DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Parts 56, 145, 146, and 147

[Docket No. APHIS–2011–0101]

RIN 0579–AD83

National Poultry Improvement Plan and Auxiliary Provisions

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Proposed rule.

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

DATES: We will consider all comments that we receive on or before March 31, 2014.

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

- Federal eRulemaking Portal: Go to *http://www.regulations.gov/#!documentDetail;D=APHIS-2011-0101-0001.*
- Postal Mail/Commercial Delivery: Send your comment to Docket No. APHIS–2011–0101, 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-2011-0101* or in our reading room, which is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 799–7039 before coming.

FOR FURTHER INFORMATION CONTACT: Dr. Denise Brinson, DVM, Acting Director, 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, flocks, hatcheries, dealers, and slaughter plants that meet certain disease control standards specified in the Plan's various programs. As a result, customers can buy poultry that has tested clean of certain diseases or that has been produced under disease-prevention conditions.

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

The proposed amendments discussed in this document are consistent with the recommendations approved by the voting delegates to the last two National Plan Conferences, which were held on September 1 and 2, 2010, and September 25 through 27, 2012. Participants in both National Plan Conferences represented flockowners, breeders, hatcherymen, slaughter plants, and Official State Agencies from all cooperating States.

We are proposing two major changes to the regulations. One is to remove tests and detailed testing procedures, as well as sanitation procedures, from the regulations in part 147. The regulations in part 147 would instead indicate that tests and sanitation procedures must be approved by the Administrator and can be found in an NPIP Program Standards document. The other is to establish U.S. H5/H7 Avian Influenza Clean Compartment and U.S. Avian Influenza Clean Compartment classifications for defined subpopulations of primary breeding turkeys, primary egg-type breeding chickens, and primary meat-type breeding chickens. These changes are the first discussed below. The remaining proposed amendments are discussed in the order they would appear in the regulations.

Moving Tests and Sanitation Procedures From 9 CFR Part 147 to a Program Standards Document

The NPIP regulations in 9 CFR parts 145 and 146 contain requirements that must be observed by flocks that participate in the Plan. These requirements include requirements to test poultry for the specific disease addressed by each classification in which the flock participates. The procedures by which that testing is conducted are largely contained in 9 CFR part 147, subparts A, B, and D. Subpart A sets out blood testing procedures, subpart B sets out bacteriological examination procedures, and subpart D sets out molecular examination procedures, which currently include polymerase chain reaction (PCR) tests.

Some of these tests are referred to specifically in 9 CFR parts 145 and 146. In addition, §§ 145.14 and 146.13 contain some requirements for the use of various tests in part 147 to determine whether flocks are eligible for certain NPIP classifications.

Subpart C of part 147 contains various sanitation procedures. These are set out as guidelines for the production of healthy poultry, although some of them are referred to in parts 145 and 146.

We are proposing to move the tests and sanitation procedures in subparts A, B, C, and D of part 147 to an NPIP Program Standards document, which would be made available to the public on the NPIP's Web site.[1] We would take public comments on changes to the NPIP Program Standards through notices published in the **Federal Register**, rather than through the rulemaking process that we currently use.

We are proposing to take this action for several reasons. First, there are constant changes in the science and technology that go into developing effective, efficient tests. In order to have a successful voluntary program to

[1] *http://www.aphis.usda.gov/animal_health/animal_dis_spec/poultry/*

reduce the incidence of disease in poultry, we need to be able to update the NPIP testing procedures when new scientific evidence indicates that different procedures can increase the reliability of a test, or when new technology is developed to make a test more efficient or accurate.

In addition, new tests are also continually developed that can provide valuable alternatives to existing approved tests. For example, there has been a great deal of progress in developing PCR tests in recent years. Adding such tests allows NPIP participants to take advantage of the latest testing technology.

Similarly, the sanitation procedures used as best practices to prevent the introduction or spread of disease in a poultry flock are constantly changing, as more information becomes available about possible sources of infection and about the effectiveness of various means of preventing infection.

In the past, we have updated the regulations once every 2 years, following the biennial Plan Conference. However, with the continual changes in diagnostic science and testing technology, and in best practices for maintaining sanitation, the biennial update schedule has resulted in the regulations becoming out-of-date between updates. When this happens, sometimes the Plan's General Conference Committee (GCC) approves interim changes to the tests or sanitation procedures in accordance with the process outlined in § 147.43(d)(5)(iii).

However, it would make the program more effective if all participants could be made aware of the new tests and sanitation procedures as soon as possible, by updating a document recognized in the regulations as a resource for tests and sanitation procedures. Moving the testing and sanitation procedures to an NPIP Program Standards document, and replacing those procedures in the regulations with performance standards as described below, would allow for quicker updates to the allowed testing and sanitation procedures while continuing to allow for public comment on the testing and sanitation procedures. This would potentially make those updates available to producers and others 2 years or more earlier than they could be made available through the rulemaking process we currently use.

Finally, tests can be difficult to render in the regulations. The current regulations in §§ 147.11 and 147.12, for example, contain diagrams and flowcharts that are part of larger processes, all of which require several pages to describe in narrative format. We believe that it that would be easier to understand some of our tests if they were laid out in another fashion, which would be possible in an NPIP Program Standards document.

The regulations in parts 145 and 146 currently refer to specific sections within part 147. We are proposing to revise these references to state more generally that tests must be conducted and sanitation must be maintained in accordance with part 147. For example, we are proposing to replace references to conducting egg yolk testing for *Mycoplasma* in accordance with § 147.8 with references to conducting such testing in accordance with 9 CFR part 147 generally. We are proposing to replace references to maintaining flocks in *Mycoplasma* classifications in compliance with the *Mycoplasma* and *Salmonella* sanitation procedures in § 147.26 with references to maintaining the flock in accordance with part 147 with respect to *Mycoplasma* isolation, sanitation, and management. Similar changes would be made with respect to other tests and sanitation procedures. The specific changes we are proposing to make are set out in the regulatory text at the end of this document.

In subparts A, B, and D of part 147, we are proposing to indicate that blood testing, bacteriological examination, and molecular examination must be conducted in a manner approved by the Administrator. We would further state that approved testing procedures are listed in the NPIP Program Standards and that testing procedures may also be approved by the Administrator, as described in provisions we are proposing to add to subpart F of part 147. Subpart C would contain a similar placeholder for sanitation procedures.

Subpart F of part 147 currently sets out procedures for approving authorized laboratories (in § 147.51) and for approving diagnostic test kits that are not licensed by the Service (in § 147.52). We are proposing to reorganize this subpart and add a new section indicating where to find tests and sanitary procedures and how they are approved.

In our proposed reorganization, a new § 147.51 would set out definitions of key terms. *Administrator, Animal and Plant Health Inspection Service (APHIS), Plan or NPIP,* and *NPIP Technical Committee* would be defined as they are elsewhere in the regulations. We are also proposing to define *NPIP Program Standards* as a document that contains tests and sanitation procedures approved by the Administrator in accordance with proposed § 147.53 for use under the regulations in parts 145 and 146. The definition would indicate that this document may be obtained from the NPIP Web site at *http://www.aphis.usda.gov/animal_health/animal_dis_spec/poultry/* or by writing to the Service at National Poultry Improvement Plan, APHIS, USDA, 1506 Klondike Road, Suite 101, Conyers, GA 30094. We would add this definition to § 145.1 as well, as amendments to that part make it necessary to refer to the NPIP Program Standards in part 145.

Proposed § 147.52 would contain the current provisions for approving authorized laboratories, although rather than referring to the laboratories' ability to perform tests in accordance with part 147, the regulations would refer to performing tests in accordance with the NPIP Program Standards or other tests approved by the Administrator in accordance with proposed § 147.53. (We are also proposing to make some changes to this section that are unrelated to the removal of tests from the regulations; these other changes are discussed later in this document.)

Proposed § 147.53 would describe where approved tests and sanitation procedures could be found and the process for changing them. Paragraph (a) of proposed § 147.53 would set out performance standards for the approval tests and sanitation procedures. Paragraph (a)(1) would indicate that all tests that are used to qualify flocks for NPIP classifications must be approved by the Administrator as effective and accurate at determining whether a disease is present in a poultry flock or in the environment. Paragraph (a)(2) would indicate that all sanitation procedures performed as part of qualifying for an NPIP classification must be approved by the Administrator as effective at reducing the risk of incidence of disease in a poultry flock or hatchery.

Paragraph (b) of proposed § 147.53 would indicate that tests and sanitation procedures that have been approved by the Administrator may be found in the NPIP Program Standards. In addition, paragraph (b) would indicate that all tests that use veterinary biologics (e.g., antiserum and other products of biological origin) that are licensed or produced by the Service and used as described in the NPIP Program Standards are approved for use in the NPIP. This provision is found in current § 147.52(a).

Under paragraph (c) of proposed § 147.53, any new tests and sanitation procedures, or changes to existing tests and sanitation procedures, that have been approved by the NPIP in accordance with the process described in 9 CFR part 147 subpart E would be

approved by the Administrator. Subpart E describes the process currently used to consider changes to the NPIP regulations and to other aspects of the NPIP. As noted earlier, it includes provisions for making immediate changes to tests or sanitation procedures when necessary. Proposed paragraph (c) would indicate that NPIP participants may submit new tests and sanitation procedures, or changes to current tests and sanitation procedures, through that process.

Proposed paragraph (d) of § 147.53 would describe the processes for submitting other tests or sanitation procedures for approval by the Administrator and the NPIP Technical Committee. The NPIP Technical Committee is made up of technical experts on poultry health, biosecurity, surveillance, and diagnostics. The committee consists of representatives from the poultry and egg industries, universities, and State and Federal governments and is appointed by the Senior Coordinator and approved by the GCC. The Technical Committee conducts primary review of tests and sanitation procedures submitted at NPIP conferences. The process described in proposed paragraph (d) would be an alternative process for interested persons who do not want to or cannot submit their ideas for changes at an NPIP conference.

Under proposed paragraph (d), persons who wish to have a test or sanitation procedure approved by the Administrator would be able to apply for approval by submitting the test or sanitation procedure, along with any supporting information and data, to the NPIP. Upon receipt of such an application, the Technical Committee would review the test or sanitation procedure and any supporting information and data supplied with the application. If the Administrator and the Technical Committee determine the test or sanitation procedure to be of potential general use, the Administrator would submit the test or sanitation procedure for consideration by the GCC of the NPIP in accordance with subpart E of part 147, and the Administrator would respond with approval or denial of the test or sanitation procedure.

Proposed paragraph (e) would describe the procedure for taking public comment on changes to the Program Standards. When the Administrator approves a new test or sanitation procedure or a change to an existing test or sanitation procedure, APHIS would publish a notice in the **Federal Register** making available the test or sanitation procedure. The notice would also provide for a public comment period, typically of 60 days.

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

- No comments were received on the notice;
- The comments on the notice supported the action described in the notice; or
- The comments on the notice were evaluated but did not change the Administrator's determination that approval of the test or sanitation procedure is appropriate based on the standards in proposed § 147.53(a).

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

Whenever APHIS adds or makes changes to tests or sanitation procedures, APHIS will make available a new version of the NPIP Program Standards that reflects the additions or changes. The new version of the NPIP Program Standards would also be available on the NPIP Web site.

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

We are proposing to move the provisions for approval of test kits from § 147.52 to § 147.54. As noted earlier, proposed § 147.53 would include the provisions currently found in § 147.52(a), meaning it would not be necessary to include § 147.52(a) in proposed § 147.54. Instead, paragraph (b) of § 147.52 would become the entire text of § 147.54.

Paragraph (c) of current § 147.52 lists specific test kits that have been approved for use. We would move this list to the NPIP Program Standards, and a new paragraph (f) would indicate that the list of approved test kits could be found in that document.

We believe these changes would make it easier for APHIS, Official State Agencies, and the poultry industry to implement timely changes to tests and sanitation procedures, while continuing to make those procedures publicly available in an easily accessible document. We welcome public comment on this approach.

At the 2010 NPIP Plan Conference, attendees approved some changes to existing tests and sanitation procedures in part 147, as well as two new molecular examination procedures and a new set of sanitation procedures. (The last of these is discussed briefly under the next heading in this document.)

At the 2012 NPIP Plan Conference, attendees approved a laboratory procedure to establish inter-laboratory equivalence for molecular identification of Plan diseases sampled in the poultry upper respiratory tract; amendments to current approved molecular examination procedures to allow for the use of equally effective diagnostic procedures; new diagnostic test kits; and a statement on the use of cloacal swabs from waterfowl as specimens for the reverse real-time PCR assay in certain circumstances.

If this proposed rule is finalized and the regulations are revised to remove tests and sanitation procedures, we will include the changes to existing tests and sanitation procedures and the new tests and sanitation procedures that were approved at the 2010 and 2012 Plan Conferences in the NPIP Program Standards. We are providing a draft version of the Program Standards that contains these new or revised tests and sanitation procedures, as well as the existing tests and sanitation procedures, to the public for review and comment. It is available on Regulations.gov (see **ADDRESSES** above for instructions on accessing Regulations.gov).

U.S. Avian Influenza Clean Compartment Classifications for Defined Subpopulations of Poultry

We are proposing to establish a new U.S. H5/H7 Avian Influenza Clean Compartment classification for defined subpopulations of primary breeding turkeys and new U.S. Avian Influenza Clean Compartment classifications for defined subpopulations of primary egg-type breeding chickens and primary meat-type breeding chickens. These classifications are based on the compartmentalization guidelines issued by the World Organization of Animal Health (OIE), an international standard-setting body for veterinary health issues in which the United States participates. If these Avian Influenza Clean Compartment classifications are internationally recognized, they would add an option for producers wishing to ensure uninterrupted trade in breeding establishment flocks and products in the event of an avian influenza (AI) outbreak.

The OIE defines a compartment as ''an animal subpopulation contained in one or more establishments under a

common biosecurity management system with a distinct health status with respect to a specific disease or specific diseases for which required surveillance, control and biosecurity measures have been applied for the purpose of international trade.'' [2] An animal subpopulation is defined as ''a distinct part of a population identifiable according to specific common animal health characteristics,'' in this case a common biosecurity level. A subpopulation can be one flock (which the OIE defines as ''a number of animals of one kind kept together under human control or a congregation of gregarious wild animals'') or can be composed of multiple flocks.

Currently, when outbreaks of H5/H7 AI occur, States impose movement restrictions on States or areas within a State that are considered to be affected with H5/H7 AI. In addition, other countries may impose restrictions on the trade of poultry and poultry products from the State or area. In these situations, the remainder of the United States is still considered free of the disease. (The OIE refers to any area treated separately from another area in a country with respect to a disease as a ''zone.'') Individual breeding poultry producers, meanwhile, have been able to use the appropriate AI classification to demonstrate that their flocks, and the hatching eggs, chicks, and poults produced from them, undergo routine serological surveillance for AI and are free from disease. However, when there is an outbreak of H5/H7 AI in a zone (a defined geographical region), all producers within the zone are typically considered to be affected with H5/H7 AI, regardless of whether the disease is present in their flocks, and are thus subject to movement restrictions, including restrictions on export of their products.

As implied above, besides resulting in domestic movement restrictions, the presence of H5/H7 AI in a zone can interrupt exports from that zone. Although low pathogenicity AI (LPAI) is normally not a disease of concern, the H5 and H7 subtypes of LPAI can mutate into highly pathogenic AI (HPAI), a serious disease of birds and other species, including humans. The OIE refers to H5/H7 LPAI and HPAI collectively as notifiable AI (NAI), while the NPIP regulations in part 145 have historically referred to H5/H7 AI as the subtypes of concern. The proposed compartment classifications refer to NAI to be consistent with the OIE standards, although the terms are equivalent.

