

HPAI Response

Surveillance Sampling of Commercial Premises in a Control Area and Surveillance Zone

January 14, 2025

Please note: These procedures may be revised as the situation develops.

DEFINITIONS (HPAI Response Overview of Zones)

Contact Premises: Premises with susceptible poultry¹ that may have been exposed to highly pathogenic avian influenza (HPAI), either directly or indirectly, including but not limited to exposure to animals, animal products, fomites, or people from Infected Premises.

Suspect Premises: Premises under investigation due to the presence of susceptible poultry¹ reported to have clinical signs compatible with HPAI. This is intended to be a short-term premises designation.

At-Risk Premises: Premises that have susceptible poultry¹, but none of those susceptible animals have clinical signs compatible with HPAI. Premises objectively demonstrates that it is not an Infected Premises, Contact Premises, or Suspect Premises. At-Risk Premises may seek to move susceptible animals or products within the Control Area by permit. Only At-Risk Premises are eligible to become Monitored Premises.

Monitored Premises: Premises objectively demonstrates that it is not an Infected Premises, Contact Premises, or Suspect Premises. Only At-Risk Premises are eligible to become Monitored Premises. Monitored Premises meet a set of defined criteria in seeking to move susceptible animals or products out of the Control Area by permit.

Infected Zone: Zone that immediately surrounds an Infected Premises; the perimeter should be at least 3 km (~1.86 miles) beyond the perimeters of the presumptive or confirmed Infected Premises. This zone may be redefined as the outbreak continues.

Buffer Zone: Zone that immediately surrounds an Infected Premises; this is the area that is at least 7 km (~4.35 miles) beyond the perimeter of the Infected Zone (10 km beyond the Infected Premises). This zone may be redefined as the outbreak continues.

Surveillance Zone: Zone outside and along the border of a Control Area. The perimeter of the zone should be at least 10 km (~6.21 miles). The Surveillance Zone is part of the Free Area.

Control Area: Consists of an Infected Zone and a Buffer Zone; the perimeter of the Control Area should be at least 10 km (~6.21 miles) beyond the perimeter of the closest Infected Premises. This area may be redefined as the outbreak continues.

Foreign Animal Disease Investigation: An investigation conducted according to <u>VS Guidance Document</u> <u>12001.5 Ready Reference Guide</u>.

INTRODUCTION

An Infected Zone and Buffer Zone (Control Area) will be created around an HPAI poultry¹ Infected Premises. A Surveillance Zone will be created around the outer edge of a Control Area and should consider jurisdictional areas, physical boundaries, and epidemiological characteristics of transmission risk. This document

¹ Poultry is defined as: 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.

provides surveillance guidance for commercial poultry premises within a Control Area and Surveillance Zone.

The objectives are to demonstrate that infection has not spread beyond the infected premises in the Control Area and that it does not extend beyond the Control Area into the Surveillance Zone. Surveillance activities and associated testing should be based on recommendations of the Unified (State-Federal) Incident Command; this guidance may require further modification based on epidemiological and situational information.

This document reflects the epidemiological information known about the behavior of currently circulating viruses and experiences from previous outbreaks. For example, there is no evidence that the circulating viruses cause sub-clinical infection in gallinaceous poultry species; clinical signs and mortality are apparent.

COMMUNICATION

It is critical to ensure that HPAI information, as well as recommended biosecurity measures, is clearly communicated to all commercial premises in a Control Area and Surveillance Zone. APHIS and State/Tribal officials must ensure that instructions are provided to owners/producers to report clinical signs and abnormal mortality. There are transparent procedures for managing reports of clinical signs or unusual mortality from commercial producers (also known as sick bird calls).

VISITING PREMISES

While it is important to locate commercial poultry premises within a Control Area, responders should not enter premises unless instructed to do so by the Incident Management Team (IMT). It is critical to remember that any real or perceived belief that responders are spreading HPAI is incredibly detrimental to the response effort. As with any premises, if a visit is necessary, appropriate biosecurity and cleaning and disinfection measures should be observed, and all guidance provided by Incident Command should be followed.

