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Prevention and Control of H5 and H7 Avian Influenza in the Live Bird Marketing System

Uniform Standards for a State- Federal-Industry Cooperative Program

Effective August 2016

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Introduction

The H5 and H7 hemagglutinin subtypes of low pathogenicity avian influenza (LPAI) virus have repeatedly been isolated from the live bird marketing system (LBMS) in the United States. Although LPAI virus infections cause little or no clinical illness in poultry, LPAI H5 and H7 subtypes can mutate into high pathogenicity avian influenza (HPAI) subtypes. Such mutations, if they occur today, would seriously harm the U.S. commercial poultry industry.

The U.S. Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS), Veterinary Services (VS) unit is responsible for protecting the health of the nation's poultry flocks and supporting trade. Our trading partners are increasingly wary of importing products from countries with H5/H7 AI. Such trade concerns, along with the risk of disease transmission posed by the virus circulating in the LBMS, have increased the need to prevent and control H5 and H7 AI in the LBMS.

To protect U.S. poultry from HPAI and prevent interruptions in trade, Federal, State, and industry officials must cooperate to also actively prevent and control LPAI. In addition, other countries have reported cases of human infection with H5/H7 avian influenza (AI) viruses. Therefore, human health would also benefit from a program that prevents the development of HPAI infections by controlling LPAI infections.

This AI prevention and control program was originally developed as a cooperative effort by State veterinarians, industry representatives, and other parties associated with poultry and poultry health. VS has approved the AI program as a voluntary measure for States. The program is designed to enhance and unify State programs and help States prevent and control H5/H7 AI in the LBMS. States will enact the regulations necessary for compliance from their live bird markets, producers, and distributors. (Requirements expressed herein reflect what would be in State regulations, the substance of which is agreed upon by both the State and VS.) VS coordinates and administers the program. APHIS also provides personnel and resources to assist States with implementation and compliance with program requirements.

This publication is intended as a working document that will change as the program develops. The standards discussed here refer only to the LBMS; the National Poultry Improvement Plan (NPIP) addresses AI surveillance for breeders and commercial poultry flocks.

The minimum national standards described in this document do not preclude the adoption of more stringent methods and rules by any geographical or political subdivision of the United States for application within that subdivision. However, regulations dealing with interstate movement must still conform to Federal regulations.

The following goals of the program apply to all participants in the LBMS, including suppliers, producers, dealers, haulers, auction markets, flea markets, swap meets, wholesalers, and live bird markets:

1. Diagnose, control, and prevent H5 and H7 AI.
2. Help participants improve biosecurity, sanitation, and disease control in their operations.
3. Minimize the effects of H5/H7 AI on the U.S. commercial poultry industry.

Part I—Definitions

Antigen capture immunoassay (ACIA) test

A USDA-licensed type A influenza antigen capture immunoassay test to detect influenza A nucleoprotein and for use as an official test to screen for AI. The ACIA must be conducted using test kits approved by USDA and the State. The ACIA is an NPIP-LBMS approved test used for the detection of influenza A nucleoprotein in swab specimens from birds exhibiting clinical signs of disease (sick birds) or dead birds. It is less sensitive than molecular tests; therefore, those collecting samples should collect additional swab samples and forward both the non-negative sample and additional samples to an approved lab for molecular testing to determine the virus status of the flock following any non-negative ACIA result.

Agar gel immunodiffusion (AGID) test

An NPIP-LBMS approved test for serologic detection of AI antibodies for use in gallinaceous poultry in which precipitates are formed by a combination of specific AI antigens and antibodies that diffuses through a gel. A positive reaction indicates exposure to AI virus, but does not indicate a specific subtype nor pathotype. Antibody detected by AGID must be further tested and subtyped using the hemagglutination inhibition (HI) test, and the neuraminidase-inhibition (NI) test. A final decision on the status of a seropositive flock should be based on further sampling and testing for the presence of virus through real-time, reverse-transcriptase-polymerase chain reaction (rRT-PCR) or virus isolation.

AI

Avian influenza (AI), caused by an influenza A virus. AI is a viral infection of birds including chickens, turkeys, guinea fowl, and other avian species. Certain subtypes of AI can cause zoonotic disease, with most human cases occurring after direct contact with infected poultry. Wild waterfowl and shore birds are considered the natural reservoir for AI viruses. The severity of disease may range from inapparent infection to reproductive disturbance (loss of egg production), respiratory disease, or an acute and fatal systemic disease. Morbidity and mortality rates generally depend on the pathogenicity type of the virus involved. For the purposes of the World Organization for Animal Health (OIE) Terrestrial Animal Health Code, avian influenza is notifiable to OIE and is defined as an infection of poultry caused by any influenza A virus with high pathogenicity (HPAI) and by H5 and H7 subtypes with low pathogenicity (H5/H7 LPAI). Influenza A viruses with high pathogenicity in birds other than poultry, including wild birds, are also notifiable. Low pathogenicity non-H5 and non-H7 influenza A viruses (i.e. H1–4, H6 and H8–16) are not defined as avian influenza and are not notifiable. The non-H5/H7 viruses typically do not cause disease in poultry although swine lineage viruses (H1 and H3) may cause reduced fertility and performance in turkeys.

