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DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Parts 56, 145, 146, and 147

[Docket No. APHIS-2011-0101]

RIN 0579-AD83

National Poultry Improvement Plan and Auxiliary Provisions

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: We are amending the National Poultry Improvement Plan (NPIP, the Plan) and its auxiliary provisions by removing the descriptions of specific tests and sanitation procedures from the regulations. Instead, we will require tests to be performed and sanitation to be maintained in a manner approved by the Administrator. Approved procedures will be listed in an NPIP Program Standards document, which we are making available on the NPIP Web site. In addition, we are establishing new compartment classifications for defined subpopulations of primary breeding turkeys, primary egg-type chickens, and primary meat-type chickens. We are also providing new or modified sampling and testing procedures for Plan participants and participating flocks. The changes in this final rule were voted on and approved by the voting delegates at the Plan's 2010 and 2012 National Plan Conferences. These changes will streamline the provisions of the Plan, keep those provisions current with changes in the poultry industry, and provide for the use of new sampling and testing procedures.

EFFECTIVE DATE: [Insert date 30 days after date of publication in the Federal Register].

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#### 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, 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, also referred to as "the Service") of the U.S. Department of Agriculture (USDA, also referred to as "the Department") amends these provisions from time to time to incorporate new scientific information and technologies within the Plan.

On January 28, 2014, we published in the Federal Register (79 FR 4538-4567, Docket No. APHIS-2011-0101) a proposal<sup>1</sup> to amend the regulations by removing tests and detailed testing procedures, as well as sanitation procedures, from part 147, and making these available in

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<sup>1</sup> To view the proposed rule and the comments we received, go to <http://www.regulations.gov/#!docketDetail;D=APHIS-2011-0101>.

an NPIP Program Standards document. In addition, we proposed to establish U.S. H5/H7 Avian Influenza Clean Compartment and U.S. Avian Influenza Clean Compartment classifications for defined subpopulations of primary breeding turkeys, primary egg-type breeding chickens, and primary meat-type breeding chickens. We also proposed several other changes.

We solicited comments concerning our proposal for 60 days ending March 31, 2014. We received 11 comments by that date. They were from producers, poultry associations, and the general public. Of the 11 comments we received, 7 directly addressed the proposed rule. These comments are discussed below.

Part 146 of the regulations contains the NPIP provisions for commercial poultry. Currently, the only disease addressed in this part is H5/H7 low pathogenic avian influenza; under part 146, table-egg layer flocks, meat-type chicken slaughter plants, meat-type turkey slaughter plants, and certain types of game birds and waterfowl may participate in U.S. H5/H7 Avian Influenza Monitored classifications.

Section 146.11 sets out the audit process for participating slaughter plants. Paragraph (b) states that flocks slaughtered at a slaughter plant will be considered to be not conforming to the required protocol of the classifications if there are no test results available, if the flock was not tested within 21 days before slaughter, or if the test results for the flocks were not returned before slaughter. We proposed to amend paragraph (b) to refer to samples being collected and tested and to results being returned prior to movement to slaughter.

The seven commenters who addressed the rule opposed this change. They stated that requiring testing prior to slaughter, rather than prior to movement to slaughter, allows companies that have been sampling flocks at processing to continue doing so. It also allows producers

whose flocks were inadvertently not sampled in the field to be tested at the slaughter plant and remain compliant.

They also stated that the proposed requirement to test prior to movement to slaughter would inadvertently combine the different testing requirements for participating slaughter plants in each subpart in part 146 into one set of testing requirements. This would prevent the different types of participating slaughter plants from setting different testing requirements. One commenter stated that the change would limit the flexibility of Official State Agencies and industry to develop alternative testing protocols in which the same number of birds are tested, as allowed under the regulations.

We believe it is important to have the test results for a flock returned prior to movement to slaughter to prevent potentially diseased birds from being exposed to other, healthy birds and possibly requiring cleaning and disinfection at the slaughter plant. The NPIP General Conference voted to approve this change at the 2012 Biennial Conference, reflecting the general consensus of NPIP participants. However, we are postponing the finalization of this change until an alternative proposal put forward by the commenters can be voted on during the 2014 NPIP Biennial Conference, which is scheduled to take place in Charlotte, NC, from July 10 through 12, 2014. Based on that vote, we will either retain this change in a stand-alone final rule or make alterations to the testing requirements in a separate proposed rule.

We are making a minor change and two corrections to the proposal in this final rule. Paragraph (a)(1)(i) of the proposed compartmentalization sections in §§ 145.45, 145.74, and 145.84 indicated that the company applying for compartmentalization would have to, upon request, work with the Official State Agency to provide data on the incidence of notifiable avian influenza (NAI) for bird populations outside of the proposed compartment in the State.

However, Official State Agencies are focused on commercial poultry populations and may not have data on the NAI status of backyard birds or migratory birds. In addition, while compartments may trade with other commercial bird populations, they should be secured against any disease risk posed by backyard birds or migratory birds. Therefore, we are changing each of these proposed paragraphs to indicate that the Official State Agency may provide data on the NAI status of other commercial poultry populations located in the State, upon request.

Paragraph (a)(1)(v) of the proposed compartmentalization sections contained a grammatical redundancy, which we have removed in this final rule.

We also requested comment on the new Program Standards document. We did not receive any comments. However, one of the approved tests listed in the Program Standards document, the Rapid Chek© Select™ Salmonella Test Kit, is now produced by Romer Labs. We have updated the Program Standards document accordingly.

Therefore, for the reasons given in the proposed rule and in this document, we are adopting the proposed rule as a final rule, with the changes discussed in this document.

#### Executive Order 12866 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.

In accordance with the Regulatory Flexibility Act, we have analyzed the potential economic effects of this action on small entities. The analysis is summarized below. Copies of the full analysis are available on the Regulations.gov Web site (see footnote 1 in this document for a link to Regulations.gov) or by contacting the person listed under FOR FURTHER INFORMATION CONTACT.

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 or modification could potentially result in a cost to certain entities, we do not expect the costs to be significant. This rule embodies changes decided upon by the NPIP's General Conference Committee on behalf of Plan members, that is, changes recognized by the poultry industry as in their interest. We note that NPIP membership is voluntary.

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 7 CFR part 3015, subpart V.)

#### 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

9 CFR Part 56

Animal diseases, Indemnity payments, Low pathogenic avian influenza, Poultry.

