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SUBCHAPTER G—LIVESTOCK IMPROVEMENT

PART 145—NATIONAL POULTRY IMPROVEMENT PLAN FOR BREEDING POULTRY

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SOURCE: 36 FR 23112, Dec. 3, 1971, unless otherwise noted. Redesignated at 44 FR 61586, Oct. 26, 1979.

Subpart A—General Provisions

§ 145.1 Definitions.

Words used in this part in the singular form shall be deemed to import the plural, and vice versa, as the case may demand. Except where the context otherwise requires, for the purposes of this part the following terms shall be construed, respectively, to mean:

Administrator. The Administrator, Animal and Plant Health Inspection Service, or any person authorized to act for the Administrator.

Affiliated flockowner. A flockowner who is participating in the Plan through an agreement with a participating hatchery.

Animal and Plant Health Inspection Service. The Animal and Plant Health Inspection Service of the U.S. Department of Agriculture.

Authorized agent. Any person designated under §145.11(a) to collect official samples for submission to an authorized laboratory in accordance with part 147 of this subchapter.

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

Authorized testing agent. Any person designated under §145.11(a) to collect official samples for submission to an authorized laboratory in accordance with part 147 of this subchapter and to perform the stained antigen, rapid whole blood test for pullorum typhoid.

Avian influenza. An infection or disease of poultry caused by viruses in the family *Orthomyxoviridae,* genus *Influenzavirus* A.

Baby poultry. Newly hatched poultry (chicks, poults, ducklings, goslings, keets, etc.).

Colon bacilli. For the purpose of this chapter, those organisms which are gram negative, non spore-forming bacilli, which ferment lactose with gas formation, and serve as an index of fecal contamination.

Dealer. An individual or business that deals in commerce in hatching eggs, newly-hatched poultry, and started poultry obtained from breeding flocks and hatcheries. This does not include an individual or business that deals in commerce in buying and selling poultry for slaughter only.

Department. The U.S. Department of Agriculture.

Domesticated. Propagated and maintained under the control of a person.

Equivalent or equivalent requirements. Requirements which are equal to or exceed the program, conditions, criteria, or classifications with which they are compared, as determined by the Official State Agency and with the concurrence of the Service.

Exposed (Exposure). Contact with birds, equipment, personnel, supplies, or any article infected with, or contaminated by, communicable poultry disease organisms.

Flock—(1) *As applied to breeding.* All poultry of one kind of mating (breed and variety or combination of stocks) and of one classification on one farm;

(2) *As applied to disease control.* All of the poultry on one farm except that, at the discretion of the Official State Agency, any group of poultry which is segregated from another group and has been so segregated for a period of at least 21 days may be considered as a separate flock.

Fluff sample. Feathers, shell membrane, and other debris resulting from the hatching of poultry.

Fowl typhoid or typhoid. A disease of poultry caused by Salmonella gallinarum.

Franchise breeder. A breeder who normally sells products under a specific strain or trade name and who authorizes other hatcheries to produce and sell products under this same strain or trade name.

Franchise hatchery. A hatchery which has been authorized by a franchise breeder to produce and sell products under the breeder's strain or trade name.

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

with a previously identified highly pathogenic avian influenza virus.

Hatchery. Hatchery equipment on one premises operated or controlled by any person for the production of baby poultry.

Independent flock. A flock that produces hatching eggs and that has no ownership affiliation with a specific hatchery.

Infected flock. A flock in which an authorized laboratory has discovered one or more birds infected with a communicable poultry disease for which a program has been established under the Plan.

Midlay. Approximately 2–3 months after a flock begins to lay or after a molted flock is put back into production.

Multiplier breeding flock. A flock that is intended for the production of hatching eggs used for the purpose of producing progeny for commercial egg or meat production or for other nonbreeding purposes.

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

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.

Official State Agency. The State authority recognized by the Department to cooperate in the administration of the Plan.

Official supervision—(1) *As applied to Plan programs*. The direction, inspection, and critical evaluation by the Official State Agency of compliance with the provisions of the Plan;

(2) *As applied to non-Plan but equivalent State poultry improvement programs*. The direction, inspection, and critical evaluation by an officer or agency of a State government, of compliance with a publicly announced State poultry improvement program.

Person. A natural person, firm, or corporation.

Plan. The provisions of the National Poultry Improvement Plan contained in this part.

Poultry. Domesticated fowl, including chickens, turkeys, ostriches, emus, rheas, cassowaries, waterfowl, and game birds, except doves and pigeons, which are bred for the primary purpose of producing eggs or meat.

Primary breeding flock. A flock composed of one or more generations that is maintained for the purpose of establishing, continuing, or improving parent lines.

Products. Poultry breeding stock and hatching eggs, baby poultry, and started poultry.

Program. Management, sanitation, testing, and monitoring procedures which, if complied with, will qualify, and maintain qualification for, designation of a flock, products produced from the flock, or a state by an official Plan classification and illustrative design, as described in §145.10 of this part.

Public exhibition. A public show of poultry.

Pullorum disease or pullorum. A disease of poultry caused by Salmonella pullorum.

Reactor. A bird that has a positive reaction to a test, required or recommended in this part or in accordance with part 147 of this subchapter, for any poultry disease for which a program has been established under the Plan.

Salmonella. Any bacteria belonging to the genus Salmonella, including the arizona group.

Sanitize. To treat with a product which is registered by the Environmental Protection Agency as germicidal, fungicidal, pseudomonocidal, or tuberculocidal, in accordance with the specifications for use as shown on the label of each product. The Official State Agency, with the concurrence of the Service, shall approve each product

or procedure according to its specified usage.

Senior Coordinator. An employee of the Service whose duties may include, but will not necessarily be limited to:

(1) Serving as executive secretary of the General Conference Committee;

(2) Serving as chairperson of the Plan Conference described in §147.47;

(3) Planning, organizing, and conducting the Plan Conference;

(4) Reviewing NPIP authorized laboratories as described in §147.52;

(5) Coordinating the State administration of the NPIP through periodic reviews of the administrative procedures of the Official State Agencies, according to the applicable provisions of the Plan and the Memorandum of Understanding;

(6) Coordinating rulemaking to incorporate the proposed changes of the provisions approved at the Plan conference into the regulations in parts 145, 146, and 147 of this subchapter;

(7) Directing the production of official NPIP publications;

(8) Proposing an annual budget for plan activities and the General Conference Committee; and

(9) Providing overall administration of the NPIP.

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

Serial. The total quantity of completed product which has been thoroughly mixed in a single container and identified by a serial number.

Sexual maturity. The average age at which a species of poultry is biologically capable of reproduction.

Started poultry. Young poultry (chicks, pullets, cockerels, capons, poults, ducklings, goslings, keets, etc.) that have been fed and watered and are less than 6 months of age.

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

State Inspector. Any person employed or authorized under §145.11(b) to perform functions under this part.

Stock. A term used to identify the progeny of a specific breeding combination within a species of poultry. These breeding combinations may include pure strains, strain crosses, breed crosses, or combinations thereof.

Strain. Poultry breeding stock bearing a given name produced by a breeder through at least five generations of closed flock breeding.

Succeeding flock. A flock brought onto a premises during the 12 months following removal of an infected flock.

Suspect flock. A flock shall be considered, for the purposes of the Plan, to be a suspect flock if any evidence exists that it has been exposed to a communicable poultry disease.

Trade name or number. A name or number compatible with State and Federal laws and regulations applied to a specified stock or product thereof.

[36 FR 23112, Dec. 3, 1971. Redesignated at 44 FR 61586, Oct. 26, 1979]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting §145.1, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at *www.fdsys.gov*.

§145.2 Administration.

(a) The Department cooperates through a Memorandum of Understanding with Official State Agencies in the administration of the Plan. In the Memorandum of Understanding, the Official State Agency must designate a contact representative to serve as a liaison between the Service and the Official State Agency.

(b) The administrative procedures and decisions of the Official State Agency are subject to review by the Service. The Official State Agency shall carry out the administration of the Plan within the State according to the applicable provisions of the Plan and the Memorandum of Understanding.

(c) An Official State Agency may accept for participation an affiliated flock located in another State under a mutual understanding and agreement, in writing, between the two Official State Agencies regarding conditions of participation and supervision.

(d) The Official State Agency of any State may, except as limited by §145.3(e), adopt regulations applicable to the administration of the Plan in such State further defining the provisions of the Plan or establishing higher standards compatible with the Plan.

(e) An authorized laboratory of the National Poultry Improvement Plan

will conduct tests in accordance with part 147 of this subchapter when determining the status of a participating flock with respect to an official Plan classification.

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

[36 FR 23112, Dec. 3, 1971. Redesignated at 44 FR 61586, Oct. 26, 1979, and amended at 48 FR 57473, Dec. 30, 1983; 67 FR 8468, Feb. 25, 2002; 74 FR 14714, Apr. 1, 2009; 79 FR 38754, July 9, 2014; 81 FR 53249, Aug. 12, 2016]

§ 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.

(b) Any person producing or dealing in products may participate in the Plan when he has demonstrated, to the satisfaction of the Official State Agency, that his 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 without signing an agreement with the Official State Agency.

(c) Each participant shall comply with the Plan throughout the operating year of the Official State Agency, or until released by such Agency.

(d) A participant in any State shall participate with all of his poultry hatching egg supply flocks and hatchery operations within such State. The participant shall report to the Official State Agency on VS Form 9–2 (formerly NPIP Form 3B) or through other appropriate means each breeding flock before the birds reach 24 weeks of age or, in the case of ostriches, emus, rheas, and cassowaries, before the birds reach 20 months of age. This report will include:

(1) Name and address of flockowner;

(2) Flock location and designation;

(3) Type: Primary or Multiplier;

(4) Breed, variety, strain, or trade name of stock;

(5) Source of males;

(6) Source of females;

(7) Number of birds in the flock; and

(8) Intended classification of flock.

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

(f) No person shall be compelled by the Official State Agency to qualify products for any of the other classifications described in §145.10 as a condition of qualification for the U.S. Pullorum-Typhoid Clean classification.

(g) Participation in the Plan shall entitle the participant to use the Plan emblem reproduced below:

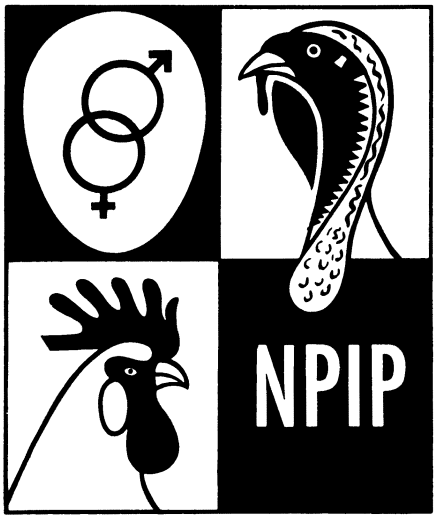

FIGURE 1.

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

[36 FR 23112, Dec. 3, 1971, as amended at 40 FR 1500, Jan. 8, 1975. Redesignated at 44 FR 61586, Oct. 26, 1979 and amended at 48 FR 57473, Dec. 30, 1983; 57 FR 57341, Dec. 4, 1992; 63 FR 40010, July 27, 1998; 65 FR 8016, Feb. 17, 2000; 79 FR 38754, July 9, 2014; 81 FR 53249, Aug. 12, 2016]

§ 145.4 General provisions for all participants.

(a) Records of purchases and sales and the identity of products handled shall be maintained in a manner satisfactory to the Official State Agency.

(b) Products, records of sales and purchase of products, and material used to advertise products shall be subject to inspection by the Official State Agency at any time.

(c) Advertising must be in accordance with the Plan, and applicable rules and regulations of the Official State Agency and the Federal Trade Commission. A participant advertising products as being of any official classification may include in his advertising reference to associated or franchised hatcheries only when such hatcheries produce the same kind of products of the same classification.

(d) Except as provided by this paragraph, participants in the Plan may not buy or receive products for any purpose from nonparticipants unless they are part of an equivalent program, as determined by the Official State Agency. Participants in the Plan may buy or receive products from flocks that are neither participants nor part of an equivalent program, for use in breeding flocks or for experimental purposes, under the following conditions only:

(1) With the permission of the Official State Agency and the concurrence of the Service; and

(2) By segregation of all birds before introduction into the breeding flock. Upon reaching sexual maturity, the segregated birds must be tested and found negative for pullorum-typhoid. The Official State Agency may require a second test at its discretion.

(e) Each participant shall be assigned a permanent approval number by the Service. This number, prefaced by the numerical code of the State, will be the official approval number of the participant and may be used on each certificate, invoice, shipping label, or other document used by the participant in the sale of his products. Each Official State Agency which requires an approval or permit number for out-of-State participants to ship into its State should honor this number. The approval number shall be withdrawn when the participant no longer qualifies for participation in the Plan.

(Approved by the Office of Management and Budget under control number 0579–0057)

[36 FR 23112, Dec. 3, 1971, as amended at 38 FR 13706, May 24, 1973; 41 FR 48723, Nov. 5, 1976. Redesignated at 44 FR 61586, Oct. 26, 1979, as amended at 47 FR 21991, May 20, 1982; 48 FR 57473, Dec. 30, 1983; 57 FR 57341, Dec. 4, 1992]

§ 145.5 Specific provisions for participating flocks.

(a) Poultry equipment, and poultry houses and the land in the immediate vicinity thereof, shall be kept in sanitary condition in accordance with part 147 of this subchapter. The participating flock, its eggs, and all equipment used in connection with the flock shall be separated from nonparticipating flocks, in a manner acceptable to the Official State Agency.

(b) All flocks shall consist of healthy, normal individuals characteristic of

the breed, variety, cross, or other combination which they are stated to represent.

(c) A flock shall be deemed to be a participating flock at any time only if it has qualified for the U.S. Pullorum-Typhoid Clean classification, as prescribed in Subparts B, C, D, E, F, G, H, or I of this part.

(d) Each bird shall be identified with a sealed and numbered band obtained through or approved by the Official State Agency: *Provided*, That exception may be made at the discretion of the Official State Agency.

[36 FR 23112, Dec. 3, 1971, as amended at 38 FR 13706, May 24, 1973. Redesignated at 44 FR 61586, Oct. 26, 1979, as amended at 63 FR 40010, July 27, 1998; 79 FR 38754, July 9, 2014]

§ 145.6 Specific provisions for participating hatcheries.

(a) Hatcheries must be kept in sanitary condition, acceptable to the Official State Agency. The sanitary procedures outlined in the NPIP Program Standards, or other procedures approved by the Administrator in accordance with § 147.53(d), will be considered as a guide in determining compliance with this provision. The minimum requirements with respect to sanitation include the following:

(1) Egg room walls, ceilings, floors, air filters, drains, and humidifiers should be cleaned and disinfected at least two times per week. Cleaning and disinfection procedures should be in accordance with part 147 of this subchapter.

(2) Incubator room walls, ceilings, floors, doors, fan grills, vents, and ducts should be cleaned and disinfected after each set or transfer. Incubator rooms should not be used for storage. Plenums should be cleaned at least weekly. Egg trays and buggies should be cleaned and disinfected after each transfer. Cleaning and disinfection procedures should be in accordance with part 147 of this subchapter.

(3) Hatcher walls, ceilings, floors, doors, fans, vents, and ducts should be cleaned and disinfected after each hatch. Hatcher rooms should be cleaned and disinfected after each hatch and should not be used for storage. Plenums should be cleaned after each hatch. Cleaning and disinfection procedures should be in accordance with part 147 of this subchapter.

(4) Chick/poult processing equipment and rooms should be thoroughly cleaned and disinfected after each hatch. Chick/poult boxes should be cleaned and disinfected before being reused. Vaccination equipment should be cleaned and disinfected after each use. Cleaning and disinfection procedures should be in accordance with part 147 of this subchapter.

(5) Hatchery residue, such as chick/poult down, eggshells, infertile eggs, and dead germs, should be disposed of promptly and in a manner satisfactory to the Official State Agency.

(6) The entire hatchery should be kept in a neat, orderly condition and cleaned and disinfected after each hatch.

(7) Effective insect and rodent control programs should be implemented.

(b) A hatchery that keeps started poultry must keep such poultry separated from the incubator room in a manner satisfactory to the Official State Agency.

(c) All baby and started poultry offered for sale under Plan terminology should be normal and typical of the breed, variety, cross, or other combination represented.

(d) Eggs incubated should be sound in shell, typical for the breed, variety, strain, or cross thereof and reasonably uniform in shape. Hatching eggs should be trayed and the baby poultry boxed with a view to uniformity of size.

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

(f) If a person is responsibly connected with more than one hatchery, all of such hatcheries must participate in the Plan if any of them participate. A person is deemed to be responsibly connected with a hatchery if he or she is a partner, officer, director, holder, owner of 10 percent or more of the voting stock, or an employee in a managerial or executive capacity.

[36 FR 23112, Dec. 3, 1971. Redesignated at 44 FR 61586, Oct. 26, 1979, and amended at 49 FR 19802, May 10, 1984; 65 FR 8016, Feb. 17, 2000; 67 FR 8468, Feb. 25, 2002; 79 FR 38754, July 9, 2014]

§ 145.7 Specific provisions for participating dealers.

Dealers in poultry breeding stock, hatching eggs, or baby or started poultry shall comply with all provisions in this part which apply to their operations.

§ 145.8 Terminology and classification; general.

(a) The official classification terms defined in §§145.9 and 145.10 and the various designs illustrative of the official classifications reproduced in §145.10 may be used only by participants and to describe products that have met all the specific requirements of such classifications.

(b) Products produced under the Plan shall lose their identity under Plan terminology when they are purchased for resale by or consigned to nonparticipants.

(c) Participating flocks, their eggs, and the baby and started poultry produced from them may be designated by their strain or trade name. When a breeder's trade name or strain designation is used, the participant shall be able by records to substantiate that the products so designated are from flocks that are composed of either birds hatched from eggs produced under the direct supervision of the breeder of such strain, or stock multiplied by persons designated and so reported by the breeder to each Official State Agency concerned.

§ 145.9 Terminology and classification; hatcheries and dealers.

Participating hatcheries and dealers shall be designated as ''National Plan Hatchery'' and ''National Plan Dealer'', respectively. All Official State Agencies shall be notified by the Service of additions, withdrawals, and changes in classification.

[36 FR 23112, Dec. 3, 1971. Redesignated at 44 FR 61586, Oct. 26, 1979, and amended at 47 FR 21991, May 20, 1982]

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

Participating flocks, products produced from them, and States that have met the requirements of a classification in this part may be designated by the corresponding illustrative design in this section.

(a) [Reserved]

(b) *U.S. Pullorum-Typhoid Clean.* (See §145.23(b), §145.33(b), §145.43(b), §§145.53(b), 145.63(a), 145.73(b), 145.83(b), and 145.93(b).)

FIGURE 3

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

Figure 4

(d) *U.S. Sanitation Monitored.* (See §145.33(d).)

FIGURE 5

(e) *U.S. M. Synoviae Clean.* (See §145.23(e), §145.23(g), §145.33(e), §145.33(g), §145.43(e), and §145.53(d)).

Figure 6

(f) *U.S. M. Meleagridis Clean*—(See § 145.43(d)).

Figure 7

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

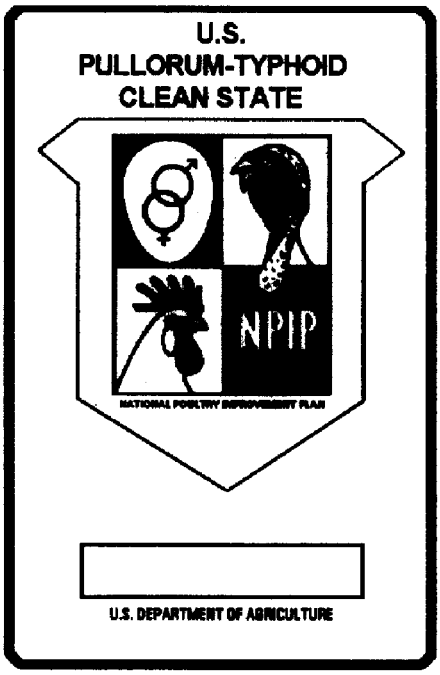

Figure 8

(h) *U.S. Pullorum-Typhoid Clean State, Turkeys.* (See § 145.44(b).)

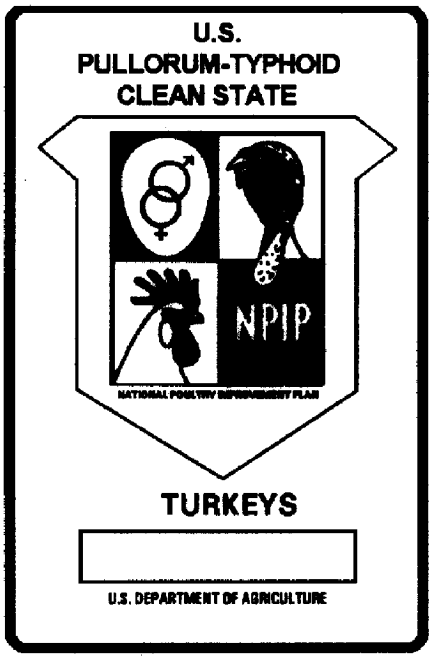

Figure 9

(i) *U.S.M. Gallisepticum Clean State, Turkeys.* (See §145.44(c).)

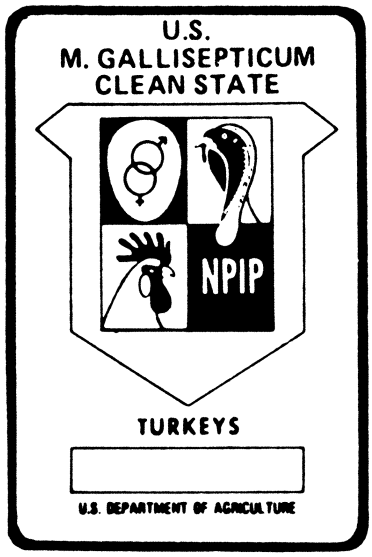

Figure 10

(j) *U.S. M. Gallisepticum Clean State, Meat-Type Chickens.* (See §145.34(b).)

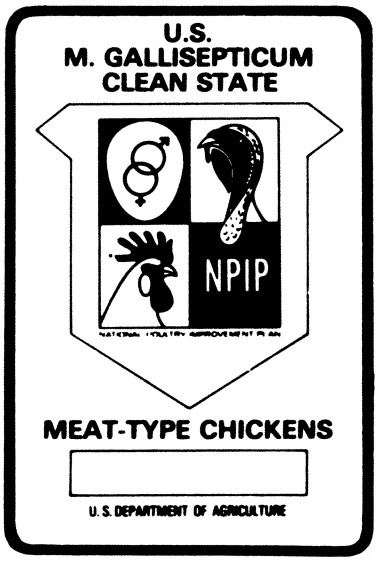

Figure 11

(k) *U.S. Sanitation Monitored, Turkeys.* (See §145.43(f).)

FIGURE 12

(l) [Reserved]

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

Figure 14

(n) *U.S. M. Synoviae Clean State, Turkeys.* (See § 145.44(d).)

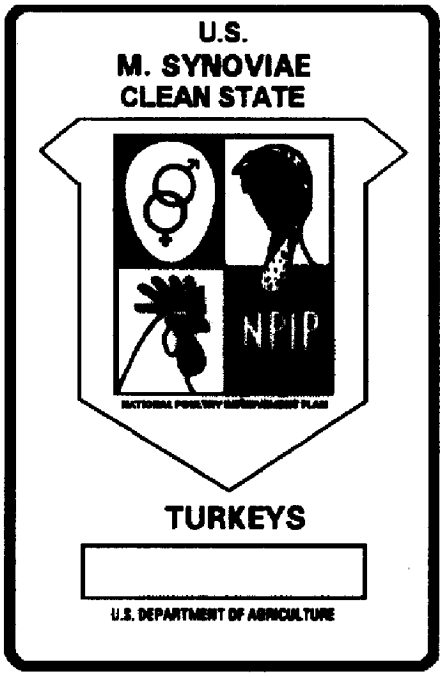

Figure 15

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

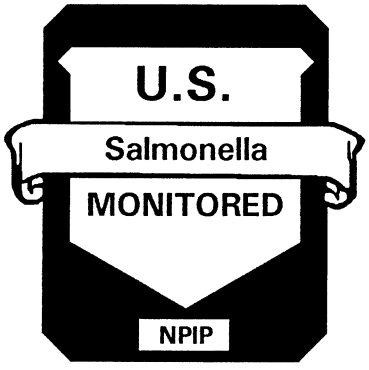

Figure 16

(p) *U.S. M. Gallisepticum Monitored.* (See § 145.33(j).)

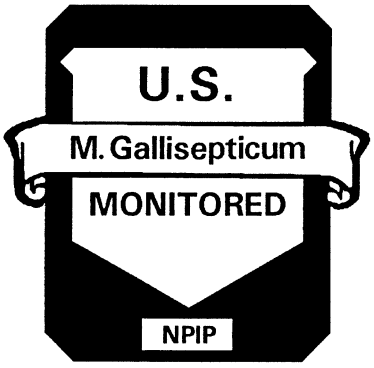

Figure 17

(q) *U.S. M. Synoviae Monitored.* (See §145.33(k).)

