SUPPORTING STATEMENT NATIONAL POULTRY IMPROVEMENT PLAN (NPIP) OMB NO. 0579-0007

NOTE: This information collection combines OMB control numbers 0579-0007 (National Poultry Improvement Plan (NPIP)) and 0579-0474 (National Poultry Improvement Plan and Auxiliary Provisions). Upon approval, OMB Control Number 0579-0474 will be retired.

A. Justification

1. Explain the circumstances that make the collection of information necessary. Identify any legal or administrative requirements that necessitate the collection. Attach a copy of the appropriate section of each statute and regulation mandating or authorizing the collection of information.

The National Poultry Improvement Plan (NPIP) is a voluntary Federal-State-industry program for controlling certain poultry diseases and for improving poultry breeding flocks and products through disease control techniques. It is authorized by the USDA Organic Act of 1944, as amended (7 U.S.C. 429) and the cooperative work is carried out through memoranda of understanding with the participating States. Specific NPIP provisions are contained in Title 9, Parts 56, 145, 146, and 147 of the *Code of Federal Regulations*. The Veterinary Services (VS) unit of USDA's Animal and Plant Health Inspection Service (APHIS) administers these regulations.

The NPIP became operative on July 1, 1935, with the approval of the Secretary of Agriculture and under the authority of a Congressional appropriation for the U.S. Department of Agriculture (USDA) to use with State authorities to administer regulations to improve poultry, poultry products, and hatcheries. The National Turkey Improvement Plan was combined with the NPIP in 1970 to create the current NPIP. Emu, rhea, ostrich, and cassowary breeding flocks are also allowed to participate in the Plan.

The NPIP requires several information collection activities, including memoranda of understanding; flock selecting and testing reports; commercial waterfowl/game bird egg producing flock surveillance reports; sales reports, including sales of hatching eggs, chicks, and poults; breeding flock and slaughter plant participation summaries; hatchery participation summaries; salmonella investigation reports; flock and hatchery inspection reports; sentinel bird identification; salmonella serotyping requests; compartment and component registrations; Newcastle disease (NDv) flock certification and compartmentalization, including testing, diagnosing, flock management, identification, auditing, biosecurity, and surveillance; auditor applications; small chick order printouts; appraisal and indemnity forms; an Initial State Response and Containment Plan; and recordkeeping.

APHIS is asking OMB to approve, for an additional 3 years, its use of these information collection activities in connection with APHIS' efforts to continually improve the health of the U.S. poultry population and the quality of U.S. poultry products.

2. Indicate how, by whom, how frequently, and for what purpose the information is to be used. Except for a new collection, indicate the actual use the agency has made of the information received from the current collection.

APHIS uses the following information activities to continually improve the health of the U.S. poultry population and the quality of U.S. poultry products.

Memorandum of Understanding; (9 CFR 145.2, 146.2); (State)

The NPIP is administered through Memoranda of Understanding (MOU) between VS and participating States. The MOUs set forth the following responsibilities for the Official State Agency in implementing the program:

- Designate a State Contact Representative to administer the MOU activities.
- Plan and execute program work jointly with VS.
- Prepare and submit an annual report (the VS Form 9-4).
- Keep accurate and detailed records of all NPIP work.
- Authorize competent persons to perform inspections; flock selecting; blood collecting and testing; and serological, bacteriological, and other diagnostic work required and to assume responsibility for their work.
- Require State inspectors and authorized agents to work with NPIP coordinators.
- Write and have signed contracts between the Official State Agency and all participants except flock owners affiliated with participating hatcheries.
- Report to NPIP any member of the poultry industry who has discontinued participation.
- Report to NPIP the results of each investigation made to locate the source of infection.
- File with NPIP all current and pending State laws, rules, and regulations related to poultry improvement work.

Flock Selecting and Testing Reports and Commercial Waterfowl/Game Bird Egg Producing Flock Surveillance (VS Form 9-2); (9 CFR 145.3, 9 CFR 145.12; 9 CFR 145.43h; 9 CFR 145.73h; 9 CFR 145.83h); (State, Business); Merged Business respondents from 0579-0474

VS Form 9-2 is used by authorized agents and State inspectors when breeding flocks are selected and tested, and commercial meat-type chicken flocks, table-egg layer flocks, and meat-type turkey flocks are tested. The form provides the following information:

- Name and address of the flock owner.
- The location of the flock.
- The date of the preceding test for this location.
- The supply flock information (name and address of hatchery or dealer).
- The breed, variety, strain, or trade name of the stock, as well as the age of the birds, NPIP approval number, and code identification.

- Source and number (separately) of males and females in the flock, together with the source and date of hatch.
- The type of testing conducted (*pullorum typhoid*, *m. gallisepticum*, *m. synoviae*, avian influenza, or other) with the number of males/females/totals tested, the number of reactors, and the number sent to the laboratory.
- Results of the test (i.e., laboratory findings).

Since many NPIP flocks supply the same hatchery, it is extremely important to know the location of each flock. Table-egg layer flocks also may be contract production flocks for the same processing company, and the meat-type chicken and meat-type turkey flocks may be supply flocks for the same slaughter plant. The information on the VS Form 9-2 is critical during investigations to determine the source of a hatchery-disseminated or egg-transmitted disease or the source of avian influenza (AI) in breeding flocks and commercial table-egg layers, meat-type chickens, and meat-type turkeys.

The regulations also include provisions for regular avian influenza (AI) surveillance of commercial waterfowl and game bird egg-producing flocks, as well as classification for breeding/hatching flocks to qualify for the Newcastle Clean program. Commercial upland game bird or waterfowl meat-producing flocks with ongoing active and passive surveillance programs for H5/H7 AI subtypes approved by the Official State Agency and APHIS must currently submit up to 30 birds of the flock for testing using VS Form 9-2. This form is used by authorized agents and State inspectors to select and test flocks. The form provides the following information:

- Flock owner name and contact information (location)
- Flock owner hatchery affiliation
- Flock owner slaughter plant affiliation
- Flock type, purpose, stock, and classification
- Number of birds tested
- Results of the test.