Although the proposed compartment classifications are concerned only with NAI, the classifications' titles would reflect the flock-level NPIP AI classifications that play crucial roles in the proposed compartment classifications: The primary breeding turkey AI classification refers to H5/H7 AI, and the primary egg-type breeding chicken and meat-type breeding chicken AI classifications refer to AI generally.

As the OIE states, the essential difference between zoning and compartmentalization is that the recognition of zones is based on geographical boundaries, whereas the recognition of compartments is based on epidemiologic boundaries, which are established by management practices and biosecurity. The new U.S. Avian Influenza Clean Compartment classifications would allow primary breeder companies to establish epidemiological boundaries for subpopulations of primary breeding turkeys, primary egg-type chickens, and primary meat-type chickens by establishing management practices and biosecurity for those subpopulations. If recognized as compartments, these subpopulations would not be considered to be affected by an NAI outbreak, even if part or all of the subpopulation was located within a State or an area within a State that was affected with H5/H7 AI, unless required active and passive surveillance showed the disease to be present within the compartment. For example, if a population of primary breeding turkeys located in two States was considered a compartment by our trading partners, and an outbreak of NAI occurred in one of those States, international trade in the products of that compartment from both States could continue uninterrupted. Thus, establishing the U.S. H5/H7 Avian Influenza Clean Compartment classification for primary breeding turkeys and the U.S. Avian Influenza Clean Compartment classifications for primary breeding egg-type chickens and meat-type chickens could give producers additional options with respect to international trade if the compartments are internationally recognized.

We are proposing to add the compartment classifications to the regulations in new §§ 145.45, 145.74, and 145.84, for primary breeding turkeys, primary egg-type breeding chickens, and primary meat-type breeding chickens, respectively. In part 145, the existing subparts for each of those types of poultry contain sections setting out classifications for individual flocks and, in the case of turkeys, for States; we believe that new sections with compartment-level classifications would help to indicate that the classifications apply to entire subpopulations of poultry, and not just individual flocks. The compartment provisions described below would be identical for turkeys, egg-type chickens, and meat-type chickens, except that references to existing flock classifications would be different for each type of poultry.

Proposed paragraph (a) of the new sections would contain the provisions of the U.S. H5/H7 Avian Influenza Clean Compartment classification for turkeys and the U.S. Avian Influenza Clean Compartment classification for egg-type chickens and meat-type chickens. The introductory text of paragraph (a) would state that the compartment program is intended to be the basis from which the primary turkey, egg-type chicken, or meat-type chicken breeding-hatchery industry may demonstrate the existence and implementation of a program that has been approved by the Official State Agency and the Service to establish a compartment consisting of a primary breeding-hatchery company that is free of NAI. This compartment would have the purpose of protecting the defined subpopulation and avoiding the introduction and spread of NAI within that subpopulation by prohibiting contact with other commercial poultry operations, other domestic and wild birds, and other intensive animal operations. (The last includes such operations as swine operations, in which the AI virus can also circulate.)

Proposed paragraph (a)(1) would set out the conditions for definition of the compartment. The primary breeder company seeking to establish a compartment would have to define the compartment with respect to NAI based on the guidelines established by the OIE in the Terrestrial Animal Health Code and the guidelines in proposed paragraph (a). Specifically, the company would have to use a comprehensive biosecurity program to define the compartment as a subpopulation of poultry with a health status for NAI that is separate from birds and poultry outside the compartment. The Official State Agency and the Service would have to approve all documentation submitted to substantiate the defined compartment as adequate to qualify for epidemiological separation from other potential sources of infection of NAI. Guidelines for the definition of the compartment would include:

[2] The OIE's Terrestrial Animal Health Code is available for review at *http://www.oie.int/en/international-standard-setting/terrestrial-code/access-online/*. The definition of a compartment is contained in the glossary. Other chapters of the Code that are relevant to compartmentalization are 4.3, ''Zoning and compartmentalisation,'' and 4.4, ''Application of compartmentalisation.''

Definition and description of the subpopulation of birds and their health status. All poultry included in the compartment would have to be U.S. H5/H7 Avian Influenza Clean in accordance with the classification in § 145.43(g) (for turkeys), or U.S. Avian Influenza Clean in accordance with the classifications in §§ 145.73(f) (for egg-type chickens) or 145.83(g) (for meat-type chickens). The poultry would also have to be located in a State that has an initial State response and containment plan approved by APHIS under § 56.10 and that participates in the diagnostic surveillance program for H5/H7 LPAI as described in § 145.15. States that have this plan and program in place are cooperators in the voluntary control program for NAI. Within the compartment, all official tests for AI, as described in § 145.14(d), would have to be conducted in NPIP authorized laboratories or in State or Federal laboratories.

In addition, the company would have to provide to the Service upon request any relevant historical and current NAI-related data for reference regarding surveillance for the disease within the compartment. Upon request, the company would also work with the Official State Agency to obtain NAI-related data for other bird populations located in the State. This would allow APHIS to evaluate the previous disease status of the compartment and other bird populations located in the State, if necessary.

Description of animal identification and traceability processes. Animal identification and traceability are essential components of a rigorous biosecurity and flock management plan. Accordingly, the primary breeder company would have to include a description of its animal identification and traceability records, including various APHIS forms, set and hatch records, egg receipts, and egg/chick invoices for the subpopulation. Documentation would also have to include breed identification (NPIP stock code). The Service would ensure that an effective flock identification system and traceability system are in place.

Definition and description of the physical components or establishments of the defined compartment. This documentation would establish that the defined compartment is epidemiologically separated from other poultry and bird populations. The documentation would have to be approved by the Official State Agency and the Service as indicating adequate epidemiological separation to maintain the compartment's separate health status with respect to NAI. The documentation would include descriptions of:

- The physical and spatial factors that separate the compartment from surrounding bird populations and affect the biosecurity status of the compartment.
- The relevant environmental factors that may affect exposure of the birds to AI.
- The functional boundary and fencing that are used to control access to the compartment.
- Facilities and procedures to prevent access by wild birds and to provide separation from other relevant hosts.
- The relevant infrastructural factors that may affect exposure to AI, including the construction and design of buildings or physical components, cleaning and disinfection of buildings and physical components between production groups with quality assurance verification, cleaning and disinfection of equipment, and introduction of equipment or material into the compartment.

Definition and description of the functional relationships between components of the defined compartment. Functional relationships between components of the compartment would include traffic movement and flow at and among premises, personnel movement at and among premises, exposure to live bird populations, and any other factors that could affect biosecurity of the compartment.

To address risks associated with functional relationships, all physical components of the compartment would have to be maintained in compliance with hygiene and biosecurity procedures for poultry primary breeding flocks and hatcheries in accordance with 9 CFR part 147. These procedures are best practices designed to address possible sources of infection within a compartment and to prevent the introduction of disease into a compartment. As part of this action, we would establish these approved procedures in the sanitation procedures section of the NPIP Program Standards. The documentation submitted by the company would have to demonstrate the company's consideration of and plan for complying with these procedures. In particular, the company would have to provide a biosecurity plan for the compartment and all included components. The plan would have to include:

- Requirements that company employees and contract growers limit their contact with live birds outside the compartment;
- An education and training program for company employees and contractors;
- Standard operating procedures for company employees, contractors, and outside maintenance personnel;
- Requirements for company employees and non-company personnel who visit any premises within the compartment;
- Company veterinary infrastructure to ensure flock monitoring and disease diagnosis and control measures;
- Policies for management of vehicles and equipment used within the compartment to connect the various premises;
- Farm site requirements (location, layout, and construction);
- Pest (insect and rodent) management program;
- Cleaning and disinfection process; and
- Requirements for litter and dead bird removal and/or disposal.

Description of other factors important for maintaining the compartment. The company veterinary infrastructure would assess sanitary measures, environmental risk factors, and management and husbandry practices that relate to the separation of the compartment and the health status of the birds contained within the compartment that may affect risk of exposure to NAI. This would include internal monitoring and auditing systems (e.g. quality assurance and quality control programs) to demonstrate the effectiveness of the compartment. We would provide the company, upon request, with information on the epidemiology of NAI and the associated risk pathways in which the components of the compartment are located.

Based on the documentation provided, as well as any other information the Service and the Official State Agency determine to be necessary, the Service and the Official State Agency would approve or deny the classification of the compartment as U.S. H5/H7 Avian Influenza Clean or U.S. Avian Influenza Clean.

Proposed paragraph (a)(2) would set out requirements for the company to maintain the U.S. Avian Influenza Clean Compartment classification once it has been established.

The primary breeder company's management of biosecurity, surveillance, and disease control efforts would have to be uniform and equivalent among all components that are a part of the compartment. Oversight and inspection of these management practices would be conducted by the company's licensed, accredited veterinarians. Specifically, veterinary

staff from the Official State Agency and the NPIP would work in partnership with licensed, accredited company veterinarians to train and certify auditors through Service-approved workshops. The trained auditors would conduct biosecurity and operational audits and inspections of facilities and components at least once every 2 years to ensure the integrity of the compartment. These audits would include evaluation of the critical control points and standard operating practices within the compartment, verification of the health status of the flock(s) contained within the compartment, and examination of the biosecurity and management system of the integrated components of the compartment.

The company would also need to maintain its AI Plan classifications for all flocks and products that comprise the compartment, continue to conduct surveillance for NAI within the compartment in accordance with § 145.15, and conduct tests in State and Federal laboratories or in NPIP authorized laboratories. Accredited veterinarians would be responsible for the enforcement of active and passive surveillance of NAI in primary breeder flocks. Baseline health status would have to be maintained and documented for all flocks or subpopulations within the compartment, indicating the dates and negative results of all avian influenza surveillance and monitoring testing, the dates and history of last disease occurrence (if any), the number of outbreaks, and the methods of disease control that were applied.

Documentation of surveillance and testing would be maintained in the company's database and would be verified as required by the Service and/or the Official State Agency, in addition to the reporting required for the AI Clean Plan classifications for all flocks and products and the reporting required under § 145.15.

Proposed paragraph (a)(3) would discuss the activities the Service, in cooperation with the Official State Agencies, will conduct to maintain the compartment once it has been established. This paragraph would clearly spell out how APHIS and the Official State Agencies would work to ensure the continued integrity of any recognized compartments, potentially helping to increase international acceptance of the proposed compartment classifications. Generally, the Service's responsibilities would include:

- Oversight of the establishment and management of compartments;
- Establishment of effective partnerships among the Service, the Plan, and the primary breeder industry;
- Approval or denial of classification of compartments as U.S. H5/H7 Avian Influenza Clean or U.S. Avian Influenza Clean under proposed paragraph (a)(1);
- Official certification of the health status of the compartment, and commodities that may be traded from it, through participation in the Plan for avian diseases, including the active surveillance programs described in §§ 145.43(g), 145.73(f), or 145.83(g), and diagnostic surveillance for H5/H7 LPAI as described in § 145.15;
- Conducting audits of compartments at least once every 2 years to confirm that the primary breeding company's establishments are epidemiologically distinct and pathways for the introduction of disease into the compartment are closed through routine operational procedures and to evaluate and assess the management and husbandry practices relating to biosecurity to determine whether they are in compliance with hygiene and biosecurity procedures for poultry primary breeding flocks and hatcheries in accordance with part 147;
- Providing, upon request, model plans for management and husbandry practices relating to biosecurity in accordance with part 147, risk evaluations in conjunction with the primary breeder industry (including disease surveillance such as VS Form 9–4, ''Summary of Breeding Flock Participation''), and diagnostic capability summaries and systems for initial State response and containment plans in accordance with § 56.10;
- Publicizing and sharing compartment information with international trading partners, upon request, to establish approval and recognition of the compartment, including timeliness and accuracy of disease reporting and surveillance measures as described in §§ 145.15 and 145.43(g), 145.73(f), or 145.83(g).

Proposed paragraph (a)(4) would address emergency response and notification. In the case of a confirmed positive of NAI in the subpopulation of the compartment, the management of the compartment would notify the Service. The Service would immediately suspend the status of the compartment. Compartments would be eligible to resume trade with importing countries only after the compartment has adopted the necessary measures to reestablish the biosecurity level and confirm that NAI is not present in the compartment and the Service has reevaluated the management and biosecurity measures of the compartment and approved said compartment for trade.

Definition of H5/H7 LPAI

The regulations in 9 CFR part 56 set out conditions for the payment of indemnity for costs associated with poultry that are infected with or exposed to H5/H7 LPAI and provisions for a cooperative control program for the disease. This control program involves APHIS, the Official State Agencies that cooperate with APHIS in the administration of the Plan, and Cooperating State Agencies. If the Official State Agency can enforce the movement restrictions and other provisions of part 56, it is the Cooperating State Agency; otherwise, the Cooperating State Agency is the State animal health authority. Part 146 of the regulations contains various active surveillance programs for H5/H7 LPAI in commercial poultry. The terms *H5/H7 low pathogenic avian influenza (LPAI)* and *H5/H7 LPAI virus infection (infected)* are defined in §§ 56.1 and 146.1.

We are proposing to make two editorial changes to the current definition of H5/H7 LPAI. The definition of this term in § 146.1 currently indicates that an H5/H7 AI virus can be considered LPAI when it has an intravenous pathogenicity index test in 6-week-old chickens less than 1.2 or less than 75 percent mortality in 4- to 8-week-old chickens infected intravenously. We would amend the definition to indicate that the pathogenicity index test can be less than or equal to 1.2, and to clarify that the virus causes the mortality in the intravenously infected chickens.

The definition of H5/H7 LPAI in § 56.1 omits the criterion of less than 75 percent mortality in 4- to 8-week-old chickens infected intravenously; we are proposing to add this criterion to the definition in § 56.1, with the proposed wording discussed above, and to make the same clarification about the pathogenicity index test as we are proposing in § 146.1. We are also proposing to add the proposed definition of H5/H7 LPAI to § 145.1, which sets out definitions for the NPIP programs for commercial breeding poultry, as the term H5/H7 LPAI is used extensively in 9 CFR part 145.

Along with providing various diagnostic criteria, the *H5/H7 LPAI virus infection (infected)* definition provides that, in the case of isolated serological positive results, H5/H7 LPAI infection may be ruled out on the basis of a thorough epidemiological investigation that does not demonstrate

further evidence of H5/H7 LPAI infection, as determined by APHIS.

We are proposing to amend this definition to indicate that, in the case of isolated serological positive results, the Cooperating State Agency and the Official State Agency would participate in the determination that a thorough epidemiological investigation does not demonstrate further evidence of H5/H7 LPAI infection. As these agencies cooperate in the administration of the Plan and the H5/H7 LPAI control provisions in part 56, it would be appropriate to involve them in making such a determination.

It is not necessary to add this definition to § 145.1, because the term ''H5/H7 LPAI infection'' is not used in that part.

Additional Information on Compliance Agreements

Section 56.4 sets out provisions for determination of indemnity amounts, including indemnity provided for cleaning and disinfection of premises, conveyances, and materials that came into contact with poultry that are infected with or exposed to H5/H7 LPAI. When indemnity is requested for disposal of poultry, the regulations in paragraph (a)(2) of § 56.4 require that disposal be performed under a compliance agreement between the claimant, the Cooperating State Agency, and APHIS. Similarly, when indemnity is requested for cleaning and disinfection of premises, conveyances, and materials or for disposal of those articles, the regulations in § 56.4(c) require that such activities be performed under a compliance agreement. Requiring such activities to be performed under compliance agreements ensures that the claimant, the Cooperating State Agency, and APHIS have a common understanding of what work is to be performed before that work is undertaken and indemnity is requested for it.

The current regulations do not specify anything about the compliance agreement beyond the fact that it must exist for certain costs to be eligible for indemnification. In the course of responding to H5/H7 LPAI outbreaks, we have developed some more specific requirements for compliance agreements to ensure that they effectively document the activities eligible for indemnity and include other information necessary for the prompt payment of indemnity. We are proposing to add a new paragraph (d) to § 56.4 to set out requirements for a compliance agreement, to ensure a common understanding of what information a compliance agreement must contain and how it will be used.

