# Proposed Rules

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

## DEPARTMENT OF AGRICULTURE

### Animal and Plant Health Inspection Service

### 9 CFR Parts 56, 145, 146, and 147

**[Docket No. APHIS–2014–0101]**

**RIN 0579–AE16**

## 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), its auxiliary provisions, and the indemnity regulations for the control of H5 and H7 low pathogenic avian influenza to clarify participation in the NPIP and amend participation requirements, amend definitions for poultry and breeding stock, amend the approval process for new diagnostic tests, and amend laboratory inspection and testing requirements. These changes would align the regulations with international standards and make them more transparent to Animal and Plant Health Inspection Service stakeholders and the general public. The proposed changes were voted on and approved by the voting delegates at the Plan's 2014 National Plan Conference.

**DATES:** We will consider all comments that we receive on or before May 23, 2016.

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

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov/#!docketDetail;D=APHIS-2014-0101.*
- *Postal Mail/Commercial Delivery:* Send your comment to Docket No. APHIS–2014–0101, 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-2014-0101* 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, 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. In addition, 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 low pathogenic avian influenza (LPAI) and provisions for a cooperative control program for the disease.

The proposed amendments discussed in this document are consistent with the recommendations approved by the voting delegates to the last National Plan Conference, which was held on July 10 through 12, 2014. Participants in the National Plan Conference represented flockowners, breeders, hatcherymen, slaughter plants, poultry veterinarians, laboratory personnel, Official State Agencies from cooperating States, and other poultry industry affiliates. The proposed amendments are discussed in the order they would appear in the regulations.

*Description of Plan Intention*

The NPIP regulations in 9 CFR parts 145 and 146 contain requirements that must be observed by flocks that participate in the Plan. Currently, § 145.3 details the process by which a person becomes eligible to participate in the Plan. Any person producing or dealing in products may participate when he/she has demonstrated, to the satisfaction of the Official State Agency, that his/her facilities, personnel, and practices are adequate for carrying out the applicable provisions of the Plan, and has signed an agreement with the Official State Agency to comply with the general and the applicable specific provisions of the Plan and any regulations of the Official State Agency under § 145.2. Affiliated flockowners may participate in the plan without signing an agreement with the Official State Agency. We are proposing to add additional language to this section to clarify that the NPIP is a cooperative Federal-State-Industry program through which new or existing diagnostic technology can be effectively applied to improve poultry and poultry products by controlling or eliminating specific poultry diseases. Because the Plan consists of programs that identify States, flocks, hatcheries, dealers, and slaughter plants that meet specific disease control standards specified in the Plan, we also propose to clarify that recordkeeping is important to demonstrate that participants adhere to the disease control programs in which they participate. We are proposing to add this language to paragraph (a) of § 145.3.

*Revision of Records Retention Requirement for Hatchery Inspections*

The regulations in § 145.12 contain requirements for the retention and

examination of records for all flocks maintained primarily for hatching eggs. Historically, testing records were retained at the hatchery, which allowed for examination of the records during annual inspections. However, not many commercial hatcheries currently keep testing records for their breeder flocks at the hatchery and may instead keep the records at the corporate office. Therefore, we are proposing a minor change to the regulations to specify that records for all breeder flock hatcheries must be made available for annual examination by a State inspector. This change also maintains flexibility in who must make the records available. Such people may include the hatchery manager, the quality assurance manager, the laboratory manager, the breeder manager, or the hatchery information specialist.

*Clarification of Official Testing Requirements for Pullorum-Typhoid, Mycoplasma gallisepticum, M. meleagridis, and M. synoviae*

The regulations in § 145.14 contain requirements for conducting official tests for pullorum-typhoid, *Mycoplasma gallisepticum, M. meleagridis, M. synoviae,* and avian influenza. Paragraph (a) outlines specific testing requirements for pullorum-typhoid. Currently, paragraph (a)(5) states that the official blood test for pullorum-typhoid shall include the testing of a sample of blood from each bird in the flock, provided that, under specified conditions in §§ 145.23, 145.33, 145.43, 145.53, and 145.63, the testing of a portion or sample of birds may be used in lieu of testing each bird. We are proposing to add §§ 145.73, 145.83, and 145.93 to the list of sections referenced in § 145.14(a)(5) as those sections are also applicable to pullorum-typhoid blood testing.

Paragraph (b) outlines specific testing requirements for *M. gallisepticum, M. meleagridis,* and *M. synoviae.* Currently, official tests for *M. gallisepticum, M. meleagridis,* and *M. synoviae* include the serum plate agglutination test, the tube agglutination test, the hemagglutination inhibition (HI) test, the microhemagglutination inhibition test, the enzyme-linked immunosorbent assay, and the polymerase chain reaction (PCR)-based test. We are proposing to remove references to the tube agglutination test because that test is outdated and no longer in use. We are also proposing to remove references to the microhemagglutination test as the term microhemagglutination is an outdated term. In addition, we are proposing to remove the reference to the PCR test and replace it with the words ''molecular based test.'' This change is necessary because there are other molecular based tests in addition to the PCR test. Also, changing the language in the regulations to ''molecular based test'' allows for greater testing flexibility in the event that a better and more cost-effective or efficient molecular based test is developed in the future. Finally, while the widely accepted industry standard has been to use either the HI test or a molecular based test to confirm the positive results of serological screening tests, this requirement has not previously been included in our regulations. Therefore, we are proposing to amend the regulations to make that clarification.