Owners of hatching flocks wishing to participate in the Newcastle Clean program must monitor the flocks for antibody response using approved serological tests as listed in 9 CFR 145.14 with results compatible with immunological response against ND vaccination. Owners must test a minimum of 30 birds with a serological monitoring program beginning at approximately 10 weeks when more than 4 months of age and prior to the onset of production, and not longer than every 90 days thereafter.

To retain classification for unvaccinated flocks, owners must:

- Have at least 30 birds per flock test negative using an approved test in 9 CFR 145.14 at intervals of 90 days; or
- Test a sample of fewer than 30 birds, with negative results, at any one time if all pens are equally represented and a total of 30 birds is tested within each 90-day period; and
- During each 90-day period, all primary spent fowl, up to a maximum of 30, must test negative to NDv within 21 days prior to movement to slaughter.

Birds must originate from flocks that were vaccinated for NDv using licensed vaccines and compliant with a program to evaluate serological response to NDv vaccination; or, if unvaccinated, have tested negative to NDv.

Report of Sales of Hatching Eggs, Chicks, and Poults (VS Form 9-3); (9 CFR 145.12); (State)

The interstate sales of hatching eggs, chicks, and poults are recorded on VS Form 9-3. The document is used by both APHIS and the receiving State to monitor the movements of these items and track down the source of a poultry disease. The form requires the following information:

- Reporting number.
- Date of shipment.
- Name and physical address of the purchaser.
- Name and physical address of the producer or shipper.
- Name and address of the destination of eggs, chicks, and/or poults.
- Quantity; variety or strain; product (hatching egg, chick, or poult); sex, type and classification of the hatching eggs, poults, or chicks being shipped.
- Any additional remarks.
- Signature of State inspector and date.

<u>Summary of Breeding Flock, Table-Egg Layer Flock, Meat-Type Chicken and Turkey Slaughter Plant Participation (VS Form 9-4); (9 CFR 145.23); (State)</u>

VS Form 9-4 is completed by State animal health authorities and summarizes blood testing and flock participation by classes and breeding status. APHIS offices distribute it to Official State Agencies at the end of the testing year in June; the State agencies must return it to APHIS in July. APHIS uses this information to publish its Tables on Hatchery, Flock, and Slaughter Plant Participation, which help monitor the health of participating flocks.

Report of Hatcheries, Dealers, and Independent Flocks, Table-Egg Producers, Meat-Type Chicken and Turkey Slaughter Plants Participating in the NPIP (VS Form 9-5); (9 CFR 145.33); (State)

Official State Agencies use VS Form 9-5 to record program participant additions and withdrawals. This information must include the location and size of each flock owned by the producer. As the disease status of one flock can affect the health of other flocks, a producer's failure to report the existence and location of all flocks could hurt APHIS' ability to effectively monitor the health of flocks within a State or to promptly contain and eradicate a disease. This document is also used to record a change in disease program classification. This form allows APHIS to monitor plan participation and maintain an up-to-date list of program participants, their addresses, and other important information concerning poultry operations.

<u>Investigation of Salmonella Isolations in Poultry (VS Form 9-7); (9 CFR 145.14, 145.53); (State, Business)</u>

If a multi-State disease outbreak occurs, the NPIP Official State Agency will investigate the outbreak and share the results with all the States involved. The VS Form 9-7 gives the investigating State agency a uniform method of compiling and analyzing information that can be

used to study trends, economic importance, and other matters. This form is arranged in sections so that the disease investigations can be completed in stages by different inspectors, depending on the location of the flock, hatchery, and breeding flock:

Section A: Flock from which infected specimens were submitted

- Name and address of owner.
- Location of flock.
- Breed, strain, or trade name of flock.
- Number of birds in the flock.
- Age of the flock.
- Purpose of flock.
- Estimated effects of the infection.
- Morbidity percentage.
- Suspected source of infection.
- Kinds of specimens collected for laboratory examination.
- Corrective measures applied.
- Whether corrective measures are adequate to prevent disease spread.

Section B: Hatchery source of flock reported in section A

- Name and location of hatchery.
- Approval number.
- Previous isolations of same serotype implicating the hatchery (prior isolations at the same hatchery) and number of such reports.
- Investigation procedures.
- Measures applied to eliminate any infection from premises.

Section C: Parent flock of flock reported in section A

- Name and address of owner of parent flock.
- Location of parent flock.
- Number of birds in parent flock.
- Source of parent flock (males and females).
- Classification and basis of qualifications.
- Examinations for suspected serotype.
- Serial numbers of VS Form 9-6 reports of positive shown and other isolations of other serotypes found during the investigation.
- Additional remarks.
- Signature of State, or another inspector.
- State of inspection.
- Date of signature.

The inspectors obtain some of the needed information by interviewing the appropriate poultry producers. When several States are involved in a pullorum-typhoid infection, the completed form will be sent to each of the States involved so that all of them will be aware of the investigation's outcome.

Flock Inspection and Check Testing Report (VS Form 9-8); (9 CFR 147.1); (State)

VS Form 9-8 is completed by a State inspector to recheck a flock that has already been tested for pullorum-typhoid. This retesting is performed randomly, periodically, and unannounced to verify that pullorum-typhoid testing was correctly carried out on a given flock. The form lists:

- The flock's location.
- The flock owner's name and address.
- The date of the last pullorum-typhoid test.
- The number of birds tested.
- The flock's current NPIP classification.
- Who selected and tested the flock?
- Flock breed, stock, and trade name.
- Number of birds in flock (males and females).
- Whether replacement stock has been purchased (if yes, give source).
- Number of reactors.
- · Health of flock.
- Upkeep of equipment.
- Egg handling conditions.
- Results of the inspection and check-testing.
- Additional remarks.
- Signature of State inspector and date.