Paragraph (d) would state that the compliance agreement is a comprehensive document that describes the depopulation, disposal, and cleaning and disinfection plans for poultry that were infected with or exposed to H5/H7 LPAI, or a premises that contained such poultry. It would also indicate that the compliance agreement sets out APHIS responsibilities, owner responsibilities, and Cooperating State Agency responsibilities. The compliance agreement would have to include the owner's name and the name and address of the affected premises. The compliance agreement would have to have signatories that include, but are not necessarily limited to, the owner, the grower (if applicable), the Cooperating State Agency representative, the State veterinarian, and the APHIS area supervisor. Concurrence from these parties would help to prevent misunderstandings.

In addition, the compliance agreement would be required to contain a flock plan with estimated cost breakdowns that include labor, materials, personal protective equipment, travel expenses for personnel involved, and any additional information deemed necessary by the Service. This would ensure a common understanding of the activities to be performed under the compliance agreement.

A compliance agreement is typically submitted in multiple stages as work is undertaken, as changing circumstances can necessitate changes in the compliance agreement. However, it is important that the final compliance agreement be submitted promptly to APHIS so that indemnity can be paid promptly. Accordingly, we would require the final compliance agreement to be submitted to the Service no later than 30 days after the premises is released from quarantine for H5 or H7 LPAI.

Controlled Marketing

Section 56.5 sets out provisions for destruction and disposal of poultry and cleaning and disinfection of premises, conveyances, and materials in the event of an H5/H7 LPAI outbreak. Paragraph (c)(1) of § 56.5 provides that, at the discretion of the Cooperating State Agency and APHIS, poultry that has been infected with or exposed to H5/H7 LPAI can be moved for controlled marketing in accordance with the initial State response and containment plan described in § 56.10, if they are not moved until 21 days after the acute phase of the infection and if they are tested within 7 days of movement and found to be free of the virus.

We are proposing to remove the requirement that poultry may only be moved for controlled marketing after 21 days have passed since the acute phase of the infection. As LPAI is by definition a low pathogenicity disease, it can be difficult to determine the exact acute phase of the infection. Determining the acute phase has caused serious delays in the marketing of LPAI-infected and -exposed flocks.

If States want to permit controlled marketing in the event of an LPAI outbreak, States are required to include provisions for it in their initial State response and containment plans for LPAI. (Section 56.10 sets out the requirements for initial State response and containment plans.) Such provisions must include adequate safeguards to prevent the transmission of the virus from the flock to be moved for controlled marketing, and we are proposing to add two new requirements to paragraph (c) of § 56.5 to ensure that flocks moved for controlled marketing do not spread the virus. Most importantly, the flocks would still need to be tested within 7 days of movement and found to be free of the virus. We believe these constitute adequate safeguards against the spread of LPAI virus. We would replace the 21-day requirement with a requirement that the poultry may not be transported for controlled marketing until approved by the Cooperating State Agency in accordance with the initial State response and containment plan.

We are proposing to add two requirements to the existing controlled marketing requirements, in new paragraphs (c)(1)(iii) and (c)(1)(iv). Proposed paragraph (c)(1)(iii) would require that poultry moved for controlled marketing be moved to slaughter along routes that avoid other commercial poultry operations whenever possible. It would also require all load-out equipment, trailers, and trucks used on premises that have housed poultry that were infected with or exposed to H5/H7 LPAI to be cleaned and disinfected and not enter other poultry premises or facilities for 48 hours after removing such poultry from their premises. These requirements would reduce the risk that poultry and equipment moved for controlled marketing would spread H5/H7 LPAI to other poultry premises or facilities.

Proposed paragraph (c)(1)(iv) would require poultry moved for controlled marketing to be the last poultry marketed during the week they are marketed. Marketing poultry moved for controlled marketing at the end of the

week gives the marketer the weekend to conduct thorough cleaning and disinfection of the market premises, to further mitigate the risk of H5/H7 LPAI transmission. It also minimizes cross traffic with other poultry arriving at the plant.

Updates to Cleaning and Disinfection Guidelines for H5/H7 LPAI

Paragraph (d) of § 56.5 sets out guidelines for the development of a cleaning and disinfection plan for a premises and the materials and conveyances on that premises. We are proposing several updates to those guidelines based on our experience conducting cleaning and disinfection for H5/H7 LPAI and on the latest scientific information regarding the disease.

We note that not all of the guidelines may be applicable to all premises. The initial State response and containment plans for H5/H7 LPAI described in § 56.10 are expected to provide cleaning and disinfection plans tailored to poultry production conditions in each State. Nevertheless, the guidelines in paragraph (d) provide a general model for the development of cleaning and disinfection plans in the initial State response and containment plans, which is why it is important to update them.

Paragraph (d)(1) provides guidelines for preparing for cleaning and disinfection. Paragraph (d)(1)(i) recommends that persons conducting cleaning and disinfection secure and remove all feathers that might blow around outside the house in which the infected or exposed poultry were held by raking them together and burning the pile. We are proposing to indicate that any debris should be secured as well, and that these materials should not be raked together and burned but rather gathered and pushed into the affected poultry house. This would allow the feathers and other materials to be addressed in the confined space of the house at the same time as the materials found inside the house, reducing the risk of spreading H5/H7 LPAI.

Paragraph (d)(1)(iii) recommends that the house in which the poultry were held be closed, maintaining just enough ventilation to remove moisture, and heated to 100 °F to begin composting. After this, the house should be left undisturbed for a minimum of 21 days and as long as possible thereafter to allow as much H5/H7 LPAI virus as possible to die a natural death. Paragraph (d)(1)(iv) then recommends that the house be reheated to 100 °F for the 72 hours prior to cleaning and disinfection. However, the initial heating to 100 °F, the 21-day period, and the subsequent reheating are not necessary, given current knowledge about the time the virus can survive outside of its host and the environmental requirements for its survival. Leaving the house undisturbed for 72 hours, rather than for 21 days and without any heating requirements, would kill H5/H7 LPAI virus that may be present in the house and in any feathers and debris collected in the house. Therefore, we are proposing to indicate that the house should be left undisturbed for a minimum of 72 hours, and we would not indicate that the house should be heated before this period or reheated prior to cleaning and disinfection.

Paragraph (d)(2) of § 56.5 provides guidelines for the cleaning and disinfection process. Paragraph (d)(2)(i) addresses disposal of manure, debris, and feed. The paragraph indicates that manure, debris, and feed should be composted in the house if possible. We are proposing to amend this guideline to indicate that windrowing should be the composting method used when composting is possible. Windrowing (piling the material to be composted into long rows) is suitable to composting large volumes of material, if necessary, and also allows for turning the composted material if necessary to increase the effectiveness of the composting.

The paragraph goes on to discuss various means of disposal of manure, debris, and feed. We are proposing to add a sentence to the guidelines indicating that manure, debris, and feed may be composted on site, left in an undisturbed pile on site, or removed from the site in covered vehicles for disposal. We are also proposing to indicate that land application of manure, debris, and feed should only be performed in accordance with the initial State response and containment plan for H5/H7 LPAI described in § 56.10. Land application can present disease and environmental hazards if not performed in accordance with approved guidelines.

Finally, the current guidelines indicate that the house should not be cleaned out and litter should not be moved or spread until any H5/H7 LPAI virus that may have contaminated the manure and litter is dead, as determined by the Cooperating State Agency. This conflicts with guidance earlier in the paragraph in which a system may be set up for moving manure, debris, and feed to an approved site for burial, piling, or composting. Instead, we would indicate that houses should be cleaned out and litter should be moved or spread only as determined by the Cooperating State Agency and in accordance with the initial State response and containment plan.

Paragraph (d)(3) of § 56.5 provides guidelines for activities after cleaning and disinfection. It currently indicates that premises should be checked for virus before repopulation in accordance with the initial State response and containment plan. We are proposing to amend this to indicate that premises should remain empty until testing provides negative virus detection results and the premises has been checked by the Cooperating State Agency in accordance with the initial State response and containment plan. The proposed text would indicate better what type of check should be made for virus on the premises.

Testing Flocks Before Movement Into Breeder Production Facilities

In § 145.3, paragraph (c) requires that participants submit reports on each breeding flock before the birds in the flock reach 24 weeks of age, or, in the case of ostriches, emus, rheas, and cassowaries, before the birds reach 20 months of age. This report includes identifying information, the source of the birds, and the intended classification of the birds. However, the Plan currently does not contain a requirement that participating flocks be tested for their classifications before moving into breeder production facilities.

It is a common practice in breeding poultry production to move pullets (sexually immature domesticated chickens grown for the primary purpose of producing hatching eggs) or spiking males (males used to increase the fertility of aging breeder hens) from a single poultry house to multiple hen houses. The movement of untested pullets and spiking males puts the industry at risk for unknowingly spreading Plan diseases. Therefore, we are proposing to add a new paragraph (d) to § 145.3 that would require flocks to be qualified for their intended Plan classifications before being moved into breeder production facilities. This proposed change would ensure that poultry being moved into breeder production facilities are free of diseases in their intended Plan classifications.

In paragraph (c) of § 145.3, we are also proposing to make a gender-specific reference gender-neutral and to add the word ''and'' to a series currently written as ''ostriches, emus, rheas, cassowaries.''

Avian Influenza Testing

In § 145.14, which discusses approved tests for breeding poultry and commercial poultry, paragraph (d) sets

out official tests for AI. In § 146.13, which discusses approved tests for commercial poultry, paragraph (b) addresses the same topic as § 145.14(d).

Approved antibody detection tests for AI are set out in paragraph (d)(1) of § 145.14 and (b)(1) of § 146.13. One of these tests is the agar gel immunodiffusion (AGID) test. While this test is reliable for most poultry, it is not reliable for waterfowl. Because the regulations do not currently reflect this, we are proposing to add a statement that the AGID test is not recommended for use in waterfowl.

Paragraph (d)(2)(ii) of § 145.14 and paragraph (b)(2)(ii) of § 146.13 discuss testing for AI with a USDA-licensed type A influenza antigen capture immunoassay (ACIA). These paragraphs indicate that positive results from the ACIA must be further tested by Federal Reference Laboratories using appropriate tests for confirmation. The ACIA test, a screening test typically used on chicken and turkey flocks, is rapid and sensitive but can result in false positives. Conducting another confirmatory test before submitting to a Federal Reference Laboratory would ensure that fewer false positive results are submitted to Federal Reference Laboratories.

Therefore, we are proposing to amend §§ 145.14(d)(2)(ii)(B) and 146.13(b)(2)(ii)(B) to require all chicken and turkey flocks that test positive on the ACIA to be retested using the real-time reverse transcriptase/polymerase chain reaction assay (RRT–PCR) or using virus isolation. If those tests are positive for AI, those results would be further tested by Federal Reference Laboratories for confirmation.

We are proposing to make one other minor change to the AI testing requirements. Paragraphs (d)(2)(i) of § 145.14 and paragraph (b)(2)(i) of § 146.13 both require the RRT–PCR to be conducted using the National Veterinary Services Laboratories (NVSL) official protocol for the RRT–PCR, which has been numbered AVPR01510. However, NVSL now uses a new numbering system, meaning the number of the official protocol has changed, and it may change again in the future. To ensure that the regulations do not point to an incorrect protocol number, we are removing the protocol number from the regulations in §§ 145.14(d)(2)(i) and 146.13(b)(2)(i).

Nest Clean Hatching Eggs for Breeding Chickens

The regulations in §§ 145.22, 145.32, 145.72, and 145.82 provide requirements for participation in the NPIP for multiplier egg-type breeding chickens, multiplier meat-type breeding chickens, primary egg-type breeding chickens, and primary meat-type breeding chickens, respectively. Paragraph (b) of each of these sections requires hatching eggs produced by these flocks to be fumigated according to the procedure in § 147.25 or otherwise sanitized.

Eggs that are collected from nests frequently, to keep them clean without further processing, are known in the poultry industry as ''nest clean'' eggs. In recent years, the chicken industry has found that nest clean eggs hatch better and provide a better chick than other eggs, even when they are sanitized. Consequently, it has become standard practice in both the egg-type and meat-type industries to avoid sanitizing eggs and instead insist on nest clean eggs.

To recognize this practice, we are proposing to amend §§ 145.22(b), 145.32(b), 145.72(b), and 145.82(b) to state that hatching eggs produced by the relevant flocks should be nest clean, and that they may be fumigated in accordance with part 147 or otherwise sanitized.

Changes to AI Clean Programs for Egg-Type Chicken Breeding Flocks

The regulations set out requirements for the U.S. Avian Influenza Clean classification for multiplier egg-type chicken breeding flocks and primary egg-type chicken breeding flocks in §§ 145.23(h) and 145.73(f), respectively. We are proposing to amend certain provisions in these programs and revise their requirements for spent fowl testing.

After breeding chickens are no longer productive, they are moved to slaughter to capture their meat value. This movement provides an opportunity for additional testing to verify a breeding flock's AI Clean status. Currently, paragraph (h)(2) of § 145.23 and paragraph (f)(2) of § 145.73 require that, during each 90-day testing period, all spent fowl up to a maximum of 30 must be tested and found negative within 21 days prior to movement to slaughter. Rather than requiring up to 30 spent fowl to be tested, we are proposing to require instead the testing of a sample of at least 11 birds prior to movement to slaughter. Generally, the entire flock of egg-type breeding chickens will be moved to slaughter at one time. Testing 11 birds per flock is consistent with the testing requirements for meat-type commercial chickens moved to slaughter under the U.S. H5/H7 Avian Influenza Monitored program in § 146.33, and would provide adequate assurance that the flock is free of AI.

In addition, both the multiplier and primary egg-type chicken AI Clean programs indicate that to qualify for the classification, a minimum of 30 birds must be tested negative for antibodies to AI when more than 4 months of age. We are proposing to clarify that the birds must be tested and found negative. We are also proposing to remove the words ''for antibodies,'' as some tests approved in § 145.14 for AI do not test for antibodies but rather for the AI virus itself; this change would allow participants in these AI Clean programs the opportunity to use all of the tests approved in § 145.14 to qualify for these programs.

Changes to AI Clean Programs for Meat-Type Chicken Breeding Flocks

The regulations set out requirements for the U.S. Avian Influenza Clean classification for multiplier meat-type chicken breeding flocks and primary meat-type chicken breeding flocks at §§ 145.33(l) and 145.83(g), respectively. We are proposing to amend certain provisions in these programs and revise their requirements for spent fowl testing, although not in the same way as for egg-type chickens.

Paragraph (l)(1) of § 145.33 and paragraph (g)(1) of § 145.83 require that, to qualify for the classification, a minimum of 30 birds from the flock test negative for antibodies to AI when more than 4 months of age. We are proposing to clarify the requirement for testing by indicating that the testing must be conducted using an approved test described in § 145.14.

Currently, paragraph (h)(2) of § 145.23 and paragraph (f)(2) of § 145.73 require that, during each 90-day testing period, all spent fowl up to a maximum of 30 must be tested and found negative within 21 days prior to movement to slaughter. We are proposing to make two changes to this requirement. First, we would require that the spent fowl be tested serologically for AI, rather than using the agent detection tests listed in paragraph (d)(2) of § 145.14, and we would clarify that the spent fowl would have to be found negative for antibodies to AI. This would make the requirement for testing of spent fowl consistent with the other requirements in the AI Clean programs for primary and multiplier meat-type chickens, which refer to serological testing for antibodies to the virus. Second, we would require the spent fowl to be tested 21 days prior to slaughter, rather than prior to movement to slaughter. This would reduce delays associated with marketing spent fowl while continuing to provide testing to assure the flock's AI Clean status.