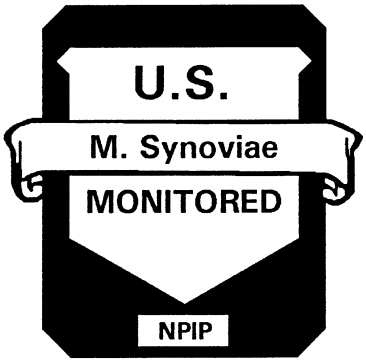

Figure 18

(r) *U.S. Avian Influenza Clean.* (See §§145.23(h), 145.33(l), 145.63(b), 145.73(f), and 145.83(g).)

FIGURE 19

(s) *U.S. M. Meleagridis Clean State, Turkeys.* (See §145.44(e).)

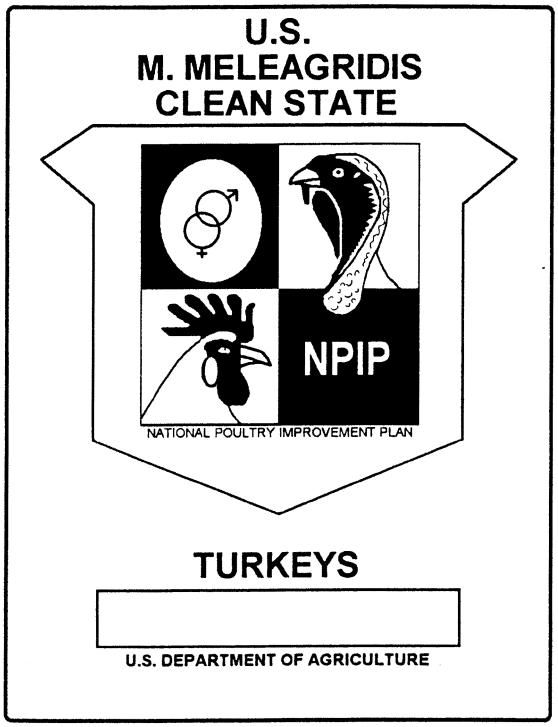
U.S.
M. MELEAGRIDIS
CLEAN STATE
NPIP
NATIONAL POULTRY IMPROVEMENT PLAN
TURKEYS
U.S. DEPARTMENT OF AGRICULTURE

FIGURE 20

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

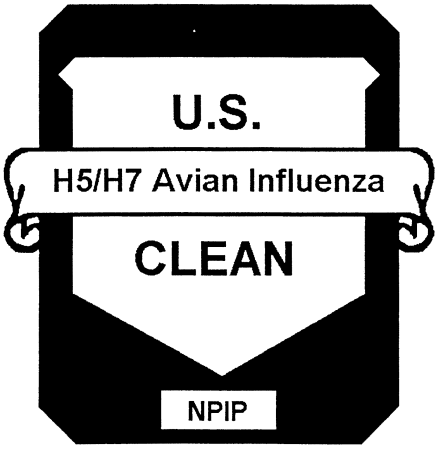

FIGURE 21

[38 FR 13706, May 24, 1973. Redesignated at 44 FR 61586, Oct. 26, 1979]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 145.10, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at *www.fdsys.gov*.

§ 145.11 Supervision.

(a) The Official State Agency may designate qualified persons as Authorized Agents to do the sample collecting provided for in § 145.14 and may designate qualified persons as Authorized Testing Agents to do the sample collecting and blood testing provided for in § 145.14.

(b) The Official State Agency shall employ or authorize qualified persons as State Inspectors to perform the qualification testing of participating flocks, and to perform the official inspections necessary to verify compliance with the requirements of the Plan.

(c) Authorities issued under the provisions of this section shall be subject to cancellation by the official State agency on the grounds of incompetence or failure to comply with the provisions of the Plan or regulations of the official State agency. Such actions shall not be taken until a thorough investigation has been made by the official State agency and the authorized person has been given notice of the proposed action and the basis therefor and an opportunity to present his views.

[36 FR 23112, Dec. 3, 1971, as amended at 38 FR 13706, May 24, 1973; 41 FR 48723, Nov. 5, 1976. Redesignated at 44 FR 61586, Oct. 26, 1979, as amended at 72 FR 1418, Jan. 12, 2007]

§ 145.12 Inspections.

(a) Each participating hatchery shall be audited at least one time annually or a sufficient number of times each year to satisfy the Official State Agency that the operations of the hatchery are in compliance with the provisions of the Plan.

(b) The records of all flocks maintained primarily for production of hatching eggs shall be made available to and examined annually by a State Inspector. Records shall include VS Form 9–2, ''Flock Selecting and Testing Report''; VS Form 9–3, ''Report of Sales of Hatching Eggs, Chicks, and Poults''; set and hatch records; egg receipts; and egg/chick orders or invoices. Records shall be maintained for 3 years. On-site inspections of flocks and premises will be conducted if the State Inspector determines that a breach of sanitation, blood testing, or other provisions has occurred for Plan programs for which the flocks have or are being qualified.

[36 FR 23112, Dec. 3, 1971, as amended at 40 FR 1501, Jan. 8, 1975. Redesignated at 44 FR 61586, Oct. 26, 1979, and amended at 54 FR 23955, June 5, 1989; 59 FR 12798, Mar. 18, 1994; 72 FR 1418, Jan. 12, 2007; 81 FR 53249, Aug. 12, 2016]

§ 145.13 Debarment from participation.

Participants in the Plan, who after investigation by the Official State Agency or its representative, are notified in writing of their apparent noncompliance with the Plan provisions or regulations of the Official State Agency, shall be afforded a reasonable time, as specified by the Official State Agency, within which to demonstrate or achieve compliance. If compliance is not demonstrated or achieved within the specified time, the Official State Agency may debar the participant from further participation in the Plan for such period, or indefinitely, as the Agency may deem appropriate. The debarred participant shall be afforded

notice of the bases for the debarment and opportunity to present his views with respect to the debarment in accordance with procedures adopted by the Official State Agency. The Official State Agency shall thereupon decide whether the debarment order shall continue in effect. Such decision shall be final unless the debarred participant, within 30 days after the issuance of the debarment order, requests the Administrator to determine the eligibility of the debarred participant for participation in the Plan. In such event the Administrator shall determine the matter de novo in accordance with the rules of practice in 7 CFR part 50, which are hereby made applicable to proceedings before the Administrator under this section. The definitions in 7 CFR 50.10 and the following definitions shall apply with respect to terms used in such rules of practice:

(a) *Administrator* means the Administrator, Animal and Plant Health Inspection Service of the U.S. Department of Agriculture or any officer or employee to whom authority has heretofore been delegated or to whom authority may hereafter be delegated to act in his stead.

[36 FR 23112, Dec. 3, 1971, as amended at 38 FR 3038, Feb. 1, 1973. Redesignated at 44 FR 61586, Oct. 26, 1979, and amended at 47 FR 21991, May 20, 1982; 67 FR 8468, Feb. 25, 2002]

§ 145.14 Testing.

Poultry must be more than 4 months of age when tested for an official classification: *Provided,* That turkey candidates under subpart D of this part may be tested at more than 12 weeks of age; game bird candidates under subpart E of this part may be tested when more than 4 months of age or upon reaching sexual maturity, whichever comes first; and ostrich, emu, rhea, and cassowary candidates under subpart F of this part may be tested when more than 12 months of age. Samples for official tests shall be collected by an Authorized Agent, Authorized Testing Agent, or State Inspector and tested by an authorized laboratory, except that the stained antigen, rapid whole-blood test for pullorum-typhoid may be conducted by an Authorized Testing Agent or State Inspector. For Plan programs in which a representative sample may be tested in lieu of an entire flock, except the ostrich, emu, rhea, and cassowary program in §145.63(a), the minimum number tested shall be 30 birds per house, with at least 1 bird taken from each pen and unit in the house. The ratio of male to female birds in representative samples of birds from meat-type chicken, waterfowl, exhibition poultry, and game bird flocks must be the same as the ratio of male to female birds in the flock. In houses containing fewer than 30 birds other than ostriches, emus, rheas, and cassowaries, all birds in the house must be tested.

(a) *For Pullorum-Typhoid.* (1) The official blood tests for pullorum-typhoid shall be the standard tube agglutination test, the microagglutination test, the enzyme-linked immunosorbent assay test (ELISA), or the rapid serum test for all poultry; and the stained antigen, rapid whole-blood test for all poultry except turkeys. Official blood tests must be conducted in accordance with part 147 of this subchapter or according to literature provided by the producer. Only antigens approved by the Department and of the polyvalent type shall be used for the rapid whole-blood and tube agglutination tests. Each serial of tube antigen shall be submitted by the antigen producer to the Department for approval upon manufacture and once a year thereafter as long as antigen from that serial continues to be made available for use. All microtest antigens and enzyme-linked immunosorbent assay reagents shall also be approved by the Department.[1]

(2) [Reserved]

(3) There shall be an interval of at least 21 days between any official blood test and any previous test with pullorum-typhoid antigen.

(4) [Reserved]

(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

[1] The criteria and procedures for Department approval of antigens and reagents may be obtained from the Animal and Plant Health Inspection Service, Veterinary Services, Center for Veterinary Biologics, 510 South 17th Street, Suite 104, Ames, IA 50010–8197.

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.

(6) Poultry from flocks undergoing qualification testing for participation in the Plan that have a positive reaction to an official blood test named in paragraph (a)(1) of this section shall be evaluated for pullorum-typhoid as follows:

(i) Serum samples that react on rapid serum test or enzyme-labeled immunosorbent assay test (ELISA), or blood from birds that react on the stained antigen, rapid whole-blood test for all birds except turkeys, shall be tested with either the standard tube agglutination test or the microagglutination test.

(ii) Reactors to the standard tube agglutination test (in dilutions of 1:50 or greater) or the microagglutination test (in dilutions of 1:40 or greater) shall be submitted to an authorized laboratory for bacteriological examination. If there are more than four reactors in a flock, a minimum of four reactors shall be submitted to the authorized laboratory; if the flock has four or fewer reactors, all of the reactors must be submitted. Bacteriological examination must be conducted in accordance with part 147 of this subchapter. When reactors are submitted to the authorized laboratory within 10 days of the date of reading an official blood test named in paragraph (a)(6)(i) of this section, and the bacteriological examination fails to demonstrate pullorum-typhoid infection, the Official State Agency shall presume that the flock has no pullorum-typhoid reactors.

(iii) If a flock owner does not wish to submit reactors for bacteriological examination, then the reactors shall be isolated and retested within 30 days using an official blood test named in paragraph (a)(1) of this section. If this retest is positive, additional examination of the reactors and flock will be performed in accordance with paragraph (a)(6)(ii) of this section. During this 30-day period, the flock must be maintained under a security system, specified or approved by the Official State Agency, that will prevent physical contact with other birds and assure that personnel, equipment, and supplies that could be a source of pullorum-typhoid spread are sanitized.

(7) When *S. pullorum* or *S. gallinarum* organisms are isolated by an authorized laboratory from baby poultry, or from fluff samples produced by hatching eggs, the infected flock shall qualify for participation in the Plan with two consecutive negative results to an official blood test named in paragraph (a)(1) of this section. A succeeding flock must be qualified for participation in the Plan's pullorum-typhoid program with a negative result to an official blood test named in paragraph (a)(1) of this section. Testing to qualify flocks for Plan participation must include the testing of all birds in infected flocks and succeeding flocks for a 12-month period, and shall be performed or physically supervised by a State Inspector; Provided, That at the discretion of the Official State Agency, a sample of at least 500 birds, rather than all birds in the flock, may be tested by the State Inspector if it is agreed upon by the Official State Agency, the flockowner, and the Administrator. If the State Inspector determines that a primary breeding flock has been exposed to *S. pullorum* or *S. gallinarum,*[2] the Official State Agency shall require:

(i) The taking of blood samples—performed by or in the presence of a State Inspector—from all birds on premises exposed to birds, equipment, supplies, or personnel from the primary breeding flock during the period when the State Inspector determined that exposure to *S. pullorum* or *S. gallinarum* occurred.[2]

(ii) The banding of all birds of these premises—performed or physically supervised by a State Inspector—in order to identify any bird that tests positive; and

(iii) The testing of blood samples at an authorized laboratory using an official blood test named in paragraph (a)(1) of this section.

[2] In making determinations of exposure, the State Inspector shall evaluate both evidence proving that exposure occurred and circumstances indicating a high probability of contacts with: infected wild birds; contaminated feed or waste; or birds, equipment, supplies, or persons from or exposed to flocks infected with *S. pullorum* or *S. gallinarum.*

(8) All domesticated fowl, except waterfowl, on the farm of the participant shall either be properly tested to meet the same standards as the participating flock or these birds and their eggs shall be separated from the participating flock and its eggs.

(9) All tests for pullorum-typhoid in flocks participating in or candidates for participation in the Plan shall be reported to the Official State Agency within 10 days following the completion of such tests. All reactors shall be considered in determining the classification of the flock.

(10) Any drug, for which there is scientific evidence of masking the test reaction or hindering the bacteriological recovery of Salmonella organisms, shall not be fed or administered to poultry within 3 weeks prior to a test or bacteriological examination upon which a Salmonella classification is based.

(11) When suitable evidence, as determined by the Official State Agency or the State Animal Disease Control Official, indicates that baby or started poultry produced by participating hatcheries are infected with organisms for which the parent flock received an official control classification and this evidence indicates that the infection was transmitted from the parent flock, the Official State Agency may, at its discretion, require additional testing of the flock involved. If infection is found in the parent flock, its classification shall be suspended until the flock is requalified under the requirements for the classification. Furthermore, the Official State Agency may require that the hatching eggs from such flocks be removed from the incubator and destroyed prior to hatching. When Salmonella organisms are isolated from a specimen which originated in a participating hatchery, the Official State Agency shall attempt to locate the source of the infection. The results of the investigation and the action taken to eliminate the infection shall be reported by the Official State Agency to the Service.

(b) *For Mycoplasma gallisepticum, M. meleagridis, and M. synoviae.* (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.

(2) The serological tests shall be conducted using *M. gallisepticum*, *M. meleagridis*, or *M. synoviae* antigens approved by the Department or the Official State Agency and shall be performed in accordance with the recommendations of the producer of the antigen.

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

(4) Any drug, for which there is scientific evidence of masking the test reaction or hindering the bacteriological recovery of mycoplasma organisms, shall not be fed or administered to poultry within three weeks prior to a test or bacteriological examination upon which a Mycoplasma classification is based.

(5) The official molecular examination procedures for *M. gallisepticum* are

[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.

the PCR test described in §147.30 of this subchapter and the real-time PCR test described in §147.31 of this subchapter. The official molecular examination procedure for *M. synoviae* is the PCR test described in §147.30 of this subchapter.

(c) [Reserved]

(d) *For avian influenza.* The official tests for avian influenza are described in paragraphs (d)(1) and (d)(2) of this section.

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

(ii) *The agar gel immunodiffusion (AGID) test.* (A) The AGID test must be conducted on all ELISA-positive samples.

(B) The AGID test must be conducted using reagents approved by the Department and the Official State Agency.

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

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

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

(i) *The real time reverse transcriptase/polymerase chain reaction (RRT–PCR) assay.* (A) The RRT–PCR tests must be conducted using reagents approved by the Department and the Official State Agency. The RRT–PCR must be conducted using the National Veterinary Services Laboratories (NVSL) official protocol for RRT–PCR and must be conducted by personnel who have passed an NVSL proficiency test.

(B) Positive results from the RRT–PCR must be further tested by Federal Reference Laboratories using appropriate tests for confirmation. Final judgment may be based upon further sampling and appropriate tests for confirmation.

(ii) *USDA-licensed type A influenza antigen capture immunoassay (ACIA).* (A) The USDA-licensed type A influenza ACIA must be conducted using test kits approved by the Department and the Official State Agency and must be conducted in accordance with the recommendations of the producer or manufacturer.

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

(3) The official determination of a flock as positive for the H5 or H7 subtypes of avian influenza may be made only by NVSL.

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

[36 FR 23112, Dec. 3, 1971]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting §145.14, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at *www.fdsys.gov*.

§145.15 Diagnostic surveillance program for low pathogenic avian influenza.

(a) The Official State Agency must develop a diagnostic surveillance program for H5/H7 low pathogenic avian influenza for all poultry in the State. The exact provisions of the program are at the discretion of the States. The Service will use the standards in paragraph (b) of this section in assessing individual State plans for adequacy, including the specific provisions that the State developed. The standards should be used by States in developing those plans.

(b) Avian influenza must be a disease reportable to the responsible State authority (State veterinarian, etc.) by all licensed veterinarians. To accomplish

this, all laboratories (private, State, and university laboratories) that perform diagnostic procedures on poultry must examine all submitted cases of unexplained respiratory disease, egg production drops, and mortality for avian influenza by both an approved serological test and an approved antigen detection test. Memoranda of understanding or other means must be used to establish testing and reporting criteria (including criteria that provide for reporting H5 and H7 low pathogenic avian influenza directly to the Service) and approved testing methods. In addition, States should conduct outreach to poultry producers, especially owners of smaller flocks, regarding the importance of prompt reporting of clinical symptoms consistent with avian influenza.

[74 FR 14715, Apr. 1, 2009]

Subpart B—Special Provisions for Multiplier Egg-Type Chicken Breeding Flocks and Products

§ 145.21 Definitions.

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

Chicks. Newly hatched chickens.

Egg type chicken breeding flocks. Flocks that are composed of stock that has been developed for egg production and are maintained for the principal purpose of producing chicks for the ultimate production of eggs for human consumption.

Started chickens. Young chickens (chicks, pullets, cockerels, capons) which have been fed and watered and are less than 6 months of age.

[36 FR 23112, Dec. 3, 1971, as amended at 38 FR 13707, May 24, 1973; 41 FR 48723, Nov. 5, 1976. Redesignated at 44 FR 61586, Oct. 26, 1979, and amended at 59 FR 12798, Mar. 18, 1994; 65 FR 8017, Feb. 17, 2000]

§ 145.22 Participation.

Participating flocks of multiplier egg type chickens, and the eggs and chicks produced from them, shall comply with the applicable general provisions of subpart A of this part and the special provisions of this subpart B.

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

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

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

[36 FR 23112, Dec. 3, 1971, as amended at 40 FR 1501, Jan. 8, 1975. Redesignated at 44 FR 61586, Oct. 26, 1979, and amended at 49 FR 19802, May 10, 1984; 57 FR 57341, Dec. 4, 1992; 65 FR 8017, Feb. 17, 2000; 68 FR 64510, Nov. 14, 2003; 72 FR 1419, Jan. 12, 2007; 79 FR 38755, July 9, 2014]

§ 145.23 Terminology and classification; flocks and products.

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

(a) [Reserved]

(b) *U.S. Pullorum-Typhoid Clean.* A flock in which freedom from pullorum and typhoid has been demonstrated to the official State agency under the criteria in one of the following paragraphs (b)(1) through (4) of this section: *Provided,* That a flock qualifying by means of a blood test shall be tested within the past 12 months, except that the retesting of a participating flock which is retained for more than 12 months shall be conducted a minimum of 4 weeks after the induction of molt. (See § 145.14 relating to the official blood test where applicable.)

(1) It has been officially blood tested with no reactors.

(2) It is a multiplier breeding flock and meets the following specifications as determined by the Official State Agency and the Service:

(i) The flock is located in a State where all persons performing poultry disease diagnostic services within the State are required to report to the Official State Agency within 48 hours the

source of all poultry specimens from which S. pullorum or S. gallinarum is isolated;

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

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

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

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

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

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

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

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

(vi) All flocks found to be infected with pullorum or typhoid are quarantined until marketed or destroyed under the supervision of the Official State Agency, or until subsequently blood tested, following the procedure for reacting flocks as contained in §145.14(a)(5), and all birds fail to demonstrate pullorum or typhoid infection;

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

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

(4) It is a multiplier breeding flock located in a State which has been determined by the Service to be in compliance with the provisions of (b)(3) of this section, and in which pullorum

disease or fowl typhoid is not known to exist nor to have existed in hatchery supply flocks within the State during the preceding 12 months.

(c) *U.S. M. Gallisepticum Clean.* (1) A flock maintained in accordance with part 147 of this subchapter with respect to Mycoplasma isolation, sanitation, and management and in which freedom from *M. gallisepticum* has been demonstrated under the criteria specified in paragraph (c)(1)(i) or (ii) of this section.

(i) [Reserved]

(ii) It is a multiplier breeding flock which originated as U.S. M. Gallisepticum Clean chicks from primary breeding flocks and from which a sample comprised of a minimum of 150 birds per flock has been tested for *M. gallisepticum* as provided in §145.14(b) when more than 4 months of age: *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, 75 birds from the flock shall be tested, *Provided*, that fewer than 75 birds from the flock may be tested at any one time if all pens are equally represented and a total of at least 75 birds from the flock is tested within each 90-day period; or

(B) At intervals of not more than 30 days, a sample of 25 cull chicks produced from the flock shall be subjected to laboratory procedures acceptable to the Official State Agency and approved by the Service, for the detection and recovery of *M. gallisepticum*; or

(C) At intervals of not more than 30 days, egg yolk testing shall be conducted in accordance with part 147 of this subchapter.

(2) A participant handling U.S. M. Gallisepticum Clean products shall keep these products separate from other products in a manner satisfactory to the Official State Agency.

(3) U.S. M. Gallisepticum Clean chicks shall be boxed in clean boxes and delivered in trucks that have been cleaned and disinfected in accordance with part 147 of this subchapter.

(d) *U.S. S. Enteritidis Clean.* This classification is intended for egg-type breeders wishing to assure their customers that the hatching eggs and chicks produced are certified free of *Salmonella enteritidis*.

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

(i) The flock originated from a U.S. *S. enteritidis* Clean flock, or meconium from the chick boxes and a sample of chicks that died within 7 days after hatching are examined bacteriologically for salmonella at an authorized laboratory. Cultures from positive samples shall be serotyped.

(ii) All feed fed to the flock shall meet the following requirements:

(A) Pelletized feed shall contain either no animal protein or only animal protein products produced under the Animal Protein Products Industry (APPI) *Salmonella* Education/Reduction Program. The protein products must have a minimum moisture content of 14.5 percent and must have been heated throughout to a minimum temperature of 190 °F., or above, or to a minimum temperature of 165 °F. for at least 20 minutes, or to a minimum temperature of 184 °F. under 70 lbs. pressure during the manufacturing process.

(B) Mash feed may contain no animal protein other than an APPI animal protein product supplement manufactured in pellet form and crumbled: *Provided*, that mash feed may contain nonpelleted APPI animal protein product supplements if the finished feed is treated with a salmonella control product approved by the Food and Drug Administration.

(iii) Feed shall be stored and transported in such a manner as to prevent possible contamination;

(iv) The flock is maintained in accordance with part 147 of this subchapter with respect to flock sanitation, cleaning and disinfection, and Salmonella isolation, sanitation, and management. Rodents and other pests should be effectively controlled;

(v) Environmental samples shall be collected from the flock by an Authorized Agent, in accordance with part 147 of this subchapter, when the flock is 2 to 4 weeks of age. The samples shall be examined bacteriologically for group D salmonella at an authorized laboratory. Cultures from positive samples shall be serotyped. The authorized

agent shall also collect samples every 30 days after the first sample has been collected.

(vi) If a *Salmonella* vaccine is used that causes positive reactions with pullorum-typhoid antigen, one of the following options must be utilized:

(A) Administer the vaccine after the pullorum-typhoid testing is done as described in paragraph (d)(1)(vii) of this section.

(B) If an injectable bacterin or live vaccine that does not spread is used, keep a sample of 350 birds unvaccinated and banded for identification until the flock reaches at least 4 months of age. Following negative serological and bacteriological examinations as described in paragraph (d)(1)(vii) of this section, vaccinate the banded, non-vaccinated birds.

(vii) Blood samples from 300 non-vaccinated birds as described in paragraph (d)(1)(vi) of this section shall be tested with either pullorum antigen or by a federally licensed Salmonella enteritidis enzyme-linked immunosorbent assay (ELISA) test when the flock is more than 4 months of age. All birds with positive or inconclusive reactions, up to a maximum of 25 birds, shall be submitted to an authorized laboratory and examined for the presence of group D salmonella, in accordance with part 147 of this subchapter. Cultures from positive samples shall be serotyped.

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

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

(2) A flock shall not be eligible for this classification if *Salmonella enteritidis* ser *enteritidis* (SE) is isolated from a specimen taken from a bird in the flock. Isolation of SE from an environmental or other specimen, as described in paragraph (d)(1)(v) of this section, will require bacteriological examination for SE in an authorized laboratory, in accordance with part 147 of this subchapter, of a random sample of 60 live birds from a flock of 5,000 birds or more, or 30 live birds from a flock with fewer than 5,000 birds. If only one specimen is found positive for SE, the participant may request bacteriological examination of a second sample, equal in size to the first sample, from the flock. If no SE is recovered from any of the specimens in the second sample, the flock will be eligible for the classification.

