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DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Parts 56, 145, 146, and 147

[Docket No. APHIS-2018-0062]

RIN 0579-AE49

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). These amendments would establish a U.S. Newcastle Disease Clean program within the NPIP, create an NPIP subpart specific to game birds, revise testing requirements, and clarify existing provisions of the regulations. We are also proposing to amend the regulations concerning the payment of indemnity and compensation for low pathogenic avian influenza to reflect current policy and operational practices, and to allow NPIP voting delegates to represent multiple States during the Biennial Conferences. These proposed changes were voted on and approved by the voting delegates at the NPIP's 2018 National Plan Conference.

DATES: We will consider all comments that we receive on or before [Insert date 60 days after date of publication in the Federal Register].

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

- Federal eRulemaking Portal: Go to <http://www.regulations.gov/#!docketDetail;D=APHIS-2018-0062>.
- Postal Mail/Commercial Delivery: Send your comment to Docket No. APHIS-2018-0062, 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-2018-0062> 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. Elena Behnke, 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 56, 145, 146, and 147 (referred to below as the regulations) contain the provisions of the Plan. The Animal and Plant Health Inspection Service (APHIS) amends these provisions from time to time to incorporate new scientific information and technologies within the Plan, and to ensure the plan reflects changes to the poultry industry itself. The changes we are proposing, which are discussed below, were approved by the voting delegates at the Plan's 2018 Biennial Conference.

Participants and voting delegates at the Biennial Conference represented the poultry industry, flock owners, breeders, hatchery men, 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.

Proposed Amendments to Part 56

Definitions

The terms *H5/H7 LPAI exposed* and *H5/H7 LPAI infection (infected)* are currently defined in § 56.1 of the regulations in a manner that describes the risks or effects of poultry being exposed to or contracting the virus.

The current definition of *H5/H7 LPAI exposed* provides that all birds or poultry associated with H5/H7 infected birds or poultry, whether it is via excrement or other materials, are automatically placed in the exposed category. This could be construed to suggest that an

exposed flock is potentially infectious because the birds in the flock have had contact with the virus in some manner. However, this is not the case. Although “exposed” birds have been exposed to the virus, they are no longer shedding the virus and no longer considered to be potentially infectious. As such, they can go to slaughter to be controlled marketed, instead of being depopulated. Therefore, we are proposing to amend the terms and definitions of *H5/H7 LPAI infection (infected)* and *H5/H7 LPAI exposed*.

The new terms would be *H5/H7 LPAI virus exposed (non-infectious)* and *H5/H7 LPAI virus actively infected (infectious)*. We are proposing to define *H5/H7 LPAI virus exposed (non-infectious)* in the following way. Poultry would be considered to be exposed (non-infectious) to H5/H7 LPAI for purposes of the regulations if:

- Antibodies to the H5 or H7 subtype of the AI virus that are not a consequence of vaccination have been detected in poultry, and
- Samples collected from the flock using real-time reverse transcription polymerase chain reaction (RT-PCR) or virus isolation are determined to be not infectious for H5/H7 LPAI.

The definition would also provide that the official determination that H5/H7 LPAI virus exposure has occurred is by the identification of antibodies to the H5 or H7 subtype of AI virus detected and may only be made by APHIS’ National Veterinary Services Laboratories (NVSL).

We are proposing to define *H5/H7 LPAI virus actively infected (infectious)* in the following way. Poultry would be considered to be infected with H5/H7 LPAI for purposes of the regulations if:

- H5/H7 LPAI virus has been isolated and identified as such from poultry; or

- Viral antigen or viral RNA specific to the H5 or H7 subtype of AI virus has been detected in poultry.

The definition would also provide that the official determination that H5/H7 LPAI virus has been isolated and identified, or viral antigen or viral RNA specific to the H5 or H7 subtype of AI virus has been detected, may only be made by NVSL.

We would also revise references to H5/H7 LPAI) infection (infected) and H5/H7 LPAI exposed throughout part 56 of the regulations to these two new terms instead.

We believe the revised terms better clarify the distinction between exposed and infected poultry.

We are also proposing to add definitions for *cleaning*, *compensation*, *disinfection*, *indemnity*, and *virus elimination (VE)* to § 56.1 of the regulations.

We would define *cleaning* as the removal of gross contamination, organic material, and debris from the premises or respective structures, via mechanical means like sweeping (dry cleaning) and/or the use of water and soap or detergent (wet cleaning), in order to minimize organic material to prepare for effective disinfection.

We would define *disinfection* as methods used on surfaces to destroy or eliminate H5/H7 LPAI virus through physical (e.g., heat) or chemical (e.g., disinfectant) means, and would further specify that a combination of methods may be required.

Section 56.3 of the regulations provides that APHIS may indemnify persons for cleaning and disinfection of premises, conveyances, and materials infected with or exposed to LPAI.

While we believe it is clear from context that § 56.3 pertains only to cleaning and disinfection associated with elimination of LPAI virus, rather than any cleaning and disinfection activities

whatsoever that may be conducted on an affected premises, adding definitions of the terms to the regulations would further clarify our intent.

For a similar reason, we are proposing to add the term virus elimination after every reference to cleaning and disinfection in part 56 of the regulations. Virus elimination is the term used in many foreign countries for cleaning and disinfection measures conducted to destroy or eliminate all virus on an affected premises; we would define it in that way in § 56.1. This would also underscore the restrictive sense in which cleaning and disinfection is being used within part 56.

The term *compensation* would also be new to part 56. We would define compensation in § 56.1 as reimbursement for the activities associated with the depopulation of infected or exposed poultry, including the disposal of contaminated carcasses and materials and the cleaning and disinfection of premises, conveyances, and materials that came into contact with infected or exposed poultry. The definition would further provide that, in the case of contaminated materials, if the cost of cleaning and disinfection would exceed the value of the materials, or cleaning and disinfection would be impracticable for any reason, APHIS would base compensation on the fair market value (depreciated value) of those materials. Finally, the definition would specify that compensation does not include payment for depopulated birds or eggs destroyed, as those payments would constitute indemnity.

We would define *indemnity* as payments representing the fair market value of destroyed birds and eggs. Indemnity would not include reimbursements for depopulation (by which we mean the act of depopulation, rather than the depopulated poultry), or for disposal, destroyed materials, or cleaning and disinfection (virus elimination) activities, as these would be covered under the definition of *compensation*.

Currently, the regulations in part 56 refer only to indemnity, regardless of the activity for which APHIS is providing reimbursement. However, the procedures for the payment of indemnity for destroyed birds or eggs differ significantly from those for the payment of indemnity for cleaning and disinfection. As a result, APHIS' Veterinary Services (VS) program, in conjunction with State departments of agriculture, has developed a guidance document, VS Guidance document 8601.2 that clarifies how the two processes differ.¹ The guidance document makes the distinction between compensation and indemnity that we are proposing to codify in the regulations themselves. We would also amend part 56 throughout to change references to "indemnity" that pertain to reimbursement for activities, rather than the destroyed poultry or eggs themselves, to "compensation."

Payment of Indemnity

The regulations in § 56.3 describe conditions for the payment of indemnity for H5/H7 LPAI. Paragraph (a) of the section lists activities that may be eligible for indemnity for H5/H7 LPAI: The destruction and disposal of infected poultry, the destruction of any eggs during outbreak testing, and disinfection of areas and materials that have come in contact with infected poultry. Paragraph (b) describes the percentage of costs that are eligible for indemnity for the listed activities, depending on certain criteria.

Currently, paragraph (b) provides that, if poultry meet the definition of *commercial*, but does not participate in their respective NPIP Avian Influenza program, the maximum amount of indemnity that may be paid for eligible activities is 25 percent. Commercial poultry that do participate in Plan AI programs, however, may receive up to 100 percent indemnity.

¹ See <http://poultryimprovement.org/documents/ISRCPGuidanceDocument.pdf>.

This paragraph currently does not reflect the fact that the NPIP regulations themselves specifically exempt poultry operations that fall below certain size thresholds from having to participate in the NPIP AI programs. The exemption numbers are currently listed in 9 CFR part 146. We are proposing to amend paragraph (b) to clarify that poultry operations that are exempted by the Plan regulations from having to participate in Plan AI programs because of their size may still receive up to 100 percent indemnity and/or compensation for eligible activities.

Determination of Indemnity

The current regulations in § 56.4 describe how APHIS determines fair market value regarding the destruction of infected or exposed poultry; this includes determining indemnity for cleaning and disinfection procedures. The regulations currently state that APHIS will use an appraisal by an APHIS official appraiser and State official appraiser, or, in instances when APHIS and State authorities agree, either the APHIS appraiser or State appraiser alone, to determine fair market value for indemnity for destroyed poultry and eggs. However, we have discontinued use of appraisers in favor of an indemnity calculator drawn from multiple data points in order to determine fair market value for destroyed birds and eggs. We are therefore proposing to amend § 56.4 to indicate that appraisal calculator values will be used to determine the amount of indemnity paid for destroyed birds and eggs.

Section 56.4 also describes how reimbursement may be paid for disposal activities. Currently, as a precondition for submitting a claim, the claimant, Cooperating State Agency, and APHIS must jointly enter into a cooperative agreement. However, State Agencies have stated that their participation in the cooperative agreement is not necessary. We are proposing to amend the regulations accordingly.

Finally, § 56.4 describes how indemnity may be paid for cleaning and disinfection activities. Currently, we require the claimant, the Cooperating State Agency, and APHIS to enter into a compliance agreement. The claimant then submits receipts or other documentation regarding the activities, and APHIS evaluates them against the cleaning and disinfection procedures in § 56.5 of the regulations and the initial State response and containment plan, the requirements for which are found in § 56.10 of the regulations.

To streamline reimbursement for cleaning and disinfection activities, we have developed a calculator for cleaning and disinfection as well, the APHIS flat-rate virus elimination (VE) calculator. The calculator provides a per-square-foot rate for premises with floor-raised birds and per-cubic-foot rate for premises with caged birds for cleaning and disinfection activities that we have previously determined to fall within the scope of the regulations as reimbursable activities.

While the VE calculator covers the majority of production types and VE scenarios, it does not cover every possibility. In such instances, the existing procedures for claiming compensation for cleaning and disinfection would apply. The floor-raised rates would be used by APHIS as the baseline for compensation in such instances, and the claimant would be afforded the opportunity to demonstrate through receipts or other documentation the uniqueness of his or her situation.

NPIP Certifications for Poultry Moved for Controlled Marketing

Section 56.5 provides that, at the discretion of APHIS and the Cooperating State Agency, poultry that has been infected with or exposed to H5/H7 LPAI may be moved for controlled marketing rather than depopulated. We are proposing to amend the section to indicate that

poultry moved for controlled marketing maintain their current NPIP certifications. This amendment would help provide assurances to slaughtering facilities that receive such flocks.

