



Department  
for Environment  
Food & Rural Affairs

## Report of an audit to France between 2 to 6 December 2024 to assess the implementation of HPAI vaccination for commercial ducks

Date: 9 April 2025

# Contents

Executive summary .....	4
1. Introduction .....	6
1.1 Background .....	6
1.2 Objective, scope and legal basis .....	7
1.2.1 Objective.....	7
1.2.2 Scope .....	7
1.2.3 Legal basis and legal references .....	8
1.2.4 Itinerary .....	8
2. Audit findings .....	9
2.1 Legislation .....	9
2.2 Competent authority structure, capacity and capability .....	10
2.2.1 Organisational structure .....	10
2.2.2 Capacity and capability of the competent authority .....	11
2.3 Poultry industry and disease prevention .....	13
2.3.1 Overview.....	13
2.3.2 Disease prevention.....	16
2.4 HPAI vaccination programme .....	17
2.4.1 Overview of HPAI vaccination programme .....	17
2.4.2 Information systems supporting the vaccination programme.....	18
2.5 Veterinary laboratories .....	19
2.5.1 Government and private laboratory structure and responsibilities.....	19
2.5.2 Capacity and quality systems .....	20
2.5.3 Sampling, testing, and reporting .....	21
2.6 Surveillance .....	22
2.6.1. Overview of surveillance.....	22
2.6.2 Event-based passive surveillance in poultry .....	25
2.6.3 Active surveillance in vaccinated duck flocks .....	25

2.6.4 Enhanced passive surveillance in vaccinated duck flocks.....	26
2.7 Traceability and export health certification.....	29
3. Conclusions.....	31
4. Recommendations.....	31
Abbreviations.....	33
ANNEX I.....	35
ANNEX II.....	36

# Executive summary

The report describes the findings and conclusions of the audit undertaken by the Department for Environment, Food and Rural Affairs (Defra) in France between 2 and 6 December 2024. The objective of the audit was to assess the level of effectiveness with which animal health controls, surveillance systems and laboratory procedures supporting the highly pathogenic avian influenza (HPAI) vaccination programme, are implemented in France.

The audit, led by Defra's UK Office for SPS Trade Assurance, assessed France's implementation and surveillance of HPAI vaccination in commercial ducks to provide the necessary animal health assurances for the export of duck meat and meat products to Great Britain.

France started a vaccination programme against highly pathogenic avian influenza (HPAI) in October 2023 for all commercial duck farms with 250 or more ducks. The vaccination programme was launched in response to significant HPAI outbreaks in previous years in commercial poultry flocks, particularly affecting commercial ducks. To ensure that vaccinated ducks are not carrying sub-clinical HPAI infection, the supporting surveillance programme must ensure a sufficient sensitivity of detection.

For meat and meat products produced from vaccinated birds to be certified for exports to Great Britain, the vaccination and associated surveillance programmes must be approved by Defra. An initial desk-based assessment of France's HPAI vaccination and surveillance programmes identified concerns around the design and implementation of certain elements of the surveillance programme. Defra was requested to undertake an in-country audit in December 2024.

The audit team visited the central competent authority (General Directorate for Food (DGAL)), 2 farm sites, one slaughterhouse, and 2 laboratories, met with regional and local competent authority (CA) veterinary officials, and verified export health certification procedures.

The report concludes that France has implemented an effective vaccination programme to reduce the impact of HPAI in commercial ducks with strong collaboration between the competent authorities and stakeholders, including industry and laboratory networks.

The CA has a clear organisational structure, with each level of the CA demonstrating understanding of their responsibilities for the vaccination programme. The CA has appropriate capacity and capability to implement vaccination and its associated surveillance programmes. The use of mandated veterinarians (VMs) to perform official tasks for the HPAI vaccination programme has been effective in ensuring the roll out and uptake of the vaccination programme in its first year.

