(a) is intended to be the basis from which the egg/meat-type game bird and egg/meat-type waterfowl industry may conduct a program to monitor for the H5/H7 subtypes of avian influenza. It is intended to determine the presence of the H5/H7 subtypes of avian influenza in egg/meat-type game birds and egg/meat-type waterfowl through routine surveillance of each participating slaughter plant or, in the case of egg-producing flocks, the regular surveillance of these flocks. A slaughter plant or flock will qualify for the classification in this paragraph (a) when the Official State Agency determines that it has met one of the following requirements:

(1) It is a meat-type game bird slaughter plant or meat-type waterfowl slaughter plant where a minimum of 11 birds per shift are tested negative for the H5/H7 subtypes of avian influenza, as provided in §146.13(b), at slaughter;

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

(3) It is a meat-type game bird slaughter plant or meat-type waterfowl slaughter plant that has an ongoing active and passive surveillance program for H5/H7 subtypes of avian influenza that is approved by the Official State Agency and the Service.

(4) It is an egg-type game bird or egg-type 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 an egg-type game bird or egg-type waterfowl flock that has an ongoing active and passive surveillance program for H5/H7 subtypes of avian influenza that is approved by the Official State Agency and the Service.

(b) [Reserved]

[74 FR 14717, Apr. 1, 2009, as amended at 76 FR 15797, Mar. 22, 2011; 81 FR 53250, Aug. 12, 2016; 85 FR 62571, Oct. 5, 2020]

PART 147—AUXILIARY PROVISIONS ON NATIONAL POULTRY IMPROVEMENT PLAN

Subpart A—Blood Testing Procedures

Sec.
147.1 Blood testing procedures.
147.2–147.9 [Reserved]

Subpart B—Bacteriological Examination Procedure

147.10 Bacteriological examination procedures.
147.11–147.17 [Reserved]

Subpart C—Sanitation Procedures

147.21 Sanitation procedures.
147.22–147.27 [Reserved]

Subpart D—Molecular Examination Procedures

147.30 Molecular examination procedures.
147.31 [Reserved]

Subpart E—Procedure for Changing National Poultry Improvement Plan

147.41 Definitions.
147.42 General.
147.43 General Conference Committee.
147.44 Submitting, compiling, and distributing proposed changes.
147.45 Official delegates.
147.46 Committee consideration of proposed changes.
147.47 Conference consideration of proposed changes.
147.48 Approval of conference recommendations by the Department.

Subpart F—Authorized Laboratories and Approved Tests and Sanitation Procedures

147.51 Definitions.
147.52 Authorized laboratories.
147.53 Approved tests and sanitation procedures.
147.54 Approval of diagnostic test kits not licensed by the Service.

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

SOURCE: 36 FR 23121, Dec. 3, 1971, unless otherwise noted. Redesignated at 44 FR 61586, Oct. 26, 1979.

Subpart A—Blood Testing Procedures

§ 147.1 Blood testing procedures.

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

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

[79 FR 38766, July 9, 2014]

§§ 147.2–147.9 [Reserved]

Subpart B—Bacteriological Examination Procedure

§ 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).

[79 FR 38766, July 9, 2014]

§§ 147.11–147.17 [Reserved]

Subpart C—Sanitation Procedures

§ 147.21 Sanitation procedures.

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

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

[79 FR 38766, July 9, 2014; 79 FR 44263, July 31, 2014]

§§ 147.22–147.27 [Reserved]

Subpart D—Molecular Examination Procedures

SOURCE: 72 FR 1425, Jan. 12, 2007, unless otherwise noted.

§ 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).

[79 FR 38766, July 9, 2014]

§ 147.31 [Reserved]

Subpart E—Procedure for Changing National Poultry Improvement Plan

§ 147.41 Definitions.

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

Department. The U.S. Department of Agriculture.

Egg type chickens. Chickens bred for the primary purpose of producing eggs for human consumption.

Exhibition Poultry. Domesticated fowl which are bred for the combined purposes of meat or egg production and competitive showing.

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

Meat type chickens. Chickens bred for the primary purpose of producing meat.

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

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

Plan Conference. A meeting convened for the purpose of recommending changes in the provisions of the Plan.

Plan or NPIP. The National Poultry Improvement Plan.

Service. The Animal and Plant Health Inspection Service, Veterinary Services, of the Department.