Revisions to Part 145

Definitions

Section 145.1 of the regulations provides general definitions of terms used within the NPIP regulations. We are proposing to add a definition for the term *Newcastle disease*, and to revise the existing definition for *avian influenza*. Both the new definition and the revised definition would be modeled on the definitions of these terms found in the World Organization for Animal Health's (OIE's) Terrestrial Animal Health Code, to which the United States is a signatory.²

Specific Provisions for Participating Dealers

Section 145.7 of the regulations requires participating dealers to follow all applicable provisions in part 145. However, the section refers to dealers in "poultry breeding stock, hatching eggs, or baby or started poultry" while the definition of *dealer* in § 145.1 refers to dealers as individuals or businesses that deal in commerce with hatching eggs, newly-hatched poultry, and/or started poultry. We are proposing to revise § 145.7 so that it refers to dealers using the same term as in the definition in § 145.1. The revised section would also indicate that dealers must comply with the regulations in the relevant part of the NPIP regulations. It would also specify the NPIP Program Standards that are applicable to such dealers, as well as the provisions of the NPIP regulations that provide for approval of alternatives to those standards.

² To view the Code, go to <https://www.oie.int/standard-setting/terrestrial-code/access-online/>.

Testing

The regulations in §§ 145.14 and 146.13 discuss the official avian influenza (AI) antibody detection tests, the enzyme-linked immunosorbent assay (ELISA) test and agar gel immunodiffusion (AGID) test, in regard to poultry testing requirements within the NPIP.

We are proposing to require that, when ELISA test samples are positive for AI, an AGID test must be conducted within 48 hours. This is because the AGID test is used as a confirmatory test on presumptive positives using the ELISA test. Timely corroboratory testing is therefore necessary in order to determine the disease status of the tested flock. Additionally, the AGID test must comply with the relevant NPIP requirements and would specify the relevant NPIP Program Standards, as well as provide a citation to the provisions for approval of alternate standards.

Additionally, these sections currently provide that agent detection tests for AI may be used to detect influenza A matrix gene or protein. We are proposing to amend these sections to provide that agent detection tests may be used to detect influenza A virus rather than specifically influenza A matrix gene or protein. The existing limitation imposes an unnecessary technical restriction on test design and precludes the use of lateral flow antigen immunoassays that target the influenza nucleoprotein and still reliably indicate the presence or absence of AI in a test sample.

For reasons that we discuss below, we are also proposing to add provisions regarding official tests for Newcastle disease (ND) to these two sections. The regulations would say that the official ND tests are serological tests for antibody detection and molecular-based tests for antigen detection that are listed in the Program Standards document as determined by APHIS to

reliably detect ND infection. The Program Standards document would indicate that the approved serological tests for ND are currently the ELISA and hemagglutination inhibition (HI) tests, and the approved molecular-based test for ND is PCR.

Proposed Newcastle Disease Clean Program

The regulations in § 145.43 provide disease-free, or Clean, classifications that may be applied to turkey breeding flocks, and eggs and poults from turkey breeding flocks, provided that they meet certain requirements demonstrating freedom from that disease. Similar classification systems exist in § 145.45 for compartments within the turkey breeding-hatchery industry; § 145.73 for egg-type chicken breeding flocks, as well as their eggs and chicks; § 145.74 for compartments within the egg-type chicken breeding-hatchery industry; § 145.83 for meat-type chicken breeding flocks, as well as their eggs and chicks; and § 145.84 for compartments within the meat-type chicken breeding-hatchery industry.

We are proposing to amend each of these sections to establish an ND Clean program. The ND Clean program is intended to allow the turkey breeding-hatchery, egg-type chicken breeding-hatchery, and meat-type chicken breeding-hatchery industries, as well as compartments within those industries, to demonstrate freedom from ND based on vaccination and/or monitoring of each participating breeding flock. Lastly, in regards to this paragraph's language, we note that the original voting resolution in § 145.43 stated "vaccination and monitoring of each participating breeding flock;" however, given that vaccination is optional, we have replaced "and" with "and/or" to accurately reflect the intended requirements.

For a flock to gain ND Clean status, the Official State Agency (OSA) would have to determine that the flock is a primary breeding flock that either (1) has been vaccinated for ND using USDA-licensed vaccines and response to vaccination is serologically monitored using an

approved serological ND test when the birds are more than 4 months of age; or (2) is unvaccinated for ND, in which a minimum of 30 birds have tested negative to ND using an approved test when more than 4 months of age. We would require serological testing for vaccinated flocks because it indicates the increased presence of antibodies in vaccinated birds.

To retain ND Clean classification for a vaccinated flock, the vaccine would have to be a USDA-licensed vaccine administered during the early stages of development through rearing, and an inactivated vaccine as final vaccination prior to the onset of egg production; the flock would have to be have been monitored for antibody response using an approved serological test (again, currently the ELISA or HI test) and the results would have to be compatible with immunological response against ND vaccination; and testing would have to include a minimum of 30 birds with a serologic monitoring program when the birds are more than 4 months of age and prior to the onset of production and not longer than every 90 days thereafter.

To retain ND Clean classification for unvaccinated flocks, during each 90-day period, all primary spent fowl, up to a maximum of 30, would have to test negative to ND within 21 days prior to movement to slaughter; and either a minimum of 30 birds for flock would have to test negative using an approved ND test (either serological or molecular-based) at intervals of 90 days, or a sample of fewer than 30 birds could be tested, provided that all pens are equally represented and a total of 30 birds is tested within each 90 day period.

Finally, for an ND Clean program for flocks to exist within a State, ND would have to be a disease reportable to the responsible State authority by all licensed veterinarians within the State. To accomplish this, all laboratories (including private, State, and university laboratories) that perform diagnostic procedures on poultry would have to examine all submitted cases of unexplained respiratory disease, egg production drops, and mortality for ND. In § 145.15 of the

regulations, as a general NPIP requirement, we require diagnostic surveillance for LPAI within participating States. Part of this diagnostic surveillance must include LPAI being a reportable disease. This requirement for the ND Clean program is modeled on that existing requirement for LPAI surveillance.

The requirements for ND Clean compartments would be similar to the existing requirements for AI Clean compartments, and we would accordingly revise sections of the regulations regarding the establishment and maintenance of AI Clean compartments so that they would also apply to the establishment and maintenance of ND Clean Compartments.

Removal of the Pullorum Typhoid Agglutination Test for S. Enteritidis Clean Classifications

The regulations in §§ 145.23(d), 145.73(d), and 145.83(d) contain requirements for *S. Enteritidis* Clean classifications in the multiplier egg-type chicken breeding industry, primary egg-type chicken breeding industry, and primary meat-type chicken breeding industry, respectively. We are proposing to remove testing using the pullorum-typhoid (PT) agglutination test from the U.S. *S. Enteritidis* Clean classification requirements.

The PT agglutination test was adopted as a test for *S. enteritidis* in the 1980s based on similarities between the two diseases, and on the presumption that it could be used for both diseases. However, the test has since proven to be unreliable in detecting the presence of *S. enteritidis*. It would, however, continue to be used for testing for PT, for which it is reliable.

Revisions to Testing Protocols for AI in the Multiplier Meat-Type Chicken Breeding Industry

Section 145.33 contains, among other things, requirements for determining a participating multiplier meat-type chicken breeding flock is free of AI for purposes of a Clean classification. Paragraph (1)(1) of that section provides three different possible testing protocols for a flock to retain Clean status.

While the first option states at least 15 birds must test negative at intervals of 90 days, and the third option requires a total of 15 samples collected and tested within a 90 day period, the second option requires 30 birds to be tested within each 90 day testing period. Our intent has always been that a total of 15 birds must be tested in each of the three options to retain the AI Clean classification; the discrepancy in the second option is the result of a drafting error. We are proposing to revise the second option to correct this error.

The section also currently requires serological tests for testing of multiplier spent fowl. This limitation is not warranted because molecular-based tests such as PCR are also reliable for such testing. We are proposing to revise the section so that any AI test approved in accordance with § 145.14 may be used.

Proposed Revisions to NPIP Provisions for Hobbyist and Exhibition Waterfowl, Exhibition Poultry and Raised-for-Release Waterfowl Breeding Flocks and Products

Subpart E of part 145, “Special Provisions for Hobbyist and Exhibition Waterfowl, Exhibition Poultry, and Game Bird Breeding Flocks and Products” (§§ 145.51-145.54), contains Plan requirements specific to the hobbyist, exhibition, and game bird industries. We are proposing several changes to this subpart.

First, we are proposing to remove all references to game birds from subpart E due to the addition of proposed subpart J to part 145. The game bird industry has grown rapidly and has become more complex since its inception, and the terminology, production methods, and end uses in the industry are now significantly different than those in other poultry industries. Currently, subpart E does not have specific requirements for any one group of birds covered by its provisions, and subpart J would add testing regimes, terminology, and programs specifically designed for the game bird industry.

In addition to the removal of game bird references, we would revise all references to “waterfowl” within the subpart to instead refer to “raised-for-release waterfowl,” and would remove the definition for *waterfowl* from § 145.51 of the regulations, and add a definition for *raised-for-release waterfowl* in its place. We are proposing to define *raised-for-release waterfowl* as domesticated fowl that normally swim, such as ducks and geese, grown under confinement for the primary purpose of producing eggs, chicks, started, or mature birds for release on game preserves or in the wild.

Waterfowl is currently defined in § 145.51 as domesticated fowl that normally swim, such as ducks and geese, and it is only apparent from subsequent sections of subpart E that the subpart does not apply to meat-type waterfowl, which are instead covered by the provisions of a separate subpart I. These revisions would help to further clarify the scope of subpart E.

We are also proposing to add a definition for *hobbyist poultry*. We would define *hobbyist poultry* as domesticated fowl which are bred for the purposes of meat and/or egg production on a small scale as determined by the Official State Agency. This would also help clarify the scope of subpart E.

Section 145.52 contains requirements that flocks of hobbyist and exhibition waterfowl, exhibition poultry, and game bird breeding flocks, and the eggs and baby poultry produced from them, must meet in order to participate in the Plan.

We are proposing to amend the introductory text of the section to remove the term “baby poultry” and instead indicate that it applies to chicks, started, and mature poultry. This will provide more clarity regarding the applicability of the section and align it with the terminology used elsewhere in part 145 of the regulations. We are also proposing revisions to the

introductory text that reflect the usage the term “raised-for-release waterfowl” throughout the subpart and the creation of a new subpart J for gamebirds.

Paragraph (c) of § 145.52 currently recommends that waterfowl and gallinaceous flocks in open-air facilities be kept separate. However, it is a best practice not to commingle waterfowl, which can act as asymptomatic vectors of disease, and gallinaceous flocks, regardless of whether they are kept in contained or open-air facilities. We are proposing to amend paragraph (c) accordingly.