New U.S. Salmonella Enteritidis Monitored Classification for Multiplier Meat-Type Breeding Chickens

We are proposing to establish in § 145.33 a new U.S. Salmonella Enteritidis Monitored classification for multiplier meat-type breeding chickens. The classification would be added in a new paragraph (m). This classification would be intended for multiplier meat-type breeders wishing to monitor their breeding flocks for *Salmonella enteritidis* (SE). As SE is both a poultry health and a public health concern, participants would also combine data to help guide decisionmaking on addressing SE and to provide overall data for outside organizations on the prevalence of SE in multiplier meat-type breeding chickens.

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

- The flock originated from a U.S. S. Enteritidis Clean primary meat-type breeding flock.
- The flock is maintained in accordance with 9 CFR part 147 with respect to Salmonella isolation, sanitation, and management.
- Environmental samples are collected from the flock in accordance with 9 CFR part 147 at 16–18 and 40–45 weeks of age. The samples would have to be examined bacteriologically for group D Salmonella at an authorized laboratory, and cultures from group D positive samples would be serotyped.

The following actions would have to be taken with respect to the test results that are generated from the proposed SE monitoring program:

- If SE is isolated from an environmental sample, a thorough evaluation of the practices and programs associated with the sampled flock would have to be conducted with the goal of ascertaining the reason(s) for the positive finding.
- The test results and the results of any evaluations after SE is isolated from an environmental sample would be reported on a quarterly basis to the Official State Agency and the NPIP Senior Coordinator.
- Participating broiler integrators would have to combine their respective test results (and the results of any associated evaluations) to help guide their decisionmaking regarding programs and practices to implement or maintain to address SE.
- Aggregate data regarding the prevalence of SE in participating U.S. meat-type parent breeding flocks would be made available to the U.S. Poultry and Egg Association and the National Chicken Council. Those bodies could use these data to better inform and guide their discussions on this topic with regulators and consumers.

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

Changes to U.S. M. Synoviae Clean Classification for Breeding Turkey Flocks

Paragraph (e) of § 145.43 sets out requirements for the U.S. M. Synoviae Clean classification for turkey breeding flocks. Paragraphs (e)(1) and (e)(2) set out testing requirements for participating flocks to demonstrate that they are free of *Mycoplasma synoviae.* Paragraph (e)(3) sets out an alternative path to qualifying for the classification. Under this paragraph, flocks located on premises which, during 3 consecutive years, have contained breeding flocks qualified as U.S. M. Synoviae Clean, as described in paragraph (e)(1) of § 145.43, may qualify for this classification by a negative blood test of at least 100 birds from flocks of more than 100 and each bird in flocks of 100 or less, when more than 12 weeks of age, and by testing a minimum of 30 samples from male flocks and 60 samples from female flocks at 28–30 weeks of age and at 45 weeks of age.

We are proposing to remove this paragraph. *M. synoviae* is difficult to diagnose in breeding turkeys, with few if any clinical signs. For this reason, we believe that samples should be collected from breeding turkeys and testing performed for this bacterium no less than every 4 to 6 weeks, as required in paragraph (e)(1) of this classification. Removing the option to qualify with less frequent testing in paragraph (e)(3) will help to validate the M. Synoviae Clean status of participating turkey breeding flocks.

In addition, we are proposing to add to the end of paragraph (e)(1), which describes the testing requirements for this classification, a sentence indicating that it is recommended that samples be collected from birds with clinical signs of *M. synoviae* infection. Although, as noted earlier, clinical signs of *M. synoviae* infection in turkeys are rare, concentrating testing on any birds that do show clinical signs of infection will help to find any *M. synoviae* present in the flock.

Changes to Spent Fowl Testing in U.S. H5/H7 Avian Influenza Clean Classification for Breeding Turkey Flocks

Paragraph (g) of § 145.43 sets out requirements for the U.S. H5/H7 Avian Influenza Clean classification for turkey breeding flocks. We are proposing to revise its requirement for spent fowl testing. Currently, paragraph (g)(3) of § 145.43 requires all spent fowl from participating flocks, up to a maximum of 30, to be tested and found negative within 21 days prior to movement to slaughter.

Although paragraph (g) requires testing turkey breeding flocks for AI every 90 days, most commercial turkey breeding flocks participating in the classification test much more frequently. Given the high level of overall surveillance, we believe it is not necessary to test 30 birds when spent fowl are moved to slaughter. Testing 6 birds per flock would be consistent with the testing requirements for meat-type commercial turkey flocks moved to slaughter plants participating in the U.S. H5/H7 Avian Influenza Monitored program in § 146.43, and would provide adequate assurance that the flock is free of AI. Accordingly, we are proposing to revise paragraph (g)(3) to require that all spent fowl from participating flocks that are being marketed for meat be tested at a rate of 6 birds per flock within 21 days prior to movement to slaughter. This change would reduce burdens on participating flockowners while continuing to assure that H5/H7 AI is not present in the flock.

Recommendation for Participating Hobbyist and Exhibition Waterfowl, Exhibition Poultry, and Game Bird Breeding Flocks

Section 145.52 discusses requirements for participation in the Plan for hobbyist and exhibition waterfowl, exhibition poultry, and game bird breeding flocks. We are proposing to add to these requirements a recommendation to keep separate waterfowl flocks and gallinaceous flocks (i.e., game birds and other ''land fowl'') that are housed in open-air facilities. Waterfowl are the primary reservoir for AI virus, and they could easily spread the virus to gallinaceous flocks if they are housed in open-air facilities and not kept separate. This would not be a requirement to participate, but a recommendation to address a potential risk associated with keeping the two types of birds in an open-air facility and improve the overall biosecurity of participating facilities that have both waterfowl and gallinaceous flocks.

Changes to U.S. H5/H7 Avian Influenza Clean Classification for Hobbyist and Exhibition Waterfowl, Exhibition Poultry, and Game Bird Breeding Flocks and Products and for Commercial Waterfowl Breeding Flocks and Products

The regulations in § 145.53 set out classifications for hobbyist and exhibition waterfowl, exhibition poultry, and game bird breeding flocks and products. Paragraph (e) in § 145.53 sets out the U.S. H5/H7 Avian Influenza Clean classification for such poultry.

We are proposing to amend this classification to provide for the testing of cloacal swabs for virus isolation in place of birds for primary and multiplier breeding flocks composed of waterfowl. Waterfowl are more prone than other avian species to AI enteric carrier status, and ducks are somewhat immunologically unresponsive to AI exposure. The lack of an immune response in ducks means that antigenic tests that determine whether the AI virus itself is present, rather than an immune response to it, would provide a more accurate determination of a waterfowl breeding flock's AI status. More accurate AI testing would also reduce the necessity of frequent antibody serotyping to determine whether the AI virus detected in the waterfowl is of the H5 or H7 subtypes that are the focus of this classification.

As noted, this subpart includes hobbyist and exhibition poultry. In such poultry, the difference between a primary breeding flock and a multiplier breeding flock can be less clear than in more commercially oriented poultry sectors. While the U.S. H5/H7 Avian Influenza Clean program currently requires primary breeding flocks of hobbyist and exhibition waterfowl, exhibition poultry, and game birds to be tested at 90-day intervals, as opposed to 180 days for multiplier breeding flocks of such poultry, we do not believe it is necessary to make a distinction between the two types of flocks in this poultry sector. Therefore, we are proposing to change the 90-day testing interval for primary breeding flocks to be the same as the 180-day interval for multiplier breeding flocks. This would make the requirements for primary and multiplier breeding flocks identical; we would retain the separate sets of requirements to parallel other NPIP classifications.

In addition, the U.S. H5/H7 Avian Influenza Clean classification for hobbyist and exhibition waterfowl, exhibition poultry, and game bird breeding flocks and products contains a provision for testing spent fowl similar to those discussed earlier in this document. Specifically, paragraph (e)(3) requires that, during each 90-day period, all spent fowl, up to a maximum of 30, must be tested and found negative within 21 days prior to movement to slaughter. The U.S. H5/H7 Avian Influenza Clean classification for commercial breeding waterfowl, in § 145.93(c), contains an identical provision. We are proposing to amend both of these classifications to require a sample of at least 30 birds to be tested prior to movement to slaughter. Testing at this level is appropriate for these types of poultry, which are at higher risk for AI. We are also proposing to amend the spent fowl testing requirements in these classifications to clarify that the spent fowl must test negative to H5/H7 AI.

Finally, in the U.S. H5/H7 Avian Influenza Clean classification for commercial breeding waterfowl, the spent fowl requirement refers to the fowl being tested serologically. We are proposing to remove the word ''serologically'' to give commercial waterfowl producers the option to use the nonserological tests approved in § 145.13(d).

U.S. Salmonella Monitored Classification for Hobbyist and Exhibition Waterfowl, Exhibition Poultry, and Game Bird Breeding Flocks and Products

We are proposing to add a new U.S. Salmonella Monitored classification for hobbyist and exhibition waterfowl, exhibition poultry, and game bird breeding flocks and products. The classification would be added in a new paragraph (f) in § 145.53. This program is intended to be the basis from which the hatching industry may conduct a program for the prevention and control of salmonellosis. It is intended to reduce the incidence of *Salmonella* organisms in day-old poultry through an effective and practical sanitation program in the hatchery. This program would afford other segments of the poultry industry an opportunity to reduce the incidence of *Salmonella* in their products.

Under this classification, an Authorized Agent would 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 would have to be performed at an authorized laboratory. To claim products are of this classification, all products would have to be derived from a hatchery that meets the requirements of the proposed classification. This classification would be revoked by the Official State Agency if the participant fails to follow recommended corrective measures.

This change would give hobbyist and exhibition waterfowl, exhibition poultry, and game bird breeders an opportunity to participate in a formal *Salmonella* control program.

Changes to U.S. S. Enteritidis Clean Classification for Primary Meat-Type Breeding Chickens

We are proposing several changes to the U.S. S. Enteritidis Clean classification for primary meat-type breeding chickens, which is found in § 145.83(e). These changes are intended to improve the sensitivity of testing and the overall ability to detect SE in primary breeding flocks with additional hatchery samples.

Paragraph (e)(1) of the classification states that a flock and the hatching eggs and chicks produced from it shall be eligible for this classification if the flock originated from a U.S. S. Enteritidis Clean flock or if one of two samples has been examined bacteriologically for *S. enteritidis* at an authorized laboratory and any group D *Salmonella* samples have been serotyped. Paragraph (e)(1)(i)(A) provides the option of testing a sample of a 25-gram sample of meconium from the chicks in the flock, paragraph (e)(1)(i)(B) provides the option of testing a sample of chick papers, and paragraph (e)(1)(i)(C) provides the option of testing a sample of 10 chicks that died within 7 days after hatching.

We are proposing to remove the option of testing meconium, as it does not provide optimal sensitivity to SE. To provide additional sensitivity for the environmental testing, we would expand the option for testing a sample of chick papers to include hatcher tray swabs or fluff. Finally, we are proposing to replace the option of testing a sample of 10 chicks that died within 7 days after hatching with an option to test samples of intestinal and liver or spleen tissues from a minimum of 30 chicks that died within 7 days after hatching and have been preserved daily by freezing prior to shipment to an authorized laboratory. The additional instructions on the type of tissue to be tested and its method of preservation, and the increase in tested samples from 10 to 30, will make the test more sensitive. The proposed options are thus better options for qualifying a primary breeding flock for the U.S. S. Enteritidis Clean classification than those currently in the regulations.

Paragraph (e)(1)(ii) currently contains requirements for feed used in U.S. S. Enteritidis Clean flocks. We are proposing to remove these requirements, as they have become standard industry practice and it is no

longer necessary to include them in the regulations. We would redesignate paragraphs (e)(1)(iii) through (e)(1)(vii) as (e)(1)(ii) through (e)(1)(vi).

Paragraph (e)(1)(iv) currently contains a general requirement to collect and test environmental samples after the flock reaches 4 months of age to maintain the flock's U.S. S. Enteritidis Clean status. We are proposing to add new, more specific requirements for environmental testing after the flock is in egg production and chicks are hatching from it. Environmental samples collected during egg production would have to include at least 4 individual test assay results every 30 days in flocks of more than 500 birds or 2 individual test assay results per month in flocks of 500 birds or fewer. This requirement would ensure that an adequate level of surveillance is conducted. One of these results would have to come from samples collected from hatched chicks at a participating hatchery derived from the flock. This requirement would ensure that the products of the flock are tested for SE on a routine basis and would give a better chance of finding any SE infection. We would indicate that the individual test assays could be derived from pooled samples from the farm or hatchery, but would have to be run as separate test assays in the laboratory, to allow the results to be traced back to the hatchery samples if necessary.

We are not proposing to make any changes to the remaining requirements currently in paragraph (e)(1) of § 145.83, except to reflect moving tests from part 147 to the NPIP Program Standards, as discussed earlier.

Paragraph (e)(3) of § 145.83 sets out followup actions if SE is isolated from an environmental sample. Currently, in such circumstances, 25 randomly selected live birds from the flock and/or 500 cloacal swabs must be bacteriologically examined for SE. If only 1 bird from the 25-bird sample is found positive for SE., the participant may request bacteriological examination of a second 25-bird sample from the flock. If no SE is recovered from any of the specimens in the second sample, the flock will be eligible for the classification and will remain eligible for this classification if the flock is subjected to blood testing each 30 days and no positive samples are found.

We are proposing to change these requirements to make the required testing more sensitive to SE. Instead of testing 25 randomly selected live birds or 500 cloacal swabs, we would require both the bacteriological examination of an additional environmental sampling and 25 live cull birds or fresh dead birds (if present), or 25 other randomly selected live birds if fewer than 25 cull birds can be found in the flock. Requiring the environmental sampling in all cases would increase the chances that this followup testing will find SE if it is present, and the testing of cull birds or fresh dead birds rather than randomly selected birds would concentrate testing on birds most likely to be infected. In addition, if the flock with the SE isolation is in egg production and eggs are under incubation, the regulations would require the next four consecutive hatches to be examined bacteriologically. Samples would be collected from all of the hatching unit's chick trays and basket trays of hatching eggs, or from all chick box papers from the flock, and tested, pooling the samples into a minimum of 10 separate assays. Any followup hatchery-positive SE isolations would result in discontinuation of subsequent hatches until the flock status is determined by bird culture. The flock would be disqualified for the U.S. S. Enteritidis Clean classification if a bird or subsequent flock environmental assay results in isolation of SE. These provisions would provide more certainty regarding the presence of SE in the flock than the current provisions do.

Paragraph (e)(6) of § 145.83 sets out provisions by which a pedigree, experimental, or great-grandparent flock that is removed from the U.S. S. Enteritidis Clean program may be reinstated to the program. We are proposing to make these provisions applicable to grandparent flocks as well, as the corrective measures and testing required in that paragraph would be equally effective at ensuring that a grandparent flock is free of SE as they are for other types of flocks.

These changes would improve the effectiveness of the U.S. S. Enteritidis Clean classification.

New U.S. Salmonella Monitored Classification for Meat-Type Waterfowl Breeding Flocks

Section 145.93 contains various classifications for meat-type waterfowl breeding flocks. (This section applies to commercial meat-type waterfowl breeding flocks, as opposed to the hobbyist and exhibition waterfowl breeding flocks covered by § 145.53.) We are proposing to add a new U.S. Salmonella Monitored classification for meat-type waterfowl breeding flocks and products. The classification would be added in a new paragraph (d) in § 145.93.

The proposed program is intended to be the basis from which the meat-type waterfowl breeding-hatching industry may conduct a program for the prevention and control of salmonellosis. It is intended to reduce the incidence of Salmonella organisms in hatching eggs and day-old waterfowl through an effective and practical sanitation program at the breeder farm and in the hatchery. This would afford other segments of the poultry industry an opportunity to reduce the incidence of Salmonella in their products.