(3) A non-vaccinated flock shall be eligible for this classification if *Salmonella enteritidis* (*S. enteritidis* ser Enteritidis) is isolated from an environmental sample collected from the flock in accordance with paragraph (d)(1)(v) of this section: *Provided,* That testing is conducted in accordance with paragraph (d)(1)(vii) of this section each 30 days and no positive samples are found.

(4) In order for a hatchery to sell products of this classification, all products handled shall meet the requirements of the classification.

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

(e) *U.S.M. Synoviae Clean.* (1) A flock maintained in accordance with part 147 of this subchapter with respect to Mycoplasma isolation, sanitation, and management and in which freedom from *M. synoviae* has been demonstrated under the criteria specified in paragraph (e)(1)(i) or (ii) of this section.

(i) [Reserved]

(ii) It is a multiplier breeding flock which originated as U.S. M. Synoviae Clean chicks from primary breeding flocks and from which a sample comprised of a minimum of 150 birds has been tested for *M. synoviae* as provided in §145.14(b) when more than 4 months of age: *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, 75 birds from the flock shall be tested: *Provided,* That fewer than 75 birds from the flock may be tested at any one time if all pens are equally represented and a total of at least 75

birds from the flock is tested within each 90-day period; or

(B) At intervals of not more than 30 days, egg yolk testing shall be conducted in accordance with part 147 of this subchapter.

(2) A participant handling U.S. M. Synoviae Clean products shall keep these products separate from other products in a manner satisfactory to the Official State Agency.

(3) U.S. M. Synoviae Clean chicks shall be boxed in clean boxes and delivered in trucks that have been cleaned and disinfected in accordance with part 147 of this subchapter.

(f) *U.S. M. Gallisepticum Clean Started Poultry.* (1) A flock which originated from U.S. M. Gallisepticum Clean breeding flocks and was hatched in a hatchery approved by the Official State Agency for the production of U.S. M. Gallisepticum Clean chicks.

(2) All other poultry on the premises of the candidate flock must originate from U.S. M. Gallisepticum Clean sources.

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

(4) The flock's freedom from *M. Gallisepticum* is demonstrated by a negative blood test, as provided in §145.14(b), of a sample of 75 birds, with a minimum of 50 birds per poultry house, between 15–20 days prior to the flock being moved to laying quarters.

(5) Started poultry shall be delivered to and from the farm premises in crates and vehicles which have been cleaned and disinfected in accordance with part 147 of this subchapter.

(g) *U.S. M. Synoviae Clean Started Poultry.* (1) A flock which originated from U.S. M. Synoviae Clean breeding flocks and was hatched in a hatchery approved by the Official State Agency for production of U.S. M. Synoviae Clean chicks.

(2) All other poultry on the premises of the candidate flock must originate from U.S. M. Synoviae Clean sources.

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

(4) The flocks's freedom from *M. synoviae* is demonstrated by a negative blood test, as provided in §145.14(b), of a sample of 75 birds, with a minimum of 50 birds per poultry house, between 15–20 days prior to the flock being moved to laying quarters.

(5) Started poultry shall be delivered to and from the farm premises in crates and vehicles which have been cleaned and disinfected in accordance with part 147 of this subchapter.

(h) *U.S. Avian Influenza Clean.* This program is intended to be the basis from which the breeding-hatchery industry may conduct a program for the prevention and control of avian influenza. It is intended to determine the presence of avian influenza in breeding chickens through routine surveillance of each participating breeding flock. A flock and the hatching eggs and chicks produced from it will qualify for this classification when the Official State Agency determines that they have met the following requirements:

(1) It is a multiplier breeding flock in which a minimum of 30 birds have been tested and found negative to avian influenza when more than 4 months of age. To retain this classification:

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

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

(iii) The flock is tested as provided in §145.14(d) at intervals of 30 days or less and found to be negative, and a total of 30 samples are collected and tested within each 90-day period; and

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

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

[36 FR 23112, Dec. 3, 1971]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting §145.23, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at *www.fdsys.gov*.

§ 145.24 Terminology and classification; States.

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

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

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

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

(b) [Reserved]

[40 FR 1502, Jan. 8, 1975. Redesignated at 44 FR 61586, Oct. 26, 1979, and amended at 54 FR 23957, June 5, 1989; 67 FR 8469, Feb. 25, 2002; 72 FR 1419, Jan. 12, 2007; 76 FR 15793, Mar. 22, 2011]

Subpart C—Special Provisions for Multiplier Meat-Type Chicken Breeding Flocks and Products

§ 145.31 Definitions.

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

Chicks. Newly hatched chickens.

Meat type chicken breeding flocks. Flocks that are composed of stock that has been developed for meat production and are maintained for the principal purpose of producing chicks for the ultimate production of meat.

Started chickens. Young chickens (chicks, pullets, cockerels, capons) which have been fed and watered and are less than 6 months of age.

[36 FR 23112, Dec. 3, 1971, as amended at 41 FR 48724, Nov. 5, 1976. Redesignated at 44 FR 61586, Oct. 26, 1979, and amended at 59 FR 12799, Mar. 18, 1994; 65 FR 8018, Feb. 17, 2000]

§ 145.32 Participation.

Participating flocks of multiplier meat type chickens, and the eggs and chicks produced from them, shall comply with the applicable general provisions of subpart A of this part and the special provisions of this subpart C.

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

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

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

[36 FR 23112, Dec. 3, 1971, as amended at 40 FR 1502, Jan. 8, 1975; 41 FR 48724, Nov. 5, 1976. Redesignated at 44 FR 61586, Oct. 26, 1979, and amended at 49 FR 19802, May 10, 1984; 57 FR 57341, Dec. 4, 1992; 65 FR 8018, Feb. 17, 2000; 68 FR 64510, Nov. 14, 2003; 72 FR 1419, Jan. 12, 2007; 79 FR 38756, July 9, 2014]

§ 145.33 Terminology and classification; flocks and products.

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

(a) [Reserved]

(b) *U.S. Pullorum-Typhoid Clean.* A flock in which freedom from pullorum and typhoid has been demonstrated to

the official State agency under the criteria in one of paragraphs (b)(1) through (4) of this section: *Provided*, That a flock qualifying by means of a blood test shall be tested within the past 12 months, except that the retesting of a participating flock which is retained for more than 12 months shall be conducted a minimum of 4 weeks after the induction of molt. (See §145.14 relating to the official blood test where applicable.)

(1) It has been officially blood tested with no reactors.

(2) It is a multiplier breeding flock and meets the following specifications as determined by the Official State Agency and the Service:

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

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

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

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

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

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

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

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

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

(vi) All flocks found to be infected with pullorum or typhoid are quarantined until marketed or destroyed under the supervision of the Official State Agency, or until subsequently blood tested following the procedure for reacting flocks as contained in §145.14(a)(5), and all birds fail to demonstrate pullorum or typhoid infection;

(vii) All poultry, including exhibition, exotic, and game birds, but excluding waterfowl, going to public exhibition shall come from U.S. Pullorum-Typhoid Clean or equivalent

flocks, or have had a negative pullorum-typhoid test within 90 days of going to public exhibition;

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

(4) It is a multiplier breeding flock located in a State which has been determined by the Service to be in compliance with the provisions of paragraph (b)(3) of this section, and in which pullorum disease or fowl typhoid is not known to exist nor to have existed in hatchery supply flocks within the State during the preceding 12 months.

(c) *U.S. M. Gallisepticum Clean.* (1) A flock maintained in accordance with part 147 of this subchapter with respect to Mycoplasma isolation, sanitation, and management and in which freedom from *M. gallisepticum* has been demonstrated under the criteria specified in paragraph (c)(1)(i) or (ii) of this section.

(i) [Reserved]

(ii) It is a multiplier breeding flock which originated as U.S. M. Gallisepticum Clean chicks from primary breeding flocks and from which a sample comprised of a minimum of 150 birds per flock has been tested for *M. gallisepticum* as provided in §145.14(b) when more than 4 months of age: *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, 75 birds from the flock shall be tested, *Provided,* That fewer than 75 birds from the flock may be tested at any one time if all pens are equally represented and a total of at least 75 birds from the flock is tested within each 90-day period; or

(B) At intervals of not more than 30 days, a sample of 25 cull chicks produced from the flock shall be subjected to laboratory procedures acceptable to the Official State Agency and approved by the Service, for the detection and recovery of *M. gallisepticum*; or

(C) At intervals of not more than 30 days, egg yolk testing shall be conducted in accordance with part 147 of this subchapter.

(2) A participant handling U.S. M. Gallisepticum Clean products must keep these products separate from other products through the use of separate hatchers and incubators, separate hatch days, and proper hatchery sanitation and biosecurity in a manner satisfactory to the Official State Agency and in accordance with part 147 of this subchapter.

(3) U.S. M. Gallisepticum Clean chicks shall be boxed in clean boxes and delivered in trucks that have been cleaned and disinfected in accordance with part 147 of this subchapter.

(4) Before male breeding birds may be added to a participating multiplier breeding flock, a sample of at least 30 birds to be added, with a minimum of 10 birds per pen, shall be tested for *M. gallisepticum* as provided in §145.14(b), or by a polymerase chain reaction (PCR)-based procedure in accordance with part 147 of this subchapter. If fewer than 30 male breeding birds are being added, all the birds shall be tested as described above. The male birds shall be tested no more than 14 days prior to their intended introduction into the flock. If the serologic testing of the birds yields hemagglutination inhibition titers of 1:40 or higher as provided in §145.14(b), or if the PCR testing is positive for *M. gallisepticum,* the male birds may not be added to the flock and must be either retested or destroyed.

(d) *U.S. Sanitation Monitored.* This program is intended to be the basis from which the breeding-hatching industry may conduct a program for the prevention and control of Salmonellosis. It is intended to reduce the incidence of Salmonella organisms in hatching eggs and chicks through an effective and practical sanitation program at the breeder farm and in the

hatchery. This will afford other segments of the poultry industry an opportunity to reduce the incidence of Salmonella in their products.

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

(i) The flock shall originate from a source where sanitation and management practices, as outlined in §145.33(d)(1) of this paragraph, are conducted;

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

(iii) If pelletized feed contains animal protein, the protein products shall be purchased from participants in the Animal Protein Products Industry (APPI) *Salmonella* Education/Reduction Program or the Fishmeal Inspection Program of the National Marine Fisheries Service. The protein products must have a minimum moisture content of 14.5 percent and must have been heated throughout to a minimum temperature of 190 °F. or above, or to a minimum temperature of 165 °F. for at least 20 minutes, or to a minimum temperature of 184 °F. under 70 lbs. pressure during the manufacturing process;

(iv) If mash feed contains animal protein, the protein products shall be purchased from participants in the Animal Protein Products Industry (APPI) *Salmonella* Education/Reduction Program or the Fishmeal Inspection Program of the National Marine Fisheries Service;

(v) Feed shall be stored and transported in such a manner as to prevent possible contamination;

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

(vii) An Authorized Agent shall take environmental samples, in accordance with part 147 of this subchapter, from each flock at 4 months of age and every 90 days thereafter. An authorized laboratory for *Salmonella* shall examine the environmental samples bacteriologically;

(viii) Owners of flocks found infected with a paratyphoid *Salmonella* may vaccinate these flocks with an autogenous bacterin with a potentiating agent.[4]

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

(3) In order for a hatchery to sell products of this classification, all products handled shall meet the requirements of the classification.

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

(e) *U.S. M. Synoviae Clean.* (1) A flock maintained in accordance with part 147 of this subchapter with respect to Mycoplasma isolation, sanitation, and management and in which freedom from *M. synoviae* has been demonstrated under the criteria specified in paragraph (e)(1)(i) or (ii) of this section.

(i) [Reserved]

(ii) It is a multiplier breeding flock which originated as U.S. M. Synoviae Clean chicks from primary breeding flocks and from which a sample comprised of a minimum of 150 birds has been tested for *M. synoviae* as provided in §145.14(b) when more than 4 months of age: *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, 75 birds from the flock shall be tested: *Provided,* That fewer than 75 birds from the flock may be tested at any one time if all pens are equally represented and a total of at least 75 birds from the flock is tested within each 90-day period; or

(B) At intervals of not more than 30 days, egg yolk testing shall be conducted in accordance with part 147 of this subchapter.

(2) A participant handling U.S. M. Synoviae Clean products shall keep these products separate from other products in a manner satisfactory to the official State Agency.

[4] Preparation and use of this type of vaccine may be regulated by State statutes.

(3) U.S. M. Synoviae Clean chicks shall be boxed in clean boxes and delivered in trucks that have been cleaned and disinfected in accordance with part 147 of this subchapter.

(4) Before male breeding birds may be added to a participating multiplier breeding flock, a sample of at least 30 birds to be added, with a minimum of 10 birds per pen, shall be tested for *M. synoviae* as provided in §145.14(b) or by a polymerase chain reaction (PCR)-based procedure in accordance with part 147 of this subchapter. If fewer than 30 male breeding birds are being added, all the birds shall be tested as described above. The male birds shall be tested no more than 14 days prior to their intended introduction into the flock. If the serologic testing of the birds yields hemagglutination inhibition titers of 1:40 or higher as provided in §145.14(b), or if the PCR testing is positive for *M. synoviae*, the male birds may not be added to the flock and must be either retested or destroyed.

(f) *U.S. M. Gallisepticum Clean Started Poultry.* (1) A flock which originated from U.S. M. Gallisepticum Clean breeding flocks and was hatched in a hatchery approved by the Official State Agency for the production of U.S. M. Gallisepticum Clean chicks.

(2) All other poultry on the premises of the candidate flock must originate from U.S. M. Gallisepticum Clean sources.

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

(4) The flock's freedom from *M. gallisepticum* is demonstrated by a negative blood test, as provided in §145.14(b), of a sample of 75 birds, with a minimum of 50 birds per poultry house, between 15–20 days prior to the flock being moved to laying quarters.

(5) Started poultry shall be delivered to and from the farm premises in crates and vehicles which have been cleaned and disinfected in accordance with part 147 of this subchapter.

(g) *U.S. M. Synoviae Clean Started Poultry.* (1) A flock which originated from U.S. M. Synoviae Clean breeding flocks and was hatched in a hatchery approved by the Official State Agency for the production of U.S. M. Synoviae Clean chicks.

(2) All other poultry on the premises of the candidate flock must originate from U.S. M. Synoviae Clean sources.

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

(4) The flock's freedom from *M. synoviae* is demonstrated by a negative blood test, as provided in §145.14(b), of a sample of 75 birds, with a minimum of 50 birds per poultry house, between 15–20 days prior to the flock being moved to laying quarters.

(5) Started poultry shall be delivered to and from the farm premises in crates and vehicles which have been cleaned and disinfected in accordance with part 147 of this subchapter.

(h)–(i) [Reserved]

(j) *U.S. M. Gallisepticum Monitored.* (1) A multiplier breeding flock in which all birds or a sample of at least 30 birds per house has been tested for *M. gallisepticum* as provided in §145.14(b) when more than 4 months of age: *Provided,* That to retain this classification, a minimum of 30 birds per house shall be tested again at 36 to 38 weeks and at 48 to 50 weeks at a minimum: *And provided further,* That each 30-bird sample should come from 2 locations within the house (15 from the front half of the house and 15 from the back half of the house). A representative sample of males and females should be sampled. The samples shall be marked ''male'' or ''female.''

(2) A participant handling U.S. M. Gallisepticum Monitored products shall keep these products separate from other products in a manner satisfactory to the Official State Agency: *Provided,* That U.S. M. Gallisepticum Monitored chicks from multiplier breeding flocks shall be produced in incubators and hatchers in which only eggs from flocks qualified under paragraph (j)(1) of this section are set. Eggs from U.S. M. Gallisepticum Monitored multiplier breeding flocks shall not be set in hatchers or incubators in which eggs from U.S. M. Gallisepticum Clean primary breeding flocks qualified under §145.83(c)(1)(i) are set.

(3) U.S. M. Gallisepticum Monitored chicks shall be boxed in clean boxes

and delivered in trucks that have been cleaned and disinfected in accordance with part 147 of this subchapter.

(k) *U.S. M. Synoviae Monitored.* (1) A multiplier breeding flock in which all birds or a sample of at least 30 birds per house has been tested for *M. synoviae* as provided in §145.14(b) when more than 4 months of age: *Provided*, That to retain this classification, a minimum of 30 birds per house shall be tested again at 36 to 38 weeks and at 48 to 50 weeks at a minimum: *And provided further*, That each 30-bird sample should come from 2 locations within the house (15 from the front half of the house and 15 from the back half of the house). A representative sample of males and females should be sampled. The samples shall be marked ''male'' or ''female.''

(2) A participant handling U.S. M. Synoviae Monitored products shall keep these products separate from other products in a manner satisfactory to the Official State Agency: *Provided*, That U.S. M. Synoviae Monitored chicks from multiplier breeding flocks shall be produced in incubators and hatchers in which only eggs from flocks qualified under paragraph (k)(1) of this section are set. Eggs from U.S. M. Synoviae Monitored multiplier breeding flocks shall not be set in hatchers or incubators in which eggs from U.S. M. Synoviae Clean primary breeding flocks qualified under §145.83(d)(1)(i) are set.

(3) U.S. M. Synoviae Monitored chicks shall be boxed in clean boxes and delivered in trucks that have been cleaned and disinfected in accordance with part 147 of this subchapter.

(l) *U.S. Avian Influenza Clean.* This program is intended to be the basis from which the breeding-hatchery industry may conduct a program for the prevention and control of avian influenza. It is intended to determine the presence of avian influenza in multiplier breeding chickens through routine surveillance of each participating breeding flock. A flock and the hatching eggs and chicks produced from it will qualify for this classification when the Official State Agency determines that they have met the following requirements:

(1) It is a multiplier breeding flock in which a minimum of 30 birds have been tested negative for antibodies to avian influenza using an approved test as described in §145.14 when more than 4 months of age. To retain this classification:

(i) A sample of at least 15 birds must be tested negative at intervals of 90 days; or

(ii) A sample of fewer than 15 birds may be tested, and found to be negative, at any one time if all pens are equally represented and a total of 30 birds is tested within each 90-day period; or

(iii) The flock is tested as provided in §145.14(d) at intervals of 30 days or less and found to be negative, and a total of 15 samples are collected and tested within each 90-day period; and

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

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

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

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

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

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

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

(i) If *S. enteritidis* is isolated from an environmental sample collected from the flock in accordance with paragraph

(m)(1)(iii) of this section, a thorough evaluation of the practices and programs associated with the sampled flock shall be conducted with the goal of ascertaining the reason(s) for the positive finding.

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

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

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

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

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

[36 FR 23112, Dec. 3, 1971]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting §145.33, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at *www.fdsys.gov*.

§ 145.34 Terminology and classification; States.

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

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

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

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

(b) *U.S. M. Gallisepticum Clean State, Meat-Type Chickens.* (1) A State will be declared a U.S. M. Gallisepticum Clean State, Meat-Type Chickens, when it has been determined by the Service that:

(i) No *M. gallisepticum* is known to exist nor to have existed in meat-type chicken breeding flocks in production within the State during the preceding 12 months;

(ii) All meat-type chicken breeding flocks in production are classified as U.S. M. Gallisepticum Clean in accordance with §§145.33(c) and 145.83(c) or have met equivalent requirements for *M. gallisepticum* control under official supervision;

(iii) All hatcheries within the State which handle products from meat-type chicken breeding flocks only handle products which are classified as U.S. M. Gallisepticum Clean or have met equivalent requirements for *M. gallisepticum* control under official supervision;

(iv) All shipments of products from meat-type chicken breeding flocks other than those classified as U.S. M. Gallisepticum Clean, or equivalent, into the State are prohibited;

(v) All persons performing poultry disease diagnostic services within the

State are required to report to the Official State Agency within 48 hours the source of all specimens from chickens from meat-type chicken breeding flocks that have been identified as being infected with *M. gallisepticum*;

(vi) All reports of *M. gallisepticum* infection in chickens from meat-type chicken breeding flocks are promptly followed by an investigation by the Official State Agency to determine the origin of the infection;

(vii) All chickens from meat-type chicken breeding flocks found to be infected with *M. gallisepticum* are quarantined until marketed under supervision of the Official State Agency.

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

[40 FR 1503, Jan. 8, 1975. Redesignated at 44 FR 61586, Oct. 26, 1979, and amended at 50 FR 19899, May 13, 1985; 54 FR 23957, June 5, 1989; 67 FR 8469, Feb. 25, 2002; 72 FR 1419, Jan. 12, 2007; 76 FR 15793, Mar. 22, 2011]

Subpart D—Special Provisions for Turkey Breeding Flocks and Products

§ 145.41 Definitions.

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

Poults. Newly hatched turkeys.

[36 FR 23112, Dec. 3, 1971, as amended at 41 FR 48725, Nov. 5, 1976. Redesignated at 44 FR 61586, Oct. 26, 1979, and amended at 59 FR 12799, Mar. 18, 1994; 65 FR 8018, Feb. 17, 2000]

§ 145.42 Participation.

(a) Participating turkey flocks, and the eggs and poults produced from them, shall comply with the applicable general provisions of subpart A of this part and the special provisions of this subpart D.

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

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

[36 FR 23112, Dec. 3, 1971, as amended at 38 FR 13707, May 24, 1973; 40 FR 1503, Jan. 8, 1975. Redesignated at 44 FR 61586, Oct. 26, 1979, and amended at 49 FR 19802, May 10, 1984; 57 FR 57341, Dec. 4, 1992; 65 FR 8018, Feb. 17, 2000; 68 FR 64511, Nov. 14, 2003; 79 FR 38757, July 9, 2014; 81 FR 53249, Aug. 12, 2016]

§ 145.43 Terminology and classification; flocks and products.

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

(a) [Reserved]

(b) *U.S. Pullorum-Typhoid Clean.* A flock in which freedom from pullorum and typhoid has been demonstrated to the official State agency under the criteria in one of the following paragraphs (b)(1) through (5) of this section: *Provided,* That a flock qualifying by means of a blood test shall be tested within the past 12 months, except that the retesting of a participating flock which is retained for more than 12 months shall be conducted a minimum of 4 weeks after the induction of molt. (See § 145.14 relating to the official blood test where applicable.)

(1) It has been officially blood tested with no reactors.

(2) It is a multiplier breeding flock, or a breeding flock composed of progeny of a primary breeding flock which is intended solely for the production of multiplier breeding flocks, and meets the following specifications as determined by the Official State Agency and the Service:

(i) The flock is located in a State where all persons performing poultry disease diagnostic services within the

State are required to report to the Official State Agency within 48 hours the source of all poultry specimens from which S. pullorum or S. gallinarum is isolated;

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

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

(3) It is a multiplier breeding flock, or a breeding flock composed of progeny of a primary breeding flock which is intended solely for the production of multiplier breeding flocks, that originated from U.S. Pullorum-Typhoid Clean breeding flocks or from flocks that met equivalent requirements under official supervision, and is located in a State in which it has been determined by the Service that:

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

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

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

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

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

(vi) All flocks found to be infected with pullorum or typhoid are quarantined until marketed or destroyed under the supervision of the Official State Agency, or until subsequently blood tested, following the procedure for reacting flocks as contained in §145.14(a)(5), and all birds fail to demonstrate pullorum or typhoid infection;

(vii) [Reserved]

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

(4) It is a multiplier breeding flock located in a State which has been determined by the Service to be in compliance with the provisions of paragraph (b)(3) of this section and in which pullorum disease or fowl typhoid is not

known to exist nor to have existed in turkey hatchery supply flocks within the State during the preceding 24 months.

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

(c) *U.S. M. Gallisepticum Clean.* (1) A flock maintained in accordance with part 147 of this subchapter with respect to Mycoplasma isolation, sanitation, and management, and in which no reactors are found when a random sample of at least 10 percent of the birds in the flock, or 300 birds in flocks of more than 300 and each bird in flocks of 300 or less, is tested when more than 12 weeks of age, in accordance with the procedures described in §145.14(b): *Provided*, That to retain this classification, a minimum of 30 samples from male flocks and 60 samples from female flocks shall be retested at 28–30 weeks of age and at 4–6 week intervals thereafter.

(2) A flock qualified as U.S. M. Gallisepticum Clean may retain the classification through its first egg-laying cycle, provided it is maintained in isolation and no evidence of *M. gallisepticum* infection is revealed. A flock which is molted following completion of an egg-laying cycle and subsequently brought back into production, shall be retested within 2 weeks prior to production, as described in paragraph (c)(1) of this section. A State inspector shall visit with the owner or manager of each flock at least once during each laying cycle to discuss and ascertain whether the flock is being maintained in accordance with part 147 of this subchapter with respect to Mycoplasma isolation, sanitation, and management. If a flock proves to be infected with *M. gallisepticum*, it shall lose this classification.

(3) In order to sell hatching eggs or poults of this classification, all hatching eggs and poults handled by the participant must be of this classification.

(d) *U.S. M. Meleagridis Clean.* (1) A flock in which freedom from *M. meleagridis* has been demonstrated under the following criteria:

(i) A sample of 100 birds from each flock has been tested for *M. meleagridis* when more than 12 weeks of age: *Provided*, That to retain this classification, a minimum of 30 samples from male flocks and 60 samples from female flocks shall be retested at 28–30 weeks of age and at 4–6 week intervals thereafter.