Hatchery Inspection Form (VS Form 9-9); (9 CFR 145.12); (State)

A State inspector completes VS Form 9-9 while inspecting a hatchery annually for compliance with NPIP standards. The inspection ensures that the facility's birds originate from approved NPIP sources. The inspector notes:

- The cleanliness of the facility and its equipment.
- The effectiveness of the facility's sanitation procedures.
- The number of incubators and their condition.
- The incubators' makes and models.
- The incubators' egg capacity for both setting and hatching trays.
- The source of the facility's supply flock.
- Whether the flock is a multiplier or primary flock.
- The flock's official health status classification.

Sentinel Birds Banded or Marked for Identification Prior to Flock Vaccination; (9 CFR 145.5, 145.14); (State, Business)

When a federally licensed *Salmonella enteritidis* bacterin is used to vaccinate a flock, 350 birds must remain unvaccinated so they can be used to conduct the necessary serological tests for *S. pullorum and S. gallinarum*. These test birds must be banded or marked so that they can be recognized as sentinel birds.

Request for Salmonella Serotyping (VS Form 10-3); (9 CFR 145.43); (State)

VS Form 10-3 is a National Veterinary Services Laboratories (NVSL) form that must be completed by State or APHIS personnel submitting samples for salmonella serotyping. The form requires the following information:

- Submitter contact information including email, address, phone number, and fax number.
- Personal number of the NVSL submitter.
- Flock owner's city, state, and premises identification number.
- Examinations requested, including whether the sample submitted is an "SE Rule Out" submission.
- Whether the samples were submitted from an NPIP participant.
- Accession or referral number (assigned by the submitter for the submitter's reference).
- Method of payment for services.
- Species or source of the animals in the flock (also covers egg pool samples).
- Clinical role (purpose of samples to confirm infection, monitor the flock, check the flock's environment, conduct research, or other).
- Specimen cultured, including culture number, O group, serotype, and phage type.
- Additional comments.
- Who submitted samples and date submitted?
- NVSL technician who performed serotyping.

If samples were sent to NVSL without this form, laboratory personnel could not identify the sample's flock of origin, or the disease for which the sample is to be tested.

Application For U.S. Avian Influenza and Newcastle Clean Compartment Registration (VS Form 9-20) (previously titled Application For U.S. Avian Influenza Clean Compartment Registration); (9 CFR 145.45 and 145..45a, 9 CFR 145.74 and 74a, 9 CFR 145.84 and 84a); (State, Business)

Compartmentalization applicants must complete this form and submit it for signature to the Official State Agencies of the States in which they operate. The last signing Official State Agency tenders the form to the NPIP, which reviews and determines whether to register the applicant and arrange for an audit. The form requires the following information:

- Company name and mailing address.
- Contact name, telephone number, and alternate contact number.
- Contact fax number and email address.
- Company NPIP classification (US AI Clean, US AI H5/H7, or ND clean).
- Breed/type of poultry.
- NPIP classification sought.
- Compartment mailing address.
- Compartment location (listing all involved States).
- Name of compartment.
- Anticipated type of components (farm, feedmill, hatchery, and egg depot) to add within the compartment.

Applicants must also certify that their operation meets all general and specific management protocols. Further, they must certify that they:

• Are participants in good standing with the NPIP in one of the following programs:

- O U.S. H5/H7 Avian Influenza Clean Program for Turkey Breeding Flocks (9 CFR 145.45).
- U.S. Avian Influenza Clean Program for Primary Egg-Type Chicken Breeding Flocks (9 CFR 145.74).
- O U.S. Avian Influenza Clean Program for Primary Meat-Type Chicken Breeding Flocks (9 CFR 145.84).
- o U.S. ND Clean.
- Compliant with all management procedures, physical requirements, and protocols found in the CFR and the NPIP Program Standards.
- Located in a State or States with an APHIS-approved Initial State Response and Containment Plan (ISRCP) (9 CFR 56.10).
- Perform routine surveillance of all flocks within the compartment in a NPIP-authorized laboratory certified to test for AI.

The primary breeding company's veterinary infrastructure assesses sanitary measures, environmental risk factors, and management and husbandry practices that relate to the separation of the compartment and the health status of the birds contained within the compartment that may affect risk of exposure to H5/H7 AI and NDv. This assessment must include a description of internal monitoring and auditing systems (e.g., quality assurance and quality control programs) to demonstrate the effectiveness of the compartment. APHIS and the Official State Agency use this documentation to approve or deny the classification of the compartment as U.S. Avian Influenza and NDV Clean.

Functional relationships between components of the compartment include traffic movement and flow at and among premises, personnel movement at and among premises, exposure to live bird populations, and any other factors that could affect the compartment's biosecurity. All physical components of the compartment must be maintained in compliance with hygiene and biosecurity procedures for poultry primary breeding flocks and hatcheries in accordance with 9 CFR part 147, and this must be documented in paperwork provided to APHIS so it can monitor the accredited flock's compliance with the requirements.

Application For U.S. Avian Influenza and Newcastle Clean Compartment Component Registration (VS Form 9-21) (previously titled Application For U.S. Avian Influenza Clean Compartment Component Registration); (9 CFR 145.45 and 45a, 9 CFR 145.74 and 74a, 9 CFR 145.84 and 84a); (State, Business)

Applicants for compartmentalization must also submit an application form listing all the different components (farm, feedmill, hatchery, and egg depot) to be included in their compartment. VS Form 9-21, like VS Form 9-20, must be submitted to the Official State Agencies for review and signature before submission to NPIP, and requires the same company contact information and NPIP compliance verification. In addition, the form asks whether the components are new facilities within a certified compartment; whether requalification for the component is due; or whether components previously removed from a certified compartment are to be reinstated. The applicant then must list the numbers of each kind of component to be registered, and provide the components' names, site plans, specifications, and management protocols.

