Proposed Rules

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This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Parts 145, 146, and 147

[Docket No. APHIS–2017–0055]

RIN 0579–AE37

National Poultry Improvement Plan and Auxiliary Provisions

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Proposed rule.

SUMMARY: We are proposing to amend the regulations governing the National Poultry Improvement Plan (NPIP) by updating and clarifying several provisions, including those concerning NPIP participation, voting requirements, testing procedures, and standards. These proposed changes were voted on and approved by the voting delegates at the NPIP's 2016 National Plan Conference.

DATES: We will consider all comments that we receive on or before May 9, 2018.

ADDRESSES: You may submit comments by either of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov/#!docketDetail;D=APHIS-2017-0055.*
- *Postal Mail/Commercial Delivery:* Send your comment to Docket No. APHIS–2017–0055, Regulatory Analysis and Development, PPD, APHIS, Station 3A–03.8, 4700 River Road, Unit 118, Riverdale, MD 20737–1238.

Supporting documents and any comments we receive on this docket may be viewed at *http://www.regulations.gov/#!docketDetail;D=APHIS-2017-0055* or in our reading room, which is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue SW, Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 799–7039 before coming.

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

SUPPLEMENTARY INFORMATION:

Background

The National Poultry Improvement Plan (NPIP, also referred to below as ''the Plan'') is a cooperative Federal-State-industry mechanism for controlling certain poultry diseases. The Plan consists of a variety of programs intended to prevent and control poultry diseases. Participation in all Plan programs is voluntary, but breeding flocks, hatcheries, and dealers must first qualify as ''U.S. Pullorum-Typhoid Clean'' as a condition for participating in the other Plan programs.

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

The regulations in 9 CFR parts 145, 146, and 147 (referred to below as the regulations) contain the provisions of the Plan. The Animal and Plant Health Inspection Service (APHIS or the Service) amends these provisions from time to time to incorporate new scientific information and technologies within the Plan. The changes we are proposing, which are discussed below, were approved by the voting delegates at the Plan's 2016 Biennial Conference.

Participants and voting delegates at the Biennial Conference represented the poultry industry, flockowners, breeders, hatcherymen, slaughter plants, poultry veterinarians, diagnostic laboratory personnel, Official State Agencies from cooperating States, and other poultry industry affiliates. The proposed amendments are discussed in the order they would appear in the regulations.

Definitions

The term *NPIP Technical Committee* is currently defined in §§ 145.1, 147.41, and 147.51 as ''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.'' We are proposing to amend the definition to specify that the committee is divided into three subcommittees (Mycoplasma, Salmonella, and Avian Influenza), and that committee members may serve on one, two, or all three of those subcommittees. For many technical committee members, belonging to all three subcommittees can be time consuming and daunting. Therefore, having the flexibility to serve on just one or two of the subcommittees if they so choose would allow members to focus their expertise on their specific disease areas. The amended definition would also explain more of the purpose of the committee, *i.e.,* that it evaluates proposed changes to the regulations and program standards and provides recommendations to the Delegates of the National Plan Conference as to whether proposals are scientifically or technically sound. In addition to amending the definition in the sections where it currently appears in parts 145 and 147, we would also add the definition to part 146 for the sake of consistency across the regulations.

Addition of Birds to Existing Flocks

In § 145.4, paragraph (d) states that participants in the Plan may not buy or receive products for any purpose from nonparticipants unless they are part of an equivalent program, as determined by the Official State Agency. The regulations do, however, make an exception to that requirement by allowing participants to buy or receive products from flocks that are neither participants nor part of an equivalent program, for use in breeding flocks or for experimental purposes, with the permission of the Official State Agency (OSA) and the concurrence of APHIS and after first segregating the birds before introducing them into the breeding flock, and introducing them only after they have reached sexual maturity and have been tested and found negative for pullorum-typhoid.

We are proposing to amend that testing requirement so that it includes testing not only for pullorum-typhoid, but also for any other disease for which

the flock they are being introduced into holds a disease classification (*e.g., M. gallisepticum* or *M. synoviae*). As noted previously, breeding flocks must first qualify as ''U.S. Pullorum-Typhoid Clean'' as a condition for participating in the other Plan programs, hence the current requirement that birds test negative for pullorum-typhoid before being introduced into a flock. Requiring that they also test negative for any other disease for which the flock holds status would ensure that the flock maintains its eligibility for those other Plan programs.

