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DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Parts 145, 146, and 147

[Docket No. APHIS-2017-0055]

RIN 0579-AE37

National Poultry Improvement Plan and Auxiliary Provisions

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: We are amending the regulations governing the National Poultry Improvement Plan (NPIP) by updating and clarifying several provisions, including those concerning NPIP participation, voting requirements, testing procedures, and standards. The changes in this final rule were voted on and approved by the voting delegates at the Plan's 2016 National Plan Conference.

DATES: Effective [Insert date 30 days after date of publication in the Federal Register].

FOR FURTHER INFORMATION CONTACT: Dr. Denise Heard, DVM, Senior Coordinator, National Poultry Improvement Plan, VS, APHIS, USDA, 1506 Klondike Road, Suite 101, Conyers, GA 30094-5104; (770) 922-3496.

SUPPLEMENTARY INFORMATION:

Background

The National Poultry Improvement Plan (NPIP, also referred to below as "the Plan") is a cooperative Federal-State-industry mechanism for controlling certain poultry diseases. The Plan

consists of a variety of programs intended to prevent and control poultry diseases. Participation in all Plan programs is voluntary, but breeding flocks, hatcheries, and dealers must first qualify as "U.S. Pullorum-Typhoid Clean" as a condition for participating in the other Plan programs.

The Plan identifies States, independent flocks, hatcheries, dealers, and slaughter plants that meet certain disease control standards specified in the Plan's various programs. As a result, customers can buy poultry that has tested clean of certain diseases or that has been produced under disease-prevention conditions.

The regulations in 9 CFR parts 145, 146, and 147 (referred to below as the regulations) contain the provisions of the Plan. The Animal and Plant Health Inspection Service (APHIS or the Service) amends these provisions from time to time to incorporate new scientific information and technologies within the Plan.

On April 9, 2018, we published in the *Federal Register* (83 FR 15082-15089, Docket No. APHIS-2017-0055) a proposal¹ to amend the regulations by updating and clarifying several provisions, including those concerning NPIP participation, voting requirements, testing procedures, and standards.

We solicited comments concerning our proposal for 30 days ending May 9, 2018. We received two comments by that date. One individual was generally opposed to the rule and the poultry industry, but did not address any specific provisions of the proposed rule. The other commenter also did not address the provisions of the proposed rule, but instead addressed his comments to the statements made by the first commenter.

Therefore, for the reasons given in the proposed rule, we are adopting the proposed rule as a final rule, without change.

¹ To view the proposed rule, supporting document, and the comments we received, go to <http://www.regulations.gov/#!docketDetail;D=APHIS-2017-0055>.

Executive Orders 12866 and 13771 and Regulatory Flexibility Act

This final rule has been determined to be not significant for the purposes of Executive Order 12866 and, therefore, has not been reviewed by the Office of Management and Budget. Further, because this rule is not significant, it is not a regulatory action under Executive Order 13771.

We have prepared an analysis regarding the economic effects of this final rule on small entities. The analysis is summarized below. Copies of the full analysis are available on the Regulations.gov website (see footnote 1 in this document for a link to Regulations.gov) or by contacting the person listed under FOR FURTHER INFORMATION CONTACT.

We are amending the NPIP, its auxiliary provisions, and the indemnity regulations for the control of H5 and H7 low pathogenic avian influenza to align the regulations with international standards and make them more transparent to stakeholders and the general public. The changes in this final rule were voted on and approved by the voting delegates at the 2016 NPIP National Plan Conference.

The establishments that will be affected by the rule -- principally entities engaged in poultry production and processing -- are predominantly small by Small Business Administration standards. In those instances in which an addition to or modification of requirements could potentially result in a cost to certain entities, we do not expect the costs to be significant. NPIP membership is voluntary. The changes contained in this final rule were decided upon by the NPIP General Conference Committee and voting delegates during the 2016 NPIP Biennial Conference; the changes were recognized by the poultry industry as being in their interest.