Primary breeder companies must provide documentation establishing that the defined compartment is epidemiologically separated from other poultry and bird populations. The documentation must be approved by the NPIP Official State Agency and APHIS as indicating adequate epidemiological separation to maintain the compartment's separate health status with respect to H5/H7 avian influenza (AI) as well as NDv. The documentation should include descriptions of:

- The physical and spatial factors that separate the compartment from surrounding bird populations and affect the biosecurity status of the compartment.
- Relevant environmental factors that may affect exposure of the birds to AI and NDv.
- The functional boundary and fencing used to control access to the compartment.
- Facilities and procedures to prevent access by wild birds and to provide separation from other relevant hosts.
- The relevant infrastructural factors that may affect exposure to AI and NDv, including the
 construction and design of buildings or physical components, cleaning and disinfection of
 buildings and physical components between production groups with quality assurance
 verification, cleaning and disinfection of equipment, and introduction of equipment or
 material into the compartment.

The primary breeder company's management of biosecurity, surveillance, and disease control efforts must be uniform and equivalent among all compartment components. The company's licensed, accredited veterinarians must oversee and inspect these management practices.

Application For U.S. Avian Influenza and Newcastle Clean Compartment Component Removal (VS Form 9-22) (previously titled Application For U.S. Avian Influenza Clean Compartment Component Removal); (9 CFR 145.45 and 45a, 9 CFR 145.74 and 74a, 9 CFR 145.84 and 84a); (State, Business)

A compartment wishing to remove a component must file VS Form 9-22 with both the applicable Official State Agencies and the NPIP. The form calls for the same company contact and NPIP compliance verification information as VS Forms 9-20 and 9-21, as well as a specific list of the reasons for requesting removal.

<u>Component Audit (9 CFR 145.45 and 45a, 9 CFR 145.74 and 74a, 9 CFR 145.84 and 84a);</u> (<u>Business</u>)

Components are audited by NPIP-certified auditors on a periodic basis to ensure continual compliance with NPIP standards.

Veterinary staff from the Official State Agency and NPIP staff work with licensed, accredited veterinarians to train and certify auditors through Service-approved workshops. The trained auditors conduct biosecurity and operational audits to ensure the compartment's integrity. These audits include evaluation of the critical control points and standard operating practices within the compartment, verification of the health status of the flock(s) contained within the compartment, and examination of the biosecurity and management system of the integrated components of the compartment. The audits:

- Confirm that the primary breeding company's establishments are epidemiologically
 distinct and pathways for the introduction of disease into the compartment are closed
 through routine operational procedures.
- Evaluate and assess the management and husbandry practices relating to biosecurity to determine whether they comply with hygiene and biosecurity procedures for poultry primary breeding flocks and hatcheries in accordance with 9 CFR part 147.

The company must also demonstrate compliance with requirements for remaining in the U.S. Avian Influenza and NDV Clean classifications, surveillance for H5/H7 AI and NDv within the compartment and conducting tests in State or Federal laboratories or in NPIP authorized laboratories. Accredited veterinarians must enforce active and passive surveillance of H5/H7 AI and NDV in primary breeder flocks. The company must maintain baseline health status for all compartment flocks or subpopulations, indicating the dates and negative results of all avian influenza and NDv surveillance and monitoring testing, the dates and history of last disease occurrence (if any), the number of outbreaks, and the methods of disease control applied. Producers must keep documentation on the company's database. APHIS and the Official State Agency verify retention of surveillance and testing documentation.

Auditor Application for NPIP AI Clean Compartment Program (VS Form 9-23) (previously titled Auditor Application for USDA-APHIS-VS-NPIP AI Clean Compartment Program; (9 CFR 145.45, 145.74, 145.84); (Business)

Prospective auditors must apply to the NPIP for acceptance as certified auditors. Applicants must have a qualified sponsor complete Section D of the form and attach a letter of recommendation. The applicant must provide his or her name, home and business addresses, telephone number (and alternate number), fax number, and email address. The applicant must also list his or her qualifications, including colleges or institutions attended; majors and minors and degrees obtained; veterinary license number; citizenship; status as a Federal veterinary medical officer or accredited veterinarian; whether he or she is a member in good standing with the American College of Poultry Veterinarians; and estimated years of poultry experience. The applicant must further explain his or her interest in becoming an auditor and verify that he or she owns no birds of avian species; has not been employed, nor has any spouse, relative, or household member employed by or in any contractual relationship with any companies belonging to the compartment program; will uphold the U.S. veterinarian's oath; has never been convicted of a felony; and has never had his or her license revoked by any State board of veterinary medicine.

Compliance Statement; (9 CFR 145 and 45a; 9 CFR 145.74a; 9 CFR 145.84a); (State, Business, Individual)

Visitors to farms, feed mills, hatcheries, and egg depots must agree in writing to follow company-established protocols regarding personal items and food. Further, APHIS works with the Official State Agencies to ensure the continued integrity of any recognized compartments. Activities include:

- Oversight of the establishment and management of compartments.
- Establishment of effective partnerships between APHIS, NPIP, and the primary breeder industry.
- Approval or denial of classification of compartments as U.S. Avian Influenza and NDV Clean Compartments.

- Official certification of the health status of the compartment, and commodities that may be traded from it through participation in NPIP for avian diseases, including the U.S. Avian Influenza Clean program as described in 9 CFR 145.43(g), 145.73(f), and 145.83(g); the NDV Clean program as described in 9 CFR 145.43(h), 145.73(h), and 145.83(h); and diagnostic surveillance for H5/H7 low pathogenicity AI (LPAI) as described in 9 CFR 145.15.
- Conducting audits as described above.
- Providing, on request, model plans for management and husbandry practices relating to biosecurity in accordance with 9 CFR part 147, risk evaluations with the primary breeder industry (including disease surveillance such as VS Form 9-4, "Summary of Breeding Flock Participation"), and diagnostic capability summaries and systems for initial State response and containment plans in accordance with 9 CFR 56.10 (see below).