Testing

The regulations in § 145.14 regarding testing state that for Plan programs in which a representative sample may be tested in lieu of an entire flock, except the ostrich, emu, rhea, and cassowary program in § 145.63(a), the minimum number tested shall be 30 birds per house, and when a house contains fewer than 30 birds, all the birds in the house must be tested. However, over the years a number of Plan programs have been amended to allow for alternative sampling and testing approaches. In order for the text of § 145.14 to not be at odds with the provisions governing those Plan programs, we would amend the introductory text of the section to include the caveat ''unless otherwise specified within the Plan program.''

We are also proposing to amend § 145.14(d) to add provisions for the use of real-time reverse transcriptase polymerase chain reaction (RRT–PCR) testing for avian influenza (AI) by primary breeder authorized laboratories. The current regulations provide that RRT–PCR testing must be conducted using reagents approved by the Department and the Official State Agency and using the National Veterinary Services Laboratories (NVSL) official protocol for RRT–PCR and performed by personnel who have passed an NVSL proficiency test.

We are proposing to allow NPIP primary breeder authorized laboratories to use federally licensed kits or NVSL tests on their own breeding flocks for more flexibility. An NPIP primary breeder authorized laboratory with an accredited quality assurance program that can satisfactorily pass a proficiency test provided by the Service using the NVSL approved protocol or federally licensed kit would be allowed to run this assay as a routine surveillance measure. An authorized laboratory's use of the test would be addressed in the memorandum of understanding between the laboratory, the Official State Agency, and the State Animal Health Official of the State or States where the laboratory and the breeding flocks are located. A follow-up of any positive results would continue to be handled by the Department and the Official State Agency and confirmed by NVSL.

Reactors

We are proposing to amend §§ 145.23, 145.33, 145.43, 145.53, 145.63, 145.73, 145.83, and 145.93 regarding the U.S. Pullorum-Typhoid Clean classification. The regulations in each of these sections describe the means by which flocks may demonstrate freedom from pullorum and typhoid to the Official State Agency. One of those means is that the flock was officially blood tested with no reactors.

In order to take into account the possibility of test results that indicate the presence of a reactor in the flock, but that upon further testing are found negative for *S. pullorum* or *S. gallinarum,* we are proposing to amend those sections. Specifically, the regulations would provide that a flock could demonstrate freedom from pullorum and typhoid when it has been officially blood tested with either no reactors or reactors that, upon further bacteriological examination conducted in accordance with part 147 of the regulations, fail to isolate *S. pullorum* or *S. gallinarum.*

Terminology

We are proposing to amend the regulations in §§ 145.45, 145.74, and 145.84 regarding avian influenza clean compartments. These sections currently use the term notifiable avian influenza, or NAI, but that term has been removed from the World Health Organization (OIE) Terrestrial Code and Terrestrial Manual. We would instead refer to H5/H7 avian influenza to harmonize the regulations with current OIE terminology.

Shipping Forms

The regulations in § 145.52(d) set out the information that participating flocks are to provide in reporting poultry sales to importing States. One of the pieces of information required is the NPIP hatchery approval number of the selling hatchery. Because the hatchery that ships the poultry may differ from the hatchery filling the order, we would amend the paragraph to also require the NPIP hatchery approval number of the shipping hatchery. This would aid in traceback efforts should the need arise.

Sampling Sites

We are proposing to amend the regulations in § 145.53 regarding the U.S. M. Gallisepticum Clean and U.S. M. Synoviae Clean classifications to add the trachea as a sampling site. The trachea is the best anatomical location to sample for those diseases, and both the choanal cleft and the trachea are recommended sampling sites for *M. gallisepticum* and *M. synoviae* detection by PCR and culture. As part of this change, we would remove references to the ''choanal palatine cleft/fissure area'' and simply refer to the choanal cleft for clarity's sake.

Those same Plan classifications also provide instructions for the number of birds to be sampled. The current regulations in § 145.53(c) and (d) call for a random sample of 50 percent of the birds in the flock, with a maximum of 200 birds and a minimum of 30 birds per flock or all birds in the flock if the flock size is less than 30 birds. The phrasing of the sample sizes has been a source of confusion for some growers and field technicians who gather the samples, so we are proposing to modify the wording to provide more clarity. The actual sample sizes would remain the same.

