Marketing and Regulatory Programs
Animal and Plant Health Inspection Service
Veterinary Services

# **VS Guidance 13401.2**

Approval and Oversight of Privately Owned Quarantine Facilities for Commercial Birds, Columbiformes, and Derived Hatching Eggs Imported into the United States

### 1. Purpose and Background

This guidance describes the procedures for Animal and Plant Health Inspection Service (APHIS), Veterinary Services (VS) approval and oversight of privately owned avian quarantine facilities. VS regulates the approval of privately owned quarantine facilities for imported animals. These facilities must have adequate safeguards to securely hold, monitor, and test (as applicable) quarantined animals; limit entry and egress to authorized personnel; and prevent the transmission of disease agents into or from the facility.

This guidance applies to privately owned facilities used to quarantine any commercial import shipment of avian animals (including eggs for hatching) and Columbiformes (pigeons and doves). Exceptions to this guidance are import shipments of ratites, zootype avian animals bound for zoos, avian animals intended for research, and eggs for hatching of any of these avian animals.

VS must inspect and approve a proposed quarantine facility before its initial use for import shipments to ensure that the facility complies with the standards in <u>title 9</u>, <u>Code of Federal Regulations</u>, section 93.106 (c) and this guidance. For re-approvals, VS must reinspect an approved facility annually to ensure it is in good repair and continues to meet all relevant standards associated with the Cooperative Service Agreement (CSA) referenced in <u>9 CFR 93.106(c)(5)</u>. Alternatively, in accordance with current VS practices, a Memorandum of Understanding (MOU) supported by user fees may be used in lieu of a CSA. If a Trust fund form of payment is used, the CSA is used in conjunction with that form of payment. The payment type determines the contracting document that should be selected. The contracting documents to manage the quarantine are either the MOU or CSA. Both document templates corresponding to this VSG are located on the <u>VS</u> cooperative agreement SharePoint site.

This guidance document represents the Agency's position on this topic and is intended solely as guidance. It does not have the force and effect of law, does not create or confer any rights for or on any person, and does not bind the U.S. Department of Agriculture (USDA) or the public. Language suggesting that this guidance is mandatory (e.g., "shall," "must," "required," or "requirement") should not be construed as binding unless the terms quote from a statutory or regulatory requirement. The information this document contains may be made available to the public. While this document provides guidance for users outside APHIS, APHIS employees may not deviate from the directions provided herein without appropriate justification and supervisory concurrence.

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#### 2. Document Status

- A. Review date: 9/15/2027.
- B. This document replaces VS Guidance 13401.1, which is canceled.

#### 3. Reason for Reissuance

VS is reissuing this guidance to update formatting and to reflect current policy.

# 4. Authority and References

- A. Authorities (Code of Federal Regulations (CFR)):
  - 7 CFR 371.4
  - 9 CFR 71.10
  - 9 CFR 93.100
  - 9 CFR 93.106
  - 9 CFR 93.209
  - 9 CFR 93.210

### B. References:

- VS Guidance 13403, Cleaning and Disinfecting Avian Quarantine Facilities
   Following Outbreaks of Communicable Avian Diseases
- VS Guidance 13410.2, Disease Testing and Sampling Requirements for Imported Live Poultry and Birds (and Hatching Eggs of Poultry, Birds, and Ratites) during Entry Quarantines
- Checklist that should be used with this VSG

### 5. Audience

VS employees, other federal and state agencies, and members of the public.

#### 6. Guidance

### A. Specific Instructions

- 1) An applicant (the owner or operator) seeking approval of a quarantine facility must submit a written application to VS Field Operations, Port Services (PS) via mail at 4700 River Road, Unit 39, Riverdale, MD 20737-1231, or via email to the port office nearest to the facility (contact information by State is available on the <u>APHIS website</u> (see APHIS Port Services entry)). Applicants should submit requests for approval to PS at least one hundred and twenty (120) calendar days before applying for local building permits.
- 2) The application must include:

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- a. The applicant's full name and mailing address.
- b. The facility's location and street address.
- c. Blueprints or other technical drawings of the proposed facility.
- d. A description of the financial resources available for the construction, operation, and maintenance of the facility.
- e. The average and maximum number of avian animals, or eggs for hatching, to be quarantined.
- f. Expected frequency of shipments to the quarantine facility.
- g. Plans for handling, care, and feeding of the avian animals from the port of entry to the quarantine facility.
- h. A plan for the necropsy and disposal of avian animals or eggs for hatching, held in the facility that may not hatch or die after hatching.