9 CFR Parts 145, 146, and 147

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

Accordingly, we are amending 9 CFR parts 56, 145, 146, and 147 as follows:

PART 56—CONTROL OF H5/H7 LOW PATHOGENIC AVIAN INFLUENZA

1. The authority citation for part 56 continues to read as follows:

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

2. Section 56.1 is amended as follows:

a. By revising the definition of H5/H7 low pathogenic avian influenza (LPAI).

b. In paragraph (1)(iii) of the definition of H5/H7 LPAI virus infection (infected), by adding the words "the Cooperating State Agency, the Official State Agency, and" before the word "APHIS".

The revision reads as follows:

§ 56.1 Definitions.

\* \* \* \* \*

H5/H7 low pathogenic avian influenza (LPAI). An infection of poultry caused by an influenza A virus of H5 or H7 subtype that has an intravenous pathogenicity index in 6-week-old chickens less than or equal to 1.2 or causes less than 75 percent mortality in 4- to 8-week-old chickens infected intravenously, or an infection with influenza A viruses of H5 or H7 subtype

with a cleavage site that is not consistent with a previously identified highly pathogenic avian influenza virus.

\* \* \* \* \*

3. Section 56.4 is amended by adding a new paragraph (d) to read as follows:

§ 56.4 Determination of indemnity amounts.

\* \* \* \* \*

(d) Requirements for compliance agreements. The compliance agreement is a comprehensive document that describes the depopulation, disposal, and cleaning and disinfection plans for poultry that were infected with or exposed to H5/H7 LPAI, or a premises that contained such poultry. The compliance agreement sets out APHIS responsibilities, owner responsibilities, and Cooperating State Agency responsibilities. The compliance agreement must include the owner's name and the name and address of the affected premises. The compliance agreement must have signatories that include, but are not necessarily limited to, the owner, the grower (if applicable), the Cooperating State Agency representative, the State veterinarian, and the APHIS area supervisor. In addition, the compliance agreement must contain a flock plan with estimated cost breakdowns that include labor, materials, personal protective equipment, travel expenses for personnel involved, and any additional information deemed necessary by the Service. A signed compliance agreement is required before beginning any work for which indemnity funds will be requested. Once work associated with the compliance agreement is completed, receipts and documentation detailing the activities specified in the agreement should be forwarded to APHIS for review, approval, and final payment. This documentation should be submitted to APHIS no later than 30 days after the quarantine release of the affected or exposed premises.

\* \* \* \* \*



4. Section 56.5 is amended as follows:

a. By revising paragraph (c)(1)(i).

b. By adding paragraphs (c)(1)(iii) and (c)(1)(iv).

c. By revising paragraphs (d)(1)(i) and (d)(1)(iii).

d. By removing paragraph (d)(1)(iv).

e. By removing the second, third, and fourth sentences after the heading of paragraph (d)(2)(i) and adding five sentences in their place.

f. By revising the first sentence after the heading of paragraph (d)(3).

The revisions and additions read as follows:

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

\* \* \* \* \*

(c) \* \* \*

(1) \* \* \*

(i) Poultry infected with or exposed to H5/H7 LPAI must not be transported to a market for controlled marketing until approved by the Cooperating State Agency in accordance with the initial State response and containment plan described in § 56.10.

\* \* \* \* \*

(iii) Routes to slaughter must avoid other commercial poultry operations whenever possible. All load-out equipment, trailers, and trucks used on premises that have housed poultry that were infected with or exposed to H5/H7 LPAI must be cleaned and disinfected and not enter other poultry premises or facilities for 48 hours after removing such poultry from their premises.

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

\* \* \* \* \*

(d) \* \* \*

(1) \* \* \*

(i) Secure all feathers and debris that might blow around outside the house in which the infected or exposed poultry were held by gathering and pushing the material into the house;

\* \* \* \* \*

(iii) Close the house in which the poultry were held, maintaining just enough ventilation to remove moisture. Leave the house undisturbed for a minimum of 72 hours.

(2) \* \* \*

(i) \* \* \* Compost manure, debris, and feed by windrowing in the house if possible.

If this is not possible, set up a system for hauling manure, debris, and feed to an approved site for burial, piling, or composting. Manure, debris, and feed may be removed from the house or premises and disposed of by composting it on site, leaving it in a undisturbed pile on site, or removing it from the site in covered vehicles. Land application of manure, debris, and feed should only be performed in accordance with the initial State response and containment plan described in § 56.10. Clean out the house or move or spread litter as determined by the Cooperating State Agency and in accordance with the initial State response and containment plan. \* \* \*

\* \* \* \* \*

(3) \* \* \* Premises should remain empty until testing provides negative virus detection results and checked by the Cooperating State Agency in accordance with the initial State response and containment plan described in § 56.10. \* \* \*

\* \* \* \* \*

#### PART 145–NATIONAL POULTRY IMPROVEMENT PLAN FOR BREEDING POULTRY

5. 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.

6. Section 145.1 is amended as follows:

a. In the definition of authorized agent, by removing the words "as described in §§ 147.1(a) and 147.12" and adding the words "in accordance with part 147" in their place.

b. In the definition of authorized laboratory, by removing the citation "§ 147.51" and adding the citation "§ 147.52" in its place; and by removing the words "the assays described in" and adding the words "assays in accordance with" in their place.

c. In the definition of authorized testing agent, by removing the words "as described in §§ 147.1(a) and 147.12" and adding the words "in accordance with part 147" in their place.

d. By adding, in alphabetical order, definitions of H5/H7 low pathogenic avian influenza (LPAI) and NPIP Program Standards.

e. In the definition of reactor, by removing the words "parts 145 or 147 of this chapter" and adding the words "this part or in accordance with part 147 of this subchapter" in their place.

f. In the definition of Senior Coordinator, in paragraph (4), by removing the citation "§ 147.51" and adding the citation "§ 147.52" in its place.

The additions read as follows:

#### § 145.1 Definitions

\* \* \* \* \*

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

\* \* \* \* \*

NPIP Program Standards. A document that contains tests and sanitation procedures approved by the Administrator in accordance with § 147.53 of this subchapter for use under this subchapter. This document may be obtained from the NPIP Web site at [http://www.aphis.usda.gov/animal\\_health/animal\\_dis\\_spec/poultry/](http://www.aphis.usda.gov/animal_health/animal_dis_spec/poultry/) or by writing to the Service at National Poultry Improvement Plan, APHIS, USDA, 1506 Klondike Road, Suite 101, Conyers, GA 30094.