U.S. Salmonella Monitored

We are proposing to amend § 145.73 by adding a new paragraph (g), entitled U.S. Salmonella Monitored. The primary egg-type breeder companies routinely monitor their flocks and chicks for all Salmonella serotypes with the goal of producing Salmonella-free product. The addition of a Salmonella Monitored program for primary egg-type breeder companies would formalize those efforts and provide recognition and potential additional marketing opportunities for flocks that choose to participate.

The provisions of the new paragraph would mirror those of existing § 145.83(f), which is the U.S. Salmonella Monitored program for primary meat-type chicken breeding flocks. We would reflect this proposed program for primary egg-type chicken breeding flocks by adding a reference to § 145.73(g) to § 145.10(o), which is where the illustrative design for the U.S. Salmonella Monitored program is located.

Biosecurity Measures

The regulations in § 145.82 set out participation requirements for primary meat-type chicken breeding flocks. We are proposing to amend this section by adding a new paragraph (d) that would provide that poultry must be protected from vectors known to be in the wild and thus must be housed in enclosed structures during brooding, rearing, grow-out, or laying periods with no intentional access to the outdoors, creatures found in the wild or raised on

open range or pasture, or be provided with untreated open source water such as that directly from a pond, stream, or spring that wild birds or vermin have access to for usage for drinking water, as a cooling agent, or during a wash down/clean out process. These additional biosecurity measures are intended to protect these flocks from the introduction of disease from natural sources.

Sample Size

We are proposing to amend § 146.23 to change the testing requirements for commercial table-egg laying flocks. The current regulations state that a sample of at least 11 birds from table-egg layer pullet flocks and table-egg layer flocks participating in the U.S. H5/H7 Avian Influenza Monitored classification must test negative to H5/H7 subtypes of avian influenza within 30 days prior to movement. We would change that time period to 21 days.

We are proposing this change to reflect the OIE's established maximum incubation period for avian influenza of 21 days. This change would also make the H5/H7 Avian Influenza Monitored program for commercial table-egg layers consistent with the corresponding programs for commercial broilers and turkeys.

General Conference Committee

We are proposing to amend § 147.43 to clarify election procedures for the regional committee members of the General Conference Committee. The current regulations simply state that regional committee members and their alternates will be elected by the official delegates of their respective regions; in practice, the nominee receiving the most votes would become the committee member and the nominee in second place would become the alternate. We are proposing to amend the regulations to specify that ballots will be printed to allow the regional delegates to cast a vote for the member and another vote for the alternate. This change would allow the region's delegates to specifically vote for their committee member and alternate rather than having the nominee with the second-most votes becoming the alternate by default.

Committee Consideration of Proposed Changes

The regulations in § 147.46 provide that various committees make recommendations to the conference as a whole concerning each proposal considered at the biennial conference. The individual committee reports are submitted to the chairman of the conference, who combines them into one report showing, in numerical sequence, the committee recommendations on each proposal. We are proposing to amend paragraph (d) of that section to provide that, after completing the combined report, the chairman will distribute copies of the report electronically to the Official State Agency in advance of the voting, which takes place on the last day of the conference. This would allow the OSA to in turn provide the full report to the delegates from their States, which would provide them more time to review and discuss the proposals and thus make more informed decisions when voting on the proposals.

Authorized Laboratories

We are proposing to amend § 147.52(a) regarding the administration of check tests at authorized laboratories. The regulations currently state that NPIP will coordinate the distribution of check tests from NVSL to authorized laboratories. An authorized laboratory must use a regularly scheduled check test for each assay that it performs.

We are proposing to provide that the NPIP may approve and authorize additional laboratories to produce and distribute check tests as needed. This change would allow us to supplement the supply of check tests produced by NVSL with kits prepared by other approved laboratories, and NPIP and NVSL would work together to ensure that laboratory tests and submissions are accurate. We would also replace the current reference to ''regularly scheduled'' check tests with a reference to ''the next available'' check test. This more accurately describes the manner in which NPIP administers check tests to its authorized laboratories.