# 3) Procedure for VS approval of facilities

- a. The Veterinarian in Charge (VIC) of the VS Port Office assigned to oversee the quarantine request reviews the initial application and the accompanying documentation. If the application is complete, the VIC will consult with the VS PS Director and VS Strategy and Policy Live Animal Imports (LAI) regarding the feasibility of the request. The VIC should notify the facility's state animal health official.
- b. The VIC determines if resources are available to support the quarantine.
- c. If PS and LAI determine that an application merits further consideration, the applicant must sign a CSA or MOU with APHIS to cover the costs associated with further evaluating the application and facility. User fees for associated services are listed in <u>9 CFR 130.30</u>.
- d. PS notifies the applicant in writing of the application review results.
- e. PS contacts the applicant to schedule an appointment to inspect the facility and confirm compliance with 9 CFR 93.106(c) and this guidance.
- f. If there are elements that cannot be met, the veterinarian inspecting the facility works with the applicant, in consultation with the LAI, to put in place viable alternatives to the missing elements. If none can be devised, VS rejects the facility. If the alternative can meet the element's intent, it should be considered in the inspection approval process.

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g. After PS has approved the facility, the applicant and VS must sign a CSA or MOU before avian animals (including eggs for hatching) or Columbiformes enter the facility.

#### 4) Reinspection and approval of facilities

- a. A privately owned avian animal import quarantine facility must undergo a separate VS inspection and re-approval for each shipment of avian commodities or after any outbreak of disease at the facility to document:
  - 1. Adequate cleaning and disinfection between shipments.
  - 2. Continual adherence to VS approval criteria.
- b. If a facility has experienced an infectious disease outbreak, affected avian animals have been depopulated, and/or the facility has been cleaned and disinfected, it may not be re-inspected and approved for subsequent use until the guidelines in VS Guidance 13403.1 regarding disease outbreaks are met.

#### B. Physical Plant Requirements

#### 1) Location

- a. The facility should be in an area within a reasonable commuting distance (considering travel impediments related to traffic density, ease of access, etc.) to international U.S. ports of entry, which has Customs and Border Protection representation and is at least 1/2 mile from any commercial avian facility. "Commercial avian facility," for the purpose of this document, includes any facility that have live avian animals on the premises, i.e., live bird market, avian animal processing plant, pigeon fanciers, and similar businesses.
- b. The facility must be a self-contained building (or group of buildings) in good repair. It does not need to be a standalone building, as long as the facility can maintain biosecurity and control the number of visitors inside.

#### 2) Construction

- a. Floors and ceilings must be of solid construction materials. Surfaces in containment areas should be durable and impervious to fluids.
- b. All construction materials in contact with any avian animal must be able to withstand repeated cleaning and disinfection.
- c. All exits from the building and the quarantine holding areas must be doublescreened. The interior screens may be metal or nylon mesh and must be intact. The exterior screens must be metal mesh and separated from the

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interior screens. The quarantine containment area must be a sufficient size to prevent overcrowding.

- d. The water supply to the quarantine containment area must be adequate for cleaning and animal maintenance. VS highly recommends an emergency water supply.
- e. Wastewater or other liquid wastes must be treated before draining to an external municipal or septic waste treatment system.
- f. Access to the animal/hatching egg containment areas must be from within the building. Containment areas must not be directly connected to any walls exterior to the building. Instead, they must have a safety or buffer zone incorporated into any entrances or exits from the exterior to limit the possibility of escape of any quarantined animals. Tamper-proof hasps and hinges on doors where pins cannot be removed are required for exterior doors leading into the facility and any other doors leading into bird containment areas.
- g. Avian animals may be contained in individual isolettes that use a standalone air-handling system. Isolettes must be of sound integrity and construction, fully operational, and used per the manufacturer's specifications. Individual isolettes must use appropriately sized, high-efficiency particulate air (HEPA) or antibacterial filters per the manufacturer's recommendations **OR**
- h. Avian animals may be contained in cages, grouped by species. Caretakers must have sufficient husbandry knowledge to ensure that individual needs are met if multiple species are in quarantine together. Cages must be well constructed without loose wires or parts that can cause injury. If perches are used, they must be constructed with materials that can be cleaned and disinfected between shipments. Water and feed containers must also be able to be cleaned and disinfected.
- i. The facility must comply with local ordinances for emergency exiting.
- j. Indoor heating and ventilation systems must be adequate in design and capacity to control the ambient temperature, humidity, and odors at levels that are not injurious to quarantined animals or PS personnel.
- k. Lighting must be adequate for PS inspections and considerate of avian animal husbandry needs.
- I. Feed and bedding storage areas must be kept vermin- and moisture-free.