There are 3 main surveillance programmes supporting the HPAI vaccination programme: event-based passive surveillance, enhanced passive surveillance, and active surveillance. The triggers for reporting for event-based passive surveillance are sufficiently robust to detect disease at an early stage. The enhanced passive and active surveillance

programmes are essential to providing appropriate guarantees that virus is not circulating undetected in the vaccinated duck population despite reduced viral shedding and transmission due to vaccination. To provide the necessary assurances regarding disease detection, sampling frequency must be addressed, and the number of submitted samples must be monitored to ensure that they comply with requirements. Greater understanding of the requirements of signing the post-vaccination certificates is essential to ensure correct certification.

For post-vaccination surveillance, each farm is currently considered a single epidemiological unit, and the CA requires that sampling is performed at the farm level basis. In effect, this may in some circumstances be more than one epidemiological unit. Viral shedding is likely to be significantly reduced in vaccinated ducks, so sampling at the farm level instead of at the flock (airspace or house) level will result in a decrease in the sensitivity of the overall surveillance. Sampling for the enhanced passive surveillance should be carried out at a flock (airspace or house) level. This recommendation aligns with EFSA's Scientific Opinion.

The laboratory network of approved and recognised laboratories, overseen by the National Reference Laboratory (NRL), are all ISO 17025 certified and accredited by COFRAC, the French Accreditation Committee for laboratory accreditation. The network provides robust testing procedures for the ongoing surveillance supporting the vaccination programme. Further guidance to laboratories on how to deal with cases of non-compliance and increasing CA oversight by improving reporting through the available information systems would aid the CA's ability to monitor compliance with the surveillance requirements.

Traceability and export certification systems utilise comprehensive electronic systems and demonstrated robust traceability from farm to export. In the event that exports destined to Great Britain are required to meet additional criteria, the level of detail in these systems would allow for batches to be differentiated.

The report makes recommendations to the French competent authorities in relation to observations and findings of the audit. The recommendations concern laboratory guidance for non-compliant samples, sampling and surveillance protocols and monitoring compliance with the post-vaccination surveillance programmes.

# 1. Introduction

The Department for Environment, Food and Rural Affairs (Defra) undertook an audit mission to France between 2 and 6 December 2024. The audit, led by Defra's UK Office for Sanitary and Phytosanitary (SPS) Trade Assurance, was carried out by a team of 4 auditors and technical experts from Defra and the Animal and Plant Health Agency (APHA). The team observed the implementation and surveillance of the highly pathogenic avian influenza (HPAI) vaccination programme for commercial domestic ducks in France at the central, regional, and local levels. Representatives of the General Directorate for Food (DGAL) and the National Establishment for Agriculture and Seafood (FranceAgriMer) accompanied the audit team for the duration of the mission.

The opening meeting took place on 2 December 2024 with representatives of the central competent authority at DGAL's central offices in Paris, France. 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 information provided by the French authorities regarding the HPAI vaccination programme, and in their response to the pre-audit questionnaire. The closing meeting was held virtually on 10 December 2024. The audit team presented a draft summary of main findings, which was acknowledged by representatives of DGAL.

## 1.1 Background

Avian Influenza virus (AIV) is an infectious disease affecting poultry and other captive and wild birds. Many different strains of AI viruses are found in birds and can be divided into 2 groups based on their virulence in poultry: HPAI and low pathogenic avian influenza (LPAI).

AIV may be spread through direct animal contact and through contaminated feed and fomites, for example vehicles, bedding or equipment. The meat of infected birds contains AIV and remains infectious without appropriate heat treatment. HPAI viruses present a serious human health risk and have serious economic implications for the poultry industry and related sectors, including indirect costs related to trade restrictions. HPAI is therefore a major animal health threat to Great Britain.

