

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 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) Positive results from the ACIA 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.

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[71 FR 56328, Sept. 26, 2006, as amended at 74 FR 14716, Apr. 1, 2009; 75 FR 10658, Mar. 9, 2010]

§ 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.

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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.

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

(1) It is a commercial table-egg layer flock in which a minimum of 11 birds or egg samples have been tested negative for antibodies to the H5/H7 subtypes of avian influenza within 30 days prior to disposal;

(2) It is a commercial table-egg layer flock in which a minimum of 11 birds or egg samples have been tested negative for antibodies to the H5/H7 subtypes of avian influenza within a 12-month period; or

(3) 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 or egg samples 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]

§ 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 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