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- m. The facility must have dedicated office space that is not in contact with avian animal containment areas.
- n. The facility must have a dedicated necropsy or sample collection area and refrigerated storage space for carcasses retained for laboratory examination.

# 3) Biosecurity

The facility has:

- a. Adequate equipment and supplies to keep the facility clean and sanitary and to control pests.
- b. A sufficient stock of disinfectant authorized in 9 CFR 71.10 (or otherwise authorized by VS) to disinfect the entire facility.
- c. A separate area for washing equipment.
- d. At least one unisex shower, for use by one individual at a time, or two walk-through showers, one for men and one for women, with an anteroom on either side of each for clothes storage and changing, at the entrance to the area of the facility involved in quarantine containment and necropsy (the dirty side of the shower(s)). A receptacle to collect clothing worn on the dirty side of the shower(s) must be present in the dirty-side anteroom of each shower. Shower(s) must be kept clean; the facility must have a Standard Operating Procedure (SOP) to help ensure this. Clean laundry, including towels and coveralls, must be available for each showering area(s). Used linens must remain on the dirty side and be placed in receptacles for that use. Toiletries should not be taken home once dedicated to the quarantine functions.
- e. Footbaths with disinfectant must be present at all entries/exits to quarantine containment areas.
- f. A way to dispose of quarantine waste that prevents release of pathogens into the environment, such as incineration or other VS-approved method. Alternatively, facility staff can bag and store waste on the premises until the end of the quarantine. At such times, with negative test results, facility personnel can dispose of the garbage at the operator's discretion. If the facility includes an incinerator, it must be in a separate building on the premises. If the incinerator is on a local site away from the quarantine facility, a VS representative must oversee all transfer of materials to the incinerator. Such transfers must be made in a biosecure manner to prevent release of pathogens into the environment during transport, in accordance with all applicable federal, state, and local regulations. Note: APHIS-operated incinerators are not for private use.

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### 4) Security

The facility must:

- a. Always be locked when facility personnel are not onsite. Access to avian animals is not allowed without VS presence.
- b. Display visible Quarantine Area signs indicating that visitors are prohibited.
- c. Provide VS with phone numbers for contact persons, at least one of whom can be reached at any time.
- d. Use a security system adequate to review and deter unauthorized entry and the escape of quarantined animals. Examples of such systems include fences, guards, and video cameras.
- e. Have a working camera monitoring system for the containment quarantine areas or a window large enough to provide a full view of the containment area (except for clothes-changing and showering areas).
  - 1. Immediately report any breaks or suspected breaks in security to supervising VS personnel. Any quarantined avian animal that escapes from the facility must be reported immediately.
  - 2. Record an initial count of avian animals entering the quarantine, using actual numbers for small consignments or listing the inventory numbers on shipping documents for larger consignments (this should only be done when obtaining an actual number may be injurious to animal health). The facility must reconcile the initial count against a final count made under VS supervision before the release of the animals from quarantine. The count factors in all mortalities occurring during quarantine.

### C. Operating Procedures

1) VS oversight of operations

A VS representative is present for the shipment's arrival at the facility and seals the facility when entry activities have been completed and all facility personnel have exited. Subsequently, until the shipment has been released, facility personnel only enter the facility if a VS representative is present to unseal the facility, monitor the activities of the personnel, and, once all personnel have exited, reseal the facility. In addition:

a. VS personnel visit the quarantine daily from day one (1) through day sixteen (16) of the minimum 30-day quarantine period to review security and

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biosecurity, account for daily deaths, and collect samples, per <u>VSG 13410.2</u> Additional visits will occur based on the following:

- 1. Operator request.
- 2. Animal husbandry needs.

