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

Uniform Standards for a State-Federal-Industry Cooperative Program,
Effective August 15, 2008

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Introduction

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

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

In order to protect U.S. poultry from HPAI and prevent interruptions in trade, Federal, State, and industry officials must cooperate to actively prevent and control LPAI. In addition, some cases of human infections of HPAI have occurred in other countries in recent years. Therefore human health would also benefit from a program that prevents the development of HPAI infections through the control of LPAI infections.

This LPAI Program was originally developed as a cooperative effort of State Veterinarians, industry representatives, and other parties associated with poultry and poultry health. The LPAI Program has been approved by USDA, APHIS, VS.

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 LPAI Program, which is federally administered, is designed to enhance and unify State programs and to assist States in meeting their goals for prevention and control of LPAI in the LBM system. This publication is intended as a working document that will change as the Program develops. The standards discussed here refer only to the LBM system; the National Poultry Improvement Plan (NPIP) addresses AI surveillance for primary breeders, commercial egg-layers, and meat-type turkeys and chickens.

Premises and other forms of identification will be important to the success of the Program.

The following goals of the Program apply to all participants in the LBM system, including the suppliers, dealers, haulers, auction markets, wholesalers, and live bird markets:

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

Part I—Definitions and Abbreviations

Accredited Veterinarian
A veterinarian approved by the Administrator of USDA, APHIS, in accordance with the provisions of title 9 of the *Code of Federal Regulations* (9 CFR), part 161, to perform functions required by State–Federal-industry cooperative programs.

Antigen Capture Immunoassay (ACIA) test – A USDA licensed type A influenza antigen capture immunoassay (ACIA) 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 and must be conducted in accordance with recommendations of the manufacturer.

Administrator
The Administrator of APHIS or any employee of USDA that the Administrator has delegated to act in his or her place.

Agar gel immunodiffusion (AGID) test
The official test for serological detection of AI in which precipitates are formed by a combination of nonspecific AI antigens and antibodies that diffuses through a gel. A positive reaction indicates exposure to AI virus, but does not indicate a specific subtype. Samples positive by AGID must be further tested and subtyped using the hemagglutination inhibition test. A final decision on the status of an AGID-positive 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

Animal health official
A full-time employee of the State animal health department or of APHIS who has authority from the State Veterinarian or the 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.

Approved laboratory
A State, Federal, university, or private laboratory that has been approved by USDA, APHIS, VS, to perform one or more types of official tests of AI diagnosis for the program.

Area Veterinarian in Charge (AVIC)
The veterinary official of APHIS, 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/or retailers meet to purchase, trade, or sell live birds.

Botanica
An establishment that sells supplies and some types of poultry and/or livestock for Santeria religious practices. Poultry and/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.

Certified poultry technician (CPT)
An individual who has been specially trained in poultry health monitoring and specimen collection by the State, and who is included on an official list of technicians certified by the State to perform inspections and specimen collections**.**

Cleaning and disinfection (C&D)
One of the steps in response to an AI-positive premises that will eliminate AI from the premises. This requires thorough removal of organic material and debris, followed by treatment with the proper concentration of an agent effective in inactivation of AI virus.

Commingled flock
Poultry from multiple sources that has been assembled for one or more shipments.

Distribution system
Businesses (such as wholesalers, dealers, haulers, and auction markets) engaged in the transportation and/or sale of poultry to live bird markets (LBMs). These are the links between production flocks and LBMs.

Distributor
Any of the businesses or an individuals working in any of the businesses within the distribution system serving the LBMs.

Enzyme-linked immunosorbent assay (ELISA)
A type-specific serological screening test to determine exposure to AI virus.

Established flock
Poultry of the same species held together on one premises for at least 21 days or, at the discretion of the State animal health official, any group of poultry on one premise that has been segregated from another group for at least 21 consecutive days.

Flock
All birds under the same biosecurity, environment, and management programs on the same premises. Types of flocks described in the Uniform Standards include monitored flocks, established flocks, commingled flocks, and non-monitored flocks.

H5, H7 LPAI
Low pathogenicity H5 and H7 subtypes of AI virus.

Hauler/trucker
A business or individual that transports poultry from producer premises to another supplier premises, to another distributor, or to an LBM.

