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# **Prevention and Control of Low Pathogenicity (LPAI) H5 and H7 Avian Influenza in the Live Bird Marketing System Uniform Standards for a State- Federal-Industry Cooperative Program**

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Table of Contents

**Contents**

Introduction 2

Part I—Definitions ..... 3

Part II—Administration of the Program..... 11

    A. State Participation .....11

    B. Federal Participation.....11

Part III—Program Elements and Procedures ..... 12

    A. Live Bird Markets .....12

        1. Licensing, Registration, and Education ..... 12

        2. Recordkeeping ..... 12

        3. Market Sanitation and Biosecurity ..... 13

        4. Market Surveillance ..... 13

        5. H5/H7 Positive Markets ..... 14

    B. Poultry Distributors .....14

        1. Licensing, Registration, and Education ..... 14

        2. Bird Testing and Recordkeeping ..... 15

        3. Distributor Sanitation and Biosecurity..... 15

        4. Distributor Surveillance..... 16

        5. H5/H7 Positive Distribution System ..... 16

    C. Production Units .....16

        1. Licensing, Registration, and Education ..... 16

        2. Bird Testing and Recordkeeping ..... 17

        3. Sanitation and Biosecurity ..... 19

        4. Producer Surveillance ..... 19

        5. H5/H7 LPAI - Positive Production Premises ..... 19

Part IV—Official Testing of LBMS Specimens for the AI Prevention and Control Program ..... 20

    A. Specimens .....20

    B. Official (Approved) Tests .....20

        1. Agar Gel Immunodiffusion (AGID).....20

        2. Real-Time Reverse-Transcriptase Polymerase Chain Reaction (rRT-PCR) ..... 21

        3. Virus Isolation (VI) ..... 21

        4. Antigen Capture Immunoassay Tests (ACIA)..... 21

Part V – General Criteria for H5 and H7 AI Indemnification and Compensation in the LBMS ..... 22

    A. Requirement for Indemnification and Compensation .....22

    B. Flocks or Premises Eligible for Indemnity and Compensation Funds .....22

    C. Fair Market Value at Distributor and Retail Market Level.....22

    D. Fair Market Value at Production Level and Breeder Birds .....22

    E. Decision to Depopulate .....23

    F. Indemnity and Compensation Funds (per 9 CFR part 56 (for LPAI) .....23

## Introduction

The H5 and H7 hemagglutinin subtypes of low pathogenicity avian influenza (LPAI) virus have occasionally been isolated from the U.S. live bird marketing system (LBMS). Although LPAI virus infections cause little or no clinical illness in poultry, LPAI H5 and H7 subtypes can mutate into highly pathogenic avian influenza (HPAI) subtypes. Such mutations can 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 LPAI. 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 LPAI in the LBMS. In addition, there have been reported cases of human infection with H5/H7 viruses.

To protect U.S. poultry from HPAI and stop trade interruptions, Federal, State, and industry officials must cooperate to actively prevent and control LPAI. Animal and human health both benefit from a program that prevents HPAI infections by controlling LPAI infections.

This LPAI 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 LPAI 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 LPAI 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 and LPAI; 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 LBMS participants, including suppliers, producers, distributors, dealers, haulers, auction markets, flea markets, swap meets, wholesalers, and live bird markets:

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

## Part I—Definitions

### **Antigen capture immunoassay (ACIA) test**

A USDA-licensed antigen capture immunoassay test to detect influenza type 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 to detect influenza A nucleoprotein in swab specimens from chickens and turkeys 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 laboratory for molecular testing to determine the virus status of the flock following any non-negative ACIA result. See [Use of the Antigen Capture Immunoassay](#).

### **Agar gel immunodiffusion (AGID) test**

An NPIP-LBMS approved test for serological 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 or pathotype. Antibodies 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 and full characterization by NVSL.

### **Avian Influenza (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 (WOAH, founded as OIE) Terrestrial Animal Health Code, reportable AI is defined as an infection with high pathogenicity avian influenza viruses; infection of birds other than poultry, including wild birds, with influenza A viruses of high pathogenicity (HPAI); and by infection of domestic and captive wild birds with low pathogenicity avian influenza (LPAI) viruses having proven natural transmission to humans associated with severe consequences.

For international trade, a country should not impose trade bans in response to a notification of infection with either HPAI or LPAI in birds other than poultry.

The non-H5/H7 viruses often 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 to detect AI virus and antibodies (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 Area Veterinarian in Charge to carry out program activities.

