigen controls.

(2) Add 0.05 ml PBS to wells 2, 3, 4, 5, and 6.

(3) Add 0.05 ml 8 unit antigen to wells 1 and 2.

(4) With empty diluter, mix contents of well 2. Continue serial twofold dilutions through well 6.

~~(5) Well 1 contains 8 units; well 2 contains 4 units; well 3 contains 2 units; well 4 contains 1 unit; well 5 contains1/2unit; and well 6 contains1/4unit.~~

~~(6) Mark off two wells for cell controls and add 0.05 ml PBS to each.~~

~~(7) After 20 to 30 minutes at average room temperature (20° - 23°C) to permit antibody-antigen reaction, add 0.05 ml of a 0.5 percent suspension of RBCs to all wells.~~

~~(8) Seal all wells (if wells are to be held over 2 hours). Shake the plate thoroughly.~~

~~(9) Incubate at room temperature for 30 to 45 minutes.~~

~~*(K) Interpretation:* The HI titer is the highest serum dilution exhibiting complete inhibition of hemagglutination as indicated by flowing of cells when the plate is tilted. Serum having a titer of 1:80 or greater is considered positive. A titer of 1:40 is suspicious.~~

~~(L) Sample test results are illustrated in Table 1 in this paragraph.~~

~~(iv) If serological results from agglutination tests complemented by the HI test are inconclusive, cultural examination, bio-assay, or retesting of samples after an interval of at least 21 days may be indicated.~~

(~~3~~2) Procedure No. ~~2~~ 1.

Purpose: To test for antibodies to avian mycoplasma by hemagglutination inhibition (HI). The test uses the constant antigen, titered-sera method for measuring antibodies to *M. gallisepticum, M. synoviae,* or *M. meleagridis.*

(i) *Materials needed.*

(A) *M. gallisepticum, M. synoviae,* and/or *M. meleagridis* HI antigens.

(B) Positive and negative control sera.

(C) Phosphate buffered saline (PBS).

(D) Microtiter plates, 96-well, U-bottom.

(E) Multi-channel micropipet, capable of delivering 25ul to 50ul, and disposable tips~~12-channel pipettor (Titerek).~~

(F) Micropipets, capable of delivering 10ul to 50ul, and disposable tips ~~50 µL pipettor (Pipetman P200).~~

(G) Reagent reservoirs ~~Pipette tips.~~

(H) 0.5 percent homologous red blood cells (RBCs) in PBS (use RBCs from the same species being tested).

(I) Plate-sealing tape.

(J) Mirrored plate reader.

(ii) *Hemagglutination antigen (HA) titration.*

(A) Perform standard hemagglutination test (HA) on mycoplasma antigen to determine the titer of the antigen.

(1) Dispense 50 ul of PBS into each well of 3 rows of a 96- well microtiter plate.

(2) Dispense 50 ul of stock antigen into the first wells of 2 rows.

(3) Perform serial twofold dilutions (50 ul) using a multi-channel micropipet~~12-channel pipettor~~. The dilution series will be from 1:2 to 1:4096.

(4) Add 50 ul of 0.5 percent homologous RBCs to each well of all 3 rows. The row without ~~no~~ antigen serves as the ~~an~~ RBC control.

(B) Incubate at room temperature (approximately 30-60 minutes) until the control RBCs give tight buttons. The HA titer is read as the last dilution ~~well~~ to give a complete lawn of ~~(~~hemagglutination~~)~~.

(C) Dilute stock antigen to 4 HA units for the HI test. The dilution required to give 4 HA units is calculated by dividing the stock antigen HA titer by 8. (Example: 1:320 HA units ÷ 8 = 40, dilute stock antigen 1:40.) The estimated dilution factor should be tested prior to use in the HI test so adjustments can be made if necessary.

(iii) *Hemagglutination inhibition assay*.

(A) Label one column (A to H) of a 96-well, U-bottom microtiter plate for each sample, each positive and negative control sera, antigen backtitration, and RBC control.

(B) Add 40ul of PBS to the top row of wells (row A) labeled for testing samples and control sera. ~~of the plate.~~

(C) Add 25ul of PBS to all remaining wells of the plate, except the RBC control column. Add 50ul of PBS to the RBC control column.

(D) Add 10 ul of each sample or control ~~test sera~~ to well A. ~~of each column (making a 1:5 sera dilution).~~

(E) Serially dilute 25 ul from well A through H using a multi-channel micropipet.~~12-channel pipettor.~~ Discard the final 25 ul. ~~Row A = 1:5...row H = 1:640.~~

(F) ~~With an Oxford doser, a~~ Add 25 ul of 4 HA unit antigen to wells B through H. Well A serves as the sera ~~a~~ control to monitor for non-specific hemagglutination or hemolysis which would invalidate the results.

(G) Prepare an antigen backtitration by adding ~~25 ul of PBS to each well of one column. Add~~ 25ul of diluted antigen to well A and serially dilute 25ul from wells A to D. This prepares 1:2, 1:4, 1:8, and 1:16 dilutions. ~~(It is recommended that the antigen control backtitration be performed before the diluted antigen is used in the assay. Dilution problems could be detected and corrected before the inappropriately diluted antigen is used in the assay.)~~