(2)–(3) [Reserved]

(4) When reactors to the official test are found and can be identified, 10 tracheal swabs and/or vaginal or phallus swabs and their corresponding blood samples shall be submitted to a laboratory for serological and cultural examination. If reactors cannot be identified, at least 30 tracheal swabs and/or vaginal or phallus swabs and their corresponding blood samples shall be submitted. In a flock with a low reactor rate (less than 5 reactors) the reactors may be submitted to the laboratory within 10 days for serology, necropsy, and thorough bacteriological examination.

(5) If a mycoplasma is isolated, the organism must be serotyped. If *M. meleagridis* is isolated, the block shall be considered infected.

(e) *U.S. M. Synoviae Clean.* (1) All birds, or a sample of at least 100 birds from flocks of more than 100 and each bird in flocks of 100 or less, have been tested for *M. synoviae* when more than 12 weeks of age in accordance with the procedures in §145.14(b): *Provided*, That to retain this classification a minimum of 30 samples from male flocks and 60 samples from female flocks shall be retested at 28–30 weeks of age and at 4–6 week intervals thereafter. It is recommended that any birds that are showing clinical signs of *M. synoviae* infection be included in samples taken.

(2) When reactors to the official test are found and can be identified, tracheal swabs and their corresponding blood samples from 10 (all if fewer than 10) reacting birds shall be submitted to an authorized laboratory for serological and cultural examination. If reactors cannot be identified, at least 30

tracheal swabs and their corresponding blood samples shall be submitted. In a flock with a low reactor rate (less than five reactors) the reactors may be submitted to the laboratory within 10 days for serology, necropsy, and thorough bacteriological examination. When reactors to the official test are found, the procedures outlined in part 147 of this subchapter will be used to determine the status of the flock.

(f) *U.S. Sanitation Monitored, Turkeys.* A flock or hatchery whose owner is controlling or reducing the level of salmonella through compliance with sanitation and management practices in accordance with part 147 of this subchapter, and where the following monitoring, testing, and management practices are conducted:

(1) Hatchery debris (dead germ hatching eggs, fluff, and meconium collected by sexors), swabs collected from hatch debris in hatcher trays, a sample of all the poults that died within 10 days after hatching up to 10 poults, or a combination of 2 or all 3 of the above, from each hatch or a candidate breeding flock produced by a primary breeder, are examined bacteriologically at an authorized laboratory for *Salmonella*.

(2) The poults for the candidate breeding flock are placed in a building that has been cleaned and disinfected. An Authorized Agent must collect environmental samples from the building and submit them to an authorized laboratory for a bacteriological examination for the presence of *Salmonella*, in accordance with part 147 of this subchapter.

(3) Feed for turkeys in the candidate and breeding flock should meet the following requirements:

(i) All feed manufactured in pellet form must have a maximum moisture content of 13.5 percent upon delivery to the farm. It should have been preconditioned to the minimum of one of the following parameters before pelleting:

(A) Feed is to reach a minimum temperature of 185 °F for a minimum of 6 minutes of retention in the conditioning chamber. The conditioned mash feed moisture must be a minimum of 16 percent during the conditioning process. This method utilizes time retention to allow permeation to the center core of each feed particle; or

(B) The feed is to be pressurized in order to expedite the transfer of the heat and moisture to the core of each feed particle. The feed should be conditioned to the parameters of a minimum of 16 percent moisture and 200 °F; or

(C) The feed should be submitted to pressurization to the extent that the initial feed temperature rises to 235 °F for 4 seconds; or

(D) The feed should be submitted to an equivalent thermal lethality treatment; or

(E) A Food and Drug Administration (FDA)-approved product for *Salmonella* control should be added to the finished pellets.

(ii) Mash feed should be treated with an FDA-approved *Salmonella* control product.

(iii) All feed is to be stored and transported in such a manner as to prevent possible contamination with pathogenic bacteria.

(iv) FDA-approved products for *Salmonella* control may be added to either unfinished or finished feed.

(4) Environmental samples shall be taken by an Authorized Agent, in accordance with part 147 of this subchapter, from each flock at 12–20 weeks of age and examined bacteriologically at an authorized laboratory for Salmonella.

(5) Owners of flocks found infected with a paratyphoid Salmonella may vaccinate these flocks with an autogenous bacterin with a potentiating agent.[5]

(6) Environmental samples shall be taken by an Authorized Agent, in accordance with part 147 of this subchapter, from each flock at 35–50 weeks of age and from each molted flock at midlay, and examined bacteriologically at an authorized laboratory for Salmonella.

(7) Hatchery debris (dead germ hatching eggs, fluff, and meconium collected by sexors), swabs collected from hatch debris in hatcher trays, a sample of all the poults that died within 10 days after hatching up to 10 poults, or a combination of 2 or all 3 of the above,

[5] Preparation and use of this type of vaccine may be regulated by state statutes.

shall be cultured as a means of evaluating the effectiveness of the control procedures.

(g) *U.S. H5/H7 Avian Influenza Clean.* This program is intended to be the basis from which the turkey breeding industry may conduct a program for the prevention and control of the H5/H7 subtypes of avian influenza. It is intended to determine the presence of the H5/H7 subtypes of avian influenza in breeding turkeys through routine surveillance of each participating breeding flock. A flock, and the hatching eggs and poults produced from it, will qualify for this classification when the Official State Agency determines that it has met one of the following requirements:

(1) It is a primary breeding flock in which a minimum of 30 birds have been tested negative to the H5/H7 subtypes of avian influenza as provided in §145.14(d) when more than 4 months of age and prior to the onset of egg production. To retain this classification:

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

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

(2) It is a multiplier breeding flock in which a minimum of 30 birds have been tested negative for antibodies for avian influenza to the H5/H7 subtypes of avian influenza as provided in §145.14(d) when more than 4 months of age and prior to the onset of egg production. To retain this classification:

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

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

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

(4) For both primary and multiplier breeding flocks, if a killed influenza vaccine against avian influenza subtypes other than H5 and H7 is used, then the hemagglutinin and the neuraminidase subtypes of the vaccine must be reported to the Official State Agency for laboratory and reporting purposes.

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[36 FR 23112, Dec. 3, 1971]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting §145.43, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at *www.fdsys.gov*.

§145.44 Terminology and classification; States.

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

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

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

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

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

(i) The State is in compliance with the provisions contained in §145.43(b)(3)(i) through (vi).

(ii) No pullorum disease or fowl typhoid is known to exist nor to have existed in turkey hatchery supply flocks within the State during the preceding 24 months.

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

(c) *U.S. M. Gallisepticum Clean State, Turkeys.* (1) A State will be declared a U.S. M. Gallisepticum Clean State, Turkeys when it has been determined by the Service that:

(i) No *M. gallisepticum* is known to exist nor to have existed in turkey breeding flocks in production within the State during the preceding 12 months.

(ii) All turkey breeding flocks in production are classified as U.S. M. Gallisepticum Clean or have met equivalent requirements for *M. gallisepticum* control under official supervision.

(iii) All turkey hatcheries within the State handle products which are classified as U.S. M. Gallisepticum Clean or have met equivalent requirements for *M. gallisepticum* control under official supervision.

(iv) All shipments of turkey products other than those classified as U.S. M. Gallisepticum Clean, or equivalent, into the State are prohibited.

(v) All persons performing poultry disease diagnostic services within the State are required to report to the Official State Agency within 48 hours the source of all turkey specimens that have been identified as being infected with *M. gallisepticum.*

(vi) All reports of *M. gallisepticum* infection in turkeys are promptly followed by an investigation by the Official State Agency to determine the origin of the infection.

(vii) All turkey flocks found to be infected with *M. gallisepticum* are quarantined until marketed under supervision of the Official State Agency.

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

(3) If a State retains this status for 2 or more years, individual breeding flocks in the State may qualify for an *M. gallisepticum* classification based on a negative test of a sample of 100 birds.

(d) *U.S. M. Synoviae Clean State, Turkeys.* (1) A State will be declared a U.S. M. Synoviae Clean State, Turkeys, if the Service determines that:

(i) No *Mycoplasma synoviae* is known to exist nor to have existed in turkey breeding flocks in production within the State during the preceding 12 months;

(ii) All turkey breeding flocks in production are tested and classified as U.S. M. Synoviae Clean or have met equivalent requirements for *M. synoviae* control under official supervision;

(iii) All turkey hatcheries within the State only handle products that are classified as U.S. M. Synoviae Clean or have met equivalent requirements for *M. synoviae* control under official supervision;

(iv) All shipments of products from turkey breeding flocks other than those classified as U.S. M. Synoviae

Clean, or equivalent, into the State are prohibited;

(v) All persons performing poultry disease diagnostic services within the State are required to report to the Official State Agency within 48 hours the source of all turkey specimens that have been identified as being infected with *M. synoviae;*

(vi) All reports of *M. synoviae* infection in turkeys are promptly followed by an investigation by the Official State Agency to determine the origin of the infection; and

(vii) All turkey breeding flocks found to be infected with *M. synoviae* are quarantined until marketed under supervision of the Official State Agency.

(2) The Service may revoke the State's classification as a U.S. M. Synoviae Clean State, Turkeys, if any of the conditions described in paragraph (d)(1) of this section are discontinued. The Service shall not revoke the State's classification as a U.S. M. Synoviae Clean State, Turkeys, until it has conducted an investigation and the Official State Agency has been given an opportunity for a hearing in accordance with rules of practice adopted by the Administrator of the Service.

(e) *U.S. M. Meleagridis Clean State, Turkeys.* (1) A State will be declared a U.S. M. Meleagridis Clean State, Turkeys, if the Service determines that:

(i) No *Mycoplasma meleagridis* is known to exist nor to have existed in turkey breeding flocks in production within the State during the preceding 12 months;

(ii) All turkey breeding flocks in production are tested and classified as U.S. M. Meleagridis Clean or have met equivalent requirements for *M. meleagridis* control under official supervision;

(iii) All turkey hatcheries within the State only handle products that are classified as U.S. M. Meleagridis Clean or have met equivalent requirements for *M. meleagridis* control under official supervision;

(iv) All shipments of products from turkey breeding flocks other than those classified as U.S. M. Meleagridis Clean, or equivalent, into the State are prohibited;

(v) All persons performing poultry disease diagnostic services within the State are required to report to the Official State Agency within 48 hours the source of all turkey specimens that have been identified as being infected with *M. meleagridis;*

(vi) All reports of *M. meleagridis* infection in turkeys are promptly followed by an investigation by the Official State Agency to determine the origin of the infection; and

(vii) All turkey breeding flocks found to be infected with *M. meleagridis* are quarantined until marketed under supervision of the Official State Agency.

(2) The Service may revoke the State's classification as a U.S. M. Meleagridis Clean State, Turkeys, if any of the conditions described in paragraph (d)(1) of this section are discontinued. The Service will not revoke the State's classification as a U.S. M. Meleagridis Clean State, Turkeys, until it has conducted an investigation and the Official State Agency has been given an opportunity for a hearing in accordance with rules of practice adopted by the Administrator.

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§ 145.45 Terminology and classification; compartments.

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

other intensive animal operations. The program shall consist of the following:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(H) Pest management program.

(I) Cleaning and disinfection process.

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

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

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

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

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

(iii) In addition, the company must demonstrate compliance with paragraph (a)(1) of this section for remaining in the U.S. H5/H7 Avian Influenza Clean classification, surveillance for NAI within the compartment, and conducting tests in State or Federal laboratories or in NPIP authorized laboratories. Accredited veterinarians are responsible for the enforcement of active and passive surveillance of NAI in primary breeder flocks. Baseline health

status must be maintained for all flocks or subpopulations within the compartment, indicating the dates and negative results of all avian influenza surveillance and monitoring testing, the dates and history of last disease occurrence (if any), the number of outbreaks, and the methods of disease control that were applied.

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

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

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

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

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

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

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

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

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

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

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

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

(b) [Reserved]

[79 FR 38757, July 9, 2014]

Subpart E—Special Provisions for Hobbyist and Exhibition Waterfowl, Exhibition Poultry, and Game Bird Breeding Flocks and Products

§145.51 Definitions.

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

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.

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

[36 FR 23112, Dec. 3, 1971. Redesignated at 44 FR 61586, Oct. 26, 1979, and amended at 59 FR 12799, Mar. 18, 1994]

§ 145.52 Participation.

Participating flocks of hobbyist and exhibition waterfowl, exhibition poultry, and game birds, and the eggs and baby poultry produced from them shall comply with the applicable general provisions of subpart A of this part and the special provisions of this subpart E. The special provisions that apply to meat-type waterfowl flocks are found in subpart I of this part.

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

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

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

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

(1) The form number ''9–3I'', printed or stamped on the invoice;

(2) The hatchery name and address;

(3) The date of shipment;

(4) The hatchery invoice number;

(5) The purchaser name and address;

(6) The quantity of products sold;

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

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

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

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

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

[36 FR 23112, Dec. 3, 1971. Redesignated at 44 FR 61586, Oct. 26, 1979, and amended at 49 FR 19803, May 10, 1984; 57 FR 57341, Dec. 4, 1992; 61 FR 11521, Mar. 21, 1996; 65 FR 8019, Feb. 17, 2000; 74 FR 14715, Apr. 1, 2009; 76 FR 15793, Mar. 22, 2011; 79 FR 38759, July 9, 2014]

§ 145.53 Terminology and classification; flocks and products.

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

(a) [Reserved]

(b) *U.S. Pullorum-Typhoid Clean.* A flock in which freedom from pullorum and typhoid has been demonstrated to the Official State Agency under the criteria in one of the following paragraphs (b)(1) through (5) of this section (See § 145.14 relating to the official blood test where applicable.):

(1) It has been officially blood tested within the past 12 months with no reactors.

(2) It is a multiplier breeding flock, or a breeding flock composed of progeny of a primary breeding flock which is intended solely for the production of multiplier breeding flocks, and meets the following specifications as determined by the Official State Agency and the Service:

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

(ii) The flock is composed entirely of birds that originated from U.S. Pullorum-Typhoid Clean breeding flocks

or from flocks that met equivalent requirements under official supervision; and

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

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

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

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

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

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

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

(vi) All flocks found to be infected with pullorum or typhoid are quarantined until marketed or destroyed under the supervision of the Official State Agency, or until subsequently blood tested, following the procedure for reacting flocks as contained in §145.14(a)(5), and all birds fail to demonstrate pullorum or typhoid infection;

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

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

(4) It is a multiplier breeding flock located in a State which has been determined by the Service to be in compliance with the provisions of paragraph (b)(3) of this section, and in which pullorum disease or fowl typhoid is not known to exist nor to have existed in hatchery supply flocks within the State during the preceding 24 months.

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

(c) *U.S. M. Gallisepticum Clean.* (1) A flock maintained in accordance with part 147 of this subchapter with respect to Mycoplasma isolation, sanitation, and management and in which freedom from M. gallisepticum has been demonstrated under the criteria specified in paragraph (c)(1)(i) or (ii) of this section.

(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

(B) At intervals of not more than 30 days, a sample of 25 cull baby poultry produced from the flock shall be subjected to laboratory procedures acceptable to the Official State Agency and approved by the Service, for the detection and recovery of M. gallisepticum.

(2) A participant handling U.S. M. Gallisepticum Clean products shall keep these products separate from other products in a manner satisfactory to the Official State Agency: *Provided*, That U.S. M. Gallisepticum Clean baby poultry from primary breeding flocks shall be produced in incubators and hatchers in which only eggs from flocks qualified under paragraph (c)(1)(i) of this section are set.

(3) U.S. M. Gallisepticum Clean baby poultry shall be boxed in clean boxes and delivered in trucks that have been cleaned and disinfected in accordance with part 147 of this subchapter.

(d) *U.S. M. Synoviae Clean.* (1) A flock maintained in accordance with part 147 of this subchapter with respect to Mycoplasma isolation, sanitation, and management and in which freedom from *Mycoplasma synoviae* has been demonstrated under the criteria specified in paragraph (d)(1)(i) or (d)(1)(ii) of this section.

(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

(B) At intervals of not more than 30 days, egg yolk testing shall be conducted in accordance with part 147 of this subchapter.

(2) A participant handling U.S. M. Synoviae Clean products shall keep those products separate from other products in a manner satisfactory to the Official State Agency: *Provided*, That U.S. M. Synoviae Clean chicks from primary breeding flocks shall be produced in incubators and hatchers in which only eggs from flocks qualified under paragraph (d)(1)(i) or (d)(1)(ii) of this section are set.

(3) U.S. M. Synoviae Clean chicks shall be boxed in clean boxes and delivered in trucks that have been cleaned and disinfected as described in in accordance with part 147 of this subchapter.

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

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

(i) A sample of at least 30 birds must be tested negative at intervals of 180 days; or

(ii) A sample of fewer than 30 birds may be tested, and found to be negative, at any one time if all pens are equally represented and a total of 30 birds are tested within each 180-day period.

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

swabs for virus isolation. To retain this classification:

(i) A sample of at least 30 birds must be tested negative at intervals of 180 days; or

(ii) A sample of fewer than 30 birds may be tested, and found to be negative, at any one time if all pens are equally represented and a total of 30 birds are tested within each 180-day period.

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

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

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

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

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

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

[36 FR 23112, Dec. 3, 1971. Redesignated at 44 FR 61586, Oct. 26, 1979]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting §145.53, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at *www.fdsys.gov*.

§ 145.54 Terminology and classification; States.

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

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

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

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

[40 FR 1504, Jan. 8, 1975. Redesignated at 44 FR 61586, Oct. 26, 1979, and amended at 54 FR 23957, June 5, 1989; 67 FR 8469, Feb. 25, 2002; 76 FR 15794, Mar. 22, 2011]

Subpart F—Special Provisions for Ostrich, Emu, Rhea, and Cassowary Breeding Flocks and Products

SOURCE: 63 FR 40010, July 27, 1998, unless otherwise noted.

§ 145.61 Definitions.

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

Chicks. Newly hatched ostriches, emus, rheas, or cassowaries.

Ostrich. Birds of the species *Struthio camelus*, including all subspecies and subspecies hybrids.

[63 FR 40010, July 27, 1998, as amended at 65 FR 8019, Feb. 17, 2000]

§ 145.62 Participation.

Participating flocks of ostriches, emus, rheas, and cassowaries, and the eggs and chicks produced from them, shall comply with the applicable general provisions of subpart A of this part and the special provisions of this subpart.

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

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

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

[63 FR 40010, July 27, 1998, as amended at 65 FR 8019, Feb. 17, 2000; 79 FR 38759, July 9, 2014]

§ 145.63 Terminology and classification; flocks and products.

Participating flocks, and the eggs and baby poultry produced from them, that have met the respective requirements specified in this section may be designated by the following terms and their corresponding designs illustrated in §145.10.

(a) *U.S. Pullorum-Typhoid Clean.* A flock in which freedom from pullorum and typhoid has been demonstrated to the Official State Agency under the criteria in paragraph (a)(1) or (a)(2) of this section. (See §145.14(a) relating to the official blood test for pullorum-typhoid where applicable.)

(1) It has been officially blood tested within the past 12 months with no reactors.

(2) It is a breeding flock that meets one of the following criteria:

(i)(A) It is a multiplier or primary breeding flock of fewer than 300 birds in which a sample of 10 percent of the birds in a flock or at least 1 bird from each pen, whichever is more, has been officially tested for pullorum-typhoid within the past 12 months with no reactors; or

(B) It is a multiplier or primary breeding flock of 300 birds or more in which a sample of a minimum of 30 birds has been officially tested for pullorum-typhoid within the past 12 months with no reactors.

(ii) It is a flock that has already been designated U.S. Pullorum-Typhoid Clean and uses a subsequent bacteriological examination monitoring program of hatcher debris or eggs for ostriches, emus, rheas, or cassowaries acceptable to the Official State Agency and approved by the Service in lieu of annual blood testing.

(iii) It is a multiplier breeding flock located in a State that has been deemed to be a U.S. Pullorum-Typhoid Clean State for the past 3 years, and during which time no isolation of pullorum or typhoid has been made that can be traced to a source in that State, that uses a bacteriological examination monitoring program of hatcher debris or eggs or a serological examination monitoring program acceptable to the Official State Agency and approved by the Service in lieu of annual blood testing.

(b) *U.S. Avian Influenza Clean.* This program is intended to be the basis from which the breeding-hatchery industry may conduct a program for the prevention and control of avian influenza. It is intended to determine the presence of avian influenza in all ostrich, emu, rhea, and cassowary breeding flocks through routine serological surveillance of each participating breeding flock. Acceptable tests include antigen and antibody detection tests, as approved by the Official State Agency. A flock, and the hatching eggs and chicks produced from it, will qualify for this classification when the Official State Agency determines that it has met one of the following requirements:

(1) It is a primary breeding flock in which 10 percent of the flock, up to a maximum of 30 birds, has been tested negative for type A influenza virus with all pens represented equally and when the tested birds are more than 4 months of age. Positive samples shall

be further tested by an authorized laboratory. To retain this classification:

(i) A sample of at least 30 birds must be tested negative at intervals of 180 days, or

(ii) A sample of less than 10 percent of the birds, up to a maximum of 30 birds, may be tested and found to be negative at any one time if all pens are equally represented and a total of 30 birds are tested within each 180-day period.

(2) It is a multiplier breeding flock in which a minimum of 30 birds has been tested negative to type A influenza virus with all pens represented equally and when the tested birds are more than 4 months of age. Positive samples shall be further tested by an authorized laboratory. To retain this classification:

(i) A sample of at least 30 birds must be tested negative at intervals of 180 days, or

(ii) A sample of at least 10 percent of birds from each pen with all pens being represented must be tested negative at intervals of 180 days; or

(iii) A sample of less than 10 percent of the birds may be tested, and found to be negative, at any one time if all pens are equally represented and a total of 10 percent of the birds are tested within each 180-day period.

[63 FR 40010, July 27, 1998, as amended at 65 FR 8019, Feb. 17, 2000; 72 FR 1420, Jan. 12, 2007; 74 FR 14715, Apr. 1, 2009]

Subpart G—Special Provisions for Primary Egg-Type Chicken Breeding Flocks and Products

SOURCE: 72 FR 1420, Jan. 12, 2007, unless otherwise noted.

§ 145.71 Definitions.

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

Chicks. Newly hatched chickens.

Primary egg-type chicken breeding flocks. Foundation flocks that are composed of pedigree, great-grandparent, and grandparent stock that has been developed for egg production and are maintained for the principal purpose of producing multiplier breeding chicks used to produce table egg layers.

Started chickens. Young chickens (chicks, pullets, cockerels, capons) which have been fed and watered and are less than 6 months of age.

§ 145.72 Participation.

Participating flocks of primary egg-type chickens, and the eggs and chicks produced from them, shall comply with the applicable general provisions of subpart A of this part and the special provisions of this subpart G.

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

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

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

[72 FR 1420, Jan. 12, 2007, as amended at 79 FR 38759, July 9, 2014]

§ 145.73 Terminology and classification; flocks and products.

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

(a) [Reserved]

(b) *U.S. Pullorum-Typhoid Clean.* A flock in which freedom from pullorum and typhoid has been demonstrated to the Official State Agency under the criteria in paragraph (b)(1) or (b)(2) of this section: *Provided,* That a flock qualifying by means of a blood test shall be tested within the past 12 months, except that the retesting of a participating flock which is retained for more than 12 months shall be conducted a minimum of 4 weeks after the induction of molt. (See § 145.14 relating to the official blood test where applicable.)

(1) It has been officially blood tested with no reactors.

(2) It is a primary breeding flock that meets the following criteria:

(i) The primary breeding flock is located in a State in which pullorum disease or fowl typhoid is not known to exist nor to have existed in hatchery supply flocks during the preceding 12 months and in which it has been determined by the Service that:

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

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

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

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

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

(F) All flocks found to be infected with pullorum or typhoid are quarantined until marketed or destroyed under the supervision of the Official State Agency, or until subsequently blood tested following the procedure for reacting flocks as contained in §145.14(a)(5), and all birds fail to demonstrate pullorum or typhoid infection;

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

(H) Discontinuation of any of the conditions or procedures described in paragraphs (b)(2)(i)(A) through (b)(2)(i)(G) of this section, or the occurrence of repeated outbreaks of pullorum or typhoid in poultry breeding flocks within or originating within the State shall be grounds for the Service to revoke its determination that such conditions and procedures have been met or complied with. Such action shall not be taken until a thorough investigation has been made by the Service and the Official State Agency has been given an opportunity to present its views; and

(ii) In the primary breeding flock, a sample of 300 birds from flocks of more than 300, and each bird in flocks of 300 or less, has been officially tested for pullorum-typhoid with no reactors: *Provided,* That a bacteriological examination monitoring program acceptable to the Official State Agency and approved by the Service may be used in lieu of blood testing.

(c) *U.S. M. Gallisepticum Clean.* (1) A flock maintained in accordance with part 147 of this subchapter with respect to Mycoplasma isolation, sanitation, and management and in which freedom from *M. gallisepticum* has been demonstrated under the criteria specified in paragraph (c)(1)(i) of this section.