France started a vaccination programme against HPAI in October 2023 for all commercial domestic duck farms. Farms with less than 250 ducks and breeding ducks whose products (hatching eggs and day-old chicks) are intended for export and other avian species are exempt from this programme. The vaccination programme was launched in response to significant and ongoing HPAI outbreaks in previous years in commercial poultry flocks, particularly affecting commercial duck flocks. To ensure that vaccinated ducks don't carry active or sub-clinical HPAI infection, the supporting surveillance programme must ensure a sufficient sensitivity of detection. Ducks are less likely to show clinical signs of AI infection which is further complicated by the protective immunity achieved through the effective vaccination programme, reducing virus shedding by infected birds, and slowing down transmission of disease.

France is a major global exporter of duck meat and foie gras. In 2023, approximately 4,000 tonnes of duck meat and duck meat products were exported from France to the UK. At the time of audit, France was authorised to export all poultry and poultry-related commodities to Great Britain, including duck meat and duck meat products. However, products from vaccinated ducks do not currently meet health certification requirements and cannot be exported to Great Britain. For meat and meat products produced from birds vaccinated against HPAI to be certified for exports to Great Britain, the vaccination programme must be approved by Defra's Secretary of State. To facilitate the recognition of the vaccination programme and its supporting surveillance, Defra carried out an assessment of the implementation and surveillance of HPAI vaccination in commercial ducks in France to provide the necessary animal health assurances for the export of meat and meat products from vaccinated ducks to Great Britain. As part of the assessment, the team conducted an in-country verification audit.

## 1.2 Objective, scope and legal basis

### 1.2.1 Objective

The objective of the audit was to assess the level of effectiveness with which animal health controls, surveillance systems and laboratory procedures support the HPAI vaccination programme implemented in France.

### 1.2.2 Scope

The scope of the audit included the evaluation of the structure and official animal health control processes implemented by the French competent authorities to mitigate the risk of HPAI disease spread both within France and to its trading partners, including Great Britain.

The following are in scope of the audit:

- the role of the different levels of the competent authority of France in the implementation of the HPAI vaccination and surveillance programmes
- the official oversight and control of the AI vaccination programme
- and the supporting surveillance programme
- the compliance of the duck sector with the requirements of the French HPAI vaccination and surveillance programmes
- the effectiveness of biosecurity measures implemented on farms with vaccinated flocks
- the design and implementation of passive and active surveillance programmes for AI implemented in vaccinated flocks
- the procedures for notification of suspected cases of AI and the related response by the French competent authority
- the testing capability and test methods used by the laboratories involved in HPAI testing in France, including the oversight and assurance by the National Reference Laboratory
- the traceability and export health certification procedures in France

### 1.2.3 Legal basis and legal references

The audit was carried out using legal powers provided by Article 120 of the Official Controls Regulation<sup>1</sup> 2017/625 specifying that the UK competent authority may conduct controls in trading partners to verify the compliance of their legislation and official control systems.

Article 11 of Regulation 798/2008 requires that a third country's vaccination plan for AI meets the requirements of Annex V of the same regulation and that the plan is approved by Defra's Secretary of State and the decision published by Great Britain.

The Avian Influenza and Influenza of Avian Origin in Mammals Order 2006 and the Notifiable Avian Disease Control Strategy for Great Britain and relevant EU legislation, including Regulations 2016/429, 2023/361 and 2020/687, have been considered for comparison with disease control measures in Great Britain. A full list of regulations relevant to the audit is included in Annex I.

Internationally agreed standards, laid down in the World Organisation for Animal Health's Terrestrial Code and in its Terrestrial Manual as of July 2024, were also taken into consideration during the audit.

### 1.2.4 Itinerary

The premises, establishments and offices visited to meet the audit objective and scope are set out below.

Central competent authority:

- opening and closing meetings with the French Central Competent Authority (DGAL)

Local and regional competent authority (CA):

- meetings with local (Département Directorate (DDPP or DD(ETS)PP)) level CA officials at DDPP 72 (Sarthe), DDPP 44 (Loire-Atlantique) and DD(ETS)PP 53 (Mayenne)
- meeting with regional level (DRAAF/SRAL) CA official in Pays de la Loire region
- interviews with mandated veterinarians (VMs) on 2 duck premises

Laboratories:

- Agency for Food, Environmental and Occupational Health & Safety (ANSES) National Reference Laboratory (NRL) for AI and ND (Ploufragan)
- one regional, approved AI laboratory (Laboceca (LDA22), Zoopole, Ploufragan)

Premises:

---

<sup>1</sup> References to EU legislation are references to those as assimilated in UK law.