Approval of Diagnostic Test Kits

We are proposing to amend the regulations in § 147.54 regarding the approval of diagnostic test kits not licensed by the Service. First, we would amend paragraph (a)(1), which currently provides that spiked samples (clinical sample matrix with a known amount of pure culture added) should only be used in the event that no other sample types are available. (Field samples are preferred due to the often unrealistic outcomes of spiked samples.) In order to ensure that spiked samples are used only as a last resort, we would add a requirement that prior approval must be obtained from the NPIP Technical Committee. The NPIP Technical Committee is made up of technical experts on poultry health, biosecurity, surveillance, and diagnostics drawn from the poultry and egg industries, universities, and State and Federal governments, and therefore would be in a position to decide whether the use of spiked samples would be useful or appropriate under a given set of circumstances.

Paragraph (a)(1) also states that when evaluating an unlicensed test, laboratories should be selected for their experience with testing for the target organism or analyte with the current NPIP approved test. For the sake of clarity, we would add an example of what is intended by that requirement. Specifically, we would add ''(*e.g.,* a Salmonella test should be evaluated by NPIP authorized laboratories that test for Salmonella routinely).''

Paragraph (a)(3) provides that, when evaluating an unlicensed test kit, the cooperating laboratories must perform a current NPIP procedure or NPIP approved test on the samples alongside the test kit for comparison. We are proposing to amend that requirement to state that the cooperating laboratory must also provide an outline of the method on the worksheet for diagnostic test evaluation and include reproducibility and robustness data. This additional requirement would allow the NPIP Technical Committee to fully evaluate the new test utilizing a concise template for information. Currently, companies submit upwards 50 pages of raw data to the Technical Committee to evaluate in order to make a recommendation. The new worksheet is only two pages, and the company submitting the test would only insert the most pertinent information needed for the Technical Committee to evaluate that test. The supporting data would also be submitted along with the 2-page worksheet, but would only need to be referenced when something was not clear on the worksheet.

Finally, the regulations in paragraph (a)(4) refer to ''raw data'' compiled during the evaluation of the unlicensed test kit. We are proposing instead to refer to ''compiled output data.'' This change would reduce the amount of information (raw data) that companies would need to submit to the Technical Committee with the worksheet described in the previous paragraph. By eliminating the need for companies to submit only their complied output data rather than all the data in its raw form, we would reduce by up to half the amount of information to be submitted, which would also benefit the Technical Committee reviewers.

Editorial Correction

The regulations in § 145.93 contains several references to paragraph (a) of that section, which is reserved. We

would correct those references to cite paragraph (b).

Executive Orders 12866 and 13771 and Regulatory Flexibility Act

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

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 by contacting the person listed under **FOR FURTHER INFORMATION CONTACT** or on the *Regulations.gov* website (see **ADDRESSES** above for instructions for accessing *Regulations.gov*).

This rulemaking would result in various changes to 9 CFR parts 145 through 147, modifying provisions of the National Poultry Improvement Plan (NPIP). The modifications are recommended by the NPIP General Conference Committee (GCC), which represents cooperating State agencies and poultry industry members and advises the Secretary on issues pertaining to poultry health. The rule would amend definitions, clarify the final determination status of pullorum-typhoid reactors, clarify requirements prior to comingling, allow for the use of reverse transcription polymerase chain reaction (RRT–PCR) for avian influenza surveillance under certain conditions, clarify testing requirements, update World Organization for Animal Health terminology, update testing requirements for *M. gallisepticum* and *M. synoviae* PCR testing, amend Form 9–31 requirements, add a U.S. Salmonella Monitored classification program, amend participation requirements, amend testing requirements for U.S. H5/H7 AI Monitored Classification Program, amend participation and voting requirements, amend Committee consideration of proposed changes, clarify check test proficiency requirements, and clarify requirements for new test submissions.

These changes would align the regulations with international standards and make them more transparent to APHIS stakeholders and the general public. The changes in this proposed rule were voted on and approved by the voting delegates at the Plan's 2016 Biennial Conference.

The establishments that would be affected by the proposed changes—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 proposed rule embodies changes decided upon by the NPIP GCC 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 2 CFR chapter IV.)

Executive Order 12988

This proposed rule has been reviewed under Executive Order 12988, Civil Justice Reform. If this proposed rule is adopted: (1) All State and local laws and regulations that are in conflict with this rule will be preempted; (2) no retroactive effect will be given to this rule; and (3) administrative proceedings will not be required before parties may file suit in court challenging this rule.