*Requirements for Nest Clean Hatching Eggs for Breeding Turkeys*

In a final rule [1] published in the **Federal Register** on July 9, 2014 (79 FR 38752–38768, Docket No. APHIS–2011–0101), with an effective date of August 8, 2014, we amended the regulations by, among other things, amending the requirements for participation in the Plan by multiplier egg-type breeding chickens, multiplier meat-type breeding chickens, primary egg-type breeding chickens, and primary meat-type breeding chickens 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. ''Nest clean'' eggs are eggs that are collected from nests frequently to keep them clean without further processing. These changes were necessary because it has become standard practice within the industry to avoid sanitizing eggs and instead insist on nest clean eggs, which have been found to hatch better and provide a better chick than other eggs, even when they are sanitized. In addition, removing the requirement for fumigation and instead stating that hatching eggs ''may be'' fumigated or otherwise sanitized addresses changes made due to health restrictions and concerns related to staff safety, as well as aligning with changes made to the provisions for multiplier egg-type and meat-type chicken breeding flocks and primary egg-type and meat-type breeding flocks, following the 2010 NPIP Plan Conference.

The regulations in § 145.42 outline the requirements with which turkey flocks, and the eggs and poults produced from them, must comply in order to participate in the Plan. Due to the same restrictions and concerns for staff safety for workers in the turkey industry and the same standard practice and benefits of requiring nest clean eggs, we are proposing to make the same changes to paragraph (b) of this section that were made in the July 2014 final rule for §§ 145.22(b), 145.32(b), 145.72(b), and 145.82(b).

We are also proposing to amend the definition of *breeding flock* in § 56.1 in order to be more inclusive of both chicken and turkey flocks. Currently, the definition for *breeding flock* refers to a ''flock that is composed of stock that has been developed for commercial egg or meat production and is maintained for the principal purpose of producing chicks for the ultimate production of eggs or meat for human consumption.'' We propose to amend this definition to remove the word ''chicks'' and replace it with the word ''progeny.'' This change is also consistent with the definition of *multiplier breeding flock* in § 145.1.

*Changes to U.S. M. gallisepticum Clean and U.S. M. synoviae Clean Classification for Breeding Flocks of Hobbyist and Exhibition Waterfowl, Exhibition Poultry, and Game Birds*

The regulations in § 145.53 set out classifications for hobbyist and exhibition waterfowl, exhibition poultry, and game bird breeding flocks and products. Paragraph (c) in § 145.53 sets out the U.S. *M. gallisepticum* Clean classification for such poultry while paragraph (d) of that section sets out the U.S. *M. synoviae* Clean classification for such poultry.

We are proposing to require targeted bird sampling of the choanal palatine cleft/fissure area using appropriate swabs as an alternative to the random serum or egg yolk sampling currently required for retention of the U.S. *M. gallisepticum* Clean classification. The choanal palatine cleft/fissure area is easier to swab and is also a very reliable site for detection of *M. gallisepticum* and *M. synoviae.* The targeted sampling of this area would provide a greater likelihood of detecting the organism of concern than either the random serum or egg yolk sampling methods.

We are also proposing to change the size of the sample for U.S. *M. gallisepticum* testing from the current 5 percent of birds in the flock to at least 30 birds, or all birds in the flock if the flock size is less than 30. We would make the same change for a multiplier breeding flock which originated as U.S. *M. gallisepticum* Clean baby poultry from primary breeding flocks. Currently, sampling of such flocks must consist of at least 2 percent of birds in the flock. These changes would provide for a more appropriate level of sampling for *M.*

[1] To view the final rule and related documents, go to *http://www.regulations.gov/#!docketDetail;D=APHIS-2011-0101.*

*gallisepticum,* particularly for those flocks that contain fewer than 30 birds.

Because *M. gallisepticum* and *M. synoviae* spread and infect birds similarly, we are proposing to amend the U.S. *M. synoviae* Clean classification to require that retention of that classification may also be obtained either by random sampling of serum or egg yolk or a targeted bird sample of the choanal palatine cleft/fissure area using appropriate swabs. Currently, the regulations do not specify how sampling is to be conducted. In addition, we are proposing to change the size of the sample for U.S. *M. synoviae* testing from at least 150 birds in the flock to at least 30 birds, or all birds in the flock if the flock size is less than 30. Finally, for a multiplier breeding flock which originated as U.S. *M. synoviae* Clean baby poultry from primary breeding flocks, we would remove the requirement for sampling a minimum of 75 birds and instead require that a random sample contain 50 percent of the birds in the flock with a maximum of 200 birds and a minimum of 30 birds, or all birds in the flock if the flock is less than 30 birds. This sampling would have to be conducted on birds that are at least 4 months of age or upon reaching sexual maturity.

Assuming a normal distribution and an infection rate of 1 percent, changing the sample sizes as proposed does not greatly affect the chance of detecting a positive sample (confidence interval approximately 95 percent). These proposed sample size changes would allow us to increase the efficiency of the NPIP program by allowing resources to be used elsewhere.