Finally, we are proposing to add a paragraph (f) to the section to indicate that all participating raised-for-release waterfowl flocks, whether breeders or non-breeders, will be considered to be enrolled under subpart E of part 145 of the regulations. While provisions for non-breeding raised-for-release flocks are contained in part 146 of the regulations, rather than part 145, the testing requirements are identical. This will afford Plan participants some discretion in revising the intended use of a particular flock without jeopardizing the flock’s status.

Terminology and classification; flocks and products

Section 145.53 of the regulations provide Clean classifications that may be applied to participating hobbyist and exhibition waterfowl, exhibition poultry, and game bird breeding flocks, and the eggs and baby poultry produced from them, provided that they meet certain requirements demonstrating freedom from that disease. We are proposing several changes to this section. This section would also discuss that hatcheries should be kept in sanitary conditions according to their relevant subpart and would specify the applicable part of the NPIP Program Standards that pertains to such hatcheries.

In paragraph (b)(5), we are proposing to remove the term “exhibition waterfowl” and use the term “exhibition poultry.”

Additionally, paragraph (f) of § 145.53 contains requirements for a Salmonella Monitored classification. The Salmonella program currently only contains *Salmonella* testing and interventions at the hatchery level, and calls for five environmental samples from a hatchery every 30 days performed at an authorized laboratory in order for breeders to claim their products are monitored for *Salmonella*. We are proposing to add requirements for representative sampling of pullets and breeder farms. Hatched chicks transferred to farms are still at risk of contracting *Salmonella*.

Special Provisions for Egg/Meat-Type Game Bird and Raised-for-Release Game Bird Breeding Flocks and Products

As we mentioned above, we are proposing to establish a new subpart J for the game bird industry. We are amending §§ 145.24, 145.34, 145.44, 145.54, and 145.94 to align them with the rest of the section regarding testing. The separation of the game bird industry from hobby and exhibition poultry in subpart E is necessary because the current definitions and provisions do not match the production methods and end uses for the game bird industry.

Subpart J would consist of four sections: §§ 145.101 for definitions, 145.102 for participation, 145.103 for terminology and classification of flocks and products, and 145.104 for terminology and classification of States.

The requirements in proposed subpart J are drawn from the existing requirements in subpart E; however, some of the definitions, terms, and provisions would be unique to subpart J, and reflect the unique nature of the game bird industry. Key differences between subpart E and subpart J include the following:

- In subpart J, we are proposing to allow breeders to also hatch and/or grow out birds and still meet the definition of *breeder*. This will have the effect of allowing premises with breeding and “grow out” birds to be covered under one NPIP number, and will account for a common production model in the game bird industry.
- We are proposing definitions for the terms *dealer*, *grower*, and *hatchery*. Subpart E relies on the general definition for dealer in § 145.1 of the regulations, and does not contain definitions for growers or hatcheries. However, in order for NPIP to accurately register game bird operations, definitions of these three terms are warranted within subpart J.
- The terms chick, egg, mature bird, and started bird, and raised-for-release bird would be defined within subpart J. Definitions are warranted in order to characterize these products within the game bird industry.
- While subpart E requires hatching eggs produced by breeding flocks to be fumigated or otherwise sanitized, subpart J would provide a third option in addition to fumigation or sanitization, “nest cleaning.” “Nest clean” eggs are produced within the game bird industry on wire or otherwise away from the litter.
- We are proposing to allow a breeder, hatchery, or grower to also be a dealer without being categorized as a dealer, provided that, when reselling products, the breeder, hatchery, or grower has purchased those products from an NPIP participant with equal or greater classifications or from a flock with equivalent or greater testing requirements under official supervision. This allowance would simplify the registration and recordkeeping process for Plan participants within the game bird industry.

- The Pullorum-Typhoid Clean classification requirements reflect the terminology and production methods in the game bird industry.

Proposed Amendments to Part 146

Part 146, subpart E, contains definitions and requirements for Plan participants within the game bird, commercial waterfowl, and raised-for-release waterfowl industries who produce meat- or egg-type flocks.

We are proposing to update the terminology in subpart E to match the other subparts within part 146 by replacing the term “commercial” with “egg/meat-type.”

Additionally, we are proposing to eliminate all provisions related to “grow-out” production from part 146; such poultry would be included in subpart E and our proposed subpart J within part 145.

Proposed Amendments to Part 147

Official delegates

Section 147.45 provides requirements regarding delegation and voter representation for the NPIP’s Biennial Conferences. The text currently states that each cooperating State is entitled to one official delegate for each of the programs in parts 145 and 146.

We are proposing to allow a single, participating delegate to represent multiple States. Companies often have operations in various States, and this change would help those companies save money by appointing a single individual to represent all of the States where the company has operations.

Approval of Conference Recommendations by the Department

Section 147.48 discusses the incorporation of recommendations from the NPIP Biennial Conferences into the NPIP provisions. The regulations do not currently have an established

timeframe for the publication of NPIP Biennial Conference proposed changes; therefore, we are proposing to establish that we would publish a proposed rule to amend the regulations in the *Federal Register* within 14 months of the Biennial Conference. This will help ensure that, when a Biennial Conference is reviewing recommendations for amendments to the regulations, the regulations are up-to-date at the time of the Conference.

Authorized Laboratories

In § 147.52, the regulations state the minimum requirements for an APHIS authorized laboratory evaluation to ensure that they are in compliance with NPIP regulations. Within § 147.52, paragraph (b) contains requirements to be a trained laboratory technician. Currently, testing procedures may only be overseen by technicians who successfully complete Service-approved laboratory workshops for Plan-specific diseases within the past 4 years.

We are proposing to amend § 147.52(b) by removing the word “within” and replacing it with the word “every.” Technicians should attend a workshop for an individual Plan at 4-year intervals versus any time during a 4-year span. We are also proposing a minor editorial change to the paragraph which will indicate that “all authorized laboratories” must be overseen by a technician who meets the aforementioned criteria.

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 regulations in 9 CFR parts 56 and 145 through 147, modifying provisions of the 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 proposed rule would, among other changes, remove the Pullorum-Typhoid agglutination test as a test under which a flock can achieve *Salmonella enteritidis* clean classification, due to its unreliability; propose a Newcastle Disease Clean Program; specify that ELISA-positive samples for Avian Influenza (AI) must be sent for corroboratory testing within 48 hours; and broaden the criteria under which AI detection tests can be approved, while still requiring that the tests reliably detect AI virus. In addition, the proposed rule would clarify the testing period for AI tests to maintain AI Clean classification by correcting an editorial error; clarify that flocks that have been designated exposed to HPAI are not considered infectious; clarify when indemnity may be paid to breeders within the NPIP program; clarify the types of poultry in commerce; and clarify that NPIP dealers must follow the Program Standards in addition to the regulations. The proposal would create NPIP provisions specific to the game bird breeders industry and would set forth *Salmonella* testing for breeders, in addition to hatchers, relative to *Salmonella* Monitored status.

These changes would align the regulations with international standards and make them more transparent to APHIS stakeholders and the general public. The changes included in this rule were voted on and approved by the voting delegates at the Plan's 2018 Biennial Conference.

The establishments that would 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 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, if promulgated, 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

In accordance with Section 3507(d) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the reporting, recordkeeping, and third-party disclosure requirements included in this proposed rule have been submitted for approval to the Office of Management and Budget

(OMB). Please send comments on the Information Collection Request (ICR) to OMB's Office of Information and Regulatory Affairs via email to oir-submissions@omb.eop.gov, Attention: Desk Officer for APHIS, Washington, DC 20503. Please state that your comments refer to Docket No. APHIS-2018-0062. Please send a copy of your comments to the USDA using one of the methods described under ADDRESSES at the beginning of this document.

APHIS is proposing to amend the National Poultry Improvement Program regulations to establish a U.S. Newcastle Disease Clean program within NPIP. The Newcastle Disease Clean program is intended to allow the turkey breeding-hatchery, egg-type chicken breeding-hatchery, and meat-type chicken breeding-hatchery industries, as well as compartments within those industries, to demonstrate freedom from ND based on vaccination and/or monitoring of each participating breeding flock. APHIS intends to determine the presence of Newcastle disease virus through vaccination and monitoring of each participating breeding flock. Implementing this rule will require information collection activities such as a revised flock selecting and testing reports; applications for U.S. Avian Flu and Newcastle Disease clean compartment, clean compartment component registrations, and compartment component removal; component audits; compliance statements; compliance agreements; description of business processes; biosecurity plans; appraisal and indemnity claims; response and containment plans; and recordkeeping.

We are soliciting comments from the public (as well as affected agencies) concerning our proposed information collection requirements. These comments will help us:

(1) Evaluate whether the proposed information collection is necessary for the proper performance of our agency's functions, including whether the information will have practical utility;

- (2) Evaluate the accuracy of our estimate of the burden of the proposed information collection, including the validity of the methodology and assumptions used;
- (3) Enhance the quality, utility, and clarity of the information to be collected; and
- (4) Minimize the burden of the information collection on those who are to respond (such as through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology; e.g., permitting electronic submission of responses).

Estimate of burden: Public burden for this collection of information is estimated to average 1.84 hours per response.

Respondents: Commercial poultry producers and State agricultural officials.

Estimated annual number of respondents: 1,361.

Estimated annual number of responses per respondent: 18.

Estimated annual number of responses: 23,857.

Estimated total annual burden on respondents: 43,810 hours. (Due to averaging, the total annual burden hours may not equal the product of the annual number of responses multiplied by the reporting burden per response.)

A copy of the information collection may be viewed on the Regulations.gov website or in our reading room. (A link to Regulations.gov and information on the location and hours of the reading room are provided under the heading ADDRESSES at the beginning of this proposed rule.) Copies can also be obtained from Mr. Joseph Moxey, APHIS' Information Collection Coordinator, at (301) 851-2483. APHIS will respond to any ICR-related comments in the final rule. All comments will also become a matter of public record.

E-Government Act Compliance

The Animal and Plant Health Inspection Service is committed to compliance with the E-Government Act to promote the use of the internet and other information technologies, to provide increased opportunities for citizen access to Government information and services, and for other purposes. For information pertinent to E-Government Act compliance related to this proposed rule, please contact Mr. Joseph Moxey, APHIS' Information Collection Coordinator, at (301) 851-2483.

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 propose to amend 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 adding, in alphabetical order, definitions for *Cleaning*, *Compensation*, and *Disinfection*;
- b. By removing the definitions for *H5/H7 LPAI exposed* and *H5/H7 LPAI infection (infected)*; and
- c. By adding, in alphabetical order, definitions for *H5/H7 LPAI virus actively infected (infectious)*, *H5/H7 LPAI virus exposed (non-infectious)*, *Indemnity*, and *Virus elimination (VE)*.

The additions read as follows:

§ 56.1 Definitions.