AI Official (Approved) Tests

Official tests as agreed by the LBMS in consultation with VS for the detection of AI virus and antibody as follows (refer to Part IV for more detail)

Animal health official

An employee of the State animal health agency or of APHIS who has authority from the State veterinarian or the District Director or Assistant Director to carry out program activities.

APHIS

The Animal and Plant Health Inspection Service, an agency of the United States Department of Agriculture (USDA).

Appropriate sample

Samples collected by an animal health official or personnel authorized by the animal health official according to the target species, and type of testing planned; refer to WI-AV-0020 "*Avian sample collection*"
https://www.aphis.usda.gov/animal_health/lab_info_services/downloads/WIAV0020.pdf

Approved laboratory

A State, Federal, university, or private laboratory that has been approved by VS (NPIP or NAHLN) to perform one or more official AI tests for the program.

Assistant Director (AD)

The veterinary official of VS assigned by the Administrator to supervise and perform the official animal health programs of APHIS in the State or States concerned.

Auction market

A business where producers, dealers, wholesalers, distributors, and retailers meet to purchase, trade, or sell live birds.

Botanica

An establishment that sells supplies and some types of poultry or livestock (or both) for sacrificial religions such as Santeria, Voodoo, etc. Poultry or livestock sold at these establishments leave alive to meet the Santeria needs. In the United States the majority of these types of establishments are located in Florida, New York and New Jersey.

Cleaning and disinfection

One of the steps in response to an AI-positive premises that may help eliminate AI from the premises. This requires thorough removal of organic material and debris, followed by treatment with the proper concentration and contact time of an agent or other APHIS-approved method effective for inactivating AI virus.

Clean and sanitary (for inspection purposes)

Free of visible accumulation of manure, feathers, or other organic materials, as determined by an animal health official.

Dealers

Individuals or businesses concerned with the commerce of poultry in the LBMS. A dealer may acquire poultry from multiple flocks and geographic areas for resale. This also may include individuals or businesses engaged solely in the transportation of poultry (hauler) or businesses with a permanent facility (wholesaler). If any of the defining characteristics of a hauler or wholesaler meet the general definition of a dealer, then the individual or business will be classified as a dealer. "Dealing" indicates the movement of live poultry between the production system and live bird markets.

Distribution system

Businesses (such as wholesalers, dealers, distributors, haulers, auction markets, and other markets) engaged consistently or intermittently in the transportation or sale of poultry to live bird markets. These are the links between production flocks and live bird markets.

Distributor

Any of the businesses or individuals working within the distribution system serving the live bird markets. Also see dealer.

District Director (DD)

The veterinary official of VS assigned by the Administrator to supervise and perform the official animal health programs of APHIS in the district concerned.

Enzyme-Linked Immunoassay (ELISA)

A species-specific NPIP-approved test for serologic detection of AI antibodies.

Established flock

A group of poultry living on a premises until movement directly to a live bird market; or poultry of the same species held together on one premises for at least 21 consecutive days; or, at the discretion of the animal health official, any group of poultry on one premises that has been segregated from other poultry for at least 21 consecutive days. To qualify as an established flock, the group must have been together without any untested (avian influenza (AI)) additions or exposure to untested (AI) poultry for a minimum of 21 days before testing for AI. Additionally, there can be no additions of other poultry or exposures to other poultry between the sample collection date and the date that the poultry leave the farm. The poultry from the established flock must move directly to the live bird market. They cannot move to another premises before going to the live bird market except to move through a dealer facility if necessary before being transported to a live bird market.

Flock

All poultry in the same environment, under the same biosecurity and management programs, on the same premises. Types of flocks described in these Standards include established flocks, monitored flocks, and tested flocks. Monitored and tested flocks are further discussed in Part III C of these Standards.

Hauler

A business or individual engaged in transporting live poultry.

High pathogenicity avian influenza (HPAI) viruses

High pathogenicity avian influenza viruses have an intravenous pathogenicity index (IVPI) in 6-week-old chickens greater than 1.2, or cause at least 75 percent mortality in 4-to 8-week-old chickens infected intravenously. H5 and H7 viruses which do not have an IVPI of greater than 1.2 or cause less than 75 percent mortality in an intravenous lethality test should be sequenced to determine whether multiple basic amino acids are present at the cleavage site of the haemagglutinin molecule (HA0); if the amino acid motif is similar to that observed for other high pathogenicity avian influenza isolates, the isolate being tested should be considered as highly pathogenicity avian influenza virus.