(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: *Provided,* That to retain this classification, a minimum of 150 birds shall be tested at intervals of not more than 90 days: *And provided further,* That a sample comprised of fewer than 150 birds may be tested at any one time, if all pens are equally represented and a total of 150 birds is tested within each 90-day period.

(ii) [Reserved]

(2) A participant handling U.S. M. Gallisepticum Clean products shall

handle only products of equivalent status.

(3) U.S. M. Gallisepticum Clean chicks shall be boxed in clean boxes and delivered in trucks that have been cleaned and disinfected in accordance with part 147.

(d) *U.S. S. Enteritidis Clean.* This classification is intended for primary egg-type breeders wishing to assure their customers that the hatching eggs and multiplier chicks produced are certified free of *Salmonella enteritidis*.

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

(i) The flock originated from a U.S. S. Enteritidis Clean flock, or meconium from the chick boxes and a sample of chicks that died within 7 days after hatching are examined bacteriologically for salmonella at an authorized laboratory. Cultures from positive samples shall be serotyped.

(ii) All feed fed to the flock shall meet the following requirements:

(A) Pelletized feed shall contain either no animal protein or only animal protein products produced under the Animal Protein Products Industry (APPI) *Salmonella* Education/Reduction Program. The protein products must have a minimum moisture content of 14.5 percent and must have been heated throughout to a minimum temperature of 190 °F, or above, or to a minimum temperature of 165 °F for at least 20 minutes, or to a minimum temperature of 184 °F under 70 lbs. pressure during the manufacturing process.

(B) Mash feed may contain no animal protein other than an APPI animal protein product supplement manufactured in pellet form and crumbled: *Provided*, That mash feed may contain nonpelleted APPI animal protein product supplements if the finished feed is treated with a salmonella control product approved by the U.S. Food and Drug Administration.

(iii) Feed shall be stored and transported in such a manner as to prevent possible contamination;

(iv) The flock is maintained in accordance with part 147 of this subchapter with respect to flock sanitation, cleaning and disinfection, and Salmonella isolation, sanitation, and management. Rodents and other pests should be effectively controlled;

(v) Environmental samples shall be collected from the flock by an Authorized Agent, in accordance with part 147 of this subchapter, when the flock is 2 to 4 weeks of age. The samples shall be examined bacteriologically for group D salmonella at an authorized laboratory. Cultures from positive samples shall be serotyped. The Authorized Agent shall also collect samples every 30 days after the first sample has been collected.

(vi) If a *Salmonella* vaccine is used that causes positive reactions with pullorum-typhoid antigen, one of the following options must be utilized.

(A) Administer the vaccine after the pullorum-typhoid testing is done as described in paragraph (d)(1)(vii) of this section.

(B) If an injectable bacterin or live vaccine that does not spread is used, keep a sample of 350 birds unvaccinated and banded for identification until the flock reaches at least 4 months of age. Following negative serological and bacteriological examinations as described in paragraph (d)(1)(vii) of this section, vaccinate the banded, non-vaccinated birds.

(vii) Blood samples from 300 non-vaccinated birds as described in paragraph (d)(1)(vi) of this section shall be tested with either pullorum antigen or by a federally licensed *Salmonella enteritidis* enzyme-linked immunosorbent assay (ELISA) test when the flock is more than 4 months of age. All birds with positive or inconclusive reactions, up to a maximum of 25 birds, shall be submitted to an authorized laboratory and examined for the presence of group D salmonella, in accordance with part 147 of this subchapter. Cultures from positive samples shall be serotyped.

(viii) Hatching eggs are collected as quickly as possible and are handled as described in §147.22 of this subchapter and are sanitized or fumigated (see §147.25 of this subchapter).

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

Agency or in accordance with part 147 of this subchapter.

(2) A flock shall not be eligible for this classification if *Salmonella enteritidis* serotype *enteritidis* (SE) is isolated from a specimen taken from a bird in the flock. Isolation of SE from an environmental or other specimen, as described in paragraph (d)(1)(v) of this section, will require bacteriological examination for SE in an authorized laboratory, in accordance with part 147 of this subchapter, of a random sample of 60 live birds from a flock of 5,000 birds or more, or 30 live birds from a flock with fewer than 5,000 birds. If only one specimen is found positive for SE, the participant may request bacteriological examination of a second sample, equal in size to the first sample, from the flock. If no SE is recovered from any of the specimens in the second sample, the flock will be eligible for the classification.

(3) A non-vaccinated flock shall be eligible for this classification if SE is isolated from an environmental sample collected from the flock in accordance with paragraph (d)(1)(v) of this section: *Provided*, That testing is conducted in accordance with paragraph (d)(1)(vii) of this section each 30 days and no positive samples are found.

(4) In order for a hatchery to sell products of this classification, all products handled shall meet the requirements of the classification.

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

(e) *U.S. M. Synoviae Clean.* (1) A flock maintained in accordance with part 147 of this subchapter with respect to Mycoplasma isolation, sanitation, and management and in which freedom from *M. synoviae* has been demonstrated under the criteria specified in paragraph (e)(1)(i) of this section.

(i) It is a flock in which a minimum of 300 birds has been tested for *M. synoviae* as provided in §145.14(b) when more than 4 months of age: *Provided*, That to retain this classification, a sample of at least 150 birds shall be tested at intervals of not more than 90 days: *And provided further*, That a sample comprised of fewer than 150 birds may be tested at any one time if all pens are equally represented and a total of 150 birds is tested within each 90-day period.

(ii) [Reserved]

(2) A participant handling U.S. M. Synoviae Clean products shall handle only products of equivalent status.

(3) U.S. M. Synoviae Clean chicks shall be boxed in clean boxes and delivered in trucks that have been cleaned and disinfected in accordance with part 147 of this subchapter.

(f) *U.S. Avian Influenza Clean.* This program is intended to be the basis from which the breeding-hatchery industry may conduct a program for the prevention and control of avian influenza. It is intended to determine the presence of avian influenza in primary breeding chickens through routine surveillance of each participating breeding flock. A flock and the hatching eggs and chicks produced from it will qualify for this classification when the Official State Agency determines that they have met the following requirements:

(1) It is a primary breeding flock in which a minimum of 30 birds have been tested and found negative for avian influenza when more than 4 months of age. To retain this classification:

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

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

(iii) The flock is tested as provided in §145.14(d) at intervals of 30 days or less and found to be negative, and a total of 30 samples are collected and tested within each 90-day period; and

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

[72 FR 1420, Jan. 12, 2007, as amended at 76 FR 15794, Mar. 22, 2011; 79 FR 38759, July 9, 2014]

§ 145.74 Terminology and classification; compartments.

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

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

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

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

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

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

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

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

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

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

(iv) *Definition and description of the functional relationships between components of the defined compartment.* Functional relationships between components of the compartment include traffic movement and flow at and among premises, personnel movement at and among premises, exposure to live bird populations, and any other factors that could affect biosecurity of the compartment. All physical components of the compartment must be maintained in compliance with hygiene and biosecurity procedures for poultry primary breeding flocks and hatcheries in accordance with part 147 of this subchapter. In addition, the company must provide a biosecurity plan for the compartment and all included components. The biosecurity plan should include but not be limited to:

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

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

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

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

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

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

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

(H) Pest management program.

(I) Cleaning and disinfection process.

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

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

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

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

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

within the compartment, and examination of the biosecurity and management system of the integrated components of the compartment.

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

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

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

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

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

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

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

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

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

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

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

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

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

(b) [Reserved]

[79 FR 38760, July 9, 2014]

Subpart H—Special Provisions for Primary Meat-Type Chicken Breeding Flocks and Products

SOURCE: 72 FR 1422, Jan. 12, 2007, unless otherwise noted.

§ 145.81 Definitions.

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

Chicks. Newly hatched chickens.

Primary meat-type chicken breeding flocks. Foundation flocks that are composed of pedigree, great-grandparent, and grandparent stock that has been developed for meat production and are maintained for the principal purpose of producing multiplier breeding chicks used to produce commercial broilers.

Started chickens. Young chickens (chicks, pullets, cockerels, capons) which have been fed and watered and are less than 6 months of age.

§ 145.82 Participation.

Participating flocks of primary meat-type chickens, and the eggs and chicks produced from them, shall comply with the applicable general provisions of subpart A of this part and the special provisions of this subpart H.

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

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

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

[72 FR 1422, Jan. 12, 2007, as amended at 79 FR 38762, July 9, 2014]

§ 145.83 Terminology and classification; flocks and products.

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

(a) [Reserved]

(b) *U.S. Pullorum-Typhoid Clean.* A flock in which freedom from pullorum and typhoid has been demonstrated to the Official State Agency under the criteria in paragraph (b)(1) or (b)(2) of this section: *Provided,* That a flock qualifying by means of a blood test shall be tested within the past 12 months, except that the retesting of a participating flock which is retained for more than 12 months shall be conducted a minimum of 4 weeks after the induction of molt. (See § 145.14 relating to the official blood test where applicable.)

(1) It has been officially blood tested with no reactors.

(2) It is a primary breeding flock that meets the following criteria:

(i) The primary breeding flock is located in a State in which pullorum disease or fowl typhoid is not known to exist nor to have existed in hatchery supply flocks within the State during the preceding 12 months and in which it has been determined by the Service that:

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

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

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

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

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

(F) All flocks found to be infected with pullorum or typhoid are quarantined until marketed or destroyed under the supervision of the Official State Agency, or until subsequently blood tested following the procedure for reacting flocks as contained in §145.14(a)(5) of this subchapter, and all birds fail to demonstrate pullorum or typhoid infection;

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

(H) Discontinuation of any of the conditions or procedures described in paragraphs (b)(2)(i)(A) through (b)(2)(i)(G) of this section, or the occurrence of repeated outbreaks of pullorum or typhoid in poultry breeding flocks within or originating within the State shall be grounds for the Service to revoke its determination that such conditions and procedures have been met or complied with. Such action shall not be taken until a thorough investigation has been made by the Service and the Official State Agency has been given an opportunity to present its views; and

(ii) In the primary breeding flock, a sample of 300 birds from flocks of more than 300, and each bird in flocks of 300 or less, has been officially tested for pullorum-typhoid with no reactors: *Provided,* That a bacteriological examination monitoring program acceptable to the Official State Agency and approved by the Service may be used in lieu of blood testing.

(c) *U.S. M. Gallisepticum Clean.* (1) A flock maintained in accordance with part 147 of this subchapter with respect to Mycoplasma isolation, sanitation, and management and in which freedom from *M. gallisepticum* has been demonstrated under the criteria specified in paragraph (c)(1)(i) of this section.

(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) of this subchapter when more than 4 months of age: *Provided,* That to retain this classification, a minimum of 40 birds shall be tested at intervals of not more than 28 days, and a total of at least 150 birds shall be tested within each 90-day period.

(ii) [Reserved]

(2) A participant handling U.S. M. Gallisepticum Clean products must handle only products of equivalent status.

(3) U.S. M. Gallisepticum Clean chicks shall be boxed in clean boxes and delivered in trucks that have been cleaned and disinfected in accordance with part 147 of this subchapter.

(d) *U.S. M. Synoviae Clean.* (1) A flock maintained in accordance with part 147 of this subchapter with respect to Mycoplasma isolation, sanitation, and management and in which freedom from *M. synoviae* has been demonstrated under the criteria specified in paragraph (d)(1)(i) of this section.

(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) of this subchapter when more than 4 months of age: *Provided,* That to retain this classification, a sample of at least 40 birds shall be tested at intervals of not more than 28 days, and a total of at least 150 birds shall be tested within each 90-day period.

(ii) [Reserved]

(2) A participant handling U.S. M. Synoviae Clean products shall handle only products of equivalent status.

(3) U.S. M. Synoviae Clean chicks shall be boxed in clean boxes and delivered in trucks that have been cleaned and disinfected in accordance with part 147 of this subchapter.

(e) *U.S. S. Enteritidis Clean.* This classification is intended for primary meat-type breeders wishing to assure their customers that the chicks produced are certified free of *Salmonella enteritidis.*

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

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

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

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

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

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

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

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

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

(2) If *Salmonella enteritidis* serotype *enteritidis* (SE) is isolated from a specimen taken from a bird in the flock, except as provided in paragraph (e)(3) of this section, the flock shall not be eligible for this classification.

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

bird culture. The flock will be disqualified for the U.S. S. Enteritidis Clean classification if a bird or subsequent flock environmental assay results in isolation of SE.

(4) In order for a hatchery to sell products of this classification, all products handled by the hatchery must meet the requirements of this paragraph.

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

(6) A pedigree, experimental, great-grandparent, or grandparent flock that is removed from the U.S. S. Enteritidis Clean program may be reinstated whenever the following conditions are met:

(i) The owner attests that corrective measures have been implemented, which may include one or more of the following:

(A) Test and slaughter infected birds based on blood tests of every bird in the flock, with either pullorum antigen or by a federally licensed *Salmonella enteritidis* enzyme-linked immunosorbent assay (ELISA) test when the flock is more than 4 months of age.

(B) Perform other corrective actions including, but not limited to, vaccination, medication, cleaning and disinfection of houses, rodent control, and movement of uninfected birds to premises that have been determined to be environmentally negative for *S. enteritidis* in accordance with par 147 of this subchapter.

(C) One hundred percent of blood samples from the birds moved to the clean premises are tested negative for *Salmonella pullorum* and group D *Salmonella*. All birds with positive or inconclusive reactions, up to a maximum of 25 birds, shall be submitted to an authorized laboratory and examined for the presence of group D *Salmonella,* in accordance with part 147 of this subchapter. Cultures from positive samples shall be serotyped.

(D) Two consecutive environmental drag swabs taken at the clean premises collected in accordance with part 147 of this subchapter 4 weeks apart are negative for *S. enteritidis.*

(E) Other corrective measures at the discretion of the Official State Agency.

(ii) Following reinstatement, a flock will remain eligible for this classification if the flock is tested in accordance with paragraph (e)(1)(v) of this section every 30 days and no positive samples are found and the flock meets the requirements set forth in § 145.83(e).

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

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

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

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

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

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

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

(vi) Any flock entering the production period that is in compliance with all the requirements of §145.83(f) with no history of *Salmonella* isolations shall be considered ''*Salmonella* negative'' and may retain this definition as long as no environmental or bird *Salmonella* isolations are identified and confirmed from the flock or flock environment by sampling on 4 separate collection dates over a minimum of a 2-week period. Sampling and testing must be performed as described in paragraph (f)(1)(iv) of this section. An unconfirmed environmental *Salmonella* isolation shall not change this *Salmonella* negative status.

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

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

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

(g) *U.S. Avian Influenza Clean.* This program is intended to be the basis from which the breeding-hatchery industry may conduct a program for the prevention and control of avian influenza. It is intended to determine the presence of avian influenza in primary breeding chickens through routine surveillance of each participating breeding flock. A flock and the hatching eggs and chicks produced from it will qualify for this classification when the Official State Agency determines that they have met the following requirements:

(1) It is a primary breeding flock in which a minimum of 30 birds have been tested negative for antibodies to avian influenza using an approved test as described in §145.14 when more than 4 months of age. To retain this classification:

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

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

(iii) The flock is tested as provided in §145.14(d) at intervals of 30 days or less and found to be negative, and a total of 30 samples are collected and tested within each 90-day period; and

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

[72 FR 1422, Jan. 12, 2007, as amended at 76 FR 15794, Mar. 22, 2011; 79 FR 38762, July 9, 2014; 79 FR 71624, Dec. 3, 2014; 81 FR 53250, Aug. 12, 2016]

§145.84 Terminology and classification; compartments.

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

(1) *Definition of the compartment.* Based on the guidelines established by the World Organization for Animal Health (OIE) in the Terrestrial Animal Health Code and the guidelines in this paragraph (a), the primary breeder company will define the compartment with respect to NAI. Specifically, the

company will use a comprehensive biosecurity program to define the compartment as a subpopulation of poultry with a health status for NAI that is separate from birds and poultry outside the compartment. The Official State Agency and the Service must first approve all documentation submitted by the company to substantiate the defined compartment as adequate to qualify for epidemiological separation from other potential sources of infection of NAI. Guidelines for the definition of the compartment include:

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

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

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

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

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

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

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

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

(iv) *Definition and description of the functional relationships between components of the defined compartment.* Functional relationships between components of the compartment include traffic movement and flow at and among premises, personnel movement at and among premises, exposure to live bird populations, and any other factors that could affect biosecurity of the compartment. All physical components of the compartment must be maintained in compliance with hygiene and biosecurity procedures for poultry primary breeding flocks and hatcheries in

accordance with part 147 of this subchapter. In addition, the company must provide a biosecurity plan for the compartment and all included components. The biosecurity plan should include but not be limited to:

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

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

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

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

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

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

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

(H) Pest management program.

(I) Cleaning and disinfection process.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(b) [Reserved]

[79 FR 38763, July 9, 2014]

Subpart I—Special Provisions for Meat-Type Waterfowl Breeding Flocks and Products

SOURCE: 76 FR 15794, Mar. 22, 2011, unless otherwise noted.

§ 145.91 Definitions.

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

Meat-type waterfowl breeding flocks. Flocks of domesticated duck or goose that are composed of stock that has been developed and is maintained for the primary purpose of producing baby poultry that will be raised under confinement for the primary purpose of producing meat for human consumption.

§ 145.92 Participation.

Participating flocks of meat-type waterfowl and the eggs and baby poultry produced from them shall comply with the applicable general provisions of subpart A of this part and the special provisions of this subpart I.

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

(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.

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

[76 FR 15794, Mar. 22, 2011, as amended at 79 FR 38764, July 9, 2014; 81 FR 53250, Aug. 12, 2016]

§145.93 Terminology and classification; flocks and products.

Participating flocks, and the eggs and baby poultry produced from them, that have met the respective requirements specified in this section may be designated by the following terms and the corresponding designs illustrated in §145.10.

(a) [Reserved]

(b) *U.S. Pullorum-Typhoid Clean.* A flock in which freedom from pullorum and typhoid has been demonstrated to the Official State Agency under the criteria in one of the following paragraphs (b)(1) through (b)(5) of this section (*See* §145.14 relating to the official blood test where applicable.):

(1) It has been officially blood tested within the past 12 months with no reactors.

(2) It is a multiplier breeding flock, or a breeding flock composed of progeny of a primary breeding flock which is intended solely for the production of multiplier breeding flocks, and meets the following specifications as determined by the Official State Agency and the Service:

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

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

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

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

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

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

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

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

(v) All reports of any disease outbreak involving a disease covered under the Plan are promptly followed

by an investigation by the Official State Agency to determine the origin of the infection; *Provided*, That if the origin of the infection involves another State, or if there is exposure to poultry in another State from the infected flock, then the National Poultry Improvement Plan will conduct an investigation;

(vi) All flocks found to be infected with pullorum or typhoid are quarantined until marketed or destroyed under the supervision of the Official State Agency, or until subsequently blood tested, following the procedure for reacting flocks as contained in §145.14(a)(5), and all birds fail to demonstrate pullorum or typhoid infection;

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

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

(4) It is a multiplier breeding flock located in a State which has been determined by the Service to be in compliance with the provisions of paragraph (a)(3) of this section, and in which pullorum disease or fowl typhoid is not known to exist nor to have existed in hatchery supply flocks within the State during the preceding 24 months.

(5) It is a primary breeding flock located in a State determined to be in compliance with the provisions of paragraph (a)(4) of this section, and in which a sample of 300 birds from flocks of more than 300, and each bird in flocks of 300 or less, has been officially tested for pullorum-typhoid within the past 12 months with no reactors: *Provided*, That when a flock is a primary breeding flock located in a State which has been deemed to be a U.S. Pullorum-Typhoid Clean State for the past 3 years, and during which time no isolation of pullorum or typhoid has been made that can be traced to a source in that State, a bacteriological examination monitoring program or a serological examination monitoring program acceptable to the Official State Agency and approved by the Service may be used in lieu of annual blood testing.

(c) *U.S. H5/H7 Avian Influenza Clean.* This program is intended to be the basis from which the breeding-hatchery industry may conduct a program for the prevention and control of the H5/H7 subtypes of avian influenza. It is intended to determine the presence of the H5/H7 subtypes of avian influenza in meat-type waterfowl breeding flocks through routine surveillance of each participating breeding flock. A flock, and the hatching eggs and baby poultry produced from it, will qualify for this classification when the Official State Agency determines that it has met one of the following requirements:

(1) It is a primary breeding flock in which a minimum of 30 birds have been tested negative to the H5/H7 subtypes of avian influenza as provided in §145.14(d) when more than 4 months of age. To retain this classification:

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

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

(2) It is a multiplier breeding flock in which a minimum of 30 birds have been tested negative to the H5/H7 subtypes of avian influenza as provided in §145.14(d) when more than 4 months of age. To retain this classification:

(i) A sample of at least 30 birds must be tested negative at intervals of 180 days; or

(ii) A sample of fewer than 30 birds may be tested, and found to be negative, at any one time if all pens are

equally represented and a total of 30 birds are tested within each 180-day period.

(3) A sample of at least 11 birds must be tested and found negative to H5/H7 avian influenza within 21 days prior to movement to slaughter.

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

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

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

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

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

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

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

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

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

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

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

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

[76 FR 15794, Mar. 22, 2011, as amended at 79 FR 38764, July 9, 2014; 81 FR 53250, Aug. 12, 2016]

§ 145.94 Terminology and classification; States.

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

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

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

(2) Discontinuation of any of the conditions described in paragraph (a)(1)(i) of this section, or repeated outbreaks of pullorum or typhoid occur in hatchery supply flocks described in paragraph (a)(1)(ii) of this section, or if an infection spreads from the originating premises, the Service shall have grounds to revoke its determination

that the State is entitled to this classification. Such action shall not be taken until a thorough investigation has been made by the Service and the Official State Agency has been given an opportunity for a hearing in accordance with rules of practice adopted by the Administrator.

(b) [Reserved]

PART 146—NATIONAL POULTRY IMPROVEMENT PLAN FOR COMMERCIAL POULTRY

Subpart A—General Provisions

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

SOURCE: 71 FR 56328, Sept. 26, 2006, unless otherwise noted.

Subpart A—General Provisions

§ 146.1 Definitions.

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

Administrator. The Administrator, Animal and Plant Health Inspection Service, or any person authorized to act for the Administrator.

Affiliated flock. A meat-type flock that is owned by or has an agreement to participate in the Plan with a slaughter plant and that participates in the Plan through that slaughter plant.

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

Authorized Agent. Any person designated under §146.10(a) to perform functions under this part.

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

Classification. A designation earned by participation in a Plan program.

Commercial meat-type flock. All of the meat-type chickens, spent fowl, meat-type turkeys, commercial upland game birds, or commercial waterfowl on one farm. However, at the discretion of the Official State Agency, any group of poultry which is segregated from another group in a manner sufficient to prevent the transmission of H5/H7 LPAI and has been so segregated for a

period of at least 21 days may be considered as a separate flock.

Commercial table-egg layer flock. All table-egg layers of common age or pullet source on one premises.

Commercial table-egg layer premises. A farm containing contiguous flocks of commercial table-egg layers under common ownership.

Commercial table-egg layer pullet flock. A table-egg layer flock prior to the onset of egg production.

Cooperating State Agency. Any State authority recognized by the Department to cooperate in the administration of the provisions of part 56 of this chapter. This may include the State animal health authority or the Official State Agency.

Department. The U.S. Department of Agriculture.

Domesticated. Propagated and maintained under the control of a person.

Equivalent. Requirements which are equal to or exceed the program, conditions, criteria, or classifications with which they are compared, as determined by the Official State Agency and with the concurrence of the Service.

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

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

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

(ii) Viral antigen or viral RNA specific to the H5 or H7 subtype of AI virus has been detected in poultry; or

(iii) Antibodies to the H5 or H7 subtype of the AI virus that are not a consequence of vaccination have been detected in poultry. If vaccine is used, methods should be used to distinguish vaccinated birds from birds that are both vaccinated and infected. In the case of isolated serological positive results, H5/H7 LPAI infection may be ruled out on the basis of a thorough epidemiological investigation that does not demonstrate further evidence of H5/H7 LPAI infection, as determined by the Cooperating State Agency, the Official State Agency, and APHIS.

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

Official State Agency. The State authority recognized by the Department to cooperate in the administration of the Plan.

Person. A natural person, firm, or corporation.

Plan. The provisions of the National Poultry Improvement Plan contained in this part.

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.

Program. Management, sanitation, testing, and monitoring procedures which, if complied with, will qualify, and maintain qualification for, designation of a flock, a slaughter plant, or a State by an official Plan classification and illustrative design, as described in §146.9 of this part.

Service. The Animal and Plant Health Inspection Service of the U.S. Department of Agriculture.

State. Any of the States, the District of Columbia, the Commonwealth of Puerto Rico, Guam, the Commonwealth of the Northern Mariana Islands, the Virgin Islands of the United States, or any territory or possession of the United States.

State Inspector. Any person employed or authorized under §146.10(b) to perform functions under this part.

United States. All of the States.

[71 FR 56328, Sept. 26, 2006, as amended at 74 FR 14715, Apr. 1, 2009; 75 FR 10658, Mar. 9, 2010; 76 FR 15796, Mar. 22, 2011; 79 FR 38765, July 9, 2014; 81 FR 53250, Aug. 12, 2016]

§ 146.2 Administration.