*Changes to U.S. Salmonella Monitored Certification Requirements*

The regulations in § 145.83 set out the requirements for the classification of participating flocks, and the eggs and chicks produced from them, with respect to certain diseases. Paragraph (f) of § 145.83 sets out requirements for preventing and controlling *Salmonella* in the breeding-hatching industry. Currently, a flock may be designated as U.S. *Salmonella* Monitored when, among other things, feed used for the flock, if containing animal proteins, adheres to certain processing requirements. We are proposing to remove these requirements because we believe that the rendering industry has appropriate standards to deal with the transmission of *Salmonella* through poultry feed and, therefore, these requirements are not necessary in the NPIP regulations. In addition, most of the primary meat type chicken industry today does not use animal protein products in their feed due to concerns of disease transmission. Therefore, we propose to amend the regulations in paragraph (f)(1)(i) to instead state that ''measures shall be implemented to control *Salmonella* challenge through the feed, feed storage, and feed transport.'' We also propose to remove paragraphs (f)(1)(ii) and (f)(1)(iii) and renumber paragraphs (f)(1)(iv) through (f)(1)(viii) as paragraphs (f)(1)(ii) through (f)(1)(vi).

*Revision to Sanitation Requirements for Meat-Type Waterfowl*

The regulations in §§ 145.91 and 145.92 set out special provisions for meat-type waterfowl and the eggs and baby poultry produced from them. Currently, paragraph (b) of § 145.92 requires that hatching eggs produced by primary breeding flocks be fumigated in accordance with part 147 or otherwise sanitized. We are proposing to remove the requirement for fumigation and instead state that hatching eggs should be ''nest clean'' and that they ''may be'' fumigated or otherwise sanitized. We would also extend these requirements to multiplier breeding flocks, as these proposed requirements are meant to mirror the changes made to the provisions for multiplier egg-type and meat-type chicken breeding flocks and primary egg-type and meat-type breeding flocks, following the 2010 NPIP conference as well as the changes we are proposing to the regulations for breeding turkeys in § 145.42.

*Revision to Sample Size for U.S. H5/H7 Avian Influenza Clean Classification*

The regulations in § 145.93 set out requirements for the classification of participating flocks of meat-type waterfowl and the eggs and baby poultry produced from them, with respect to certain diseases. Paragraph (c) of § 145.93 sets out requirements for the classification of such flocks as U.S. H5/H7 Avian Influenza Clean. Currently, the regulations state that, in order for multiplier breeding flocks to retain this classification, a sample of at least 30 birds must either be tested negative for avian influenza at intervals of 180 days, a sample of fewer than 30 birds may be tested and found negative for avian influenza at any one time if all pens are equally represented and a total of 30 birds are tested within each 180-day period, or a sample of at least 30 birds are tested and found negative to H5/H7 avian influenza within 21 days prior to movement to slaughter.

In the July 2014 final rule, we amended the regulations by changing the number of breeding birds required to be tested for avian influenza prior to movement to slaughter in §§ 145.23, 145.33, and 145.73. Rather than requiring 30 spent fowl to be tested, we now require the testing of a sample of 11 birds prior to movement to slaughter. This change was necessary because, generally, the entire flock of egg-type breeding chickens will be moved to slaughter at one time. Testing 11 birds per flock is also 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 provides adequate assurance that the flock is free of avian influenza. We are proposing to make the same change for meat-type waterfowl breeding flocks. Aligning sample numbers across similar flocks simplifies plan participation.

*Changes to the List of Commercial Poultry Plan Participants*

Part 146 of the regulations contains the NPIP provisions for commercial poultry. Section 146.3 provides requirements for participation in the Plan by commercial table-egg producers, raised-for-release upland game bird or waterfowl premises, commercial upland game bird or waterfowl slaughter plants, and meat-type chicken or turkey slaughter plants. We propose to amend the regulations to add commercial table-egg layer pullet flocks to the list of Plan participants in paragraph (c)(1) of § 146.2 and paragraph (a) in § 146.3. A *commercial table-egg layer pullet flock* is currently defined in § 146.1 as a table-egg layer flock prior to the onset of egg production. The inclusion of these flock owners as Plan participants provides a means for NPIP staff to identify participation in the Plan and to help facilitate the movement of birds within States and across State lines.

Finally, we are proposing to amend the definition of *poultry* in § 146.1 to make it more inclusive of all domesticated fowl bred for the purpose of providing eggs or meat, including waterfowl and game birds. This change would be consistent with the *poultry* definition in § 56.1 and § 145.1.

*Amendment to Slaughter Plant Inspection Requirements*

Section 146.11 of the regulations 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 state that a flock will be considered to be conforming to protocol if it meets the requirements described in §§ 146.33(a), 146.43(a), or 146.53(a). This change would correct problems inadvertently caused by combining all allowed testing requirements in 9 CFR part 146, subparts C, D, and E for participating slaughter plants into one set of testing requirements. One such problem was that the language in paragraph (b) directly contradicted the requirement allowing for testing at the slaughter plant on a shift basis. This change would also allow for future amendments to testing requirements for each subpart independent of one another and without having to amend the regulations in § 146.11.

*Addition of Testing Commercial Table-Egg Producing Upland Game Birds and Waterfowl for Avian Influenza*

The regulations in §§ 146.51 through 146.53 contain special provisions related to the participation in the NPIP program by commercial upland game birds, commercial waterfowl, raised-for-release upland game birds, and raised-for-release waterfowl and the classification of such flocks as U.S. H5/H7 Avian Influenza Monitored. Commercial upland game birds and waterfowl are sometimes grown for the primary purpose of producing eggs for human consumption, notably in specialty markets, restaurants, and health food outlets. Because a significant number of these flocks are large in size, we believe that the creation of a mechanism for NPIP participation and avian influenza surveillance for such flocks would be beneficial to the poultry industry as a whole. Therefore, we are proposing to amend the definition for *commercial upland game birds* and *commercial waterfowl* in § 146.51 to include birds grown for egg production. Currently, the definitions for these categories of birds include only those birds grown for the primary purpose of producing meat for human consumption.