* * * * *

Cleaning. The removal of gross contamination, organic material, and debris from the premises or respective structures, via mechanical means like sweeping (dry cleaning) and/or the use of water and soap or detergent (wet cleaning), in order to minimize organic material to prepare for effective disinfection.

* * * * *

Compensation. In the case of H5/H7 LPAI detection, compensation specifically refers to reimbursement for the activities associated with the depopulation of infected or exposed poultry, including the disposal of contaminated carcasses and materials and the cleaning and disinfection of premises, conveyances, and materials that came into contact with infected or exposed poultry. In the case of contaminated materials, if the cost of cleaning and disinfection would exceed the value of the materials, or cleaning and disinfection would be impracticable for any reason, APHIS will base compensation on the fair market value (depreciated value) of those materials. Compensation does not include payment for depopulated birds or eggs destroyed (see definition of *Indemnity* in this section).

* * * * *

Disinfection. Methods used on surfaces to destroy or eliminate H5/H7 LPAI virus through physical (e.g., heat) or chemical (e.g., disinfectant) means. A combination of methods may be required.

* * * * *

H5/H7 LPAI virus actively infected (infectious). (1) Poultry will be considered to be infected with H5/H7 LPAI for the purposes of this part if:

- (i) H5/H7 LPAI virus has been isolated and identified as such from poultry; or
- (ii) Viral antigen or viral RNA specific to the H5 or H7 subtype of AI virus has been detected in poultry.

(2) The official determination that H5/H7 LPAI virus has been isolated and identified, or viral antigen or viral RNA specific to the H5 or H7 subtype of AI virus has been detected, may only be made by the National Veterinary Services Laboratories.

H5/H7 LPAI virus exposed (non-infectious). (1) Poultry will be considered to be exposed (non-infectious) to H5/H7 LPAI for the purposes of this part if:

- (i) Antibodies to the H5 or H7 subtype of the AI virus that are not a consequence of vaccination have been detected in poultry; and
- (ii) Samples collected from the flock using real-time reverse transcription polymerase chain reaction (RT-PCR) or virus isolation are determined to be not infectious for H5/H7 LPAI.

(2) The official determination that H5/H7 LPAI virus exposure has occurred is by the identification of antibodies to the H5 or H7 subtype of AI virus detected and may only be made by the National Veterinary Services Laboratories.

Indemnity. Payments representing the fair market value of destroyed birds and eggs. Indemnity does not include reimbursements for depopulation, disposal, destroyed materials, or cleaning and disinfection (virus elimination) activities (see definition of *Compensation* in this section).

* * * * *

Virus elimination (VE). Cleaning and disinfection measures conducted to destroy or eliminate all AI virus on an affected premises.

3. Section 56.3 is amended by revising the section heading and paragraphs (a) introductory text and (b) and (c) to read as follows:

§ 56.3 Payment of indemnity and/or compensation.

(a) *Activities eligible for indemnity and/or compensation.* The Administrator may pay indemnity and/or compensation for the activities listed in this paragraph (a), as provided in paragraph (b) of this section:

* * * * *

(b) *Percentage of costs eligible for indemnity.* Except for poultry that are described by the categories in this paragraph (b), the Administrator is authorized to pay 100 percent of the costs and/or compensation, as determined in accordance with § 56.4, of the activities described in paragraphs (a)(1) through (3) of this section, regardless of whether the infected or exposed poultry participate in the Plan. For infected or exposed poultry that are described by the categories in this paragraph (b), the Administrator is authorized to pay 25 percent of the costs of the activities described in paragraphs (a)(1) through (3) of this section:

(1)(i) The poultry are from a breeding flock, commercial flock, or slaughter plant that participates in any Plan program in part 145 or 146 of this chapter but that does not participate in the U.S. Avian Influenza Clean, U.S. H5/H7 Avian Influenza Clean, or U.S. H5/H7 Avian Influenza Monitored program of the Plan available to the flock in part 145 or 146 of this chapter; and

(ii) The poultry are from:

(A) A commercial table-egg laying premises with at least 75,000 birds; or

(B) A meat-type chicken slaughter plant that slaughters at least 200,000 meat-type chickens in an operating week; or

(C) A meat-type turkey slaughter plant that slaughters at least 2 million meat-type turkeys in a 12 month period; or

(D) A commercial waterfowl and commercial upland game bird slaughter plant that slaughters at least 50,000 birds annually; or

(E) A raised-for-release upland game bird premises, raised-for-release waterfowl premises, and commercial upland game bird or commercial waterfowl producing eggs for human consumption premises that raise at least 25,000 birds annually; or

(F) A breeder flock premises with at least 5,000 birds.

(2) The poultry are located in a State that does not participate in the diagnostic surveillance program for H5/H7 LPAI, as described in § 146.14 of this chapter, or that does not have an initial State response and containment plan for H5/H7 LPAI that is approved by APHIS under § 56.10, unless such poultry participate in the Plan with another State that does participate in the diagnostic surveillance program for H5/H7 LPAI, as described in § 146.14 of this chapter, and has an initial State response and containment plan for H5/H7 LPAI that is approved by APHIS under § 56.10.

(c) *Other sources of payment.* If the recipient of indemnity and/or compensation for any of the activities listed in paragraphs (a)(1) through (3) of this section also receives payment for any of those activities from a State or from other sources, the indemnity and/or compensation provided under this part may be reduced by the total amount of payment received from the State or other sources to the extent that total payments do not exceed 100 percent of total reimbursable indemnity and/or compensation amounts.

4. Section 56.4 is revised to read as follows:

§56.4 Determination of indemnity and/or compensation amounts.

(a) *Destruction and disposal of poultry.* (1) Indemnity for the destruction of poultry and/or eggs infected with or exposed to H5/H7 LPAI will be based on the fair market value of the poultry and/or eggs, as determined by an appraisal. The appraisal will use the current APHIS appraisal calculator values; if no such calculator value exists, an APHIS official appraiser will provide an appraisal of fair market value. An indemnity request form must be signed by the owners and grower (if applicable) of the poultry and received by APHIS prior to the destruction of the poultry and eggs, unless the owners, grower, APHIS, and the Cooperating State Agency agree in writing that the poultry may be destroyed immediately. Reports of appraisals must show the number of birds and the value per head. Complete inventory records of all birds and/or eggs on the premises must be provided to APHIS prior to the start of depopulation.

(2) Compensation for disposal of poultry and/or eggs infected with or exposed to H5/H7 LPAI will be based on receipts or other documentation maintained by the claimant verifying expenditures for disposal activities authorized by this part. Any disposal of poultry infected with or exposed to H5/H7 LPAI for which compensation is requested must be performed under a compliance agreement between the claimant and APHIS. APHIS will review claims for compensation for disposal to ensure that all expenditures relate directly to activities described in § 56.5 and in the initial State response and containment plan described in § 56.10. If disposal is performed by the Cooperating State Agency, APHIS will compensate the Cooperating State Agency for disposal under a cooperative agreement.

(3) The destruction and disposal of the poultry and/or eggs must be conducted in accordance with the initial State response and containment plan for H5/H7 LPAI, as described in § 56.10.

(b) *Cleaning and disinfection (virus elimination)*. (1) Compensation for cleaning and disinfection (virus elimination) of premises, conveyances, and materials that came into contact with poultry that are infected with or exposed to H5/H7 LPAI will be determined using the current APHIS flat-rate virus elimination (VE) calculator in effect at the time of the infection.

(2) For premises types for which a flat-rate VE calculator is not available, reimbursement will be based on receipts or other documentation maintained by the claimant verifying expenditures for cleaning and disinfection (virus elimination) activities authorized by this part. Any cleaning and disinfection (virus elimination) of premises, conveyances, and materials for which compensation is requested must be performed under a compliance agreement between the claimant, the Cooperating State Agency, and APHIS. APHIS will review claims for compensation for cleaning and disinfection (virus elimination) to ensure that all expenditures relate directly to activities described in § 56.5 and in the initial State response and containment plan described in § 56.10.

(i) In the case of materials, if the cost of cleaning and disinfection (virus elimination) would exceed the value of the materials or cleaning and disinfection (virus elimination) would be impracticable for any reason, compensation for the destruction of the materials will be based on the fair market value (depreciated value) of those materials, as determined by an appraisal. Materials will be appraised by an APHIS official appraiser. Compensation for disposal of the materials will be based on receipts or other documentation maintained by the claimant verifying expenditures for disposal activities authorized by this part. Appraisals of materials must be

reported on forms furnished by APHIS and must be signed by the appraisers and by the owners of the materials to indicate agreement with the appraisal amount. Appraisals of materials must be signed and received by APHIS prior to the disassembly or destruction of the materials, unless the owners, APHIS, and the Cooperating State Agency agree in writing that the materials may be disassembled and/or destroyed immediately. Any disposal of materials for which compensation is requested must be performed under a compliance agreement between the claimant, the Cooperating State Agency, and APHIS. APHIS will review claims for compensation for disposal to ensure that all expenditures relate directly to activities described in § 56.5 and in the initial State response and containment plan described in § 56.10.

(ii) [Reserved]

(c) *Requirements for compliance agreements.* The compliance agreement is a comprehensive document that describes the depopulation, disposal, and cleaning and disinfection (virus elimination) plans for poultry that were infected with or exposed to H5/H7 LPAI, or a premises that contained such poultry. The compliance agreement must set out cost estimates that include labor, materials, supplies, equipment, personal protective equipment, and any additional information deemed necessary by APHIS. A compliance agreement must indicate what tasks will be completed, who will be responsible for each task, and how much the work is expected to cost. 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.

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

5. Section 56.5 is amended as follows:

a. By revising the section heading;

b. In paragraph (c)(1) introductory text, by adding the words “and maintain their current National Poultry Improvement Plan (NPIP) certifications” after the words “controlled marketing”; and

c. By revising paragraphs (c)(2) and (d).

The revisions read as follows:

§ 56.5 Destruction and disposal of poultry and cleaning and disinfection (virus elimination) of premises, conveyances, and materials.

* * * * *

(c) * * *

(2) Poultry moved for controlled marketing will not be eligible for indemnity under § 56.3. However, any costs related to cleaning and disinfection (virus elimination) of premises, conveyances, and materials that came into contact with poultry that are moved for controlled marketing will be eligible for compensation under § 56.3.

(d) *Cleaning and disinfection (virus elimination) of premises, conveyances, and materials.* Premises, conveyances, and materials that came into contact with poultry infected with or exposed to H5/H7 LPAI must be cleaned and disinfected; *Provided*, that materials for which the cost of cleaning and disinfection would exceed the value of the materials or for which cleaning and disinfection would be impracticable for any reason may be destroyed and disposed. Cleaning and disinfection must be performed in accordance with the initial State response and containment plan described in § 56.10, which must be approved by APHIS. Cleaning and disinfection must also be performed in accordance with any applicable State and local environmental regulations.