(a) The Department cooperates through a Memorandum of Understanding with the Official State Agency in the administration of the Plan. In the Memorandum of Understanding, the Official State Agency must designate a contact representative to serve as a liaison between the Service and the Official State Agency.

(b) The administrative procedures and decisions of the Official State Agency are subject to review by the Service. The Official State Agency shall carry out the administration of the Plan within the State according to the applicable provisions of the Plan and the Memorandum of Understanding.

(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.

(d) The Official State Agency of any State may adopt regulations applicable to the administration of the Plan in such State further defining the provisions of the Plan or establishing higher standards, compatible with the Plan.

(e) An authorized laboratory will conduct tests in accordance with part 147 of this subchapter when determining the status of a participating flock with respect to an official Plan classification.

(f) Cooperating State Agencies will be responsible for making the determination to request Federal assistance under part 56 of this chapter in the event of an outbreak of H5/H7 LPAI.

[71 FR 56328, Sept. 26, 2006, as amended at 74 FR 14716, Apr. 1, 2009; 75 FR 10658, Mar. 9, 2010; 79 FR 38765, July 9, 2014; 81 FR 53250, Aug. 12, 2016]

§ 146.3 Participation.

(a) Any commercial table-egg layer pullet flock, table-egg producer, raised-for-release upland game bird premises, and raised-for-release waterfowl premises and any commercial upland game bird, commercial waterfowl, meat-type chicken or meat-type turkey slaughter plant, including its affiliated flocks, may participate in the Plan when the producer or plant has demonstrated, to the satisfaction of the Official State Agency, that its facilities, personnel, and practices are adequate for carrying out the relevant special provisions of this part and has signed an agreement with the Official State Agency to comply with the relevant special provisions of this part.

(b) Each participant shall comply with the Plan throughout the operating year, or until released by the Official State Agency.

(c) A participating slaughter plant shall participate with all of the commercial upland game bird, commercial waterfowl, meat-type chicken, spent fowl, and/or meat-type turkey flocks that are processed at the facility, including affiliated flocks. Affiliated flocks must participate through a written agreement with a participating slaughter plant that is approved by the Official State Agency.

(d) Participation in the Plan shall entitle the participant to use the Plan emblem reproduced as follows:

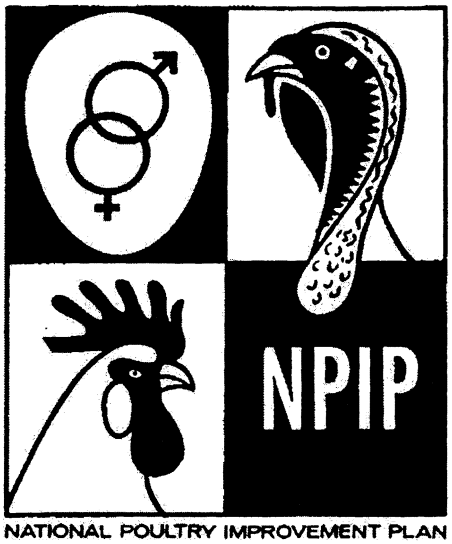

FIGURE 1.

[71 FR 56328, Sept. 26, 2006, as amended at 74 FR 14716, Apr. 1, 2009; 79 FR 38765, July 9, 2014; 81 FR 53250, Aug. 12, 2016]

§ 146.4 General provisions for all participating flocks and slaughter plants.

(a) Records that establish the identity of products handled shall be maintained in a manner satisfactory to the Official State Agency.

(b) Material that is used to advertise products shall be subject to inspection by the Official State Agency at any time.

(c) Advertising must be in accordance with the Plan, and applicable rules and regulations of the Official State Agency and the Federal Trade Commission. A participant advertising products as being of any official classification may include in their advertising reference to associated or franchised slaughter or production facilities only when such facilities produce products of the same classification.

(d) Each participant shall be assigned a permanent approval number by the Service. This number, prefaced by the numerical code of the State, will be the official approval number of the participant and may be used on each certificate, invoice, shipping label, or other document used by the participant in the sale of the participant's products. Each Official State Agency which requires an approval number for out-of-State participants to ship into its State shall honor this number.

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

[71 FR 56328, Sept. 26, 2006, as amended at 75 FR 10658, Mar. 9, 2010]

§ 146.5 Specific provisions for all participating flocks.

(a) Participating flocks, and all equipment used in connection with the flocks, shall be separated from nonparticipating flocks in a manner acceptable to the Official State Agency.

(b) Poultry equipment, and poultry houses and the land in the immediate vicinity thereof, shall be kept in sanitary condition in accordance with part 147 of this subchapter.

[71 FR 56328, Sept. 26, 2006, as amended at 79 FR 38765, July 9, 2014]

§ 146.6 Specific provisions for participating slaughter plants.

(a) Only commercial upland game bird, commercial waterfowl, meat-type chicken, and meat-type turkey slaughter plants that are under continuous inspection by the Food Safety and Inspection Service of the Department or under State inspection that the Food Safety and Inspection Service has recognized as equivalent to Federal inspection may participate in the Plan.

(b) To participate in the Plan, meat-type chicken, meat-type turkey, and commercial upland game bird and commercial waterfowl slaughter plants must follow the relevant special provisions in §§146.33(a), 146.43(a), and 146.53(a), respectively, for sample collection and flock monitoring, unless they are exempted from the special provisions under §§146.32(b), 146.42(b), or 146.52(b), respectively.

[74 FR 14716, Apr. 1, 2009]

§ 146.7 Terminology and classification; general.

The official classification terms defined in §§146.8 and 146.9 and the various designs illustrative of the official classifications reproduced in §146.9 may be used only by participants and to describe products that have met all

of the specific requirements of such classifications.

§ 146.8 Terminology and classification; slaughter plants.

Participating slaughter plants shall be designated as ''U.S. H5/H7 Avian Influenza Monitored.'' All Official State Agencies shall be notified by the Service of additions, withdrawals, and changes in classification.

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

Participating flocks, products produced from them, and States that have met the requirements of a classification in this part may be designated by the corresponding illustrative design in this section.

(a) *U.S. H5/H7 Avian Influenza Monitored.* (See §§ 146.23(a), 146.33(a), 146.43(a), and 146.53(a) and (b).)

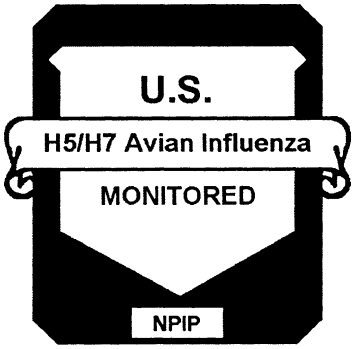

Figure 2.

(b) *U.S. H5/H7 Avian Influenza Monitored State, Layers.* (See § 146.24.)

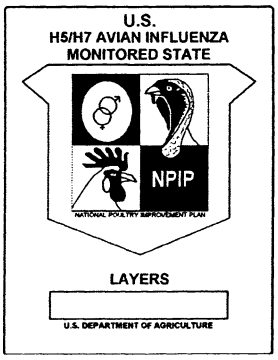

Figure 3.

(c) *U.S. H5/H7 Avian Influenza Monitored State, Turkeys.* (See § 146.44.)

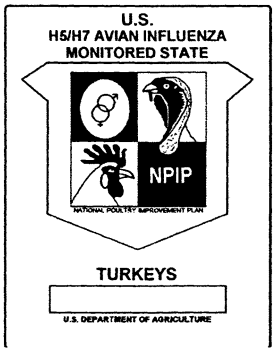

Figure 4.

[71 FR 56328, Sept. 26, 2006, as amended at 74 FR 14716, Apr. 1, 2009; 76 FR 15796, Mar. 22, 2011]

§ 146.10 Supervision.

(a) The Official State Agency may designate qualified persons as Authorized Agents to do the sample collecting provided for in § 146.13 of this part.

(b) The Official State Agency shall employ or authorize qualified persons as State Inspectors to perform the selecting and testing of participating flocks and to perform the official inspections necessary to verify compliance with the requirements of the Plan.

(c) Authorities issued to Authorized Agents or State Inspectors under the provisions of this section shall be subject to cancellation by the Official State Agency on the grounds of incompetence or failure to comply with the provisions of the Plan or regulations of the Official State Agency. Such actions shall not be taken until thorough investigation has been made by the Official State Agency and the authorized person has been given notice of the proposed action and the basis thereof and an opportunity to present his or her views.

§ 146.11 Inspections.

(a) Each participating slaughter plant shall be audited at least once annually or a sufficient number of times each year to satisfy the Official State Agency that the participating slaughter plant is in compliance with the provisions of this part. The yearly audit will consist of an evaluation of 2 weeks' worth of records, selected at random, of the following data:

(1) The actual flock slaughter date for each flock. This information must come from a verifiable source. Verifiable sources include electronic record systems that have oversight from the Department's Grain Inspectors, Packers and Stockyards Administration or Food Safety and Inspection Service (FSIS) documents such as FSIS Form 9061–2.

(2) Laboratory test results for each flock slaughtered with the sample collection date and test result. The test must be NPIP-approved and performed in an authorized laboratory of the NPIP.

(b) A flock will be considered to be conforming to protocol if it meets the requirements as described in § 146.33(a), § 146.43(a), or § 146.53(a).

(c) Two or more flocks that are found to be not conforming to protocol in the yearly audit for a slaughter plant shall be cause for a deficiency rating for that plant. However, if the root cause for the deficiency was identified, corrected, and documented, the plant will be eligible for an immediate reevaluation of 2 additional weeks' worth of records, again selected at random. If no more than one missed flock is identified in this reevaluation, the plant will be considered in compliance and no further action will be required. Plants found to be deficient must provide a written corrective action plan to the auditor within 2 weeks of receipt of the deficiency rating. A followup audit on the information in paragraphs (a)(1) and (a)(2) of this section will occur within 90 days from the receipt of the corrective action plan. Slaughter plants will retain their classification and may continue to use the Plan emblem in § 146.9(a) during this process. A failure on the followup audit may result in disbarment from participation according to the procedures in § 146.12.

(d) On-site inspections of any participating flocks and premises will be conducted if a State Inspector determines that a breach of testing has occurred for the Plan programs for which the flocks are certified.

(e) The official H5/H7 LPAI testing records of all participating flocks and slaughter plants shall be examined annually by a State Inspector. Official H5/H7 LPAI testing records shall be maintained for 3 years.

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

[71 FR 56328, Sept. 26, 2006, as amended at 74 FR 14716, Apr. 1, 2009; 75 FR 10658, Mar. 9, 2010; 81 FR 53250, Aug. 12, 2016]

§ 146.12 Debarment from participation.

Participants in the Plan who, after investigation by the Official State Agency or its representative, are notified in writing of their apparent noncompliance with the Plan provisions or regulations of the Official State Agency shall be afforded a reasonable time, as specified by the Official State Agency, within which to demonstrate or achieve compliance. If compliance is not demonstrated or achieved within the specified time, the Official State Agency may debar the participant from further participation in the Plan for such period, or indefinitely, as the Official State Agency may deem appropriate. The debarred participant shall be afforded notice of the bases for the debarment and opportunity to present his or her views with respect to the debarment in accordance with procedures adopted by the Official State Agency. The Official State Agency shall thereupon decide whether the debarment

order shall continue in effect. Such decision shall be final unless the debarred participant, within 30 days after the issuance of the debarment order, requests the Administrator to determine the eligibility of the debarred participant for participation in the Plan. In such an event, the Administrator shall determine the matter de novo in accordance with the rules of practice in 7 CFR part 50, which are hereby made applicable to proceedings before the Administrator under this section. The definitions in 7 CFR 50.10 and the following definitions shall apply with respect to terms used in such rules of practice:

(a) *Administrator* means the Administrator, Animal and Plant Health Inspection Service of the U.S. Department of Agriculture, or any officer or employee to whom authority has heretofore been delegated or to who authority may hereafter be delegated to act in his or her stead.

(b) [Reserved]

§ 146.13 Testing.

(a) *Samples*. Either egg or blood samples may be used for testing. Samples must be collected in accordance with the following requirements:

(1) *Egg samples*. Egg samples must be collected and prepared in accordance with part 147 of this subchapter.

(2) *Blood samples*. Blood samples obtained in the slaughter plant should be collected after the kill cut with birds remaining on the kill line. Hold an open 1.5 mL snap cap micro-centrifuge tube under the neck of the bird directly after the kill cut and collect drips of blood until the tube is half full. Keep the blood tubes at room temperature for the clot to form, which should require a minimum of 4 hours and a maximum of 12 hours. Refrigerate the tube after the clot has formed. Put tubes in a container and label it with plant name, date, shift (A.M. or Day, P.M. or Night), and flock number. After the clot is formed, the clot should be removed by the Authorized Agent in order to ensure good-quality sera. Prepare a laboratory submission form and ship samples with submission forms to the laboratory in a polystyrene foam cooler with frozen ice packs. Submission forms and the manner of submission must be approved by the Official State Agency and the authorized laboratory to ensure that there is sufficient information to identify the samples and that the samples are received in an acceptable condition for further tests to be reliably performed. Blood samples should be shipped routinely to the laboratory. Special arrangements should be developed for samples held over the weekend to ensure that the samples can be reliably tested. Blood samples for official tests shall be drawn by an Authorized Agent or State Inspector.

(b) *Avian influenza*. The official tests for avian influenza are described in paragraphs (b)(1) and (b)(2) of this section:

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

(ii) *The agar gel immunodiffusion (AGID) test*. (A) The AGID test must be conducted on all ELISA-positive samples.

(B) The AGID test must be conducted using reagents approved by the Department and the Official State Agency.

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

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

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

(i) *The real time reverse transcriptase/polymerase chain reaction (RRT–PCR) assay*. (A) The RRT–PCR tests must be conducted using reagents approved by the Department and the Official State

Agency. The RRT–PCR must be conducted using the National Veterinary Services Laboratories (NVSL) official protocol for RRT–PCR and must be conducted by personnel who have passed an NVSL proficiency test.

(B) Positive results from the RRT–PCR must be further tested by Federal Reference Laboratories using appropriate tests for confirmation. Final judgment may be based upon further sampling and appropriate tests for confirmation.

(ii) *USDA-licensed type A influenza antigen capture immunoassay (ACIA).* (A) The USDA-licensed type A influenza ACIA must be conducted using test kits approved by the Department and the Official State Agency and must be conducted in accordance with the recommendations of the producer or manufacturer.

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

(3) The official determination of a flock as positive for the H5 or H7 subtypes avian influenza may be made only by NVSL.

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

[71 FR 56328, Sept. 26, 2006, as amended at 74 FR 14716, Apr. 1, 2009; 75 FR 10658, Mar. 9, 2010; 79 FR 38765, July 9, 2014]

§ 146.14 Diagnostic surveillance program for H5/H7 low pathogenic avian influenza.

(a) The Official State Agency must develop a diagnostic surveillance program for H5/H7 low pathogenic avian influenza for all poultry in the State. The exact provisions of the program are at the discretion of the States. The Service will use the standards in paragraph (b) of this section in assessing individual State plans for adequacy, including the specific provisions that the State developed. The standards should be used by States in developing those plans.

(b) Avian influenza must be a disease reportable to the responsible State authority (State veterinarian, etc.) by all licensed veterinarians. To accomplish this, all laboratories (private, State, and university laboratories) that perform diagnostic procedures on poultry must examine all submitted cases of unexplained respiratory disease, egg production drops, and mortality for avian influenza by both an approved serological test and an approved antigen detection test. Memoranda of understanding or other means must be used to establish testing and reporting criteria (including criteria that provide for reporting H5 and H7 low pathogenic avian influenza directly to the Service) and approved testing methods. In addition, States should conduct outreach to poultry producers, especially owners of smaller flocks, regarding the importance of prompt reporting of clinical symptoms consistent with avian influenza.

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

[71 FR 56328, Sept. 26, 2006, as amended at 75 FR 10658, Mar. 9, 2010]

Subpart B—Special Provisions for Commercial Table-Egg Layer Flocks

§ 146.21 Definitions.

Table-egg layer. A domesticated chicken grown for the primary purpose of producing eggs for human consumption.

Table-egg layer pullet. A sexually immature domesticated chicken grown for the primary purpose of producing eggs for human consumption.

[71 FR 56328, Sept. 26, 2006, as amended at 76 FR 15796, Mar. 22, 2011]

§ 146.22 Participation.

(a) Participating commercial table-egg layer flocks shall comply with the applicable general provisions of subpart A of this part and the special provisions of subpart B of this part.

(b) Commercial table-egg laying premises with fewer than 75,000 birds are exempt from the special provisions of subpart B of this part.

§ 146.23 Terminology and classification; flocks and products.

Participating flocks which have met the respective requirements specified in this section may be designated by the following terms and the corresponding designs illustrated in § 146.9 of this part:

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

(i) It is a commercial table-egg layer pullet flock in which a minimum of 11 birds have been tested negative to the H5/H7 subtypes of avian influenza as provided in § 146.13(b) within 30 days prior to movement; or

(ii) It is a commercial table-egg layer pullet flock that has an ongoing active and diagnostic surveillance program for the H5/H7 subtypes of avian influenza in which the number of birds tested is equivalent to the number required in paragraph (a)(1)(i) of this section and that is approved by the Official State Agency and the Service.

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

(i) It is a commercial table-egg layer flock in which a minimum of 11 birds have been tested negative to the H5/H7 subtypes of avian influenza as provided in § 146.13(b) within 30 days prior to disposal; and either

(ii) It is a commercial table-egg layer flock in which a minimum of 11 birds have been tested negative for the H5/H7 subtypes of avian influenza as provided in § 146.13(b) within a 12-month period; or

(iii) It is a commercial table-egg layer flock that has an ongoing active and diagnostic surveillance program for the H5/H7 subtypes of avian influenza in which the number of birds tested is equivalent to the number required in paragraph (a)(2)(i) or paragraph (a)(2)(ii) of this section and that is approved by the Official State Agency and the Service.

(b) [Reserved]

[71 FR 56328, Sept. 26, 2006, as amended at 76 FR 15796, Mar. 22, 2011; 79 FR 38765, July 9, 2014; 79 FR 71624, Dec. 3, 2014]

§ 146.24 Terminology and classification; States.

(a) *U.S. H5/H7 Avian Influenza Monitored State, Layers.* (1) A State will be declared a U.S. H5/H7 Avian Influenza Monitored State, Layers when it has been determined by the Service that:

(i) All commercial table-egg layer flocks and all commercial table-egg layer pullet flocks that supply those flocks in production within the State that are not exempt from the special provisions of this subpart B under § 146.22 are classified as U.S. H5/H7 Avian Influenza Monitored under § 146.23(a) of this part;

(ii) All egg-type chicken breeding flocks in production within the State are classified as U.S. Avian Influenza Clean under § 145.23(h) of this subchapter;

(iii) All persons performing poultry disease diagnostic services within the State are required to report to the Official State Agency, within 24 hours, the source of all table-egg layer and table-egg layer pullet specimens that were deemed positive on an official test for avian influenza, as designated in § 146.13(a) of this chapter;

(iv) All table-egg layer and table-egg layer pullet specimens that were deemed positive on an official test for avian influenza, as designated in § 146.13(a) of this chapter, are sent to an authorized laboratory for subtyping; and

(v) All table-egg layer and table-egg layer pullet flocks within the State that are found to be infected with the H5/H7 subtypes of avian influenza are quarantined, in accordance with an initial State response and containment plan as described in part 56 of this chapter and under the supervision of the Official State Agency.

(2) If there is a discontinuation of any of the conditions described in paragraph (a)(1) of this section, or if repeated outbreaks of the H5/H7 subtypes of avian influenza occur in commercial table-egg layer flocks as described in paragraph (a)(1)(i) of this section, or if an infection spreads from the originating premises, the Service shall have grounds to revoke its determination that the State is entitled to this classification. Such action shall not be taken until a thorough investigation has been made by the Service and the Official State Agency has been given an opportunity for a hearing in accordance with rules of practice adopted by the Administrator.

(b) [Reserved]

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

[71 FR 56328, Sept. 26, 2006, as amended at 75 FR 10658, Mar. 9, 2010; 76 FR 15797, Mar. 22, 2011]

Subpart C—Special Provisions for Meat-Type Chicken Slaughter Plants

§ 146.31 Definitions.

Meat-type chicken. A domesticated chicken grown for the primary purpose of producing meat, including but not limited to broilers, roasters, fryers, and cornish.

Meat-type chicken slaughter plant. A meat-type chicken slaughter plant that is federally inspected or under State inspection that the Food Safety Inspection Service has recognized as equivalent to federal inspection.

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

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

[71 FR 56328, Sept. 26, 2006, as amended at 79 FR 38766, July 9, 2014]

§ 146.32 Participation.

(a) Participating meat-type chicken slaughter plants shall comply with applicable general provisions of subpart A of this part and the special provisions of this subpart C.

(b) Meat-type chicken slaughter plants that slaughter fewer than 200,000 meat-type chickens in an operating week are exempt from the special provisions of this subpart C.

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

[71 FR 56328, Sept. 26, 2006, as amended at 79 FR 38766, July 9, 2014]

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

Participating meat-type chicken slaughter plants that have met the respective requirements specified in this section may be designated by the following terms and the corresponding designs illustrated in § 146.9 of this part:

(a) *U.S. H5/H7 Avian Influenza Monitored.* This program is intended to be the basis from which the meat-type chicken 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 meat-type chickens through routine surveillance of each participating meat-type chicken slaughter plant. A meat-type chicken slaughter plant will qualify for this classification when the Official State Agency determines that it has met one of the following requirements:

(1) It is a meat-type chicken 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; *Provided,* that with the approval of the Official State Agency, fewer than 11 birds per shift may be tested on any given shift if the total number of birds tested during the operating month is equivalent to testing 11 birds per shift; or

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

(3) It is a meat-type chicken slaughter plant that has an ongoing active and diagnostic surveillance program for the H5/H7 subtypes of avian influenza in which the number of birds tested is equivalent to the number required in paragraph (a)(1) or (a)(2) and that is approved by the Official State Agency and the Service.

(b) [Reserved]

[71 FR 56328, Sept. 26, 2006, as amended at 76 FR 15797, Mar. 22, 2011; 79 FR 38766, July 9, 2014]

Subpart D—Special Provisions for Meat-Type Turkey Slaughter Plants

§ 146.41 Definitions.

Meat-type turkey. A domesticated turkey grown for the primary purpose of producing meat.

Meat-type turkey slaughter plant. A meat-type turkey slaughter plant that is federally inspected or under State inspection that the Food Safety Inspection Service has recognized as equivalent to federal inspection.

§ 146.42 Participation.

(a) Participating meat-type turkey slaughter plants shall comply with applicable general provisions of subpart A of this part and the special provisions of this subpart D.

(b) Meat-type turkey slaughter plants that slaughter fewer than 2 million meat-type turkeys in a 12-month period are exempt from the special provisions of this subpart D.

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

Participating meat-type turkey slaughter plants which have met the respective requirements specified in this section may be designated by the following terms and the corresponding designs illustrated in §146.9 of this part:

(a) *U.S. H5/H7 Avian Influenza Monitored*. This program is intended to be the basis from which the meat-type turkey industry may conduct a program to monitor for the H5/H7 subtypes of avian influenza. It is intended to determine the presence of avian influenza in meat-type turkeys through routine surveillance of each participating meat-type turkey slaughter plant. A participating meat-type turkey slaughter plant will qualify for this classification when the Official State Agency determines that it has met one of the following requirements:

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

(2) It is a meat-type turkey slaughter plant that has an ongoing active and diagnostic surveillance program for the H5/H7 subtypes of avian influenza in which the number of birds tested is equivalent to the number required in paragraph (a)(1) and that is approved by the Official State Agency and the Service.

(b) [Reserved]

[71 FR 56328, Sept. 26, 2006, as amended at 74 FR 14717, Apr. 1, 2009; 76 FR 15797, Mar. 22, 2011; 79 FR 38766, July 9, 2014]

§ 146.44 Terminology and classification; States.

(a) *U.S. H5/H7 Avian Influenza Monitored State, Turkeys*. (1) A State will be declared a U.S. H5/H7 Avian Influenza Monitored State, Turkeys when it has been determined by the Service that:

(i) All meat-type turkey slaughter plants within the State that are not exempt from the special provisions of this subpart D under §146.42 are classified as U.S. H5/H7 Avian Influenza Monitored under §146.43(a) of this part;

(ii) All turkey breeding flocks in production within the State are classified

as U.S. H5/H7 Avian Influenza Clean under §145.43(g) of this subchapter;

(iii) All persons performing poultry disease diagnostic services within the State are required to report to the Official State Agency, within 24 hours, the source of all meat-type turkey specimens that were deemed positive on an official test for avian influenza, as designated in §146.13(a) of this chapter;

(iv) All meat-type turkey specimens that were deemed positive on an official test for avian influenza, as designated in §146.13(a) of this chapter, are sent to an authorized laboratory for subtyping; and

(v) All meat-type turkey flocks within the State that are found to be infected with the H5/H7 subtypes of avian influenza are quarantined, in accordance with an initial State response and containment plan as described in part 56 of this chapter, and under the supervision of the Official State Agency.