State. Any State, the District of Columbia, or Puerto Rico.

Waterfowl. Domesticated fowl that normally swim, such as ducks and geese.

[36 FR 23121, Dec. 3, 1971, as amended at 38 FR 3038, Feb. 1, 1973. Redesignated at 44 FR 61586, Oct. 26, 1979; 59 FR 12805, Mar. 18, 1994, as amended at 79 FR 38766, July 9, 2014; 83 FR 28355, June 19, 2018]

§ 147.42 General.

Changes in this subchapter shall be made in accordance with the procedure described in this subpart: *Provided*, That the Department reserves the right to make changes in this subchapter without observance of such procedure when such action is deemed necessary in the public interest.

§ 147.43 General Conference Committee.

(a) The General Conference Committee Chairperson and the Vice Chairperson shall be elected by the members of the General Conference Committee. A representative of the Animal and Plant Health Inspection Service will serve as Executive Secretary and will provide the necessary staff support for the General Conference Committee. The General Conference Committee shall consist of one member-at-large who is a participant in the National Poultry Improvement Plan and one member to be elected, as provided in paragraph (b) of this section, from each of the following regions:

(1) North Atlantic: Maine, New Hampshire, Vermont, Massachusetts, Rhode Island, Connecticut, New York, New Jersey, and Pennsylvania.

(2) East North Central: Ohio, Indiana, Illinois, Michigan, and Wisconsin.

(3) West North Central: Minnesota, Iowa, Missouri, North Dakota, South Dakota, Nebraska, and Kansas.

(4) South Atlantic: Delaware, District of Columbia, Maryland, Virginia, West Virginia, North Carolina, South Carolina, Georgia, Florida, and Puerto Rico.

(5) South Central: Kentucky, Tennessee, Alabama, Mississippi, Arkansas, Louisiana, Oklahoma, and Texas.

(6) Western: Montana, Idaho, Wyoming, Colorado, New Mexico, Arizona, Utah, Nevada, Washington, Oregon, California, Alaska, and Hawaii.

(b) The regional committee members and their alternates will be elected by the official delegates of their respective regions, and the member-at-large will be elected by all official delegates. There must be at least two nominees for each position, the voting will be by secret ballot, and the results will be recorded. The ballots for electing regional committee members and their alternates will be printed in such a way as to allow the specific selection of one nominee for member, and one nominee for alternate from the remaining nominees. At least one nominee from each region must be from an underrepresented group (minorities, women, or persons with disabilities). The process for soliciting nominations for regional committee members will include, but not be limited to: Advertisements in at least two industry journals, such as the newsletters of the American Association of Avian Pathologists, the National Chicken Council, the United Egg Producers, and the National Turkey Federation; a FEDERAL REGISTER announcement; and special inquiries for nominations from universities or colleges with minority/disability enrollments and faculty members in poultry science or veterinary science.

(c) Three regional members shall be elected at each Plan Conference. All members shall serve for a period of 4 years, subject to the continuation of

the Committee by the Secretary of Agriculture, and may not succeed themselves: *Provided*, That an alternate member who assumed a Committee member vacancy following mid-term would be eligible for re-election to a full term. When there is a vacancy for the member-at-large position, the General Conference Committee shall make an interim appointment and the appointee shall serve until the next Plan Conference at which time an election will be held. If a vacancy occurs due to both a regional member and alternate being unable to serve, the vacant position will be filled by an election at the earliest regularly scheduled national or regional Plan Conference, where members of the affected region have assembled.

(d) The duties and functions of the General Conference Committee shall be as follows:

(1) Advise and make recommendations to the Department on the relative importance of maintaining, at all times, adequate departmental funding for the NPIP to enable the Senior Coordinator and staff to fully administer the provisions of the Plan.

(2) Advise and make yearly recommendations to the Department with respect to the NPIP budget well in advance of the start of the budgetary process.

(3) Assist the Department in planning, organizing, and conducting the biennial National Poultry Improvement Plan Conference.

(4) Consider each proposal submitted as provided in §147.44 and make recommendations to subpart Committees and the Conference. Meet jointly with the NPIP Technical Committee and consider the technical aspects and accuracy of each proposal. Recommend whether new proposals (*i.e.*, proposals that have not been submitted as provided in §147.44) should be considered by the delegates to the Plan Conference.

