



Department  
for Environment  
Food & Rural Affairs

# Report of an audit to the United States of America between 10 and 17 February 2023 to review poultry compartments providing assurances of freedom from avian influenza and Newcastle disease

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# Executive summary

The report sets out the findings and conclusions of the audit undertaken by the Department for Environment, Food and Rural Affairs (Defra) in the United States of America (US) between 10 and 17 February 2023.

The audit, led by Defra's UK Office for SPS Trade Assurance, assessed the design, management and administration of the breeding poultry compartment scheme in the US, which is designed to provide the necessary animal health assurances for the continued export of hatching eggs and day-old chicks to Great Britain from areas under restrictions following an avian influenza (AI) or Newcastle disease (ND) outbreak in the US. Currently there are 2 certified compartments in the US, which belong to 2 individual breeding companies with primary broiler breeder flocks. The first US AI Clean Compartment was established and certified in 2017, with the second certified in 2019.

The assessment was carried out at the request of the Animal and Plant Health Inspection Service (APHIS) of the United States Department of Agriculture (USDA) as the US central competent authority. The US competent authority completed a pre-audit questionnaire on its compartment scheme in January 2023. During the in-country audit Defra also assessed:

- the efficacy of the organisation and controls delivered by the competent authorities of the US for the compartment scheme
- the effectiveness of the biosecurity of US compartments to prevent introduction of disease
- the robustness of the certification procedures.

The audit team visited the central competent authority, the National Poultry Improvement Plan Office (NPIP), several sites operated by the 2 companies that have approved poultry compartments, and the Georgia Poultry Laboratory Network (GPLN). GPLN is an approved laboratory within both the NPIP and the National Animal Health Laboratory Network (NAHLN) and also serves as the Official State Agency (OSA) for the state of Georgia.

This report concludes that the US competent authorities have a well-established compartment scheme with 2 large operational compartments. The NPIP and within that, the US Avian Influenza Clean Compartment programme, is overseen and managed by a dedicated team of competent APHIS staff. The US Compartment Program Standards are comprehensive, clearly written, and accessible online, including practical checklists to aid auditing processes required for the initial certification and annual recertification. The rotation of trained and certified auditors and the random selection of farm components for annual recertification audits guarantees a successful and consistent certification and reapproval process of compartments. The biosecurity requirements of the Compartment Program Standards for the US AI and ND Clean Compartment programmes are broadly equivalent to those required by Great Britain's Compartment Scheme Schedules.

Whilst the framework exists within the US Compartment Program Standards for the establishment of a 'ND Clean Compartment', the ND Clean Compartment programme has not yet been implemented. With regards to ND, the vaccination and testing requirements of

the US AI Clean Compartment programme are similar to those of Great Britain's Compartment Scheme and provide assurances that the approved compartments are free from ND. Therefore, despite the current lack of a formal ND Clean Compartment certification in the US, the existing assurances provided through requirements for vaccination and testing meet the standard of Great Britain's Compartment Scheme.

The report makes recommendations to the US competent authorities in relation to observations and findings made by the audit team during its visit to the US. The recommendations concern updates and clarifications to the Compartment Program Standards and audit checklists, biosecurity protocols, routine testing requirements and quarantine procedures for hatching eggs, day-old chicks and birds entering compartments.

## 1. Introduction

The Department for Environment, Food and Rural Affairs (Defra) undertook a comprehensive audit mission to the United States of America to assess the US Avian Influenza and Newcastle disease Clean Compartment Programs (the "Programs") between 10 and 17 February 2023. The audit was carried out at the request of the Central Competent Authority of the United States by a team of 5 auditors from Defra and the Animal and Plant Health Agency (APHA). The team divided into 2 sub-teams with each sub-team focusing on one of the 2 poultry companies currently participating in the US compartment scheme; the 'US Avian Influenza Clean Compartment' programme. Both sub-teams were accompanied by representatives of the Animal and Plant Health Inspection Service (APHIS) for the duration of the audit.

The opening meeting took place on 10 February 2023 with representatives of the central competent authority at the United States Department of Agriculture (USDA) in Washington, D.C. Additional information was provided to the audit team at the opening meeting and throughout the audit by the relevant representatives of the competent authority to supplement the comprehensive material provided by the US authorities in their response to the pre-audit questionnaire.

The closing meeting was held on 17 February 2023 at the offices of the Georgia Poultry Laboratory Network (GPLN) where the audit team presented a draft summary of main findings, which was acknowledged by representatives of the competent authority.

### 1.1 Background

Compartmentalisation is a principle first proposed by the World Organisation for Animal Health (WOAH) in 2004 as an alternative means to regionalisation, enabling international trade to continue from high biosecurity premises during a disease outbreak whilst mitigating disease risk to an acceptable level.

A 'compartment' is a group of related farms and associated facilities, defined primarily by shared management and husbandry practices related to biosecurity. This differs from

regionalisation or zoning, where the animal health status of a subpopulation is defined based on its geographical location and measures are applied to defined areas.

The UK was the first country to approve a compartment in breeding poultry in 2010 and successfully demonstrate the effectiveness of the system to trading partners. The US approved their first breeding poultry compartment in 2017.

Regionalisation agreements are currently operating between the UK and US, which allow trade of live poultry and hatching eggs to continue when either country is affected by avian influenza (AI) or Newcastle disease (ND), subject to certain restrictions in disease control zones around infected premises.

One aim of the US breeding poultry compartment is to enable consignments of live poultry (hatching eggs and day-old poultry) to be certified in accordance with the compartment freedom requirements against AI and ND of the relevant health certificates in case the source premises are located within an area under animal health restrictions for either of those diseases, due to the stringent biosecurity measures required on compartment premises.

## 1.2 Objective, scope, and legal basis

### 1.2.1 Objective

APHIS requested an assessment by Defra to approve the US AI and Newcastle disease Clean Compartment programmes to enable continued safe trade in poultry genetic material from premises with a verified high animal health status and enhanced biosecurity. In response to this request, Defra carried out an assessment of the 'US Avian Influenza and Newcastle Disease Clean Compartment' programmes on behalf of the Devolved Administrations of Great Britain (England, Scotland, and Wales) to determine whether it provides equivalent animal health guarantees to Great Britain's Compartment Scheme.

The assessment consisted of an initial information gathering exercise and desktop review following completion of a questionnaire by the US central competent authority in January 2023. This was followed by an in-country verification audit from 10 to 17 February 2023. Further information gathering was then conducted during the audit covering:

- general background information on the US competent authority for animal health
- poultry demographics and the US poultry industry
- the structure and administration of the US poultry compartments
- the effectiveness of the US compartments to prevent introduction of AI and ND
- the systems in place to ensure continued disease surveillance to guarantee freedom from AI and ND
- the efficacy of the organisation, supervision and controls delivered by the competent authorities of the US for the compartment scheme
- the robustness of the certification procedures.

## 1.2.2 Scope

The following were included in the scope of the assessment:

- the organisation of the competent authorities of the US, including veterinary supervision, control, and statutory surveillance and diagnostic capability
- disease history, relevant disease control protocols (including reporting) and contingency planning for AI and ND
- the structures, organisation, management controls and administration of the US compartment scheme to provide the required guarantees
- an assessment of the approval / authorisation and continuous supervision of compartments
- an assessment on the movement of animals and traceability
- an evaluation of export certification processes.

## 1.2.3 Legal basis and legal references

The audit was conducted under the general provisions of the following regulations:

Retained Regulation 2017/625 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection.

The legal basis for the establishment of poultry compartments in Great Britain is retained [Regulation 616/2009](#). This Regulation contains the requirements for the approval of poultry compartments with respect to AI and details additional preventive biosecurity measures in these compartments.

Great Britain's Compartment Scheme for Breeding Poultry is based on the above retained Regulation but adopts a more stringent suite of biosecurity measures and conditions with the aim of providing added assurances of freedom from AI and ND in the event of outbreaks of those diseases in the UK. The Summary document provides an overview of the conditions that are required. The detailed rules for operating UK compartments are set out in the Schedules for Hatcheries and Schedules for Flock Farms. These documents are available [online](#)<sup>1</sup>.