\* \* \* \* \*

§ 145.2 [Amended]

7. In § 145.2, paragraph (e) is amended by removing the words "follow the laboratory protocols outlined in part 147 of this chapter" and adding the words "conduct tests in accordance with part 147 of this subchapter" in their place.

8. Section 145.3 is amended as follows:

a. In paragraph (c), second sentence, by removing the word "He" and adding the words "The participant" in its place; and by adding the word "and" before the word "cassowaries,".

b. By redesignating paragraphs (d) and (e) as paragraphs (e) and (f), respectively.

c. By adding a new paragraph (d).

The addition reads as follows:

§ 145.3 Participation.

\* \* \* \* \*

(d) To ensure that Plan diseases are not spread, flocks must be qualified for their intended Plan classifications before being moved into breeder production facilities.

\* \* \* \* \*

§ 145.5 [Amended]

9. Section 145.5 is amended as follows:

a. In paragraph (a), by removing the words "as recommended in §§ 147.21 and 147.22 (a) and (e) of this chapter" and adding the words "in accordance with part 147 of this subchapter" in their place.

b. In paragraph (c), by removing the words "or F" and adding the words "F, G, H, or I" in their place.

10. Section 145.6 is amended as follows:

a. By revising the second sentence in paragraph (a) introductory text.

b. In paragraphs (a)(1), (a)(2), (a)(3), and (a)(4), by removing the words "as outlined in § 147.24 of this chapter" and adding the words "in accordance with part 147 of this subchapter" in their place.

The revision reads as follows:

§ 145.6 Specific provisions for participating hatcheries.

(a) \* \* \* The sanitary procedures outlined in the NPIP Program Standards, or other procedures approved by the Administrator in accordance with § 147.53(d), will be considered as a guide in determining compliance with this provision. \* \* \*

\* \* \* \* \*

11. Section 145.10 is amended as follows:

a. In paragraph (b) introductory text, by removing the words "and 145.63(a)" and adding the words "145.63(a), 145.73(b), 145.83(b), and 145.93(b)" in their place.

b. By revising paragraph (c) introductory text, paragraph (g) introductory text, paragraph (m) introductory text, paragraph (o) introductory text, and paragraph (t) introductory text.

The revisions read as follows:

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

\* \* \* \* \*

(c) U.S. M. Gallisepticum Clean. (See §§ 145.23(c), 145.23(f), 145.33(c), 145.33(f), 145.43(c), 145.53(c), 145.73(c), and 145.83(c).)

\* \* \* \* \*

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

\* \* \* \* \*

(m) U.S. S. Enteritidis Clean. (See §§ 145.23(d), 145.73(d), and 145.83(e).)

\* \* \* \* \*

(o) U.S. Salmonella Monitored. (See §§ 145.53(f), 145.83(f), and 145.93(d).)

\* \* \* \* \*

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

\* \* \* \* \*

12. Section 145.14 is amended as follows:

- a. In paragraph (a)(1), by revising the second sentence.
- b. In paragraph (a)(6)(ii), by revising the third sentence.
- c. In paragraph (b)(1), by adding a sentence after the second sentence.
- d. By revising paragraph (b)(3).
- e. By revising paragraph (d)(1)(ii)(C).
- f. In paragraph (d)(2)(i)(A), by removing the word "(AVPR01510)".
- g. By revising paragraph (d)(2)(ii)(B).

The revisions and addition read as follows:

§ 145.14 Testing.

(a) \* \* \*

(1) \* \* \* Official blood tests must be conducted in accordance with part 147 of this subchapter or according to literature provided by the producer. \* \* \*

\* \* \* \* \*

(6) \* \* \*

(ii) \* \* \* Bacteriological examination must be conducted in accordance with part 147 of this subchapter. \* \* \*

\* \* \* \* \*

(b) \* \* \*

(1) \* \* \* Tests must be conducted in accordance with this paragraph (b) and in accordance with part 147 of this subchapter. \* \* \*

\* \* \* \* \*

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

\* \* \* \* \*

(d) \* \* \*

(1) \* \* \*

(ii) \* \* \*

(C) The AGID test for avian influenza must be conducted in accordance with part 147 of this subchapter. The test can be conducted on egg yolk or blood samples. The AGID test is not recommended for use in waterfowl.

\* \* \* \* \*

(2) \* \* \*

(ii) \* \* \*

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

\* \* \* \* \*

13. In § 145.22, paragraph (b) is revised to read as follows:

§ 145.22 Participation.

\* \* \* \* \*

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



\* \* \* \* \*

14. Section 145.23 is amended as follows:

a. In paragraph (b) introductory text, by removing the citation "(5)" and adding the citation "(4)" in its place.

b. In paragraph (c)(1) introductory text, by removing the words "in compliance with the provisions of § 147.26 of this chapter" and adding the words "in accordance with part 147 of this subchapter with respect to Mycoplasma isolation, sanitation, and management" in their place.

c. In paragraph (c)(1)(ii)(C), by removing the words "§ 147.8 of this chapter" and adding the words "part 147 of this subchapter" in their place.

d. In paragraph (c)(3), by removing the words "as described in § 147.24(a) of this chapter" and adding the words "in accordance with part 147 of this subchapter" in their place.

e. In paragraph (d)(1)(iv), by removing the words "in compliance with §§ 147.21, 147.24(a), and 147.26 of this chapter" and adding the words "in accordance with part 147 of this subchapter with respect to flock sanitation, cleaning and disinfection, and Salmonella isolation, sanitation, and management" in their place.

f. In paragraph (d)(1)(v), by removing the words "as described in § 147.12 of this chapter" and adding the words "in accordance with part 147 of this subchapter" in their place.

g. In paragraph (d)(1)(vii), by removing the words "as described in § 147.11 of this chapter" and adding the words "in accordance with part 147 of this subchapter" in their place.

h. By revising paragraphs (d)(1)(viii) and (d)(1)(ix).

i. In paragraph (d)(2), by removing the words "as described in § 147.11(a) of this chapter" and adding the words "in accordance with part 147 of this subchapter" in their place.

j. In paragraph (e)(1) introductory text, by removing the words "in compliance with the provisions of § 147.26 of this chapter" and adding the words "in accordance with part 147 of this subchapter with respect to Mycoplasma isolation, sanitation, and management" in their place.