Paperwork Reduction Act

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

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

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

Accordingly, we propose to amend 9 CFR parts 145, 146, and 147 as follows:

PART 145—NATIONAL POULTRY IMPROVEMENT PLAN FOR BREEDING POULTRY

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

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

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

§ 145.1 Definitions.

* * * * *

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

* * * * *

§ 145.4 [Amended]

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

§ 145.10 [Amended]

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

■ 5. Section 145.14 is amended as follows:

■ a. In the introductory text, in the third sentence, by adding the words ''unless otherwise specified within the Plan program,'' after the words ''30 birds per house,'' and in the last sentence, by adding the words '', unless otherwise specified within the Plan program'' after the words ''must be tested''; and

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

The revision reads as follows:

§ 145.14 Testing.

* * * * *

(d) * * *

(2) * * *

(i) * * *

(A) The RRT–PCR tests must be conducted using reagents approved by the Department and the Official State Agency. The RRT–PCR must be conducted using the National Veterinary Services Laboratories (NVSL) official protocol for RRT–PCR or a test kit licensed by the Department and approved by the Official State Agency and the State Animal Health Official, and must be conducted by personnel who have passed an NVSL proficiency test. For non-National Animal Health Laboratory Network (NAHLN) authorized laboratories:

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

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

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

(*4*) The use of the RRT–PCR test by the authorized laboratory must be approved in the memorandum of understanding (MOU) between the authorized laboratory, the Official State Agency, and the State Animal Health Official(s) of both the location of the authorized laboratory and the location where the breeding flocks reside.

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

* * * * *

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

§ 145.23 Terminology and classification; flocks and products.

* * * * *

(b) * * *

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

* * * * *

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

§ 145.33 Terminology and classification; flocks and products.

* * * * *

(b) * * *

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

* * * * *

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

§ 145.43 Terminology and classification; flocks and products.

* * * * *

(b) * * *

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

* * * * *

(5) It is a primary breeding flock located in a State determined to be in compliance with the provisions of paragraph (b)(4) of this section and in which a sample of 300 birds from flocks of more than 300, and each bird in flocks of 300 or less, has been officially tested for pullorum-typhoid with either no reactors or reactors that, upon further bacteriological examination conducted in accordance with part 147 of this subchapter, fail to isolate *S. pullorum* or *S. gallinarum: Provided,* That a bacteriological examination monitoring program acceptable to the Official State Agency and approved by APHIS may be used in lieu of blood testing.

* * * * *

■ 9. Section 145.45 is amended as follows:

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

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

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

■ ii. Paragraph (a)(1)(i);

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

■ iv. Paragraph (a)(1)(v);

■ v. Paragraph (a)(2)(iii); and

■ vi. Paragraph (a)(4).

The revision reads as follows:

§ 145.45 Terminology and classification; compartments.

(a) *US H5/H7 AI Clean Compartment.* This program is intended to be the basis from which the primary turkey breeding-hatchery industry may demonstrate the existence and implementation of a program that has been approved by the Official State Agency and APHIS to establish a compartment consisting of a primary breeding-hatchery company that is free of H5/H7 avian influenza (AI). For the purpose of the compartment, avian influenza is defined according to the OIE Terrestrial Animal Health Code Chapter 10.4. This compartment has the purpose of protecting the defined subpopulation and avoiding the introduction and spread of H5/H7 AI within that subpopulation by prohibiting contact with other commercial poultry operations, other domestic and wild birds, and other intensive animal operations. The program shall consist of the following:

* * * * *

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

§ 145.52 Participation.

* * * * *

(d) * * *

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

* * * * *

■ 11. Section 145.53 is amended as follows:

■ a. By revising paragraphs (b)(1) and (b)(5);

■ b. In paragraph (c)(1)(i), by adding the words ''trachea or'' before the word ''choanal'' and by removing the words ''palatine cleft/fissure area'' and adding the word ''cleft'' in their place.

■ c. By revising paragraph (c)(1)(ii) introductory text;

■ d. In paragraph (c)(1)(ii)(A), by adding the words ''trachea or'' before the word ''choanal'' and by removing the words ''palatine cleft/fissure area'' and adding the word ''cleft'' in their place;

■ e. In paragraph (d)(1)(i), by adding the words ''trachea or'' before the word ''choanal'' and by removing the words ''palatine cleft/fissure area'' and adding the word ''cleft'' in their place.