~~(H) Leave a column of wells blank for an RBC control.~~

		Sample #1	Sample #2	Positive control	Negative control	RBC control	Back-titration
		1	2	3	4	5	6
A	Serum controls	40 ul PBS + 10 ul serum	40 ul PBS + 10 ul serum	40 ul PBS + 10 ul serum	40 ul PBS + 10 ul serum	50 ul PBS	25 ul PBS + 25 ul diluted Myco antigen (1:2 dilution)
B	Final test dilution 1:20	25 ul PBS	25 ul PBS	25 ul PBS	25 ul PBS	50 ul PBS	25 ul PBS (1:4)
C	1:40	25 ul PBS	25 ul PBS	25 ul PBS	25 ul PBS	50 ul PBS	25 ul PBS (1:8)
D	1:80	25 ul PBS	25 ul PBS	25 ul PBS	25 ul PBS	50 ul PBS	25 ul PBS (1:16)
E	1:160	25 ul PBS	25 ul PBS	25 ul PBS	25 ul PBS	50 ul PBS	
F	1:320	25 ul PBS	25 ul PBS	25 ul PBS	25 ul PBS	50 ul PBS	
G	1:640	25 ul PBS	25 ul PBS	25 ul PBS	25 ul PBS	50 ul PBS	
H	1:1280	25 ul PBS	25 ul PBS	25 ul PBS	25 ul PBS	50 ul PBS	

~~(I) Agitate~~ Tap the edge of the plate gently to mix and incubate for 30 minutes at room temperature.

(J) Mix the 0.5 percent RBC solution gently to evenly resuspend the cells. Add 50 ul of 0.5 percent RBCs to all wells. Note: Do not agitate the plate after the RBCs have been added (agitation may result in false positive reactions by causing the RBCs to fall, resulting in “false” buttons).

(K) Cover the plate with sealing tape. Incubate at room temperature for ~~30~~60 minutes or until control RBC's give a tight button.

(L) Read the reaction on a mirrored plate reader.

(iv) *Results.*

(A) The titer is reported as the reciprocal of the last dilution to give a tight button of RBCs. The final dilution scheme includes the antigen in the dilution calculation and is as follows: B=1:20, C=1:40, D=1:80, E=1:160, F=1:320, G=1:640, H=1:1,280.

(B) For the assay to be valid:

(1) The positive control sera must give a result within one dilution of the previously determined titer.

(2) The negative control sera must be negative.

(3) The backtitration of the antigen must be 1:4 or 1:8.

(4) The RBC control must give tight, non-hemolyzed buttons.

(5) Sera controls (well A of each test sera) must not have non- specific agglutination or hemolysis. If negative, report as “negative with non-specific agglutination or non-specific hemolysis” or “unable to evaluate due to non-specific agglutination or hemolysis” or treat the serum to remove the non-specific agglutination

and repeat the test. (See paragraph (e)(2)(v) of this section.)

(iv) Treatment to remove non-specific agglutination—

(A) *Purpose.* Treatment of serum to remove non-specific agglutination that is interfering with HI assays.

(B) Specimen. Serum.

(C) Materials. Homologous RBCs (chicken or turkey), 50 percent solution in PBS, centrifuge, incubator, 4C (refrigerator).

(D) Procedure.

(1) Prepare a 1:5 dilution of test serum by adding 50 ul of serum to 200 ul of PBS.

(2) Prepare a 50 percent solution of RBCs by adding equal volumes of packed RBCs to PBS. Mix well.

(3) Add 25 ul of 50 percent RBC solution to the serum dilutions.

(4) Vortex gently to mix.

(5) Incubate at 4°C for 1 hour.

(6) Centrifuge to pellet the RBCs.

(7) Use the supernatant to perform the HI assay. Modify the dilution scheme in the assay to consider the initial 1:5 dilution prepared in the treatment. For the 1:5 dilution scheme, do not add PBS to row A. Add 50 ul of the 1:5 treated supernatant to row A. Serially dilute 25 ul from rows A through H. This prepares a serum dilution of 1:10 through 1:640 in rows B through H.

Reason: NVSL recommendations accompanying the MG and MS HA antigen are: **10. Storage Conditions: This reagent should be stored between -75 C and -55 C.** For all labs having a Quality Program, especially those seeking AAVLD Accreditation, the manufacturer's recommendations should be followed.

Corrected typo in Section b) Hemagglutination Test, 1) Preparation of Materials, (v): Should read, "For the test, 2 ml of the 25 percent RBCs is added to 98 ml of buffered saline to make a 0.5 percent RBC suspension" rather than 0.25 percent.

Removed HI Procedure No. 1 because equipment is obsolete. Microdiluters and droppers were replaced by micropipets over 20 years ago. Micropipets are more accurate and calibration can be objectively verified. Microdiluters lose calibration over time and should be replaced, however we could not identify a vendor selling them in the USA.

Revised HI Procedure No. 2 by removing references to equipment brand names. Added reagent reservoirs to the materials list. Reworded instructions and added a diagram for clarification. Step iii G, moved instructions for verifying the antigen dilution to step ii C. Step iii K, changed incubation period from 30-60 minutes, to be 60 minutes, as this is what was stipulated at the 2016 NPIP training workshop.

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Program Standards - Proposal No. 3

Delegates: **Combined**

Subpart A – Blood Testing Procedures

(8) Standard test procedures for avian influenza

(a) *Agar gel immunodiffusion (AGID) test.* The agar gel immunodiffusion (AGID) test should be considered the ~~basic~~ ~~screening~~ primary confirmatory test for ~~antibodies to Type A influenza viruses~~ all ELISA-positive samples or ELISA positive flocks. Instructions regarding additional confirmatory tests that can be used are provided in the 9 CFR 145.14(d) and 9 CFR 146.13(b). 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.

(b) The enzyme-linked immunosorbent assay (ELISA). The enzyme-linked immunosorbent assay (ELISA) ~~may~~ must be used as ~~a~~ the initial screening test for avian influenza. Use only federally licensed ELISA kits and follow the manufacturer's instructions. All ELISA-positive serum samples or ELISA positive flocks must be confirmed with the AGID test conducted in accordance with paragraph (a) of this section.