k. In paragraph (e)(1)(ii)(B), by removing the words "§ 147.8 of this chapter" and adding the words "part 147 of this subchapter" in their place.

l. In paragraph (e)(3), by removing the words "as described in § 147.24(a) of this chapter" and adding the words "in accordance with part 147 of this subchapter" in their place.

m. In paragraph (f)(3), by removing the words "in compliance with the provisions of § 147.26 of this chapter" and adding the words "in accordance with part 147 of this subchapter with respect to Mycoplasma isolation, sanitation, and management" in their place.

n. In paragraph (f)(5), by removing the words "as described in § 147.24(a) of this chapter" and adding the words "in accordance with part 147 of this subchapter" in their place.

o. In paragraph (g)(3), by removing the words "in compliance with the provisions of § 147.26 of this chapter" and adding the words "in accordance with part 147 of this subchapter with respect to Mycoplasma isolation, sanitation, and management" in their place.

p. In paragraph (g)(5), by removing the words "as described in § 147.24(a) of this chapter" and adding the words "in accordance with part 147 of this subchapter" in their place.

q. In paragraph (h)(1) introductory text, by adding the words "and found" before the word "negative" and by removing the words "for antibodies".

The revisions read as follows:

§ 145.23 Terminology and classification; flocks and products.

\* \* \* \* \*

(d) \* \* \*

(1) \* \* \*

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

(ix) Hatching eggs produced by the flock are incubated in a hatchery whose sanitation is maintained in accordance with part 147 of this subchapter and sanitized either by a procedure approved by the Official State Agency or in accordance with part 147 of this subchapter.

\* \* \* \* \*

15. In § 145.32, paragraph (b) is revised to read as follows:

§ 145.32 Participation.

\* \* \* \* \*

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

\* \* \* \* \*

16. Section 145.33 is amended as follows:

a. In paragraph (b) introductory text, by removing the citation "(5)" and adding the citation "(4)" in its place.

b. In paragraph (c)(1) introductory text, by removing the words "in compliance with the provisions of § 147.26 of this chapter" and adding the words "in accordance with part 147 of this subchapter with respect to Mycoplasma isolation, sanitation, and management" in their place.

c. In paragraph (c)(1)(ii)(C), by removing the words "§ 147.8 of this chapter" and adding the words "part 147 of this subchapter" in their place.

d. In paragraph (c)(2), by removing the words "(see §§ 147.22, 147.23, and 147.24)" and by adding the words "and in accordance with part 147 of this subchapter" before the period at the end of the paragraph.

e. In paragraph (c)(3), by removing the words "as described in § 147.24(a) of this chapter" and adding the words "in accordance with part 147 of this subchapter" in their place.

f. In paragraph (c)(4), by removing the words "approved by the Department" and adding the words "in accordance with part 147 of this subchapter" in their place.

g. In paragraph (d)(1)(ii), by removing the words "in compliance with §§ 147.21, 147.24(a), and 147.26 of this chapter" and adding the words "in accordance with part 147 of this subchapter with respect to flock sanitation, cleaning and disinfection, and Salmonella isolation, sanitation, and management" in their place.

h. By revising paragraph (d)(1)(vi).

i. In paragraph (d)(1)(vii), by removing the words "as described in § 147.12 of this chapter" and adding the words "in accordance with part 147 of this subchapter" in their place.

j. By revising paragraph (d)(2).

k. In paragraph (e)(1) introductory text, by removing the words "in compliance with the provisions of § 147.26 of this chapter" and adding the words "in accordance with part 147 of this subchapter with respect to Mycoplasma isolation, sanitation, and management" in their place.

l. In paragraph (e)(1)(ii)(B), by removing the words "§ 147.8 of this chapter" and adding the words "part 147 of this subchapter" in their place.

m. In paragraph (e)(3), by removing the words "as described in § 147.24(a) of this chapter" and adding the words "in accordance with part 147 of this subchapter" in their place.

n. In paragraph (e)(4), by removing the words "approved by the Department" and adding the words "in accordance with part 147 of this subchapter" in their place.

o. In paragraph (f)(3), by removing the words "in compliance with the provisions of § 147.26 of this chapter" and adding the words "in accordance with part 147 of this subchapter with respect to Mycoplasma isolation, sanitation, and management" in their place.

p. In paragraph (f)(5), by removing the words "as described in § 147.24(a) of this chapter" and adding the words "in accordance with part 147 of this subchapter" in their place.

q. In paragraph (g)(3), by removing the words "in compliance with the provisions of § 147.26 of this chapter" and adding the words "in accordance with part 147 of this subchapter with respect to Mycoplasma isolation, sanitation, and management" in their place.

r. In paragraph (g)(5), by removing the words "as described in § 147.24(a) of this chapter" and adding the words "in accordance with part 147 of this subchapter" in their place.

s. In paragraph (j)(2), by removing the words "paragraph (c)(1)(i) of this section" and adding the words "§ 145.83(c)(1)(i)" in their place.

t. In paragraphs (j)(3) and (k)(3), by removing the words "as described in § 147.24(a) of this chapter" and adding the words "in accordance with part 147 of this subchapter" in their place.

u. In paragraph (k)(2), by removing the words "paragraph (e)(1)(i) of this section" and adding the words "§ 145.83(d)(1)(i)" in their place.

v. In paragraph (l)(1) introductory text, by adding the words "using an approved test as described in § 145.14" after the word "influenza".

w. By adding paragraph (m).

The revisions and addition read as follows:

§ 145.33 Terminology and classification; flocks and products.

\* \* \* \* \*

(d) \* \* \*

(1) \* \* \*

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

\* \* \* \* \*

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

\* \* \* \* \*

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

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

(i) The flock originated from a U.S. S. Enteritidis Clean primary meat-type breeding flock.

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

(iii) Environmental samples are collected from the flock in accordance with part 147 of this subchapter at 16-18 and 40-45 weeks of age. The samples shall be examined

bacteriologically for group D Salmonella at an authorized laboratory, and cultures from group D positive samples shall be serotyped.

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

(i) If S. enteritidis is isolated from an environmental sample collected from the flock in accordance with paragraph (m)(1)(iii) of this section, a thorough evaluation of the practices and programs associated with the sampled flock shall be conducted with the goal of ascertaining the reason(s) for the positive finding.