**APHIS**

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

**Appropriate sample**

Samples collected by animal health officials or personnel authorized by the animal health official according to the target species and type of testing planned; refer to [NVSL-WI-0023 “Avian Sample Collection for Influenza A and Newcastle Disease”](#).

**Approved laboratory**

A State, Federal, university, or private laboratory approved by VS (NPIP or National Animal Health Laboratory Network) to perform one or more official AI tests for the program.

**Area Veterinarian in Charge**

The VS veterinary official assigned by the Administrator to supervise and perform official APHIS animal health programs 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 most of these types of establishments are 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.

**Compensation**

In the case of AI infection, compensation specifically refers to reimbursement for the activities associated with the depopulation of infected or exposed poultry, the disposal of contaminated carcasses and materials, and the cleaning and disinfection of premises, conveyances, and materials that encountered infected or exposed poultry. In the case of materials, if the cost of cleaning and disinfection would exceed the value of the materials, or cleaning and disinfection would be impracticable for any reason, VS bases compensation on the fair market value of those materials. Compensation does NOT include payment for depopulated birds or eggs destroyed (see definition of Indemnity).

**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 transporting 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 live bird sales (non-slaughter)} engaged consistently or intermittently in transporting or selling 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 VS veterinary official assigned by the APHIS Administrator to supervise and perform APHIS official animal health programs in the District concerned.

**Enzyme-linked immunoassay (ELISA)**

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

**Established flock (for LBMS)**

A group of poultry living on a premises until moved directly to a live bird market; or poultry of the same species held together on one premises for at least 14 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 14 consecutive days. To qualify as an established flock, the group must have been together without any

untested (AI) additions or exposure to untested (AI) poultry for a minimum of 14 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. [Chapter 10.4. \(woah.org\)](#)

**Flock (for LBMS)**

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.

**Highly pathogenic avian influenza (HPAI) viruses**

Highly pathogenic 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 hemagglutinin 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 pathogenic avian influenza virus.

The official designation of a flock with a notifiable infection (H5 or H7 regardless of pathotype) will be made by the State veterinarian in consultation with the District Director or Area Veterinarian in Charge following confirmation by the National Veterinary Services Laboratory (NVSL).

**Indemnity**

AI indemnity specifically refers to payments representing the fair market value of destroyed birds and eggs. This is the inventory on the date of depopulation of destroyed birds and the presumptive positive date for destroyed eggs. AI indemnity does not include reimbursements for depopulation, disposal, destroyed materials, or cleaning and disinfection activities; these are covered under compensation.

**Licensing, registration**

A requirement to conduct business in the LBMS. This consists of 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 poultry slaughter exempt) that procures live poultry to hold or display for more than 24 hours and sells such poultry for onsite slaughter or offsite ritual use.

**Live bird marketing system (LBMS)**

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

**Live bird sales (non-slaughter)**

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

**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.

The official designation of a flock with a notifiable infection (H5 or H7 regardless of pathotype) will be made by the State veterinarian in consultation with the District Director or Area Veterinarian in Charge following confirmation by the NVSL.

**National Animal Health Laboratory Network (NAHLN)**

Go to: <https://www.nahln.org/>

**National Poultry Improvement Plan (NPIP)**

Go to: [www.poultryimprovement.org](http://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/labs/about-nvsl>

**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 NAHLN laboratory. Any specimen non-negative for AI must be immediately forwarded to NVSL for confirmatory testing. Confirmation of a non-negative flock or market will be based on results of diagnostic testing as well as the collection of epidemiological data; collection of additional samples for testing may be needed.

**Positive flock, distribution system, or market**

Domestic poultry or environmental specimens from which an H5 or H7 subtype has been confirmed by NVSL with determination of pathogenicity (HPAI or LPAI) as described in the WOAHP 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 District Director or Area Veterinarian in Charge following confirmation by the NVSL.

**Positive sample/specimen**

A diagnostic specimen confirmed by 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). Use of vaccination impacts trade and therefore requires State and Federal permission before use.