6. Section 56.6 is amended as follows:

a. By revising the section heading;

b. In paragraph (a), by removing the word “Compensation” and adding the word “Indemnity” in its place;

c. By revising paragraph (b); and

d. In paragraph (c), by adding the words “(virus elimination)” after the word “disinfection” each time it appears.

The revisions read as follows:

§ 56.6 Presentation of claims for indemnity and/or compensation.

* * * * *

(b) Indemnity for the value of eggs to be destroyed due to infection or exposure to H5/H7 LPAI; and

* * * * *

7. Section 56.8 is amended as follows:

a. In paragraph (a) introductory text, by removing the word “may” and adding the word “shall” in its place; and

b. By revising paragraph (b).

The revision reads as follows:

§ 56.8 Conditions for payment.

* * * * *

(b)(1) If indemnity for the destroyed poultry or eggs is being provided for 100 percent of eligible costs under § 56.3(b), the Administrator may pay contractors eligible for indemnity under this section 100 percent of the amount determined in paragraph (a) of this section.

(2) If indemnity for the destroyed poultry or eggs is being provided for 25 percent of eligible costs under § 56.3(b), the Administrator may pay contractors eligible for indemnity 25 percent of the amount determined in paragraph (a) of this section.

* * * * *

§ 56.9 [Amended]

8. Section 56.9 is amended as follows:

a. In paragraph (a), by removing the citation “§ 56.4(a)(1)” and adding the citation “§ 56.4(a)” in its place; and

b. In paragraph (b), by adding the words “and/or compensation” after the word “indemnity” both times it appears.

§ 56.10 [Amended]

9. In § 56.10, paragraph (a) introductory text is amended by adding the words “and/or compensation” after the word “indemnity”.

PART 145–NATIONAL POULTRY IMPROVEMENT PLAN FOR BREEDING POULTRY

10. 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.

11. Section 145.1 is amended as follows:

a. By revising the definition for *Avian influenza*;

b. By adding a definition for *Newcastle disease* in alphabetical order; and

c. By revising the definition for *NPIP Program Standards*.

The revisions and addition read as follows:

§ 145.1 Definitions.

* * * * *

Avian influenza. Avian influenza is defined as an infection of poultry caused by any influenza A virus of the H5 or H7 subtypes or by any influenza A virus with an intravenous pathogenicity index (IVPI) greater than 1.2 (or as an alternative at least 75 percent mortality).

* * * * *

Newcastle disease. Newcastle disease (ND) is defined as an infection of poultry caused by Newcastle disease virus (NDV), which is an avian paramyxovirus serotype 1 (APMV-1) that meets one of the following criteria for virulence:

(1) The virus has an intracerebral pathogenicity index (ICPI) in day-old chicks (*Gallusgallus*) of 0.7 or greater; or

(2) Multiple basic amino acids have been demonstrated in the virus (either directly or by deduction) at the C-terminus of the F2 protein and phenylalanine at residue 117, which is the N-terminus of the F1 protein. The term ‘multiple basic amino acids’ refers to at least three arginine or lysine residues between residues 113 and 116. Failure to demonstrate the characteristic pattern of amino acid residues as described above would require characterization of the isolated virus by an ICPI test.

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 National Poultry Improvement Plan (NPIP) website 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.

* * * * *

12. Section 145.7 is revised to read as follows:

§ 145.7 Specific provisions for participating dealers.

Dealers in hatching eggs, newly hatched poultry, or started poultry shall comply with the provisions in this part (within the NPIP Program Standards document, Program Standard C applies to hatcheries; alternatives to the program standards may also be approved by the Administrator under § 147.53).

13. Section 145.14 is amended as follows:

- a. By revising paragraphs (d)(1) and (2) introductory text; and
- b. By adding paragraph (e).

The revisions and addition read as follows:

§ 145.14 Testing.

* * * * *

(d) * * *

(1) *Antibody detection tests*—(i) *ELISA test.* (A) The ELISA test must be conducted using test kits approved by the Department and the Official State Agency and must be conducted in accordance with the recommendations of the producer or manufacturer.

(B) When positive ELISA samples are identified, an AGID test must be conducted within 48 hours.

(ii) *Agar gel immunodiffusion (AGID) test.* (A) The AGID test must be conducted using reagents approved by the Department and the Official State Agency.

(B) The AGID test for avian influenza must be conducted in accordance with this section (within the NPIP Program Standards document, Program Standard A applies to blood and yolk testing procedures; alternatives to the program standards may also be approved by the Administrator under § 147.53) for the avian influenza agar gel immunodiffusion (AGID) test.

The test can be conducted on egg yolk or blood samples. The AGID test is not recommended for use in waterfowl.

(C) Positive tests for the AGID must be further tested by Federal Reference Laboratories using appropriate tests for confirmation. Final judgment may be based upon further sampling and appropriate tests for confirmation.

(2) *Agent detection tests.* Agent detection tests may be used to detect influenza A virus but not to determine hemagglutinin or neuraminidase subtypes. Samples for agent detection testing should be collected from naturally occurring flock mortality or clinically ill birds.

* * * * *

(e) *For Newcastle Disease (ND).* The official tests for ND are serological tests for antibody detection or molecular-based tests for antigen detection.

* * * * *

§ 145.23 [Amended]

14. Section 145.23 is amended as follows:

a. By removing paragraphs (d)(1)(vi) and (vii) and redesignating paragraphs (d)(1)(viii) and (ix) as paragraphs (d)(1)(vi) and (vii), respectively; and

b. By removing paragraph (d)(3) and redesignating paragraphs (d)(4) and (5) as paragraphs (d)(3) and (4), respectively.

§ 145.24 [Amended]

15. In § 145.24, paragraph (a)(1)(i) is amended by removing “§ 145.23(b)(3)(i) through (vii), § 145.33(b)(3)(i) through (vii), § 145.43(b)(3)(i) through (vi), § 145.53(b)(3)(i) through (vii), § 145.73(b)(2)(i), § 145.83(b)(2)(i), and § 145.93(b)(3)(i) through (vii)” and adding “§§ 145.23(b)(3)(i) through (vii), 145.33(b)(3)(i) through (vii), 145.43(b)(3)(i) through (vi),

145.53(b)(3)(i) through (vii), 145.73(b)(2)(i), 145.83(b)(2)(i), 145.93(b)(3)(i) through (vii), and 145.103(b)(3)(i) through (ix)” in its place.

16. Section 145.33 is amended as follows:

a. In paragraph (l)(1)(ii), by removing the number “30” and adding the number “15” in its place; and

b. By revising paragraph (l)(2).

The revision reads as follows:

§ 145.33 Terminology and classification; flocks and products.

* * * * *

(l) * * *

(2) During each 90-day period, all multiplier spent fowl, up to a maximum of 30, must be tested and found negative for avian influenza within 21 days prior to movement to slaughter.

* * * * *

§ 145.34 [Amended]

17. In § 145.34, paragraph (a)(1)(i) is amended by removing “§ 145.23(b)(3)(i) through (vii), § 145.33(b)(3)(i) through (vii), § 145.43(b)(3)(i) through (vi), § 145.53(b)(3)(i) through (vii), § 145.73(b)(2)(i), § 145.83(b)(2)(i), and § 145.93(b)(3)(i) through (vii)” and adding “§§ 145.23(b)(3)(i) through (vii), 145.33(b)(3)(i) through (vii), 145.43(b)(3)(i) through (vi), 145.53(b)(3)(i) through (vii), 145.73(b)(2)(i), 145.83(b)(2)(i), 145.93(b)(3)(i) through (vii), and 145.103 (b)(3)(i) through (ix)” in its place.

18. Section 145.43 is amended by adding paragraph (h) to read as follows:

§ 145.43 Terminology and classification; flocks and products.

* * * * *

(h) *U.S. Newcastle Disease Clean*. The program in this paragraph (h) is intended to be the basis from which the breeding-hatchery industry may conduct a program for the prevention and control of Newcastle disease. It is intended to determine the presence of Newcastle disease in primary breeding turkeys through vaccination and/or monitoring of each participating breeding flock. A flock and the hatching eggs and poults produced from it will qualify for the classification in this paragraph (h) when the Official State Agency determines that they have met the following requirements:

(1) It is a primary breeding flock that is either:

(i) Vaccinated for Newcastle disease using USDA-licensed vaccines and response to vaccination is serologically monitored using an approved test as described in § 145.14 when more than 4 months of age, and meets the criteria in paragraph (h)(2) of this section to retain classification; or

(ii) Unvaccinated for Newcastle disease, in which a minimum of 30 birds have tested negative to ND using an approved test as described in § 145.14 when more than 4 months of age and meets the criteria in paragraph (h)(3) of this section to retain classification.

(2) To retain the classification in this paragraph (h), for vaccinated flocks:

(i) Vaccines for ND must be USDA-licensed vaccines administered during early stages of development through rearing, and inactivated vaccines as final vaccination prior to the onset of egg production; and

(ii) The flock has been monitored for antibody response using approved serological tests as listed in § 145.14 and the results are compatible with immunological response against ND vaccination; and

(iii) Testing must include a minimum of 30 birds with a serologic monitoring program when more than 4 months of age and prior to the onset of production and not longer than every 90 days thereafter.

(3) To retain the classification in this paragraph (h) for unvaccinated flocks:

(i) A minimum of 30 birds per flock must test negative using an approved test in § 145.14 at intervals of 90 days; or

(ii) A sample of fewer than 30 birds may be tested, and found negative, at any one time if all pens are equally represented and a total of 30 birds is tested within each 90-day period; and

(iii) During each 90-day period, all primary spent fowl, up to a maximum of 30, must test negative to ND within 21 days prior to movement to slaughter.

(4) Newcastle disease must be a disease reportable to the responsible State authority (State veterinarian, etc.) by all licensed veterinarians. To accomplish this, all laboratories (private, State, and university laboratories) that perform diagnostic procedures on poultry must examine all submitted cases of unexplained respiratory disease, egg production drops, and mortality for ND.

* * * * *

§ 145.44 [Amended]

19. In § 145.44, paragraph (a)(1)(i) is amended by removing “§ 145.23(b)(3)(i) through (vii), § 145.33(b)(3)(i) through (vii), § 145.43(b)(3)(i) through (vi), §145.53(b)(3)(i) through (vii), § 145.73(b)(2)(i), § 145.83(b)(2)(i), and § 145.93(b)(3)(i) through (vii)” and adding “§§ 145.23(b)(3)(i) through (vii), 145.33(b)(3)(i) through (vii), 145.43(b)(3)(i) through (vi), 145.53(b)(3)(i) through (vii), 145.73(b)(2)(i), §145.83(b)(2)(i), 145.93(b)(3)(i) through (vii), and 145.103(b)(3)(i) through (ix)” in this place.