(ii) The test results and the results of any evaluations performed in accordance with paragraph (m)(2)(i) of this section will be reported on a quarterly basis to the Official State Agency and the NPIP Senior Coordinator.

(iii) Participating broiler integrators shall combine their respective test results (and the results of any associated evaluations) to help guide their decisionmaking regarding programs and practices to implement or maintain to address S. enteritidis.

(iv) Aggregate data regarding the prevalence of S. enteritidis in participating U.S. meat-type parent breeding flocks shall be made available to the U.S. Poultry and Egg Association and the National Chicken Council.

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

\* \* \* \* \*

§ 145.42 [Amended]

17. In § 145.42, paragraph (b) is amended by removing the words "(see §147.25 of this chapter)" and adding the words "in accordance with part 147 of this subchapter" after the word "sanitized".

18. Section 145.43 is amended as follows:

a. In paragraph (c)(1), by removing the words "in accordance with the conditions and procedures described in § 147.26 of this chapter" and adding the words "in accordance with part 147 of this subchapter with respect to Mycoplasma isolation, sanitation, and management" in their place.

b. In paragraph (c)(2), by removing the words "applicable conditions outlined in § 147.26 of this chapter are being met" and adding the words "flock is being maintained in accordance with part 147 of this subchapter with respect to Mycoplasma isolation, sanitation, and management" in their place.

c. By adding a sentence at the end of paragraph (e)(1).

d. In paragraph (e)(2), by removing the words " § 147.6 of this chapter" and by adding the words " part 147 of this subchapter" in their place.

e. By removing paragraph (e)(3).

f. In paragraph (f) introductory text, by removing the words "as described in subpart C of part 147 of this chapter" and adding the words "in accordance with part 147 of this subchapter" in their place.

g. In paragraphs (f)(2), (f)(4), and (f)(6), by removing the words ", as described in § 147.12 of this chapter" and adding the words "in accordance with part 147 of this subchapter" in their place.

h. By revising paragraph (g)(3).



The addition and revision read as follows:

§ 145.43 Terminology and classification; flocks and products.

\* \* \* \* \*

(e) \* \* \*

(1) \* \* \* It is recommended that any birds that are showing clinical signs of M. synoviae infection be included in samples taken.

\* \* \* \* \*

(g) \* \* \*

(3) All spent fowl being marketed for meat from flocks that have been tested as required by this paragraph shall be tested at a rate of 6 birds per flock within 21 days prior to movement to slaughter.

\* \* \* \* \*

19. Section 145.45 is added to subpart D to read as follows:

§ 145.45 Terminology and classification; compartments.

(a) U.S. H5/H7 Avian Influenza 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). This compartment has the purpose of protecting the defined subpopulation and avoiding the introduction and spread of 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 NAI. Specifically, the company will use a comprehensive biosecurity program to define the compartment as a subpopulation of poultry with a health status for 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 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 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 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 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 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 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 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 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 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]

20. Section 145.52 is amended as follows:

- a. In paragraph (b), by removing the words "(see §147.25 of this chapter)" and adding the words "in accordance with part 147 of this subchapter" after the word "sanitized".
- b. By redesignating paragraphs (c) and (d) as paragraphs (d) and (e), respectively.
- c. By adding a new paragraph (c).

The addition reads as follows:

§ 145.52 Participation.

\* \* \* \* \*

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

\* \* \* \* \*

21. Section 145.53 is amended as follows:

- a. In paragraph (c)(1) introductory text, by removing the words "in compliance with the provisions of § 147.26 of this chapter" and adding the words "in accordance with part 147 of this subchapter with respect to Mycoplasma isolation, sanitation, and management" in their place.
- b. In paragraph (c)(3), by removing the words "as described in § 147.24(a) of this chapter" and adding the words "in accordance with part 147 of this subchapter" in their place.



c. In paragraph (d)(1) introductory text, by removing the words "in compliance with the provisions of § 147.26 of this chapter" and adding the words "in accordance with part 147 of this subchapter with respect to Mycoplasma isolation, sanitation, and management" in their place.

d. In paragraph (d)(1)(ii)(B), by removing the words "§ 147.8 of this chapter" and adding the words "part 147 of this subchapter" in their place.

e. In paragraph (d)(3), by removing the words "as described in § 147.24(a) of this chapter" and adding the words "in accordance with part 147 of this subchapter" in their place.

f. By revising paragraphs (e)(1) introductory text and (e)(2) introductory text.

g. In paragraphs (e)(1)(i) and (e)(1)(ii), by removing the number "90" and adding the number "180" in its place.

h. By revising paragraph (e)(3).

i. By adding paragraph (f).

The revisions and addition read as follows:

§ 145.53 Terminology and classification; flocks and products.

\* \* \* \* \*

(e) \* \* \*

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

\* \* \* \* \*

(2) It is a multiplier breeding flock in which a minimum of 30 birds has been tested negative to the H5 and H7 subtypes of avian influenza as provided in § 145.14(d) when more

than 4 months of age; Provided, that waterfowl flocks may test a minimum of 30 cloacal swabs for virus isolation. To retain this classification:

\* \* \* \* \*

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

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

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

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

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

\* \* \* \* \*

§ 145.62 [Amended]

22. In § 145.62, paragraph (b) is amended by removing the words "(see § 147.22 of this chapter)" and adding the words "in accordance with part 147 of this subchapter" in their place.

23. In § 145.72, paragraph (b) is revised to read as follows:

§ 145.72 Participation.

\* \* \* \* \*

(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.

\* \* \* \* \*

24. Section 145.73 is amended as follows:

a. In paragraph (c)(1) introductory text, by removing the words "in compliance with the provisions of § 147.26 of this subchapter" and adding the words "in accordance with part 147 of this subchapter with respect to Mycoplasma isolation, sanitation, and management" in their place.

b. In paragraph (c)(3), by removing the words "as described in § 147.24(a)" and adding the words "in accordance with part 147" in their place.

c. In paragraph (d)(1)(iv), by removing the words "in compliance with §§ 147.21, 147.24(a), and 147.26 of this subchapter" and adding the words "in accordance with part 147 of this subchapter with respect to flock sanitation, cleaning and disinfection, and Salmonella isolation, sanitation, and management" in their place.

d. In paragraph (d)(1)(v), by removing the words "as described in § 147.12" and adding the words "in accordance with part 147" in their place.

e. In paragraph (d)(1)(vii), by removing the words "as described in § 147.11" and adding the words "in accordance with part 147" in their place.

f. By revising paragraph (d)(1)(ix).

g. In paragraph (d)(2), by removing the words "as described in § 147.11(a)" and adding the words "in accordance with part 147" in their place.

h. In paragraph (e)(1) introductory text, by removing the words "in compliance with the provisions of § 147.26 of this subchapter" and adding the words "in accordance with part 147 of this subchapter with respect to Mycoplasma isolation, sanitation, and management" in their place.

i. In paragraph (e)(3), by removing the words "as described in § 147.24(a)" and adding the words "in accordance with part 147" in their place.

j. In paragraph (f)(1) introductory text, by adding the words "and found" before the word "negative" and by removing the words "antibodies to".

k. By revising paragraph (f)(2).