Reason: This reasoning presented hereafter can be used to explain all the proposed changes.

Avian Influenza (AI) surveillance programs within the NPIP are designed to achieve a major goal which is to detect any circulating H5/H7 Low Pathogenic Avian Influenza (LPAI) virus in the commercial poultry population as early as possible with the goal of preventing their transformation into Highly Pathogenic Avian Influenza (HPAI). This task is challenging with the LPAI viruses, due to their relatively more silent clinical presentation and weaker immune response compared to HPAI viruses.

The characteristics of any test dictate how it can be used in a surveillance program. These test characteristics as it pertains to surveillance include primarily two parameters: sensitivity and specificity. Sensitivity can be defined as “the probability of a tested sample to be actually negative given the test result is negative”. So, when the sensitivity of a test is 90%, it means that there is a 90% chance that the sample is actually negative when the test result is negative. Specificity can be defined as “the probability of a tested sample to be actually positive given the test result is positive”. So, when the specificity of a test is 90%, it means that there is a 90% chance that the sample is actually positive when the test result is positive. Sensitivity and specificity are typically inversely correlated for a given test. In other words, tests with high sensitivity typically have low specificity and vice versa (there are exceptions to this rule). Tests with high sensitivity and low specificity (sensitive tests) are prone to false positive, and tests with high specificity and low sensitivity (specific tests) are prone to false negative.

There is more than one way to utilize both sensitive and specific tests in a surveillance program, a common way that is to use a “series testing” setup. In this setup, a sensitive test is used as a screening test first, and then any positive samples on the screening test are tested for a second time with a specific confirmatory test. It is imperative that the tests in the series testing surveillance program used in that order, the sensitive screening test first followed by a confirmatory specific test for the positive samples. This series testing setup achieves high degree of certainty in a couple

of situations; first, a negative sample on the screening test is considered negative with high probability. Second, a positive sample on both the screening and the confirmatory test is considered positive with high probability. However, there is one situation in which the results of a series testing are considered suspected positive. This situation is when the sample is positive on the screening test and negative on the confirmatory test. In this situation a second confirmatory test is required to clear the uncertainty.

Given the previously stated goals of detecting any circulating H5/H7 LPAI as early as possible; the surveillance programs within the NPIP utilize two serological tests to achieve that goal: 1. the Enzyme-Linked Immunosorbent Assay (ELISA) and 2. the Agar Gel Immunodiffusion test (AGID). Additionally, agent detection tests are also available for the AI programs, namely, the real time reverse transcriptase/polymerase chain reaction (RRTPCR) assay and USDA-licensed type A influenza antigen capture immunoassay (ACIA). It is widely accepted that among these two serological tests, ELISA has the higher sensitivity and the AGID is considered the more specific test (see references 1, 2, 3). The current language of the discussed text in this document allows for the use of the AGID as a single test surveillance program. Other tests have also been used as a single test surveillance process.

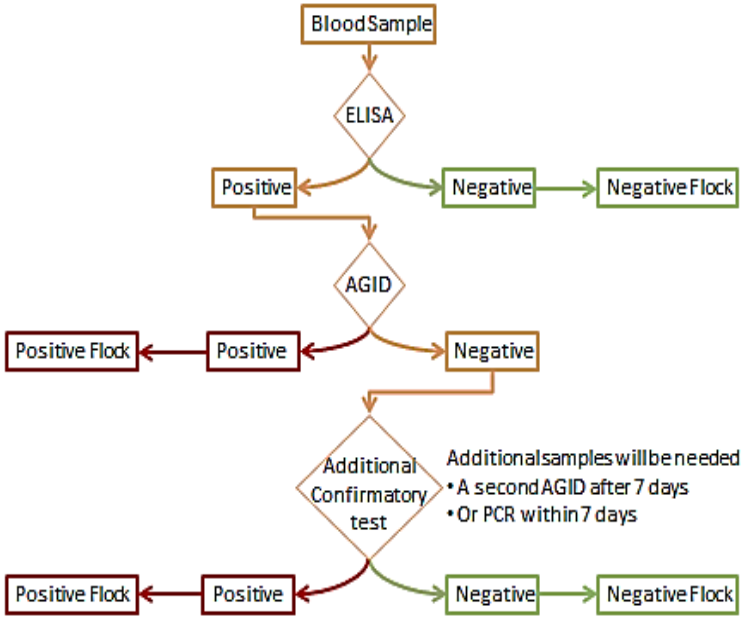
Using a less sensitive test as the sole screening test makes the surveillance program prone to false negatives. In other words, it makes it possible for an actually positive sample to be missed and passed as a negative sample. This may give the chance to the H5/H7 influenza viruses to circulate in the commercial poultry population unnoticed. This is particularly possible in case of LPAI, which elicits relatively weaker immune response and clinical signs. This could allow the LPAI time to circulate, mutate and adapt to the commercial poultry, which may eventually lead to their transformation to HPAI. So, using a less sensitive test as the screening test defies the purpose of the whole surveillance program.

The changes in the text above are proposed with the purpose of making sure that the more sensitive test (ELISA) is used as the screening test, and the more specific test (AGID) is used as the confirmatory test. The changes also encourages that additional confirmatory tests could be run with AGID. Additional confirmatory tests are particularly useful in the situation of positive ELISA but negative AGID. In this situation specific recommendations were made to use PCR or a second AGID as an additional confirmatory test.