We are also proposing to add commercial upland game birds and commercial waterfowl producing eggs for human consumption to the list of Plan participants in paragraphs (a) and (c) of § 146.52. We would also change the word ''purpose'' under both the definition for *commercial upland game birds* and *commercial waterfowl* to ''purposes.''

Paragraph (a) of § 146.53 contains the U.S. H5/H7 Avian Influenza Monitored classification for commercial waterfowl and commercial upland game birds. Currently, the commercial waterfowl and commercial upland game bird industry may earn U.S. H5/H7 Influenza Monitored classification by participating in routine surveillance for H5/H7 avian influenza through participating slaughter plants. We are proposing to add provisions for the regular surveillance of commercial waterfowl and game bird egg-producing flocks for avian influenza in new paragraphs (a)(4) and (a)(5). These provisions would require that a minimum of 11 birds per flock be tested negative to H5/H7 avian influenza as provided in § 146.13 within 30 days of disposal or within a 12 month period or that the participating flock has an on-going active and passive surveillance program for H5/H7 avian influenza approved by the Official State Agency and the Service.

*Amendments to Authorized Laboratory Requirements*

Subpart F of part 147 contains provisions for authorized laboratories and approved test and sanitation procedures under the NPIP. Section 147.52 contains the current provisions for approving authorized laboratories. While these provisions currently require laboratories to undergo an annual site visit and recordkeeping audit by their Official State Agency in order to maintain authorization, laboratory procedures and personnel generally do not change on a yearly basis. In addition, the need for Official State Agencies to inspect laboratories in other States serving industry members within their own States has proven to unnecessarily consume time and travel funds best utilized in other areas of the Plan. Therefore, we are proposing to amend the regulations to require that site visits take place at least once every 2 years.

*Amendments to the Approval Process for New Diagnostic Tests*

Section 147.54 outlines the required procedures for the approval of diagnostic test kits that are not licensed by APHIS. Current paragraph (a) states that the sensitivity of the kit will be estimated by testing known positive samples, as determined by official NPIP procedures found in the NPIP program standards or via other procedures approved by the Administrator. Because it is difficult to define a minor test modification versus a major test modification and to determine what data might be needed beforehand for a new test, we are proposing to allow the conditional use of a modified test side by side with the approved versions using field samples. This would make it easier for laboratories to participate in the test validation process. Field samples would have to be composed of those samples for which the presence or absence of the target organism or analyte has been determined by the current NPIP test rather than spiked samples or pure cultures. In addition, samples would have to come from a variety of field cases representing a range of low, medium, and high analyte concentrations. Spiked samples should only be used in the event that no other sample types are available. These changes would ensure that samples used for validation represent real samples and contain the same analytes and extraneous material that would be found in clinical samples. Realistic samples are critical to ensuring that a test will perform adequately with normal use. We are also proposing to clarify that laboratories should only be selected for their experience with testing for the target organism or analyte with the current NPIP approved test. Finally, we are proposing to remove the requirement that authorized laboratories be selected by the Service and clarify that the specificity of the kit will be ''evaluated'' rather than ''estimated'' in both current paragraphs (a) and (b) to provide more specific information on test performance. We are proposing this change because authorized NPIP laboratories use the same standards and guidelines. Therefore, any NPIP-authorized laboratory should be able to be utilized by any company seeking approval of a new test.

We are also proposing to revise the regulations in current paragraph (c) to remove the requirement for clinical samples to be supplied by the manufacturer of the test kit. Further, we propose to require that at least 50 known negative samples be tested by each laboratory rather than the currently required 50 known negative clinical samples. Because it can be difficult to find clinical samples and to share clinical samples for logistical reasons, removing the requirements for clinical samples and for samples to be supplied by the test kit manufacturer would allow any entity to provide clinical samples. However, the negative samples would have to contain relevant sample matrices/extraneous material which would be found in clinical samples. In addition, requiring at least 50 known negative samples rather than 50 known negative samples is necessary because, in the past, we have received fewer than 50 samples from a company when more samples were unavailable. This change would make it clearer that we view any sample sets consisting of fewer than 50 samples as incomplete and that we

would not review such sample sets. We are also proposing to add language allowing cooperating laboratories to perform a current NPIP procedure or test on samples alongside the test kit for comparison, and specific testing procedures for *Salmonella, Mycoplasma,* and avian influenza, as well as molecular-based testing procedures to better account for the differences among the three agents.

Paragraph (d) states that laboratories must submit assay response data to the kit manufacturer along with the official NPIP procedure. We are proposing to require that a worksheet for diagnostic test evaluation be submitted along with the raw data from the assay response and that the data and completed worksheet be submitted to the NPIP Senior Coordinator 4 months before the next General Conference Committee meeting, which is when test approval would be sought. Worksheets would be obtained by contacting the NPIP Senior Coordinator. The diagnostic test evaluation worksheet is intended to provide a standardized template to ensure that all needed data for test evaluation has been prepared and that the data is available in a uniform manner. This would make review of the data easier for the NPIP Technical Committee, which would facilitate the test approval process.