Under these circumstances, the Administrator of the Animal and Plant Health Inspection Service has determined that this action will not have a significant economic impact on a substantial number of small entities.

Executive Order 12372

This program/activity is listed in the Catalog of Federal Domestic Assistance under No. 10.025 and is subject to Executive Order 12372, which requires intergovernmental consultation with State and local officials. (See 2 CFR chapter IV.)

Executive Order 12988

This final rule has been reviewed under Executive Order 12988, Civil Justice Reform. This rule: (1) Preempts all State and local laws and regulations that are in conflict with this rule; (2) has no retroactive effect; and (3) does not require administrative proceedings before parties may file suit in court challenging this rule.

Paperwork Reduction Act

This final rule contains no new information collection or recordkeeping requirements under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

List of Subjects in 9 CFR Parts 145, 146, and 147

Animal diseases, Poultry and poultry products, Reporting and recordkeeping requirements.

Accordingly, we are amending 9 CFR parts 145, 146, and 147 as follows:

PART 145-NATIONAL POULTRY IMPROVEMENT PLAN FOR BREEDING POULTRY

1. The authority citation for part 145 continues to read as follows:

Authority: 7 U.S.C. 8301-8317; 7 CFR 2.22, 2.80, and 371.4.

2. In § 145.1, the definition of *NPIP Technical Committee* is amended by adding three sentences after the last sentence to read as follows:

§ 145.1 Definitions.

* * * * *

NPIP Technical Committee. * * * The NPIP Technical Committee is divided into three subcommittees (Mycoplasma, Salmonella, and Avian Influenza). NPIP Technical Committee Members may serve on one, two, or all three subcommittees. The committee will evaluate proposed changes to the Provisions and Program Standards of the Plan which include, but are not limited to, tests and sanitation procedures, and provide recommendations to the Delegates of the National Plan Conference as to whether they are scientifically or technically sound.

* * * * *

§ 145.4 [Amended]

3. In § 145.4, paragraph (d)(2) is amended by adding the words “and any other disease for which the flock into which the birds are being introduced holds a disease classification” after the words “pullorum-typhoid”.

§ 145.10 [Amended]

4. In § 145.10, paragraph (o) is amended by adding the citation “§ 145.73(g),” after the citation “§ 145.53(f),”.

5. Section 145.14 is amended as follows:

a. In the introductory text, in the third sentence, by adding the words “unless otherwise specified within the Plan program,” after the words “30 birds per house,” and in the last

sentence, by adding the words “, unless otherwise specified within the Plan program” after the words “must be tested”; and

b. By revising paragraph (d)(2)(i)(A).

The revision reads as follows:

§ 145.14 Testing.

* * * * *

(d) * * *

(2) * * *

(i) * * *

(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 Official State Agency and the State Animal Health Official, and must be conducted by personnel who have passed an NVSL proficiency test. For non-National Animal Health Laboratory Network (NAHLN) authorized laboratories:

(1) RRT-PCR testing may be used by primary breeder company authorized laboratories.

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

(3) The authorized laboratory must have a quality system that is accredited as ISO/IEC 17025 or equivalent to perform the avian influenza RRT-PCR assay.

(4) The use of the RRT-PCR test by the authorized laboratory must be approved in the memorandum of understanding (MOU) between the authorized laboratory, the Official State

Agency, and the State Animal Health Official(s) of both the location of the authorized laboratory and the location where the breeding flocks reside.

(5) Split samples for testing must occur between the authorized laboratory and a NAHLN laboratory at a frequency designated in the MOU.

* * * * *

6. In § 145.23, paragraph (b)(1) is revised to read as follows:

§ 145.23 Terminology and classification; flocks and products.

* * * * *

(b) * * *

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

* * * * *

7. In § 145.33, paragraph (b)(1) is revised to read as follows:

§ 145.33 Terminology and classification; flocks and products.