(5) During the interim between Plan Conferences, represent the cooperating States in:

(i) Advising the Department with respect to administrative procedures and interpretations of the Plan provisions as contained in 9 CFR.

(ii) Assisting the Department in evaluating comments received from interested persons concerning proposed amendments to the Plan provisions.

(iii) Recommending to the Secretary of Agriculture any changes in the provisions of the Plan as may be necessitated by unforeseen conditions when postponement until the next Plan Conference would seriously impair the operation of the program. Such recommendations shall remain in effect only until confirmed or rejected by the next Plan Conference, or until rescinded by the committee.

(6) Serve as an official advisory committee for the study of problems relating to poultry health and as the need arises, to make specific recommendations to the Secretary of Agriculture concerning ways in which the Department may assist the industry in solving these problems.

(7) Serve as a direct liaison between the NPIP and the United States Animal Health Association.

(8) Advise and make recommendations to the Department regarding NPIP involvement or representation at poultry industry functions and activities as deemed necessary or advisable for the purposes of the NPIP.

[36 FR 23121, Dec. 3, 1971, as amended at 40 FR 1505, Jan. 8, 1975. Redesignated at 44 FR 61586, Oct. 26, 1979, and amended at 45 FR 10316, Feb. 15, 1980; 47 FR 21996, May 20, 1982; 50 FR 19900, May 13, 1985; 59 FR 12805, Mar. 18, 1994; 61 FR 11525, Mar. 21, 1996; 65 FR 8023, Feb. 17, 2000; 67 FR 8475, Feb. 25, 2002; 74 FR 14718, Apr. 1, 2009; 83 FR 28355, June 19, 2018]

§147.44 Submitting, compiling, and distributing proposed changes.

(a) Changes in this subchapter may be proposed by any participant, Official State Agency, the Department, or other interested person or industry organization.

(b) Except as provided in §147.43(d)(4), 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, and participants in the Plan shall submit their proposed changes through their Official State Agency.

(c) The name of the proponent shall be indicated on each proposed change when submitted. Each proposal should

be accompanied by a brief supporting statement.

(d) The Service will notify all persons on the NPIP mailing lists concerning the dates and general procedure of the conference. Hatchery and dealer participants will be reminded of their privilege to submit proposed changes and to request copies of all the published proposed changes.

(e) The proposed changes, together with the names of the proponents and supporting statements, will be compiled by the Service and issued in processed form. When two or more similar changes are submitted, the Service will endeavor to unify them into one proposal acceptable to each proponent. Copies will be distributed to officials of the Official State Agencies cooperating in the NPIP. Additional copies will be made available for meeting individual requests.

[36 FR 23121, Dec. 3, 1971. Redesignated at 44 FR 61586, Oct. 26, 1979, and amended at 49 FR 19807, May 10, 1984; 79 FR 38766, July 9, 2014]

§ 147.45 Official delegates.

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

[85 FR 62572, Oct. 5, 2020]

§ 147.46 Committee consideration of proposed changes.

(a) The following committees shall be established to give preliminary consideration to the proposed changes falling in their respective fields:

(1) Egg-type breeding chickens.

(2) Meat-type breeding chickens.

(3) Breeding turkeys.

(4) Breeding waterfowl, exhibition poultry, and game birds.

(5) Breeding ostriches, emus, rheas, and cassowaries.

(6) Egg-type commercial chickens.

(7) Meat-type commercial chickens.

(8) Meat-type commercial turkeys.

(9) Commercial upland game birds and waterfowl and raised-for-release upland game birds and waterfowl.

(b) Each official delegate shall be appointed a voting member in one of the committees specified in paragraph (a) of this section.

(c) Since several of the proposals may be interrelated, the committees shall consider them as they may relate to others, and feel free to discuss related proposals with other committees.

(d) The committees shall make recommendations to the conference as a whole concerning each proposal. The committee report shall show any proposed change in wording and the record of the vote on each proposal, and suggest an effective date for each proposal recommended for adoption. The individual committee reports shall be submitted to the chairman of the conference, who will combine them into one report showing, in numerical sequence, the committee recommendations on each proposal. Once completed, the combined committee report will be distributed electronically to the Official State Agencies prior to the delegates voting on the final day of the biennial conference.

(e) The committee meetings shall be open to any interested person. Advocates for or against any proposal should feel free to appear before the appropriate committee and present their views.

