

NPIP 43rd NPIP Biennial Conference
 Bellevue, WA -- September 1, 2016 Voting Results

Report of Voting Results on 9- CFR Proposed Changes

9-CFR Proposal No.	Committee Referred To:	Committee Recommendations: Passed, Passed as Amended by Technical Committee, Passed as amended by Break-Out group, Passed as amended by Coordinating Committee, Passed as Amended on Floor, Died, Died for lack of motion, Died for lack of second
1	Combined	Died - Lack of second
2	Combined	Passed - As amended by TC
3	145 Combined	Passed - As amended by TC
4	145 Combined	Passed - As amended by TC
5	145 Combined	Died - Lack of motion
6	145 Combined	Passed - As written
7	145 Combined	Died - Lack of motion
8	Combined	Died - Lack of motion
9	Combined	Passed - As amended on floor
10	Combined	Died - Lack of motion
11	145 Combined	Passed - As written
12	B	Died - Lack of motion
13	C	Failed
14	D	Died - Lack of motion
15	D	Died - Lack of motion
16	D,G,H	Passed - As written
17	E	Passed - As amended by TC
18	E	Passed - As amended by Subpart E
19	G	Died - Lack of motion
20	G	Passed - As written
21	H	Passed - As written
22	H	Died - Lack of motion
23	H	Died - Lack of motion
24	6B	Passed - As written
25	Combined	Passed - As written
26	Combined	Passed - As amended by CC
27	Combined	Failed
28	Combined	Passed - As written
29	Combined	Died - Lack of motion
30	Combined	Passed - as amended by CC

Report of Voting Results on Program Standards

Program Standard No.	Committee Referred To:	Committee Recommendations: Passed, Passed as Amended by Technical Committee, Passed as amended by Break-Out group, Passed as amended by Coordinating Committee, Passed as Amended on Floor, Died, Died for lack of motion, Died for lack of second
1	Combined	Passed - As amended by CC
2	Combined	Passed - As written
3	Combined	Died – Lack of motion
4	Combined	Failed
5	Combined	Passed - As written
6	Combined	Failed - As amended by Turkey Subgroup
7	Combined	Passed - As written
8	Combined	Died – Lack of motion
9	Combined	Passed - As amended on the floor
10	D, G, H	Passed - As amended by CC
11	Combined	Passed – As amended by the TC

**THE FOLLOWING PROPOSALS ARE THOSE IN WHICH
 WERE ADOPTED BY THE 43RD NPIP BIENNIAL
 CONFERENCE DELEGATION AND WILL BE SUBMITTED
 FORWARD TO USDA.**

Proposal No. 2 (As amended by Technical Committee)

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, two or all three 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, two or all three 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 – (As amended by Technical Committee)

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. isolate Pullorum or Gallinarum.

§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. isolate Pullorum or Gallinarum.

§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. isolate Pullorum or Gallinarum.

(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 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 isolate Pullorum or Gallinarum: *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 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.~~ isolate Pullorum or Gallinarum.

(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 isolate Pullorum or Gallinarum: *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. isolate Pullorum or Gallinarum.

(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 isolate Pullorum or Gallinarum; 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. isolate Pullorum or Gallinarum.

§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. isolate Pullorum or Gallinarum.

(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 isolate Pullorum or Gallinarum: 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, isolate Pullorum or Gallinarum.

(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 isolate Pullorum or Gallinarum: *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. isolate Pullorum or Gallinarum.

(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 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 isolate Pullorum or Gallinarum: 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 (As amended by Technical Committee)

Delegates: 145

§ 145.1 Definitions

Air Space: 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).~~

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. 6 (Passed as written)

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. 9 (As amended on the floor)

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 the State Animal Health Official, and must be conducted by personnel who have passed an NVSL proficiency test.

(a) For non-National Animal Health Laboratory Network (NAHLN) Authorized Laboratories:

(i) RRT-PCR testing can only be used by primary breeder company Authorized Laboratories,

(ii) RRT-PCR testing can only be performed on their own breeding flocks and only used for routine surveillance,

(iii) the Authorized Laboratory has a quality system that is accredited as ISO/IEC 17025 or equivalent to

perform the avian influenza RRT-PCR assay,
(iv) the Authorized Laboratory Memorandum of Understanding (MOU) included approval of use between the Authorized Laboratory, the Official State Agency (OSA), and the State Animal Health Official(s) of both the location of the Authorized Laboratory and the location where the breeder flocks reside,
(v) split samples for testing must occur between the Authorized Laboratory and a NAHLN laboratory at a frequency designated in the MOU.

(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 the State Animal Health Official, and must be conducted by personnel who have passed an NVSL proficiency test.

(a) For non-National Animal Health Laboratory Network (NAHLN) Authorized Laboratories:

(i) RRT-PCR testing can only be used by primary breeder company Authorized Laboratories,

(ii) RRT-PCR testing can only be performed on their own breeding flocks and only used for routine surveillance,

(iii) the Authorized Laboratory has a quality system that is accredited as ISO/IEC 17025 or equivalent to perform the avian influenza RRT-PCR assay,

(iv) the Authorized Laboratory Memorandum of Understanding (MOU) included approval of use between the Authorized Laboratory, the Official State Agency (OSA), and the State Animal Health Official(s) of both the location of the Authorized Laboratory and the location where the breeder flocks reside,

(v) split samples for testing must occur between the Authorized Laboratory and a NAHLN laboratory at a frequency designated in the MOU.