(2) If there is a discontinuation of any of the conditions described in paragraph (a)(1) of this section, or if repeated outbreaks of the H5/H7 subtypes of avian influenza occur in meat-type turkey flocks as described in paragraph (a)(1)(i) of this section, or if an infection spreads from the originating premises, the Service shall have grounds to revoke its determination that the State is entitled to this classification. Such action shall not be taken until a thorough investigation has been made by the Service and the Official State Agency has been given an opportunity for a hearing in accordance with rules of practice adopted by the Administrator.

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

[71 FR 56328, Sept. 26, 2006, as amended at 75 FR 10658, Mar. 9, 2010]

Subpart E—Special Provisions for Commercial Upland Game Birds, Commercial Waterfowl, Raised-for-Release Upland Game Birds, and Raised-for-Release Waterfowl

SOURCE: 74 FR 14717, Apr. 1, 2009, unless otherwise noted.

§146.51 Definitions.

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

Commercial upland game birds. Upland game bird pheasants, quail, or partridges grown under confinement for the primary purposes of producing eggs and/or meat for human consumption.

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

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

Raised-for-release upland game birds. Pheasants, quail, and partridge that are raised under confinement for release in game preserves and are not breeding stock.

Raised-for-release waterfowl. Waterfowl that are raised under confinement for release in game preserves and are not breeding stock.

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

[74 FR 14717, Apr. 1, 2009, as amended at 81 FR 53250, Aug. 12, 2016]

§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.

(b) Commercial waterfowl and commercial upland game bird slaughter plants that slaughter fewer than 50,000

birds annually are exempt from 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.

[74 FR 14717, Apr. 1, 2009, as amended at 81 FR 53250, Aug. 12, 2016]

§ 146.53 Terminology and classification; slaughter plants and premises.

Participating flocks which have met the respective requirements specified in this section may be designated by the following terms and the corresponding designs illustrated in § 146.9 of this part:

(a) *U.S. H5/H7 Avian Influenza Monitored.* This program is intended to be the basis from which the commercial waterfowl and commercial upland game bird 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 commercial waterfowl and commercial upland game birds 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 will qualify for this classification when the Official State Agency determines that it has met one of the following requirements:

(1) It is a commercial upland game bird slaughter plant or commercial 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 commercial upland game bird slaughter plant or commercial waterfowl slaughter plant that only accepts commercial upland game birds or commercial 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; or

(3) It is a commercial upland game bird slaughter plant or commercial 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 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 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) *U.S. H5/H7 Avian Influenza Monitored.* This program is intended to be the basis from which the raised-for-release upland game bird and raised-for-release waterfowl industries 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 through routine surveillance of each participating premises. A premises will qualify for the classification when the Official State Agency determines that a representative sample of 30 birds from the participating premises has been tested with negative results for the H5/H7 subtypes of avian influenza, as provided in § 146.13(b), every 90 days.

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

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.
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147.51 Definitions.
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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.

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]

§ 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. 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]

§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 chapter 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. Each official delegate shall endeavor to obtain, prior to the Conference, the recommendations of industry members of his State with respect to each proposed change.

[41 FR 48727, Nov. 5, 1976. Redesignated at 44 FR 61586, Oct. 26, 1979, and amended at 45 FR 10317, Feb. 15, 1980; 65 FR 8023, Feb. 17, 2000; 71 FR 56333, Sept. 26, 2006; 74 FR 14718, Apr. 1, 2009; 76 FR 15797, Mar. 22, 2011]

§ 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.

(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]

§ 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 NPIP. 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.

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.

§ 147.52 Authorized laboratories.

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

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

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

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

(d) *State site visit.* The Official State Agency will conduct a site visit and recordkeeping audit 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]]

§ 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 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.

[81 FR 53251, Aug. 12, 2016]

PART 149—VOLUNTARY TRICHINAE CERTIFICATION PROGRAM

Sec.

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AUTHORITY: 7 U.S.C. 1622 and 8301–8317; 21 U.S.C. 136a; 7 CFR 2.22, 2.80, and 371.4.

SOURCE: 73 FR 60479, Oct. 10, 2008, unless otherwise noted.

§ 149.0 Purpose and scope.

The Trichinae Certification Program described in this part is intended to enhance the ability of swine producers, as well as slaughter facilities and other persons that handle or process swine from pork production sites that have been certified under the program, to export fresh pork and pork products to foreign markets.

§ 149.1 Definitions.

Accredited veterinarian. A veterinarian approved by the APHIS Administrator in accordance with part 161 of this chapter to perform functions specified in subchapters B, C, D, and G of this chapter.

Agricultural Marketing Service (AMS). The Agricultural Marketing Service of the United States Department of Agriculture.

AMS Administrator. The Administrator, Agricultural Marketing Service, or any person authorized to act for the AMS Administrator.

AMS representative. Any individual employed by or acting as an agent on behalf of the Agricultural Marketing Service who is authorized by the AMS Administrator to perform services required by this part.

Animal and Plant Health Inspection Service (APHIS). The Animal and Plant Health Inspection Service of the United States Department of Agriculture.

Animal disposal plan. A written document that describes methods for the removal and disposal of dead swine or swine remains from a pork production site.

Animal movement record. A written record of the movement of swine into or from a pork production site.

APHIS Administrator. The Administrator, Animal and Plant Health Inspection Service, or any person authorized to act for the APHIS Administrator.

APHIS representative. Any individual employed by or acting as an agent on behalf of the Animal and Plant Health Inspection Service who is authorized

by the APHIS Administrator to perform the services required by this part.

Approved laboratory. A non-Federal laboratory approved by the Agricultural Marketing Service and recognized by the APHIS Administrator or FSIS Administrator for performing validated tests to determine the presence of trichinae infection in reference to the Trichinae Certification Program.

Audit. An inspection process, as provided in this part, that generates a written record documenting a pork production site's adherence to the required good production practices.

Auditor. A qualified accredited veterinarian (QAV) or a qualified veterinary medical officer (QVMO) who is trained and authorized by APHIS to perform auditing activities under the Trichinae Certification Program.

Certification (certified). A designation given by the APHIS Administrator to a pork production site for compliance with good production practices and other program requirements of the Trichinae Certification Program as provided in this part.

Certified pork. Pork products originating from certified swine from a certified production site with identity of such animals or carcasses maintained throughout receiving, handling, and processing.[1]

Certified production site. A pork production site that has attained a program status of Stage II or higher, based on adherence to good production practices and other program requirements as provided in this part.

Certified swine. Swine produced under the Trichinae Certification Program on a certified production site.

Confinement unit. A structure on a pork production site in which swine are housed and fed that is totally roofed and that is constructed in such a manner as to prevent swine from being exposed to free-flying birds and other wildlife, and from coming into contact with the carrion of free-flying birds or other wildlife.

Decertification (decertified). Removal of the certified status of a production site by the APHIS Administrator when it has been determined that the criteria of the Trichinae Certification Program are not being met or maintained.

Enzyme-linked immunosorbent assay (ELISA). A method of testing swine for the presence of trichinae infection by looking for antibodies to *Trichinella* spp. in the sera, plasma, whole blood, tissue fluid, or meat juice of swine.

EPA. The United States Environmental Protection Agency.

Feed mill quality assurance affidavit. A written statement signed by the feed mill representative and the producer that documents the quality and safety of feed or feed ingredients delivered from the feed mill to the pork production site.

Food Safety and Inspection Service (FSIS). The Food Safety and Inspection Service of the United States Department of Agriculture.

FSIS Administrator. The Administrator, Food Safety and Inspection Service, or any person authorized to act for the Administrator.

FSIS program employee. Any individual employed by or acting as an agent on behalf of the Food Safety and Inspection Service who is authorized by the FSIS Administrator to perform the services required by this part.

Good manufacturing practices. Feed manufacturing practices that reduce, eliminate, or avoid the risk of exposure of swine to *Trichinella* spp.

Good production practices. Pork production management practices that reduce, eliminate, or avoid the risk of exposure of swine to *Trichinella* spp.

Harborage. Any object, debris, clutter, or area that could serve as shelter or refuge for rodents or wildlife.

Laboratory approval audit. An audit performed by AMS representatives to determine if a laboratory meets minimum requirements for approval, as established by AMS, for performing validated tests under this part.

National Trichinae Certified Herd. All swine raised on certified production sites in the United States.

Person. Any individual, corporation, company, association, firm, partnership, society, joint stock company, or other legal entity.

[1] The labeling of all certified pork or pork products leaving a slaughter or processing facility must comply with 9 CFR 317.4 and all other applicable FSIS labeling regulations.

Pest control operator. A person trained and State-licensed in the control of pests and vermin (particularly rodents).

Pooled sample digestion method (digestion method). A method of testing swine for trichinae infection by identifying the presence of *Trichinella* spp. from a sample of the animal's muscle tissue.

Pork production site (site). A geographically definable area that includes pork production facilities and ancillary structures under common ownership or management systems and the surrounding space within a 100-foot perimeter of the confinement unit.

Positive test result. Outcome of a validated test indicating the presence of *Trichinella* spp.

Premises Identification Number (PIN). A number assigned to a pork production site by the APHIS Administrator.

Process-verification testing. Testing of a statistically valid sample of swine belonging to the National Trichinae Certified Herd at the time of slaughter using a validated test to verify that the adherence to good manufacturing practices and good production practices is resulting in the absence of *Trichinella* spp. infection in swine from that herd.

Producer. An individual or entity that owns or controls the production or management of swine.

Qualified accredited veterinarian (QAV). An accredited veterinarian who has been granted a program certification by the APHIS Administrator pursuant to §161.5 of this chapter based on completion of an APHIS-approved training program in good production practices in swine management, and who is authorized by the APHIS Administrator to perform site audits and other specified program services required by this part.[2]

Qualified veterinary medical officer (QVMO). A VMO of the State or Federal Government who is trained in good production practices and is authorized by the APHIS Administrator to perform site audits, spot audits, and other specified program services required by this part.

Rodent control logbook. A written record that documents a rodent control program for a pork production site.

Site audit. An audit, performed by a QAV or a QVMO, to determine the trichinae risk factor status of a pork production site based on the site's adherence to all of the required good production practices that reduce, eliminate, or avoid the risk of exposure of swine to *Trichinella* spp.

Slaughter facility. A slaughtering establishment operating under the Federal Meat Inspection Act (21 U.S.C. 601 *et seq.*) or a State meat inspection act that receives certified swine under the Trichinae Certification Program.

Slaughter facility representative. Any individual employed by, or acting as an agent on behalf of, a slaughter facility who is authorized by the slaughter facility to perform the specified program services required by this part.

Spot audit. An audit of a certified pork production site performed by a QVMO to ensure program integrity and consistency.

Stage I enrolled. Preliminary program status of a pork production site attained when the APHIS Administrator approves the outcome of an initial site audit.

Stage II certified. Program status attained upon APHIS approval of a site audit of a Stage I enrolled site.

Stage III certified. Program status attained upon APHIS approval of a site audit of a Stage II certified site and maintained upon APHIS approval of subsequent site audits for renewal of Stage III certified status.

Sterile zone. An open area immediately adjacent to and surrounding the confinement unit that serves as both a buffer and detection zone for rodent and wildlife activity.

Temporary withdrawal. The voluntary withdrawal of a certified production site from the Trichinae Certification Program at the request of the producer for a period not to exceed 180 days.

Trichinae. A generic term that refers to *Trichinella* spp.

Trichinae Certification Program (program). A voluntary pre-harvest pork

[2] Accredited veterinarians interested in obtaining program certification related to the Trichinae Certification Program should contact APHIS' National Trichinae Coordinator at (515) 284–4122 or write to: USDA, APHIS, Veterinary Services, Trichinae Certification Program, 210 Walnut St., Room 891, Des Moines, IA 50309.

safety program in which APHIS certifies pork production sites that follow all of the required good production practices that reduce, eliminate, or avoid the risk of exposure of swine from their sites to *Trichinella* spp.

Trichinella spp. Parasitic nematodes (roundworms) capable of infecting many warm-blooded carnivores and omnivores, including swine.

USDA. The United States Department of Agriculture.

Validated test. An analytical method licensed by APHIS or accepted by AMS for the diagnosis of *Trichinella* spp. in swine.

Veterinary medical officer (VMO). A veterinarian employed by the State or Federal Government who is authorized to perform official animal health activities on their behalf.

[73 FR 60479, Oct. 10, 2008, as amended at 74 FR 65010, Dec. 9, 2009]

§ 149.2 Program participation.

A producer's initial enrollment and continued participation in the Trichinae Certification Program requires that the producer adhere to all of the good production practices, as confirmed by periodic site audits, and comply with other recordkeeping and program requirements provided in this part. Pork production sites accepted into the program by APHIS will participate under one of the following three program stages:

(a) *Stage I enrolled status.* (1) Stage I enrolled status signifies that the site has met good production practices and other recordkeeping and program requirements provided in this part.

(2) Swine from a Stage I enrolled site cannot be identified as products from a certified production site.

(3) A Stage I enrolled site must complete a site audit for Stage II certified status in accordance with §149.3(d). Under §149.3(d), the site audit must be performed no sooner than 150 days from the date the site was awarded Stage I enrolled status, and must be completed, with the audit form and payment submitted to APHIS, no later than 210 days from the date the site was awarded Stage I enrolled status.

(4) A Stage I enrolled site that is found not to be adhering to one or more good production practices as a result of a site audit or spot audit, or that fails to follow the prescribed timetable for completing a site audit and submitting the completed audit form and payment for consideration as a Stage II certified site, will be subject to a review by APHIS to consider the nature of the infraction(s), and may lose its status as a Stage I enrolled site.

(b) *Stage II certified status.* (1) Stage II certified status signifies that the site is adhering to all of the required good production practices and other recordkeeping and program requirements provided in this part.

(2) An APHIS-issued certificate or letter indicating the site's status as a Stage II certified site must be filed at the site and be readily available for inspection.

(3) Swine from a Stage II certified site may be identified as certified products from a certified production site.

(4) A Stage II certified site must complete a site audit for Stage III certified status in accordance with §149.3(e). Under §149.3(e), the site audit must be performed no sooner than 240 days from the date the site was awarded Stage II certified status, and must be completed, with the audit form and payment submitted to APHIS, no later than 300 days from the date the site was awarded Stage II certified status.

(5) A Stage II certified site that is found not to be adhering to one or more good production practices as a result of a site audit or spot audit, or that fails to meet the Stage III site audit requirements of §149.3(e) within the prescribed timetable, will be subject to a review by APHIS to consider the nature of the infraction(s) and determine whether to decertify the site, as provided in paragraph (e)(1) of this section. During the time a site is decertified, swine from that site cannot be identified as certified products from a certified production site.

(c) *Stage III certified status.* (1) Stage III certified status signifies that the site is adhering to all of the required good production practices and other recordkeeping and program requirements provided in this part.

(2) An APHIS-issued certificate or letter indicating the site's status as a Stage III certified site must be filed at

the site and be readily available for inspection.

(3) Swine from a Stage III certified site may be identified as certified products from a certified production site.

(4) In order to maintain Stage III certified status, sites must arrange for site audits to renew such status according to the timetable set forth in §149.3(f). Under §149.3(f), the site audit must be performed no sooner than 14 months from the date the site was awarded Stage III certified status or the date that status was last renewed, and must be completed, with the audit form and payment submitted to APHIS, no later than 16 months from either the date the site was awarded Stage III certified status or the date that status was last renewed.

(5) A Stage III certified site that is found not to be adhering to one or more good production practices as a result of a site audit or spot audit, or that fails to follow the prescribed timetable for completing a site audit and submitting the completed audit form and payment to determine its continued participation as a Stage III certified site, will be subject to a review by APHIS to consider the nature of the infraction(s) and determine whether to decertify the site, as provided in paragraph (e)(1) of this section. During the time a site is decertified, swine from that site cannot be identified as certified products from a certified production site.

(d) *Change of ownership*—(1) *Stage I enrolled site.* If there is a change in ownership in a Stage I enrolled site, and the new ownership wishes to remain in the program, then the Stage I enrolled site will remain on the same timetable as under the previous ownership for purposes of completing a site audit for Stage II certified status. No additional site audit is necessary as a result of the change of ownership of the site.

(2) *Stage II or Stage III certified sites.* When a change of ownership occurs at a Stage II or Stage III certified site, the previous owner of the site must notify APHIS of this change as soon as the transaction is finalized. Within 60 days of this notification, a site audit must be performed in order for the site to maintain its certified status. It is the new ownership's responsibility that a site audit be performed within 60 days of this notification, otherwise the site may be subject to decertification, in accordance with paragraph (e)(1) of this section. If the site audit is satisfactory, then the Stage II or Stage III certified site will continue in the program, initially as a Stage II certified site. However, a new program anniversary date for that site will be established based on the date the site was audited to continue in the program as a Stage II certified site, and the producer of the site must arrange for a site audit to gain (or regain) Stage III certified status based on that new anniversary date and according to the timetable prescribed in §149.3(e). If the results of the site audit do not meet program requirements, the Stage II or Stage III site will be subject to a review by APHIS to consider the nature of the infraction(s) and determine whether to decertify the site, as provided in paragraph (e)(1) of this section. Once a site is decertified by APHIS, either because the new ownership fails to arrange for a site audit to be performed within the allotted 60-day time period, or because the site is found not to meet program requirements, a producer wishing to participate in the program again must follow the procedures for requesting an initial audit for Stage I enrolled status. If a decertified site is reenrolled after a successful Stage I site audit, a new program anniversary date for that site will be established based on the date of reenrollment.

(e) *Site decertification and program withdrawal*—(1) *Decertification by APHIS.* (i) A Stage II or Stage III certified site that is found not to be adhering to one or more of the good production practices as a result of a site audit, or that fails to follow the prescribed timetable for completing a site audit and submitting the completed audit form and payment to continue participation in the program, will be subject to a review by APHIS to consider the nature of the infraction(s) and to determine whether the site should be decertified. Decertification will result from infraction(s) that APHIS determines to be substantive,

prolonged, and/or repeated as a result of this review.

(ii) During the time a site is decertified, swine from such sites cannot be identified as certified products from a certified production site.

(iii) Once a site is decertified by APHIS, a producer wishing to participate in the program again must follow the procedures for requesting a site audit for Stage I enrolled status. If a decertified site is reenrolled after a successful Stage I site audit, a new program anniversary date for that site will be established based on the date of recertification. If a decertified site is recertified after a successful Stage II site audit, a new program anniversary date for that site will be established based on the date of recertification.

(2) *Temporary withdrawal by producer.* (i) A producer may request that one or more certified production sites be temporarily withdrawn. A producer's request must be made in writing and is subject to the APHIS Administrator's approval.

(ii) Each certified production site can be temporarily withdrawn no more than once every 2 years for a period not to exceed 180 days.

(iii) During the time a site is temporarily withdrawn:

(A) Swine from such sites cannot be identified as certified products from a certified production site; and

(B) The producer must continue to adhere to all good production practices and other recordkeeping and program requirements provided in this part, including documentation in the animal movement record of the arrival and departure of all swine from this site, as well as whether the swine arriving at the site are from certified or noncertified sources, unless a program requirement is specifically waived by the Administrator.

(iv) If granted a waiver by the Administrator, a producer may receive swine 5 weeks of age or older originating from a noncertified source during the period of withdrawal.

(v) Before being reinstated as a certified production site, the temporarily withdrawn site must pass a site audit to indicate that it is now adhering to all good production practices (including any practices waived by the Administrator at the beginning of the period of withdrawal) as follows:

(A) The site audit must be performed while the site is still under temporary withdrawal status. If swine 5 weeks of age or older originating from a noncertified source have been received at the site during the time of withdrawal, then the site audit for reinstatement must be performed within 30 days of the date the last swine from a noncertified source was removed from the site, but no later than 180 days from the date the site was granted temporary withdrawal status.

(B) If the results of the site audit are satisfactory and it is determined that the site is now adhering to good production practices and other program requirements provided in this part, then the withdrawn site will be reinstated as a Stage II certified site. The timetable for performing future site audits for attaining and renewing Stage III certified status will be based on the date the site was reinstated as a Stage II certified site.

(C) If the results of the site audit are not satisfactory, or, if the period of temporary withdrawal has exceeded 180 days, then the site will be subject to a review by APHIS to consider the nature of the infraction(s) and to determine whether to decertify the site, as provided in paragraph (e)(1) of this section. Once the site is decertified by APHIS, the producer must follow the procedures for requesting an initial site audit for Stage I enrolled status in order for the site to be reenrolled in the program. If a site is decertified by APHIS and then reenrolled after a successful Stage I site audit, a new program anniversary date for that site will be established based on the date of enrollment.

(3) *Program withdrawal.* (i) If a producer decides to withdraw one or more of pork production sites from the program, then it is the producer's responsibility to notify the APHIS Administrator in writing of this intent. When this is done, the site will be removed from the program.

(ii) If at a later date the producer requests that a site be reinstated in the program, then the producer must follow the procedures for requesting an

initial audit for Stage I enrolled status. If a withdrawn site is reenrolled after a successful Stage I site audit, then a new program anniversary date for that site will be established based on the date of reenrollment.

(f) *Request for review.* If there is a conflict as to any material fact relating to the results of a site audit, spot audit, or other determination affecting a producer's program status or ability to participate in the program, the producer may submit a written request for review to the Administrator. The producer must include in the request the reasons, including any supporting documentation, why the audit result or other determination should be different than the result or determination made by the Administrator. The initial audit result or other determination will remain in force pending the completion of the Administrator's review. The decision by the Administrator upon reviewing the producer's written request will be final.

§ 149.3 Site audit.

(a) *General.* (1) The producer must contact a QAV or QVMO to request a site audit. A list of available QAVs may be obtained by accessing the Trichinae Certification Program Web site on the Internet at *http://www.aphis.usda.gov/vs/trichinae.* If a QAV is not available to perform a site audit, the producer must then contact the APHIS area office to request that a QVMO perform the site audit. The site audit is to be arranged at a mutually agreed-upon time.

(2) The producer or the producer's designated representative will accompany the auditor during the site audit.

(3) During the site audit, the auditor will record whether the producer is adhering to all of the required good production practices at the site, as provided in paragraph (b) of this section, in order to reduce, eliminate, or avoid the risk of exposure of swine to *Trichinella* spp.

(4) The auditor will use APHIS-approved audit forms in performing the site audit. After the auditor has completed all sections of the audit form, the producer or the producer's designated representative must sign the audit form attesting to the accuracy of the information obtained during the site audit and to evidence his or her intent to continue adhering to the good production practices and other program requirements, as provided in this part. The auditor also must sign the audit form at this time.

(5) If a QVMO performs the site audit, then the producer will pay the QVMO at the time the site audit is performed in accordance with the rate and other conditions set by the QVMO's governmental employer. If an APHIS-employed QVMO performs the site audit, then the producer will pay APHIS by certified check or U.S. money order for this service at a rate determined in accordance with § 149.8.

(6) In addition to the possible cost of the site audit, the producer is also responsible for paying a separate program fee in an amount specified in § 149.8 to cover APHIS' administrative costs in processing the audit and operating the program. This program fee, payable to APHIS by certified check or U.S. money order, must be remitted to the auditor at the time each site audit is performed.

(7) The auditor will submit the completed audit form, program fee, and payment for the services of an APHIS-employed QVMO, if applicable, to the nearest APHIS area office. If a QAV performs the site audit, the producer will be responsible for ensuring that the QAV submits the completed audit form and program fee to APHIS in a timely manner.

(8) Upon receipt of the completed audit form and payment, APHIS will determine the initial enrollment or certification status for the site based on an evaluation of the site audit. APHIS will provide the producer with written notification of the audit results. Pork production sites that meet all good production practices as provided in paragraph (b) of this section, as well as other program requirements provided in this part, will be issued program status at the appropriate program stage.

(9) If the site audit shows that the site does not substantively meet all good production practices or other program requirements, APHIS will provide the producer with written notification

that includes documentation of the deficiencies that prevented the site from being conferred program status.

(b) *Good production practices.* In a site audit, the auditor will determine whether all of the required good production practices are being carried out at the site to reduce, eliminate, or avoid the risk of exposure of swine to *Trichinella* spp. as follows:

(1) The movement of all non-breeding swine 5 weeks of age or older into or from the pork production site must be documented in an animal movement record, as provided in §149.7, that ensures that all such swine moved into or from the site can be subsequently traced back to that site, or to any previous site (if applicable).

(2) All non-breeding swine entering a site must have originated from another certified production site, except that non-breeding swine less than 5 weeks of age may have originated from either a certified or noncertified production site. The animal movement record must include the PIN of the certified production site from which the swine originated. If the swine are less than 5 weeks of age and come from a noncertified site, then the animal movement record must provide the name and full address of the noncertified site where the swine originated.

(3) Feed or feed ingredients from offsite sources that are used at the site must meet good manufacturing practices or other quality assurance standards recognized by the feed industry. The adherence to good manufacturing practices or other quality assurance standards must be documented in a feed mill quality assurance affidavit, as provided in §149.7.