A flock and the hatching eggs and day-old waterfowl produced from it would have to meet the following requirements, as determined by the Official State Agency, to be eligible for this classification:

- The flock would have to be maintained in compliance with isolation, sanitation, and management procedures for Salmonella in accordance with part 147.
- If feed contains animal protein, the protein products would have to have been heated throughout to a minimum temperature of 190 °F or above, or to a minimum temperature of 165 °F for at least 20 minutes, or to a minimum temperature of 184 °F under 70 lbs. pressure during the manufacturing process. These heating requirements would prevent Salmonella from being introduced into the flock via feed.
- Feed would have to be stored and transported in a manner that prevents contamination.
- Waterfowl would have to be hatched in a hatchery whose sanitation is maintained in accordance with part 147 and sanitized or fumigated in accordance with part 147.
- An Authorized Agent would take environmental samples from the hatchery every 30 days, i.e., meconium or box liner paper. An authorized laboratory for Salmonella would examine the samples bacteriologically.
- In addition, an Authorized Agent would take environmental samples in accordance with part 147 from each flock at 4 months of age and every 30 days thereafter, and an authorized laboratory for Salmonella would examine the environmental samples bacteriologically.
- Flocks would be allowed to be vaccinated with a paratyphoid vaccine (which helps to protect birds against Salmonella), provided that a sample of at least 100 birds is segregated and remains unvaccinated until the flock reaches at least 4 months of age. Requiring some birds to be segregated and unvaccinated would ensure that they can be tested for Salmonella without the antibodies from the vaccine causing false-positive results.

The Official State Agency would monitor the effectiveness of the egg

sanitation practices in accordance with part 147. To claim products are of this classification, all products would have to be derived from a hatchery and flock that meet the requirements of the proposed classification. Finally, this classification would be revoked by the Official State Agency if the participant fails to follow recommended corrective measures.

Clarification of Testing Requirements for Participating Slaughter Plants

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

Under subparts C, D, and E of part 146, slaughter plants for various types of poultry can participate, provided that they meet certain testing requirements. One option available for all types of slaughter plants is to slaughter only birds from flocks where a specified number of birds have been tested and found negative for H5/H7 AI no more than 21 days prior to slaughter.

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

We are proposing to amend paragraph (b) to refer to samples being collected and tested and to results being returned prior to movement to slaughter. These changes would clarify the requirements and make the regulations in § 146.11(b) consistent with the relevant U.S. H5/H7 Avian Influenza Monitored classifications. In addition, it is important to have the test results for a flock returned prior to movement to slaughter to prevent the flock from being exposed to other, healthy birds and possibly requiring cleaning and disinfection at the slaughter plant.

Clarifying Testing Requirements for Commercial Table-Egg Layer Pullet Flocks and Table-Egg Layer Flocks

The regulations in § 146.23(a) provide the U.S. H5/H7 Avian Influenza Monitored classification for table-egg layer pullet flocks and table-egg layer flocks. Separate testing requirements are set out for each type of flock in paragraphs (a)(1) and (a)(2), respectively. The introductory text for paragraph (a) addresses the table-egg layer industry generally, including both table-egg layer pullet flocks and table-egg layer flocks. This has caused some confusion. To make it clear that each type of flock needs to participate and maintain its classification separately, we are proposing to reformat paragraph (a) so that it includes introductory text in paragraphs (a)(1) and (a)(2) that is specific to each type of flock. The testing requirements would remain the same.

Providing for Spent Fowl To Participate in H5/H7 LPAI Control Program for Commercial Meat-Type Chickens

The regulations in part 146 do not provide explicitly for the participation of spent fowl. Spent fowl are domesticated poultry, typically chickens, that were in production of hatching eggs or commercial table eggs and have been removed from such production. Although they were not raised for the primary purpose of meat production, such fowl no longer have value as layers and thus are slaughtered for meat at meat-type chicken slaughter plants.

However, the special provisions for the participation of meat-type chicken slaughter plants in subpart C of part 146 (§§ 146.31 through 146.33) define *meat-type chicken* as a domesticated chicken grown for the primary purpose of producing meat, including but not limited to broilers, roasters, fryers, and cornish, meaning spent fowl are not specifically authorized to participate under those provisions. Accordingly, we are proposing to amend subpart C to provide for the participation of spent fowl in the meat-type chicken slaughter plant provisions.

We are proposing to define *spent fowl* in § 146.31 with the definition given above. We would add a new paragraph (c) to § 146.32, which discusses participation in the special provisions for meat-type chicken slaughter plants, indicating that spent fowl slaughtered at meat-type chicken slaughter plants that participate in the NPIP may participate in the NPIP under the provisions of subpart C.

We are also proposing to amend the U.S. H5/H7 Avian Influenza Monitored classification in § 146.33. This classification provides three options for participation in the program. Two of those options refer generically to birds tested at the slaughter plants or otherwise under surveillance testing and thus could apply both to meat-type chickens and spent fowl without modification. The third requires meat-type chicken slaughter plants to accept only meat-type chickens from flocks where surveillance is performed for H5/H7 AI. We would amend this option to indicate that meat-type chicken slaughter plants could also accept spent fowl from flocks where surveillance was being performed for H5/H7 AI. The surveillance requirements for meat-type chickens and spent fowl would be the same, as they are based on statistical principles for disease detection.

These changes would necessitate two minor changes elsewhere in part 146. To accommodate spent fowl flocks that may wish to participate in a State other than the State in which they are located, we would amend the definition of *commercial meat-type flock* in § 146.1 to include spent fowl, so that provisions allowing commercial meat-type flocks to participate with another Official State Agency in § 146.2(c) would apply to spent fowl as well. In § 146.3, we would amend the requirement in paragraph (c) that a participating slaughter plant participate with all the poultry processed at that facility to include spent fowl.

These changes would allow spent fowl flocks to participate in the U.S. H5/H7 Avian Influenza Monitored program, thus providing for additional surveillance for H5/H7 LPAI in the poultry industry overall.

Changes to the U.S. H5/H7 Avian Influenza Monitored Classifications for Commercial Meat-Type Chickens and Turkey Slaughter Plants

Besides the changes related to including spent fowl in the classification, we are proposing to clarify some wording in the U.S. H5/H7 Avian Influenza Monitored classification for commercial meat-type chicken slaughter plants. Paragraph (a)(2) of § 146.33 provides participating slaughter plants the option to qualify for the classification if they accept only meat-type chickens from flocks where a minimum of 11 birds have been tested negative for antibodies to the H5/H7 subtypes of avian influenza, as provided in § 146.13(b), no more than 21 days prior to slaughter. This wording has confused some participants in the program regarding when samples should be collected. We are proposing to change it to read ''where samples from a minimum of 11 birds have been collected no more than 21 days prior to slaughter and tested negative to the H5/H7 subtypes of avian influenza.'' We believe this wording will better convey that it is the testing that has to occur no more than 21 days prior to slaughter; the results can come later, as long as they

are available prior to slaughter, consistent with our proposed changes to § 146.11.

Both paragraphs (a)(1) and (a)(2) of this classification refer to testing for antibodies to H5/H7 AI; we are proposing to remove the words ''for antibodies'' to allow for the use of the agent detection tests approved in § 146.13(b).

Paragraph (a) of § 146.43 contains the U.S. H5/H7 Avian Influenza Monitored classification for commercial turkey slaughter plants. Paragraph (a)(1) allows meat-type turkey slaughter plants to participate in the classification if they accept only meat-type turkeys from flocks where a minimum of 6 birds per flock has tested negative for antibodies to type A avian influenza, as provided in § 146.13(b), with an approved test no more than 21 days prior to slaughter. The regulations indicate that positive samples shall be further tested by an authorized laboratory using the hemagglutination inhibition test to detect antibodies to the hemagglutinin subtypes H5 and H7. They also recommend that samples be collected from flocks over 10 weeks of age with respiratory signs such as coughing, sneezing, snicking, sinusitis, or rales; depression; or decreases in food or water intake, to maximize the chances of finding AI should it be present.

We are proposing to revise the testing requirement to read ''where a minimum of 6 samples per flock have been collected no more than 21 days prior to movement to slaughter and tested negative.'' This revised language would help to clarify what is involved in testing. We would require the testing to take place prior to movement to slaughter, rather than prior to slaughter, as an additional precaution. We would also remove the current reference to testing for antibodies.

Finally, we would remove the sentence describing how positive samples would be handled. It is not necessary to specify this in the regulations, as this process is handled by APHIS internally, and we may wish to change the process in the future.

Other Changes to 9 CFR Part 147

As discussed earlier, we are retaining subpart E and revising F of part 147. We are proposing minor changes to those subparts. Subpart E refers to the NPIP Technical Committee, which is defined in § 145.1 but not in part 147. We would add to § 147.41 a definition of *NPIP Technical Committee* that would be identical to the definition in § 145.1. That definition reads: ''A committee made up of technical experts on poultry health, biosecurity, surveillance, and diagnostics. The committee consists of representatives from the poultry and egg industries, universities, and State and Federal governments and is appointed by the Senior Coordinator and approved by the General Conference Committee.''

Besides the proposed changes to the requirements for authorized laboratories discussed earlier, including moving those requirements from § 147.51 to § 147.52, we are proposing some additional amendments. Paragraph (a) of current § 147.51 requires an authorized laboratory to use a regularly scheduled check test for all the tests it performs. We would add text indicating that the NPIP will serve as the lead agency for the coordination of available check tests from the NVSL, which among its other duties provides check tests for authorized laboratories.

Paragraph (b) of current § 147.51 indicates that testing procedures at an authorized laboratory must be run or overseen by a laboratory technician who has attended and satisfactorily completed Service-approved laboratory workshops for Plan-specific diseases within the past 3 years. Cuts to both State and Federal budgets have made it more difficult to provide and attend workshops in recent years. Given these constraints, we are proposing to increase the interval at which the workshops must be given to 4 years. We do not believe this would adversely affect laboratory technician performance given the other requirements for authorized laboratories, which include site visits from the Official State Agency and the Service and reporting requirements; increasing the interval would ease a burden on State and Federal participants.

Paragraph (c) of current § 147.51 indicates that official Plan assays must be performed and reported as described in part 147. Besides amending this paragraph to refer to the NPIP Program Standards or other procedures approved by the Administrator, we would also add that assays must be performed using control reagents approved by the Plan or the reagent manufacturer. This would ensure that control assays are accurate and effective.

Paragraph (d) of current § 147.51 states that the Official State Agency will conduct a site visit and recordkeeping audit annually, but does not describe what the site visit and audit will entail. We would add text indicating that these would include, but may not be limited to, review of technician training records, check test proficiency, and test results. The information from the site visit and recordkeeping audit would also be made available to the NPIP upon request.

We are also proposing to update references to § 147.51 in the definition of *authorized laboratory* in parts 145 and 146, and in the definition of *Senior Coordinator* in part 145, to refer to § 147.52.

Miscellaneous Corrections

The regulations in paragraph (c) of § 145.5 require a flock to participate in the U.S. Pullorum-Typhoid Clean classification in order to participate in the Plan. The list of subparts in 9 CFR part 145 that contain such a classification is out of date. We are proposing to update it to include subparts G, H, and I.

Section 145.10 shows illustrative designs corresponding to various classifications. For some of the classifications, the references to classifications are out of date; for example, the U.S. Pullorum-Typhoid Clean classification whose illustrative design is included in paragraph (a) of § 145.10 now includes classifications in §§ 145.73(b), 145.83(b), and 145.93(b). We are proposing to update that paragraph and other paragraphs in § 145.10 to include all of the classifications in the regulations that correspond to the specified illustrative designs.

In §§ 145.23 and 145.33, paragraph (b) sets out the U.S. Pullorum-Typhoid Clean classification for multiplier breeding egg-type chickens and meat-type chickens, respectively. The introductory text refers to meeting one of the criteria in paragraphs (b)(1) through (b)(5) to qualify for the classification, but these paragraphs only contain subparagraphs (b)(1) through (b)(4). We are proposing to correct the reference accordingly.

In § 145.33, paragraphs (j) and (k) set out requirements for the U.S. M. Gallisepticum Monitored and U.S. M. Synoviae Monitored classifications, respectively, for multiplier breeding meat-type chickens. These classifications prohibit setting eggs from these classifications in hatchers or incubators in which U.S. M. Gallisepticum Clean or U.S. M. Synoviae Clean primary breeding flocks are set. However, the paragraph references for these primary breeding flock classifications are out of date, as the provisions for primary breeding flocks were moved from § 145.33 to § 145.83. We would correct the citations.

In § 146.3, which discusses participation in the Plan for commercial poultry, paragraph (e) states that commercial table-egg layers will cease to participate in the Plan after September 26, 2008, unless the majority

of the commercial table-egg layer delegates vote to continue participation. As the table-egg layer delegates have voted to continue participation, it is not necessary to retain this provision in the regulations, and we are proposing to remove paragraph (e).

Section 147.44 sets out the process for submitting, compiling, and distributing proposed changes to the NPIP. Paragraph (b) of that section indicates that proposed changes shall be submitted in writing so as to reach the Service not later than 150 days prior to the opening date of the Plan Conference, except as provided in paragraph (d)(2) of § 147.43. However, paragraph (d)(2) of § 147.43 does not discuss submission of proposals for changes to the Plan; paragraph (d)(4) does. We would correct the reference in § 147.44(b) accordingly.

Executive Order 12866 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.

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 Web site (see **ADDRESSES** above for instructions for accessing Regulations.gov).

The changes in this proposed rule are recommended by the NPIP GCC, which represents cooperating State agencies and poultry industry members and advises the Secretary of Agriculture on issues pertaining to poultry health. The proposed amendments to these regulations would improve the regulatory environment for poultry and poultry products.

This proposed rule would move approved tests and testing procedures from the Code of Federal Regulations to a program standards document; add compartmentalization standards to the NPIP regulations; and make a number of specific changes, including adding or amending definitions of technical terms to specific sections, amending poultry disease classifications and laboratory procedures, and adding specific tests for certain poultry diseases.

The establishments that would be affected by the proposed 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 would not have a significant economic impact on a substantial number of small entities.

Executive Order 12372

This program/activity is listed in the Catalog of Federal Domestic Assistance under No. 10.025 and is subject to Executive Order 12372, which requires intergovernmental consultation with State and local officials. (See 7 CFR part 3015, subpart V.)

Paperwork Reduction Act

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

List of Subjects

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 revising the definition of *H5/H7 low pathogenic avian influenza (LPAI).*
■ b. In the definition of *H5/H7 LPAI virus infection (infected),* by adding the words ''the Cooperating State Agency, the Official State Agency, and'' before the word ''APHIS''.

The revision reads as follows:

§ 56.1 Definitions.

* * * * *

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

* * * * *

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

§ 56.4 Determination of indemnity amounts.

* * * * *

(d) *Requirements for compliance agreements.* The compliance agreement is a comprehensive document that describes the depopulation, disposal, and cleaning and disinfection plans for poultry that were infected with or exposed to H5/H7 LPAI, or a premises that contained such poultry. The compliance agreement sets out APHIS responsibilities, owner responsibilities, and Cooperating State Agency responsibilities. The compliance agreement must include the owner's name and the name and address of the affected premises. The compliance agreement must have signatories that include, but are not necessarily limited to, the owner, the grower (if applicable), the Cooperating State Agency representative, the State veterinarian, and the APHIS area supervisor. In addition, the compliance agreement must contain a flock plan with estimated cost breakdowns that include labor, materials, personal protective equipment, travel expenses for personnel involved, and any additional information deemed necessary by the Service. The final compliance agreement must be submitted to the Service no later than 30 days after the affected premises is released from quarantine for H5 or H7 LPAI.