The official designation of a flock as infected with H5 or H7 HPAI will be made by the State veterinarian in consultation with the DD or AD following confirmation by the National Veterinary Services Laboratory (NVSL).

Licensing, registration

A requirement to conduct business in the LBMS. This consists of the licensing or registration of facilities by the State, allowing for oversight of such facilities as recommended in these standards. States may elect licensing or registration procedures that best fit their statutes.

Live bird market

Any facility (including botanica, poultry store, or custom slaughter) that sells live poultry for onsite slaughter or for offsite ritual use.

Live bird marketing system (LBMS)

The LBMS includes live bird markets and their production and distribution systems.

Low pathogenicity avian influenza H5 and H7 program

The State-Federal-industry cooperative program for the prevention and control of H5 and H7 LPAI. This is a voluntary program for States, but participating States are encouraged to enact regulations to enforce program standards and requirements.

Low pathogenicity avian influenza (LPAI) viruses

Low pathogenicity avian influenza viruses are all influenza A viruses of H5 and H7 subtypes that are not high pathogenicity avian influenza viruses.

LPAI H5/H7: Often cause either no disease signs or result in mild cases, but may cause increased mortality, decreased feed consumption, respiratory signs (e.g., nasal discharge, coughing, sneezing), and decreased egg production (Dunn *et al.* 2003).

The official designation of a flock as infected with H5 or H7 LPAI will be made by the State veterinarian in consultation with the DD or AD following confirmation by the National Veterinary Services Laboratory (NVSL).

National Animal Health Laboratory Network (NAHLN)

Go to: https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/lab-info-services/nahln/ct_national_animal_health_laboratory_network

National Poultry Improvement Plan (NPIP)

Go to: www.poultryimprovement.org

National Veterinary Services Laboratories (NVSL)

The National Veterinary Services Laboratories is the national reference laboratory for AI. Go to: <https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/lab-info-services>

Non-negative flock, distribution system or market

A flock, distribution system or market from which specimens yielded non-negative results for AI by an official and appropriate test performed at an approved laboratory. Any specimen non-negative for AI must be confirmed by the NVSL. Confirmation of a non-negative flock or market will be based on results of diagnostic testing and epidemiological data; collection of additional samples for testing may be needed.

Other markets

A place to purchase, sell, or barter poultry or their eggs including but not limited to farmers' markets, flea markets, swap meets, and small poultry sales.

Positive flock, distribution system or market

Domestic poultry or environmental specimens from which an H5 or H7 subtype has been confirmed by the NVSL with determination of pathogenicity (HPAI or LPAI) as described in the OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals. The official designation of a flock, distribution system or market as infected with H5 or H7 will be made by the State veterinarian in consultation with the DD or AD following confirmation by the National Veterinary Services Laboratory (NVSL).

Positive sample/specimen

A diagnostic specimen that has been confirmed by the NVSL by: (1) detection of H5 or H7 virus; or (2) detection of antibodies to H5 or H7 that are not a consequence of vaccination (sample collectors should collect appropriate swab samples for molecular testing to determine the virus status of the flock following antibody detection in production flocks).

Poultry (OIE definition)

All domesticated birds, including backyard poultry, used for the production of meat or eggs for consumption, for the production of other commercial products, for restocking supplies of game, or for breeding these categories of birds, as well as fighting cocks used for any purpose.

Poultry store

A retail store with a permanent facility that purchases birds from sources such as producers, distributors, or auction markets or other markets and then sells live poultry to its customers mainly intended for home slaughter. The business sells poultry species only and does not sell feed or pets. The operation is consistent with the live bird market definition of operational characteristics, except that it is a non-slaughter facility. A poultry store sells retail only and does not trade birds or resell to auctions.

Poultry waste

This definition includes dead birds, feathers, offal, and poultry litter.

Premises identification number

A nationally unique number assigned by a State, Tribal, or Federal animal health authority to a premises such as a live bird market, distributor, or supply flock, that is, in the judgment of the State, Tribal, or Federal animal health authority, a geographically distinct location from other premises.

Production or supplier flock

The production facility or farm that is the origin of poultry offered for sale in a live bird market.

Program

See “Low Pathogenicity Avian Influenza H5 and H7 Program.”

Real-time reverse-transcriptase polymerase chain reaction (rRT-PCR)

VS-approved highly sensitive molecular tests for the detection of AI viral RNA from appropriate swabs or tissues from any avian species.