A full list of legislative instruments relevant to the audit referred to in this report is included in the Annex I.

## 1.2.4 Itinerary

The itinerary outlines the establishments and offices visited during the audit to meet the objectives and scope of the audit. The audit team split into 2 sub-teams to enable the team

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<sup>1</sup> <https://britishpoultry.org.uk/about-bpc/defra-compartments/>

to visit sites belonging to both companies (“Company A” and “Company B”) with approved compartments.

### **Competent authority meetings**

- Opening meeting (Washington, D.C.)
- National Poultry Improvement Plan (Conyers, GA)
- Closing meeting (GPLN, Gainesville, GA)

### **Compartment company offices**

- Company A
- Company B

### **Operator sites (physical and virtual visits)**

- 4 pedigree farms
- One great grandparent farm
- 3 hatcheries
- One egg depot
- 2 feed mills

### **Laboratories**

- One company laboratory
- One non-profit state laboratory under Official State Agency (OSA) management (GPLN, Gainesville, GA)

## 2. Audit findings

### 2.1 Legislation

#### 2.1.1 US Code of Federal Regulations and Compartment Program Standards

Overall, the provisions of the US national legislation and the US Compartment Program Standards are in line with Great Britain's relevant legislation and Great Britain's Compartment Scheme Schedules.

The main regulations providing the US legal basis for the establishment and official supervision of the US poultry compartment scheme are as follows:

- The Animal Health Protection Act (AHPA) of 2002 provides APHIS with its regulatory authority to act on behalf of the Secretary of Agriculture to prevent and control endemic, exotic and emerging animal diseases and pests.
- Subchapter G (Livestock Improvement, Part 145) of Title 9 of the Code of Federal Regulations (9 CFR) details the regulations for the NPIP programme for Breeding Poultry and provides APHIS with the authority over the administration of breeding poultry through the NPIP using powers within the AHPA.
- 9 CFR 145.45, 145.74 and 145.84 provide APHIS the powers to grant or deny approval to eligible poultry premises under the relevant AI or ND free compartment scheme. The same regulations give APHIS the responsibility to undertake the required official supervision and audit duties on premises approved to be part of a compartment.

Poultry premises wishing to be approved under the Compartment Program must be approved under the relevant [National Poultry Improvement Plan \(NPIP\) Program Standards](#)<sup>2</sup>.

The approval and supervision under the AI and ND Compartment Programs are carried out using 2 core documents that effectively form the Compartment Program Standards: the Management Guidelines and the Audit Checklists. The most up to date version of these Standards is published [online](#)<sup>3</sup>.

#### 2.1.2 Revising and updating the Compartment Program Standards

There is a formal process through which amendments can be made to the Compartment Program Standards through the NPIP Biennial Conference. This process is regulated by the

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<sup>2</sup> <https://www.poultryimprovement.org/documents/ProgramStandardsA-E.pdf>

<sup>3</sup> [NPIP | Animal Health \(poultryimprovement.org\)](#)

CFR and listed in [9 CFR Part 147 - Auxiliary Provisions on National Poultry Improvement Plan](#)<sup>4</sup>.

The Biennial Conference is a meeting of elected delegates from state and federal bodies and the US poultry industry representing all 50 participating states and Puerto Rico. It is a forum to discuss, debate, and vote on changes and improvements to the provisions of all NPIP programmes within 9 CFR, including the US AI Clean Compartment Program Standards. Amendments are proposed by the delegates prior to the Biennial Conference. The proposed amendments are voted on and once approved by the conference are subject to a public comment period. Following this, the updates are recommended to the USDA for incorporation into the NPIP standards. It is uncommon for the USDA to reject the recommendations of the conference, but the USDA's right to do so is an essential part of its supervisory role of the NPIP. The USDA publishes the recommendations in the Federal Register within 14 months following the NPIP Biennial Conference.

The most recent Biennial Conference was held in June 2022, and while some proposed changes were approved, these changes have not yet been integrated and implemented into the Compartment Program Standards. This is due to the delay between the conference's approval of an amendment and its approval and publication by the USDA. Until USDA approval has been granted and the amendment adopted into 9 CFR, these changes cannot be officially adopted into the Compartment Program Standards or implemented in the field.

Although the above process ensures that all views are considered when amending the compartment standards, it takes a considerable amount of time from the approval of an amendment at the Biennial Conference to the adoption of the amendment by the USDA (up to 2 years). Being unable to implement amendments until after the full USDA approval process clearly affects the agility of the system. Decoupling the Compartment Program Standards from the CFR may improve the time from approval to implementation and allow for a reduced period of time required to implement technical changes to the programme.

## 2.2 Competent authority assessment

The basic structure of the competent authority, as understood by the audit team at the time of the audit, is outlined below.

### 2.2.1 Federal level

The USDA APHIS Veterinary Services (VS) is the Central Competent Authority for animal health in the US. VS is led by the Deputy Administrator and US Chief Veterinary Officer (CVO). VS comprises one support unit (Resources, People, and Services) and 3 functional units, each of which is led by an Associate Deputy Administrator:

- (1) Strategy and Policy (S&P)

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<sup>4</sup> <https://www.ecfr.gov/current/title-9/chapter-I/subchapter-G/part-147>

- (2) Field Operations
- (3) Diagnostics and Biologics.

Within the S&P unit of VS, there are 3 teams that contribute to the operation of the US compartment scheme: Regionalization Evaluation Services (RES), Live Animal Imports and Exports, and the Aquaculture, Swine, Equine and Poultry Health Center (ASEP). RES mainly conducts import risk assessments, evaluates requests for regionalisation and the disease status of US trading partners, and assesses market access requests for imports into the US. RES is also responsible for conducting a Compartmentalization Service Review every 4 years, examining all aspects of the programme, to ensure that NPIP is managing the US compartment scheme in line with the Compartment Program Standards. Live Animal Imports and Exports provides technical advice and support regarding international trade to compartment programme participants. The NPIP team sits within ASEP, and its oversight and administration of the AI Clean Compartment programme is explained in more detail below.

## **2.2.2 The National Poultry Improvement Plan (NPIP)**

The team overseeing the NPIP is part of the Poultry Health Team within the Aquaculture, Swine, Equine and Poultry Health Center (ASEP), which sits within the S&P unit of APHIS VS. The NPIP team is in Conyers, Georgia and its responsibilities include the management of the US compartment scheme.

There are 3 veterinary medical officers (VMOs) and 2 programme analysts employed by APHIS to oversee the NPIP, including the NPIP authorised laboratories and the compartmentalisation programme.

The NPIP is a collaborative disease surveillance and control programme between the federal and state governments and industry, with the aim to improve the animal health standards and thereby trade potential of the US poultry industry. The NPIP is a voluntary programme, which was initially established to help control the vertically transmitted diseases *Salmonella* Pullorum, *Salmonella* Gallinarum, *Salmonella* Enteritidis, *Mycoplasma gallisepticum*, *Mycoplasma synoviae*, and *Mycoplasma meleagridis* within the US poultry industry.

Participation in specific NPIP programmes is possible on various levels: the “monitored” or “clean” status for the different diseases can be applied for and certified on an individual establishment level, such as for hatcheries, flocks, farms or slaughterhouses. Such status can however also be certified for an entire federal state, where every relevant business is compliant with the requirements and disease control standards of the specific programme in question. As a result, customers are made aware of the disease “monitored” or “clean” status of the poultry they purchase.

Specific programmes are only available to certain species and production type and the various programme modules typically build on each other. For example, all participants must first qualify as ‘US Pullorum-Typhoid Clean’ as a condition for participating in any other NPIP programme. APHIS added the ‘US AI Clean’ programme for breeding chickens and breeding

turkeys to the NPIP in the 1990s. The 'US H5/H7 AI Monitored' programmes for commercial table egg layers, broilers, and meat turkeys were added to the NPIP in 2006, whereas the 'US AI Clean Compartment' programme for chicken and turkey breeders was added in 2015. The prerequisite for participation in the 'US AI Clean Compartment' programme is that all proposed compartment premises are first certified under the US AI Clean programme as this programme is designed to provide assurances on freedom from AI<sup>5</sup>.