**Poultry Slaughter Exempt**

A business or person who provides slaughter and processing poultry service to a customer that meets exemption from full inspection requirements under the USDA Food Safety and Inspection Service Poultry Products Inspection Act. Exemption categories include retail exemption, personal use exemption, custom slaughter exemption, producer/grower with 1,000 or 20,000 limit exemption, producer grower other person, and small enterprise exemption. See FSIS' [Guidance for Determining Whether a Poultry Slaughter or Processing Operation is Exempt from Inspection Requirements Poultry Products Inspection Act](#)

**Poultry store**

A retail store with a permanent facility that purchases birds from sources such as producers, distributors, or auction markets or live bird sales (non-slaughter) 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 from which poultry offered for sale in a live bird market originate.

**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 to detect 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 APHIS division charged with monitoring animal health activities and the movement of animals within the United States.

**Virus isolation**

Procedure to isolate AI virus in embryonated chicken eggs.

**WOAH poultry**

All birds reared or kept in captivity for the production of any commercial animal products, or for breeding for this purpose; fighting cocks used for any purpose; and all birds used for restocking supplies of game or for breeding for this purpose, until they are released from captivity. [Glossary \(woah.org\)](http://woah.org)

**WOAH non-poultry**

Birds kept in a single household, the products of which are used within the same household exclusively, are not considered poultry if they have no direct or indirect contact with poultry or poultry facilities.

Birds kept in captivity for other reasons including those kept for shows, racing, exhibitions, zoological collections, and competitions, and for breeding or selling for these purposes, as well as pet birds, are not considered poultry if they have no direct or indirect contact with poultry or poultry facilities.

**Wholesaler**

A business with a permanent facility that buys birds from producers, distributors, or auction markets or live bird sales (non-slaughter), 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 LPAI 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 VS Strategy & Policy (S&P) Poultry Health Staff coordinates the LBMS LPAI prevention and control program. 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. VS will support monitoring, surveillance, and educational activities as defined in the State's work plan.

The program may provide Federal indemnification for States and facilities at all LBMS levels. Indemnification will require a consultation with and prior approval by VS S&P Poultry Health Staff. The amount of indemnification depends on Federal regulations and Federal resources. For established flocks and distribution systems, indemnity for destroyed birds will be based on the birds' appraised value. Indemnity may be paid for birds remaining in the live bird market after a designated period provided to sell down, if appropriate, at the discretion of USDA after a 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 its location State and must comply with all program requirements. 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, premises address, telephone number, and email address.
  - (2) Owner's name, mailing address, telephone number, and email address.
  - (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 inspect and test the birds in the facility and to examine 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. Upon hire, all personnel who work in the market must be trained in biosecurity procedures by animal health officials or by a trained company representative, as arranged by the owner or manager, and annually thereafter. The premises must keep a record of employee training on file for at least 12 months. The record 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. 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 always kept clean and sanitary, 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. All birds entering a live bird market should be slaughtered within 10 days of entering the market. Keep records to document this.
- f. Live bird markets must undergo regular, periodic closures with depopulation and complete sanitation, cleaning and disinfection, and downtime. Emphasize removing items that are not easy to clean and disinfect from LBMs such as cloth sofas, electronics, miscellaneous items, etc. Manage animal inventory (including livestock species, in addition to poultry) to be sold out during routine Quarterly Closures (QCs) and following positive detections to facilitate cleaning. If selling out of mammals is not possible during QCs, remove the animals for cleaning and disinfection of the area until the area is properly dried. The closures should occur at least quarterly with a minimum of 24 hours of downtime. An animal health official must inspect and approve the market before it can reopen.
- g. Contain poultry waste in a manner approved by an animal health official to prevent disease transmission while it is awaiting disposal by a method acceptable to the market's location jurisdiction.

### **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.

A minimum of one 5-swab (bird) pools should be collected per bird type prioritizing sick and dead birds. Collect samples as described in [NVSL-WI-0023](#).

- c. Part IV of this document covers preferred specimens and the types of tests to be run for each.

## 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 at least 72 hours and up to 5 days to sell down bird inventory, if the animal health official deems it appropriate. The 72-hour countdown begins when the market is notified of a positive sample. No additional birds should be allowed to enter the market after notification of a non-negative AI status while awaiting confirmation, or 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. Collect post cleaning and disinfection environmental samples when the facility is observed to be clean and sanitary (for inspection purposes) and dry. Environmental samples should prioritize high risk areas, including bird contact areas, high-touch surfaces, feeders, waterers, and boot covers and gloves (if used). State or Federal regulatory officials may collect environmental samples. Please refer to the [Post C&D Environmental Sampling Guidance](#) for instructions on how to sample. The animal health official may allow the market to reopen while awaiting test results from collected environmental samples. 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 (within 72 hours and 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 (within 72 hours and 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 monthly 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, VS initiates an epidemiological investigation.