PCR is both sensitive and specific, and could be used as a screening and as a confirmatory test. However, PCR, unlike serology, is unable to detect past infections in the flock. So, unless the infection is current and the virus is still actively circulating in the flock, PCR cannot detect the infection. For this reason, ELISA is still the preferred screening test, but PCR can be used as a confirmatory test.

These changes are intended to render the surveillance program simple and efficient in achieving the goal which is detecting any circulating H5/H7 LPAI as early as possible with the goal of preventing them from transforming into HPAI. In summary if the proposed changes are adapted the program will look as follows:

Blood sample: Tested by ELISA → Negative → Test is negative and the flock is considered negative for Influenza A.
Tested by ELISA → Positive → Confirmatory test → AGID
ELISA Positive samples tested by AGID → Positive → Test is positive and the flock is considered positive for influenza A.
ELISA Positive samples tested by AGID → Negative → A second confirmatory test is required: Swabs for PCR within 7 days from the first blood sample or a second blood sample for a second AGID after 7 days from the first blood sample. A side note out of the scope of surveillance, the swabs for PCR can also be used for virus isolation.
Second confirmatory test → Negative → Test is negative and the flock is considered negative for influenza A.
Second confirmatory test → Positive → Test is positive and the flock is considered positive for influenza A.



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Program Standards - Proposal No. 4

Delegates: **Combined**

Subpart B—Bacteriological Examination Procedure
(2) Laboratory procedure recommended for the bacteriological examination of salmonella from birds

(a) For egg- and meat-type chickens, turkeys, waterfowl, exhibition poultry, and game birds
~~All~~ R~~r~~eactors to the pullorum-typhoid ~~tests~~ standard tube agglutination test (in dilutions of 1:50 or greater) or the microagglutination test (in dilutions of 1:40 or greater) and up to 25 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 and if the flock has four or fewer reactors, all reactors must be submitted as provided for in 9 CFR 145.14(a)(6)(ii) to the authorized laboratory for bacteriological examination. Careful aseptic technique should be used when collecting all tissue samples.

Reason: The current language is confusing regarding the constituency of the samples. This revision clarifies that up to 25 birds are intended to be cultured from SE positive environments while up to a minimum of 4 birds are intended to be cultured from PT reactors. Additionally, the language now parallels that which is found in 145.14(a)(6)(ii).

Sponsor: Dr. Elena Behnke
NPIP Veterinary Coordinator

Program Standards - Proposal No. 5

Delegates: **Combined**

Subpart B—Bacteriological Examination Procedure
(2) Laboratory procedure recommended for the bacteriological examination of salmonella from birds

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

(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.

Reason: The word "normal" appears to be a mistake and should be "abnormal" instead.

Sponsor: Dr. Doug Waltman
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Program Standards - Proposal No. 6

Delegates: **Combined**

Subpart C—Sanitation Procedures
(1) Flock sanitation.
To aid in the maintenance of healthy flocks, the following procedures should be practiced:

(a) ~~Baby p~~Poultry should be started in a ~~clean brooder~~ house managed to reduce or eliminate exposure to program organisms.~~and~~ Flocks should be maintained in constant isolation from older birds and other animals. Personnel that are ~~in contact with older birds and other animals~~ entering poultry ready or occupied airspaces 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 by ~~through droppings~~ biological agents that may adhere to the shoes, clothing or hands. Also sanitation focus must be directed to anything entering occupied or unoccupied air spaces such as cell phones, tool bags, or cigarette lighters. (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 of such premises by any ~~contagious~~ program disease that causes the existence of a carrier population or a reservoir in the environment. Any deviation from this process (as might possibly desired by unique or rare breeding stock housed in non-infected, well isolated and managed airspaces on the same farm), must be agreed upon by the enterprise involved, the State Veterinarian, the NPIP / OSA, and the Service in the form of a written documented communication that will outline how the remaining stock will be managed and monitored to assure freedom of the plan disease going forward.

(c) Poultry houses ~~should~~ shall be screened and proofed against free-flying wild birds. ~~An a~~Active rodent and insect eradication/control programs are ~~campaign 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 meters distance to facilitate control of vermin. Dogs, cats, sheep, cattle, horses, and swine should never have access to within 3 meters of poultry air spaces ~~operations~~. Visitors should not be admitted to poultry areas, and authorized personnel should take the necessary precautions to prevent the introduction of disease.

(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.~~ Structural and operational biosecurity principles shall be in place in each poultry house / airspace to minimize the risk of disease introduction and transmission.

(e) In areas where the disposal of used poultry litter is problematic and at the discretion of the flock owner, reuse of the previous flock poultry litter is allowable provided the previous flock in the housing was free of the avian pathogens that are officially represented in the Plan disease classifications listed in §145.10 and the official NPIP top 3 *Salmonella*'s of human health concern detected during the previous flock or by other monitoring linked to the air space (when planned incoming flock is to participate in category where *Salmonella* types of human health are to be involved). In order to utilize this option it is essential that house / air space biosecurity is fully maintained (as described above in steps (a) to (d) between the removal of the last flock of birds and the introduction of new birds.

(e f)~~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 known to facilitate *Salmonella* replication. Nesting areas should be kept clean, dry and free of fecal material.

(~~f~~ g) When an outbreak of disease occurs in a flock, every effort should be made to identify the causative agent. ~~dead and/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~~ h) Introduction of started or mature birds should be ~~avoided~~ managed to reduce the possible hazard of introducing infectious diseases. If birds are to be introduced, the health status of both the flock and introduced birds should be evaluated with recent testing results for applicable plan disease agents prior to movement.