Compliance with the US AI Clean programme standards and subsequent federal endorsement by APHIS is required for all interstate and international movements of commercial poultry breeding stock. For this reason, 100% of the primary breeding industry currently participate in the voluntary NPIP programme.

### **2.2.3 State level**

Twelve federal states contain compartment premises, also known as "components": Alabama, Arkansas, Georgia, Kentucky, Maryland, Mississippi, Missouri, Oklahoma, South Carolina, Tennessee, Texas, and Virginia. Each of the 50 US states and one of the 3 US territories has an Official State Agency (OSA), which oversees the NPIP programme and reviews and approves the certification and removal of compartment components for their state or territory. The NPIP has the federal oversight over OSAs across the US. Official State Agents carrying out NPIP work may be state veterinarians or laboratory officials, officials of the relevant state department of agriculture, members of the Poultry Federation or state poultry association and university staff. The OSAs oversee the authorised laboratories performing the testing for the NPIP programmes and ensure that companies participating in the compartment scheme meet the required testing requirements of the AI Clean programme, which is a prerequisite for participation in the scheme.

An up to date list of Official State Agents and state contact representatives is maintained on the [NPIP website](#)<sup>6</sup>.

### **2.2.4 Further observations**

Throughout the audit, a close working relationship between APHIS veterinarians, NPIP veterinarians, and veterinarians and employees from the compartment companies was demonstrated ensuring that the Compartment Program Standards are followed to operate the compartments to the required standards. Evidence of recent communications between the parties was provided to the audit team documenting these ongoing relationships.

At the time of the audit, there were no vacant positions related to the administration and oversight of the compartment scheme. The NPIP and within that, the US poultry

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<sup>5</sup> Avian Influenza (AI) is defined by 9 CFR 145 as "an infection of poultry caused by any influenza A virus of the H5 or H7 subtypes or by any influenza A virus with an intravenous pathogenicity index (IVPI) greater than 1.2 (or as an alternative at least 75 percent mortality)".

<sup>6</sup> <https://www.poultryimprovement.org/documents/OfficialStateAgencies.pdf>

compartment scheme, is overseen and managed by a small team of dedicated and competent APHIS staff. The capacity of the team may be stretched by high work demands, especially during extended HPAI outbreaks. These may be unsustainable, particularly if existing workloads increase further by the growth of the scheme in terms of its components, or an increase in its scope.

## 2.3 Compartments: approval and supervision

### 2.3.1 Overview of the US compartment scheme

The US Avian Influenza and Newcastle Disease Clean Compartment programmes, being part of the national voluntary NPIP programme, have been designed to be utilised by the poultry breeding industry, which includes broiler (meat-type chicken) breeders, layer (egg-type chicken) breeders, and turkey breeders. Only primary breeders can participate in the compartment programmes, specifically flocks at the pedigree, great-grandparent (GGP) and grandparent (GP) levels. The programmes aim to establish compartments consisting of primary breeding and hatchery premises that are free of H5/H7 AI or ND.

Currently there are 2 certified compartments in the US, which belong to 2 individual breeding companies with primary broiler breeder flocks. The first US AI Clean Compartment was established and certified in 2017, with the second certified in 2019. To date, there have been no suspensions of either compartment due to AI or for any other reason.

Both compartments are certified as 'AI Clean Compartments' only at present. Whilst the framework exists within the Compartment Standards for the establishment of a 'ND Clean Compartment', the ND Clean Compartment programme has not yet been implemented. Just as it is a prerequisite of the 'US AI Clean Compartment' programme that compartment premises are first certified under the 'US AI Clean' programme, it is a requirement of the Compartment Program Standards that a 'ND Clean Compartment' is first certified under the 'ND Clean' programme. However, there is not yet an established ND Clean programme within the NPIP programmes. The NPIP team confirmed that efforts towards establishment of a ND Clean programme are ongoing and that the ability to award ND Clean Compartment classification will follow. Despite this administrative complication in certifying compartments as free from ND, it is a requirement for AI Clean Compartments to undertake routine vaccination and serology testing for ND to demonstrate disease freedom, which is described in more detail in Section 2.4.1. Thus, the remainder of this report will focus on the AI Clean Compartment classification, which is currently operational in the US.

The US poultry compartment scheme is not yet recognised by other trading partners for the purpose of permanent imports, although some countries have permitted transits of hatching eggs and day-old chicks originating from US compartments during periods when country level freedom from AI could not be certified. Equally, there are no compartment schemes operated by other countries that are currently recognised by the USDA.

The Compartment Program Standards state that National Import Export Services (NIES) "will conduct a Compartmentalization Service Review every 4 years, examining all aspects

of the programme”. However, this review has been delayed due to Covid-19 and an organisational restructure within APHIS means that this responsibility will now be fulfilled by RES, which is not yet reflected in the Compartment Program Standards.

### **2.3.2 Applying for compartment approval**

Prior to applying for ‘US AI Clean Compartment’ certification, a company must be a participant in the ‘US AI Clean’ programme. On initial application for ‘AI Clean Compartment’ status, the applying company must submit a formal application and provide documentation to APHIS and the OSA regarding the definition of the proposed compartment subpopulation and evidence of its health status, a description of the physical components of the compartment, and other evidence required to demonstrate that the defined compartment is suitable to qualify for compartment status.

A trained NPIP compartment auditor will then audit each of the individual compartment premises (‘components’) within the proposed compartment. On initial certification, 100% of farm and non-farm components must be audited. The national NPIP office reviews the auditor checklists and either approves or rejects certification of the proposed compartment. The compartment will only be approved after successful completion of the initial audit. Applications and checklists are kept on record by the NPIP office.

### **2.3.3 Annual recertifications and compartment requirements**

Annual recertification audits are carried out each year for all certified compartments, where 100% of non-farm components (feed mills, egg depots, and hatcheries) and at least 25% of farm components are audited. The selection of the farm components to be audited is done on a randomised basis. There is no minimum audit frequency in the standard. This random selection of farm components ensures that a representative sample of components across each compartment is audited annually and removes the element of predictability from the audit programme.

**Recommendation 1: To include a requirement for a minimum audit frequency in future updates of the Compartment Program Standards.**

During the in-country audit, the NPIP compartmentalization team explained that every year, 25% of all farm components of one of the compartments are audited, whilst for the other AI Clean Compartment, 25% of poultry houses on each farm complex are audited. This is due to the physical difference in farm size for each of the participating companies, referred to as Companies ‘A’ and ‘B’. Farms of company A typically consist of a small number of individual poultry houses for each site (approximately 1-4 houses per farm). For this company, each farm site is registered within the compartment scheme as one farm component. During annual recertification, 25% of Company A’s farm sites or ‘components’ are audited. For Company B, each farm site (also referred to as ‘complex’) consists of many individual poultry houses (up to 44 houses per farm complex). NPIP decided that due to the size of Company B’s complexes and to guarantee that each complex is in continuous compliance with the Compartment Program Standards, every complex should receive an annual visit by an

auditor. For this reason, each individual poultry house on each of the farm complexes is registered within the compartment as an individual component. A farm with 44 poultry houses would be registered as 44 components within Company B's compartment, and a randomly selected 25% of them would be audited annually.

This ability to adapt to the varying structure of poultry breeding companies helps to ensure that the compartment standards will be complied with by any additional compartments certified as US AI Clean Compartments in future.

**Recommendation 2: To clarify the definition of “component” in the Compartment Program Standards to reflect the flexibility in the approach to registration of components within compartments.**

Minor changes occurring to individual components or the entire compartment between annual recertification audits are highlighted during the audit and reflected in updated Standard Operating Procedures (SOPs). Major changes made or damage occurring to a component that could alter or potentially compromise a biosecure zone are notified to the NPIP staff by the compartment company. The NPIP then determines if the biosecurity of the compartment has been or could be compromised and whether the affected component should be removed from the compartment.