Printing and Mailing Computerized Printouts; (9 CFR 147.21); (Business, State)

Hatchery operators who ship large numbers of small chick orders across the United States must provide computerized printouts containing all the information from the VS 9-3. The printout reduces the paperwork load. They are mailed every month to those States that request them. The States use these printouts to monitor the number of small chicks they are receiving.

<u>Description of Animal ID and Traceability Processes; (9 CFR 145.45a, .74a, .84a);</u> (Business); Merged from 0579-0474

A primary breeder company wishing to become NDv certified must provide APHIS with a description of its animal identification and traceability records. Documentation must also include breed identification (NPIP stock code). Providing this information allows APHIS to ensure that the company has an effective flock identification system and traceability system in place.

<u>Laboratory Examination for NDv and Reporting; (9 CFR 145.43h, .73h, .83h); (Business);</u> <u>Merged from 0579-0474</u>

All licensed veterinarians in a State must report NDv outbreaks to the responsible State authority. To accomplish this, all laboratories (private, State, and university laboratories) that perform diagnostic procedures on poultry must examine all submitted cases of unexplained respiratory disease, egg production drops, and mortality for NDv.

Diagnostic Test Evaluation; (9 CFR 147.53); (Business)

The regulations require labs to submit a worksheet for diagnostic test evaluation along with the raw data from the assay response. Worksheets would be obtained by contacting the NPIP Senior Coordinator. When submitting sensitivity and specificity data on a diagnostic test kit pending approval, NPIP-authorized cooperating laboratories will submit to the kit manufacturer all raw data regarding the assay response. Each sample tested will be reported as positive or negative, and the official NPIP procedure used to classify the sample must be submitted in addition to the assay response value. This raw data (e.g., testing results, or the number of samples run and number positive/negative) and the completed worksheet for diagnostic test evaluation must also be submitted to the NPIP Senior Coordinator 4 months before the next scheduled General Conference Committee meeting, which is when assay approval will be sought.

ND Biosecurity Plan; (9 CFR 145.45a, .74a, .84a); (Business); Merged from 0579-0474

The primary breeder company must provide a biosecurity plan for the compartment and all included components. The biosecurity plan should include:

- Requirements that company employees and contract growers limit their contact with live birds outside the compartment.
- An education and training program for company employees and contractors.
- Standard operating procedures for company employees, contractors, and outside maintenance personnel.
- Requirements for company employees and non-company personnel who visit any premises within the compartment.
- Company veterinary infrastructure to ensure flock monitoring and disease diagnosis and control measures.
- Policies for managing vehicles and equipment used within the compartment to connect the various premises.
- Farm site requirements (location, layout, and construction).
- Pest management program (insect and rodent eradication and control).
- Cleaning and disinfection processes.
- Requirements for litter and dead bird removal and/or disposal.
- Sanitation policies, including procedures for managing feed and water supplies.

Indemnity Compliance Agreement (9 CFR 56.4); (State, Business); Merged from 0579-0474

Any disposal of poultry infected with or exposed to H5/H7 LPAI for which indemnity compensation is requested must be performed under a compliance agreement between the claimant, the Cooperating State Agency, and APHIS. APHIS reviews claims for indemnity compensation for disposal to ensure that all expenditures relate directly to activities described in 9 CFR 56.5 and in the initial State response and containment plan described in 9 CFR 56.10 and below. If disposal is performed by the Cooperating State Agency, APHIS will compensate the Cooperating State Agency for disposal under a cooperative agreement.

The compliance agreement is a comprehensive document that describes the depopulation, disposal, and cleaning and disinfection plans for poultry infected with or exposed to H5/H7 LPAI, or a premises that contained such poultry. The compliance agreement sets out cost estimates that include labor, materials, supplies, equipment, personal protective equipment, and any additional information APHIS deems necessary. The compliance agreement indicates what tasks will be completed, who will be responsible for each task, and how much the work is expected to cost. Once work associated with the compliance agreement is completed, receipts and documentation detailing the activities specified in the agreement should be forwarded to APHIS for review, approval, and final payment. This documentation should be submitted to APHIS no later than 30 days after the quarantine release of the affected or exposed premises.

Appraisal and Indemnity Claim for Animals Destroyed or Materials Destroyed (VS Forms 1-23, 1-24, and 1-26); (9 CFR 56.4, 56.9); (State, Business)

VS Forms 1-23, 1-24, and 1-26 are included as placeholders in the event a highly pathogenic avian influenza, Newcastle disease, or similar disease outbreak occurs in the poultry industry. The forms record appraisals made and approved for payment to owners or claimants. They are completed by either personnel from the State VS office or a Federal and State approved appraiser (usually a Federal employee) with input from the flock owner. The forms are signed by both the appraiser and the owner and list:

- Premises information: Name, identification number, where birds are located (address, city, county, State, ZIP code).
- Claimant full legal name and address (the claimant may be the poultry owner and/or contract grower, as applicable).
- Claimant Data Universal Number System (DUNS) number and confirmation that the claimant has registered in the Federal System for Award Management (SAM). For electronic payment processing, the claimant name on the VS 1-23 must be the same as the vendor name associated with the DUNS number provided.
- Confirmation of mortgage status (claimant initials required): If there is a mortgage, the form must also be signed by each person holding a mortgage. By signing the form, each mortgage holder is consenting to the payment of indemnity to the owner or lien holder.
- Appraisal Date: For indemnified birds and eggs, this is the date that the appraisal values are assigned to the birds or eggs (usually the presumptive positive date). For indemnified materials, this is the date that the fair market value was determined.
- For indemnified birds and eggs, detailed specific flock information as described in the Appraisal and Indemnity Request Form (flock type, age, sex, inventories, organic status, number of animals/eggs for which the owner is seeking payment, and the appraised value of each animal/lot of eggs using criteria specific to each type of poultry/flock).
- The date of cleaning and disinfection.
- Country Code.
- Congressional District, if known (often APHIS personnel must add this later).
- A statement (yes or no) where the recipient attests that this is the only payment received for this incident. If "no," APHIS needs to know who provided the additional payment, how much was received, and the date. APHIS would then reduce the indemnity payment by that amount.