* * * * *

(b) * * *

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

* * * * *

8. In § 145.43, paragraphs (b)(1) and (5) are revised to read as follows:

§ 145.43 Terminology and classification; flocks and products.

* * * * *

(b) * * *

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

* * * * *

(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 isolate *S. pullorum* or *S. gallinarum*: *Provided*, That a bacteriological examination monitoring program acceptable to the Official State Agency and approved by APHIS may be used in lieu of blood testing.

* * * * *

9. Section 145.45 is amended as follows:

a. By revising paragraph (a) introductory text; and

b. By removing the word “NAI” and adding the words “H5/H7 AI” in its place each time

it appears in the following paragraphs:

i. Paragraph (a)(1) introductory text;

ii. Paragraph (a)(1)(i);

iii. Paragraph (a)(1)(iii) introductory text;

iv. Paragraph (a)(1)(v);

v. Paragraph (a)(2)(iii); and

vi. Paragraph (a)(4).

The revision reads as follows:

§ 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 APHIS to establish a compartment consisting of a primary breeding-hatchery company that is free of H5/H7 avian influenza (AI). 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 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:

* * * * *

10. Section 145.52 is amended by redesignating paragraphs (d)(7) and (d)(8) as paragraphs (d)(8) and (d)(9), respectively, and by adding a new paragraph (d)(7) to read as follows:

§ 145.52 Participation.

* * * * *

(d) * * *

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

* * * * *

11. Section 145.53 is amended as follows:

- a. By revising paragraphs (b)(1) and (b)(5);
- b. In paragraph (c)(1)(i), by adding the words “trachea or” before the word “choanal” and by removing the words “palatine cleft/fissure area” and adding the word “cleft” in their place.
- c. By revising paragraph (c)(1)(ii) introductory text;
- d. In paragraph (c)(1)(ii)(A), by adding the words “trachea or” before the word “choanal” and by removing the words “palatine cleft/fissure area” and adding the word “cleft” in their place;
- e. In paragraph (d)(1)(i), by adding the words “trachea or” before the word “choanal” and by removing the words “palatine cleft/fissure area” and adding the word “cleft” in their place.
- f. By revising paragraph (d)(1)(ii) introductory text; and
- g. In paragraph (d)(1)(ii)(A), by adding the words “trachea or” before the word “choanal” and by removing the words “palatine cleft/fissure area” and adding the word “cleft” in their place.

The revisions read as follows:

§ 145.53 Terminology and classification; flocks and products.

* * * * *

(b) * * *

(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 isolate *S. pullorum* or *S. gallinarum*.

* * * * *

(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 isolate *S. pullorum* or *S. 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 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.

(c) * * *

(1) * * *

(ii) It is a multiplier breeding flock which originated as U.S. *M. Gallisepticum* Clean baby poultry from primary breeding flocks and from which a random sample of 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 more than 400 birds, 200 birds shall be tested. For flocks of 60 to 400 birds, 50 percent 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:

* * * * *

(d) * * *

(1) * * *

(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 of 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 more than 400 birds, 200 birds shall be tested. For flocks of 60 to 400 birds, 50 percent 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:

* * * * *

12. Section 145.63 is amended by revising paragraphs (a)(1) and (a)(2)(i) to read as follows:

§ 145.63 Terminology and classification; flocks and products.

* * * * *

(a) * * *

(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 isolate *S. pullorum* or *S. gallinarum*.

(2) * * *

(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 isolate *S. pullorum* or *S. 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 isolate *S. pullorum* or *S. gallinarum*.

* * * * *

13. Section 145.73 is amended as follows:

- a. By revising paragraphs (b)(1) and (b)(2)(ii); and
- b. By adding paragraph (g).

The revisions and addition read as follows:

§ 145.73 Terminology and classification; flocks and products.