Note: APHIS user fees apply for these activities.

- b. Between day seventeen (17) and the release date, VS personnel visit the quarantine at least every other day to review security and biosecurity and inspect the animals. Additional visits occur based on the following:
  - 1. Operator request. See <u>VS Bulletin 2019</u> for more information on the frequency of visits after day sixteen (16).
  - 2. Animal husbandry needs.
- c. Any additional access requested by the facility operator must be coordinated with VS in advance to ensure appropriate sealing or re-sealing.
- 2) VS oversight of personnel (facility personnel and visitors)
  - a. Visitors may only access the quarantine containment area if VS has approved the visit, or a VS representative is present. Visitors must adhere to all biosecurity standards in effect at the facility when entering and leaving the facility.
  - b. All personnel with access must sign an agreement stipulating that they will follow the terms of the agreement (MOU or CSA) and any related instructions from VS pertaining to quarantine operations.
  - c. All designated personnel employed by the importer, except veterinary practitioners providing emergency care, must provide VS a signed statement stating they will not have contact with any other birds or poultry outside the quarantine for that quarantine cycle and an additional three (3) days afterward.

### 3) Sanitary practices

- a. All equipment used to maintain the quarantine should only be used for this purpose. All equipment within the facility must be cleaned and disinfected before use. This includes hatchery equipment.
- b. Vehicles must be cleaned and disinfected before entering or leaving locations within any quarantined area.

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- c. Any area that held quarantined avian animals or hatching eggs must be cleaned and disinfected after use under the supervision of VS personnel before a new lot may enter the area.
- d. The operator provides clean protective clothing and footwear for anyone granted access to the facility before entry into the quarantine area.
- e. The operator is responsible for properly cleaning and disposing of soiled and contaminated clothing used in the facility. Anyone granted access to the quarantine area must:
  - 1. Shower before entering and when leaving the quarantine containment areas.
  - 2. Wear clean, protective work clothing and footwear provided by the operator while performing quarantine functions.
  - 3. Wear disposable gloves when handling sick animals.
- f. See <u>VS Guidance 13403.1</u> for further information on post-diagnosis guarantine cleanup.
- 4) Handling of avian animals/hatching eggs in quarantine

VS ensures the facility handles avian animals and eggs in the following manner:

- a. Avian animals/hatching eggs quarantined.
  - 1. Each shipment must be placed in the facility on an "all-in-all-out" basis. VS may allow sequential shipments (up to the stipulated holding capacity) to enter a quarantine facility, but the quarantine period begins with the entry of the first shipment and extends until the last shipment has been in the facility for at least thirty (30) days and all the avian animals in the quarantine are eligible for release. If VS agrees to sequential shipments, the last shipment must arrive no later than five (5) days from the first arrival.
  - 2. Shipments of avian animals on the same plane but destined for different federal quarantines must have negative test results before any one quarantine period has ended. If the shipments belong to different importers, VS must make each importer aware of the exposure on the plane and the date the quarantine ends, which will be thirty (30) days from when the last shipment entered quarantine or longer if there are diagnostic reasons to hold the shipment in quarantine.
- b. Hatching eggs shipments remain in quarantine for thirty (30) days plus hatch.

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Eggs laid by avian animals in quarantine, which the importer is interested in incubating, must be placed an additional room designated to hold eggs/chicks during incubation. After hatching, send egg debris to the VS National Veterinary Services Laboratories (NVSL) for testing. Offspring do not have to be tested if avian animals already in quarantine have been tested and the facility owners wait for thirty (30) days to elapse. Once the thirty (30) days have passed, offspring can be released along with other avian animals in the shipment, so long as no disease is found within avian animals in the same shipment.