For initial certification and recertification audits, the auditors utilise checklists specific to the component type (Farm, Egg Depot, Feed mill, Hatchery, and Office) being audited. The checklists are part of the Compartment Program Standard documentation. The auditors verify each part of the checklists and record any non-compliances by reviewing records, such as biosecurity protocols, internal company SOPs, and staff training records, and observing physical buildings and processes in place at each component.

The Compartment Program Standards are accessible and well formatted. They include practical checklists which ensure consistency and aid the initial certification and annual recertification audits. The creation of multiple checklists for each operational area provides clarity within the auditing process for both the auditor and the companies operating compartments. The checklists within the Program Standards are not version controlled. Prior to each audit the NPIP Compartmentalization Coordinator assigns an auditor to the audit. Auditors are rotated between farm components and companies each year. The Compartmentalization Coordinator emails the most up to date version of the required checklist(s) to the auditor. The auditor conducts the audit, completes and signs the checklist before returning it to the NPIP with their findings and a corrective action plan, if relevant. The Compartmentalization Coordinator reviews the completed checklist and discusses it with the auditor, if necessary, before signing it and either approving or rejecting the certification or recertification of the component. The completed checklists are stored by the NPIP office. The rotation of auditors between components and compartments for annual recertification audits improves consistency and prevents complacency across the compartment scheme.

**Recommendation 3: To add version control to the checklists within the Compartment Program Standards to ensure that the correct version is completed, and the latest compartment requirements are met.**

Electronic data management of the compartment scheme by NPIP is performed with word processing software. Records are held electronically in Microsoft Office programmes (for example Excel spreadsheets). The NPIP Compartmentalization Coordinator demonstrated the record keeping system and the individual master lists of each compartment company's components and approvals stored as Excel documents. Separate Excel documents are maintained by the Compartmentalization Coordinator to ensure random selection of the components for annual recertification audits and rotation of auditors between components and compartments.

The Compartment Program Standards require each company's compartment scheme to be overseen by licensed, accredited veterinarians employed by the compartment company. The responsible veterinarians and other employees of the 2 participating compartment companies implementing the compartment standards and protocols within their respective companies provided evidence of their internal management processes. These processes ensure that the requirements of the compartment scheme are consistently met across all certified components. There are no compartment specific requirements for the compartment companies to conduct internal audits or other verification activities under the Compartment Program Standards, except to describe effective general internal monitoring and auditing systems upon initial certification. Both compartment companies demonstrated evidence throughout the audit that they routinely undertake such activities for example audits of their staff training programme.

### **2.3.4 Suspension of compartment approval**

#### **Major non-compliances**

According to the Compartment Program Standards, if at any time a component within a certified compartment is found to have a major non-compliance, the entire compartment (all farm and non-farm components within the compartment), are to be suspended immediately. Items considered as "major" are clearly marked on the audit checklists in the Compartment Program Standards. Any non-compliances for these items would result in failure of the entire compartment, without the option for corrective action.

There are specific scenarios that would result in a major non-compliance and immediate suspension of the compartment:

1. Loss of the NPIP US AI Clean status (in the case of broiler and layer breeders) or loss of the NPIP US H5/H7 Avian Influenza Clean status (for turkey breeders), either by failure to adequately test or by confirmed detection of AI in the compartment confirmed by the National Veterinary Services Laboratory (NVSL).
2. Failure to renew the compartment certification on time.
3. Failure to satisfactorily action any documented minor non-compliances by applying appropriate and effective corrective measures.

To date, no major non-compliances have been found by the compartment audit programme that would have resulted in immediate compartment failure or suspension. To regain certified compartment status after suspension the entire suspended compartment, including each component within that compartment, must wait at least 30 days following the date of suspension. It must then repeat the process for initial certification, including auditing of all components and testing to demonstrate AI freedom.

### **Minor non-compliances**

If an auditor detects a minor non-compliance during an initial certification or annual recertification audit, the issue will be listed on the audit checklist requiring corrective action. The auditors use their professional judgment to determine an appropriate time frame to complete specific corrective actions. Depending on the nature of the non-compliance, corrective actions may be immediate (corrected at the time of identification), performed whilst the auditor is still on site, or within 7 days or 30 days of the audit. The auditor reviews all corrective actions to ensure they are acceptable. If necessary, the auditor will revisit the component to verify that the non-compliance has been corrected to an acceptable standard and updates the checklist with the method and time of correction in the comment box on the audit checklist. A copy of the audit checklist is then submitted to the NPIP Compartmentalization Coordinator for review and to be kept on record. If a minor non-compliance is found during the initial certification audit and not fixed within the specified time, the affected component will not be granted certification and must wait 30 days before re-applying. For recertification audits, if the company fails to correct the non-compliance within the time specified, the entire certified compartment will be suspended, even if the non-compliance is confined to an individual component.

Auditors are able to make recommendations that would not be considered non-compliances with the Compartment Standards in the 'Additional Comments' column on the audit checklist, which is returned to both the NPIP and the compartment company.

On average, 115 compartment components are audited each year, with an average of 54 checklist items verified per component. In previous years, an average of 55 minor non-compliances were documented each year across all compartment components audited. This accounts for 0.8% of all items verified on the checklists resulting in minor non-compliances.

### **2.3.5 Requirements for compartment scheme auditors**

Compartment auditors must be trained to conduct initial certification and annual recertification audits and must meet the specifications outlined in the Compartment Program Standards. Auditors must be federal Veterinary Medical Officers (VMOs), preferably with poultry experience, or be private veterinarians who are board certified by the American College of Poultry Veterinarians and US licensed and accredited. Practising veterinarians must be 'licensed' to practise in one or more state and can then voluntarily choose to apply to become a USDA 'accredited' veterinarian by completing formal training from the National Veterinary Accreditation Program (NVAP) in the state(s) they are licensed to practise in. The compartment auditors must not have a conflict of interest with any of the participating

compartment companies or those seeking compartment certification. There were 9 trained compartment auditors at the time of this audit; 7 federal VMOs and 2 private veterinarians.

Veterinary staff from the OSA and NPIP work in partnership with licensed, accredited veterinarians to train and certify auditors through official USDA-NPIP compartment auditor training courses. Prior to conducting on-site audits, auditors must attend an official training course and pass an examination to become a certified compartment auditor. Auditors must be recertified at least once every 4 years.

The training courses are designed to expose auditors to the primary poultry breeder industry, familiarise them with the contents of the management guidelines and protocols as well as the official audit checklists, and train them to perform audits accurately and consistently in line with the code of ethics for the US compartment scheme.

The use of trained and certified auditors ensures a consistent approach during the certification and reapproval process across all compartment components.

At the time of audit, there were 21 certified non-farm components which require annual recertification audits and 118 farm sites consisting of 373 farm components, 25% of which require annual recertification audits. There are 9 part-time compartment auditors to conduct annual recertification audits. This means resource pressures may occur, especially in the event of redeployment to outbreak response during a notifiable disease outbreak. During disease outbreaks and heightened risk periods, downtime requirements between farm visits also increase, adding further to the resource pressures. Future growth of the compartment scheme, either through the addition of new components or new compartments, or an increase in the scheme's scope could lead to further demand for auditors.

### **2.3.6 Further observations**

In the US AI Clean Compartment programme, feed mills are considered a non-farm compartment component and must be audited every year to maintain their certification status. Feed mills were designated as components to have a higher level of control of supplies entering farm components. This is aided by the integration of the US primary breeding industry, where pedigree, GGP and GP farms are supplied by company-owned feed mills. Feed mills have a specific compartment checklist used for certification and recertification audits. This differs to Great Britain's Compartment Scheme, where feed mills are not included within a compartment but must comply with strict biosecurity standards. Bedding production facilities are not considered components and are not typically owned by companies participating in the compartment scheme. However, they must follow company biosecurity protocols.