20. Section 145.45 is amended as follows:

a. By revising paragraph (a) introductory text;

b. In paragraph (a)(1) introductory text, by adding the words “and ND” after the word “AI” each time it appears;

c. In paragraph (a)(1)(i):

i. By adding the words “and ND Clean in accordance with § 145.43(h)” after the citation “§ 145.43(g)”;

ii. By adding the words “and ND” after the words “official tests for AI” and adding the words “and (e)” after the citation “§ 145.14(d)”;

iii. By removing the word “AI-related” and adding the words “AI and ND-related” in its place;

d. In paragraphs (a)(1)(iii) introductory text, (a)(1)(iii)(B) and (E), and (a)(1)(v), by adding the words “and ND” after the word “AI” each time it appears;

e. In paragraph (a)(1)(vi), by adding the words “and ND” after the word “Influenza”;

f. In paragraph (a)(2)(iii):

i. By removing the words “Clean classification” and adding the words “and ND Clean classifications” in their place;

ii. By adding the words “and ND” after the word “AI” both times it appears; and

iii. By removing the words “avian influenza surveillance” and adding the words “avian influenza and ND surveillance” in their place;

g. In paragraph (a)(3)(iii), by adding the words “and ND” after the word “Influenza”;

h. In paragraph (a)(3)(iv), by adding the words “and ND Clean program as described in § 145.43(h)” after the citation “§ 145.43(g)”;

i. In paragraph (a)(3)(vii), by adding the words “and (h)” after the citation “145.43(g)”.

The revision reads as follows:

§ 145.45 Terminology and classification; compartments.

(a) *US H5/H7 AI and ND Clean Compartment.* The program in this section 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) and ND. This compartment has the purpose of protecting the defined subpopulation and avoiding the introduction and spread of H5/H7 AI and ND 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:

* * * * *

21. The heading for subpart E, consisting of §§ 145.51 through 146.54, is revised to read as follows:

Subpart E—Special Provisions for Hobbyist and Exhibition Poultry, and Raised-for-Release Waterfowl Breeding Flocks and Products

22. Section 145.51 is amended as follows:

a. By removing the definition for *Game birds*;

b. By adding, in alphabetical order, definitions for *Hobbyist poultry* and *Raised-for-release waterfowl*; and

c. By removing the definition for *Waterfowl*.

The additions read as follows:

§ 145.51 Definitions.

* * * * *

Hobbyist poultry. Domesticated fowl which are bred for the purposes of meat and/or egg production on a small scale as determined by the Official State Agency.

Raised-for-release waterfowl. Domesticated fowl that normally swim, such as ducks and geese, grown under confinement for the primary purpose of producing eggs, chicks, started, or mature birds for release on game preserves or in the wild.

23. Section 145.52 is amended as follows:

- a. By revising the introductory text;
- b. In paragraph (c), by removing the words “in open air facilities”; and
- c. By adding paragraph (f).

The revision and addition read as follows:

§ 145.52 Participation.

Participating flocks of hobbyist and exhibition poultry, raised-for-release waterfowl, and the eggs, chicks, started, and mature poultry produced from them shall comply with the applicable general provisions of subpart A of this part and the special provisions of this subpart. The special provisions that apply to meat-type waterfowl flocks are found in subpart I of this part. The special provisions that apply to game bird flocks are found in subpart J of this part.

* * * * *

(f) All participating raised-for-release waterfowl flocks, regardless of whether they are breeders or non-breeders, shall be enrolled under this subpart.

24. Section 145.53 is amended as follows:

- a. In paragraph (b)(5), by removing the words “exhibition waterfowl or”; and
- b. By revising paragraph (f).

The revision reads as follows:

§ 145.53 Terminology and classification; flocks and products.

* * * * *

(f) *U.S. Salmonella Monitored.* The program in this paragraph (f) 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 poultry through an effective and practical sanitation and testing 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. The following requirements must be met for a flock or hatchery to be eligible for the classification in this paragraph (f) as determined by the Official State Agency:

(1) Hatcheries must be kept in a sanitary condition as applicable and as outlined in § 145.6 (within the NPIP Program Standards document, Program Standard C applies to hatcheries; alternatives to the program standards may also be approved by the Administrator under § 147.53).

(2) An Authorized Agent shall collect and submit to an authorized laboratory:

(i) A minimum of five samples from the hatchery at least every 30 days while in operation. These samples may include: Hatchery debris, swabs from hatching, setters, hatchery environment, hatchery equipment, sexing tables and belts, meconium, chick box papers, hatching trays, or chick transfer devices. Samples will be examined bacteriologically at an authorized laboratory for *Salmonella*; and

(ii) Annual environmental samples from each pullet and breeder farm in accordance with this section (within the NPIP Program Standards document, Program Standard B applies to bacteriological examination procedures; alternatives to the program standards may also be approved by the Administrator under § 147.53). Samples will be examined bacteriologically at an authorized laboratory for *Salmonella*.

(3) If *Salmonella* is identified through this testing:

(i) A qualified poultry health professional knowledgeable with the operation will be consulted and will:

(A) Review test results to evaluate the *Salmonella* monitoring program.

(B) Use the *Salmonella* monitoring program test results to develop appropriate and practical *Salmonella* intervention measures.

(ii) [Reserved]

(4) To claim products are of the classification in this paragraph (f), all products shall be derived from a farm or hatchery that meets the requirements of the classification.

* * * * *

§ 145.54 [Amended]

25. In § 145.54, paragraph (a)(1)(i) is amended by removing “§ 145.23(b)(3)(i) through (vii), § 145.33(b)(3)(i) through (vii), § 145.43(b)(3)(i) through (vi), § 145.53(b)(3)(i) through (vii), § 145.73(b)(2)(i), § 145.83(b)(2)(i), and § 145.93(b)(3)(i) through (vii)” and adding “§§ 145.23(b)(3)(i) through (vii), 145.33(b)(3)(i) through (vii), 145.43(b)(3)(i) through (vi), 145.53(b)(3)(i) through (vii), 145.73(b)(2)(i), 145.83(b)(2)(i), 145.93(b)(3)(i) through (vii), and 145.103(b)(3)(i) through (ix)” in its place.

26. Section 145.73 is amended as follows:

a. By removing paragraphs (d)(1)(vi) and (vii) and redesignating paragraphs (d)(1)(viii) and (ix) as paragraphs (d)(1)(vi) and (vii), respectively;

b. By removing paragraph (d)(3) and redesignating paragraphs (d)(4) and (5) as paragraphs (d)(3) and (4), respectively; and

c. By adding paragraph (h).

The addition reads as follows:

§ 145.73 Terminology and classification; flocks and products.

* * * * *

(h) *U.S. Newcastle Disease Clean*. The program in this paragraph (h) is intended to be the basis from which the breeding-hatchery industry may conduct a program for the prevention and control of Newcastle disease. It is intended to determine the presence of Newcastle disease in primary breeding chickens through vaccination and/or monitoring of each participating breeding flock. A flock and the hatching eggs and chicks produced from it will qualify for the classification in this paragraph (h) when the Official State Agency determines that they have met the following requirements:

(1) It is a primary breeding flock that is either:

(i) Vaccinated for Newcastle disease using USDA-licensed vaccines and response to vaccination is serologically monitored using an approved test as described in § 145.14 when more than 4 months of age and meets the criteria in paragraph (h)(2) of this section to retain classification; or

(ii) Unvaccinated for Newcastle disease, in which a minimum of 30 birds have tested negative to ND using an approved test as described in § 145.14 when more than 4 months of age and meets criteria in paragraph (h)(3) of this section to retain classification.

(2) To retain the classification in this paragraph (h), for vaccinated flocks:

(i) Vaccines for ND must be USDA-licensed vaccines administered during early stages of development through rearing, and inactivated vaccines as final vaccination prior to the onset of egg production; and

(ii) The flock has been monitored for antibody response using approved serological tests as listed in § 145.14 and the results are compatible with immunological response against ND vaccination; and

(iii) Testing must include a minimum of 30 birds with a serologic monitoring program when more than 4 months of age and prior to the onset of production and not longer than every 90 days thereafter.

(3) To retain the classification in this paragraph (h) for unvaccinated flocks:

(i) A minimum of 30 birds per flock must test negative using an approved test as described in § 145.14 at intervals of 90 days; or

(ii) A sample of fewer than 30 birds may be tested, and found negative, at any one time if all pens are equally represented and a total of 30 birds is tested within each 90-day period; and

(iii) During each 90-day period, all primary spent fowl, up to a maximum of 30, must test negative to ND within 21 days prior to movement to slaughter.

(4) Newcastle disease must be a disease reportable to the responsible State authority (State veterinarian, etc.) by all licensed veterinarians. To accomplish this, all laboratories (private, State, and university laboratories) that perform diagnostic procedures on poultry must examine all submitted cases of unexplained respiratory disease, egg production drops, and mortality for ND.

27. Section 145.74 is amended as follows:

a. In paragraph (a) introductory text, by revising the paragraph heading, adding the words “and Newcastle disease (ND)” after the word “(AI)”, and adding the words “and ND” after the word “AI”;

b. In paragraph (a)(1) introductory text, by adding the words “and ND” after the word “AI” each time it appears;

c. In paragraph (a)(1)(i):

i. By adding the words “and ND Clean in accordance with § 145.73(h)” after the words “in accordance with § 145.73(f)”;

ii. By adding the words “and ND” after the words “official tests for AI” and adding the words “and (e)” after the citation “§ 145.14(d)”;

iii. By removing the word “AI-related” and adding the words “AI and ND-related” in its place;

d. In paragraphs (a)(1)(iii), (a)(1)(iii)(B) and (E), and (a)(1)(v), by adding the words “and ND” after the word “AI” each time it appears;

e. In paragraph (a)(1)(vi), by adding the words “and ND” after the word “Influenza”;

f. In paragraph (a)(2)(iii):

i. By removing the words “Clean classification” and adding the words “and ND Clean classifications” in their place;

ii. By adding the words “and ND” after the word “AI” both times it appears; and

iii. By removing the words “avian influenza surveillance” and adding the words “avian influenza and ND surveillance” in their place;

g. In paragraph (a)(3)(iii), by adding the words “and ND” after the word “Influenza”;

h. In paragraph (a)(3)(iv), by adding the words “and ND Clean program as described in § 145.73(h)” after the citation “§ 145.73(f)”;

i. In paragraph (a)(3)(vii), by adding the words “and (h)” after the citation “145.73(f); and

j. In paragraph (a)(4), by adding the words “and/or ND” after the word “AI” both times it appears.

The revision reads as follows:

§ 145.74 Terminology and classification; compartments.