- one commercial meat duck farm (2 houses, approximately 30,000 ducks in total)
- one commercial foie gras duck farm (2 houses, growing and fattening, approximately 3,400 ducks in total)
- one duck slaughterhouse (approximately 90,000 meat ducks slaughtered per week including for the Great Britain export market)

## 2. Audit findings

### 2.1 Legislation

National legislation in France is primarily determined by EU regulations. The 2 primary EU Regulations on animal health and veterinary public health controls related to the audit scope include:

- EU Regulation 2016/429 on transmissible animal diseases ('Animal Health Law')
- EU Commission Delegated Regulation 2023/361 as regards rules for the use of certain veterinary medicinal products for the purpose of prevention and control of certain listed diseases

In addition to Regulation 2016/429, French legislation is based on the provisions of the French Rural and Maritime Fishing Code (Code Rural et de la Pêche Maritime (CRPM)) concerning surveillance and control measures.

The Animal Health Law includes definitions relevant to the audit:

- "epidemiological unit" is defined as "a group of animals with the same likelihood of exposure to a disease agent"
- "establishment" is defined as "any premises, structure, or, in the case of open-air farming, any environment or place, where animals or germinal products are kept, on a temporary or permanent basis, except for: (a) households where pet animals are kept; and (b) veterinary practices or clinics"

France's HPAI vaccination strategy and associated post-vaccination surveillance is based on EU Commission Delegated Regulation 2023/361. This regulation does not provide a definition for epidemiological unit, but it is assumed to be that of the Animal Health Law.

'Epidemiological unit' is defined by France, for the purposes of the HPAI vaccination programme, as "a group of animals with a similar probability of exposure to a pathogen, it is assimilated to the farm site (which may consist of several buildings)"<sup>2</sup>. The post-vaccination surveillance plan for the HPAI vaccination programme considers a farm a single epidemiological unit and requires surveillance sampling on this basis. This approach is supported by EU Commission Delegated Regulation 2020/687 which requires the culling of birds at farm level rather than flock level following confirmation of HPAI.

---

<sup>2</sup> Source: ['Factsheet 5 – Post-Vaccination Surveillance'](#)

EU Commission Delegated Regulation 2023/361 details the post-vaccination surveillance sampling requirements following preventive HPAI vaccination. It also stipulates that vaccine distribution and administration, and active post-vaccination surveillance must be carried out by an official veterinarian.

A list of relevant EU and French regulations relevant to the audit are listed in Annex II. EU delegated legislation and the national legal framework in France provides adequate provisions and powers to the competent authorities for the effective implementation of the HPAI vaccination programme of commercial ducks in France.

## **2.2 Competent authority structure, capacity and capability**

### **2.2.1 Organisational structure**

The Ministry of Agriculture and Food Sovereignty is the central competent authority in France and is organised into 4 central administrative directorates: Food, Education and Research, Economic and Environmental Performance of Businesses, and Maritime Fisheries and Aquaculture, coordinated by a General Secretariat.

The Directorate General for Food (Direction Générale de l'Alimentation, DGAL) is responsible for food safety throughout the food chain in France, including animal health. There are 2 units responsible for animal health controls:

1. The Office for Animal Health (Bureau de la Santé Animale, BSA) responsible for contagious and emerging diseases, animal health policy, and epidemiological surveillance.
2. The Office for Animal Identification and Movement Control (Bureau de l'Identification et du Contrôle des Mouvements des Animaux, BICMA) responsible for animal identification and movement control in France and ensuring compliance with national and EU regulations regarding livestock traceability.