Registration

See Licensing.

State, participating

This definition applies to any of the 50 States (plus the District of Columbia and U.S. Territories) participating in the AI program. This term applies each time the word “State” is used in this document.

Test certificate

A report that contains, at a minimum, negative AI test results obtained from official tests conducted at an approved laboratory, and identifying information about the tested poultry and the source premises.

USDA

United States Department of Agriculture.

Veterinary Services (VS)

Veterinary Services is the division of APHIS charged with monitoring animal health activities and the interstate movements of animals within the United States.

Virus isolation

Procedure to isolate AI virus in embryonated chicken eggs.

Wholesaler

A business with a permanent facility that buys birds from producers, distributors, or auction markets or other markets, and then trades or resells them. A wholesaler is part of the distribution system.

Part II—Administration of the Program

A. State Participation

The LBMS AI prevention and control program recognizes three basic components of the LBMS: Production units, distribution units, and live bird markets. A State can participate in the program when all or some components of the LBMS operating within the State are required to be registered or licensed, and program participation is required for State registration or licensure.

LBMS participants that do not comply with these Program Standards are subject to administrative actions as determined by the State's regulatory authority. States are responsible for enforcing the Program Standards.

B. Federal Participation

The LBMS AI prevention and control program will be coordinated by the VS Surveillance, Preparedness, and Response Services (SPRS) team. Under the terms and conditions of the program, VS may provide personnel and resources to help States implement the program and comply with program requirements. Monitoring, surveillance, and educational activities will be supported as defined in the State's work plan.

The program may provide Federal indemnification for States and facilities at all levels of the LBMS. Indemnification will require a consultation with and prior approval by VS-SPRS Avian Health Staff. The amount of indemnification will depend on Federal regulations and Federal resources. For established flocks and distribution systems, indemnity for destroyed birds will be based on the appraised value of the birds. For birds in the live bird market, indemnity may be paid for birds remaining in the market after a designated period provided to sell down, if appropriate, at the discretion of USDA after request from the State.

Part III—Program Elements and Procedures

A. Live Bird Markets

1. Licensing, Registration, and Education

- a. A live bird market must be licensed or registered by the State within which it is located and must comply with the requirements of the program. The State will provide a unique premises identification number. Live bird markets must also comply with all other applicable animal and public health laws and regulations. These include State environmental laws, city or county sanitation requirements, public health regulations, and the Federal Poultry Products Inspection Act. Information required for a live bird market to become licensed or registered includes:
 - (1) Business name, address, and telephone number.
 - (2) Owner's name, address, and telephone number.
 - (3) Hours of operation.
 - (4) Global Positioning System location.
 - (5) Other live bird market facilities under the same ownership, including dealerships, bird transportation businesses, and commercial poultry operations.
 - (6) A list of all avian and non-avian species marketed.
- b. As a program participant, the live bird market must allow access to the facility and the birds in the facility for inspection and testing and for examination of market records of bird receipts and bird sales.
- c. Live bird market owners or managers are required to attend the biosecurity and State regulation training provided by or approved by the State or USDA.
- d. All personnel who work in the market must be trained in biosecurity procedures as arranged by the owner or manager. A record of employee training will be maintained on file on the premises for at least 12 months, but must be maintained as long as necessary to demonstrate the training of all current employees, and must be presented on request to any animal health official inspectors.

2. Bird Testing and Recordkeeping

- a. Markets are responsible for maintaining records indicating bird description, source information, and any available identification. The birds may not enter the market if these records are not available.
- b. Records for avian species received by the live bird market must include the date of entry; the source name, address, and telephone number; and color, species, and type of birds in the lot. A copy of the test certificate or equivalent documentation of the established flock must be filed as part of the records, if required by animal health officials.
- c. All records must be maintained for a minimum of 12 months from the birds' date of entry into the market.
- d. Any indication noted by a live bird market that paperwork has been altered or that it misrepresents the sources or test status of birds coming into the market must be reported to an animal health official.

3. Market Sanitation and Biosecurity

- a. A biosecurity protocol must be developed by the live bird market and approved by an animal health official.
- b. Live bird market environments and crates must be kept clean and sanitary at all times, as defined by the biosecurity protocol.
- c. Employees must follow biosecurity protocols.
- d. Once delivered to a market, birds must be killed and processed before leaving the facility, unless otherwise provided for in the biosecurity protocol.
- e. Live bird markets must undergo regular, periodic closures with depopulation and complete sanitation, cleaning and disinfection, and downtime. The closures should occur at least quarterly with a minimum of 24 hours of downtime. The market must be inspected and approved by an animal health official before being allowed to reopen.
- f. Poultry waste must be contained in a manner approved by an animal health official to prevent disease transmission while it is awaiting disposal by a method acceptable to the jurisdiction where the market is located.