* * * * *

(b) * * *

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

(2) * * *

(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 isolate *S. pullorum* or *S. gallinarum*: *Provided*, That a bacteriological examination monitoring program acceptable to the Official State Agency and approved by APHIS may be used in lieu of blood testing.

* * * * *

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

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

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

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

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

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

(v) An Authorized Agent shall take environmental samples in accordance with part 147 of this subchapter from each flock at 4 months of age and every 30 days thereafter. An authorized laboratory for Salmonella shall examine the environmental samples bacteriologically.

All Salmonella isolates from a flock shall be serogrouped and shall be reported to the Official State Agency on a monthly basis.

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

(vii) Any flock entering the production period that is in compliance with all the requirements of this paragraph (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 four 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 (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.

§ 145.74 [Amended]

14. Section 145.74 is amended as follows:

a. In paragraph (a) introductory text, in the first sentence, by removing the words “, also referred to as notifiable avian influenza (NAI)” and, in the second sentence, by removing the word “NAI” and adding the words “H5/H7 AI” in its place.

b. By removing the word “NAI” and adding the words “H5/H7 AI” in its place each time it appears in the following paragraphs:

i. Paragraph (a)(1) introductory text;

ii. Paragraph (a)(1)(iii) introductory text;

iii. Paragraph (a)(1)(v);

iv. Paragraph (a)(2)(iii); and

v. Paragraph (a)(4).

c. By removing the word “NAI-related” and adding the words “H5/H7 AI-related” in its place in paragraph (a)(1)(i).

15. Section 145.82 is amended by adding paragraph (d) to read as follows:

§ 145.82 Participation.

* * * * *

(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, or 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.

16. Section 145.83 is amended by revising paragraphs (b)(1) and (b)(2)(ii) to read as follows:

§ 145.83 Terminology and classification; flocks and products.

* * * * *

(b) * * *

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

(2) * * *

(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 isolate *S. pullorum* or *S. gallinarum*: *Provided*, That a bacteriological examination monitoring program acceptable to the Official State Agency and approved by APHIS may be used in lieu of blood testing.

* * * * *

§ 145.84 [Amended]

17. Section 145.84 is amended as follows:

a. In the introductory text of paragraph (a), in the first sentence, by removing the words “, also referred to as notifiable avian influenza (NAI)” and, in the second sentence, by removing the word “NAI” and adding the words “H5/H7 AI” in its place; and

b. By removing the word “NAI” and adding the words “H5/H7 AI” in its place each time it appears in the following paragraphs:

- i. Paragraph (a)(1) introductory text;
- ii. Paragraph (a)(1)(iii) introductory text;
- iii. Paragraph (a)(1)(v);
- iv. Paragraph (a)(2)(iii); and
- v. Paragraph (a)(4).

c. By removing the word “NAI-related” and adding the words “H5/H7 AI-related” in its place in paragraph (a)(1)(i).

18. Section 145.93 is amended as follows:

- a. By revising paragraph (b)(1);
- b. In paragraph (b)(3)(viii), by removing the words “paragraphs (a)(3)(i),” and adding the words “paragraphs (b)(3)(i),” in their place;
- c. In paragraph (b)(4), by removing the words “paragraph (a)(3)” and adding the words “paragraph (b)(3)” in their place; and
- d. By revising paragraph (b)(5).

The revisions read as follows:

§ 145.93 Terminology and classification; flocks and products.

* * * * *

(b) * * *

(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 isolate *S. pullorum* or *S. gallinarum*.

* * * * *

(5) It is a primary breeding flock located in a State determined to be in compliance with provisions of paragraph (b)(3) 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 isolate *S. pullorum* or *S. 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.

* * * * *

PART 146-NATIONAL POULTRY IMPROVEMENT PLAN FOR COMMERCIAL
POULTRY

19. The authority citation for part 146 continues to read as follows:

Authority: 7 U.S.C. 8301-8317; 7 CFR 2.22, 2.80, and 371.4.