Paragraph (e) puts forth the process by which the NPIP Technical Committee will make their decision about whether to approve a new diagnostic test. We propose to clarify that a majority of the members of the Technical Committee would have to recommend whether to approve the test kit and that this recommendation would have to occur at the next scheduled General Conference Committee meeting.

Currently, the regulations do not provide procedures for modifying or removing diagnostic tests. Therefore, we are proposing to redesignate the introductory paragraph for § 147.54 as paragraph (a) and the following paragraphs (a) through (f) as paragraphs (a)(1) through (6) and add a new paragraph (b) to describe how diagnostic tests may be modified or removed. The proposed requirements would require the submission of data in support of modifying or removing the test in question to the NPIP Technical Committee in a manner similar to that in place for the approval of new test kits in current paragraph (e).

**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 General Conference Committee, 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 rulemaking would result in various changes to 9 CFR parts 56 and 145–147, modifying provisions of the NPIP. The proposed rule would clarify participation in the NPIP and amend participation requirements, amend definitions for poultry and breeding stock, amend the approval process for new diagnostic tests, and amend inspection and laboratory testing requirements. The proposed amendments to these regulations would improve the regulatory environment for poultry and poultry products.

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 General Conference Committee on behalf of Plan members, that is, changes recognized by the poultry industry as in their interest. We note that NPIP membership is voluntary.

Under these circumstances, the Administrator of the Animal and Plant Health Inspection Service has determined that this action 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 2 CFR chapter IV.)

**Paperwork Reduction Act**

In accordance with section 3507(d) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the information collection or recordkeeping requirements included in this proposed rule have been submitted for approval to the Office of Management and Budget (OMB). Please send written comments to the Office of Information and Regulatory Affairs, OMB, Attention: Desk Officer for APHIS, Washington, DC 20503. Please state that your comments refer to Docket No. APHIS–2014–0101. Please send a copy of your comments to: (1) APHIS, using one of the methods described under **ADDRESSES** at the beginning of this document, and (2) Clearance Officer, OCIO, USDA, Room 404–W, 14th Street and Independence Avenue SW., Washington, DC 20250. A comment to OMB is best assured of having its full effect if OMB receives it within 30 days of publication of this proposed rule.

We are proposing to amend the NPIP, its auxiliary provisions, and the indemnity regulations for the control of H5 and H7 low pathogenic avian influenza to clarify participation in the NPIP and amend participation requirements, amend definitions for poultry and breeding stock, amend the approval process for new diagnostic tests, and amend laboratory inspection and testing requirements. These changes would align the regulations with international standards and make them more transparent to APHIS stakeholders and the general public.

Implementing this rule will require certain new information collection activities such as Waterfowl and Game Bird Surveillance and Diagnostic Test Evaluation Worksheets. APHIS is asking OMB to approve, for 3 years, its use of these information collection activities in connection with APHIS' efforts to continually improve the health of the U.S. poultry population and the quality of U.S. poultry products. The NPIP has an existing information collection under OMB control number 0579–0007. At the next renewal of 0579–0007, we will merge the activities added by this proposed rule, subject to OMB approval.

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

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

(2) Evaluate the accuracy of our estimate of the burden of the proposed information collection, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the information collection on those who are to respond (such as through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology; *e.g.,* permitting electronic submission of responses).

*Estimate of burden:* Public reporting burden for this collection of information is estimated to average 1.8 hours per response.

*Respondents:* Flock owners, breeders, hatchery owners, table egg producers, laboratory personnel, and State animal health officials.

*Estimated annual number of respondents:* 10.

*Estimated annual number of responses per respondent:* 1.

*Estimated annual number of responses:* 10.

*Estimated total annual burden on respondents:* 18 hours. (Due to averaging, the total annual burden hours may not equal the product of the annual number of responses multiplied by the reporting burden per response.)

Copies of this information collection can be obtained from Ms. Kimberly Hardy, APHIS' Information Collection Coordinator, at (301) 851–2727.

**E-Government Act Compliance**

The Animal and Plant Health Inspection Service is committed to compliance with the E-Government Act to promote the use of the Internet and other information technologies, to provide increased opportunities for citizen access to Government information and services, and for other purposes. For information pertinent to E-Government Act compliance related to this proposed rule, please contact Ms. Kimberly Hardy, APHIS' Information Collection Coordinator, at (301) 851–2727.

**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 by revising the definition of *breeding flock* to read as follows:

**§ 56.1 Definitions.**

* * * * *

*Breeding flock.* A flock that is composed of stock that has been developed for commercial egg or meat production and is maintained for the principal purpose of producing progeny for the ultimate production of eggs or meat for human consumption.

* * * * *

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

■ 3. 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.

**§ 145.2 [Amended]**

■ 4. In § 145.2, paragraph (d) is amended by removing the words ''§ 145.3(d)'' and adding the words ''§ 145.3(e)'' in their place.

■ 5. Section 145.3 is amended as follows:

■ a. By redesignating paragraphs (a) through (f) as paragraphs (b) through (g), respectively.

■ b. By adding a new paragraph (a).

The addition reads as follows:

**§ 145.3 Participation.**

(a) The National Poultry Improvement Plan is a cooperative Federal-State-Industry program through which new or existing diagnostic technology can be effectively applied to improve poultry and poultry products by controlling or eliminating specific poultry diseases. The Plan consists of programs that identify States, flocks, hatcheries, dealers, and slaughter plants that meet specific disease control standards specified in the Plan. Participants shall maintain records to demonstrate that they adhere to the disease control programs in which they participate.