(a) *U.S. Avian Influenza and Newcastle Disease Clean Compartment.* * * *

* * * * *

28. Section 145.83 is amended as follows:

a. By removing paragraph (e)(1)(iv) and redesignating paragraphs (e)(1)(v) and (vi) as paragraphs (e)(1)(iv) and (v), respectively; and

b. By adding paragraph (h).

The addition reads as follows:

§ 145.83 Terminology and classification; flocks and products.

* * * * *

(h) *U.S. Newcastle Disease (ND) Clean.* The program in this paragraph (h) is intended to be the basis from which the breeding-hatchery industry may conduct a program for the prevention and control of Newcastle disease. It is intended to determine the presence of Newcastle disease in primary breeding chickens through vaccination and/or monitoring of each participating breeding flock. A flock and the hatching eggs and chicks produced from it will qualify for the classification in this paragraph (h) when the Official State Agency determines that they have met the following requirements:

(1) It is a primary breeding flock that is either:

(i) Vaccinated for Newcastle disease using USDA-licensed vaccines and response to vaccination is serologically monitored using an approved test as described in § 145.14 when more than 4 months of age and meets the criteria in paragraph (h)(2) of this section to retain classification; or

(ii) Unvaccinated for Newcastle disease, in which a minimum of 30 birds have tested negative to ND using an approved test as described in § 145.14 when more than 4 months of age and meets criteria in paragraph (h)(3) of this section to retain classification.

(2) To retain the classification in this paragraph (h), for vaccinated flocks:

(i) Vaccines for ND must be USDA-licensed vaccines administered during early stages of development through rearing, and inactivated vaccines as final vaccination prior to the onset of egg production; and

(ii) The flock has been monitored for antibody response using approved serological tests as described in § 145.14 and the results are compatible with immunological response against ND vaccination; and

(iii) Testing must include a minimum of 30 birds with a serologic monitoring program when more than 4 months of age and prior to the onset of production, and not longer than every 90 days thereafter.

(3) To retain the classification in this paragraph (h) for unvaccinated flocks:

(i) A minimum of 30 birds per flock must test negative using an approved test as described in § 145.14 at intervals of 90 days; or

(ii) A sample of fewer than 30 birds may be tested, and found negative, at any one time if all pens are equally represented and a total of 30 birds is tested within each 90-day period; and

(iii) During each 90-day period, all primary spent fowl, up to a maximum of 30, must test negative to ND within 21 days prior to movement to slaughter.

(4) Newcastle disease must be a disease reportable to the responsible State authority (State veterinarian, etc.) by all licensed veterinarians. To accomplish this, all laboratories (private, State, and university laboratories) that perform diagnostic procedures on poultry must examine all submitted cases of unexplained respiratory disease, egg production drops, and mortality for ND.

29. Section 145.84 is amended as follows:

a. In paragraph (a) introductory text, by revising the heading, adding the words “and Newcastle disease (ND)” after the words “influenza (AI)”, and adding the words “and ND” after the words “H5/H7 AI”;

b. In paragraph (a)(1) introductory text, by adding the words “and ND” after the word “AI” each time it appears;

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

d. In paragraphs (a)(1)(iii) introductory text, (a)(1)(iii)(B) and (E), and (a)(1)(v), by adding the words “and ND” after the word “AI” each time it appears;

e. In paragraph (a)(1)(vi), by adding the words “and ND” after the word “Influenza”;

f. In paragraph (a)(2)(iii):

i. Removing the words “Clean classification” and adding the words “and ND Clean classifications” in their place;

ii. Adding the words “and ND” after the word “AI” both times it appears; and

iii. Removing the words “avian influenza surveillance” and adding the words “avian influenza and ND surveillance” in their place;

g. In paragraph (a)(3)(iv), by adding the words “and ND Clean program as described in § 145.83(h)” after the citation “§ 145.83(g)”; and

h. In paragraph (a)(3)(vii), by adding the words “ and (h)” after the citation “145.83(g)”.

The revisions read as follows:

§ 145.84 Terminology and classification; compartments.

(a) *U.S. Avian Influenza and Newcastle Disease Clean Compartment.* * * *

(1) * * *

(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) and ND Clean in accordance with § 145.83(h). 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 and ND, as described in § 145.14(d) and (e), must be conducted in State or Federal laboratories or in NPIP authorized laboratories that meet the minimum standards described in § 147.52 of this subchapter. In addition, the company must provide to the Service upon request any relevant historical and current H5/H7 AI and ND-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.

* * * * *

§ 145.94 [Amended]

30. In § 145.94, paragraph (a)(1)(i) is amended by removing the word “and” and adding the words “, and 145.103(b)(3)(i) through (ix)” after the words “145.93(b)(3)(i) through (vii)”.

31. Subpart J, consisting of §§ 145.101 through 145.104, is added to read as follows:

Subpart J—Special Provisions for Egg/Meat-Type Game Bird and Raised-for-Release Game

Bird Breeding Flocks and Products

Sec.

145.101 Definitions.

145.102 Participation.

145.103 Terminology and classification; flocks and products.

145.104 Terminology and classification; States.

Subpart J—Special Provisions for Egg/Meat-Type Game Bird and Raised-for-Release Game

Bird Breeding Flocks and Products

§ 145.101 Definitions.

Except where the context otherwise requires, for the purposes of this subpart the following terms shall be construed, respectively, to mean:

Egg/meat-type bird. Birds grown under confinement for the primary purpose of producing eggs and/or meat for human consumption.

Game birds. Domesticated fowl such as pheasants, partridge, quail, grouse, and guineas, but not doves and pigeons.

Raised-for-release bird. Birds grown under confinement for the primary purpose of producing eggs, chicks, started, or mature birds for release on game preserves or in the wild.

§ 145.102 Participation.

Participating flocks of egg/meat-type game birds, raised-for-release game birds, and the products produced from them shall comply with the applicable general provisions of subpart A

of this part and the special provisions of this subpart. Participation is broken into the following categories of operation and products:

(a) The categories for operation are:

(1) *Breeder*. An individual or business that maintains a breeding flock for the purpose of producing eggs, chicks, started, or mature birds. A breeder that is also a hatchery and/or grower shall be categorized as a breeder.

(2) *Hatchery*. A category of operations in which an individual or business does not have a breeding flock, but hatches eggs for the purpose of producing chicks, started, or mature birds. A hatchery that is also a grower shall be categorized as a hatchery.

(3) *Grower*. A category of operations in which an individual or business does not have a breeding flock or hatchery, but raises birds for the purpose of selling started or mature birds.

(4) *Dealer*. An individual or business that resells eggs, chicks, started, or mature birds. Products a dealer handles are typically resold within 30 days or less.

(b) The categories for products are:

(1) *Egg*. An egg laid by a female bird for the purpose of hatching a chick.

(2) *Chick*. A bird that is newly hatched from an egg.

(3) *Started Bird*. A bird that is between the age of a newly hatched chick and a mature bird.

(4) *Mature Bird*. A bird that is fully colored and has reached the average maximum size specific to each species.

(c) Products shall lose their identity under Plan terminology when not maintained by Plan participants under the conditions prescribed in § 145.5(a).

(d) Hatching eggs produced by breeding flocks shall be nest clean, fumigated, or otherwise sanitized in accordance with part 147 of this subchapter.

(e) It is recommended that gallinaceous flocks and waterfowl flocks be kept separate.

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

(g) A flock of game birds that are not breeders, but are located on the same premise as game bird breeders, shall be covered under the same NPIP hatchery approval number as long as the appropriate testing requirements have been met.

(h) All participating raised-for-release game bird flocks, regardless of whether they are breeders or non-breeders, shall be enrolled under this subpart.

(i) A breeder, hatchery, or grower may also be a dealer without being categorized as a dealer. To resell products under the assigned NPIP number and avoid losing NPIP flock classifications, products must be purchased from an NPIP participant with equal or greater classifications or from a flock with equivalent or greater testing requirements under official supervision.

(j) Subject to the approval of the Service and the Official State Agencies in the importing and exporting States, participating flocks may report poultry sales to importing States by using either VS Form 9-3, "Report of Sales of Hatching Eggs, Chicks, and Poults," or by using an invoice form (9-3I) approved by the Official State Agency and the Service to identify poultry sales to clients. If the 9-3I form is used, the following information must be included on the form:

- (1) The form number "9-3I", printed or stamped on the invoice;
- (2) The seller name and address;
- (3) The date of shipment;

(4) The invoice number;

(5) The purchaser name and address;

(6) The quantity of products sold;

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

(8) The appropriate NPIP illustrative design in § 145.10. One of the designs in § 145.10(b) or (g) must be used. The following information must be provided in or near the NPIP design:

(i) The NPIP State number and NPIP approval number; and

(ii) The NPIP classification for which product is qualified (e.g., U.S. Pullorum-Typhoid Clean).

§ 145.103 Terminology and classification; flocks and products.

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

(a) [Reserved]

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

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

(2) It is a started or mature bird flock that meets the following specifications as determined by the Official State Agency and the Service:

(i) The flock is located in a State where all persons performing poultry disease diagnostic services within the State are required to report to the Official State Agency within 48 hours the source of all poultry specimens from which *S. pullorum* or *S. gallinarum* is isolated;

(ii) The flock is composed entirely of birds that originated from U.S. Pullorum-Typhoid Clean breeding flocks or from flocks that met equivalent requirements under official supervision; and

(iii) The flock is located on a premises where a flock not classified as U.S. Pullorum-Typhoid Clean was located the previous year; *Provided*, That an Authorized Testing Agent must blood test up to 300 birds per flock, as described in § 145.14, if the Official State Agency determines that the flock has been exposed to pullorum-typhoid. In making determinations of exposure and setting the number of birds to be blood tested, the Official State Agency shall evaluate the results of any blood tests, described in § 145.14(a)(1), that were performed on an unclassified flock located on the premises during the previous year; the origins of the unclassified flock; and the probability of contacts between the flock for which qualification is being sought and infected wild birds, contaminated feed or waste, or birds, equipment, supplies, or personnel from flocks infected with pullorum-typhoid.

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

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

(ii) All hatchery supply flocks within the State, are qualified as U.S. Pullorum-Typhoid Clean or have met equivalent requirements for pullorum-typhoid control under official supervision: *Provided*, That if other domesticated fowl, except waterfowl, are maintained on the same premises as the participating flock, freedom from pullorum-typhoid infection shall be demonstrated by an official blood test of each of these fowl;

(iii) All shipments of products other than U.S. Pullorum-Typhoid Clean, or equivalent, into the State are prohibited;

(iv) All persons performing poultry disease diagnostic services within the State are required to report to the Official State Agency within 48 hours the source of all poultry specimens from which *S. pullorum* or *S. gallinarum* is isolated;

(v) All reports of any disease outbreak involving a disease covered under the Plan are promptly followed by an investigation by the Official State Agency to determine the origin of the infection; *Provided*, That if the origin of the infection involves another State, or if there is exposure to poultry in another State from the infected flock, then the National Poultry Improvement Plan will conduct an investigation;

(vi) All flocks found to be infected with pullorum or typhoid are quarantined until marketed or destroyed under the supervision of the Official State Agency, or until subsequently

blood tested, following the procedure for reacting flocks as contained in § 145.14(a)(5), and all birds fail to demonstrate pullorum or typhoid infection;

(vii) All poultry, including exhibition, exotic, and game birds, but excluding waterfowl, going to public exhibition shall come from U.S. Pullorum-Typhoid Clean or equivalent flocks, or have had a negative pullorum-typhoid test within 90 days of going to public exhibition; and

(viii) The flock is located in a State in which pullorum disease or fowl typhoid is not known to exist nor to have existed in hatchery supply flocks within the State during the preceding 24 months.