[36 FR 23121, Dec. 3, 1971, as amended at 41 FR 48727, Nov. 5, 1976. Redesignated at 44 FR 61586, Oct. 26, 1979, as amended at 65 FR 8023, Feb. 17, 2000; 71 FR 56333, Sept. 26, 2006; 74 FR 14718, Apr. 1, 2009; 83 FR 28355, June 19, 2018]

§ 147.47 Conference consideration of proposed changes.

(a) The chairman of the conference shall be a representative of the Department.

(b) At the time designated for voting on proposed changes by the official delegates, the chairman of the General Conference Committee and the four committee chairmen shall sit at the speaker's table and assist the chairman of the conference.

(c) Each committee chairman shall present the proposals which his committee approves or recommends for adoption as follows: ''Mr. Chairman. The committee for Egg-type chickens recommends the adoption of Proposal No. _____, for the following reasons (stating the reasons): I move the adoption of Proposal No. _____.'' A second will then be called for. If the recommendation is seconded, discussion and a formal vote will follow.

(d) Each committee chairman shall present the proposals which his committee does not approve as follows: ''Mr. Chairman. The Committee for Egg-type chickens does not approve Proposal No. _____.'' The chairman will then ask if any official delegate wishes to move for the adoption of the proposal. If moved and seconded, the proposal is subject to discussion and voted. If there is no motion for approval, or if moved but not seconded, there can be no discussion or vote.

(e) Discussion on any motion must be withheld until the motion has been properly seconded, except that the delegate making the motion is privileged, if he desires, to give reasons for his motion at the time of making it. To gain the floor for a motion or for discussion on a motion, the official delegate in the case of a motion, or anyone in case of discussion on a motion, shall rise, address the chair, give his name and State, and be recognized by the chair before proceeding further. While it is proper to accept motions only from official delegates and to limit voting only to such delegates, it is, however, equally proper to accept discussion from anyone interested. To conserve time, discussion should be pointed and limited to the pertinent features of the motion.

(f) Proposals that have not been submitted in accordance with § 147.44 will be considered by the conference only with the unanimous consent of the General Conference Committee. Any such proposals must be referred to the appropriate committee for consideration before being presented for action by the conference.

(g) Voting will be by States, and each official delegate, as determined by § 147.45, will be allowed one vote on each proposal pertaining to the program prescribed by the subpart which he represents.

(h) A roll call of States for a recorded vote will be used when requested by a delegate or at the discretion of the chairman.

(i) All motions on proposed changes shall be for adoption.

(j) Proposed changes shall be adopted by a majority vote of the official delegates present and voting.

(k) The conference shall be open to any interested person.

[36 FR 23121, Dec. 3, 1971, as amended at 41 FR 48727, Nov. 5, 1976. Redesignated at 44 FR 61586, Oct. 26, 1979]

§ 147.48 Approval of conference recommendations by the Department.

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

[85 FR 62572, Oct. 5, 2020]

Subpart F—Authorized Laboratories and Approved Tests and Sanitation Procedures

SOURCE: 79 FR 38766, July 9, 2014, unless otherwise noted.

§ 147.51 Definitions.

The following definitions apply in this subpart:

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

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

NPIP or Plan. The National Poultry Improvement Plan.

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

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

[79 FR 38766, July 9, 2014, as amended at 83 FR 28355, June 19, 2018]

§ 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. Further, the NPIP may approve and authorize additional laboratories to produce and distribute a check test as needed. The authorized laboratory must use the next available check test for each assay that it performs.

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

(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 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.

(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.

[79 FR 38766, July 9, 2014, as amended at 81 FR 53251, Aug. 12, 2016; 83 FR 28355, June 19, 2018; 85 FR 62572, Oct. 5, 2020]

§ 147.53 Approved tests and sanitation procedures.

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

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

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

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

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

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

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

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

(A) No comments were received on the notice;

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

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

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

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

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

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

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

(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 must test at least 50 known negative samples obtained from several sources, to provide a representative sampling of the general population. The cooperating laboratories must perform a current NPIP procedure or NPIP approved test on the samples alongside the test kit for comparison and must provide an outline of the method on the worksheet for diagnostic test evaluation. Reproducibility and robustness data should also be included.

(4) Cooperating laboratories will submit to the kit manufacturer all compiled output data regarding the assay

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

(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.

[81 FR 53251, Aug. 12, 2016, as amended at 83 FR 28356, June 19, 2018]