The revisions read as follows:

§ 145.73 Terminology and classification; flocks and products.

\* \* \* \* \*

(d) \* \* \*

(1) \* \* \*

(ix) Hatching eggs produced by the flock are incubated in a hatchery whose sanitation is maintained in accordance with part 147 of this subchapter and sanitized either by a procedure approved by the Official State Agency or in accordance with part 147 of this subchapter.

\* \* \* \* \*

(f) \* \* \*

(2) A sample of at least 11 birds must be tested and found negative for avian influenza within 21 days prior to movement to slaughter.

25. Section 145.74 is added to subpart G to read as follows:

§ 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 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 NAI. Specifically, the company will use a comprehensive biosecurity program to define the compartment as a subpopulation of poultry with a health status for 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 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 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 Poult”; 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 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 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 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 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 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 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 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]

26. In § 145.82, paragraph (b) is revised to read as follows:

§ 145.82 Participation.

\* \* \* \* \*

(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.

\* \* \* \* \*

27. Section 145.83 is amended as follows:

a. In paragraph (c)(1) introductory text, by removing the words "in compliance with the provisions of § 147.26 of this subchapter" and adding the words "in accordance with part 147 of this subchapter with respect to Mycoplasma isolation, sanitation, and management" in their place.

b. In paragraph (c)(3), by removing the words "as described in § 147.24(a)" and adding the words "in accordance with part 147" in their place.

c. In paragraph (d)(1) introductory text, by removing the words "in compliance with the provisions of § 147.26 of this subchapter" and adding the words "in accordance with part 147 of this subchapter with respect to Mycoplasma isolation, sanitation, and management" in their place.

d. In paragraph (d)(3), by removing the words "as described in § 147.24(a)" and adding the words "in accordance with part 147" in their place.

e. By revising paragraphs (e)(1) and (e)(3).

f. In paragraph (e)(6) introductory text, by removing the words "or great-grandparent" and adding the words "great-grandparent, or grandparent" in their place.

g. In paragraph (e)(6)(i)(B), by removing the words "as described in § 147.12(a)" and adding the words "in accordance with part 147" in their place.

h. In paragraph (e)(6)(i)(C), by removing the words "as described in § 147.11" and adding the words "in accordance with part 147" in their place.

i. In paragraph (e)(6)(i)(D), by removing the words "as specified in § 147.12(a)" and adding the words "in accordance with part 147" in their place.

j. In paragraph (f)(1)(i), by removing the words "in compliance with §§ 147.21, 147.24(a), and 147.26 of this subchapter" and adding the words "in accordance with part 147 of this subchapter with respect to flock sanitation, cleaning and disinfection, and Salmonella isolation, sanitation, and management" in their place.

k. By revising paragraph (f)(1)(iv).

l. In paragraph (f)(1)(vi), by removing the words "as described in § 147.12" and adding the words "in accordance with part 147" in their place.

m. By revising paragraph (f)(2).

n. In paragraph (g)(1) introductory text, by adding the words "using an approved test as described in § 145.14" after the word "influenza".

The revisions read as follows:

§ 145.83 Terminology and classification; flocks and products.

\* \* \* \* \*

(e) \* \* \*

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

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

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

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

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

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

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

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

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

\* \* \* \* \*

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

\* \* \* \* \*

(f) \* \* \*

(1) \* \* \*

(iv) 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.

\* \* \* \* \*

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

\* \* \* \* \*

28. Section 145.84 is added to subpart H to read as follows:

§ 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 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 NAI. Specifically, the company will use a comprehensive biosecurity program to define the compartment as a subpopulation of poultry with a health status for 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 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 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 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 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 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 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 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 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 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]

§ 145.92 [Amended]

29. In § 145.92, paragraph (b) is amended by removing the words "(see §147.25 of this chapter)" and adding the words "in accordance with part 147 of this subchapter" after the word "sanitized".

30. Section 145.93 is amended as follows:

- a. By revising paragraph (c)(3).
- b. By adding paragraph (d).

The revision and addition read as follows:

§ 145.93 Terminology and classification; flocks and products.

\* \* \* \* \*

(c) \* \* \*

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

(d) U.S. Salmonella Monitored. This program is intended to be the basis from which the breeding-hatching industry may conduct a program for the prevention and control of salmonellosis. It is intended to reduce the incidence of Salmonella organisms in hatching eggs and day-old waterfowl 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 day-old waterfowl produced from it must meet the following requirements, as determined by the Official State Agency, to be eligible for this classification:

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

(ii) If feed contains animal protein, the protein products must have been heated throughout to a minimum temperature of 190 °F or above, or to a minimum temperature of 165 °F for at least 20 minutes, or to a minimum temperature of 184 °F under 70 lbs. pressure during the manufacturing process.

(iii) Feed shall be stored and transported in a manner that prevents contamination.

(iv) Waterfowl 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.

(v) An Authorized Agent shall take environmental samples from the hatchery every 30 days, i.e., meconium or box liner paper. An authorized laboratory for Salmonella shall examine the samples bacteriologically.

(vi) 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.

(vii) Flocks may be vaccinated with a paratyphoid vaccine: Provided, that a sample of at least 100 birds will be segregated and shall remain unvaccinated until the flock reaches at least 4 months of age.



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

(3) To claim products are of this classification, all products shall be derived from a hatchery and flock that 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.

PART 146–NATIONAL POULTRY IMPROVEMENT PLAN FOR COMMERCIAL  
POULTRY

31. 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.