High pathogenicity avian influenza (HPAI) virus
Any influenza virus that kills at least 75 percent of 4- to 6-week-old susceptible chickens within 10 days following intravenous inoculation of 0.2 ml of a 1:10 dilution of infectious allantoic fluid; or any H5 or H7 influenza virus that has an amino acid sequence at the hemagglutination cleavage site compatible with HPAI; or any influenza virus that grows in cell culture in the absence of trypsin. This is consistent with the World Organization for Animal Health (OIE) definition and the definition included in 9 CFR 53.1.

Infected premises
A premises that houses a flock(s) that has been confirmed to be positive for AI virus, subtype H5 or H7, by an approved laboratory using an official test.

Licensing, registration
The requirement to conduct business in the LBM system. 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/ing (LBM)
Any facility that gathers live poultry to be slaughtered and sold onsite. Other end-stage poultry markets in a participating State that are not "slaughter-only" markets will require development and approval of special biosecurity safeguards and inspections to assure that they meet Program Standards and are successful in the prevention and control of LPAI.

Live bird marketing system (LBMS)
The LBM system includes LBMs and their production and distribution systems.

Live haul
A process, and the personnel and equipment used in that process, in which live poultry are transported to a different location.

Low Pathogenicity Avian Influenza H5 and H7 Program (LPAIP)
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 must have regulations to enforce program standards and requirements.

Low pathogenicity avian influenza (LPAI) virus
Any AI virus that does not meet the criteria for high pathogenicity.

Memorandum of Understanding (MOU)
An agreement enacted between an official State animal health agency and USDA, APHIS, VS.

Animal Disease Traceability
A program that will be used as the basis for bird identification under the LPAI Program.

National Veterinary Services Laboratories (NVSL)
The USDA, APHIS, National Veterinary Services Laboratories is the national diagnostic reference laboratory for AI.

Official identification
An official tag or other identification device approved by USDA, APHIS, VS.

Positive flock
A flock that has been confirmed to be positive for AI virus, subtype H5 or H7, by an official test from an approved laboratory. Specimens positive by the AGID test must be further tested by the hemagglutination-inhibition (HI) test and neuraminidase-inhibition (NI) test at the NVSL or an NVSL-approved laboratory. Final judgment on a seropositive flock will be based upon epidemiological data and additional serological and virological (RRT-PCR and virus isolation) testing. The official designation of a flock as infected with H5 or H7 will be made only by the State Veterinarian, following confirmation by the NVSL.

Positive sample
A diagnostic specimen that is: (1) positive for AI virus, subtype H5 or H7, by RRT-PCR, by gene sequencing, or by virus isolation; and/or (2) positive for specific antibodies to AI virus, subtype H5 or H7, but not as a consequence of vaccination. Specimens positive for subtypes H5 and H7 must be confirmed by the NVSL or an NVSL-approved laboratory.

Poultry
Any species of domestic fowl (including chickens, turkeys, ostriches, emus, rheas, cassowaries, waterfowl, and game birds) raised for food production or other purposes.

Poultry dealers
Individuals in businesses or the businesses themselves concerned with the commerce of birds in the LBMS, acquiring birds from multiple flocks and geographic areas for resale, and/or movement of live poultry between the production system and LBMs. This also may include individuals or businesses involved in transporting poultry (hauler/trucker), and /or business with a permanent facility (wholesaler). If any of the defining characteristics of a hauler/trucker or wholesaler also are true of the general poultry dealer, then the individual or business will be classified as a poultry dealer.

Poultry Store
A retail store with a permanent facility that purchases birds from sources such as producers, distributors, or auction 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 LBM definition of operational characteristics, with the exception

that it is a non-slaughter facility. A poultry store sells retail only and does not trade birds or resell to auctions or swap meets.

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

Premises identification number
A unique number obtained from NAIS and assigned by the State animal health official to an LBM, distributor, or production flock. The premises identification number consists of seven characters.

Production or supplier flock
The production facility or farm that is the origin of poultry offered for sale in an LBM.

Program
See "Low Pathogenicity Avian Influenza H5 and H7 Program."

Qualified bird
A Qualified Bird is a bird from an AI monitored flock. This bird will maintain its qualified status when only licensed/registered distributors are used between the production unit and the LBM. To maintain its qualified status, it also must not have been commingled with untested birds.

Real-time reverse-transcriptase polymerase chain reaction (RRT-PCR)
An official test to detect the RNA of H5 or H7 subtypes of AI virus.

Registration
See Licensing.

State, participating
This definition applies to any of the 50 States (plus the District of Columbia and Puerto Rico) that are participating in the LPAIP. This term applies each time the word "State" is used in this document.