20. In § 146.1, a definition of *NPIP Technical Committee* is added in alphabetical order to read as follows:

§ 146.1 Definitions.

* * * * *

NPIP Technical Committee. A committee made up of technical experts on poultry health, biosecurity, surveillance, and diagnostics. 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 NPIP Technical Committee is divided into three subcommittees (Mycoplasma, Salmonella, and Avian Influenza). NPIP Technical Committee Members may serve on one, two, or all three subcommittees. The committee will evaluate proposed changes to the Provisions and Program Standards of the Plan which include, but are not limited to, tests and sanitation procedures, and provide recommendations to the Delegates of the National Plan Conference as to whether they are scientifically or technically sound.

* * * * *

§ 146.23 [Amended]

21. In § 146.23, paragraphs (a)(1)(i) and (a)(2)(i) are amended by removing the number “30” and adding the number “21” in its place.

PART 147-AUXILIARY PROVISIONS ON NATIONAL POULTRY IMPROVEMENT PLAN

22. The authority citation for part 147 continues to read as follows:

Authority: 7 U.S.C. 8301-8317; 7 CFR 2.22, 2.80, and 371.4.

23. In § 147.41, the definition of *NPIP Technical Committee* is amended by adding three sentences after the last sentence to read as follows:

§ 147.41 Definitions.

* * * * *

NPIP Technical Committee. * * * The NPIP Technical Committee is divided into three subcommittees (Mycoplasma, Salmonella, and Avian Influenza). NPIP Technical Committee Members may serve on one, two, or all three subcommittees. The committee will evaluate proposed changes to the Provisions and Program Standards of the Plan which include, but are not limited to, tests and sanitation procedures, and provide recommendations to the

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

* * * * *

24. In § 147.43, paragraph (b) is amended by adding a sentence after the second sentence to read as follows:

§ 147.43 General Conference Committee.

* * * * *

(b) * * * The ballots for electing regional committee members and their alternates will be printed in such a way as to allow the specific selection of one nominee for member, and one nominee for alternate from the remaining nominees. * * *

* * * * *

25. In § 147.46, paragraph (d) is amended by adding a sentence after the last sentence to read as follows:

§147.46 Committee consideration of proposed changes.

* * * * *

(d) * * * Once completed, the combined committee report will be distributed electronically to the Official State Agencies prior to the delegates voting on the final day of the biennial conference.

* * * * *

26. In § 147.51, the definition of *NPIP Technical Committee* is amended by adding three sentences after the last sentence to read as follows:

§ 147.51 Definitions.

* * * * *

NPIP Technical Committee. * * * The NPIP Technical Committee is divided into three subcommittees (Mycoplasma, Salmonella, and Avian Influenza). NPIP Technical Committee Members may serve on one, two, or all three subcommittees. The committee will evaluate proposed changes to the Provisions and Program Standards of the Plan which include, but are not limited to, tests and sanitation procedures, and provide recommendations to the Delegates of the National Plan Conference as to whether they are scientifically or technically sound.

27. In § 147.52, paragraph (a) is revised to read as follows:

§ 147.52 Authorized laboratories.

* * * * *

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

* * * * *

28. In § 147.54, paragraphs (a)(1), (3), and (4) are revised to read as follows:

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

(a) * * *

(1) 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. 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 samples may be necessary, prior approval from the NPIP Technical Committee is required. Pure cultures should never be used. Additionally, laboratories 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 by 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.

* * * * *

(3) 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 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.

(4) Cooperating laboratories will submit to the kit manufacturer all compiled output 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 data and may be obtained by contacting the NPIP Senior Coordinator. Data and the completed worksheet for diagnostic test evaluation must be submitted to the NPIP Senior Coordinator 4 months prior to the next scheduled General Conference Committee meeting, which is when approval will be sought.

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Done in Washington, DC, this 13th day of June 2018.

Kevin Shea,

Administrator, Animal and Plant Health Inspection Service.
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