- c. The operator must provide sufficient bedding and vermin-free, unspoiled feed.
- d. Facility personnel must point out to VS personnel any losses, suspected illness, or deaths of avian animals observed. VS personnel will store (or direct facility personnel to store) carcasses in an onsite refrigerator for later removal or disposal if circumstances are such that they cannot be removed from the facility immediately. Eggs that have not hatched at the end of a hatching cycle must be destroyed under VS supervision.
- e. Avian animals that die enroute from the port of arrival to the facility must be refrigerated on arrival and made available to VS personnel for examination and determination of cause of mortality.
- f. All quarantined avian animals or eggs for hatching will be tested as VS deems necessary to determine health or disease status at the importers' expense.
- 5) Disease found in avian animals during quarantine.
  - a. If either highly pathogenic avian influenza (HPAI) or Newcastle disease (ND) is diagnosed, birds will be refused entry.
  - b. If any other poultry-related disease (not HPAI or ND) occurs, avian animals can be refused entry or will be held for an additional period in quarantine until determined to be free of evidence of any communicable disease as per 9 CFR 93.106 (a).
  - c. If the disease is not poultry-related, avian animals will be held for an additional period in quarantine until they are determined to be disease-free. The importer is allowed to obtain treatment from an outside practicing veterinarian.

#### 6) Recordkeeping

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- a. The facility operator must keep a daily log of personnel entering and exiting the facility.
- b. The facility operator must keep all records related to the quarantine for at least twelve (12) months after the release of the animals. The facility operator must make these records available to VS on request.
- c. The facility must maintain a daily log of mortalities, hatchings, or other quarantine events. The operator must also list all laboratory specimens removed from the facility.
- d. Written SOPs for the following should be made available for VS review upon request:
  - 1. Daily operations.
  - 2. Waste management.
  - 3. Managing birds medically (accredited veterinarian orders).
- e. If a licensed, accredited veterinarian determines medication should be given to birds while in quarantine, there should be standing orders with an annual review of such orders, or sooner, based on the scope of practice of the issuing veterinarian.

### D. Noncompliance with Regulations

- 1) VS may suspend a facility's approval if either of the following occurs:
  - a. The facility is not in compliance.
  - b. The facility fails to prevent, contain, or eliminate a communicable avian disease outbreak.
- 2) VS will specify a period for the operator to correct the deficiency or deficiencies that lead to the suspension. If the operator does not take sufficient remedial action within that time, VS will change the suspension to a revocation.
- 3) VS coordinates suspension or revocation of approval for existing facilities through a discussion led by the VIC of the VS Port Office assigned to oversee the facility with the LAI Director.
- 4) Any VS suspension or revocation of facility approval must be documented in writing and sent from PS to the facility operator. VS will also notify the animal health official of the facility's state.
- 5) VS personnel will oversee operations at any facility that loses approval until animals within that quarantine cycle have completed quarantine requirements.

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The operator incurs all additional costs, including the costs of any extension of quarantine length resulting from the revocation, if applicable.

- 6) Before VS suspends or withdraws facility approval, PS writes to or tells the operator the reasons for the proposed action. If the operator disagrees with the proposed action, they can write to request a hearing to contest the matter.
- 7) VS may withdraw approval of an existing facility at any time before a final determination in a hearing if VS determines such action is necessary to protect animal health or public health, interest, or safety. This withdrawal will continue in effect pending completion of the hearing and any judicial review unless VS orders otherwise.
- 8) In addition to withdrawing approval for the reasons provided in this section, VS will also automatically withdraw approval when the operator of any approved facility notifies VS in writing that the facility is no longer in operation.
- 9) VS can arrange to provide alternative quarantine services for a shipment of commercial birds, poultry, or hatching eggs if the facility's operator is negligent. In such cases, VS may dispose of a shipment or take other measures to recoup VS expenses. The operator can request in writing from VS a copy of an inspection report that determines any negligence.

#### E. Requests for Variances

- 1) Applicants or facility operators may seek a variance to the requirements in this guidance by requesting in writing from VS at least thirty (30) days before any avian animals or hatching eggs covered under a specific CSA or MOU are scheduled to arrive at the facility. VS will only grant variances for justifications it finds acceptable.
- 2) During emergencies such as power failures or natural disasters, VS may, at its discretion, grant permission for the importer or facility operator to break intact USDA seals and enter the facility. However, even under these circumstances, quarantined animals or hatching eggs may not be removed from the facility during quarantine unless specifically approved in advance by VS personnel. Every effort will be made to have a VS inspector present during such emergencies.

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# 7. Inquiries

Please send all inquiries to:

Strategy and Policy, Live Animal Imports 301-851-3300, select option 2

Email: LAIE@usda.gov.