## 2.4 Compartments: management

### 2.4.1 Differences in testing protocols between Great Britain and US

There are certain differences between the testing requirements for Great Britain's Compartment Scheme and the US AI Clean Compartment programme. The following tables allow comparison of the testing requirements of Great Britain's Compartment Scheme and the US AI Clean Compartment programme. They provide an overview of:

1. Table 1: Testing requirements for initial compartment approval
2. Table 2: Routine AI testing requirements to maintain compartment approval
3. Table 3: Testing requirements in AI high-risk periods

A comparison of ND vaccination and testing requirements between the Great Britain's Compartment Scheme and the US AI Clean Compartment programme is also provided.

Although there are minor differences in the initial testing regime for flocks to be approved as compartment components in the relevant national scheme (Table 1), both US and Great Britain's testing regimes appear to achieve similar outcomes by providing sufficient evidence that birds are negative for AI at the time of compartment (or component) approval.

There are minor differences in the timing and number of samples collected for the routine testing requirements to maintain compartment approval (Table 2). However, US and Great Britain's sampling and testing approaches achieve similar outcomes in providing guarantees regarding the compartment's ongoing freedom from AI. Therefore, assurances are provided that the commodities exported from these compartments are free from AI.

There are significant differences in the testing requirements for AI between Great Britain's Compartment Scheme and the US compartment scheme during an AI high-risk period (HRP) (Table 3). The US AI Clean Compartment programme does not require an increase in routine testing during an AI HRP, although requires that birds and litter/manure are tested for AI within 48 hours of all types of movement. There is no formal requirement during a HRP for parent flocks to be tested before eggs are moved out of a compartment premises or exported. Although both companies approved under the US AI Clean Compartment programme apply additional testing as per their own internal company requirements, these are not mandated by the competent authority within the requirements of the compartment scheme.

**Recommendation 4: To include in future versions of the Compartment Program Standards a requirement to carry out more intensive surveillance during high AI risk periods to provide additional assurances that eggs or chicks exported from compartment premises are free from AI. This would formalise the additional testing already carried out by the existing compartment companies.**

Although no formal programme for a "ND Clean Compartment" has been established yet by the US competent authority, it is a formal requirement for AI Clean Compartments to undertake routine vaccination or serological testing for ND. The existing ND vaccination and

testing requirements in place for the AI Clean Compartments provide equivalent assurances regarding ND freedom compared to Great Britain's Compartment Scheme. Despite the current lack of formal ND Clean Compartment certification in the US, compartments approved under the US AI Clean Compartment Scheme are of equivalent health status regarding ND as compartments approved under Great Britain's Compartment Scheme.

In the US Compartment Program Standards, 'flock' is defined as:

"Flock: (1) As applied to breeding: All poultry of one kind of mating (breed and variety or combination of stocks) and of one classification on one farm; (2) As applied to disease control: All of the poultry on one farm, except that any group of poultry which is segregated from another group and has been so segregated for a period of at least 21 days may be considered as a separate flock."

Under the current definition of 'flock', it could be interpreted that when birds are moved into the compartment, a total of 30 samples could be collected from multiple poultry houses and therefore multiple airspaces. This is unlikely to be sufficiently representative to demonstrate disease freedom at an appropriate confidence level. The current participating compartment companies undertake AI testing at the airspace level, which is more than the Compartment Program Standards require.

**Recommendation 5: To include in future versions of the Compartment Program Standards a requirement that testing for AI is done on an airspace basis to ensure sufficiently representative sampling to demonstrate freedom from AI. This would formalise the additional testing already carried out by the existing compartment companies.**

There are no items on the checklists contained within the Compartment Program Standards for the auditors to verify that a component is fulfilling the AI surveillance or pre-movement testing requirements.

**Recommendation 6: To include in future versions of the audit checklists in the Compartment Program Standards a requirement for auditors to verify compliance with routine AI testing requirements.**

**Table 1: Testing requirements at the time of application for initial compartment approval (applicable for each farm component).**

Great Britain’s Compartment Scheme		US AI Clean Compartment Program (9 CFR 145.83(g))
<b>Type of test</b>	Serology	Serology - Antibody detection (ELISA or AGID)
<b>Frequency</b>	At least 3 tests at regular intervals during last 6 months, the most recent being no more than 28 days prior to the date of application for approval	At least one test when birds are at least 4 months old
<b>Sample size</b>	20 birds per production unit <sup>1</sup>	30 birds per flock
<b>Laboratory</b>	At least one set of samples must be tested at National Reference Laboratory (NRL), but other sets may be tested either at the NRL or an accredited laboratory for AI serology under ISO 17025	NPIP or NAHLN approved laboratory

<sup>1</sup> “Production unit” is defined as “a group of animals with the same likelihood of exposure to a pathogenic agent”.

**Table 2: Routine AI testing requirements for each approved premises to maintain compartment approval (excluding hatcheries which do not have routine testing requirements).**

	Great Britain Compartment Scheme	Great Britain Compartment Scheme	US AI Clean Compartment Program
<b>Type of test</b>	Serology <sup>1</sup>	Serology <sup>1</sup>	Serology
<b>Frequency</b>	At least once every 6 months	Flocks prior to lay: at least once within 28 days prior to the start of lay  Flocks in lay: intervals no longer than 28 days	At intervals of 90 days; or at a frequency less than 90 days if at the end of each 90 day period at least 15 samples were collected and equally represented from all the pens
<b>Sample size</b>	20 birds per production unit	11 birds per production unit (statistical sampling 95/25) <sup>2</sup>	Initial test 30 birds over 4 months old.  To retain classification: 15 birds equally representing all the pens in the flock
<b>Laboratory</b>	National reference laboratory (NRL)	NRL or laboratory accredited for avian influenza serology testing under ISO 17025	NPIP or NAHLN approved laboratory

<sup>1</sup> For Great Britain Compartment Scheme, both serological testing schedules are required.

<sup>2</sup> If Galliformes, birds under 4 weeks of age can be exempted from testing.

**Table 3: Testing requirements in AI high-risk period.**

	Great Britain Compartment Scheme	Great Britain Compartment Scheme	Great Britain Compartment Scheme	US AI Clean Compartment Program
<b>High risk period</b>	HPAI confirmed in Great Britain in last 6 months	If compartment is located in PZ or SZ due to confirmed HPAI outbreak. OR  If HPAI confirmed within 30km of the compartment, and until the control zones are lifted or 3 months has elapsed since the last confirmation	If compartment is located in PZ or SZ due to confirmed HPAI outbreak	High risk period: when AI is reported in a state or within a 30 mile radius of a compartment facility and until any control zones are released.
<b>Type of test</b>	Serology	Serology	Virology	Virology
<b>Frequency</b>	Every 3 months	Within 1 week of the outbreak, and then every 21 days thereafter	Within 1 week of the outbreak, and every 21 days thereafter	48 hours prior to the movement of birds, litter or manure
<b>Sample size</b>	20 birds per production unit	20 birds per production unit (statistical sampling 95/15) <sup>1</sup>	20 tracheal swabs and 20 cloacal swabs per production unit, and 5 sick or dead birds, if present	30 birds per flock prior to movement
<b>Laboratory</b>	NRL or a laboratory accredited for avian influenza serology testing under ISO 17025	NRL or a laboratory accredited for avian influenza serology testing under ISO 17025	NRL	NPIP or NAHLN approved laboratory

<sup>1</sup> If Galliformes, birds under 4 weeks of age can be exempted from testing.

## **Comparison of ND vaccination and testing requirements between the Great Britain's Compartment Scheme and the US AI Clean Compartment Program.**

ND requirements in Great Britain compartments:

- Birds may or may not be vaccinated against ND.
- If vaccinated, companies can decide, although it is not a requirement, to sample to assess immune response.
- If the flock is not vaccinated, the testing programme followed must be similar to the one for AI.