4. Market Surveillance

- a. Live bird markets may be tested for AI virus by the State at any time, but they should be tested at least quarterly.
- b. Specimens tested may include appropriate samples collected from birds in the market or upon arrival; swabs or tissues from sick or dead birds, or environmental surface samples such as those from floors, conveyances, or crates.
- c. Preferred specimens and the types of tests to be run for each are covered in Part IV of this document.

5. H5/H7 Positive Markets

- a. When NVSL confirms H5 or H7 AI virus in samples from live bird markets, the State must quarantine such markets and require their depopulation and cleaning and disinfection. Such markets may first be allowed up to 5 calendar days to sell down bird inventory, if this is deemed appropriate by the animal health official. No additional birds should be allowed to enter the market after notification of a non-negative AI status while awaiting confirmation, nor throughout the sell-down period after confirmation.
- b. Before the live bird market can reopen for business, it must pass inspection by an animal health official. Post cleaning and disinfection environmental samples may be collected when the facility is dry. When environmental samples are collected for testing, the market may be permitted to reopen while awaiting environmental test results at the discretion of animal health officials. If AI RNA is detected, the specimens must be tested by virus isolation to confirm the presence of viable virus. If viable H5/H7 virus is detected, the market must close again (with up to 5 days to permit sell-down, if appropriate) and clean and disinfect within the next 24 hours, followed by inspection and retesting.
- c. A live bird market that tests positive for viable virus from environmental samples during quarterly inspection must undergo subsequent monthly testing. If H5 or H7 is confirmed on a monthly test, the market must close (with up to 5 days to permit sell-down, if appropriate) and will again clean and disinfect within the next 24 hours, followed by inspection and retesting.
- d. After three consecutive negative tests, the live bird market can return to a schedule of quarterly testing and routine quarterly closures.

- e. When birds are found to be non-negative for AI in the live bird market or on delivery to the market, an epidemiological investigation will be initiated.

B. Poultry Distributors

1. Licensing, Registration, and Education

- a. Poultry distributors (dealers, haulers, auction markets, and wholesalers) must be licensed or registered in each State in which they conduct business. This includes the States from which birds are acquired, as well as the States that have live bird markets to which the birds are sold or delivered. The distributor's premises will get a premises identification number in the State in which it is located. This number may be used when the distributor registers in other States. Minimum information required to register for a distributor license includes:
 - (1) Business name, address, and telephone number.
 - (2) Owner's name, address, and telephone number.
 - (3) Hours of operation.
 - (4) Global Positioning System location of premises.
 - (5) Other bird and animal premises involved with production, sales facilities, dealerships, or hauler operations under the same ownership.
 - (6) A list of all avian and non-avian species distributed.
- b. To register to transport birds within the LBMS, distributors must agree to allow animal health officials to review records on request and to permit official inspections and testing of premises and equipment as required.
- c. A distributor should not be licensed or registered until his or her facility, record system, and biosecurity protocol has been inspected and approved by an animal health official.
- d. All personnel who work for the company must be trained in biosecurity by animal health officials or by a trained company representative. The company must maintain and make available for inspection certification of employee training.

2. Bird Testing and Recordkeeping

- a. Distributors must provide documentation of negative test results from the established flock with each delivery of birds as required by recipient State regulations.
- b. Distributors must maintain records for bird pickups and delivery for 12 months that include: Copies of test certificates (if required by recipient State regulations); dates and locations of pickup and delivery; and the number, species, and types of poultry in the delivery. In addition, distributors must keep records of premises and conveyance cleaning and disinfection.
- c. Any indication noted by a distributor that paperwork has been altered or that it misrepresents the sources or test status of birds coming into the live bird market must be reported to an animal health official.

3. Distributor Sanitation and Biosecurity

- a. Distributor vehicles, bird-holding devices, and any premises where birds may be held must be maintained according to State guidelines or requirements.
- b. Documented biosecurity protocols, developed by the distributor and approved by the State, must be in place.

- c. Distributors must use State-approved all-season crate and conveyance washing equipment and present cleaning and disinfection documentation when obtaining birds from producers and from other distributors.
- d. Once emptied of poultry, all conveyances, coops, cages, vehicles, and other equipment must undergo cleaning and disinfection before visiting a poultry premises.
- e. Distributors may not transport live birds or other live animals from live bird markets.