(~~h~~ i) 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~~ j) 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.~~

(k) Poultry in Subparts B, C, D, G, or H must be protected from vectors known to be in the wild and thus must be housed in enclosed structures with no access to the outdoors or open range. Poultry shall not be provided with untreated water such as from an open pond, stream or open springs for purposes of drinking, ventilation or facility washing that wild birds or vermin might have had access to.

(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 following practices should be observed:

(a) Cleaned and disinfected containers, such as egg flats, should be used in collecting the nest eggs for hatching. Egg handlers should thoroughly wash their hands with soap and

water before, during (if contact with birds, or they become soiled) 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 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 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 shall be physically cleared of organic material on a very 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 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.

(4) Cleaning and disinfecting.

The following procedures are recommended:

(a) In the poultry houses: House Clean Out (HCO)

(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 if possible ~~the tank~~. 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) Add additional perimeter bait stations and add fresh bait to all as a means of monitoring for rodent activity as you move along with the clean out process.

(3) As part of an integrated pest management program apply appropriate insect intervention steps (boric acid, lime, or approved insecticide(s)) as soon as possible after birds are removed.

~~(2~~ 4) 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 infectious disease organisms that may be present. Housing where poultry infected with a ~~mycoplasmal~~ *Mycoplasma* disease were kept should remain closed for 7 days before removal of the litter after the birds are depopulated.

~~(3~~ 5) Wash down using clean water–avoiding untreated pond or stream water for this process, the entire inside surfaces of the building and all the installed equipment such as curtains, ventilation ducts, light traps and openings, fans, fan housings and shutters, feeding equipment, watering equipment, etc. 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 HCO process. Make sure any chemical cleaning and disinfecting agents deployed in the full HCO process are compatible.

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

~~(4~~ 7) Spray with a disinfectant which is registered by the Environmental Protection Agency as germicidal, fungicidal, pseudomonocidal, virocidal and tuberculocidal, in accordance with the specifications for use, as shown on the label of such disinfectant.

(8) If part of an integrated pest management program apply appropriate insect intervention steps (boric acid, lime, and or approved insecticides).

(9) Check for activity, rebait and redistribute any rodent control baiting stations to all locations around house perimeter and if necessary, inside the physical housing units keeping in mind the objective should be to never have rodents inside the Poultry Air Spaces. Focus additional control to any areas at the perimeter where rodent activity as measured by bait consumption during HCO was identified.

(10) 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 registered by the U.S. Environmental Protection Agency as germicidal, fungicidal, pseudomonocidal, virocidal 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~~ appropriate water pressure ~~(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.

(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 Subpart 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 Subpart 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 or occupied Air Spaces should take precautions, including washing of and or sanitation of hands, and wearing of premises specific clothing and footwear.

(~~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 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 3) 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 that are commonly being employed by NPIP Participants. The proposed changes will clarify additional parts of the NPIP Program Standards in the Subpart C (1) Flock sanitation, (2) Hatching egg sanitation, (3) Hatchery sanitation, and (4) Cleaning and disinfection that collectively will emphasize the importance of biosecurity practices at all levels for Plan Participants. These proposed Program Standards changes will also allow flexibility for some industry practices (such as re-use of poultry litter in a responsible manner), that are and have been common for many years while providing some allowances if these practices need to be modified.

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Delegates: **Combined**

Subpart D—Molecular Examination Procedures
(1) Laboratory procedure recommended for the polymerase chain reaction (PCR) test for Mycoplasma gallisepticum and M. synoviae.

(a) DNA isolation.

Isolate DNA from 1 mL of eluate from tracheal or choanal cleft swabs in PBS, PCR grade water or BHI broth or 1 mL of broth culture by a non-phenolic procedure. Centrifuge samples at 14,000 x g for 5 to 10 minutes. Decant supernatant and wash the pellet with 1 mL of PBS. Centrifuge as above and re-suspend the pellet in 25 to 50 µl of 0.1 percent ~~DEP (Diethyl Pyrocarbonate; Sigma)~~ PCR grade water. Boil at 100 °C for 10 minutes followed by 10 minutes incubation at 4 °C. Centrifuge as above and transfer the supernatant DNA to a nuclease-free tube. Estimate the DNA concentration and purity by spectrophotometric reading at 260 nm and 280 nm. Commercially available column or magnetic bead based purification can give more consistent results than the boiling preparation described here. The inclusion of an internal positive control can help detect PCR inhibition.

Reason: We request that choanal cleft swabs be added as a suitable sample type for the PCR test for *M. gallisepticum* and *M. synoviae*. Both tracheal and choanal cleft swabs are recommended samples for *M. gallisepticum* and *M. synoviae* detection by PCR.

The boiling preparation procedure is an inexpensive and rapid technique, however research has shown that alternatives to the boiling method more consistently result in extracts of higher purity and better quality and reduce the possibility of false negatives. Both PCR grade water and BHI broth are equivalent to PBS as sample preparation media for PCR.

References:

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-Rachel L. Jude, and Naola Ferguson-Noel. Optimal Sample Processing for Diagnostic Avian Mycoplasma Real-time PCR. American Veterinary Medical Association (AVMA) Annual Convention, Boston, MA Jul 11-14, 2015.
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Program Standards - Proposal No. 8

Delegates: **Combined**

Subpart D – Molecular Examination Procedures
(6) Use of rRt-PCR for AI testing in Waterfowl.
The NPIP supports the use of cloacal swabs from domestic ducks and poultry as an approved specimen for the rRT-PCR matrix test assay when performed with the Ambion MagMAX (catalog No. AM1835 from Life Technologies) magnetic bead procedure for the NPIP NAI US H5/H7 Avian Influenza Clean and the US H5/H7 Avian Influenza Monitored Programs. The rRT-PCR ~~procedure will remain a screening test and all positive findings will need to be further tested as~~ should be used according to the recommendations provided in 9 CFR 145.14(d) and 9 CFR 146.13(b).