* * * * *

**§ 145.12 [Amended]**

■ 6. Section 145.12 is amended by adding, in paragraph (b), the words ''made available to and'' before the word ''examined''.

■ 7. Section 145.14 is amended as follows:

■ a. By revising paragraph (a)(5).

■ b. By revising paragraph (b)(1).

The revisions read as follows:

**§ 145.14 Testing.**

* * * * *

(a) * * *

(5) The official blood test shall include the testing of a sample of blood from each bird in the flock: Provided, That under specified conditions (see applicable provisions of §§ 145.23, 145.33, 145.43, 145.53, 145.63, 145.73, 145.83, and 145.93) the testing of a portion or sample of the birds may be used in lieu of testing each bird.

* * * * *

(b) * * *

(1) The official tests for *M. gallisepticum, M. meleagridis,* and *M. synoviae* shall be the serum plate agglutination test, the hemagglutination inhibition (HI) test, the enzyme-linked immunosorbent assay (ELISA) test [3], or a molecular based test. The HI test or molecular based test shall be used to confirm the positive results of other serological screening tests. HI titers of 1:40 or more may be interpreted as suspicious, and final judgment must be based on further samplings and/or culture of reactors. Tests must be conducted in accordance with this paragraph (b) and in accordance with part 147 of this subchapter.

* * * * *

[3] Procedures for the enzyme-linked immunosorbent assay (ELISA) test are set forth in the following publications:

A.A. Ansari, R.F. Taylor, T.S. Chang, ''Application of Enzyme-Linked Immunosorbent Assay for Detecting Antibody to Mycoplasma gallisepticum Infections in Poultry,'' *Avian Diseases,* Vol. 27, No. 1, pp. 21–35, January-March 1983; and

H.M. Opitz, J.B. Duplessis, and M.J. Cyr, ''Indirect Micro-Enzyme-Linked Immunosorbent Assay for the Detection of Antibodies to Mycoplasma synoviae and M. gallisepticum,'' *Avian Diseases,* Vol. 27, No. 3, pp. 773–786, July-September 1983; and

H.B. Ortmayer and R. Yamamoto, ''Mycoplasma Meleagridis Antibody Detection by Enzyme-Linked Immunosorbent Assay (ELISA),'' *Proceedings, 30th Western Poultry Disease Conference,* pp. 63–66, March 1981.

■ 8. In § 145.42, paragraph (b) is revised to read as follows:

**§ 145.42 Participation.**

* * * * *

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

* * * * *

■ 9. Section 145.53 is amended as follows:

■ a. By revising paragraphs (c)(1)(i), (c)(1)(ii) introductory text, and (c)(1)(ii)(A).

■ b. By revising paragraphs (d)(1)(i), (d)(1)(ii) introductory text, and (d)(1)(ii)(A).

The revisions read as follows:

**§ 145.53 Terminology and classification; flocks and products.**

* * * * *

(c) * * *

(1) * * *

(i) It is a flock in which all birds or a sample of at least 300 birds has been tested for *M. gallisepticum* as provided in § 145.14(b) when more than 4 months of age or upon reaching sexual maturity: *Provided,* That to retain this classification, a random sample of serum or egg yolk or a targeted bird sample of the choanal palatine cleft/fissure area using appropriate swabs from all the birds in the flock if the flock size is less than 30, but at least 30 birds, shall be tested at intervals of not more than 90 days: *And provided further,* That a sample comprised of less than 30 birds may be tested at any one time, with the approval of the Official State Agency and the concurrence of the Service, provided that a total of at least 30 birds, or all birds in the flock if flock size is less than 30, is tested within each 90-day period; or

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

(A) At intervals of not more than 90 days, a random sample of serum or egg yolk or a targeted bird sample of the choanal palatine cleft/fissure area using appropriate swabs from all the birds in the flock if flock size is less than 30, but at least 30 birds, shall be tested; or

* * * * *

(d) * * *

(1) * * *

(i) It is a flock in which all birds or a sample of at least 300 birds has been tested for *M. synoviae* as provided in § 145.14(b) when more than 4 months of age or upon reaching sexual maturity: *Provided,* That to retain this classification, a random sample of serum or egg yolk or a targeted bird sample of the choanal palatine cleft/fissure area using appropriate swabs (C.P. swabs) from all the birds in the flock if flock size is less than 30, but at least 30 birds, shall be tested at intervals of not more than 90 days: *And provided further,* That a sample comprised of less than 30 birds may be tested at any one time with the approval of the Official State Agency and the concurrence of the Service, provided that a total of at least 30 birds is tested within each 90-day period; or

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

(A) At intervals of not more than 90 days, a random sample of serum or egg yolk or a targeted bird sample of the choanal palantine cleft/fissure area using appropriate swabs from all the birds in the flock if the flock size is less than 30, but at least 30 birds shall be tested: *Provided,* That a sample of fewer than 30 birds may be tested at any one time with the approval of the Official State Agency and the concurrence of the Service, provided that a total of at least 30 birds, or the entire flock if flock size is less than 30, is tested each time and a total of at least 30 birds is tested within each 90-day period; or

* * * * *

■ 10. Section 145.83 is amended as follows:

■ a. By revising paragraph (f)(1)(i).

■ b. By removing paragraphs (f)(1)(ii) and (f)(1)(iii).

■ c. By redesignating paragraphs (f)(1)(iv) through (f)(1)(viii) as paragraphs (f)(1)(ii) through (f)(1)(vi).