SURVEILLANCE PLAN- PASSIVE SURVEILLANCE

General Guidance Start and Duration

Passive surveillance, observer-initiated reporting of sick birds, is utilized in the United States to support foreign animal disease investigations (per <u>VS Guidance Document 12001.5</u>). In the event of an HPAI detection, passive surveillance is strongly encouraged through rapid and clear communication to all producers in the Control Area. Producers, hobbyists, and practitioners located in the Surveillance Zone are encouraged to voluntarily report suspect cases according to the Procedures below.

Procedures

Mortality threshold levels that signal the need for investigation have been established for the different commercial poultry sectors by the <u>Secure Poultry Supply</u>. Commercial flocks, as defined in <u>9 CFR</u> <u>Part 145</u>, located in a control area that exceed the mortality thresholds² listed below are investigated and sampled as rapidly as possible for avian influenza.

- **Commercial broilers:** mortality exceeding 3.5 birds/1,000 per day.
- Commercial layers: mortality exceeding 3 times the normal daily mortality per day (normal: 0.13 birds/1,000 per day for layers from 2 to 50 weeks, and 0.43 birds/1,000 per day for layers over 50 weeks); OR 5 percent drop in egg production for 3 consecutive days.
- **Commercial turkeys:** mortality exceeding 2 birds/1,000 per day.

² Per the H5/H7 avian influenza case definition.

- Broiler breeders: mortality exceeding 2 birds/1,000 per day.
- Layer breeders: mortality exceeding 3 times the normal daily mortality per day (normal: 0.2 birds/1,000 per day up to 50 weeks, and 0.37 birds/1,000 per day after 50 weeks).
- **Turkey breeders:** mortality exceeding 2 birds/1,000 per day; OR a decrease in egg production of 15 percent occurring over a 2-day period.
- Small-volume high-value commercial poultry flocks and other commercial flocks not listed here: any sudden and significant mortality event or sudden drop in egg production should be investigated.

At the State's discretion, investigation, and sampling of flocks which exceed the mortality thresholds can be performed by a company veterinarian, a Foreign Animal Disease Diagnostician, or other IMT-designated response personnel.

- 1. Schedule an appointment to collect samples as quickly as possible.
- 2. Conduct sampling according to the recommended sampling scheme below and submit samples to the designated National Animal Health Laboratory Network (NAHLN) lab as indicated by the IMT.
- 3. Record all relevant information in the Emergency Management Response System (EMRS). Follow IMT guidance on any additional information to enter.

SURVEILLANCE SCHEMES

Bird selection, specimen collection, and submission procedures are identical regardless of the premises designation or whether the premises is located in the CA or SZ. Surveillance schemes differ only in the proportion of the total number of premises surveyed and the frequency of the surveillance. Record all relevant information in EMRS (see Documentation section at the end of this document) and follow IMT guidance on additional information to enter. If premises are not commercial premises or known BYRF or if additional information is needed on surveillance options, please contact the Center for Epidemiology and Animal Health, Surveillance Design and Analysis Unit at <u>VS.CEAH.Surveillance@usda.gov</u>.