* * * * *

■ 4. Section 56.5 is amended as follows:
■ a. By revising paragraph (c)(1)(i).
■ b. By adding new paragraphs (c)(1)(iii) and (c)(1)(iv).
■ c. By revising paragraphs (d)(1)(i) and (d)(1)(iii).
■ d. By removing paragraph (d)(1)(iv).
■ e. By revising the second, third, and fourth sentences after the heading of paragraph (d)(2)(i) and the first sentence after the heading of paragraph (d)(3).

The revisions and additions read as follows:

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

* * * * *

(c) * * *

(1) * * *

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

* * * * *

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

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

* * * * *

(d) * * *

(1) * * *

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

* * * * *

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

(2) * * *

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

* * * * *

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

* * * * *

PART 145—NATIONAL POULTRY IMPROVEMENT PLAN FOR BREEDING POULTRY

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

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

■ 6. Section 145.1 is amended as follows:

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

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

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

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

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

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

The additions read as follows:

§ 145.1 Definitions.

* * * * *

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

* * * * *

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

* * * * *

§ 145.2 [Amended]

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

■ 8. Section 145.3 is amended as follows:

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

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

■ c. By adding a new paragraph (d).

The addition reads as follows:

§ 145.3 Participation.

* * * * *

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

* * * * *

§ 145.5 [Amended]

■ 9. Section 145.5 is amended as follows:

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

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

■ 10. Section 145.6 is amended as follows:

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

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

The revision reads as follows:

§ 145.6 Specific provisions for participating hatcheries.

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

* * * * *

■ 11. Section 145.10 is amended as follows:

■ a. In paragraph (b) introductory text, by removing the words ''and 145.63(a)'' and adding the words ''145.63(a), 145.73(b), 145.83(b), and 145.93(b)'' in their place.
■ b. By revising paragraph (c) introductory text, paragraph (g) introductory text, paragraph (m) introductory text, paragraph (o) introductory text, and paragraph (t) introductory text.

The revisions read as follows:

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

* * * * *

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

* * * * *

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

* * * * *

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

* * * * *

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

* * * * *

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

* * * * *

■ 12. Section 145.14 is amended as follows:
■ a. In paragraph (a)(1), by revising the second sentence.
■ b. In paragraph (a)(6)(ii), by revising the second sentence.
■ c. In paragraph (b)(1), by adding a sentence after the second sentence.
■ d. By revising paragraph (b)(3).
■ e. By revising paragraph (d)(1)(ii)(C).
■ f. In paragraph (d)(2)(i), by removing the word ''(AVPR01510)''.
■ g. By revising paragraph (d)(2)(ii)(B).

The revisions read as follows:

§ 145.14 Testing.

(a) * * *

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

* * *

* * * * *

(6) * * *

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

* * * * *

(b) * * *

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

* * * * *

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

* * * * *

(d) * * *

(1) * * *

(ii) * * *

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

* * * * *

(2) * * *

(ii) * * *

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

* * * * *

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

§ 145.22 Participation.

* * * * *

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

* * * * *

■ 14. Section 145.23 is amended as follows:
■ a. In paragraph (b) introductory text, by removing the citation ''(5)'' and adding the citation ''(b)(4)'' in its place.
■ b. In paragraph (c)(1) introductory text, by removing the words ''in compliance with the provisions of § 147.26 of this chapter'' and adding the words ''in accordance with part 147 of this subchapter with respect to Mycoplasma isolation, sanitation, and management'' in their place.
■ c. In paragraph (c)(1)(ii)(C), by removing the words ''§ 147.8 of this chapter'' and adding the words ''part 147 of this subchapter'' in their place.
■ d. In paragraph (c)(3), by removing the words ''as described in § 147.24(a) of this chapter'' and adding the words ''in accordance with part 147 of this subchapter'' in their place.
■ e. In paragraph (d)(1)(iv), by removing the words ''in compliance with §§ 147.21, 147.24(a), and 147.26 of this chapter'' and adding the words ''in accordance with part 147 of this subchapter with respect to flock sanitation, cleaning and disinfection, and Salmonella isolation, sanitation, and management'' in their place.
■ f. In paragraph (d)(1)(v), by removing the words ''as described in § 147.12 of this chapter'' and adding the words ''in accordance with part 147 of this subchapter'' in their place.
■ g. In paragraphs (d)(1)(vii), by removing the words ''as described in § 147.11 of this chapter'' and adding the words ''in accordance with part 147 of this subchapter'' in their place.
■ h. By revising paragraphs (d)(1)(viii) and (d)(1)(ix).
■ i. In paragraph (d)(2), by removing the words ''as described in § 147.11(a) of this chapter'' and adding the words ''in accordance with part 147 of this subchapter'' in their place.
■ j. In paragraph (e)(1) introductory text, by removing the words ''in compliance with the provisions of § 147.26 of this chapter'' and adding the words ''in accordance with part 147 of this subchapter with respect to Mycoplasma isolation, sanitation, and management'' in their place.
■ k. In paragraph (e)(1)(ii)(B), by removing the words ''§ 147.8 of this chapter'' and adding the words ''part 147 of this subchapter'' in their place.
■ l. In paragraph (e)(3), by removing the words ''as described in § 147.24(a) of this chapter'' and adding the words ''in accordance with part 147 of this subchapter'' in their place.
■ m. In paragraph (f)(3), by removing the words ''in compliance with the provisions of § 147.26 of this chapter'' and adding the words ''in accordance with part 147 of this subchapter with respect to Mycoplasma isolation, sanitation, and management'' in their place.
■ n. In paragraph (f)(5), by removing the words ''as described in § 147.24(a) of this chapter'' and adding the words ''in accordance with part 147 of this subchapter'' in their place.
■ o. In paragraph (g)(3), by removing the words ''in compliance with the provisions of § 147.26 of this chapter'' and adding the words ''in accordance with part 147 of this subchapter with respect to Mycoplasma isolation, sanitation, and management'' in their place.
■ p. In paragraph (g)(5), by removing the words ''as described in § 147.24(a) of this chapter'' and adding the words ''in accordance with part 147 of this subchapter'' in their place.
■ q. In paragraph (h)(1) introductory text, by adding the words ''and found'' before the word ''negative'' and by removing the words ''for antibodies''.
■ r. By revising paragraph (h)(2).

The revisions read as follows:

§ 145.23 Terminology and classification; flocks and products.

* * * * *

(d) * * *

(1) * * *

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

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

* * * * *

(h) * * *

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

* * * * *

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

§ 145.32 Participation.

* * * * *

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

* * * * *

■ 16. Section 145.33 is amended as follows:

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

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

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

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

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

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

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

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

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

■ j. By revising paragraph (d)(2).

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

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

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

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

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

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

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

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

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

■ t. In paragraphs (j)(3) and (k)(3), by removing the words ''as described in § 147.24(a) of this chapter'' and adding the words ''in accordance with part 147 of this subchapter'' in their place.

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

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

■ w. By revising paragraph (l)(2).

■ x. By adding a new paragraph (m).

The revisions read as follows:

§ 145.33 Terminology and classification; flocks and products.

* * * * *

(d) * * *

(1) * * *

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

* * * * *

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

* * * * *

(l) * * *

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

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

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

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

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

(iii) Environmental samples are collected from the flock in accordance with part 147 of this subchapter at 16–18 and 40–45 weeks of age. The samples shall be examined bacteriologically for group D Salmonella at an authorized laboratory, and cultures from group D positive samples shall be serotyped.

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

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

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

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

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

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

* * * * *

§ 145.42 [Amended]

■ 17. In § 145.42, paragraph (b) is amended by removing the words ''(see § 147.25 of this chapter)'' and adding the words ''in accordance with part 147 of this subchapter'' in their place.

■ 18. Section 145.43 is amended as follows:

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

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

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

■ d. In paragraph (e)(2), by removing the words ''the procedures outlined in § 147.6 of this chapter will be used to determine'' and by adding the words ''will be determined in accordance with part 147 of this subchapter'' before the period at the end of the paragraph.

■ e. By removing paragraph (e)(3).

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

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

■ h. By revising paragraph (g)(3).

The revisions read as follows:

§ 145.43 Terminology and classification; flocks and products.

* * * * *

(e) * * *

(1) * * * It is recommended that samples be collected from birds with clinical signs of *M. synoviae* infection.

* * * * *

(g) * * *

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

* * * * *

■ 19. Add § 145.45 to read as follows:

§ 145.45 Terminology and classification; compartments.

(a) *U.S. H5/H7 Avian Influenza Clean Compartment.* This program is intended to be the basis from which the primary turkey breeding-hatchery industry may demonstrate the existence and implementation of a program that has been approved by the Official State Agency and the Service to establish a compartment consisting of a primary breeding-hatchery company that is free of H5/H7 avian influenza (AI), also referred to as notifiable avian influenza (NAI). This compartment has the purpose of protecting the defined subpopulation and avoiding the introduction and spread of NAI within that subpopulation by prohibiting contact with other commercial poultry operations, other domestic and wild birds, and other intensive animal operations. The program shall consist of the following:

(1) *Definition of the compartment.* Based on the guidelines established by the World Organization for Animal Health (OIE) in the Terrestrial Animal Health Code and the guidelines in this paragraph (a), the primary breeder company will define the compartment with respect to NAI. Specifically, the company will use a comprehensive biosecurity program to define the compartment as a subpopulation of poultry with a health status for NAI that is separate from birds and poultry outside the compartment. The Official State Agency and the Service must approve all documentation submitted to substantiate the defined compartment as adequate to qualify for epidemiological separation from other potential sources of infection of NAI. Guidelines for the definition of the compartment include:

(i) *Definition and description of the subpopulation of birds and their health status.* All birds included in the compartment must be U.S. H5/H7 Avian Influenza Clean in accordance with § 145.43(g). The poultry must also be located in a State that has an initial State response and containment plan approved by APHIS under § 56.10 of this chapter and that participates in the diagnostic surveillance program for H5/H7 low pathogenicity AI as described in § 145.15. Within the compartment, all official tests for AI, as described in § 145.14(d), must be conducted in State or Federal laboratories or in NPIP authorized laboratories that meet the minimum standards described in § 147.52 of this subchapter. In addition, the company must provide to the Service upon request any relevant historical and current NAI-related data for reference regarding surveillance for the disease within the compartment. Upon request, the company must also work with the Official State Agency to provide such data for other bird populations located in the State.

(ii) *Description of animal identification and traceability processes.* The primary breeder company must also include a description of its animal identification and traceability records, including examples of Veterinary Services (VS) Form 9–5, ''Report of Hatcheries, Dealers and Independent Flocks''; VS Form 9–2, ''Flock Selection and Testing Report''; VS Form 9–3, ''Report of Sales of Hatching Eggs, Chicks and Poults''; VS Form 9–9, '' Hatchery Inspection Report''; set and hatch records; egg receipts; and egg/chick invoices for the subpopulation. Documentation must also include breed identification (NPIP stock code). The Service should ensure that an effective flock identification system and traceability system are in place.

(iii) *Definition and description of the physical components or establishments of the defined compartment.* The

primary breeder company must provide documentation establishing that the defined compartment is epidemiologically separated from other poultry and bird populations. The documentation must be approved by the Official State Agency and the Service as indicating adequate epidemiological separation to maintain the compartment's separate health status with respect to NAI. The documentation should include descriptions of:

(A) The physical and spatial factors that separate the compartment from surrounding bird populations and affect the biosecurity status of the compartment.

(B) Relevant environmental factors that may affect exposure of the birds to AI.

(C) The functional boundary and fencing that are used to control access to the compartment.

(D) Facilities and procedures to prevent access by wild birds and to provide separation from other relevant hosts.

(E) The relevant infrastructural factors that may affect exposure to AI, including the construction and design of buildings or physical components, cleaning and disinfection of buildings and physical components between production groups with quality assurance verification, cleaning and disinfection of equipment, and introduction of equipment or material into the compartment.

(iv) *Definition and description of the functional relationships between components of the defined compartment.* Functional relationships between components of the compartment include traffic movement and flow at and among premises, personnel movement at and among premises, exposure to live bird populations, and any other factors that could affect biosecurity of the compartment. All physical components of the compartment must be maintained in compliance with hygiene and biosecurity procedures for poultry primary breeding flocks and hatcheries in accordance with part 147 of this subchapter. In addition, the company must provide a biosecurity plan for the compartment and all included components. The biosecurity plan should include:

(A) Requirements that company employees and contract growers limit their contact with live birds outside the compartment.

(B) An education and training program for company employees and contractors.

(C) Standard operating procedures for company employees, contractors, and outside maintenance personnel.

(D) Requirements for company employees and non-company personnel who visit any premises within the compartment.

(E) Company veterinary infrastructure to ensure flock monitoring and disease diagnosis and control measures.

(F) Policies for management of vehicles and equipment used within the compartment to connect the various premises.

(G) Farm site requirements (location, layout, and construction).

(H) Pest management program.

(I) Cleaning and disinfection process.

(J) Requirements for litter and dead bird removal and/or disposal.

(v) *Description of other factors important for maintaining the compartment.* The company veterinary infrastructure will assess sanitary measures, environmental risk factors, and management and husbandry practices that relate to the separation of the compartment and the health status of the birds contained within the compartment that may affect risk of exposure to NAI. This assessment must include a description of internal monitoring and auditing systems (e.g., quality assurance and quality control programs) to demonstrate the effectiveness of the compartment. Upon request, the Service will provide the company with information on the epidemiology of NAI and the associated risk pathways in which the components of the compartment are located is available from the Service.

(vi) *Approval or denial.* Based on this documentation provided under this paragraph (a)(1), as well as any other information the Service and the Official State Agency determine to be necessary, the Service and the Official State Agency will approve or deny the classification of the compartment as U.S. H5/H7 Avian Influenza Clean.

(2) *Company activities for maintenance of the compartment.* (i) The primary breeder company's management of biosecurity, surveillance, and disease control efforts must be uniform and equivalent among all components that are a part of the compartment. Oversight and inspection of these management practices must be conducted by the company's licensed, accredited veterinarians.

(ii) Veterinary staff from the Official State Agency and NPIP staff will work in partnership with licensed, accredited veterinarians to train and certify auditors through Service-approved workshops. The trained auditors will conduct biosecurity and operational audits at least once every 2 years to ensure the integrity of the compartment. These audits will include evaluation of the critical control points and standard operating practices within the compartment, verification of the health status of the flock(s) contained within the compartment, and examination of the biosecurity and management system of the integrated components of the compartment.

(iii) In addition, the company must demonstrate compliance with paragraph (a)(1) of this section for remaining in the U.S. H5/H7 Avian Influenza Clean classification, surveillance for NAI within the compartment, and conducting tests in State or Federal laboratories or in NPIP authorized laboratories. Accredited veterinarians are responsible for the enforcement of active and passive surveillance of NAI in primary breeder flocks. Baseline health status must be maintained for all flocks or subpopulations within the compartment, indicating the dates and negative results of all avian influenza surveillance and monitoring testing, the dates and history of last disease occurrence (if any), the number of outbreaks, and the methods of disease control that were applied.

(iv) Documentation will be maintained in the company's database and will be verified as required by the Service and/or the Official State Agency.