(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

Dr. Julie Helm, Dr. Brandon Doss, Dr. Charlie Hatcher
Amended on Floor

Proposal No. 11 (Passed as written)

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. 16 (Passed as written)

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 (As amended by Technical Committee)

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 Mycoplasma*, 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 (As amended by Subpart E)

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

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

(89) 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. 20 (Passed as written)

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 (Passed as written)

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. 24 (Passed as written)

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 (Passed as written)

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. 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. 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 (As amended by Coordinating Committee)

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 OSAs 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. 28 (Passed as written)

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. 30 (As amended by Coordinating Committee)

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

Program Standards - Proposal No. 1
(As amended by Coordinating 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

Program Standards - Proposal No. 2

(Passed as written)

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 °C and -55 °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 ₂ PO 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 0.255 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:	1:1	1:2	1:4	1:8	1:16	1:32	1:64	1:12	1:25
Serum A (HI)	=	+	+	+	+	+	+	+	+	+
Serum B (HI)	=	=	=	=	+	+	+	+	+	+
Serum C (HI)	=	=	=	=	=	=	+	+	+	+
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 $640 \div 8 = 80$, or a dilution of 1:80 containing 8 HA units. Or $640 \div 4 = 160$, 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 contains 1/2 unit; and well 6 contains 1/4 unit.

(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.

(32) 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- μ L 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 ~~an~~ 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: $1:320 \text{ HA units} \div 8 = 40$, 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,~~ 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 μ l of PBS to each well of one column. Add 25 μ l of diluted antigen to well A and serially dilute 25 μ l 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 μ l PBS + 10 μ l serum	40 μ l PBS + 10 μ l serum	40 μ l PBS + 10 μ l serum	40 μ l PBS + 10 μ l serum	50 μ l PBS	25 μ l PBS + 25 μ l diluted Myco. antigen (1:2 dilution)
B	Final test dilution 1:20	25 μ l PBS	25 μ l PBS	25 μ l PBS	25 μ l PBS	50 μ l PBS	25 μ l PBS (1:4)
C	1:40	25 μ l PBS	25 μ l PBS	25 μ l PBS	25 μ l PBS	50 μ l PBS	25 μ l PBS (1:8)
D	1:80	25 μ l PBS	25 μ l PBS	25 μ l PBS	25 μ l PBS	50 μ l PBS	25 μ l PBS (1:16)
E	1:160	25 μ l PBS	25 μ l PBS	25 μ l PBS	25 μ l PBS	50 μ l PBS	
F	1:320	25 μ l PBS	25 μ l PBS	25 μ l PBS	25 μ l PBS	50 μ l PBS	
G	1:640	25 μ l PBS	25 μ l PBS	25 μ l PBS	25 μ l PBS	50 μ l PBS	
H	1:1280	25 μ l PBS	25 μ l PBS	25 μ l PBS	25 μ l PBS	50 μ l 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 μ l 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.

Sponsors: Michelle Davidson
CAHFS Laboratory System – UC Davis School of Veterinary
Medicine

Brenda Glidewell
Georgia Poultry Laboratory Network

Program Standards - Proposal No. 5
(Passed as written)

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
Georgia Poultry Laboratory Network

Program Standards - Proposal No. 7

(Passed as written)

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:

-Ferguson-Noel, Naola and S.H. Kleven. A laboratory manual for the Isolation and Identification of Avian Pathogens, 6th edition. *In Press*.

-Lungu, B. & Ferguson-Noel, N. (2011). Evaluation of three DNA extraction methods for the detection of *Mycoplasma spp.* with an MG/MS multiplex real-time PCR method. AVMA Convention Notes on CD, Abstract #11137.

-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.

-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 Mycoplasma*, Vol. II. J.G. Tully, ed. Academic Press, Inc., New York. 283-292.

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Program Standards - Proposal No. 9
(As amended on the Floor)

Delegates: Combined

Subpart Standard E – Biosecurity Principles

Based on flock size as stated in the 9 CFR 53.10, the following minimum 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~~ poultry 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) and 146.11(e).

(3) Line of Separation (LOS)

The Line of Separation (LOS) is a functional line separating the poultry house(s) and the ~~birds~~ poultry 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~~ non-farm personnel. 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) Wild Birds, Rodents and Insects

Poultry operations should have control measures to prevent contact with and protect poultry from wild 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,~~ of equipment 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 Mortality Disposal

Dead birds Mortality should be collected daily, stored and disposed in a manner that does not attract wild birds, rodents, insects, and other animals and avoids/minimizes the potential for cross-contamination from other facilities or between premises. It is highly recommended that dead bird mortality disposal be on-site, if possible. Dead bird Mortality 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 wild 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 drinking water comes from a surface water source, water treatment ~~should~~ must 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, bedding, and litter should be delivered, stored and maintained in a manner that limits exposure to and contamination by ~~of~~ wild 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

Auditing of the biosecurity principles is ~~mandatory for indemnity~~ based on flock size as outlined in 9 CFR 53.10. ~~Each participant shall be audited~~ Audits shall be conducted at least once every two years or a sufficient number of times during that period ~~to satisfy their~~ by the 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~~ participants who failed the initial document audit conducted by the NPIP OSA may elect to have a check audit performed by a team appointed by National NPIP Office including: an APHIS poultry subject matter expert, the OSA, and a licensed, accredited, ~~board certified, industry~~ poultry veterinarian familiar with that type of operation. If these ~~producers~~ participants 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
(As amended by Coordinating Committee)

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 ([See compartmentalization document](#))
“All visitors sign acknowledgment agree to follow company-established policy regarding personal items and food.”
([see and change pg. 55, 56, 61, 65, 69](#)).
- 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
(As amended by Technical Committee)**

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.