4. Distributor Surveillance

- a. Distributors should be randomly inspected by animal health officials in the State in which they are located. These random inspections should occur at least quarterly to ensure that conveyances, crates, and facilities are clean and sanitary and records are being kept according to program requirements.
- b. Distributors should be tested at least quarterly for AI by official and appropriate tests at an approved laboratory. Testing may include facility environmental surface samples such as those from conveyances, crates, and/or appropriate samples from birds, if present.
- c. Specimens of choice and the types of tests to be run for each are covered in Part IV of this document.

5. H5/H7 - Positive Distribution System

- a. Any specimens with non-negative results for AI will be submitted to the NVSL for confirmation. The premises may be quarantined until results are obtained from the NVSL.
- b. Environmental samples may be collected for testing if indicated.
- c. Premises from which H5 or H7 detection is confirmed positive by the NVSL must be quarantined and inventoried. An epidemiological investigation will occur. The premises may be depopulated and cleaned and disinfected in accordance with the initial APHIS-approved State response and containment plan. A flock plan will be developed.
- d. A distributor that fails biosecurity inspections or has non-negative AI results upon quarterly testing will have to undergo monthly inspections and testing until there have been 3 consecutive months of negative testing, at which time quarterly testing will resume.

C. Production Units

1. Licensing, Registration, and Education

- a. States will give production units unique premises identification numbers to be used for all business pertaining to live bird markets and for interstate movement. Production units are required to keep records of their operations on file on the premises for at least 12 months. The records must be presented on request to animal health official inspectors. Information required for the production unit records includes:
 - (1) Business name, address, and telephone number.
 - (2) Owner's name, address, and telephone number.
 - (3) Global Positioning System location.
 - (4) Other bird and animal premises involved with production, sales facilities, dealerships, or hauler operations under the same ownership.
 - (5) A list of all avian and non-avian species produced.

- b. To participate in the program, production units must allow animal health officials to review all records and inspect equipment when requested by the program authority. Testing may be conducted as indicated by animal health officials.
- c. Flock and farm managers are encouraged to attend biosecurity training.

2. Bird Testing and Recordkeeping

- a. All birds provided to a distributor or directly to the live bird market must originate from a flock that has tested negative for AI before movement and must be traceable to a premises of origin. AI testing must be performed using an official and appropriate test (as specified in Part IV of this document) at approved laboratories. The categories of production units and the testing requirements for each category are as follows:

- (1) AI Monitored Flock: To be certified as an AI Monitored Flock, a flock must meet the following requirements:
 - a) The group must have been together without any additions from non-tested or non-monitored flocks for a minimum of 21 days before testing and no birds may be added between the testing date and the date they leave the farm.
 - b) Swab and/or blood samples from 30 birds, 3 weeks of age and older from all pens and houses on the premises, shall be collected between 21 and 30 days after the previous collection.
 - c) The 30 birds selected for testing shall be selected randomly and shall be representative of the flock (birds of testing age tested from all pens and houses on the premises).
 - d) The first test should be conducted within 30 days of placement except for the following:
 - i. For serology, blood collection from silkies and other small breeds of chickens may be delayed until the birds are 6 to 8 weeks of age.
 - ii. For serology, blood collection from guineas, chukars, and quail may be delayed until the birds are 5 to 6 weeks of age.
 - iii. Eggs from gallinaceous poultry may be substituted for blood samples for testing by AGID only at the discretion of the receiving State. Collect appropriate swab samples for molecular testing to determine the virus status of the flock following antibody detection in egg yolk from production flocks.
 - e) A flock must test negative by official and appropriate test for 3 consecutive months before it is considered a monitored flock in good standing. When new birds are added to the premises, birds coming from a source of equal or higher status (for example, another monitored flock) assume the monitored flock status of the previous flock and must be tested once together as a monitored flock before moving into the LBMS. Chicks coming directly from an NPIP AI Clean hatchery must be tested once as part of a monitored flock before moving into the LBMS. If the added birds are from other sources, not equal to or of higher status, the flock must be tested for 3 months consecutively (with negative results) to be considered a monitored flock in good standing.
 - f) To re-qualify for monitored flock status after any breaks in the required monthly testing, 30 birds must be tested by official and appropriate test within 10 days before the date of movement into the LBMS.