Test certificate
Certificate issued by a State agency based on negative AI test results obtained from official tests conducted from an approved laboratory. The certificate bears the unique premises number, test results, and other pertinent information.

USDA
U.S. Department of Agriculture

Veterinary Services (VS)
Veterinary Services, the division of APHIS charged with animal health activities within the United States.

Wholesaler
A business with a permanent facility that buys birds from producers, distributors, or auction markets, and then trades or resells them.

Part II—Administration of the Program

A. State Participation

The LPAIP recognizes three basic components of the LBM system: production units, distribution units, and LBMs. A State can participate in the Program when all components of the LBM system operating within the State are required to be registered and/or licensed, and participation in the Program is a requirement of State registration or licensure. State participation is defined in each State's Memorandum of Understanding (MOU) between the State and VS.

LBM system participants that do not comply with the Program standards defined in this document are subject to administrative actions as determined by the State's regulatory authority. States are responsible for enforcement of Program standards.

B. Federal Participation

The LPAIP will be coordinated by the USDA, APHIS, VS, National Center for Animal Health Programs (NCAHP). Under the terms and conditions of the Program, USDA will provide personnel and resources to assist States with implementation of the Program and with compliance with Program requirements. Monitoring, surveillance, and educational activities will be supported, as defined in the State's MOU.

Federal indemnification will be provided through the Program for participating States and facilities at all levels of the LBM system in these States if they are in good standing within the Program. Indemnification will require a positive diagnosis of H5 or H7 LPAI. The amount of indemnification will depend on Federal regulations and Federal resources. For source flocks and distribution units, indemnity for destroyed birds will be based on the appraised value of the birds at the time of their disposal. For birds in the LBMs, indemnity will be paid for birds remaining in the market after a designated period provided to sell down, if appropriate, at the discretion of the State.

Part III—Program Elements and Procedures

A. Live Bird Markets (LBMs)

1. Licensing/registration and education

a. An LBM must be licensed or registered by the State within which it is located and must comply with the requirements of the Program. A unique premises identification number will be assigned by the State through the National Animal Identification System (NAIS). LBMs must also comply with all other applicable animal and public health laws and regulations, such as State environmental laws, city/county sanitation requirements, public health licenses, and the Poultry Products Inspection Act. Information required for an LBM to become licensed 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) Market capacity;
(6) Other LBM facilities under the same ownership, including dealerships, bird transportation businesses, and commercial poultry operations; and
(7) A list of all avian and nonavian species marketed.

b. As a Program participant, the LBM 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. LBM owners or managers are required to attend the training that is provided. This training is to be developed and funded by USDA with input from State Veterinarians from participating States.
d. All personnel that work in the market must be trained in biosecurity procedures as arranged by the owner/manager. Certificates of employee training will be maintained on file on the premises for 12 months and must be presented upon request by any Federal or State inspectors.

2. Bird testing and recordkeeping

a. Markets are responsible for verifying bird identification and obtaining documentation that all birds at the time of their receipt are sourced from test-negative flocks. If records are not available, the birds must not enter the market.
b. Records for avian species must include the date of entry, the premises-of-origin identification number with lot identifier, the number and species of birds in the lot, the distributor license number, and the date of sale. A copy of the document indicating AI negative status of the source flock must be filed as part of the records.
c. All records must be maintained for a minimum of 12 months from date of entry into the market. A copy of the form to be used may be obtained from the office of the Area Veterinarian in Charge (AVIC) or State Veterinarian.

d. Any indication noted by an LBM that paperwork has been altered or that it misrepresents the sources or test status of birds coming into the market must be reported to a Federal or State animal health official.

3. Market sanitation and biosecurity

a. A biosecurity protocol must be developed by the LBM and approved by the State.
b. LBM environments and crates must be kept in clean and sanitary conditions at all times, as defined by the biosecurity protocol.
c. Employees must be required to 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. LBMs are required to undergo regular, periodic closures with depopulation and complete sanitation, cleaning and disinfection (C&D), 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 a State or Federal animal health official before being allowed to reopen.
f. Poultry waste must be placed in plastic bags, sealed, and disposed of daily through procedures acceptable to the jurisdiction where the market is located.