■ d. In newly redesignated paragraphs (f)(1)(v) and (f)(1)(vi) by removing the words ''(f)(1)(vi)'' and adding the words ''(f)(1)(iv)'' in their place.

■ e. By revising paragraph (f)(3).

The revisions read as follows:

**§ 145.83 Terminology and classification; flocks and products.**

* * * * *

(f) * * *

(1) * * *

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

* * * * *

(3) In order for a hatchery to sell products of paragraphs (f)(1)(i) through (f)(1)(vi) of this section, all products handled shall meet the requirements of the classification.

* * * * *

■ 11. In § 145.92, paragraph (b) is revised to read as follows:

**§ 145.92 Participation.**

* * * * *

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

* * * * *

**§ 145.93 [Amended]**

■ 12. In § 145.93, paragraph (c)(3) is amended by removing the number ''30'' and adding the number ''11'' in its place.

## PART 146—NATIONAL POULTRY IMPROVEMENT PLAN FOR COMMERCIAL POULTRY

■ 13. 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.

■ 14. Section 146.1 is amended by revising the definition of *poultry* to read as follows:

**§ 146.1 Definitions.**

* * * * *

*Poultry.* Domesticated fowl, including chickens, turkeys, waterfowl, and game birds, except doves and pigeons, that are bred for the primary purpose of producing eggs or meat.

* * * * *

■ 15. Section 146.2 is amended by revising paragraph (c) to read as follows:

**§ 146.2 Administration.**

* * * * *

(c)(1) An Official State Agency may accept for participation a commercial table-egg layer pullet flock, commercial table-egg layer flock, or a commercial meat-type flock (including an affiliated flock) located in another participating State under a mutual understanding and

agreement, in writing, between the two Official State Agencies regarding conditions of participation and supervision.

(2) An Official State Agency may accept for participation a commercial table-egg layer pullet flock, commercial table-egg layer flock, or a commercial meat-type flock (including an affiliated flock) located in a State that does not participate in the Plan under a mutual understanding and agreement, in writing, between the owner of the flock and the Official State Agency regarding conditions of participation and supervision.

* * * * *

**§ 146.3 [Amended]**

■ 16. In § 146.3, paragraph (a) is amended by adding the words ''commercial table-egg layer pullet flock,'' before the words ''table-egg producer''.

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

**§ 146.11 Inspections.**

* * * * *

(b) A flock will be considered to be conforming to protocol if it meets the requirements as described in § 145.33(a), § 146.43(a), or § 146.53(a) of this chapter.

* * * * *

**§ 146.51 [Amended]**

■ 18. Section 146.51 is amended as follows:

■ a. In the definition of *commercial upland game birds* by changing the word ''purpose'' to ''purposes'' and adding the words ''eggs and/or'' before the word ''meat''.

■ b. In the definition of *commercial waterfowl,* by changing the word ''purpose'' to ''purposes'' and adding the words ''eggs and/or'' before the word ''meat''.

■ 19. Section 146.52 is amended by revising paragraphs (a) and (c) to read as follows:

**§ 146.52 Participation.**

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

* * * * *

(c) Raised-for-release upland game bird premises, raised-for-release waterfowl premises, and commercial upland game bird and commercial waterfowl producing eggs for human consumption premises that raise fewer than 25,000 birds annually are exempt from the special provisions of this subpart E.

■ 20. Section 146.53 is amended as follows:

■ a. In paragraph (a) introductory text, by adding the words ''or, in the case of egg-producing flocks, the regular surveillance of these flocks'' after the words ''participating slaughter plant''.

■ b. By adding paragraphs (a)(4) and (a)(5).

The additions read as follows:

**§ 146.53 Terminology and classification; slaughter plants and premises.**

* * * * *

(a) * * *

(4) It is a commercial upland game bird or waterfowl flock that produces eggs for human consumption where a minimum of 11 birds per flock have been tested negative to the H5/H7 subtypes of avian influenza as provided in § 146.13 (b) within 30 days of disposal or within a 12 month period.

(5) It is a commercial upland game bird or waterfowl flock that has an on-going active and passive surveillance program for H5/H7 subtypes of avian influenza that is approved by the Official State Agency and the Service.

* * * * *

## PART 147—AUXILIARY PROVISIONS ON NATIONAL POULTRY IMPROVEMENT PLAN

■ 21. 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.

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

**§ 147.52 Authorized laboratories.**

* * * * *

(d) *State site visit.* The Official State Agency will conduct a site visit and recordkeeping audit at least once every 2 years. 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.

* * * * *

■ 23. Section 147.54 is revised to read as follows:

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

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

(1) The sensitivity of the kit will be evaluated in at least three NPIP authorized laboratories by testing known positive samples, as determined by the official NPIP procedures found in the NPIP Program Standards or through other procedures approved by the Administrator. Field samples for which the presence or absence of the target organism or analyte has been determined by the current NPIP test should be used, not spiked samples or pure cultures. Samples from a variety of field cases representing a range of low, medium, and high analyte concentrations should be used. In some cases it may be necessary to utilize samples from experimentally infected animals. Spiked samples (clinical sample matrix with a known amount of pure culture added) should only be used in the event that no other sample types are available. Pure cultures should never be used. Additionally, laboratories should be selected for their experience with testing for the target organism or analyte with the current NPIP approved test. 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.

(2) The specificity of the kit will be evaluated in at least three NPIP authorized laboratories 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.