- (2) Tested flock: A flock that has been established for a minimum of 21 days with no contact with other birds and no birds added to the flock during this time, and from which 30 birds are randomly sampled and tested negative for AI by official and appropriate test according to the specific requirements listed below, within 10 days before the date of movement into the LBMS. No poultry may be added to or have contact with this flock after testing and before movement. If the flock contains fewer than 30 birds, all birds within the flock must be tested.
- a) Swab and/or blood samples from 30 birds, 3 weeks of age and older, from all pens and houses on the premises shall be collected. Eggs from gallinaceous poultry may be substituted for blood samples for testing by AGID only at the discretion of the receiving State. Collect appropriate swab samples for molecular testing to determine the virus status of the flock following antibody detection in egg yolk from production flocks.
 - b) The 30 birds for testing shall be selected randomly and shall be representative of the flock.
 - c) Flock test records, as well as records of bird transfers, must be maintained and made readily available for inspection for 12 months by the bird owner, manager, or program participant as approved by the State animal health agency.
 - d) Birds loaded for transport to a distributor must be identified by premises of origin and must contain an appropriate date of movement or lot number that will distinguish this shipment from others. This information must be recorded on the test certificate or other paperwork if a test certificate is not required for movement to the distributor.
 - e) Flocks with non-negative AI serological test results must be quarantined until confirmation testing is complete. The animal health official may require swab collection to determine the virus status of the flock, especially if clinical signs are present.

3. Sanitation and Biosecurity

- a. Production unit facilities, conveyances, bird-holding devices, and other any premises where birds may be held must be maintained according to State guidelines or requirements at all times.
- b. Producers should have access to equipment for cleaning and disinfection of premises, conveyances, and crates. They must maintain records of downtime and cleaning and disinfection, if applicable.
- c. To prevent the transmission of AI virus between species, premises should not commingle chickens, turkeys, or game birds with ducks or geese.
- d. All direct or indirect exposure to free-ranging migratory waterfowl and ponds must be prevented.

4. Producer Surveillance

- a. Premises may be subjected to random inspections by animal health officials to ensure that premises, conveyances, and coops are clean and sanitary. Random samples may be collected for AI testing from birds or the environment at the time of inspection.
- b. Records will be reviewed during site inspections.
- c. H5 or H7 virus detection, as confirmed by the NVSL, will result in quarantine of the premises. Premises may be depopulated and undergo cleaning and disinfection in

accordance with the initial APHIS-approved State response and containment plan.

5. H5/H7- Positive Production Premises

- a. Premises with H5 or H7 detection confirmed positive by the NVSL must be quarantined and be inventoried. An epidemiological investigation will occur. The premises may be depopulated and cleaned and disinfected in accordance with the initial APHIS-approved State response and containment plan. A flock plan will be developed.
- b. The premises may be quarantined based on non-negative AI results until confirmation testing at the NVSL can be completed.

Part IV—Official Testing of Specimens from the LBMS for the AI Prevention and Control Program

A. Specimens

Specimens should be collected from live bird markets and distribution and production units by an animal health official or personnel authorized by the animal health official. Specific collection in distribution units and markets may include appropriate samples collected from newly arrived live or dead birds; or environmental surface samples taken from (for example) floors, conveyances, or crates.

B. Official (Approved) Tests

The official AI tests for the LBMS include serology (species-appropriate AGID or ELISA), and virus detection (rRT-PCR, virus isolation, ACIA (only for sick/dead birds)). The LBMS working group determined these to be the official tests in consultation with VS.

Approved laboratories must pass proficiency tests for rRT-PCR, ELISA, and AGID as administered by the NPIP and the NAHLN and implemented by the NVSL for program participation. All specimens that test non-negative for AI per official protocol in approved laboratories will be submitted to the NVSL for confirmation and further characterization.

1. Agar Gel Immunodiffusion (AGID)

- a. An NPIP-LBMS approved test for serologic detection of AI antibodies for use in gallinaceous poultry. Sera from domestic ducks or geese should not be tested by the AGID test as duck antibody does not precipitate well and thus these sera are not appropriate for this test. Eggs from gallinaceous poultry may be substituted for blood samples for testing of yolk by AGID only at the discretion of the receiving State.
- b. The AGID test is type-A specific and will not determine the hemagglutinin (H), neuraminidase (N) subtype, nor pathotype of AI.
- c. Non-negative AGID results indicate that birds were exposed at least 1 week previously to AI of unknown subtype.
- d. Non-negative AGID specimens must be forwarded to the NVSL for H- and N-subtyping. Collect appropriate swab samples for molecular testing to determine the virus status of the flock following AI antibody detection.

2. Enzyme-Linked Immunoassay (ELISA)

- a. A species-specific NPIP-LBMS approved test for serologic detection of AI antibodies. Any USDA-licensed enzyme-linked immunoassay (ELISA) kit may be used in accordance with recommendations of the manufacturer and as appropriate to the species being tested. Currently there is only one ELISA kit licensed for ducks.
- b. The ELISA test is specific for AI and will not determine the hemagglutinin (H), neuraminidase (N) subtype, nor pathotype of AI.
- c. Non-negative ELISA results indicate that birds were exposed at least 1 week previously to AI of unknown subtype.
- d. Non-negative specimens by ELISA must be forwarded to the NVSL for H- and N-subtyping. Collect appropriate swab samples for molecular testing to determine the virus status of the flock following AI antibody detection.