Bird Selection Procedures

- Active surveillance should be conducted separately in each barn/house or other grouping of birds on a premises using the numbers specified below. With appropriate justification that barns or houses have the same exposure to disease and that biosecurity measures do not separate or prevent spread among a set of structures or groups of birds, the required number of specimens collected can be distributed across those structures or groups rather than collected separately within each structure or group.
- 2. When selecting **gallinaceous** birds for specimen collection, the surveillance objective is to achieve a 95% confidence of detection at a 40% prevalence among **gallinaceous** birds in a barn/house or other group of birds with the same exposure risks, assuming a diagnostic testing protocol sensitivity of 85%.
 - a. Target sick and dead birds to provide **two pooled specimen tubes with up to 11-bird specimens per tube or three pooled specimen tubes with 5-bird specimens per tube**. A minimum of two pooled specimen tubes must be collected.
 - b. Obtaining specimens from apparently healthy birds is not recommended and is of negligible benefit since circulating viruses typically **do not** cause subclinical infection in gallinaceous species thus clinical signs and mortality will be apparent.
- 3. When selecting **domestic waterfowl** for specimen collection, the surveillance objective is to achieve a 95% confidence of detection at a 10% prevalence among domestic waterfowl in a

barn/house or other group of birds with the same exposure risks, assuming a diagnostic testing protocol sensitivity of 85%.

- a. Target sick and dead birds to provide a minimum of **seven pooled specimen tubes of up to 5-bird specimens per tube.**
- b. Obtaining specimens from apparently healthy birds may be considered if sick and dead are not available, as domestic waterfowl do not readily show clinical signs.
- 4. See <u>Specimen Collection and Submission Procedures</u> in this document for more details.

SURVEILLANCE PLAN- ROUTINE/ACTIVE SURVEILLANCE

General Guidance

In addition to passive surveillance, routine active surveillance is conducted to provide evidence that HPAI is not present. Active surveillance in commercial premises is composed of two components: premovement surveillance and routine active surveillance. This document describes routine active surveillance activities only and is meant to complement any surveillance conducted in preparation to move product. Please refer to the <u>Secure Food Supply Plans</u> for additional pre-movement surveillance guidelines or refer to the document <u>Testing Requirements for Movement from the Control Area</u>.

Start and Duration

APHIS and/or State officials will determine the time length for active surveillance. Active surveillance may continue after the Control Area has been released for international or bilateral trading partners. A test sensitivity of 85% was used to inform the following surveillance procedures.

Procedures

- 1. Testing of all commercial premises in a control area is required.
- 2. When selecting birds to sample in barns/houses or animals held in a similar manner with the same exposure risks, the goal is to achieve a 95% confidence of detection at a 40% prevalence among **gallinaceous** birds.
 - a. Target sick and dead birds to provide a minimum of <u>two</u> pooled specimen tubes with up to 11 bird specimens per tube.
 - b. Obtaining specimens from healthy birds is not recommended and of negligeable benefit.

When selecting **domestic waterfowl** from each barn/house or other group of birds with the same exposure risks, the goal is to achieve a 95% confidence of detection at a 10% prevalence.

- c. Target sick and dead birds to collect <u>seven</u> pooled specimen tubes of up to 5 bird specimens per tube for laboratory submission.
- d. Obtaining specimens from apparently healthy birds may be considered in domestic waterfowl, if sick and dead are not available, as they do not readily show clinical signs.
- 3. Determine if the premises is, or will be, engaged in pre-movement surveillance:
 - a. If yes, use samples collected from pre-movement surveillance to count towards routine active surveillance requirements where possible. Do not duplicate surveillance efforts.
 - b. If no, continue with frequency and sampling guidelines as described below.
- 4. Frequency of sampling is determined by classification of premises.
 - a. Suspect Premises (SP) is a temporary designation. Disposition of SP is determined by State Animal Health Official, APHIS, and/or Incident Management Team (IMT).
 - Immediately investigate and collect specimen following the Specimen Collection Procedures below.