■ f. By revising paragraph (d)(1)(ii) introductory text; and

■ g. In paragraph (d)(1)(ii)(A), by adding the words ''trachea or'' before the word ''choanal'' and by removing the words ''palatine cleft/fissure area'' and adding the word ''cleft'' in their place.

The revisions read as follows:

§ 145.53 Terminology and classification; flocks and products.

* * * * *

(b) * * *

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

* * * * *

(5) It is a primary breeding flock located in a State determined to be in compliance with the provisions of paragraph (b)(4) of this section, and in which a sample of 300 birds from flocks of more than 300, and each bird in flocks of 300 or less, has been officially tested for pullorum-typhoid within the past 12 months with either no reactors or reactors that, upon further bacteriological examination conducted in accordance with part 147 of this subchapter, fail to isolate *S. pullorum* or *S. gallinarum: Provided,* That a bacteriological examination monitoring program or serological examination monitoring program for game birds acceptable to the Official State Agency and approved by the Service may be used in lieu of annual blood testing: *And Provided further,* That when a flock is a hobbyist or exhibition waterfowl or exhibition poultry primary breeding flock located in a State which has been deemed to be a U.S. Pullorum-Typhoid Clean State for the past 3 years, and during which time no isolation of

pullorum or typhoid has been made that can be traced to a source in that State, a bacteriological examination monitoring program or a serological examination monitoring program acceptable to the Official State Agency and approved by the Service may be used in lieu of annual blood testing.

(c) * * *

(1) * * *

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

* * * * *

(d) * * *

(1) * * *

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

* * * * *

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

§ 145.63 Terminology and classification; flocks and products.

* * * * *

(a) * * *

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

(2) * * *

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

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

* * * * *

■ 13. Section 145.73 is amended as follows:

■ a. By revising paragraphs (b)(1) and (b)(2)(ii); and

■ b. By adding paragraph (g).

The revisions and addition read as follows:

§ 145.73 Terminology and classification; flocks and products.

* * * * *

(b) * * *

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

(2) * * *

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

* * * * *

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

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

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

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

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

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

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

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

(vii) Any flock entering the production period that is in compliance with all the requirements of this paragraph (g) with no history of Salmonella isolations shall be considered ''Salmonella negative'' and may retain this definition as long as no environmental or bird Salmonella isolations are identified and confirmed from the flock or flock environment by sampling on four separate collection dates over a minimum of a 2-week period. Sampling and testing must be performed as described in paragraph (g)(1)(vi) of this section. An unconfirmed environmental Salmonella isolation shall not change this Salmonella negative status.

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

(3) In order for a hatchery to sell products of paragraphs (g)(1)(i) through (vii) of this section, all products

handled shall meet the requirements of the classification.

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

§ 145.74 [Amended]

■ 14. Section 145.74 is amended as follows:

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

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

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

■ ii. Paragraph (a)(1)(i);

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

■ iv. Paragraph (a)(1)(v);

■ v. Paragraph (a)(2)(iii); and

■ vi. Paragraph (a)(4).

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

§ 145.82 Participation.

* * * * *

(d) Poultry must be protected from vectors known to be in the wild and thus must be housed in enclosed structures during brooding, rearing, grow-out, or laying periods with no intentional access to the outdoors, creatures found in the wild, or raised on open range or pasture, or be provided with untreated open source water such as that directly from a pond, stream, or spring that wild birds or vermin have access to for usage for drinking water, as a cooling agent, or during a wash down/clean out process.

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

§ 145.83 Terminology and classification; flocks and products.

* * * * *

(b) * * *

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

(2) * * *

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

* * * * *

§ 145.84 [Amended]

■ 17. Section 145.84 is amended as follows:

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

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

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

■ ii. Paragraph (a)(1)(i);

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

■ iv. Paragraph (a)(1)(v);

■ v. Paragraph (a)(2)(iii); and

■ vi. Paragraph (a)(4).

■ 18. Section 145.93 is amended as follows:

■ a. By revising paragraph (b)(1);

■ b. In paragraph (b)(3)(viii), by removing the words ''paragraphs (a)(3)(i),'' and adding the words ''paragraphs (b)(3)(i),'' in their place;

■ c. In paragraph (b)(4), by removing the words ''paragraph (a)(3)'' and adding the words ''paragraph (b)(3)'' in their place; and

■ d. By revising paragraph (b)(5).