4. Market surveillance

a. LBMs may be tested for LPAI virus by the State at any time, but they must be tested at least quarterly.
b. Specimens tested may include swab samples collected from live birds or the environment within the LBM; swabs collected on arrival from birds, conveyances, and crates; and swabs or tissues from sick and dead birds detected in the LBM.
c. Specimens of choice and the types of tests to be run for each are covered in Part IV.

5. Market positives

a. LBMs that test positive on RRT-PCR or virus isolation at an approved laboratory will undergo mandatory market closure by the State. Such markets will be required to depopulate and perform C&D, but may first be allowed up to 5 calendar days to sell down its bird inventory, if such action is deemed appropriate by the State Veterinarian. No additional birds will be allowed to enter the LBM following the notification of positive status and throughout the sell-down period.
b. Before the LBM can reopen for business, it must pass inspection by a State or Federal animal health official. Environmental samples may be taken for testing at this time, but the LBM can be allowed to reopen while it awaits environmental test results. If results are positive, the LBM will again be required to close (with up to 5 days to permit sell-down, if appropriate) and will again perform C&D procedures within the next 24 hours, followed by inspection and retesting.
c. All samples that test positive for H5 or H7 at an approved State or university laboratory will be submitted to the NVSL for further characterization of the virus.

d. An LBM that has a positive environmental test on quarterly inspection will be required to undergo monthly testing. If results are positive, the LBM will again be required to close (with up to 5 days to permit sell-down, if appropriate) and will again perform C&D procedures within the next 24 hours, followed by inspection and retesting.
e. After three consecutive negative tests, the LBM will be allowed to return to a schedule of quarterly testing and routine quarterly closures.
f. When birds are found to be positive in the LBM or upon delivery into the market, an investigation will be initiated. This may require use of market records in order to conduct appropriate tracebacks to determine where the positives are occurring in the system. State and Federal animal health officials and, if necessary, compliance personnel will work together in the investigation.

B. Poultry Distributors

1. Licensing/registration and education

a. Poultry distributors (consisting of dealers, haulers, the live haul process, 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 LBMs to which the birds are sold or delivered. The distributor's business premises will be given one unique identification number through NAIS in the State in which it is located. This identification number will be used when the distributor registers for licenses in other States. Information required for a distributor's 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 or residence;
(5) Bird capacity;
(6) Other businesses under the same ownership in the LBM system, including other dealerships, bird transportation businesses, and commercial poultry operations; and
(7) A list of all avian and nonavian species distributed.

b. To register to transport birds within the LBM system, distributors must agree to allow State and/or Federal animal health officials to have access to records upon request and to permit official inspections and testing of premises and equipment as required.
c. A license will not be issued until there has been an inspection and approval of the facility, its record system, and the C&D equipment that will be used.
d. All personnel that work for the company must be trained in biosecurity by State or Federal personnel or by a trained company representative. Certification of employee training must be maintained in the personnel files. This training protocol is to be developed and funded by USDA with input from State Veterinarians in participating States.

2. Bird testing and recordkeeping

a. Distributors may only accept qualified birds from test-negative flocks that are identified and documented in accordance with State-accepted standards.
b. Distributors must provide documentation and certification of negative test results from the source flock with each delivery of birds.
c. Distributors must comply with recordkeeping requirements. They must maintain records for 12 months of bird pickups and deliveries that include: copies of test certification, dates of pickup and delivery, locations, species, numbers of birds, and farm premises identification numbers that include lot identification. In addition, distributors must keep records of C&D of premises and/or conveyances. A copy of the records form may be obtained from the office of the AVIC or State Veterinarian.
d. 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 LBM must be reported to a Federal or State animal health official.

3. Distributor sanitation and biosecurity

a. Distributor vehicles, bird-holding devices, and any premises where birds may be held must be clean and sanitary at all times.
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 C&D documentation when obtaining birds from producers and from other distributors. Once emptied of birds, conveyances and coops must undergo C&D between all deliveries.
d. Before the distributor returns to a farm after visiting an LBM, all cages, vehicles, and other equipment must undergo C&D.
e. Distributors may not transport live birds or other live animals from LBMs.