- SP should be reclassified expeditiously, after investigation and results from testing are received.
- b. Contact Premises (CP):
 - Collect samples on each premises every other day for 14 days.
 - CP that test negative in the above sampling regime should then be sampled as described for the MP and ARP (below).
- c. At Risk Premises (ARP):
 - Collect samples on each premises once every 5-7 days for the duration of the quarantine, or similar sampling frequency depending on the available resources and guidance provided by the IMT.
 - ARP may be sampled more frequently depending on pre-movement surveillance guidelines.
- d. Monitored Premises (MP):
 - Collect samples once every 5-7 days for the duration of the quarantine, or similar sampling frequency depending on the available resources and guidance provided by the IMT.
 - MP may be sampled more frequently depending on pre-movement surveillance guidelines/requirements for movement.
- 5. If HPAI compatible clinical signs, mortality, or epidemiological links are reported on a CP, ARP, or MP, premises are reclassified as SP. Conduct surveillance immediately according to 4.a above.
- 6. Record all relevant information in EMRS. Follow IMT guidance on additional information to enter.
- 7. If premises do not fit the above criteria or if additional information is needed on surveillance options, please contact the USDA APHIS VS Center for Epidemiology and Animal Health, Surveillance Design and Analysis Unit.

ACTIVE SURVEILLANCE IN A SURVEILLANCE ZONE

General Guidance

Active surveillance is conducted in the SZ among a selection of commercial premises to detect previously unknown IPs, support that control actions are effective at preventing the outbreak from spreading beyond the CA, and to support establishment of disease-free status.

Premises Selection

Include a subset of premises within the SZ for active surveillance, prioritizing premises with highest likelihood of spread, highest likelihood of exposure, or highest consequence of infection (recommended). A statistically random selection of premises from the list of commercial premises is also appropriate and may be preferred. The number of premises necessary varies by the total number of premises stocked with susceptible species in the SZ as shown in Table 2. The surveillance objective should achieve or exceed 95% confidence of detection of an IP if the prevalence of IP in the SZ is 10%. If possible, select a new subset of premises for each round of testing. See Table 2 for guidance on surveillance of SP and CP in the Free Area (including the SZ).

If surveillance guidance assuming a different prevalence level is desired, please contact the Center for Epidemiology and Animal Health, Surveillance Design and Analysis Unit at <u>VS.CEAH.Surveillance@usda.gov</u>.

 Table 1. Minimum number of premises actively stocked with birds to select for surveillance from a Surveillance

 Zone to achieve 95% confidence¹ of detecting at least one infected premises when the prevalence of infected premises in the SZ is 10%.

Total number of premises in zone (to be selected from)	Number of premises to select assuming 10% premises level prevalence
11 or less	All
12 to 15	13*
16 to 40	21*
40 to 50	23
51 to 75	25
76 to 100	26
101 to 150	27
151 to 200	28
201 to 500	29
>500	30

¹These sample sizes assume <u>pooled-bird specimen are collected</u> and tested to achieve a 95% confidence in detection among birds within a barn/house or other group of birds with the same exposure risks. *Select all premises if the number of premises within the zone or area is less than the value given.

Start, Duration, and Frequency of Surveillance

Surveillance zone (SZ) surveillance should begin in the subset of premises selected according to the guidance above shortly after CA surveillance starts and can end immediately prior to CA closure as long all surveillance is completed. At a minimum, surveillance of selected SZ premises should occur in two rounds, once near the opening of and again ideally before the closing of the CA. However, the final round of surveillance in the SZ may occur after the CA has been released. Surveillance rounds should be separated by at least 14 days.

SP and CP in the Free Area (including the SZ) are not included in the subset of premises described above and frequency of surveillance is determined by the premises type as seen in Table 3.

Table 2. Guidelines for the frequency and duration of surveillance in the Free Area (including the SurveillanceZone) by premises designation.

Premises Type	Frequency of Surveillance	Duration of Surveillance
Suspect Premises (SP)	Once	Temporary designation, reclassify based on results
Contact Premises (CP)	Every other day	For 14 days

Conditions

- If HPAI compatible clinical signs, mortality, or epidemiological links are reported on any premises in the SZ, the premises are reclassified as an SP and surveillance should be conducted immediately as described for SP in the Free Area.
- If HPAI is detected and confirmed on a commercial premises in the SZ, a new CA centered on the new IP will be created and appropriate restrictions applied.
- Negative findings in the SZ support that control actions are working and contribute to establishment of disease freedom of the region or country.