ND requirements in US compartments:

- Birds may or may not be vaccinated (USDA licensed vaccine).
- Vaccinated flock:
  - Flock has been monitored for antibody response.
  - A minimum of 30 birds when birds are more than 4 months of age and not longer than every 90 days thereafter.
- Unvaccinated flocks:
  - A minimum of 30 birds must be sample for serology testing with negative results for ND. Using an approved test when the birds are more than 4 months of age.
- To retain this classification:
  - A sample of at least 30 birds must be tested negative at intervals of 90 days; OR
  - A sample of fewer than 30 birds may be tested, and found negative, 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 be tested negative to ND within 21 days prior to movement to slaughter.

## **2.4.2 Movement and traceability of hatching eggs, day-old chicks and poultry**

The audit found differences in the testing and quarantine requirements for the movement of hatching eggs and birds into a compartment between Great Britain's Compartment Scheme and the US AI Clean Compartment programme (Table 4). These differences were particularly pronounced for hatching eggs coming from a non-compartment premises into a compartment hatchery in the US, where only the flock of origin is tested for AI within 21 days of the shipment of eggs. There is no requirement for the quarantine or post-movement testing of the chicks.

**Recommendation 7: To require that hatching eggs, day-old chicks or birds introduced into the compartment from non-compartment premises are quarantined until confirmation has been received that they have tested negative for AI.**

**Table 4: Comparison of the requirements for Great Britain’s Compartment Scheme and the US AI Clean Compartment Program for movement of hatching eggs, day-old chicks and birds within and into an approved compartment<sup>1</sup>.**

Type of Poultry	Great Britain: movements to a compartment in Great Britain from another establishment.	Great Britain: movements within the same compartment	US: movements within the compartment	US: movements from outside the compartment
<b>Birds</b>	<p><b>An establishment in Great Britain:</b>                      Either from an approved Compartment Scheme or an approved Poultry Health Scheme establishment (all birds sourced from outside the compartment scheme must undergo quarantine).</p> <p>No additional requirements apply during the routine period. However, during the heightened risk period, birds older than day-old chicks need to be tested for AI (and ND if not vaccinated).                      Recommended sampling: 95:15 (95% confidence 15% prevalence, equivalent to 20 birds per airspace) within 21 days prior to the movement.</p> <p><b>An establishment in another country:</b>                      - Either from an approved compartment considered fully equivalent to the standards of Great Britain’s Poultry Compartment Scheme by Defra,                      - Or a flock which is part of a government supervised poultry health scheme.</p> <p><b>All birds sourced from outside Great Britain’s compartment scheme must undergo quarantine for 21 days.</b></p>	Directly from a flock within the same approved compartment in Great Britain.	Negative AI test within 21 days prior to movement. From flocks that were vaccinated for NDV using licensed vaccines and compliant with a programme to evaluate serological response to NDV vaccination OR if unvaccinated, flocks have tested negative to ND.	Tested negative for AI within 21 days of shipment. A minimum of 30 samples per flock must be tested by serology and 15 samples by antigen detection. Flocks must be inspected by an official veterinarian or designee within 30 days of movement. Birds must originate from flocks that were vaccinated for NDV using licensed vaccines and compliant with a programme to evaluate serological response to NDV vaccination OR if unvaccinated, flocks have tested negative to ND.

Type of Poultry	Great Britain: movements to a compartment in Great Britain from another establishment.	Great Britain: movements within the same compartment	US: movements within the compartment	US: movements from outside the compartment
<b>Day-old chicks</b>	As for movement of birds.	As for movement of birds.	Derived from NPIP AI Clean Program source flocks.	Source flock that has tested negative for AI within 21 days of shipment. A minimum of 30 samples per source flock must be tested using an approved NPIP assay. The source flocks must participate in a national AI plan equivalent to the NPIP.
<b>Hatching eggs</b>	<p><b>A flock farm in Great Britain:</b></p> <ul style="list-style-type: none"> <li>- From a different approved compartment in Great Britain. Sanitation of the eggs at point of collection and prior to setting at hatchery is required.</li> <li>- Or from a flock from an approved Poultry Health Scheme (PHS) in Great Britain. All eggs must be kept isolated, and birds must undergo quarantine once hatched.</li> </ul> <p><b>A flock farm in another country:</b></p> <ul style="list-style-type: none"> <li>- Either from a flock in an approved compartment considered fully equivalent to the standards of Great Britain's Poultry Compartment Scheme by Defra,</li> <li>- Or from a flock farm member of a government supervised poultry health scheme in its own country and subject to additional conditions.</li> </ul> <p>Hatching eggs originated from an establishment in another country, must be kept isolated from all in-housed eggs and all birds hatched from imported eggs must undergo quarantine.</p>	<p>Directly from the same approved compartment in Great Britain.</p> <p>No additional requirements apply.</p>	Hatching eggs should be sanitized with an EPA-approved disinfectant at the farm, hatchery, or egg depot prior to delivery at a compartment facility.	<p>Derived from a flock that has tested negative for AI within 21 days of shipment. A minimum of 30 samples per source flock must be tested using an approved NPIP assay. The source flocks must participate in a national AI plan equivalent to the NPIP.</p> <p>Must originate from flocks that were vaccinated for NDV using licensed NDV vaccines and compliant with a programme to evaluate serological response to NDV vaccination. If source flocks were not vaccinated for NDV, they must test negative to ND.</p>

<sup>1</sup> Detailed rules for Great Britain's Compartment Scheme can be found in the guidance for compartments for the protection against avian influenza and Newcastle disease in poultry breeding companies in Great Britain and in the US AI Clean Compartment Program Standards.

## 2.4.3 Management during a high-risk period (HRP)

A high-risk period (HRP) is defined by the Compartment Program Standards as “when AI or ND is reported in a state or within a 30-mile radius of a compartment facility. The HRP ends when any control zones are released”. During a HRP, companies must follow advanced biosecurity protocols, which are highlighted on the checklists within the Compartment Program Standards. Evidence of following these protocols during high-risk periods was presented by the compartment companies. Auditors may request to see proof that companies were following these protocols during HRPs, if applicable for premises, during annual recertification audits.

USDA and APHIS has an up to date public-facing website that notifies the general public of [recent HPAI detections](#)<sup>7</sup>. This is the only public source of information available and only provides location information of the county and state of outbreak. This is due to privacy concerns of companies who do not want the accurate location of an infected premises (IP) to be publicly released. The exact locations of IPs are known by veterinarians involved in export certification and APHIS countersign every export health certificate for live animals and hatching eggs. This provides confidence that there is no possibility of exports originating from a restriction zone.

This process could potentially lead to components not being aware that they have entered a HRP and need to implement necessary protocols. The NPIP Compartmentalization Coordinator, APHIS, the OSA, and informal poultry industry communication channels ensure that compartment companies are aware of any outbreaks that are within 30 miles, or within a state that contains any of their certified components or that may affect their operations and require HRP protocols to be implemented. Evidence was provided by one of the compartment companies of the NPIP Compartmentalization Coordinator informing them that one of their components had entered a HRP. However, the audit team noted that this is not a formal requirement of the Compartment Program Standards and should be considered for inclusion as one.

**Recommendation 8: To ensure that the competent authority notifies compartment companies when they enter a High-Risk Period and to include this requirement in future versions of the Compartment Program Standards.**

## 2.4.4 Further observations

The biosecurity requirements of the Compartment Program Standards for the US AI and ND Clean Compartment programmes were largely equivalent to those required by Great Britain’s Compartment Scheme Schedules.

Equivalence was demonstrated in the following areas:

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<sup>7</sup> <https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/animal-disease-information/avian/avian-influenza/hpai-2022/2022-hpai-commercial-backyard-flocks>

- routine biosecurity measures, including husbandry and management practices
- site maintenance
- biosecurity protocols for personnel based on compartment premises and visitors including contractors, vets, other company employees and officials
- policies on introduction and movement of equipment, supplies and goods onto and between compartment premises
- requirements on personnel authorised to collect samples for routine AI and ND testing
- cleaning and disinfection for vehicles entering biosecure areas
- requirements for feed and bedding supplied to compartment premises
- cleaning and disinfection of compartment premises after depopulation of flocks
- control programmes for vermin, wild birds, insects and rodents
- requirement for exclusion of livestock
- disposal of dead birds and animal by-products
- policies for keeping/contact with avian species outside of work for visitors and employees
- methods used to deter unauthorised entry into biosecure areas
- record keeping for the origin, production, identification, traceability and movement of hatching eggs, day-old chicks, poults and birds, including spent hens
- annual biosecurity training of staff and documentation of training.

