(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 the requirements in §147.8 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) Standard test procedures for the AGID test for avian influenza are set forth in §147.9 of this subchapter. The test can be conducted on egg yolk or blood samples.

(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 (AVPR01510) 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
§ 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)


§ 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.

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(71 FR 56328, Sept. 26, 2006, as amended at 75 FR 10658, Mar. 9, 2010)

§ 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. 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 layers and table-egg layer pullets through routine surveillance of each participating commercial table-egg layer and table-egg layer pullet flock.