Procedures

 Premises Selection: Include a subset of premises within the Surveillance Zone for active surveillance, prioritized by epidemiological investigation or other risk factors. The number of premises necessary to sample will vary by total number of premises which are stocked with susceptible species in the Surveillance Zone (Table 1). The surveillance plan should achieve or exceed 95% confidence of detection of an infected premises if the prevalence of infected premises in the Surveillance Zone is 10%.

Table 3. Minimum number of premises actively stocked with birds to select for sampling from a Surveillance Zone (to achieve 95% confidence¹ of detecting at least one infected premises at a 10% prevalence design).

Number of Premises in Zone	10% Premises level Prevalence
11 or less	All
12 to 15	13*
16 to 40	21*
40 to 50	23
51 to 75	25
76 to 100	26
101 to 150	27
151 to 200	28
201 to 500	29
>500	30

¹These sample sizes assume pooled-bird specimens are collected and tested to achieve a 95% confidence in detection as described for each animal groups sampled.

*Select all premises if the number of premises within the zone or area is less than the value given.

2. Selecting birds in each barn/house on a premises: All houses or smaller epidemiological units, animals held in a similar manner with the same exposure risks, on a selected Surveillance Zone premises should be sampled. The surveillance plan goal is to target sick or dead birds for sampling to achieve or exceed a 95% confidence of detection of an infected house or smaller epidemiological unit within a flock at a 40% prevalence among gallinaceous birds and 10% prevalence among domestic waterfowl. A test sensitivity of 85% is used to inform the surveillance guidance and procedures are as described in Recommended Specimen Collection Procedures below.

ACTIVE SURVEILLANCE FOR CONTROL AREA RELEASE

General Guidance

The release of a CA requires meeting conditions related to the depopulation, cleaning, and disinfecting/virus elimination activities on all IP and dangerous CP in the CA as described in the <u>HPAI Control Area Release</u> document on the <u>HPAI FAD PReP site</u>. In addition to these conditions, surveillance in the CA and SZ must be completed as outlined in the above sections regarding Active Surveillance in a Control Area and in a Surveillance Zone. The specifics for CA release may be refined based on the epidemiology of the outbreak and trading partners may require enhanced surveillance procedures prior to and after the release of the CA.

Conditions

 A CA can be released 14 days after depopulation/disposal and initial virus elimination activities of the IP if all other conditions designated by the unified IC have been met including conducting CA and SZ surveillance as described above.

- If HPAI compatible clinical signs, mortality, or epidemiological links are reported on a premises during this time, that premises is reclassified as an SP and surveillance should be conducted immediately as described in <u>Table 2</u>.
- If HPAI is detected and confirmed on a Commercial Premises in the CA when conducting surveillance for CA release, a new CA centered on the new IP should be created. This allows for release of premises in the original CA that are not within the new CA if all conditions are met for these premises including all surveillance in the CA and SZ.

RECOMMENDED SPECIMEN COLLECTION PROCEDURES

Select birds to sample as follows and in line with the current version of *Avian Sample Collection for Influenza A and Newcastle Disease* (NVSL-WI-0023 available <u>here</u>):