(ix) Discontinuation of any of the conditions or procedures described in paragraphs (b)(3)(i) through (viii) of this section, or the occurrence of repeated outbreaks of pullorum or typhoid in poultry breeding flocks within or originating within the State shall be grounds for the Service to revoke its determination that such conditions and procedures have been met or complied with. Such action shall not be taken until a thorough investigation has been made by the Service and the Official State Agency has been given an opportunity to present its views.

(c) *U.S. H5/H7 Avian Influenza Clean*. The program in this paragraph (c) is intended to be the basis from which the game bird industry may conduct a program for the prevention and control of the H5 and H7 subtypes of avian influenza. It is intended to determine the presence of the H5 and H7 subtypes of avian influenza in game bird flocks through routine surveillance of each participating flock. A flock or premise, and the hatching eggs, chicks, started, and mature birds produced from it, will qualify for the classification in this paragraph (c) when the Official State Agency determines that it has met the following requirements:

(1) It is a 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. To retain the classification in this paragraph (c):

(i) A sample of at least 30 birds must be tested negative at intervals of 90 days; or

(ii) A sample of fewer than 30 birds may be tested, and found to be negative, at any one time if all pens are equally represented and a total of 30 birds are tested within each 90-day period.

(2) For participants with non-breeding flocks retained for raised-for-release or other purposes on the same premises as a breeding flock, a representative sample of at least 30 birds from the participating premise must be tested negative to the H5 and H7 subtypes of avian influenza as provided in § 145.14(d) when more than 4 months of age, every 90 days.

(d) *U.S. Salmonella Monitored.* The program in this paragraph (d) is intended to be the basis from which the game bird 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 the classification in this paragraph (d):

(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 the classification in this paragraph (d), all products shall be derived from a hatchery that meets the requirements of the classification.

(3) The classification in this paragraph (d) may be revoked by the Official State Agency if the participant fails to follow recommended corrective measures.

§ 145.104 Terminology and classification; States.

(a) *U.S. Pullorum-Typhoid Clean State.* (1) A State will be declared a U.S. Pullorum-Typhoid Clean State when it has been determined by the Service that:

(i) The State is in compliance with the provisions contained in §§ 145.23(b)(3)(i) through (vii), 145.33(b)(3)(i) through (vii), 145.43(b)(3)(i) through (vi), 145.53(b)(3)(i) through (vii), 145.73(b)(2)(i), 145.83(b)(2)(i), 145.93(b)(3)(i) through (vii), and 145.103(b)(3)(i) through (ix).

(ii) No pullorum disease or fowl typhoid is known to exist nor to have existed in hatchery supply flocks within the State during the preceding 12 months: *Provided*, That pullorum disease or fowl typhoid found within the preceding 24 months in waterfowl, exhibition poultry, and game bird breeding flocks will not prevent a State, which is otherwise eligible, from qualifying.

(2) Discontinuation of any of the conditions described in paragraph (a)(1)(i) of this section, or repeated outbreaks of pullorum or typhoid occur in hatchery supply flocks described in paragraph (a)(1)(ii) of this section, or if an infection spreads from the originating premises, the Service shall have grounds to revoke its determination that the State is entitled to the classification in this paragraph (a). Such action shall not be taken until a thorough investigation has been made by the Service and the Official State Agency has been given an opportunity for a hearing in accordance with rules of practice adopted by the Administrator.

(b) [Reserved]

PART 146–NATIONAL POULTRY IMPROVEMENT PLAN FOR COMMERCIAL
POULTRY

32. 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.

33. Section 146.13 is amended as follows:

a. By revising paragraph (b)(1); and

b. In paragraph (b)(2) introductory text, by removing the words “matrix gene or protein” and adding the word “virus” in their place.

The revision reads as follows:

§ 146.13 Testing.

* * * * *

(b) * * *

(1) *Antibody detection tests--(i) Enzyme-linked immunosorbent assay (ELISA) test.* (A)

The ELISA test must be conducted using test kits approved by the Department and the Official State Agency and must be conducted in accordance with the recommendations of the producer or manufacturer.

(B) When positive ELISA samples are identified, an AGID test must be conducted within 48 hours.

(ii) *Agar gel immunodiffusion (AGID) test.* (A) The AGID test must be conducted using reagents approved by the Department and the Official State Agency.

(B) The AGID test for avian influenza must be conducted in accordance with this section (within the NPIP Program Standards, Program Standard A applies to blood and yolk testing procedures; alternatives to the program standards may also be approved by the Administrator under § 147.53) for the avian influenza agar gel immunodiffusion (AGID) test. The test can be conducted on egg yolk or blood samples. The AGID test is not recommended for use in waterfowl.

(C) Positive tests for the AGID must be further tested by Federal Reference Laboratories using appropriate tests for confirmation. Final judgment may be based upon further sampling and appropriate tests for confirmation.

* * * * *

34. Section 146.51 is revised to read as follows:

§ 146.51 Definitions.

Except where the context otherwise requires, for the purposes of this subpart the following terms shall be construed, respectively, to mean:

Egg/meat-type game birds. Domesticated fowl such as pheasants, partridge, quail, grouse, and guineas, but not doves and pigeons grown under confinement for the primary purposes of producing eggs and/or meat for human consumption.

Egg/meat-type waterfowl. Domesticated ducks or geese grown under confinement for the primary purposes of producing eggs and/or meat for human consumption.

Meat-type game bird slaughter plant. A meat-type game bird slaughter plant that is federally inspected or under State inspection that the U.S. Department of Agriculture's Food Safety and Inspection Service has recognized as equivalent to Federal inspection.

Meat-type waterfowl slaughter plant. A meat-type waterfowl slaughter plant that is federally inspected or under State inspection that the U.S. Department of Agriculture's Food Safety and Inspection Service has recognized as equivalent to Federal inspection.

Shift. The working period of a group of employees who are on duty at the same time.

35. Section 146.52 is revised to read as follows:

§ 146.52 Participation.

(a) Participating meat-type game bird slaughter plants, meat-type waterfowl slaughter plants, and egg-type game bird and egg-type waterfowl premises producing eggs for human consumption shall comply with the applicable general provisions of subpart A of this part and the special provisions of this subpart.

(b) Meat-type game bird slaughter plants and Meat-type waterfowl slaughter plants that slaughter fewer than 50,000 birds annually are exempt from the special provisions of this subpart.

(c) Egg-type game bird and egg-type waterfowl premises with fewer than 25,000 birds are exempt from the special provisions of this subpart.

36. Section 146.53 is amended as follows:

a. In the introductory text, by adding the words “slaughter plants and” after the word “participating”;

b. By revising paragraph (a) introductory text;

c. In paragraph (a)(1), by removing the words “commercial upland” and adding the word “meat-type” in their place and by removing the word “commercial” and adding the word “meat-type” in its place;

d. By revising paragraph (a)(2);

e. In paragraph (a)(3), by removing the words “commercial upland” and adding the word “meat-type” in their place and by removing the word “commercial” and adding the word “meat-type” in its place;

f. In paragraph (a)(4), by removing the words “a commercial upland” and adding the words “an egg-type” in their place and by adding the word “egg-type” after the words “game bird or”.

g. In paragraph (a)(5), by removing the words “a commercial upland” and adding the words “an egg-type” in their place and by adding the word “egg-type” after the words “game bird or”.

h. By removing and reserving paragraph (b).

The revisions read as follows:

§ 146.53 Terminology and classification; slaughter plants and premises.

* * * * *

(a) *U.S. H5/H7 Avian Influenza Monitored.* The program in this paragraph (a) is intended to be the basis from which the egg/meat-type game bird and egg/meat-type waterfowl 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 egg/meat-type game birds and egg/meat-type waterfowl through routine surveillance of each participating slaughter plant or, in the case of egg-producing flocks, the regular surveillance of these flocks. A slaughter plant or flock will qualify for the classification in this paragraph (a) when the Official State Agency determines that it has met one of the following requirements:

* * * * *

(2) It is a meat-type game bird slaughter plant or meat-type waterfowl slaughter plant that only accepts egg/meat-type game birds or egg/meat-type waterfowl from flocks where a minimum of 11 birds per flock have been tested negative for the H5/H7 subtypes of avian influenza, as provided in § 146.13(b), no more than 21 days prior to slaughter;

* * * * *

PART 147–AUXILIARY PROVISIONS ON NATIONAL POULTRY IMPROVEMENT
PLAN

37. 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.

38. Section 147.45 is revised to read as follows:

§ 147.45 Official delegates.

Each cooperating State shall be entitled to one official delegate for each of the programs prescribed in parts 145 and 146 of this subchapter in which it has one or more participants at the time of the Conference. The official delegates shall be elected by a representative group of participating industry members and be certified by the Official State Agency. It is recommended but not required that the official delegates be Plan participants. Individuals may be allowed to be an official delegate or alternate delegate for up to three States in which that delegate has flocks or is a plan participant with acknowledgement and approval of the Official State Agencies. Each official delegate shall endeavor to obtain, prior to the Conference, the recommendations of industry members of their State with respect to each proposed change.

39. Section 147.48 is revised to read as follows:

§ 147.48 Approval of conference recommendations by the Department.

Proposals adopted by the official delegates will be recommended to the Department for incorporation into the provisions of the National Poultry Improvement Plan (NPIP) in parts 56, 145, and 146 of this chapter and this subpart. The Department reserves the right to approve or disapprove the recommendations of the conference as an integral part of its sponsorship of the National Poultry Improvement Plan. The Department will publish the recommendations in the *Federal Register* within 14 months following the NPIP Biennial Conference.

40. In § 147.52, paragraph (b) is revised to read as follows:

§ 147.52 Authorized laboratories.

* * * * *

(b) *Trained technicians.* Testing procedures at all authorized laboratories must be run or overseen by a laboratory technician who every 4 years has attended, and satisfactorily completed, Service-approved laboratory workshops for Plan-specific diseases.

* * * * *

Done in Washington, DC, this 28th day of October 2019 .

Kevin Shea

Administrator, Animal and Plant Health Inspection Service.
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