Reason: This reasoning presented hereafter can be used to explain all the proposed changes.

Avian Influenza (AI) surveillance programs within the NPIP are designed to achieve a major goal which is to detect any circulating H5/H7 Low Pathogenic Avian Influenza (LPAI) virus in the commercial poultry population as early as possible with the goal of preventing their transformation into Highly Pathogenic Avian Influenza (HPAI). This task is challenging with the LPAI viruses, due to their relatively more silent clinical presentation and weaker immune response compared to HPAI viruses.

The characteristics of any test dictate how it can be used in a surveillance program. These test characteristics as it pertains to surveillance include primarily two parameters: sensitivity and specificity. Sensitivity can be defined as “the probability of a tested sample to be actually negative given the test result is negative”. So, when the sensitivity of a test is 90%, it means that there is a 90% chance that the sample is actually negative when the test result is negative. Specificity can be defined as “the probability of a tested sample to be actually positive given the test result is positive”. So, when the specificity of a test is 90%, it means that there is a 90% chance that the sample is actually positive when the test result is positive. Sensitivity and specificity are typically inversely correlated for a given test. In other words, tests with high sensitivity typically have low specificity and vice versa (there are exceptions to this rule). Tests with high sensitivity and low specificity (sensitive tests) are prone to false positive, and tests with high specificity and low sensitivity (specific tests) are prone to false negative.

There is more than one way to utilize both sensitive and specific tests in a surveillance program, a common way that is to use a “series testing” setup. In this setup, a sensitive test is used as a screening test first, and then any positive samples on the screening test are tested for a second time with a specific confirmatory test. It is imperative that the tests in the series testing surveillance program used in that order, the sensitive screening test first followed by a confirmatory specific test for the positive samples. This series testing setup achieves high degree of certainty in a couple of situations; first, a negative sample on the screening test is considered negative with high probability. Second, a positive sample on both the screening and the confirmatory test is considered positive with high probability. However, there is one situation in which the results of a series testing are considered suspected positive. This situation is when the sample is positive on the screening test and negative on the confirmatory test. In this situation a second confirmatory test is required to clear the uncertainty.

Given the previously stated goals of detecting any circulating H5/H7 LPAI as early as possible; the surveillance programs within the NPIP utilize two serological tests to achieve that goal: 1. the Enzyme-Linked Immunosorbent Assay (ELISA) and 2. the Agar Gel Immunodiffusion test (AGID). Additionally, agent detection tests are also available for the AI programs, namely, the real time reverse transcriptase/polymerase chain reaction (RRTPCR) assay and USDA-licensed type A influenza antigen capture immunoassay (ACIA). It is widely accepted that among these two serological tests, ELISA has the higher sensitivity and the AGID is considered the more

specific test (see references 1, 2, 3). The current language of the discussed text in this document allows for the use of the AGID as a single test surveillance program. Other tests have also been used as a single test surveillance process.

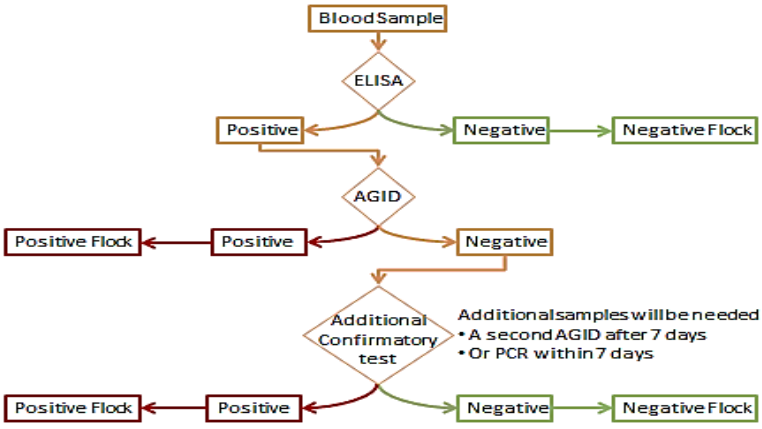
Using a less sensitive test as the sole screening test makes the surveillance program prone to false negatives. In other words, it makes it possible for an actually positive sample to be missed and passed as a negative sample. This may give the chance to the H5/H7 influenza viruses to circulate in the commercial poultry population unnoticed. This is particularly possible in case of LPAI, which elicits relatively weaker immune response and clinical signs. This could allow the LPAI time to circulate, mutate and adapt to the commercial poultry, which may eventually lead to their transformation to HPAI. So, using a less sensitive test as the screening test defies the purpose of the whole surveillance program.

The changes in the text above are proposed with the purpose of making sure that the more sensitive test (ELISA) is used as the screening test, and the more specific test (AGID) is used as the confirmatory test. The changes also encourages that additional confirmatory tests could be run with AGID. Additional confirmatory tests are particularly useful in the situation of positive ELISA but negative AGID. In this situation specific recommendations were made to use PCR or a second AGID as an additional confirmatory test.

PCR is both sensitive and specific, and could be used as a screening and as a confirmatory test. However, PCR, unlike serology, is unable to detect past infections in the flock. So, unless the infection is current and the virus is still actively circulating in the flock, PCR cannot detect the infection. For this reason, ELISA is still the preferred screening test, but PCR can be used as a confirmatory test.