4. Distributor surveillance

a. Distributors will be subjected to random inspections by State or Federal officials of the State in which they are located. These random inspections will be done at least quarterly to ensure that conveyances, crates, and facilities are clean and sanitary and that records are being kept according to Program requirements.
b. Distributors will be tested at least quarterly for LPAI virus. Testing may include facility environment, conveyances, crates, and 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. AI-positive distributions units

a. Distributors' facilities that test positive by RRT-PCR or virus isolation at an approved laboratory will undergo depopulation of any birds on the premises, followed by C&D.
b. Environmental samples may be taken for testing if indicated.

c. Any specimen testing positive at an approved laboratory will be submitted to the NVSL for virus isolation and further characterization of the virus. However, premises will be depopulated on the basis of the original positive RRT-PCR or virus isolation results and will not await the results of testing at the NVSL.
d. A distributor that fails biosecurity inspections and/or is positive on 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.
e. When birds are found to be positive within the distribution system, an investigation will be initiated. This may require use of distributor records in order to complete traceouts to determine where the positives occurred in the LBM system. State and Federal animal health officials and, if necessary, compliance personnel will work together with LBM personnel in the investigation.

C. Production Units

1. Licensing/registration and education

a. Production units will receive unique premises identification numbers to be used for all business pertaining to the LBMs and for interstate movement. Premises identification numbers are assigned by States through NAIS. Information required for the records include:

(1) Business name, address, and telephone number;
(2) Owner's name, address, and telephone number;
(3) Global Positioning System location;
(4) Premises capacity; and
(5) Other bird and animal production or sales facilities, as well as dealerships and bird transportation operation, under the same ownership.
(6) A list of all avian and non-avian species produced.

b. To participate in the Program, production units are required to allow State or Federal animal health officials to have access to all records and equipment for inspections when requested by the Program authority. Testing may be conducted as indicated by State or Federal animal health officials.
c. Flock and farm managers are required to attend the training that is provided. This training is to be developed and funded by USDA with input by State Veterinarians from participating States.

2. Bird testing and recordkeeping

a. All birds provided to a distributor or directly to the LBM must minimally originate from a flock that has tested negative 10 days prior to movement and must bear or be accompanied by identification to a premises of origin. The categories of production units and the testing requirements for each category are as follows:

(1) AI-monitored flock: is tested monthly for AI with negative results for at least 3 consecutive months using AGID on serum or egg yolk samples from gallinaceous birds, RRT-PCR on tracheal swabs from gallinaceous birds, or virus isolation on cloacal swabs from waterfowl and other birds. At least 30 birds per flock are tested monthly by an approved laboratory.
(2) Established flock: has been maintained together for at least 21 days prior to sample collection with no additions to the flock. For an established flock to qualify for the first shipment into the LBM system or to requalify after any breaks in the monthly sample-testing regimen, 30 birds must be tested by AGID or other official test procedure within 10 days prior to movement.
(3) Commingled flock: is a group of poultry from multiple sources that has been assembled for one or more shipments. When untested birds are added to the flock, previous test reports are void and the flock must requalify as an established flock by waiting 21 days before resampling, and then following the protocol as for a nonmonitored flock.
(4) Nonmonitored flock: has not been on a program of monthly testing for at least 3 months. To qualify for sale in the LBM system, 30 birds in a nonmonitored flock must have been tested within 10 days of movement.

b. Samples for testing may be collected by certified poultry technicians (CPTs), State or Federal animal health technicians or veterinary medical officers, or accredited veterinarians.
c. Flock test records, as well as records of bird transfers, must be maintained for 12 months. A copy of the form to be used may be obtained from the AVIC or State Veterinarian.
d. Birds loaded for transportation to a distributor must be identified by premises of origin and must contain an appropriate date or lot number that will distinguish this shipment from others. This information must be recorded on the test certificate that will be provided to the distributor.
e. Birds from production units may not be transported by a flock owner or manager directly to the LBMs for sale unless the flock owner or manager also is registered as a distributor, with the necessary State approval for protocols and equipment to ensure effective C&D of conveyances and equipment.
f. Premises with birds that test positive on serology at an approved laboratory will be quarantined according to State authority while results are being confirmed.
g. Seropositive flocks must be quarantined and tested using a virus-detection procedure. Birds such as quail, guineas, and other gallinaceous species will be tested by RRT-PCR or by virus isolation using tracheal swabs. Waterfowl will be tested by virus isolation of cloacal swabs.
h. Premises that have results confirmed as positive for H5 or H7 LPAI virus will be required to depopulate and undergo C&D. The premises must then be inspected and tested by virus isolation. A negative environmental test result is required before restocking. Under special circumstances, at the discretion of the State Veterinarian, small positive flocks may be exempted from depopulation if they are determined to be low risk for disease transmission. In such cases, the State Veterinarian will approve and implement a special biosecurity protocol. Under this protocol, the flock

will be quarantined and allowed to remain in its environment until it tests negative and the quarantine is lifted by the State.

i. Premises positive on AGID but negative for H5 and H7 will not be considered positive by these Program standards, but will be subject to State protocols.