There were some differences in management and requirements between US AI Clean Compartments and Great Britain's Compartments noted by the audit team.

All disinfectants used on site must be an approved, registered and licensed by the US Environmental Protection Agency (EPA), including for the disinfection of hatching eggs at the farm, hatchery, or egg depot and prior to movement.

Requirements for persons entering compartment premises for downtime between bird contact are shorter for the US AI Clean Compartment programme than Great Britain's Compartment Scheme. The US Compartment Program Standards require "a minimum 24-hour downtime from contact with non-compartment birds (including shower and change of clothing)" which is increased by an additional 24 hours during HRPs. Great Britain's Schedules always require 72 hours without bird contact before entering a compartment premises. The companies participating in the US AI Clean Compartment programme are currently implementing longer periods of downtime in their own company policies than is required by the Compartment Program Standards.

For compartment farms in Great Britain, a fence is required as a barrier around the biosecure zone. The external walls of buildings may constitute the biosecurity barrier. In the US Compartment Program Standards, a biosecure zone barrier must define the limits of the biosecure zone. The biosecure zone barrier may include the external walls of buildings. The biosecure zone is then surrounded by a 'controlled access zone', which only authorised personnel or vehicles may enter. Barriers may constitute a perimeter fence where practical, except where a geographical barrier is present such as a cliff or body of water. The use of

geographical barriers as the perimeter of the biosecure zone or the farm perimeter does not fully prevent access by wildlife.

**Recommendation 9: To ensure that future versions of the Compartment Program Standards and their application is robust enough to prevent wildlife access to the biosecure zone.**

## 2.5 Laboratory testing capability and capacity

To retain their US AI Clean classification, participating compartment companies must demonstrate compliance with testing requirements as described in the Program Standards to conduct surveillance for H5/H7 AI within the compartment. All official tests for AI and ND within a compartment must be carried out in state or federal laboratories or in private laboratories authorised by NPIP that meet the minimum standards described in 9 CFR 147.52, including testing proficiency, record keeping, staff training, and regular internal and external auditing. Compartment companies must have accredited veterinarians responsible for the active and passive surveillance of HPAI across their compartment premises. Results of the testing must be kept on record and compartment companies must be able to provide relevant H5/H7 AI and ND testing results on request by the competent authority. Records must be maintained for all flocks within the compartment, including the dates and results of all AI and, if applicable, ND surveillance and monitoring testing.

There are 2 laboratory networks overseen by APHIS VS and the USDA, that undertake AI testing for active and passive surveillance programmes required by either the 'US AI Clean' or the 'US AI Clean Compartment' programmes. The NPIP laboratory network includes private laboratories authorised for conducting AI screening tests. The National Animal Health Laboratory Network (NAHLN) is a network of animal disease diagnostic laboratories that have partnered with State and University laboratories across the US under the oversight of USDA. NAHLN laboratories are certified for AI testing and overseen by the NVSL, which serves as National Reference Laboratory for several diseases. All non-negative results for AI and ND by NPIP and NAHLN laboratories must be submitted to the NVSL in Ames, Iowa for confirmatory testing.

Up to date lists of laboratories authorised to conduct AI testing are available. There are currently 91 [NPIP laboratories approved for Avian Influenza monitoring](#)<sup>8</sup> and 57 [NAHLN Laboratories approved for IAV-A Preparedness and Surge Capacity Testing](#)<sup>9</sup>.

Serology testing (screening) is performed at NPIP authorised laboratories and PCR testing is performed at either a NAHLN laboratory or a primary breeder laboratory with NPIP authorisation as stipulated in 9 CFR 145.14 (d)(2)(i). The SOPs for PCR used in the NPIP laboratories are provided by NVSL.

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<sup>8</sup> <https://www.poultryimprovement.org/labs/index.cfm> (updated 19 May 2023)

<sup>9</sup> [https://www.aphis.usda.gov/animal\\_health/nahln/downloads/ai\\_lab\\_list.pdf](https://www.aphis.usda.gov/animal_health/nahln/downloads/ai_lab_list.pdf) (updated 9 June 2023)

The NAHLN laboratories are required to be ISO accredited for the test or processes which they are using, including AI testing. As part of their ISO accreditation, the NAHLN laboratories follow SOPs for AI PCR testing that are provided by the NVSL. Laboratories authorised for PCR testing under the NPIP programme must follow the regulations in 9 CFR 145.14, requiring them to be accredited to the ISO 17025 Standard through a recognised accreditation body. All NPIP authorised laboratories are required to follow the regulations in 9 CFR 147, which requires participation in PCR proficiency testing. Evidence of validation testing according to 9 CFR 147.52 by NPIP authorised and NAHLN laboratories was presented during the audit.

The well-established NPIP US AI Clean programme formed a strong basis from which to launch the US AI Clean Compartment programme. The compartment scheme is further strengthened by the routine testing of individual compartment companies going above and beyond the requirements of the compartment programme to provide evidence of AI freedom of the compartments. APHIS and the NPIP have adequate oversight of laboratories involved in the US AI Clean Compartment programme. NPIP laboratories are overseen and audited at least once every 2 years by the OSAs. Every 3 years the NPIP conducts an audit of the NPIP authorised laboratory system. This audit includes records, laboratory protocols, test proficiency, technician training, and peer review processes. Evidence of well-functioning laboratory processes were demonstrated and supported by the SOPs and required accreditation of relevant AI and ND testing methods at NPIP and NAHLN laboratories.

## 2.6 Certification

The 2 companies currently part of the US compartment scheme have dedicated export/sales departments. These departments are responsible for applying for export health certificates through the APHIS website. As part of the process, members of the compartment scheme must provide the accredited veterinarian with a completed Part I of the certificate.

Before signing the certificate, the accredited veterinarian confirms that the details of Part I are correct. The accredited veterinarian assesses whether the animal health requirements have been met and completes any information required in Part II. Once the certificate is signed, it is sent to an APHIS office with the authority to endorse export health certificates. After reviewing the certificate and confirming compliance with the requirements, a VMO endorses the export health certificate and assigns a unique reference number. Once completed, the certificate travels with the consignment as a hard copy.

The procedure in place to certify live poultry, including hatching eggs, appears to be sufficiently robust, ensuring integrity of the assurance process through the verification and endorsement by a full time Government VMO.

APHIS developed a new Veterinary Export Health Certification System (VEHCS), an electronic certification system used by the US to export live animals to importing countries that have agreed to use the system. There are several benefits from having electronic certification; the shortened time frames of the procedures making logistics easier, and the facility for the importing country to verify authenticity of the certificate online.

### 3. Conclusions

The audit found that the US competent authorities have a well-established compartment scheme with 2 compartments certified and currently operating under the programme. The NPIP and within that, the US poultry compartment scheme, is overseen and managed by a competent and generally well-resourced team of APHIS staff.

The US Compartment Program Standards are accessible online and include practical checklists to aid the initial certification and annual recertification auditing processes. The creation of multiple checklists for each operational area provides clarity within the auditing process for the auditor and the participating companies.

The rotation of appropriately trained and certified auditors combined with the random selection of farm components for annual recertification audits guarantees a robust compartment certification and reapproval audit process, with a consistent approach applied across all compartment components located anywhere within the US.

The biosecurity requirements of the Compartment Program Standards for the US AI and ND Clean Compartment programmes were broadly equivalent to those required by Great Britain's Compartment Scheme Schedules and appear to provide similar assurances in terms of protection from incursion of disease into an AI or ND free compartment.