These changes are intended to render the surveillance program simple and efficient in achieving the goal which is detecting any circulating H5/H7 LPAI as early as possible with the goal of preventing them from transforming into HPAI. In summary if the proposed changes are adapted the program will look as follows:

Blood sample: Tested by ELISA → Negative → Test is negative and the flock is considered negative for Influenza A.
Tested by ELISA → Positive → Confirmatory test → AGID
ELISA Positive samples tested by AGID → Positive → Test is positive and the flock is considered positive for influenza A.
ELISA Positive samples tested by AGID → Negative → A second confirmatory test is required: Swabs for PCR within 7 days from the first blood sample or a second blood sample for a second AGID after 7 days from the first blood sample. A side note out of the scope of surveillance, the swabs for PCR can also be used for virus isolation.
Second confirmatory test → Negative → Test is negative and the flock is considered negative for influenza A.
Second confirmatory test → Positive → Test is positive and the flock is considered positive for influenza A.



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Program Standards - Proposal No. 9

Delegates: **Combined**

Subpart E – Biosecurity Principles
Management practices and principles which are designed to prevent the introduction and spread of infectious diseases.

(1) Biosecurity responsibility
The Biosecurity Coordinator is responsible for the development, implementation, maintenance and ongoing effectiveness of the biosecurity program. Depending on the type and size of poultry operation, the Biosecurity Coordinator's responsibility could be at the farm, production site, production complex, or company level. The Biosecurity Coordinator should be knowledgeable in the principles of biosecurity, or should consult with a veterinarian or a person appropriately qualified by training or experience in poultry production medicine or biosecurity for assistance in the development of an effective program that, at a minimum, addresses the principles described below. The biosecurity program should include provisions for both farm site-specific procedures as well as complex-wide or company-wide procedures as appropriate. The Biosecurity Coordinator, along with the personnel and caretakers on the farms and production sites are responsible for the implementation of the biosecurity program. The Biosecurity Coordinator should review the biosecurity program at least once during each calendar year and make revisions as necessary.

(2) Training
The biosecurity program should include training materials that cover both farm site-specific procedures as well as premises-wide and/or company-wide procedures as appropriate. All bird owners and caretakers that regularly enter the perimeter buffer area (PBA) must complete this training. The training must be done at least once per calendar year and documented. New poultry caretakers should be trained at hire, prior to starting work on the farm site. Training records should be retained as stated in Title 9-CFR §145.12(b).

(3) Line of Separation (LOS)
The Line of Separation (LOS) is a functional line separating the poultry house(s) and the birds inside from exposure to potential disease sources. Generally, it is defined by the walls of the

poultry building with practical deviations to account for entry points, structural aspects, or outside access areas. The site-specific biosecurity plan should describe or illustrate the boundaries of the LOS and clearly outline the procedures to be followed when caretakers, visitors, or suppliers cross it.

For poultry enclosed in outdoor pens, similar principles for the LOS can be applied for defining and controlling the LOS for each pen. In this circumstance, the walls of the outdoor pens would provide template for defining the LOS to be used when entering or exiting the pens.

For poultry with non-enclosed outdoor access, the LOS is recommended but not required. Further, in an emergency disease state where the transmissible disease risk is heightened, it is highly recommended to enclose all poultry and enforce a LOS.

(4) Perimeter Buffer Area (PBA)

The perimeter buffer area is a functional zone surrounding the poultry houses or poultry raising area that separates them from areas unrelated to poultry production on that site and/or adjoining properties. It is comprised of the poultry houses and poultry raising areas as well as nearby structures and high traffic areas involved in the daily function of the poultry farm. This would usually include but not be limited to such things as feed bins, manure sheds, composting areas, egg rooms, generators, pump rooms, etc. The site-specific biosecurity plan should describe or illustrate the boundaries of the PBA and clearly outline the procedures that caretakers, visitors, or suppliers must follow when entering and leaving the PBA.

(5) Personnel

The biosecurity program and/or the site-specific biosecurity plan should include provisions specifically addressing procedures and biosecurity PPE for site-dedicated personnel. The plan should likewise address the procedures and biosecurity PPE for visitors and suppliers. The plan should also specify procedures which all personnel having had recent contact with other poultry or avian species should follow before re-entering the PBA.

(6) Birds, Rodents and Insects

Poultry operations should have control measures to prevent contact with and protect poultry from birds, their feces and their feathers as appropriate to the production system. These procedures should be reviewed further during periods of heightened risks of disease transmission. Control programs for rodents, insects, and other animals should be in place and documented.

(7) Equipment and Vehicles.

The biosecurity plan should include provisions for procedures or restrictions relating to equipment/vehicles that may enter/depart the PBA or cross the LOS. These provisions should include procedures for cleaning, disinfection, or restriction of sharing, where applicable. Equipment/vehicles that enter poultry house(s) containing live poultry can serve as a fomite of disease agents. Such equipment should be cleaned and disinfected prior to use. Sharing of equipment should be minimized, and a plan for cleaning, disinfecting, and inspecting equipment between farms or sets of houses should be in place if equipment is shared. To prevent cross-contamination, there should also be a plan for movement of equipment and vehicles across the LOS and entering/departing the PBA. Vehicle access and traffic patterns should be defined in the site-specific biosecurity plan.

(8) Dead Bird Disposal

Dead birds should be collected daily, stored and disposed in a manner that does not attract birds, rodents, insects, and other animals and avoids the potential for cross-contamination from other facilities or between premises. It is highly recommended that dead bird disposal be on-site, if possible. Dead bird disposal should be described in the site-specific biosecurity plan.

(9) Manure and Litter Management
Manure and spent litter should be removed, stored and disposed of in a manner to prevent exposure of susceptible poultry to disease agents. Onsite litter and manure storage should limit attraction of birds, rodents, insects, and other animals.