- 1. For premises with gallinaceous birds, swab and pool specimens collected by the same specimen collection route and from the same species according to Section 3 "Pooling procedures" of NVSL-WI-0023.
 - a. Collect up to 5 swab suspensions in 3 mls of acceptable virus transport media (VTM) for any species, and up to 11 swab suspensions (for **gallinaceous** poultry only) in 5.5 mls VTM; refer to WI-AV-0020 for options on collection of 11 swab pools. A minimum of <u>two</u> pooled specimen tubes with up to 11 bird specimens per tube should be collected.
 - b. Select daily dead birds for swabbing followed by euthanized sick gallinaceous birds from <u>each house or epi unit</u> on the premises. If there are not enough daily dead or euthanized sick birds to fill the required minimum number of pools, evenly distribute the sick and dead between the required number of pools.
 - c. Random selection and swabbing of apparently healthy gallinaceous birds provide negligible detection benefit and should be avoided.
- 2. For premises with **domestic waterfowl** only, collect <u>seven</u> pooled specimen tubes of up to 5 swab and pool specimens from a single flock and species in at least 3 mls VTM for laboratory submission.
 - a) Select daily dead birds for swabbing followed by euthanized sick domestic waterfowl from each house or epi unit on the premises. If there are not enough daily dead or euthanized sick birds to fill the required number of pooled specimens per tube, evenly distribute the sick and dead specimens between the tubes. If clusters of sick/dead birds are detected (e.g., in the same cage, or in one corner of the house), these should also be evenly distributed among tubes.
 - b) If no dead or sick birds are available (waterfowl may not show clinical signs of infection), selecting apparently healthy birds per house/epi unit is appropriate.

Collect swab specimens according to the current version of *Avian Sample Collection for Influenza A and Newcastle Disease* (NVSL-WI-0023 available <u>here</u>):

- 1. Oropharyngeal swabs are preferred for gallinaceous birds.
- 2. Cloacal swabs are preferred for waterfowl unless H5 goose/Guangdong lineage viruses are suspected in which case both OP and CL swabs are recommended.
- 3. Do not combine swab specimens from different domestic bird species or from different specimen collection routes.
- If pooling is conducted, only pool swab suspensions collected by the same specimen collection route (e.g., cloacal) from the same species according to Section 3 "Pooling procedures" of NVSL-WI-0023.
 - a. Collect up to 5 swab suspensions in 3 mls of acceptable virus transport media (VTM) for any species, and up to 11 swab suspensions (for gallinaceous poultry only) in 5.5 mls VTM; refer to NVSL-WI-0023 for options on collection of 11 swab pools.

5. Prepare, package, and process swabs for NAHLN laboratory submission according to the guidance found in the *FAD Investigation Manual*.

DOCUMENTATION

As with all surveillance activities, documentation is critically important. EMRS is the system of record for all HPAI outbreaks in the United States. This data may be reported internally and externally through situation or close-out reports or other means.

At a minimum, the following items are important to maintain and report:

- Number of commercial premises in Control Area.
- Number of premises contacted, and means of contact, for active surveillance.
- Number of premises visited and selected for data collection (including dates) for active surveillance.
- Total birds selected and swabbed at each premises and visit.
- Detail of pooling performed at each premises, such as 11-swab pool suspensions or 5-swab pool suspensions.
- Laboratory results for all submissions.

Include data from pre-movement surveillance that is used to meet routine active surveillance requirements. Refer to IMT guidance for how to appropriately record these and other data.

FOR MORE INFORMATION

Code of Federal Regulations 9 CFR 145. National Poultry Improvement Plan.

USDA APHIS VS. 2022. Avian Influenza Case Definition.

USDA APHIS VS. 2024. Avian Sample Collection for Influenza A and Newcastle Disease (NVSL-WI-0023)

USDA APHIS VS. 2022. Foreign Animal Disease Investigation Manual (FAD PReP Manual 4-0).

USDA APHIS VS. 2017. Highly Pathogenic Avian Influenza (HPAI) Response Plan: The Red Book.

USDA APHIS VS. 2015. <u>HPAI Response Ready Reference Guide – Overview of Zones.</u>

USDA APHIS VS. 2024. Guidance Document 12001.5: Policy for the Investigation of Potential Foreign Animal Disease/Emerging Disease Incidents (FAD/EDI).

USDA APHIS VS. 2025. Surveillance of Backyard Flocks in a Control Area or Surveillance Zone.

USDA APHIS VS. 2022. Testing Requirements for Movement from the Control Area.

University of Minnesota. <u>Secure Poultry Supply</u>.