The revisions read as follows:

§ 145.93 Terminology and classification; flocks and products.

* * * * *

(b) * * *

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

* * * * *

(5) It is a primary breeding flock located in a State determined to be in compliance with provisions of paragraph (b)(3) of this section, and in which a sample of 300 birds from flocks of more than 300, and each bird in flocks of 300 or less, has been officially tested for pullorum-typhoid within the past 12 months with either no reactors or reactors that, upon further bacteriological examination conducted in accordance with part 147 of this subchapter, fail to isolate *S. pullorum* or *S. gallinarum: Provided,* That when a flock is a primary breeding flock located in a State which has been deemed to be a U.S. Pullorum-Typhoid Clean State for the past 3 years, and during which time no isolation of pullorum or typhoid has been made that can be traced to a source in that State, a bacteriological examination monitoring program or a serological examination monitoring program acceptable to the Official State Agency and approved by the Service may be used in lieu of annual blood testing.

* * * * *

PART 146—NATIONAL POULTRY IMPROVEMENT PLAN FOR COMMERCIAL POULTRY

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

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

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

§ 146.1 Definitions.

* * * * *

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

* * * * *

§ 146.23 [Amended]

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

PART 147—AUXILIARY PROVISIONS ON NATIONAL POULTRY IMPROVEMENT PLAN

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

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

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

§ 147.41 Definitions.

* * * * *

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

* * * * *

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

§ 147.43 General Conference Committee.

* * * * *

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

* * * * *

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

§ 147.46 Committee consideration of proposed changes.

* * * * *

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

* * * * *

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

§ 147.51 Definitions.

* * * * *

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

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

§ 147.52 Authorized laboratories.

* * * * *

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

* * * * *

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

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

(a) * * *

(1) The sensitivity of the kit will be evaluated in at least three NPIP authorized laboratories by testing known positive samples, as determined by the official NPIP procedures found in the NPIP Program Standards or through other procedures approved by the Administrator. Field samples, for which the presence or absence of the target organism or analyte has been determined by the current NPIP test, are the preferred samples and should be used when possible. Samples from a variety of field cases representing a range of low, medium, and high analyte concentrations should be used. In some cases it may be necessary to utilize samples from experimentally infected animals. Spiked samples (clinical sample matrix with a known amount of pure culture added) should only be used in the event that no other sample types are available. When the use of spiked samples may be necessary, prior approval from the NPIP Technical Committee is required. Pure cultures should never be used. Additionally, laboratories should be selected for their experience with testing for the target organism or analyte with the current NPIP approved test. (*e.g.,* a Salmonella test should be evaluated by NPIP authorized laboratories that test for Salmonella routinely). If certain conditions or interfering substances are known to affect the performance of the kit, appropriate samples will be included so that the magnitude and significance of the effect(s) can be evaluated.

* * * * *

(3) The kit will be provided to the cooperating laboratories in its final form and include the instructions for use. The cooperating laboratories must perform the assay exactly as stated in the supplied instructions. Each laboratory must test a panel of at least 25 known positive samples. In addition, each laboratory must test at least 50 known negative samples obtained from several sources, to provide a representative sampling of the general population. The cooperating laboratories must perform a current NPIP procedure or NPIP approved test on the samples alongside the test kit for comparison and must provide an outline of the method on the worksheet for diagnostic test evaluation. Reproducibility and robustness data should also be included.

(4) Cooperating laboratories will submit to the kit manufacturer all compiled output data regarding the assay response. Each sample tested will be reported as positive or negative, and the official NPIP procedure used to classify the sample must be submitted in addition to the assay response value. A completed worksheet for diagnostic test evaluation is required to be submitted with the compiled output data and may be obtained by contacting the NPIP Senior Coordinator. Data and the completed worksheet for diagnostic test evaluation must be submitted to the NPIP Senior Coordinator 4 months prior to the next scheduled General Conference Committee meeting, which is when approval will be sought.

* * * * *

Done in Washington, DC, this 3rd day of April 2018.

Kevin Shea,

Administrator, Animal and Plant Health Inspection Service.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 73

[Docket No. FDA–2018–C–1007]

Aker BioMarine; Filing of Color Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of petition.