There are minor differences between Great Britain's and the US compartment schemes in the initial AI testing regime for flocks and in the requirements regarding the timing and number of samples collected for routine testing to maintain compartment approval. Both schemes appear to require a continuous and thorough active and passive surveillance to sufficiently demonstrate freedom from AI and ND. Differences in testing requirements during AI high-risk periods were more significant between Great Britain's and the US scheme and consideration should be given to assess whether the current requirement guarantees early detection and provide guarantees for continued freedom from AI. Compartment companies in Great Britain and the US regularly go beyond the requirements of the programme standards and monitor the health of their compartments through additional voluntary testing. The recommendations in this report address this by recommending that some of the voluntary testing currently carried out is formalised into the Compartment Program Standards.

With regards to ND, the current vaccination and testing requirements of the AI Clean Compartments are similar to those of Great Britain's Compartment Scheme providing assurances that the approved compartments are free from ND. Therefore, despite the current lack of a formal ND Clean Compartment certification in the US, the existing reassurances provided through requirements for vaccination or testing meet the standard of Great Britain's Compartment Scheme.

The laboratory network available for AI and ND testing to satisfy the requirements of the Program Standards meets the standards of the testing arrangements required by Great Britain's Compartment Scheme by operating a well-resourced and functional laboratory

facilities with adequately accredited testing processes. There is a sufficient degree of official oversight by the competent authorities via the NPIP programme and the relevant National Reference Laboratory.

Export health certification processes are robust and reliable. Each certificate is reviewed by a VMO for compliance before it is endorsed and assigned a unique reference number, providing additional assurance on the integrity of the process and that the requirements of the importing country have been met.

The audit has made recommendations that will require a response from the US competent authority. They are set out in the recommendations in the corresponding sections of this report. They relate to frequency of annual recertification audits; updates and clarifications to the Compartment Program Standards and audit checklists; biosecurity protocols; routine testing requirements; and quarantine procedures for hatching eggs, day-old chicks and birds entering compartments. These are listed in full in Section 4.

## 4. Recommendations

The central competent authority of the US is invited to respond to this audit report with an action plan addressing the recommendations set out in the report and listed below:

1. To include a requirement for a minimum audit frequency in future updates of the Compartment Program Standards (page 16).
2. To clarify the definition of “component” in the Compartment Program Standards to reflect the flexibility in the approach to registration of components within compartments (page 17).
3. To add version control to the checklists within the Compartment Program Standards to ensure that the correct version is completed, and the latest compartment requirements are met (page 18).
4. To include in future versions of the Compartment Program Standards a requirement to carry out more intensive surveillance during high AI risk periods to provide additional assurances that eggs or chicks exported from compartment premises are free from AI. This would formalise the additional testing already carried out by the existing compartment companies (page 22).
5. To include in future versions of the Compartment Program Standards a requirement that testing for AI is done on an airspace basis to ensure sufficiently representative sampling to demonstrate freedom from AI. This would formalise the additional testing already carried out by the existing compartment companies (page 23).
6. To include in future versions of the audit checklists in the Compartment Program Standards a requirement for auditors to verify compliance with routine AI testing requirements (page 23).
7. To require that hatching eggs, day-old chicks or birds introduced into the compartment from non-compartment premises are quarantined until confirmation has been received that they have tested negative for AI (page 28).

8. To ensure that the competent authority notifies compartment companies when they enter a High-Risk Period and to include this requirement in future versions of the Compartment Program Standards (page 31).
9. To ensure that future versions of the Compartment Program Standards and their application is robust enough to prevent wildlife access to the biosecure zone (page 33).

# Abbreviations

ABP	Animal by-products
ACPV	American College of Poultry Veterinarians
AHPA	Animal Health Protection Act
AI	Avian influenza
APHA	Animal and Plant Health Agency
APHIS	Animal and Plant Health Inspection Service
ASEP	Aquaculture, Swine, Equine and Poultry Health Center
CFR	Code of Federal Regulations
CVO	Chief Veterinary Officer
Defra	Department for Environment, Food and Rural Affairs
EPA	Environmental Protection Agency
GGP	Great-grandparents
GP	Grandparents
GPLN	Georgia Poultry Laboratory Network
HPAI	High pathogenic avian influenza
HRP	High-risk period
NAHLN	National Animal Health Laboratory Network
ND	Newcastle disease
NPIP	National Poultry Improvement Plan
NRL	National Reference Laboratory
NVSL	National Veterinary Services Laboratory
OSA	Official state agency/agent
PCR	Polymerase Chain Reaction
S&P	Strategy and policy
SOP	Standard Operating Procedure

UK	United Kingdom
US	United States of America
USDA	United States Department of Agriculture
VMO	Veterinary Medical Officer
VS	Veterinary Services of APHIS
WOAH	World Organisation for Animal Health (previously OIE)

## ANNEX I

### List of Retained EU Regulations and Great Britain's National Legislation referred to in this report

Title of Legislation	Link to Legislation
Retained Regulation 616/2009	<a href="#">Commission Regulation (EC) No 616/2009 of 13 July 2009 implementing Council Directive 2005/94/EC as regards the approval of poultry compartments and other captive birds compartments with respect to avian influenza and additional preventive biosecurity measures in such compartments (Text with EEA relevance) (legislation.gov.uk)</a>
Retained Regulation 2019/625	<a href="#">Commission Delegated Regulation (EU) 2019/625 of 4 March 2019 supplementing Regulation (EU) 2017/625 of the European Parliament and of the Council with regard to requirements for the entry into the Union of consignments of certain animals and goods intended for human consumption (Text with EEA relevance) (legislation.gov.uk)</a>
Retained Regulation 2016/429	<a href="#">Regulation (EU) 2016/429 of the European Parliament and of the Council of 9 March 2016 on transmissible animal diseases and amending and repealing certain acts in the area of animal health ('Animal Health Law') (Text with EEA relevance) (legislation.gov.uk)</a>
Directive 2005/94	<p><a href="#">Council Directive 2005/94/EC of 20 December 2005 on Community measures for the control of avian influenza and repealing Directive 92/40/EEC (legislation.gov.uk)</a></p> <p>Directive 2005/94 sets out certain preventive measures relating to the surveillance and the early detection of avian influenza and the minimum control measures and movement restrictions to be applied in the event of an outbreak of that disease in poultry or other captive birds. Certain of those measures are to be applied in poultry compartments or in other captive bird compartments, as defined in that Directive.</p> <p>Directive 2005/94 provides a definition of poultry compartments and other captive birds' compartments and also provides that additional biosecurity</p>

	<p>measures may be applied in those compartments in order to prevent the spread of avian influenza.</p>
<p>Commission Decision 2006/437/EC</p>	<p><a href="#">Commission Decision of 4 August 2006 approving a Diagnostic Manual for avian influenza as provided for in Council Directive 2005/94/EC (notified under document number C(2006) 3477) (Text with EEA relevance) (2006/437/EC) (legislation.gov.uk)</a></p> <p>Commission Decision 2006/437/EC of 4 August 2006 approving a Diagnostic Manual for avian influenza as provided for in Council Directive 2005/94/EC, lays down diagnostic procedures, sampling methods and criteria for the evaluation of the results of laboratory tests for the confirmation of an outbreak of avian influenza. In the interests of consistency of Community legislation in this area, those procedures and methods should be followed in the framework of a compartment.</p>
<p>Commission Regulation 798/2008</p>	<p><a href="#">Commission Regulation (EC) No 798/2008 of 8 August 2008 laying down a list of third countries, territories, zones or compartments from which poultry and poultry products may be imported into and transit through the Community and the veterinary certification requirements (Text with EEA relevance) (legislation.gov.uk)</a></p> <p>Serology and virology Annex III and VIII</p>
<p>Directive 2009/158</p>	<p><a href="#">Council Directive 2009/158/EC of 30 November 2009 on animal health conditions governing intra-Community trade in, and imports from third countries of, poultry and hatching eggs (codified version) (Text with EEA relevance)</a></p>