France is divided into 18 regions, each with a Regional Directorate for Agriculture, Food and Forestry (Direction Régionale de l'Alimentation, de l'Agriculture et de la Forêt, DRAAF). Each DRAAF is overseen by DGAL and is a decentralized service of the Ministry of Agriculture and Food Sovereignty. The DRAAFs are responsible for implementing national and EU policies related to food safety, agricultural development, and forestry at the regional level.

Within each DRAAF is a Regional Food Service (Service Régional de l'Alimentation, SRAL). Each SRAL is responsible for the effective implementation of food safety policies and for coordinating multiple départements within their respective regions.

There are 101 départements across the 18 regions (96 in metropolitan France, which includes Corsica, and 5 overseas départements). Each département contains a Département Directorate (called a Direction Départementale de la Protection des Populations (DDPPs) or Direction Départementale de l'Emploi, du Travail, des Solidarités

et de la Protection des Populations (DD(ETS)PPs)), which hosts the local veterinary services. The staff of the Département Directorates includes veterinary inspectors with civil-servant status and technical and administrative personnel.

DGAL is responsible for the national level implementation of the HPAI vaccination and surveillance programme in commercial ducks. Governance of the HPAI vaccination programme is divided between 2 committees, a strategic Steering Committee and an operational Monitoring Committee. These committees include representatives of all levels of the CA, the National Reference Laboratory (NRL), which is part of the French Agency for Food, Environmental and Occupational Health & Safety (ANSES), the National Veterinary School of Toulouse (ENVT), the French Technical Institute for Poultry (ITAVI), professional trade associations, and veterinary groups.

There are regional vaccination programme monitoring units, which include representatives of the Département Directorates, and agricultural and veterinary organisations. These units, which are the responsibility of the DRAAFs, monitor the vaccination programme at the regional level, anticipate logistical issues, and report progress to DGAL and the national monitoring committee.

The Département Directorates are responsible for monitoring and implementing the vaccination programme at a local level by:

- updating farm data in the relevant information systems (described in more detail in 'Information Systems')
- verifying vaccine orders placed by private veterinarians with the consignee and distributor
- verifying compliance with vaccination in the field
- verifying performance of active post-vaccination surveillance
- organising payment of vets and laboratories for post-vaccination active surveillance sampling and testing
- managing cases of non-compliance, with appropriate corrective actions and/or sanctions

The CA structure and line of command is clear. Each level of the CA demonstrated a clear understanding of their responsibilities for the vaccination programme.

### **2.2.2 Capacity and capability of the competent authority**

Each Département Directorate employs a small number of official veterinarians who are responsible for overseeing animal health controls and for overseeing specific official controls, such as export certification and border controls. As the number of official veterinarians employed by the CA is relatively small, veterinarians working in private practice are relied upon to carry out the bulk of official veterinary services in the field. Private veterinarians performing official tasks must be registered with the French veterinary accreditation body (L'Ordre National des Vétérinaires) to practise veterinary medicine in France (known as 'Authorised Veterinarians' (Vétérinaires Habilités, VHs)). Most Authorised

Veterinarians will have undertaken the necessary training to become a 'Sanitary Veterinarian' (Vétérinaires Sanitaire, VS).

In France, the majority of private practising veterinarians, approximately 14,700, are VSs and can perform official tasks on behalf of the CA. VSs must renew their sanitary authorisation every 5 years and are limited to the species and activity required. VSs are required to undertake compulsory continuous training provided by the CA every 5 years to maintain their sanitary authorisation. Authorised Veterinarians (VHs) without this additional training may be authorised by the State to conduct specified routine animal health related activities to support the State during crises and outbreak management. VHs working in private practice can become VSs by completing one week of training hosted by a French veterinary university. This is usually completed by French veterinary undergraduates in the final year of their undergraduate veterinary course but can be completed post-graduation, for example if a veterinarian did not graduate from a French veterinary school.