If applicable, separate forms are prepared for owners and growers. APHIS personnel obtain the claimant's signature (poultry owner and/or contract grower). If payment is to be split, the owner and the grower will sign separate forms. The signatures indicate agreement with the appraised value of each animal. The appraiser also signs the form.

<u>Initial State Response and Containment Plan; (9 CFR 56.10); (State); Merged from 0579-0474</u>

For poultry owners within a State to be eligible for indemnity and/or compensation for up to 100 percent of eligible indemnity costs, the State in which the poultry participate in the Plan must have in place an initial State response and containment plan approved by APHIS. The initial State response and containment plan must be developed by the Official State Agency. In States where the Official State Agency is different than the Cooperating State Agency, the Cooperating

State Agency must also participate in the development of the plan. The plan must be administered by the Cooperating State Agency of the relevant State. This plan must include:

- Provisions for a standing emergency disease management committee, regular meetings, and exercises, including coordination with any affected Tribal governments.
- A minimum biosecurity plan followed by all poultry producers.
- Provisions for adequate diagnostic resources.
- Detailed, specific procedures for initial handling and investigation of suspected cases of H5/H7 LPAI.
- Detailed, specific procedures for reporting test results to APHIS. These procedures must be developed after appropriate consultation with poultry producers in the State and must provide for the reporting only of confirmed cases of H5/H7 LPAI in accordance with 9 CFR 146.13.
- Detailed, strict quarantine measures for presumptive and confirmed index cases.
- Provisions for developing flock plans for infected and exposed flocks.
- Detailed plans for disposal of infected flocks, including preexisting agreements with regulatory agencies and detailed plans for carcass disposal, disposal sites, and resources for conducting disposal, and detailed plans for disposal of materials that come into contact with poultry infected with or exposed to H5/H7 LPAI.
- Detailed plans for cleaning and disinfection of premises, repopulation, and monitoring after repopulation.
- Provisions for appropriate control/monitoring zones, contact surveys, and movement restrictions.
- Provisions for monitoring activities in control zones.
- If vaccination is considered as an option, a written plan for use in place with proper controls and provisions for APHIS approval of any use of vaccine.
- Plans for H5/H7 LPAI-negative flocks that provide for quarantine, testing, and controlled marketing.
- Public awareness and education programs regarding avian influenza.

Recordkeeping; (9 CFR 145.4, 9 CFR 145.12, 9 CFR 145.45, 9 CFR 145.74, 9 CFR 145.84, 9 CFR 146.4, 9 CFR 146.12); (State, Business)

Plan participants must maintain records of purchases and sales and the identity of products handled in a manner satisfactory to State veterinary authorities. The records of all flocks maintained primarily to produce hatching eggs must be examined annually by a State inspector. These records must be maintained for 3 years and include VS Forms 9-2, 9-3, 9-4, and 9-5; set and batch records; egg receipts; and egg/chick orders or invoices.

3. Describe whether, and to what extent, the collection of information involves the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses, and the basis for the decision for adopting this means of collection. Also describe any consideration of using information technology to reduce burden.

VS Forms 1-23, 1-24, and 1-26 are fillable and initiated by VS.

The VS 9-2 form's original purpose is not being fulfilled due to advances in technology. APHIS has studied and discussed making the VS Form 9-2 electronic. The VS 9-2 needs to be a submission form rather than a summary of findings form. Therefore, APHIS hopes to move to an electronic form once it settles other outstanding issues of security and numeration.

VS Forms 9-3, 9-4, 9-5, 9-7, 9-8, and 9-9 are now electronic and accessed and completed within the NPIP database at www.poultryimprovement.org. A username and password is required to access the database and use the forms. Access to the forms is requested by the Official State Agency and approved by the NPIP office.

VS Forms 9-20, 9-21, 9-22, and 9-23 forms are fillable and will be available on the NPIP website.

VS Form 10-3 is a screen-fillable Adobe PDF form available from the APHIS Forms Library Web page at http://www.aphis.usda.gov/library/forms/pdf/VS_Form10_3.pdf. It may be completed and saved or printed within the user's Web browser. APHIS plans to make it one of the next NVSL electronic submission forms for NCAH Portal access.

4. Describe efforts to identify duplication. Show specifically why any similar information already available cannot be used or modified for use for the purpose described in item 2 above.

The information that APHIS collects is not available from any other source. APHIS is the only Federal agency responsible for preventing the entry of exotic animal and poultry diseases into the United States.

5. If the collection of information impacts small businesses or other small entities, describe any methods used to minimize burden.

APHIS estimates approximately 5 percent of the business respondents are considered small entities. The information APHIS collects is the minimum needed to protect the U.S. poultry population from communicable diseases.

6. Describe the consequence to Federal program or policy activities if the collection is not conducted or is conducted less frequently, as well as any technical or legal obstacles to reducing burden.

If the information were collected less frequently or not collected, APHIS could not effectively monitor the health of the nation's poultry population.

- 7. Explain any special circumstances that require the collection to be conducted in a manner inconsistent with the general information collection guidelines in 5 CFR 1320.5.
 - requiring respondents to report information to the agency more often than quarterly;
 - requiring respondents to prepare a written response to a collection of information in fewer than 30 days after receipt of it;
 - requiring respondents to submit more than an original and two copies of any document;
 - requiring respondents to retain records, other than health, medical, government contract, grant-in-aid, or tax records for more than 3 years;
 - Plan participants must maintain records of purchases and sales and the identity of products handled in a manner satisfactory to State veterinary authorities. The records of all flocks maintained primarily to produce hatching eggs must be examined annually by a State inspector. Includes VS Forms 9-2, 9-3, 9-4, and 9-5; set and batch records; egg receipts; and egg/chick orders or invoices.
 - in connection with a statistical survey, that is not designed to produce valid and reliable results that can be generalized to the universe of study;
 - requiring the use of a statistical data classification that has not been reviewed and approved by OMB;
 - that includes a pledge of confidentiality that is not supported by authority
 established in statute or regulation, that is not supported by disclosure and data
 security policies that are consistent with the pledge, or which unnecessarily impedes
 sharing of data with other agencies for compatible confidential use; or
 - requiring respondents to submit proprietary trade secret, or other confidential information unless the agency can demonstrate that it has instituted procedures to protect the information's confidentiality to the extent permitted by law.