(3) *Service and Official State Agency activities for maintenance of the compartment.* The Service will work in cooperation with the Official State Agencies to ensure the continued integrity of any recognized compartments. Activities will include:

(i) Oversight of the establishment and management of compartments;

(ii) Establishment of effective partnerships between the Service, the Plan, and the primary breeder industry;

(iii) Approval or denial of classification of compartments as U.S. H5/H7 Avian Influenza Clean Compartments under paragraph (a)(1) of this section;

(iv) Official certification of the health status of the compartment, and commodities that may be traded from it through participation in the Plan for avian diseases, including the U.S. H5/H7 Avian Influenza Clean program as described in § 145.43(g) and diagnostic surveillance for H5/H7 low pathogenicity AI as described in § 145.15;

(v) Conducting audits of compartments at least once every 2 years to:

(A) Confirm that the primary breeding company's establishments are

epidemiologically distinct and pathways for the introduction of disease into the compartment are closed through routine operational procedures; and

(B) Evaluate and assess the management and husbandry practices relating to biosecurity to determine whether they are in compliance with hygiene and biosecurity procedures for poultry primary breeding flocks and hatcheries in accordance with part 147 of this subchapter;

(vi) Providing, upon request, model plans for management and husbandry practices relating to biosecurity in accordance with part 147 of this subchapter, risk evaluations in conjunction with the primary breeder industry (including disease surveillance such as VS Form 9–4, ''Summary of Breeding Flock Participation''), and diagnostic capability summaries and systems for initial State response and containment plans in accordance with § 56.10 of this chapter; and

(vii) Publicizing and sharing compartment information with international trading partners, upon request, to establish approval and recognition of the compartment, including timeliness and accuracy of disease reporting and surveillance measures as described in §§ 145.15 and 145.43(g).

(4) *Emergency response and notification.* In the case of a confirmed positive of NAI in the subpopulation of the compartment, the management of the compartment must notify the Service. The Service will immediately suspend the status of the compartment. A compartment will be eligible to resume trade with importing countries only after the compartment has adopted the necessary measures to reestablish the biosecurity level and confirm that NAI is not present in the compartment and the Service has reevaluated the management and biosecurity measures of the compartment and approved said compartment for trade.

(b) [Reserved]

■ 20. Section 145.52 is amended as follows:

■ a. In paragraph (b), by removing the words ''(see § 147.25 of this chapter)'' and adding the words ''in accordance with part 147 of this subchapter'' in their place.

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

■ c. By adding a new paragraph (c).

The addition reads as follows:

§ 145.52 Participation.

* * * * *

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

* * * * *

■ 21. Section 145.53 is amended as follows:

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

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

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

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

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

■ f. By revising paragraphs (e)(1) introductory text and (e)(2) introductory text to read as set forth below.

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

■ h. By revising paragraph (e)(3).

■ i. By adding paragraph (f).

The revision and addition read as follows:

§ 145.53 Terminology and classification; flocks and products.

* * * * *

(e) * * *

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

* * * * *

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

* * * * *

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

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

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

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

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

* * * * *

§ 145.62 [Amended]

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

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

§ 145.72 Participation.

* * * * *

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

* * * * *

■ 24. Section 145.73 is amended as follows:

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

■ b. In paragraph (c)(3), by removing the words ''as described in § 147.24(a)'' and

adding the words ''in accordance with part 147'' in their place.
■ c. In paragraph (d)(1)(iv), by removing the words ''in compliance with §§ 147.21, 147.24(a), and 147.26 of this subchapter'' and adding the words ''in accordance with part 147 of this subchapter with respect to flock sanitation, cleaning and disinfection, and Salmonella isolation, sanitation, and management'' in their place.
■ d. In paragraph (d)(1)(v), by removing the words ''as described in § 147.12'' and adding the words ''in accordance with part 147'' in their place.
■ e. In paragraph (d)(1)(vii), by removing the words ''as described in § 147.11'' and adding the words ''in accordance with part 147'' in their place.
■ f. By revising paragraph (d)(1)(ix).
■ g. In paragraph (d)(2), by removing the words ''as described in § 147.11(a)'' and adding the words ''in accordance with part 147'' in their place.
■ h. In paragraph (e)(1) introductory text, by removing the words ''in compliance with the provisions of § 147.26 of this subchapter'' and adding the words ''in accordance with part 147 of this subchapter with respect to Mycoplasma isolation, sanitation, and management'' in their place.
■ i. In paragraph (e)(3), by removing the words ''as described in § 147.24(a)'' and adding the words ''in accordance with part 147'' in their place.
■ j. In paragraph (f)(1) introductory text, by adding the words ''and found'' before the word ''negative'' and by removing the words ''for antibodies''.
■ k. By revising paragraph (f)(2).
The revisions read as follows:

§ 145.73 Terminology and classification; flocks and products.

* * * * *

(d) * * *

(1) * * *

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

* * * * *

(f) * * *

(2) A sample of at least 11 birds must be tested and found negative to avian influenza within 21 days prior to movement to slaughter.
■ 25. A new § 145.74 is added to read as follows:

§ 145.74 Terminology and classification; compartments.

(a) *U.S. Avian Influenza Clean Compartment.* This program is intended to be the basis from which the primary egg-type chicken breeding-hatchery industry may demonstrate the existence and implementation of a program that has been approved by the Official State Agency and the Service to establish a compartment consisting of a primary breeding-hatchery company that is free of H5/H7 avian influenza (AI), also referred to as notifiable avian influenza (NAI). This compartment has the purpose of protecting the defined subpopulation and avoiding the introduction and spread of NAI within that subpopulation by prohibiting contact with other commercial poultry operations, other domestic and wild birds, and other intensive animal operations. The program shall consist of the following:

(1) *Definition of the compartment.* Based on the guidelines established by the World Organization for Animal Health (OIE) in the Terrestrial Animal Health Code and the guidelines in this paragraph (a), the primary breeder company will define the compartment with respect to NAI. Specifically, the company will use a comprehensive biosecurity program to define the compartment as a subpopulation of poultry with a health status for NAI that is separate from birds and poultry outside the compartment. The Official State Agency and the Service must approve all documentation submitted to substantiate the defined compartment as adequate to qualify for epidemiological separation from other potential sources of infection of NAI. Guidelines for the definition of the compartment include:

(i) *Definition and description of the subpopulation of birds and their health status.* All birds included in the compartment must be U.S. Avian Influenza Clean in accordance with § 145.73(f). The poultry must also be located in a State that has an initial State response and containment plan approved by APHIS under § 56.10 of this chapter and that participates in the diagnostic surveillance program for H5/H7 low pathogenicity AI as described in § 145.15. Within the compartment, all official tests for AI, as described in § 145.14(d), must be conducted in State or Federal laboratories or in NPIP authorized laboratories that meet the minimum standards described in § 147.52 of this subchapter. In addition, the company must provide to the Service upon request any relevant historical and current NAI-related data for reference regarding surveillance for the disease within the compartment. Upon request, the company must also work with the Official State Agency to provide such data for other bird populations located in the State.

(ii) *Description of animal identification and traceability processes.* The primary breeder company must also include a description of its animal identification and traceability records, including examples of Veterinary Services (VS) Form 9–5, ''Report of Hatcheries, Dealers and Independent Flocks''; VS Form 9–2, ''Flock Selection and Testing Report''; VS Form 9–3, ''Report of Sales of Hatching Eggs, Chicks and Poults''; VS Form 9–9, ''Hatchery Inspection Report''; set and hatch records; egg receipts; and egg/chick invoices for the subpopulation. Documentation must also include breed identification (NPIP stock code). The Service should ensure that an effective flock identification system and traceability system are in place.

(iii) *Definition and description of the physical components or establishments of the defined compartment.* The primary breeder company must provide documentation establishing that the defined compartment is epidemiologically separated from other poultry and bird populations. The documentation must be approved by the Official State Agency and the Service as indicating adequate epidemiological separation to maintain the compartment's separate health status with respect to NAI. The documentation should include descriptions of:

(A) The physical and spatial factors that separate the compartment from surrounding bird populations and affect the biosecurity status of the compartment.

(B) Relevant environmental factors that may affect exposure of the birds to AI.

(C) The functional boundary and fencing that are used to control access to the compartment.

(D) Facilities and procedures to prevent access by wild birds and to provide separation from other relevant hosts.

(E) The relevant infrastructural factors that may affect exposure to AI, including the construction and design of buildings or physical components, cleaning and disinfection of buildings and physical components between production groups with quality assurance verification, cleaning and disinfection of equipment, and introduction of equipment or material into the compartment.

(iv) *Definition and description of the functional relationships between components of the defined compartment.* Functional relationships between components of the compartment include traffic movement and flow at and among premises, personnel movement at and among

premises, exposure to live bird populations, and any other factors that could affect biosecurity of the compartment. All physical components of the compartment must be maintained in compliance with hygiene and biosecurity procedures for poultry primary breeding flocks and hatcheries in accordance with part 147 of this subchapter. In addition, the company must provide a biosecurity plan for the compartment and all included components. The biosecurity plan should include:

(A) Requirements that company employees and contract growers limit their contact with live birds outside the compartment.

(B) An education and training program for company employees and contractors.

(C) Standard operating procedures for company employees, contractors, and outside maintenance personnel.

(D) Requirements for company employees and non-company personnel who visit any premises within the compartment.

(E) Company veterinary infrastructure to ensure flock monitoring and disease diagnosis and control measures.

(F) Policies for management of vehicles and equipment used within the compartment to connect the various premises.

(G) Farm site requirements (location, layout, and construction).

(H) Pest management program.

(I) Cleaning and disinfection process.

(J) Requirements for litter and dead bird removal and/or disposal.

(v) *Description of other factors important for maintaining the compartment.* The company veterinary infrastructure will assess sanitary measures, environmental risk factors, and management and husbandry practices that relate to the separation of the compartment and the health status of the birds contained within the compartment that may affect risk of exposure to NAI. This assessment must include a description of internal monitoring and auditing systems (e.g., quality assurance and quality control programs) to demonstrate the effectiveness of the compartment. Upon request, the Service will provide the company with information on the epidemiology of NAI and the associated risk pathways in which the components of the compartment are located is available from the Service.

(vi) *Approval or denial.* Based on the documentation provided under this paragraph (a)(1), as well as any other information the Service and the Official State Agency determine to be necessary, the Service and the Official State Agency will approve or deny the classification of the compartment as U.S. Avian Influenza Clean.

(2) *Company activities for maintenance of the compartment.* (i) The primary breeder company's management of biosecurity, surveillance, and disease control efforts must be uniform and equivalent among all components that are a part of the compartment. Oversight and inspection of these management practices must be conducted by the company's licensed, accredited veterinarians.

(ii) Veterinary staff from the Official State Agency and NPIP staff will work in partnership with licensed, accredited veterinarians to train and certify auditors through Service-approved workshops. The trained auditors will conduct biosecurity and operational audits at least once every 2 years to ensure the integrity of the compartment. These audits will include evaluation of the critical control points and standard operating practices within the compartment, verification of the health status of the flock(s) contained within the compartment, and examination of the biosecurity and management system of the integrated components of the compartment.

(iii) In addition, the company must demonstrate compliance with paragraph (a)(1) of this section for remaining in the U.S. Avian Influenza Clean classification, surveillance for NAI within the compartment, and conducting tests in State or Federal laboratories or in NPIP authorized laboratories. Accredited veterinarians are responsible for the enforcement of active and passive surveillance of NAI in primary breeder flocks. Baseline health status must be maintained for all flocks or subpopulations within the compartment, indicating the dates and negative results of all avian influenza surveillance and monitoring testing, the dates and history of last disease occurrence (if any), the number of outbreaks, and the methods of disease control that were applied.

(iv) Documentation will be maintained in the company's database and will be verified as required by the Service and/or the Official State Agency.

(3) *Service and Official State Agency activities for maintenance of the compartment.* The Service will work in cooperation with the Official State Agencies to ensure the continued integrity of any recognized compartments. Activities will include:

(i) Oversight of the establishment and management of compartments;

(ii) Establishment of effective partnerships between the Service, the Plan, and the primary breeder industry;

(iii) Approval or denial of classification of compartments as U.S. Avian Influenza Clean Compartments under paragraph (a)(1) of this section;

(iv) Official certification of the health status of the compartment, and commodities that may be traded from it through participation in the Plan for avian diseases, including the U.S. Avian Influenza Clean program as described in § 145.73(f) and diagnostic surveillance for H5/H7 low pathogenicity AI as described in § 145.15;

(v) Conducting audits of compartments at least once every 2 years to:

(A) Confirm that the primary breeding company's establishments are epidemiologically distinct and pathways for the introduction of disease into the compartment are closed through routine operational procedures; and

(B) Evaluate and assess the management and husbandry practices relating to biosecurity to determine whether they are in compliance with hygiene and biosecurity procedures for poultry primary breeding flocks and hatcheries in accordance with part 147 of this subchapter;

(vi) Providing, upon request, model plans for management and husbandry practices relating to biosecurity in accordance with part 147 of this subchapter, risk evaluations in conjunction with the primary breeder industry (including disease surveillance such as VS Form 9–4, ''Summary of Breeding Flock Participation''), and diagnostic capability summaries and systems for initial State response and containment plans in accordance with § 56.10 of this chapter; and

(vii) Publicizing and sharing compartment information with international trading partners, upon request, to establish approval and recognition of the compartment, including timeliness and accuracy of disease reporting and surveillance measures as described in §§ 145.15 and 145.73(f).

(4) *Emergency response and notification.* In the case of a confirmed positive of NAI in the subpopulation of the compartment, the management of the compartment must notify the Service. The Service will immediately suspend the status of the compartment. A compartment will be eligible to resume trade with importing countries only after the compartment has adopted the necessary measures to reestablish the biosecurity level and confirm that NAI is not present in the compartment

and the Service has reevaluated the management and biosecurity measures of the compartment and approved said compartment for trade.

(b) [Reserved]

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

§ 145.82 Participation.

* * * * *

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

* * * * *

■ 27. Section 145.83 is amended as follows:

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

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

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

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

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

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

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

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

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

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

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

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

■ m. By revising paragraph (f)(2).

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

■ o. By revising paragraph (g)(2).

The revisions read as follows:

§ 145.83 Terminology and classification; flocks and products.

* * * * *

(e) * * *

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

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

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

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

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

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

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

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

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

(2) * * *

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

* * * * *

(f) * * *

(1) * * *

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

* * * * *

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

* * * * *

(g) * * *

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

■ 28. Add § 145.84 to read as follows:

§ 145.84 Terminology and classification; compartments.

(a) *U.S. Avian Influenza Clean Compartment.* This program is intended to be the basis from which the primary meat-type chicken breeding-hatchery industry may demonstrate the existence and implementation of a program that has been approved by the Official State Agency and the Service to establish a compartment consisting of a primary breeding-hatchery company that is free of H5/H7 avian influenza (AI), also referred to as notifiable avian influenza (NAI). This compartment has the purpose of protecting the defined subpopulation and avoiding the introduction and spread of NAI within that subpopulation by prohibiting contact with other commercial poultry operations, other domestic and wild birds, and other intensive animal operations. The program shall consist of the following:

(1) *Definition of the compartment.* Based on the guidelines established by the World Organization for Animal Health (OIE) in the Terrestrial Animal Health Code and the guidelines in this paragraph (a), the primary breeder company will define the compartment with respect to NAI. Specifically, the company will use a comprehensive biosecurity program to define the compartment as a subpopulation of poultry with a health status for NAI that is separate from birds and poultry outside the compartment. The Official State Agency and the Service must approve all documentation submitted to substantiate the defined compartment as adequate to qualify for epidemiological separation from other potential sources of infection of NAI. Guidelines for the definition of the compartment include:

(i) *Definition and description of the subpopulation of birds and their health status.* All birds included in the compartment must be U.S. Avian Influenza Clean in accordance with § 145.83(g). The poultry must also be located in a State that has an initial State response and containment plan approved by APHIS under § 56.10 of this chapter and that participates in the diagnostic surveillance program for H5/H7 low pathogenicity AI as described in § 145.15. Within the compartment, all official tests for AI, as described in § 145.14(d), must be conducted in State or Federal laboratories or in NPIP authorized laboratories that meet the minimum standards described in § 147.52 of this subchapter. In addition, the company must provide to the Service upon request any relevant historical and current NAI-related data for reference regarding surveillance for the disease and the health status of the compartment. Upon request, the company must also work with the Official State Agency to provide such data other bird populations located in the State.