Each commercial farm must designate a VS to conduct certain regulatory tasks that are the responsibility of the farmer, such as preventive screening. VSs are paid for by the farmer for the services they provide but they may also be contracted by the government to provide some veterinary services, such as blood sampling and disease monitoring.

The CA can mandate VSs to perform certain official tasks, such as official inspections for intracommunity trade and implementing animal protection controls. In this capacity, VSs act as 'Mandated Veterinarians' (Vétérinaires Mandatés, VMs). VMs operate under the authority of the regional SRAL and Département Directorate. They are remunerated by government but are not government employees. VMs are required to undergo initial and ongoing training on the laws and regulations related to public health management. VMs have 'approved veterinarian' status as defined by EU legislation and are the equivalent of Official Veterinarians in the UK who carry out certain official tasks on behalf of the government whilst working in private practice.

Before the start of the HPAI vaccination programme, a prefectural order was issued by each département to mandate all VSs appointed by poultry farmers to perform certain official tasks and act as VMs. The mandated VSs:

- plan and organise vaccination in accordance with the vaccination schedules described by the vaccine producers
- order and manage vaccine vials ensuring that the vaccination teams and farmers administering the vaccine follow good vaccination practices, which includes training, verifying competence, collecting vaccination reports, taking serology samples for self-monitoring, and auditing vaccination in the field
- carry out active post-vaccination surveillance visits to take the samples requested by the CA, to check the status of vaccinated animals, and to ensure that passive post-vaccination surveillance has been properly carried out by the farmer
- follow up any identified non-conformities that do not require direct intervention by the local Département Directorate

- report to the CA by entering the necessary information for monitoring the vaccination programme into the Calypso information system (described in more detail in 'Information Systems')

Mandating VSs to perform these tasks for the HPAI vaccination programme has been effective in ensuring the roll out of the vaccination programme in its first year. These VMs are updated and informed through semi-regular meetings with their local Département Directorate. During the audit, VMs were confident in the systems in place and their responsibilities in ordering vaccines, supervising vaccination, and reporting any information required by the CA to monitor the vaccination programme.

## 2.3 Poultry industry and disease prevention

### 2.3.1 Overview

Poultry, including duck, rearing takes place throughout mainland France with the highest densities of poultry and duck farms in the northwest and southwest of France. The French commercial duck industry is split into 2 main sectors: (1) meat or roasting duck production and (2) foie gras (fattening) duck production. The structure and demographics of the 2 sectors are outlined in Tables 1 and 2.

Approximately 6% of French poultry production is ducks, producing approximately 8 million meat ducks and 7.7 million ducks for fattening per year. This compares to 140.4 million broiler chickens, which account for 53% of France's poultry production.

Ducks used for meat production are primarily ducks of the Pekin breed (*Anas platyrhynchos domesticus*) or Muscovy ducks (*Cairina moschata domestica*), which are also known as Barbary ducks. Ducks used for foie gras production are predominantly male Mulard ducks, which are a hybrid between a male Muscovy duck and a female Pekin duck. Geese are also used for a small proportion (less than 2%) of foie gras production in France.

**Table 1: Structure of the meat duck and foie gras sectors in France**

<b>Sector</b>	<b>Meat duck</b>	<b>Foie gras</b>
<b>Breeding</b>	2 breeding companies	2 breeding companies
<b>Hatching (incubation period)</b>	10 hatcheries (35 days)	12 hatcheries (35 days)
<b>Rearing (rearing period)</b>	~700 producers (~80 days)	Nearly 3,000 producers (> 3 months)
<i>1- Starting phase</i>	Not applicable	Nearly 3,000 producers (3-4 weeks)
<i>2- Growing phase</i>	Not applicable	Nearly 3,000 producers (4-5 weeks)
<i>3- Preparation for fattening</i>	Not applicable	Nearly 3,000 producers (3-5 weeks)
<b>Fattening (fattening period)</b>	Not applicable	Nearly 3,000 producers (10-12 days)
<b>Slaughter</b>	10 slaughterhouses	18 centralized slaughterhouses
<b>Processors</b>	-	More than 500 businesses ranging from artisanal companies to major national brands