3. Sanitation and biosecurity

a. Production unit facilities, conveyances, bird holding devices, and other equipment must be clean and sanitary at all times.
b. Biosecurity protocols must be developed by the producer and be in place in all production units on the premises.
c. Certification of training must be maintained in the company personnel files.
d. Producers must have approved equipment available for C&D of premises, conveyances, and crates. They must maintain records of downtime and C&D.

4. Producer surveillance

a. Premises may be subjected to random inspections by State and Federal animal health officials to ensure that premises, conveyances, and coops are clean and sanitary. Random samples may be collected for virus identification from birds or environment at the time of inspection.
b. Records will be reviewed during site inspections.
c. Positive H5 or H7 LPAI virus isolation or RRT-PCR test results, confirmed at the NVSL, will result in quarantine of the premises, depopulation, and C&D.

5. LPAI-positive facilities

a. Any specimens positive for virus will be submitted to the NVSL for virus isolation and characterization. The premises will be quarantined until results are obtained from the NVSL.
b. Premises testing positive for H5 or H7 will remain under quarantine and be inventoried. Records will be examined, and all traceouts will be conducted. The premises will be depopulated and will undergo C&D.
c. RRT-PCR or VI positives at LBMs and distribution facilities will result in tracebacks to a supplier of origin by State or Federal personnel in the State of origin.

Part IV—Official Testing of Specimens from LBMS for the LPAI Program

A. Specimens

1. Serum and swab specimens will be collected from LBMs, distribution units, and production units by Federal or State animal health officials. Production units may also be sampled by CPTs for routine surveillance activities.
2. The specimen of choice for the RRT-PCR is the tracheal swab. For smaller birds, small Dacron or cotton swabs may be used. (Use of the calcium alginate swab is contraindicated because it interferes with test results). The RRT-PCR procedure has been standardized for gallinaceous species and should be used for this group of birds only.
3. Virus isolation should be used for waterfowl, other non-gallinaceous species, and environmental samples. The specimen of choice for virus isolation is the tracheal swab except for waterfowl, where only cloacal swabs should be used.
4. Specimens for virus identification will be tested by USDA-approved laboratories or by the NVSL. Laboratories approved by the NVSL must pass annual check tests required for Program participation.
5. All specimens that test positive in approved laboratories will be submitted to the NVSL for virus isolation and characterization.

B. Official Tests

1. The official tests for the LPAI Program in LBMS are as follows:

   a. For virus identification, the RRT-PCR test and virus isolation.
   b. For serological antibody detection, the AGID test.
   c. For antigen detection, the ACIA test.

2. Laboratory approval for official testing (see further information below):

   a. For virus identification, laboratories must be federally (USDA) approved.
   b. AGID testing may be performed in State or university laboratories approved by the State.
   c. ACIA tests must be performed by personnel approved by the State.

C. Federally Approved Laboratories

1. All official tests used in the Program for virus identification must be conducted only in federally approved laboratories. Requirements for laboratory approval are as follows:

   a. Laboratories must have the instrumentation required to perform the procedures;
   b. Technicians at the laboratory may be trained at the NVSL or they may be certified as competent in RRT-PCR and other test procedures by their laboratory director. Technicians must then pass a check test provided by the NVSL before the laboratory is placed on the approved list; and

c. Laboratory technicians must pass an annual proficiency test to remain on the approved list.

2. Records of the number of tests performed and the number of positive tests must be provided to State and Federal officials, including the NCAHP staff at VS headquarters in Riverdale, Maryland.

3. All positive specimens must be sent overnight to the NVSL for characterization of the agents identified.

D. Virus Identification Procedures (To Be Done Only in Federally Approved Laboratories)

1. RRT-PCR

a. This test detects viral RNA and can be used to determine if the H5 or H7 gene is present. It is highly sensitive and is the test of choice for gallinaceous birds.

b. The specimen of choice for gallinaceous birds (chickens, turkeys, guinea fowl, etc.) is the tracheal swab.

c. Specimens containing high concentrations of bacteria and debris, such as in cloacal swabs, are contraindicated for the use of RRT-PCR because these agents will interfere with test results.

d. Environmental specimens should also not be tested using RRT-PCR because the sensitivity of the test may result in positives on swabs containing non-viable virus that may have been inactivated during the disinfection procedure.