(10) Replacement Poultry
Replacement poultry should be sourced from health-monitored flocks which are in compliance with NPIP guidelines. They should be transported in equipment and vehicles that are regularly cleaned, disinfected and inspected. Biosecurity protocols should be in place for equipment and personnel involved in the transport of replacement poultry.

(11) Water Supplies
It is recommended that drinking water or water used for evaporative cooling be sourced from a contained supply such as a well or municipal system. If water comes from a surface water source, water treatment should be used to reduce the level of disease agents. If surfaces have been cleaned or flushed with surface water, subsequent disinfection should be employed to prevent disease transmission. If water treatment is not possible, a risk analysis should be performed to determine actions needed to mitigate risks.

(12) Feed and Replacement Litter
Feed, feed ingredients and litter should be stored and maintained in a manner that limits exposure to and contamination by or birds, rodents, insects, and other animals. Feed spills within the PBA (outside of the LOS) should be cleaned up and disposed in a timely fashion. Fresh litter should be brought onto the premises in a manner that reduces the likelihood of the introduction of disease agents.

(13) Reporting of Elevated Morbidity and Mortality
Elevation in morbidity and/or mortality above expected levels, as defined by the biosecurity plan, should be reported as required in the site-specific biosecurity plan and appropriate actions should be taken to rule out reportable disease agents.

(14) Auditing
Each participant shall be audited at least once every two years or a sufficient number of times during that period to satisfy their Official State Agency to ensure the participant is in compliance with the provisions of these Biosecurity Principles. Each audit shall require the biosecurity plan's training materials, documentation of implementation of the 14 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 producers who failed the 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, board-certified industry poultry veterinarian. If these producers seek to be reinstated as being in compliance with the 14 Biosecurity Principles by the NPIP OSA, they must demonstrate that corrective actions were taken following the audit by the team appointed by NPIP.

Reason: To standardize biosecurity practices and expectations in the NPIP. USDA APHIS has proposed an interim rule for HPAI which will require large owners and contractors to provide a statement that at the time of detection of HPAI in their facilities, they had in place and were following a written biosecurity plan to address the potential spread of Avian Influenza. The NPIP General Conference Committee is submitting this proposal consisting of a set of poultry biosecurity principles to be added to the NPIP Program Standards. These principles will serve as the minimum biosecurity

principles that any poultry operation should follow. Site specific plans for each poultry farm can be extrapolated from the minimum biosecurity principles.

Sponsor: NPIP General Conference Committee

Program Standards - Proposal No. 10

Delegates: **145 D, G, H**

Subpart F – Primary Breeder AI Clean Compartmentalization

1	Specifications for: Management Procedures, Physical Requirements, and Protocols
2	Application Form Instructions
3	Application Algorithm
4	Application Form A - Compartment Registration
5	Application Form B - Component Registration
6	Application Form C - Component Removal
7	Auditor Application
8	Auditor FAQs
9	Audit Checklist Flowchart
10	Audit Checklist-Office
11	Audit Checklist-Farms
12	Audit Checklist-Feedmills
13	Audit Checklist-Hatchery
14	Audit Checklist-Egg Depot

Subpart F – Primary Breeder AI Clean Compartmentalization
See documents attached.

Reason: The devastating HPAI outbreak of 2015 has highlighted the enormous impact trade restrictions can have on distributing breeding stock to customers around the globe. Our customers rely on delivery of genetic improvement to maintain business continuity. Current estimates are 60% of global poultry breeding stock is derived from USA based pedigree programs. US primary breeder companies have invested in biosecurity, monitoring, and laboratory infrastructure to prevent disease introduction and ensure diseases such as AI are rapidly detected in our facilities. Our aim is to preserve trade with key countries in the face of future AI outbreaks through use of compartmentalization, but only when regionalization is no longer feasible. Furthermore, compartmentalization may preserve interstate movement of breeding stock to domestic customers and operations if future AI outbreaks occur.

Avian influenza (AI) compartmentalization for poultry primary breeders was approved and adopted by the NPIP under the 9CFR at the 41st biennial conference in 2010. The Association of Poultry Primary Breeder Veterinarians (represented by active participation on this project by Aviagen, Cobb, and Hy-Line International) has collaborated with the NPIP national office and the US Poultry and Egg Association over the past two years to create the Primary Breeder AI Clean and H5/H7 AI Clean Compartmentalization Program Standards. The development of the Program Standards, including guidelines and auditing checklists, was based on the corresponding 9CFR language. The guidelines and audit instruments incorporate all the requirements for the corresponding NPIP/AI Clean and/or H5/H7 classifications for meat-type, egg-type and turkey

primary breeding stock, in addition to extra precautions to prevent introduction of avian influenza to primary breeding flocks. The NPIP General Conference Committee granted interim approval of the Primary Breeder AI Clean Compartmentalization program in 2015. We are seeking full approval at this Conference.

Sponsors: The Association of Poultry Primary Breeder Veterinarians
Hy-Line North America
Cobb-Vantress, Inc.
Aviagen, Inc.

Program Standards - Proposal No. 11

Delegates: **Combined**

Subpart 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 SE Kit, Neogen, Neogen Corporation, Lansing, MI 48912.
9. DNAble® Salmonella Detection Kit, EnviroLogix, Inc., Portland, Maine 04103-1486.
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. IDEXX RealPCR Salmonella DNA Mix-IDEXX Laboratories, Inc. Westbrook, ME 04092.
17. Qiagen *mericon* ® Salmonella spp. real-time PCR kit-Qiagen, Germantown, MD 20874.