(ii) *Description of animal identification and traceability processes.* The primary breeder company must also include a description of its animal identification and traceability records, including examples of Veterinary Services (VS) Form 9–5, ''Report of Hatcheries, Dealers and Independent Flocks''; VS Form 9–2, ''Flock Selection and Testing Report''; VS Form 9–3, ''Report of Sales of Hatching Eggs, Chicks and Poults''; VS Form 9–9, '' Hatchery Inspection Report''; set and hatch records; egg receipts; and egg/chick invoices for the subpopulation. Documentation must also include breed identification (NPIP stock code). The Service should ensure that an effective flock identification system and traceability system are in place.

(iii) *Definition and description of the physical components or establishments of the defined compartment.* The primary breeder company must provide documentation establishing that the defined compartment is epidemiologically separated from other poultry and bird populations. The documentation must be approved by the Official State Agency and the Service as indicating adequate epidemiological separation to maintain the compartment's separate health status with respect to NAI. The documentation should include descriptions of:

(A) The physical and spatial factors that separate the compartment from surrounding bird populations and affect the biosecurity status of the compartment.

(B) Relevant environmental factors that may affect exposure of the birds to AI.

(C) The functional boundary and fencing that are used to control access to the compartment.

(D) Facilities and procedures to prevent access by wild birds and to provide separation from other relevant hosts.

(E) The relevant infrastructural factors that may affect exposure to AI, including the construction and design of buildings or physical components, cleaning and disinfection of buildings and physical components between production groups with quality assurance verification, cleaning and disinfection of equipment, and introduction of equipment or material into the compartment.

(iv) *Definition and description of the functional relationships between components of the defined compartment.* Functional relationships between components of the compartment include traffic movement and flow at and among premises, personnel movement at and among premises, exposure to live bird populations, and any other factors that could affect biosecurity of the compartment. All physical components of the compartment must be maintained in compliance with hygiene and biosecurity procedures for poultry primary breeding flocks and hatcheries in accordance with part 147 of this subchapter. In addition, the company must provide a biosecurity plan for the compartment and all included components. The biosecurity plan should include:

(A) Requirements that company employees and contract growers limit their contact with live birds outside the compartment.

(B) An education and training program for company employees and contractors.

(C) Standard operating procedures for company employees, contractors, and outside maintenance personnel.

(D) Requirements for company employees and non-company personnel who visit any premises within the compartment.

(E) Company veterinary infrastructure to ensure flock monitoring and disease diagnosis and control measures.

(F) Policies for management of vehicles and equipment used within the compartment to connect the various premises.

(G) Farm site requirements (location, layout, and construction).

(H) Pest management program.

(I) Cleaning and disinfection process.

(J) Requirements for litter and dead bird removal and/or disposal.

(v) *Description of other factors important for maintaining the compartment.* The company veterinary infrastructure will assess sanitary measures, environmental risk factors, and management and husbandry practices that relate to the separation of the compartment and the health status of the birds contained within the compartment that may affect risk of exposure to NAI. This assessment must include a description of internal monitoring and auditing systems (e.g., quality assurance and quality control programs) to demonstrate the effectiveness of the compartment. Upon request, the Service will provide the company with information on the epidemiology of NAI and the associated risk pathways in which the components of the compartment are located is available from the Service.

(vi) *Approval or denial.* Based on the documentation provided under this paragraph (a)(1), as well as any other information the Service and the Official State Agency determine to be necessary, the Service and the Official State Agency will approve or deny the classification of the compartment as U.S. Avian Influenza Clean.

(2) *Company activities for maintenance of the compartment.* (i) The primary breeder company's management of biosecurity, surveillance, and disease control efforts must be uniform and equivalent among all components that are a part of the compartment. Oversight and inspection of these management practices must be conducted by the company's licensed, accredited veterinarians.

(ii) Veterinary staff from the Official State Agency and NPIP staff will work in partnership with licensed, accredited veterinarians to train and certify auditors through Service-approved workshops. The trained auditors will conduct biosecurity and operational audits at least once every 2 years to ensure the integrity of the compartment. These audits will include evaluation of the critical control points and standard operating practices within the compartment, verification of the health status of the flock(s) contained within the compartment, and examination of the biosecurity and management system of the integrated components of the compartment.

(iii) In addition, the company must demonstrate compliance with paragraph (a)(1) of this section for remaining in the U.S. Avian Influenza Clean classification, surveillance for NAI within the compartment, and conducting tests in State or Federal laboratories or in NPIP authorized laboratories. Accredited veterinarians are responsible for the enforcement of active and passive surveillance of NAI in primary breeder flocks. Baseline health status must be maintained for all flocks or subpopulations within the compartment, indicating the dates and negative results of all avian influenza surveillance and monitoring testing, the dates and history of last disease occurrence (if any), the number of outbreaks, and the methods of disease control that were applied.

(iv) Documentation will be maintained in the company's database and will be verified as required by the Service and/or the Official State Agency.

(3) *Service and Official State Agency activities for maintenance of the compartment.* The Service will work in cooperation with the Official State Agencies to ensure the continued integrity of any recognized compartments. Activities will include:

(i) Oversight of the establishment and management of compartments;

(ii) Establishment of effective partnerships between the Service, the Plan, and the primary breeder industry;

(iii) Approval or denial of classification of compartments as U.S. Avian Influenza Clean Compartments under paragraph (a)(1) of this section;

(iv) Official certification of the health status of the compartment, and commodities that may be traded from it through participation in the Plan for avian diseases, including the U.S. Avian Influenza Clean program as described in § 145.83(g) and diagnostic surveillance for H5/H7 low pathogenicity AI as described in § 145.15;

(v) Conducting audits of compartments at least once every 2 years to:

(A) Confirm that the primary breeding company's establishments are epidemiologically distinct and pathways for the introduction of disease into the compartment are closed through routine operational procedures; and

(B) Evaluate and assess the management and husbandry practices relating to biosecurity to determine whether they are in compliance with hygiene and biosecurity procedures for poultry primary breeding flocks and hatcheries in accordance with part 147 of this subchapter;

(vi) Providing, upon request, model plans for management and husbandry practices relating to biosecurity in accordance with part 147 of this subchapter, risk evaluations in conjunction with the primary breeder industry (including disease surveillance such as VS Form 9–4, ''Summary of Breeding Flock Participation''), and diagnostic capability summaries and systems for initial State response and containment plans in accordance with § 56.10 of this chapter; and

(vii) Publicizing and sharing compartment information with international trading partners, upon request, to establish approval and recognition of the compartment, including timeliness and accuracy of disease reporting and surveillance measures as described in §§ 145.15 and 145.83(g).

(4) *Emergency response and notification.* In the case of a confirmed positive of NAI in the subpopulation of the compartment, the management of the compartment must notify the Service. The Service will immediately suspend the status of the compartment. A compartment would be eligible to resume trade with importing countries only after the compartment has adopted the necessary measures to reestablish the biosecurity level and confirm that NAI is not present in the compartment and the Service has reevaluated the management and biosecurity measures of the compartment and approved said compartment for trade.

(b) [Reserved]

§ 145.92 [Amended]

■ 29. In § 145.92, paragraph (b) is amended by removing the words ''(see § 147.25 of this chapter)'' and adding the words ''in accordance with part 147 of this subchapter'' in their place.

■ 30. Section 145.93 is amended as follows:

■ a. By revising paragraph (c)(3).

■ b. By adding a new paragraph (d).

The revision and addition read as follows:

§ 145.93 Terminology and classification; flocks and products.

* * * * *

(c) * * *

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

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

(1) A flock and the hatching eggs and day-old waterfowl produced from it must meet the following requirements, as determined by the Official State Agency, to be eligible for this classification:

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

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

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

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

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

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

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

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

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

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

PART 146—NATIONAL POULTRY IMPROVEMENT PLAN FOR COMMERCIAL POULTRY

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

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

■ 32. Section 146.1 is amended as follows:

■ a. By revising the definition of *authorized laboratory.*

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

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

■ d. In the definition of *H5/H7 LPAI virus infection (infected),* by adding the words ''the Cooperating State Agency, the Official State Agency, and'' before the word ''APHIS''.

The revision reads as follows:

§ 146.1 Definitions.

* * * * *

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

* * * * *

§ 146.2 [Amended]

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

§ 146.3 [Amended]

■ 34. Section 146.3 is amended as follows:

■ a. In paragraph (c), by adding the words '', spent fowl,'' after the word ''chicken''.

■ b. By removing paragraph (e).

§ 146.5 [Amended]

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

■ 36. In § 146.11, paragraph (b) is revised to read as follows:

§ 146.11 Inspections.

* * * * *

(b) A flock will be considered to be not conforming to protocol if there are no test results available, if samples from the flock were not collected and tested within 21 days prior to slaughter, or if the test results for the flocks were not returned prior to movement to slaughter.

* * * * *

■ 37. Section 146.13 is amended as follows:

■ a. In paragraph (a)(1), by removing the words ''the requirements in § 147.8'' and adding the words ''part 147'' in their place.

■ b. By revising paragraph (b)(1)(ii)(C).

■ c. In paragraph (b)(2)(i), by removing the word ''(AVPR01510)''.

■ d. By revising paragraph (b)(2)(ii)(B).

The revisions read as follows:

§ 146.13 Testing.

* * * * *

(b) * * *

(1) * * *

(ii) * * *

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

* * * * *

(2) * * *

(ii) * * *

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

* * * * *

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

§ 146.23 Terminology and classification; flocks and products.

* * * * *

(a) *U.S. H5/H7 Avian Influenza Monitored.*

(1) *Table-egg layer pullet flocks.* This program is intended to be the basis from which the table-egg layer industry may conduct a program to monitor for the H5/H7 subtypes of avian influenza. It is intended to determine the presence of the H5/H7 subtypes of avian influenza in table-egg layer pullets through routine surveillance of each participating commercial table-egg layer pullet flock. A flock will qualify for this classification when the Official State Agency determines that it has met one of the following requirements:

* * * * *

(2) *Table-egg layer flocks.* This program is intended to be the basis from which the table-egg layer industry may conduct a program to monitor for the H5/H7 subtypes of avian influenza. It is intended to determine the presence of the H5/H7 subtypes of avian influenza

in table-egg layer through routine surveillance of each participating commercial table-egg layer flock. A flock will qualify for this classification when the Official State Agency determines that it has met one of the following requirements:

* * * * *

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

§ 146.31 Definitions.

* * * * *

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

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

§ 146.32 Participation.

* * * * *

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

■ 41. Section 146.33 is amended as follows:

■ a. In paragraph (a)(1), by removing the words ''for antibodies''.

■ b. By revising paragraph (a)(2).

The revision reads as follows:

§ 146.33 Terminology and classification; meat-type chicken slaughter plants.

* * * * *

(a) * * *

(2) It is a meat-type chicken slaughter plant which accepts only meat-type chickens or spent fowl from flocks where samples from a minimum of 11 birds have been collected no more than 21 days prior to slaughter and tested negative to the H5/H7 subtypes of avian influenza, as provided in § 146.13(b); or

* * * * *

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

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

* * * * *

(a) * * *

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

* * * * *

PART 147–AUXILIARY PROVISIONS ON NATIONAL POULTRY IMPROVEMENT PLAN

■ 43. 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.

■ 44. Section 147.1 is revised to read as follows:

§ 147.1 Blood testing procedures.

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

§§ 147.2 through 147.9 [Removed and Reserved]

■ 45. Sections 147.2 through 147.9 are removed and reserved.

■ 46. Section 147.10 is revised to read as follows:

§ 147.10 Bacteriological examination procedures.

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

§§ 147.11 through 147.17 [Removed and Reserved]

■ 47. Sections 147.11 through 147.17 are removed and reserved.

■ 48. Section 147.21 is revised to read as follows:

§ 147.21 Sanitation procedures.

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

§§ 147.22 through 147.27 [Removed and Reserved]

■ 49. Sections 147.22 through 147.27 are removed and reserved.

■ 50. Section 147.30 is revised to read as follows:

§ 147.30 Molecular examination procedures.

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

§ 147.31 [Removed and Reserved]

■ 51. Section 147.31 is removed and reserved.

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

§ 147.41 Definitions.

* * * * *

NPIP Technical Committee. A committee made up of technical experts on poultry health, biosecurity, surveillance, and diagnostics. The committee consists of representatives from the poultry and egg industries, universities, and State and Federal governments and is appointed by the Senior Coordinator and approved by the General Conference Committee.

* * * * *

§ 147.44 [Amended]

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

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

Subpart F—Authorized Laboratories and Approved Tests and Sanitation Procedures

Sec.

Subpart F—Authorized Laboratories and Approved Tests and Sanitation Procedures

§ 147.51 Definitions.

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

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

NPIP or Plan. The National Poultry Improvement Plan.

NPIP Program Standards. A document that contains tests and

sanitation procedures approved by the Administrator under § 147.53 for use under this subchapter. This document may be obtained from the NPIP Web site at *http://www.aphis.usda.gov/animal_health/animal_dis_spec/poultry/* or by writing to the Service at National Poultry Improvement Plan, APHIS, USDA, 1506 Klondike Road, Suite 101, Conyers, GA 30094.

NPIP Technical Committee. A committee made up of technical experts on poultry health, biosecurity, surveillance, and diagnostics. The committee consists of representatives from the poultry and egg industries, universities, and State and Federal governments and is appointed by the Senior Coordinator and approved by the General Conference Committee.

§ 147.52 Authorized laboratories.

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

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

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

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

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

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

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

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

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

§ 147.53 Approved tests and sanitation procedures.

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

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

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

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

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

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

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

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

(A) No comments were received on the notice;

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

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

standards in paragraph (a) of this section.

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

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

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

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

Diagnostic test kits that are not licensed by the Service (e.g., bacteriological culturing kits) may be approved through the following procedure:

(a) The sensitivity of the kit will be estimated in at least three authorized laboratories selected by the Service by testing known positive samples, as determined by the official NPIP procedures found in the NPIP Program Standards or through other procedures approved by the Administrator. If certain conditions or interfering substances are known to affect the performance of the kit, appropriate samples will be included so that the magnitude and significance of the effect(s) can be evaluated.

(b) The specificity of the kit will be estimated in at least three authorized laboratories selected by the Service by testing known negative samples, as determined by tests conducted in accordance with the NPIP Program Standards or other procedures approved by the Administrator in accordance with § 147.53(d)(1). If certain conditions or interfering substances are known to affect the performance of the kit, appropriate samples will be included so that the magnitude and significance of the effect(s) can be evaluated.

(c) The kit will be provided to the cooperating laboratories in its final form and include the instructions for use. The cooperating laboratories must perform the assay exactly as stated in the supplied instructions. Each laboratory must test a panel of at least 25 known positive clinical samples supplied by the manufacturer of the test kit. In addition, each laboratory will be asked to test 50 known negative clinical samples obtained from several sources, to provide a representative sampling of the general population. The identity of the samples must be coded so that the cooperating laboratories are blinded to identity and classification. Each sample must be provided in duplicate or triplicate, so that error and repeatability data may be generated.

(d) Cooperating laboratories will submit to the kit manufacturer all raw data regarding the assay response. Each sample tested will be reported as positive or negative, and the official NPIP procedure used to classify the sample must be submitted in addition to the assay response value.

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

(f) Diagnostic test kits that are not licensed by the Service (e.g., bacteriological culturing kits) and that have been approved for use in the NPIP in accordance with this section are listed in the NPIP Program Standards.

Done in Washington, DC, this 15th day of January 2014.

Kevin Shea,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2014–01036 Filed 1–27–14; 8:45 am]

BILLING CODE 3410–34–P