2. Virus isolation

a. This identifies the presence of viable virus through exposure of embryonated eggs to test specimens.

b. Use virus isolation for:

(1) Specimens that may contain concentrations of the virus too low to identify by RRT-PCR;
(2) Environmental samples;
(3) Cloacal swabs; and
(4) Waterfowl and other nongallinaceous bird species.

E. State-Approved Laboratories

1. The AGID test on specimens from LBMs may be performed in State laboratories and in university laboratories approved by the State.

2. Records of the number of tests performed and the number of positive tests must be provided to State and Federal officials, including the NCAHP staff at VS headquarters in Riverdale, Maryland.

3. All positive specimens must be sent overnight to the NVSL for subtyping and/or characterization of viruses identified.

F. Serological Tests (May Be Done in State-Approved Laboratories)

1. Serological tests for the LPAI Program in LBMs may be performed at State laboratories or at university laboratories approved by their State.

2. **AGID test for antibody detection**

   a. This is the official serological procedure for identification of antibodies in serum specimens for all birds within the LBM system.
   b. The AGID test must be conducted in approved State or university laboratories on specimens collected by CPTs, State or Federal animal health officials, or accredited veterinarians.
   c. The AGID test is type-specific and will not determine whether birds have been exposed specifically to H5 or H7 subtypes of AI.
   d. Positive AGID results indicate that birds were exposed at least 1 week previously to some unidentified subtype of AI.
   e. AGID-positive specimens should be forwarded to the NVSL for H- and N-subtyping.
   f. A final decision on the status of the flock may require further sampling and use of RRT-PCR or virus isolation to identify the presence of a virus.

3. **Enzyme-linked immunosorbent assay (ELISA)**

   a. ELISA is not an official test for the LPAI Program in LBMs.
   b. The specificity of the ELISA test indicates that nonspecific positives may occur.
   c. A positive ELISA must be confirmed with the use of AGID.

G. Antigen Detection Tests

1. **Antigen capture immunoassay (ACIA) test**

   a. An official test to screen for the detection of Type A avian influenza antigen in swab specimens from birds exhibiting clinical signs of disease (sick birds) or dead birds within the LBM system.
   b. The ACIA test must be conducted using test kits approved by USDA and the State and must be conducted in accordance with recommendations of the manufacturer.
   c. The ACIA test detects Type A influenza and will not determine whether birds have been exposed specifically to H5 or H7 subtypes of AI.
   d. ACIA positive specimens must be forwarded to federally (USDA) approved laboratories or the NVSL for confirmation and H- and N- subtyping.
   e. A final decision on the status of the flock will require further sampling and use of RRT-PCR or virus isolation to identify the presence of an AI virus.

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

Requirement for indemnification:

- Any positive H5 or H7 specimen confirmed by the NVSL.
  - Even when the requirement is met, indemnity is not guaranteed, but should be discussed by the Federal and State officials as an option.
  - Presumptive positive H5 or H7 results from a National Animal Health Laboratory Network 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 APHIS VS.

Flocks or premises eligible for indemnity funds:

- Live bird marketing system participants (markets, distributors and producers) are eligible. Once the LPAI program is established in a given State, participants must comply with the Uniform Standards and all State regulations.

Fair Market Value at distributor/wholesale and retail market level:

- 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 production level if the bird is currently located at a wholesaler or distributor.
- In addition to an inventory verified by State or Federal officials at the time of depopulation, valid documentation of purchase is required.
- Alternatively – without receipts – authorized State or Federal officials will conduct a survey of relevant wholesalers to determine the value.

Fair Market Value at production level and Breeder birds:

- 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.
- 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 upon 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.
- Appraisal value for all other birds will be determined by either APHIS-developed valuation lists or by official Federal and/or State appraising officials.

Decision to depopulate:

- Made by the State in consultation with industry/stakeholders and APHIS VS. VS must concur with the State approach to controlling H5/H7 LPAI in each incident before indemnity funds can be distributed.

- Depopulation is not the only possible response to H5/H7 LPAI. Quarantine or controlled marketing or quarantine/vaccination (for production flocks only) may also be appropriate.

Indemnity funds (per 9 CFR 56) may be used for:

- 100 percent of the appraised value of depopulated birds and costs of depopulation, disposal, cleaning and disinfection.

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