**Table 2: Demographics of meat duck and foie gras farms in France<sup>1</sup>**

Activity (production stage)	Number of farms	Average number of buildings per farm	Average flock size (Number of animals)	1 building per farm (% of farms)	2 buildings per farm (% of farms)	3 buildings per farm (% of farms)	4 buildings per farm (% of farms)	5 or more buildings per farm (% of farms)
Meat duck sector	701	1.6	9560 per building	59.9	28.8	6.4	4.7 (4 or more buildings per farm)	-
Foie gras sector: rearing ducks and geese ready for fattening	1154	2.8	8077 per farm	29.5	24.6	19.5	11.9	14.5
Foie gras sector: fattening of ducks and geese	1013	1.1	1184 per farm	85	12	3 (3 or more buildings per farm)	-	-
Foie gras sector: rearing and fattening ducks and geese on the same site	669	4.9	5153 per rearing farm; 1030 per fattening farm	2.7	16.8	17.4	18.3	44.8

<sup>1</sup> All data in Table 2 is presented as reported by the French authorities in their response to the pre-audit questionnaire.

In the meat duck sector, approximately 97% of meat ducks are reared indoors, with approximately 95% of farms part of an integrated production chain. There are on average 1.6 houses on a meat duck farm and an average flock size of 9,600 birds per house (Table 2).

Foie gras production is usually free-range during the growing phase. Exceptions include during winter when birds are kept indoors and during AI risk periods, when birds are required to be housed. Birds on foie gras farms are typically split between rearing (approximately days 0 to 90 of production) and fattening stages (a 10 to 12 day period between days 90 to 110 of production) usually in separate buildings. Some premises may focus on either the rearing or the fattening stages, with birds transferred from a rearing to fattening premises for the final stage of production before slaughter. The number of houses and average flock size per farm varies depending on which phase of production takes place on the farm. This is shown in Table 2: rearing (2.8 houses/farm with 8,100 birds/farm), fattening (1.1 houses per farm with 1,200 birds per farm), or both rearing and fattening (4.9 houses per farm with 5,200 birds per farm).

Approximately 95% of meat and foie gras farms belong to intertrade groups. The intertrade groups are agricultural production organisations who represent groups of farmers and negotiate contracts with slaughterhouses and processing plants, who in turn market and/or export the final product to consumers. The intertrade groups provide technical support to farmers and encourage participation in assurance schemes.

There are also 2 main professional trade associations representing the foie gras and meat duck sectors, Comité Interprofessionnel des Palmipèdes à Foie Gras (CIFOG) and Comité Interprofessionnel du Canard à Rôtir (CICAR). These are lobbying organisations, which focus on promoting and regulating the production and marketing of duck meat and foie gras and representing the interests of their members. All commercial duck farms must be part of either CIFOG or CICAR.

Other professional organisations involved in the French commercial duck industry and the HPAI vaccination programme include the French National Hatchery Association (Syndicat National des Accouveurs, SNA), representing and supporting professionals in the hatchery sector across France, the French National Poultry Association (Association Nationale Interprofessionnelle de la Volaille de Chair, ANVOL), which represents the poultry meat sector, including producers, processors, and distributors, and the Union of the Veterinary Medicine and Diagnostics Industry (Syndicat de l'Industrie du Médicament et du Diagnostic Vétérinaires, SIMV), which represents companies that develop, manufacture, and market veterinary medicines, in vitro diagnostics, and medical devices for animal health.

### **2.3.2 Disease prevention**

France experienced concurrent HPAI outbreaks in 2016 to 2017, triggering a review and improvements of biosecurity across the commercial duck sector. According to the EURL Avian Flu Data portal, there were 101 HPAI outbreaks in France between 2015 to 2019; 14 wild bird cases and 87 poultry (commercial and backyard) and captive bird cases. In 2020

to 2021, this increased to 576 outbreaks (39 wild bird cases and 537 poultry (commercial and backyard) and captive bird cases). These outbreaks resulted in extensive culling of infected flocks and heightened biosecurity protocols across the poultry industry.