(4) Swine at the site must be housed and fed in a confinement unit. The confinement unit, feed preparation and storage areas, and office areas and connecting hallways at the site must be inspected regularly and found free of signs of rodent and wildlife activity (evidence of rodent activity consists of fresh rodent droppings, fresh gnawing marks, new structural damage, rodent urine, rodent blood, rodent smear marks (body oil), rodent tracks, or recent burrowing or burrow use. Evidence of wildlife activity consists of wildlife feces, footprints, fur, or hair observed in or near the stored feed or feed ingredients, dead or live wildlife observed in or near the stored feed or feed ingredients, or wildlife burrows or nests observed in or near the stored feed or feed ingredients). Any movable harborage (exterior or interior) on the site that is not necessary to the day-to-day operation of the site must be removed. Harborage that cannot be removed or is movable but necessary to the day-to-day operation of the site (e.g., equipment) must be checked for signs of rodent or wildlife activity. In addition, domesticated animals, including pets such as dogs and cats, must be excluded from the confinement unit and feed preparation and storage areas at the site. Exterior rodent bait stations and/or traps must be placed around the perimeter of the confinement unit. Exterior rodent bait stations and/or traps also must be placed around areas of potential rodent entry into the confinement unit (*i.e.*, doorways, vent openings, loading chutes, cool cells, etc.). Interior rodent bait stations and/or traps must be placed near high-risk rodent zones such as entryways, hallways, office areas, swine load-out areas, vents, cool cells, storage areas, utility rooms, cabinets, locker rooms, bathrooms, and break rooms, and systematically maintained. Interior rodent bait stations and/or traps must be placed so that swine will not come in contact with the bait or trap. Rodent bait stations and/or traps also must be placed near exterior or interior harborage on the site that cannot be removed or that is movable but necessary to the day-to-day operation of the site. In all instances, rodent bait stations must be intact, systematically maintained, and contain fresh bait that consists of an EPA-registered rodenticide formulation that is applied according to its label. In addition, a sterile zone must be maintained around the perimeter of the confinement unit. The sterile zone must be devoid of any harborage or feed or water sources that could attract rodents or wildlife, but must contain rodent bait stations and/or rodent traps. The sterile zone also must be devoid of any vegetation unless it is decorative vegetation that is well maintained (*i.e.*, residential height

grass, flowers, shrubs, or trees). A sterile zone with decorative vegetation will require increased rodent control measures. The producer must provide documentation of rodent control practices by maintaining at the site an up-to-date rodent control logbook with a site diagram and other recordkeeping evidencing implementation of rodent control measures, which can include documents provided by a pest control operator, as provided in §149.7.

(5) Feed or feed ingredients stored at the site must be prepared, maintained, and handled in a manner that protects the feed or feed ingredients from possible exposure to or contamination by rodents or wildlife. Any movable harborage in the immediate vicinity of feed production and feed storage areas that is not necessary to the day-to-day operation of the site must be removed. Harborage that cannot be removed or harborage that is movable but necessary to the day-to-day operation of the site (e.g., equipment, etc.) must be checked for signs of rodent or wildlife activity. Rodent bait stations and/or traps must be placed around (and in, if applicable) all feed preparation and storage areas, as well as near any harborage in the vicinity that cannot be removed or that is movable but necessary to the day-to-day operation of the site. Rodent bait stations must be intact, systematically maintained, and contain fresh bait that consists of an EPA-registered rodenticide formulation that is applied according to its label. In addition, feed or feed ingredients that are stored in paper bags must be elevated off the floor and be a sufficient distance away from the walls to allow for inspection, baiting, and/or trapping. The rodent control logbook, as provided in §149.7, must document that adequate rodent control procedures have been implemented in the feed production and feed storage areas.

(6) Swine must not have access to dead or live wildlife at the site. Dead or live wildlife must not be intentionally fed to swine.

(7) Swine at the site must not be fed waste that contains meat.

(8) Procedures must be in place and carried out for the prompt removal and proper disposal of dead swine or swine remains found in pens in order to eliminate the opportunity for cannibalism, as well as to prevent the attraction of rodents or wildlife. Such procedures must be documented in the animal disposal plan, as provided in §149.7.

(9) General hygiene and sanitation of the site must be maintained at all times to prevent the attraction of rodents and wildlife. Solid non-fecal waste (facility refuse) must be placed in covered receptacles and be regularly removed from the site. Spilled feed also must be regularly removed and properly disposed of.

(10) All records required under §149.7 must be kept up to date and readily available for inspection at the site.

(c) *Initial site audit for Stage I enrolled status.* (1) Producers interested in participating in the program should request and review a pre-audit information packet prepared by APHIS that discusses the program, as well as the steps in preparing for and requesting an initial site audit.[3] When the producer and the producer's herd health personnel believe that a site meets program standards, the producer must arrange for an initial site audit, as provided in paragraph (a) of this section.

(2) Upon completion of the initial site audit and submission of the completed audit form and payment, APHIS will review the completed audit form and make a determination within 30 days as to enrollment of the site in the program. A pork production site that is found to meet all good production practices and other program requirements in this part will be awarded Stage I enrolled status.

(d) *Site audit for Stage II certified status.* (1) A producer of a Stage I enrolled site must arrange for another site audit for Stage II certified status. The site audit must be performed no sooner than 150 days (*i.e.*, approximately 5

[3] The pre-audit information packet may be obtained from a qualified accredited veterinarian (QAV), State or Federal animal health offices, or the National Pork Board, or by writing to: USDA, APHIS, Veterinary Services, Trichinae Certification Program, 210 Walnut St., Room 891, Des Moines, IA 50309. A pre-audit packet also may be requested electronically through the program Web site on the Internet at *http://www.aphis.usda.gov/vs/trichinae.*

months) from the date the site was awarded Stage I enrolled status, and must be completed, with the audit form and payment submitted to APHIS, no later than 210 days (*i.e.*, approximately 7 months) from the date the site was awarded Stage I enrolled status.

(2) APHIS will review the completed audit form and make a determination as to Stage II certified status within 7 days of receipt of the audit form and payment.

(i) A Stage I enrolled site that is found to meet all good production practices and other program requirements in this part will be awarded Stage II certified status.

(ii) A Stage I enrolled site that is found, during a site audit, not to be adhering to one or more good production practices, or that fails to follow the prescribed timetable for completing a site audit and submitting the completed audit form and payment, will be subject to a review by APHIS to consider the nature of the infraction(s), and may lose its status as a Stage I site.

(e) *Site audit for Stage III certified status.* (1) A producer of a Stage II enrolled site must arrange for another site audit for Stage III certified status. The site audit must be performed no sooner than 240 days (*i.e.*, approximately 8 months) from the date the site was awarded Stage II certified status, and must be completed, with the audit form and payment submitted to APHIS, no later than 300 days (*i.e.*, approximately 10 months) from the date the site was awarded Stage II certified status.

(2) APHIS will review the completed audit form and make a determination as to Stage III certified status within 30 days of receipt of the audit form and payment.

(i) A Stage II certified site that is found to meet all good production practices and other program requirements in this part will be awarded Stage III certified status.

(ii) A Stage II certified site that is found, during a site audit, not to be adhering to one or more good production practices, or that fails to follow the prescribed timetable for completing a site audit and submitting the completed audit form and payment, will be subject to a review by APHIS to consider the nature of the infraction(s) and determine whether to decertify the site, as provided in §149.2(e)(1).

(f) *Site audit for renewal of Stage III certified status.* (1) A producer seeking to renew a site's Stage III certified status must arrange for another site audit. The site audit must be performed no sooner than 14 months from the date the site was awarded Stage III certified status or the date that status was last renewed, and must be completed, with the audit form and payment submitted to APHIS, no later than 16 months from either the date the site was awarded Stage III certified status or the date the that status was last renewed.

(2) APHIS will review the completed audit form and make a determination as to renewing the site's Stage III certified status within 30 days of receipt of the audit form and payment.

(i) A Stage III certified site that is found to meet all good production practices and other program requirements in this part will have its status as a Stage III certified site renewed.

(ii) A Stage III certified site that is found, during a site audit, not to be adhering to one or more good production practices, or that fails to follow the prescribed timetable for completing a site audit and submitting the completed audit form and payment, will be subject to a review by APHIS to consider the nature of the infraction(s) and determine whether to decertify the site, as provided in §149.2(e)(1).

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§149.4 Spot audit.

(a) In addition to regularly scheduled site audits, certified production sites will be subject to spot audits.

(1) *Random spot audit.* Certified production sites will be selected by the APHIS Administrator at random for a spot audit in order to:

(i) Ensure the integrity of the audit process;

(ii) Verify that the audit process is performed in a consistent manner across the program; and

(iii) Verify that all required good production practices are being maintained between regularly scheduled site audits.

(2) *Spot audit for cause.* A certified production site may be subject to a spot audit to trace back and investigate any positive test results as a result of testing of certified swine from that site at the slaughter facility.

(b) All spot audits will be performed by a QVMO. The producer of the certified production site subject to spot audit will not be charged for the spot audit. APHIS will provide the producer with written notification of the results of the spot audit, including documentation of any deficiencies noted during the audit. If the site is found not to be adhering to one or more of the required good production practices, then the site will be subject to a review by APHIS to consider the nature of the infraction and to determine whether to decertify the site, as provided in §149.2(e)(1). Unless a spot audit results in decertification, it does not otherwise affect the timetables for the completion of site audits set forth in paragraphs (e) and (f) of §149.3.

§149.5 Offsite identification and segregation of certified swine.

Certified swine moved from a certified production site to another location, whether to another certified production site, buying station, collection point, or slaughter facility, must remain segregated from noncertified swine at all times and otherwise maintain their identity as certified swine in such a way that they could be readily traced back to the certified production site from which they came. Information relating to the identification of the certified swine must be documented in the animal movement record maintained by the producer. Failure to properly segregate or maintain the identity of certified swine from noncertified swine after leaving the certified production site will result in the loss of certified status for that shipment of swine.

§149.6 Slaughter facilities.

Only slaughter facilities that are under continuous inspection by the Food Safety and Inspection Service or under State inspection that the Food Safety and Inspection Service has recognized as equivalent to Federal inspection may participate in the program. To participate in the program, slaughter facilities must follow the relevant provisions of this section relating to verification, segregation, testing, and recordkeeping. Participating slaughter facilities that fail to comply with any of the applicable requirements of this section will not be allowed to continue to participate in the Trichinae Certification Program and the pork or pork products prepared by the facility will not be eligible for a certificate of export that identifies the product as meeting the standards of the Trichinae Certification Program.

(a) *Verification of certification.* A slaughter facility receiving certified swine must verify the current certification status of the pork production site from which the animals came. The current certification status may be verified by maintaining dated certification documentation on file or by accessing the Trichinae Certification Program Web site on the Internet at *http://www.aphis.usda.gov/vs/trichinae.* If the slaughter facility is unable to verify a site's certification status through documentation on file or through the program Web site, the slaughter facility then should contact the APHIS area office in the State where the site is located.

(b) *Maintaining identity and segregation of certified swine and pork products.* For certified swine to be identified as certified pork, certified swine and edible pork products derived from certified swine must remain segregated from swine and edible pork products from noncertified sites throughout receiving, handling, and processing at the slaughter facility, as well as while awaiting shipment from the facility. The slaughter facility must maintain the identity of the certified swine or pork in a manner that allows the certified swine or pork to be traced back to the certified production site from which it came. A slaughter facility's failure to properly segregate or maintain the identity of certified swine and edible pork products derived from the certified swine will result in the loss of certified status for that shipment of

swine, as well as the edible pork products derived from those animals.

(c) *Process-verification testing.* A slaughter facility processing certified swine is responsible for performing process-verification testing to determine the *Trichinella* spp. infection status of certified swine under its control as follows:

(1) *Validated tests.* Process-verification testing must be performed by using a validated test. When testing involves meat, the sample used for such testing must be at least 20 grams.[4]

(2) *Laboratory approval.* Process-verification testing must be performed in an approved laboratory that has been approved for trichinae testing by the Agricultural Marketing Service (AMS).[5] The approved laboratory may be maintained and operated by the slaughter facility or by another business entity either on the premises of the slaughter facility or at another location. Laboratory staff performing process-verification testing must be accredited by AMS to perform this program function. For purposes of quality assurance, all laboratory staff approved to perform process-verification testing will receive periodic proficiency test panels from AMS that must be analyzed correctly in order to maintain their approval status.

(3) *Testing sample size and frequency.* Process-verification testing must meet the following minimum requirements relating to sample size and frequency:

(i) Slaughter facility representatives shall determine the yearly processing capacity of the slaughter facility for the next 12 months. Officials may use the processing capacity over the previous 12 months if this period is representative of a typical processing year.

(ii) Slaughter facility representatives shall estimate the percentage of swine processed that are likely to come from certified production sites considering all swine expected to be processed at the slaughter facility during the selected 12-month period. Swine that come from certified production sites are considered the eligible population to be sampled.

(iii) Slaughter facility representatives shall use the Trichinae Certification Slaughter Facility Sample Size Determination Table on the Internet at *http://www.aphis.usda.gov/vs/trichinae* to find the number of samples to collect from the population of swine from certified production sites.[6] If the eligible population is not listed in that table, the next largest number will be used to determine the number of samples to collect. Select the number of samples to collect from the column on that table that reflects a 99 percent confidence level of detecting a positive carcass in a population with a prevalence rate of 0.013 percent. The number selected from the table will be the total number of samples that slaughter facility representatives must collect and test per year and per month during the selected 12-month period.

(iv) For each sample collected, slaughter facility representatives must maintain the identity of the sample using the PIN of the certified production site that was the source of the swine from which the sample was taken.

(v) FSIS program employees at the slaughter facility will review and verify that an adequate number of samples have been collected and that proper frequency of collection is maintained. FSIS will report this information to APHIS.

(vi) AMS representatives will verify through a laboratory approval audit that the laboratory performing process-verification testing is correctly following written procedures relating to the receipt, handling, identification,

[4] A copy of the testing methods and checklist for conducting validated tests may be obtained by contacting the AMS Trichinae Analyst and Laboratory Certification Program Manager, USDA, AMS, Science and Technology Programs, Technical Services Branch, 1400 Independence Ave., SW., Mail Stop 0272, Washington, DC 20250–0272. The manager may be contacted by phone at (202) 690–0621.

[5] A copy of the AMS Trichinae Accredited Laboratory Program Requirements may be obtained by contacting the AMS Trichinae Analyst and Laboratory Certification Program Manager (see footnote 4).

[6] More information regarding sampling sizes may be obtained by writing to USDA, APHIS, Veterinary Services, Trichinae Certification Program, 210 Walnut St., Room 891, Des Moines, IA 50309.

and testing of samples. These written procedures must be maintained by the laboratory in a quality assurance manual, as provided in paragraph (c)(6) of this section. In addition, a laboratory that performs process-verification testing at a location other than the slaughter facility must include a declaration of methodology used to test samples when providing test results.

(vii) The APHIS Administrator may, at APHIS' expense, periodically request that testing be performed on swine brought to the slaughter facility from specific certified production sites. Requests to test swine from specific certified production sites will count towards the slaughter facility's total monthly testing requirement.

(4) *Results of testing.* (i) The results of all process-verification testing relating to certified swine handled at the slaughter facility must be retained in a separate file or notebook as written records at the slaughter facility and must be readily available for inspection by FSIS program employees.

(ii) FSIS will report to APHIS the results of all process-verification testing.

(iii) In the event of a positive test result, the slaughter facility representative must notify the FSIS program employee designated by the FSIS Administrator immediately, who in turn will report the PIN of the certified production site that was the source of the swine from which the sample was taken and the test results of the affected sample to the respective APHIS area office. The following sequence of events must take place following a positive test result:

(A) If a test sample yields a positive test result based on the digestion method, the certified production site that was the source of the swine from which the sample was taken will be decertified.

(B) If a test sample yields a positive test result based on an ELISA method and is confirmed positive by further testing using the digestion method, the certified production site that was the source of the swine from which the sample was taken will be decertified.

(C) If a test sample yields a positive test result based on an ELISA method, but is not confirmed positive by further testing using the digestion method, then the certified production site that was the source of the swine from which the sample was taken will be investigated by APHIS.

(*1*) The investigation may include a spot audit of the affected site. Further testing of animals or carcasses from the affected site also may be performed as part of the investigation. This investigation would determine if the production facility has sufficient safeguards and is following good production practices.

(*2*) While the affected site is under investigation, its program status as a certified production site will be suspended. While the site is under suspension, the producer must continue to adhere to all of the required good production practices and other recordkeeping and program requirements provided in this part. During this suspension, swine at the site may be sent to slaughter; however, swine from the suspended site cannot be identified as product from a certified production site. The Administrator will determine the program status of the affected site within 30 days of the initiation of the suspension.

(*3*) A finding that risk factors are inadequately addressed in the site investigation or the finding of additional positive test results based on samples from animals or carcasses from the affected site will be grounds for APHIS decertification of the site.

(5) *Slaughter facility recordkeeping.* (i) All slaughter facilities that receive certified swine must maintain records relating to such animals, including the number of certified swine processed, the source of the certified swine, including the PIN of the certified production site from which the swine came from, and all test results relating to process-verification testing. Records relating to certified swine must be retained at the slaughter facility for a period of at least 3 years following the processing of such animals.

(ii) All slaughter facilities must have documented procedures on how certified swine under its control, and edible pork products derived from certified swine, will remain segregated from swine and edible pork products from noncertified sites throughout receiving, handling, and processing at the facility, as well as while awaiting

shipment from the facility. The slaughter facility must also have documented procedures for maintaining the identity of the certified swine or pork with respect to the certified production site from which it came.

(iii) All such records and other documentation required to be maintained by slaughter facilities under this part must be readily available for inspection by FSIS program employees.

(6) *Approved laboratory recordkeeping.* Approved laboratories must have written procedures that specify standards for sample size, sample handling, sample identification, and sample test methods used in process-verification testing. All such written procedures must be maintained in a laboratory quality assurance manual specifically for this program, or as a separate section of an existing laboratory quality assurance manual, and must be retained at the approved laboratory throughout the time the approved laboratory is performing process-verification testing under this program. All such written procedures relating to process-verification testing must be readily available for inspection by FSIS program employees or AMS representatives.

(7) *Slaughter facility overall responsibility for process-verification testing.* The slaughter facility is responsible for obtaining testable samples and for ensuring that the correct number of testable samples are sent to the testing laboratory. Once the slaughtering facility receives the test results, it is responsible for reporting those results in its facility trichinae testing record. Moreover, the slaughter facility is responsible for ensuring that process-verification testing is carried out in accordance with this part, including the reporting of test results, regardless of whether it is performed at the slaughter facility or another location, and regardless of whether the testing is performed by slaughter facility personnel or other persons.

§ 149.7 Recordkeeping at site.

(a) Stage I enrolled sites, Stage II or Stage III certified sites, and any site that has been suspended or voluntarily decertified must maintain the following program records: Animal disposal plan, animal movement record, feed mill quality assurance affidavit (if applicable), and rodent control logbook. All such records must be readily available for inspection at the pork production site at the time of an audit by a QAV or QVMO, or by other APHIS representatives during normal business hours.

(1) *Animal disposal plan.* The animal disposal plan must meet the following minimum requirements:

(i) It must provide for the removal of all dead swine or swine remains from swine pens immediately upon detection. Inspections for purposes of detecting dead animals must occur at least once every 24 hours.

(ii) It must specify how often and at what intervals the swine pens are observed each day.

(iii) It must provide for the proper storage of dead swine or swine remains in accordance with local, State, and Federal laws and regulations. If the carcass storage facility or composting facility is located on the site, then the animal disposal plan must provide for a storage or composting facility that precludes rodent or wildlife contact with dead swine or swine remains being stored or composted.

(iv) It must provide for the disposal of swine and other mammals by rendering, incineration, composting, burial, or other means, as allowed by and in accordance with local, State, and Federal laws and regulations. For sites that use rendering services, the animal disposal plan also must include the name, address, and phone number of the renderer.

(v) It must be updated as animal disposal practices are changed at the site.

(vi) It must be signed and dated by the producer, as well as the caretaker of the site (if the caretaker is a different person than the producer).

(vii) It may be valid for a period no longer than 2 years after the date of signature by the producer and (if applicable) the site caretaker.

(2) *Animal movement record.* The animal movement record must meet the following minimum requirements:

(i) It must be filled out completely and properly, accounting for the movement of all non-breeding swine into and from the pork production site.

(ii) In the case of non-breeding swine coming into the site, it must include the date and number of arriving animals, as well as the PIN of the certified production site where the animals originated, or alternatively, if the swine are less than 5 weeks of age and originated from a noncertified site, the name and full address of the noncertified site where the animals originated. The animal movement record must clearly document that all non-breeding swine 5 weeks of age or older arriving at the site originated from another certified production site.

(iii) In the case of non-breeding swine leaving the site, it must include the date and number of departing animals, and their destination.

(iv) It must document the number of dead non-breeding swine that are removed from the site, as well as the number of dead non-breeding swine that are buried or composted at the site, if swine burial or composting is permitted in that State or locality.

(v) All entries to the animal movement record must be signed or initialed and dated by the producer or other site caretaker making the entry.

(3) *Rodent control logbook.* The rodent control logbook, which may include records from a pest control operator, must meet the following minimum requirements:

(i) It must include a rodent control diagram for the site indicating the location of all rodent bait stations and rodent traps at the site. The diagram must be updated whenever bait stations are added, moved, or removed.

(ii) It must document the number of rodent traps set (if applicable), the number of new rodent bait stations set, and how often bait is refreshed.

(iii) It must document the disposal method for all unused bait that is replaced.

(iv) It must document the brand name and active ingredient of bait, which must be EPA-registered and applied according to its label, as well as the quantity of bait used (number of pounds).

(v) If possible, it should document the number of rodents caught or killed and indicate how many were rats.

(vi) If possible, it should document the number of rats sighted monthly.

(vii) All entries to the rodent control logbook must be signed or initialed, as well as dated by the producer or other site caretaker making the entry. It must be updated at least monthly.

(4) *Feed mill quality assurance affidavit.* The feed mill quality assurance affidavit, to be used in conjunction with feed or feed ingredients delivered to the pork production site, must meet the following minimum requirements:

(i) It must include the name of the producer and the identity of the site, including the PIN if it has been issued, and the site address, as well as the name and address of the feed mill and the name and title of the feed mill representative.

(ii) It must provide information that the feed mill is following good manufacturing practices, and further specify, as evidence of these good manufacturing practices, the following:

(A) That the feed mill has a rodent control system that is maintained by the feed mill itself or by a pest control firm (include name and address of pest control firm).

(B) The frequency with which such rodent control system is maintained (*i.e.*, on a weekly basis, etc.); and

(C) That the feed mill maintains records of pest management practices or has records generated by a pest control operator, which must be made available to the producer upon request.

(iii) It must be signed by the feed mill representative and by the producer or the producer's designated representative, to remain in effect for a period of 2 years.

(b) All such records and other documentation required under this section must be retained at the pork production site for a period of 2 years.

(c) All such records and other documentation required under this section must be readily available for inspection at the pork production site at the time of an audit by a QAV or QVMO, or by other APHIS representatives during normal business hours.

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§ 149.8 Program fees and charges.

(a) *Site audit.* If a QVMO performs the site audit, then the producer will pay the QVMO at the time the site audit is

performed in accordance with the rate and other conditions set by the QVMO's governmental employer. Further, if the QVMO who performs the site audit is employed by APHIS, then the producer will pay APHIS for this service at the hourly rate listed in table 1 for each employee required to perform the service. If the APHIS-employed QVMO performs the site audit on a Sunday, on a holiday, or at any time outside the normal tour of duty of that employee, then the producer will pay APHIS for this service at the hourly rate listed in table 2 for each employee required to perform the service. Payment to APHIS for the services of an APHIS-employed QVMO, by certified check or U.S. money order, must be remitted to the QVMO at the time the site audit is performed.

TABLE 1—RATES FOR SERVICES OF QVMO

Hourly rate:	
Per hour	$84.00
Per quarter hour	21.00
Per service minimum fee	25.00

TABLE 2—OVERTIME RATES FOR SERVICES OF QVMO (OUTSIDE THE EMPLOYEE'S NORMAL TOUR OF DUTY)

Premium hourly rate Monday through Saturday and holidays:	
Per hour	$100.00
Per quarter hour	25.00
Premium hourly rate for Sundays:	
Per hour	112.00
Per quarter hour	28.00

(b) *Program fee.* The producer must pay APHIS a program fee at the time of each site audit in the amount of $51 to cover APHIS' administrative costs in processing the audit and operating the program. This program fee, payable to APHIS by certified check or U.S. money order, is due at the time of submitting the completed site audit form for APHIS evaluation.

(c) A producer will not be charged for the cost of having a spot audit performed at the pork production site.

§ 149.9 Pilot program sites.

Pork production sites participating in an APHIS-approved trichinae pilot program at the time of implementation of the Trichinae Certification Program on November 10, 2008 will maintain their same program status as either a Stage I enrolled, Stage II certified, or Stage III certified site, as well as their same program anniversary date for purposes of completing a site audit and submitting the completed audit form and payment.