32. Section 146.1 is amended as follows:

a. By revising the definition of authorized laboratory.

b. In the definition of commercial meat-type flock, by adding the words "spent fowl," after the word "chickens,".

c. In the definition of H5/H7 low pathogenic avian influenza (LPAI), by adding the words "or equal to" before the number "1.2" and by adding the word "causes" before the words "less than 75".

d. In paragraph (1)(iii) of the definition of H5/H7 LPAI virus infection (infected), by adding the words "the Cooperating State Agency, the Official State Agency, and" before the word "APHIS".

The revision reads as follows:

§ 146.1 Definitions.

\* \* \* \* \*

Authorized laboratory. An authorized laboratory is a laboratory that meets the requirements of § 147.52 and is thus qualified to perform the assays in accordance with part 147 of this subchapter.

\* \* \* \* \*

§ 146.2 [Amended]

33. In § 146.2, paragraph (e) is amended by removing the words "follow the laboratory protocols outlined in part 147 of this chapter" and adding the words "conduct tests in accordance with part 147 of this subchapter" in their place.

§ 146.3 [Amended]

34. Section 146.3 is amended as follows:

- a. In paragraph (c), by adding the words ", spent fowl," after the word "chicken".
- b. By removing paragraph (e).

§ 146.5 [Amended]

35. In § 146.5, paragraph (b) is amended by removing the words "as recommended in § 147.21(c)" and adding the words "in accordance with part 147" in their place.

36. Section 146.13 is amended as follows:

- a. In paragraph (a)(1), by removing the words "the requirements in § 147.8" and adding the words "part 147" in their place.
- b. By revising paragraph (b)(1)(ii)(C).
- c. In paragraph (b)(2)(i), by removing the word "(AVPR01510)".
- d. By revising paragraph (b)(2)(ii)(B).

The revisions read as follows:

§ 146.13 Testing.

\* \* \* \* \*

(b) \* \* \*

(1) \* \* \*

(ii) \* \* \*

(C) The AGID test for avian influenza must be conducted in accordance with part 147 of this subchapter. The test can be conducted on egg yolk or blood samples. The AGID test is not recommended for use in waterfowl.

\* \* \* \* \*

(2) \* \* \*

(ii) \* \* \*

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

\* \* \* \* \*

37. Section 146.23 is amended by revising the heading of paragraph (a), removing the introductory text of paragraph (a), and revising the introductory text of paragraphs (a)(1), and (a)(2) to read as follows:

§ 146.23 Terminology and classification; flocks and products.

\* \* \* \* \*

(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:

\* \* \* \* \*

(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 one of the following requirements:

\* \* \* \* \*

38. Section 146.31 is amended by adding, in alphabetical order, a definition of spent fowl to read as follows:

§ 146.31 Definitions.

\* \* \* \* \*

Spent fowl. Domesticated poultry that were in production of hatching eggs or commercial table eggs and have been removed from such production.

39. Section 146.32 is amended by adding a new paragraph (c) to read as follows:

§ 146.32 Participation.

\* \* \* \* \*

(c) If spent fowl are slaughtered at meat-type chicken slaughter plants that participate in the Plan, they may participate in the Plan through the provisions of this subpart C.

§ 146.33 [Amended]

40. In § 146.33, paragraph (a)(1) is amended by removing the words "antibodies to".

41. In § 146.43, paragraph (a)(1) is revised to read as follows:

§ 146.43 Terminology and classification; meat-type turkey slaughter plants.

\* \* \* \* \*

(a) \* \* \*

(1) It is a meat-type turkey slaughter plant that accepts only meat-type turkeys from flocks where a minimum of 6 samples per flock have been collected no more than 21 days prior to movement to slaughter and tested negative with an approved test for type A avian influenza, as provided in §146.13(b). It is recommended that samples be collected from flocks over 10 weeks of age with respiratory signs such as coughing, sneezing, snicking, sinusitis, or rales; depression; or decreases in food or water intake.

\* \* \* \* \*

PART 147–AUXILIARY PROVISIONS ON NATIONAL POULTRY IMPROVEMENT PLAN

42. 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.

43. Section 147.1 is revised to read as follows:

§ 147.1 Blood testing procedures.

Blood testing must be conducted in a manner approved by the Administrator. Approved blood testing procedures are listed in the NPIP Program Standards, as defined in § 147.51.

Blood testing procedures may also be approved by the Administrator in accordance with § 147.53(d)(1).

(Approved by the Office of Management and Budget under control number 0579-0007)

§§ 147.2 through 147.9 [Removed and Reserved]

44. Sections 147.2 through 147.9 are removed and reserved.

45. Section 147.10 is revised to read as follows:

§ 147.10 Bacteriological examination procedures.

Bacteriological examination must be conducted in a manner approved by the Administrator. Approved bacteriological examination procedures are listed in the NPIP Program Standards, as defined in § 147.51. Bacteriological examination procedures may also be approved by the Administrator in accordance with § 147.53(d)(1).

§§ 147.11 through 147.17 [Removed and Reserved]

46. Sections 147.11 through 147.17 are removed and reserved.

47. Section 147.21 is revised to read as follows:

§ 147.21 Sanitation procedures.

Sanitation must be maintained in a manner approved by the Administrator. Approved procedures for maintaining sanitation are listed in the NPIP Program Standards, as defined in § 147.51. Sanitation procedures may also be approved by the Administrator in accordance with § 147.53(d)(2).

(Approved by the Office of Management and Budget under control number 0579-0007)

§§ 147.22 through 147.27 [Removed and Reserved]

48. Sections 147.22 through 147.27 are removed and reserved.

49. Section 147.30 is revised to read as follows:

§ 147.30 Molecular examination procedures.

Molecular examination must be conducted in a manner approved by the Administrator. Approved molecular examination procedures are listed in the NPIP Program Standards, as defined in § 147.51. Molecular examination procedures may also be approved by the Administrator in accordance with § 147.53(d)(1).

§ 147.31 [Removed and Reserved]

50. Section 147.31 is removed and reserved.

51. In § 147.41, a new definition of NPIP Technical Committee is added, in alphabetical order, to read as follows:

§ 147.41 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.

\* \* \* \* \*

§ 147.44 [Amended]

52. In § 147.44, paragraph (b) is amended by removing the citation "§ 147.43(d)(2)" and adding the citation "§ 147.43(d)(4)" in its place.

53. In part 147, subpart F is revised to read as follows:

Subpart F—Authorized Laboratories and Approved Tests and Sanitation Procedures

Sec.