There are no special circumstances associated with this information collection. This information collection is conducted in a manner consistent with the guidelines established in 5 CFR 1320.5.

8. Describe efforts to consult with persons outside the agency to obtain their views on the availability of data, frequency of collection, the clarity of instructions and recordkeeping, disclosure, or reporting form, and on the data elements to be recorded, disclosed, or reported. If applicable, provide a copy and identify the date and page number of publication in the Federal Register of the agency's notice, soliciting comments on the information collection prior to submission to OMB.

APHIS engaged in productive consultations with the following individuals in connection with the information collection requirements associated with this program. APHIS contacted them by email and phone to discuss the information APHIS collects to administer its NPIP activities. We discussed with them how we and they obtain the necessary data and how frequently; how much data is available; the convenience and clarity of reporting formats and other collection instruments; and the clarity of, and necessity for, any recordkeeping requirements. The respondents stated via email or phone that they had no concerns with any of these items and had no further recommendations.

Dr. Kate Hayes, Vice President of Veterinary Services Aviagen, North America 920 Explorer Blvd. NW Huntsville, AL 35806

Phone: 256-732-3574

Email: khayes@aviagen.com

JC Essler, Executive Vice-President Texas Poultry Federation 595 Round Rock Drive W, Suite 305 Round Rock, TX 78681

Phone: 512-248-0600

Email: jcessler@texaxpoultry.org

Melissa Phillips, QA Auditor/NPIP Coordinator

Cobb-Vantress

Phone: 606-340-2713

Email: melissa.phillips@cobb-vantress.com

On Monday, July 19, 2021, APHIS published in the Federal Register (86 FR 37989) a 60-day notice seeking public comments on its plans to request a 3-year renewal of this collection of information. APHIS received no comments from the public.

9. Explain any decision to provide any payment or gift to respondents, other than reenumeration of contractors or grantees.

This information collection activity involves no payments or gifts to respondents.

10. Describe any assurance of confidentiality provided to respondents and the basis for the assurance in statute, regulation, or agency policy.

No additional assurance of confidentiality is provided with this information collection. Any and all information obtained in this collection shall not be disclosed except in accordance with 5 U.S.C.552a.

11. Provide additional justification for any questions of a sensitive nature, such as sexual behavior or attitudes, religious beliefs, and other matters that are commonly considered private. This justification should include the reasons why the agency considers the questions necessary, the specific uses to be made of the information, the explanation to be given to persons from whom the information is requested, and any steps to be taken to obtain their consent.

This information collection activity will ask no questions of a personal or sensitive nature.

- 12. Provide estimates of the hour burden of the collection of information. Indicate the number of respondents, frequency of response, annual hour burden, and an explanation of how the burden was estimated.
 - Indicate the number of respondents, frequency of response, annual hour burden, and an explanation of how the burden was estimated. If this request for approval covers more than one form, provide separate hour burden estimates for each form and aggregate the hour burdens in Item 13 of OMB Form 83-1.

See APHIS Form 71. Burden estimates were developed from discussions with flock owners, breeders, hatchery operators, table-egg producers, meat-type chicken and turkey slaughter plant workers, personnel at approved laboratories, and State personnel who assist with the program.

 Provide estimates of annualized cost to respondents for the hour burdens for collections of information, identifying and using appropriate wage rate categories.

APHIS estimates the total annualized cost to the above respondents to be \$5,641,717. APHIS arrived at this figure by multiplying the hours of estimated response time (111,339 hours) by the estimated average hourly wage of the above respondents (\$34.97) and then multiplying the result by 1.449 to capture benefit costs.

The average hourly rates used to calculate the estimate are for flock owners, breeders, hatchery operators, and table egg producers (\$36.93, SOCC 11-9013 (farmers, ranchers, and other agricultural managers)); slaughterers and meat packers (\$15.00, SOCC 51-3023); personnel at approved laboratories (\$35.84, SOCC 19-1011 (animal scientists)); and State personnel assisting with the program (\$52.09, SOCC 29-1131 (veterinarians)).

The rates were found at the U.S. Bureau of Labor Statistics website https://www.bls.gov/oes/current/oes_stru.htm.

According to DOL BLS news release USDL-21-0437 released March 18, 2021, employee benefits account for 31 percent of employee costs, and wages account for the remaining 69 percent. Mathematically, total costs can be calculated as a function of wages using a multiplier of 1.449.

13. Provide estimates of the total annual cost burden to respondents or record keepers resulting from the collection of information (do not include the cost of any hour burden shown in items 12 and 14). The cost estimates should be split into two components: (a) a total capital and start-up cost component annualized over its expected useful life; and (b) a total operation and maintenance and purchase of services component.

Businesses reimburse APHIS for the audits they receive. The average cost for a complete audit is \$50,000 and the agency averages three per year for a total of \$150,000.

14. Provide estimates of annualized cost to the Federal government. Provide a description of the method used to estimate cost and any other expense that would not have been incurred without this collection of information.

See APHIS Form 79. The annual cost to the Federal government is estimated to be \$8,747,530.

15. Explain the reasons for any program changes or adjustments reported in Items 13 or 14 of the OMB Form 83-i.

	Requested	Program Change Due to New Statute	Program Change Due to Agency Discretion	Change Due to Adjustment in Agency Estimate	Change Due to Potential Violation of the PRA	Previously Approved
Annual Number of Responses	234,630	0	118	(451)	0	234,963
Annual Time Burden (Hours)	111,339	0	551	(6,470)	0	117,258

This request for renewal is for 234,630 estimated responses and 111,339 estimated burden hours, reflecting a decrease of 333 responses and of 5,919 hours of burden from the previous request. The number of respondents decreased from 6,851 to 2,867.