3. Real-Time Reverse-Transcriptase Polymerase Chain Reaction (rRT-PCR)

- a. VS-approved highly sensitive molecular tests for the detection of AI viral RNA from appropriate swabs or tissues from any avian species. Specimens are initially tested by an influenza A test followed by H5 and H7 specific tests if RNA is detected. The H5 and H7 tests are designed to detect both LPAI and HPAI viruses.
- b. Non-negative specimens by any official AI molecular test should be forwarded to NVSL for confirmation.
- c. Contact the NVSL if interested in conducting molecular testing of post-cleaning environmental samples. An NVSL-approved internal control to monitor for PCR inhibitors is required along with use of a specific virus isolation protocol.

4. Virus Isolation

This test is intended to determine if viable AI virus is present in a specimen through exposure of embryonated eggs. Swabs, tissues, and environmental samples may be tested by virus isolation in State-approved laboratories or by the NVSL. Virus isolates should be forwarded to the NVSL for confirmation and characterization.

5. Antigen Capture Immunoassay Tests (ACIA)

- a. An NPIP-LBMS approved test to screen for AI using any USDA-licensed antigen capture immunoassay (ACIA) for the detection of influenza A nucleoprotein only from swab specimens from birds exhibiting clinical signs of disease (sick birds) or dead birds and is only appropriate for birds intended for immediate slaughter.
- b. The ACIA test must be conducted using test kits approved by USDA and the State and must be conducted in accordance with the regulations at title 9, *Code of Federal Regulations* (9 CFR) 145.14(d)(2)(ii) and manufacturer recommendations.
- c. The test is less sensitive than a molecular test and will not determine whether birds have been exposed specifically to H5 or H7 subtypes of AI.
- d. Collect additional swab samples and forward both the non-negative sample and additional samples to an approved lab for molecular testing to determine the virus status of the flock following any non-negative ACIA result.

Part V – General Criteria for H5 and H7 AI Indemnification in the LBMS

A. Requirement for Indemnification

Any specimen found to be non-negative for AI H5 or H7 must be confirmed by the NVSL.

1. Even when the requirements are met, indemnity is not guaranteed. It should be discussed by the Federal and State officials as an option.
2. Non-negative H5 or H7 results from an approved laboratory should initiate quarantine and possible sell down of the affected premises, at the State's discretion. However, eligibility for indemnity requires confirmation by the NVSL unless otherwise approved by VS.

B. Flocks or Premises Eligible for Indemnity Funds

LBMS participants (markets, distributors, and producers) are eligible. Once an H5/H7 AI program is established in a State, participants must comply with these Standards and all related State regulations.

C. Fair Market Value at Distribution System (e.g. distributor/wholesale) and Retail Market Level

1. This is the purchase price of the bird at wholesale if the bird is currently located at the retail market, or the purchase price of the bird at the production level if the bird is currently located at a wholesaler or distributor.
2. In addition to an inventory verified by animal health officials at the time of appraisal, valid documentation of purchase is required.
3. Alternatively – without receipts – authorized animal health officials survey relevant wholesalers to determine the value.

D. Fair Market Value at Production Level and Breeder Birds

1. Appraisal value of production (meat-type) birds is the expected (or past) price the owner has received from a wholesaler (retailer, if no wholesaler) adjusted for actual age (weight) of the bird at time of destruction.
2. Appraisal value of chicken meat-type breeder birds, at a minimum, is the same as commercial parent broiler-breeder birds. Higher appraisal values for chicken meat-type breeder birds may be obtained if the owner can provide the necessary production and financial records required for determining value using an income appraisal approach. Minimum appraisal value of other types of breeder birds used in the LBMS shall be the price the producer receives for his or her adult birds based on receipts or other evidence of prices received. Higher appraisal values for other types of breeder birds may be obtained if the owner can provide the necessary production and financial records required for determining value using an income appraisal approach.
3. Appraisal value for all other birds will be determined by either APHIS-developed valuation lists or by official animal health official appraising officials.

E. Decision to Depopulate

1. The decision to depopulate is made by the State in consultation with industry, stakeholders, and VS. VS must concur with the State approach to controlling H5/H7 AI in each incident before distributing indemnity funds.
2. Depopulation is not the only possible response to H5/H7 LPAI. Quarantine or controlled marketing or quarantine with vaccination (for production flocks only) may also be

appropriate. USDA approval is required for vaccination.

F. Indemnity Funds (per 9 CFR part 53 (for HPAI) and part 56 (for LPAI))

Indemnity funds may be used for 100 percent of the appraised value of depopulated birds and costs of depopulation, disposal, cleaning and disinfection.