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

(4) 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. A completed worksheet for diagnostic test evaluation is required to be submitted with the raw data and may be obtained by contacting the NPIP Senior Coordinator. Raw data and the completed worksheet for diagnostic test evaluation must be submitted to the NPIP Senior Coordinator 4 months prior to the next scheduled General Conference Committee meeting, which is when approval will be sought.

(5) The findings of the cooperating laboratories will be evaluated by the NPIP Technical Committee, and the Technical Committee will make a majority recommendation whether to approve the test kit to the General Conference Committee at the next scheduled General Conference Committee meeting. If the Technical Committee recommends approval, the final approval will be granted in accordance with the procedures described in §§ 147.46, 147.47, and 147.48.

(6) 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.

(b) *Approved tests modification and removal.* (1) The specific data required for modifications of previously approved tests will be taken on a case-by-case basis by the technical committee.

(2) If the Technical Committee determines that only additional field data is needed at the time of submission for a modification of a previously approved test, allow for a conditional approval for 60 days for data collection side-by-side with a current test. The submitting party must provide complete protocol and study design, including criteria for pass/fail to the Technical Committee. The Technical Committee must review the data prior to final approval. This would only apply to the specific situation where a modified test needs additional field data with poultry to be approved.

(3) Approved diagnostic tests may be removed from the Plan by submission of a proposed change from a participant, Official State Agency, the Department, or other interested person or industry organization. The data in support of removing an approved test will be compiled and evaluated by the NPIP Technical Committee, and the Technical Committee will make a majority recommendation whether to remove the test kit to the General Conference Committee at the next scheduled General Conference Committee meeting. If the Technical Committee recommends removal, the final decision to remove the test will be granted in accordance with the procedures described in §§ 147.46, 147.47, and 147.48.

Done in Washington, DC, this 18th day of March 2016.

**Kevin Shea,**

*Administrator, Animal and Plant Health Inspection Service.*

[FR Doc. 2016–06664 Filed 3–23–16; 8:45 am]

**BILLING CODE 3410–34–P**

## SECURITIES AND EXCHANGE COMMISSION

### 17 CFR Part 241

**[Release No. 34–77407; File No. S7–03–16]**

### Notice of Proposed Commission Interpretation Regarding Automated Quotations Under Regulation NMS

**AGENCY:** Securities and Exchange Commission.

**ACTION:** Proposed interpretation; request for comment.

**SUMMARY:** The Securities and Exchange Commission is publishing for comment a proposed interpretation with respect to the definition of automated quotation under Rule 600(b)(3) of Regulation NMS.

**DATES:** Comments should be received on or before April 14, 2016.

**ADDRESSES:** Comments may be submitted by any of the following methods:

*Electronic Comments*

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number S7–03–16 on the subject line.

*Paper Comments*

- Send paper comments in triplicate to Brent J. Fields, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number S7–03–16. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/other.shtml*). Comments are also available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make publicly available.

**FOR FURTHER INFORMATION CONTACT:** Richard Holley III, Assistant Director, at (202) 551–5614, Michael Bradley, Special Counsel, at (202) 551–5594, or Michael Ogershok, Attorney-Advisor, at 202–551–5541, all in the Office of Market Supervision, Division of Trading and Markets, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–7010.

**SUPPLEMENTARY INFORMATION:**

#### I. Background

*A. IEX's Form 1*

On August 21, 2015, Investors' Exchange LLC (''IEX'') submitted to the Commission a Form 1 application seeking registration as a national securities exchange under Section 6 of the Securities Exchange Act of 1934 (''Act'').[1] On September 9, 2015, IEX submitted Amendment No. 1 to its Form 1 application.[2] Notice of IEX's filing of its Form 1 application, as amended, was published for comment in the **Federal Register** on September 22, 2015.[3] Recently, IEX submitted three additional amendments to its Form 1 application.[4] Simultaneously with the

[1] 15 U.S.C. 78f.

[2] In Amendment No. 1, IEX submitted updated portions of its Form 1 application, including revised exhibits, a revised version of the proposed IEX Rule Book, and revised Addenda C–2, C–3, C–4, D–1, D–2, F–1, F–2, F–3, F–4, F–5, F–6, F–7, F–8, F–9, F–10, F–11, F–12, and F–13. IEX's Form 1 application, as amended, including all of the Exhibits referenced above, is available online at *www.sec.gov/rules/other.shtml* as well as at the Commission's Public Reference Room.

[3] *See* Securities Exchange Act Release No. 75925 (September 15, 2015), 80 FR 57261. On December 18, 2015, IEX consented to an extension of time to March 21, 2016 for Commission consideration of its Form 1 application. *See* Letter from Sophia Lee, General Counsel, IEX, to Brent J. Fields, Secretary, Commission, dated December 18, 2015.

[4] In Amendment No. 2, filed on February 29, 2016, IEX proposed changes to its Form 1 application to, among other things, redesign its outbound routing functionality to direct routable orders first to the IEX router instead of directly to the IEX matching engine. *See* Letter from Sophia Lee, General Counsel, IEX, to Brent J. Fields, Secretary, Commission, dated February 29, 2016, at 1. In this manner, the IEX router would ''interact with the IEX matching system over a 350 microsecond speed-bump in the same way an independent third party broker would be subject to a speed bump.'' *See id.* In Amendment No. 3, filed on March 4, 2016, IEX proposed changes to its Form 1 application to clarify and correct revisions to its