## 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 its location State. 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, premises address, telephone number, and email address.
  - (2) Owner's name, mailing address, telephone number, and email address.

- (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 their facility, record system, and biosecurity protocol has been inspected and approved by an animal health official.
  - d. Upon hire, all personnel who work for the company must be trained in biosecurity by animal health officials or by a trained company representative and annually thereafter. The premises must keep a record of employee training on file for at least 12 months. The business must maintain the record as long as necessary to demonstrate the training of all current employees and must present it on request to any animal health official inspectors.

## **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 and disinfectant use.
- 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 guidelines, including cleaning and disinfection protocols, must be developed by the distributor and approved by the State.
- 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. State animal health officials should randomly inspect distributors. 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. Testing of distributors can occur as needed based on disease traceback or suspicion of inappropriate sanitation. For routine distributor inspections, a thorough visual inspection of cleaned and disinfected conveyances, crates, and facilities may be more efficient due to the length of time for final virus isolation results.

Testing may include facility environmental surface samples such as those from conveyances, crates, and/or appropriate samples from birds, if present. All samples should undergo official and appropriate tests at an approved laboratory. Environmental samples should prioritize high risk areas including bird contact areas, high-touch surfaces, feeders, waterers, and boot covers and gloves (if used). Follow [Post C&D Environmental Sampling Guidance](#) as an example using gauze pads for large areas. You can also use sterile polyester swabs.

- 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 immediately submitted to NVSL for confirmation. The premises may be quarantined until NVSL returns results.
- b. Environmental samples as described above (B.4.b.) may be collected for testing if indicated.
- c. Premises from which H5 or H7 detection is confirmed positive by NVSL must be quarantined and inventoried. VS will conduct an epidemiological investigation. The premises may be depopulated and cleaned and disinfected in accordance with the initial APHIS-approved State response and containment plan. The premises must develop a flock plan.
- 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, premises address, telephone number, and email address.
  - (2) Owner's name, mailing address, telephone number, and email address.
  - (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 protocols 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) Qualify as an established flock.
    - 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. Collect appropriate swab samples from sick or dead birds for molecular testing to determine the virus status of the flock following AI antibody detection.
    - c) Select 30 birds for testing that represent the flock (birds of testing age tested from all pens and houses on the premises). Collect appropriate swab samples from sick or dead birds for molecular testing to determine the virus status of the flock following AI antibody detection.
    - d) Conduct the first test within 21 to 30 days of placement by blood samples for serology or swab samples for rRT-PCR. Subsequent sample collections will be every 21-30 days as long as poultry are onsite.
  - i. Substitute eggs from gallinaceous poultry for blood samples for testing by agar gel immunodiffusion (AGID) only at the discretion of the receiving State. Collect appropriate swab samples from sick or

dead birds for molecular testing to determine the virus status of the flock following AI antibody detection.

- 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) The bird owner, manager, service technician, authorized tester, and/or poultry company as approved by the State animal health agency must maintain flock test records, as well as records of bird transfers, and make them readily available for inspection for 12 months.
  - g) If there are any breaks in required monthly testing, there is a loss of monitored flock status and the tested flock procedure must be followed for any movement of birds to the LBMS in the interim. To requalify for monitored flock status, follow the monitored flock status procedure.
- (2) Tested flock: A flock that has been established for a minimum of 14 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 an 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) Collect swab and/or blood samples from 30 birds, 3 weeks of age and older, from all pens and houses on the premises. Eggs from gallinaceous poultry may be substituted for blood samples for AGID testing only at the discretion of the receiving State. Collect appropriate swab samples from sick or dead birds for molecular testing to determine the virus status of the flock following AI antibody detection.
  - b) Select 30 birds for testing that represent the flock. Prioritize sampling from sick or dead birds.
  - c) The bird owner, manager, service technician, authorized tester, and/or poultry company as approved by the State animal health agency must maintain flock test records, as well as records of bird transfers, and make them readily available for inspection for 12 months.
  - 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. Record this information 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.

### **3. Sanitation and Biosecurity**

- a. Production unit facilities, conveyances, bird-holding devices, and other any premises where birds may be held must be always maintained according to State guidelines or requirements.
- b. Producers should have access to equipment to clean and disinfect 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 gallinaceous poultry (e.g. chickens, turkeys, guineas, quail, chukars, etc.) with waterfowl (ducks, geese, swans, etc.).
- d. Prevent all direct or indirect exposure to free-ranging migratory waterfowl and ponds.