The changes are the result of the leveling off of participation in the NPIP compartmentalization and AI and ND control programs, despite the merging of the description of animal identification and traceability processes, laboratory examination for NDv and reporting, the biosecurity plan, and the initial State response and containment plan from 0579-0474.

An increase of 7 hours in the total annual time estimate was due to a rounding adjustment in the following activities: Flock Selecting and Testing Reports-Flock Test Meat Chicken Slaughter (State) and (Business); Flock Selecting and Testing Reports-Flock Test Meat Turkey Slaughter Plants (State); Investigation of Salmonella Isolations in Poultry (Business); Flock Inspection and Check Testing Report (State); Compliance Statement (Individual); and Printing and Making Computerized Printouts (State) and (Business).

The following two tables provide a summary of the adjustments and discretionary changes (new activity or program merger) for this information collection. Under respondents (RESP), "S" refers to state, local and tribal governments; "B" refers to businesses.

CHANGES IN RESPONSES

<u>9 CFR</u>	<u>ACTIVITY</u>	RESP	PREVIOUS RESPONSES	NEW RESPONSES	DIFFERENCE	TYPE OF CHANGE
145.3, .12	VS 9-2, Flock Select & Test	S	20,139	20,467	328	adjustment
145.45 et al	VS 9-20	S	7	14	7	adjustment
145.45 et al	VS 9-20	В	7	3	(4)	adjustment
145.45 et al	VS 9-21	S	175	28	(147)	adjustment
145.45 et al	VS 9-21	В	175	30	(145)	adjustment
145.45 et al	VS 9-22	S	1	43	42	adjustment
145.45 et al	VS 9-22	В	1	3	2	adjustment
145.45 et al	Component Audit	В	300	108	(192)	adjustment
145.45 et al	Compliance Statement	S	249	14	(280)	adjustment
145.45a et al	Description of ID/Trace	В	0	3	3	program (merger)
145.43h et al	Lab Exam for ND/Reporting	В	0	1	1	program (merger)
145.45a et al	ND Biosecurity Plan	В	0	1	1	program (merger)
56.4	Indem Compl Agree	S	0	1	1	program (merger)
56.4	Indem Compl Agree	В	0	1	1	program (merger)
56.10	ISRCP	S	0	49	49	program (merger)
			21,054	20,766	(333)	

CHANGES IN BURDEN HOURS

<u> 9 CFR</u>	ACTIVITY	RESP	PREVIOUS BURDEN	NEW <u>BURDEN</u>	DIFFERENCE	TYPE OF CHANGE
145.3, .12	VS 9-2, Flock Select & Test	S	3,222	3,275	53	adjustment
145.45 et al	VS 9-20	S	7	14	7	adjustment
145.45 et al	VS 9-20	В	280	120	(160)	adjustment
145.45 et al	VS 9-21	S	175	28	(147)	adjustment
145.45 et al	VS 9-21	В	7,000	1,200	(5,800)	adjustment
145.45 et al	VS 9-22	S	1	18	17	adjustment
145.45 et al	VS 9-22	В	1	3	2	adjustment
145.45 et al	Component Audit	В	600	216	(384)	adjustment
145.45 et al	Compliance Statement	S	15	4	(11)	adjustment
	Description of ID/Trace	В	0	3	3	program (merger)
145.43h et a	l Lab Exam for ND/Reporting	В	0	1	1	program (merger)
145.45a et a	ND Biosecurity Plan	В	0	1	1	program (merger)
56.4	Indem Compl Agree	S	0	1	1	program (merger)
56.4	Indem Compl Agree	В	0	1	1	program (merger)
56.10	ISRCP	S	0	490	490	program (merger)
					7	rounding errors
			11,301	5,375	(5,919)	

16. For collections of information whose results are planned to be published, outline plans for tabulation and publication.

The Summary of Breeding and Table-Egg Layer Flock and Meat-Type Chicken and Turkey Slaughter Plant Participation (VS Form 9-4) contains a summary of blood testing work and of flock participation by classes and breeding status. It is used to publish APHIS' Tables on Hatchery, Slaughter Plant, and Flock Participation, an important tool in monitoring the health status of NPIP flocks.

17. If seeking approval to not display the expiration date for OMB approval of the information collection, explain the reasons that display would be inappropriate.

The VS Forms 1-23, 1-24, and 1-26 are used in multiple information collections. It would not be practical to include an OMB expiration date because of the various expiration dates for each collection. APHIS is seeking approval to not display the OMB expiration date on these forms. Also, APHIS is exploring creating one information collection for animal and animal product indemnity which will include these forms. It is also considering making these forms common forms.

The VS Forms 9-2 is a paper form and including an expiration date would require the destruction of unused stocks during the information collection renewal window. Rendering the forms obsolete because of the date would be wasteful; further, managing a form's OMB IC expiration date as well as its version date unnecessarily complicates form management efforts. APHIS is seeking approval to not display the OMB expiration date.

VS Forms 9-20, 9-21, and 9-22 will be posted to the NPIP online website for downloading. APHIS requests an expiration date not be included on the forms to preclude users from downloading and locally storing a form that may accidentally become obsolete at the next information collection renewal. Applying a PRA IC expiration date as well as a form version date unnecessarily complicates form management efforts.

APHIS will display the expiration date on the remaining forms in this information collection.

APHIS has many forms which are used across multiple ICRs. In most instances, the ICRs have different renewal dates and keeping up with expiration dates can be difficult. At this time, IMB is working on developing a generic ICR for forms utilized across multiple collections to streamline and improve forms being utilized.

18. Explain each exception to the certification statement, "Certification for Paperwork Reduction Act."

APHIS can certify compliance with all the provisions under the Act.

B. Collections of Information Employing Statistical Methods

No statistical methods are associated with the information collection activities used in this program.