147.51 Definitions.

147.52 Authorized laboratories.

147.53 Approved tests and sanitation procedures.

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

#### Subpart F—Authorized Laboratories and Approved Tests and Sanitation Procedures

##### § 147.51 Definitions.

The following definitions apply in this subpart:

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

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

NPIP or Plan. The National Poultry Improvement Plan.

NPIP Program Standards. A document that contains tests and sanitation procedures approved by the Administrator under § 147.53 for use under this subchapter. This document may be obtained from the NPIP Web site at <http://www.poultryimprovement.org/> or by writing to the Service at National Poultry Improvement Plan, APHIS, USDA, 1506 Klondike Road, Suite 101, Conyers, GA 30094.

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.

##### § 147.52 Authorized laboratories.



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

(a) Check-test proficiency. The NPIP will serve as the lead agency for the coordination of available check tests from the National Veterinary Services Laboratories. The authorized laboratory must use a regularly scheduled check test for each assay that it performs.

(b) Trained technicians. The testing procedures at the laboratory must be run or overseen by a laboratory technician who has attended and satisfactorily completed Service-approved laboratory workshops for Plan-specific diseases within the past 4 years.

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

(d) State site visit. The Official State Agency will conduct a site visit and recordkeeping audit annually. This will include, but may not be limited to, review of technician training records, check test proficiency, and test results. The information from the site visit and recordkeeping audit will be made available to the NPIP upon request.

(e) Service review. Authorized laboratories will be reviewed by the Service (NPIP staff) every 3 years. The Service's review may include, but will not necessarily be limited to, checking records, laboratory protocol, check-test proficiency, technician training, and peer review.

(f) Reporting. (1) A memorandum of understanding or other means shall be used to establish testing and reporting criteria to the Official State Agency, including criteria that provide for reporting H5 and H7 low pathogenic avian influenza directly to the Service.

(2) Salmonella pullorum and Mycoplasma Plan disease reactors must be reported to the Official State Agency within 48 hours.

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

§ 147.53 Approved tests and sanitation procedures.

(a)(1) All tests that are used to qualify flocks for NPIP classifications must be approved by the Administrator as effective and accurate at determining whether a disease is present in a poultry flock or in the environment.

(2) All sanitation procedures performed as part of qualifying for an NPIP classification must be approved by the Administrator as effective at reducing the risk of incidence of disease in a poultry flock or hatchery.

(b) Tests and sanitation procedures that have been approved by the Administrator may be found in the NPIP Program Standards. In addition, all tests that use veterinary biologics (e.g., antiserum and other products of biological origin) that are licensed or produced by the Service and used as described in the NPIP Program Standards are approved for use in the NPIP.

(c) New tests and sanitation procedures, or changes to existing tests and sanitation procedures, that have been approved by the NPIP in accordance with the process described in subpart E of this part are subject to approval by the Administrator. NPIP participants may submit new tests and sanitation procedures, or changes to current tests and sanitation procedures, through that process.

(d)(1) Persons who wish to have a test approved by the Administrator as effective and accurate at determining whether a disease is present in a flock or in the environment may apply for approval by submitting the test, along with any supporting information and data, to the National Poultry Improvement Plan, APHIS, USDA, 1506 Klondike Road, Suite 101, Conyers, GA 30094. Upon receipt of such an application, the NPIP Technical Committee will review the test and any supporting information and data supplied with the application. If the NPIP Technical Committee determines the test to be of potential general use, the test will be submitted for consideration by the General Conference Committee of the NPIP in accordance with subpart E of this part, and the Administrator will respond with approval or denial of the test.

(2) Persons who wish to have a sanitation procedure approved by the Administrator as effective at reducing the risk of incidence of disease in a poultry flock or hatchery may apply for approval by submitting the sanitation procedure, along with any supporting information and data, to the National Poultry Improvement Plan, APHIS, USDA, 1506 Klondike Road, Suite 101, Conyers, GA 30094. Upon receipt of such an application, the NPIP Technical Committee will review the sanitation procedure and any supporting information and data supplied with the application. If the NPIP Technical Committee determines the sanitation procedure to be of potential general use, the sanitation procedure will be submitted for consideration by the General Conference Committee of the NPIP in accordance with subpart E of this part, and the Administrator will respond with approval or denial of the test.

(e)(1) When the Administrator approves a new test or sanitation procedure or a change to an existing test or sanitation procedure, APHIS will publish a notice in the Federal Register making available the test or sanitation procedure. The notice will also provide for a public comment period.

(2)(i) After the close of the public comment period, APHIS will publish a notice in the Federal Register indicating that the test or sanitation procedure will be added to the NPIP Program Standards, or that the NPIP Program Standards will be updated to reflect changes to an existing test or sanitation procedure, if:

(A) No comments were received on the notice;

(B) The comments on the notice supported the action described in the notice; or

(C) The comments on the notice were evaluated but did not change the Administrator's determination that approval of the test or sanitation procedure is appropriate based on the standards in paragraph (a) of this section.

(ii) If comments indicate that changes should be made to the test or sanitation procedure as it was made available in the initial notice, APHIS will publish a notice in the Federal Register indicating that changes were made to the initial test or sanitation procedure.

(iii) Whenever APHIS adds or makes changes to tests or sanitation procedures, APHIS will make available a new version of the NPIP Program Standards that reflects the additions or changes.

(iv) If comments present information that causes the Administrator to determine that approval of the test or sanitation procedure would not be appropriate, APHIS will publish a notice informing the public of this determination after the close of the comment period.

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

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 estimated in at least three authorized laboratories selected by the Service 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. 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 estimated in at least three authorized laboratories selected by the Service 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 clinical samples supplied by the manufacturer of the test kit. In addition, each laboratory will be asked to test 50 known negative clinical samples obtained from several sources, to provide a representative sampling of the general population. The identity of the samples must be coded so that the cooperating laboratories are blinded to identity and classification. Each sample must be provided in duplicate or triplicate, so that error and repeatability data may be generated.

(d) Cooperating laboratories will submit to the kit manufacturer all 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.

(e) The findings of the cooperating laboratories will be evaluated by the NPIP Technical Committee, and the Technical Committee will make a recommendation regarding whether to approve the test kit to the General Conference Committee. If the Technical Committee recommends approval, the final approval will be granted in accordance with the procedures described in §§ 147.46 and 147.47.

(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.

Done in Washington, DC, this 3rd day of July 2014.

Kevin Shea,

Administrator, Animal and Plant Health Inspection Service.

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