### **4. Producer Surveillance**

- a. Animal health officials may randomly inspect premises to ensure that premises, conveyances, and coops are clean and sanitary. Officials may randomly collect samples for AI testing from birds or the environment at the time of inspection.
- b. Officials will review records during site inspections.
- c. Premises with H5 or H7 LPAI virus detection, as confirmed by NVSL, will be quarantined. Premises may be depopulated and undergo cleaning and disinfection in accordance with the initial APHIS-approved State response and containment plan.

### **5. H5/H7 LPAI - Positive Production Premises**

- a. Premises with H5 or H7 LPAI detection confirmed positive by NVSL must be quarantined and inventoried. VS will initiate an epidemiological investigation. The premises may be depopulated and cleaned and disinfected in accordance with the initial APHIS-approved State response and containment plan. VS and other officials will work with the premises to develop a USDA flock plan.
- b. The premises may be quarantined based on non-negative AI results until NVSL can complete confirmation testing.

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

### A. Specimens

Animal health officials, or personnel authorized by them, should collect specimens from live bird markets and distribution and production units. 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 agar gel immunodiffusion (AGID) or enzyme-linked immunoassay (ELISA), and virus detection (real-time reverse transcriptase polymerase chain reaction (rRT-PCR), virus isolation, and antigen capture immunoassay (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 National Animal Health Laboratory Network (NAHLN) and implemented by NVSL for program participation. All specimens that test non-negative for AI per official protocol in approved laboratories will be submitted to NVSL for confirmation and further characterization.

#### 1. Agar Gel Immunodiffusion (AGID)

- a. An NPIP-LBMS approved test for serological detection of AI antibodies for use in gallinaceous poultry. Do not test sera from domestic ducks or geese with the AGID test as duck antibody does not precipitate well; 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, or 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 NVSL for H- and N-subtyping. Collect appropriate swab samples from sick or dead birds 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 serological detection of AI antibodies. Any USDA-licensed ELISA kit may be used in accordance with the manufacturer's recommendations 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, or 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 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 must be forwarded to NVSL for confirmation.
- c. Contact NVSL for conducting molecular testing of post-cleaning environmental samples (only non-negative samples and those with internal control failure would require onward virus isolation attempt). An NVSL-approved internal control to monitor for PCR inhibitors is required along with use of a specific virus isolation protocol ([Post C&D Environmental Sampling Guidance](#))

**4. Virus Isolation (VI)**

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 approved laboratories or by NVSL. Virus isolates must be forwarded to NVSL for confirmation and characterization.

**5. Antigen Capture Immunoassay Tests (ACIA)**

[https://www.aphis.usda.gov/sites/default/files/acia\\_testpolicy.pdf](https://www.aphis.usda.gov/sites/default/files/acia_testpolicy.pdf)

- a. An NPIP-LBMS approved test to screen for AI using any USDA-licensed antigen capture immunoassay to detect influenza A nucleoprotein. Only swab samples from chickens and turkeys exhibiting clinical signs of disease (sick birds) or dead birds are appropriate for ACIA tests.
- 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 AI subtypes.
- 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 and Compensation in the LBMS**

### **A. Requirement for Indemnification and Compensation**

Any specimen found to be non-negative for AI H5 or H7 must be immediately forwarded to NVSL for confirmation.

1. Even when the premises meets all requirements, indemnity and compensation are not guaranteed. Federal and State officials should discuss them as options.
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 NVSL confirmation unless VS otherwise approves.

### **B. Flocks or Premises Eligible for Indemnity and Compensation Funds**

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

### **C. Fair Market Value at Distributor and Retail Market Level**

1. This is the purchase price of the bird at wholesale or the distributor if the bird is currently located at the retail market. It can also be 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. Indemnity 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 or weight of the bird at time of depopulation.
2. Indemnity 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. Minimum appraisal value of other types of breeder birds used in the LBMS shall be the price the producer receives for 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.
3. Indemnity value for all other birds will be determined by APHIS-developed valuation lists.

**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, controlled marketing, or quarantine with vaccination (for production flocks only) may also be appropriate. USDA must approve all H5/H7 LPAI response methods.

**F. Indemnity and Compensation Funds (per 9 CFR part 56 (for LPAI))**

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