On 16 March 2016, a Ministerial Decree was introduced to create a HPAI risk level identification system for the HPAI risk posed by wild birds. The system has 3 risk levels: negligible, moderate, and high. Use of these levels enabled promotion of the implementation of basic biosecurity measures within the commercial poultry industry, including surveillance in wild bird and poultry populations.

On 29 September 2021, another Ministerial Decree was introduced outlining compulsory biosecurity measures for all poultry and captive bird establishments. Every owner or keeper of birds must conduct a risk analysis for their establishment and create a comprehensive biosecurity plan. The biosecurity plan must cover all production stages and must include a site description, staff details, cleaning and disinfection protocols, pest and wild bird control policies, and record-keeping requirements. The plan must also detail biosecurity evaluations, corrective actions for non-compliance, additional measures during high-risk periods, and an emergency plan for AI outbreaks. The Decree states that the plan must be kept up to date and available for inspection in paper or electronic form.

Additionally, several farm assurance schemes within the French poultry industry promote quality, animal welfare, and sustainability. These schemes collectively aim to enhance biosecurity in the poultry sector, addressing the need for robust measures to prevent disease outbreaks such as AI. They reflect a commitment to maintaining high standards and quality of poultry products. Adherence to biosecurity measures and particular assurance schemes is a requirement of membership to certain professional trade associations.

Despite the introduction of these measures and the widespread uptake of farm assurance schemes, the impact of the 2020 to 2022 HPAI outbreaks on industry was severe. There were 2646 outbreaks (746 wild bird cases and 1,900 poultry (commercial and backyard) and captive bird cases) in France from 1 January 2022 to 31 December 2024.

## **2.4 HPAI vaccination programme**

### **2.4.1 Overview of HPAI vaccination programme**

The HPAI vaccination programme was launched on 1 October 2023 with the aim to vaccinate 64 million ducks (Muscovy, Mulard and Pekin) across 2,700 establishments in metropolitan France, excluding Corsica. Farms with less than 250 ducks and breeding ducks whose products (hatching eggs and day-old chicks) are intended for export and other avian species are exempt from this programme. The second year of the vaccination programme began on 1 October 2024 and is planned to end on 30 September 2025.

2 vaccines meet the criteria for the vaccination programme as being effective against the clade 2.3.4.4.b HPAI strain, which is currently circulating worldwide and responsible for ongoing poultry outbreaks. They also allow a DIVA (Differentiating Infected from Vaccinated

Animals) strategy based on nucleoprotein enzyme-linked immunosorbent assay (NP ELISA) serology:

- VOLVAC BEST AI+ND vaccine (Boehringer Ingelheim Animal Health France)
- CEVA RESPONS AI H5 (Ceva Sante Animale)

These vaccines have been approved under an authorisation for temporary use by France's National Agency for Veterinary Medicines (ANMV).

These vaccines had not been issued a marketing authorisation in the EU at the time of this audit. However, in the event of an outbreak of a listed disease, Article 110(2) of Regulation (EU) 2019/6 permits EU member states to use nationally approved vaccines, which do not have a marketing authorisation in the EU.

The VOLVAC BEST AI+ND is an inactivated subunit vaccine containing the H5 haemagglutinin of the HPAI H5N1 produced by Boehringer Ingelheim. It is administered subcutaneously. In Muscovy and Mulard ducks, the first 0.5ml dose is administered from 10 days of age, followed by the second 0.5ml dose 18 days later. Alternatively, for Mulard ducks, the first 0.5ml dose can be given from one day of age followed by a second 0.5ml dose 28 days later. In Pekin ducks, the first 0.5ml dose can be given from one day of age followed by a second 0.5ml dose 18 days later.

The CEVA RESPONS AI H5 is an mRNA vaccine, produced by Ceva. It contains a self-amplifying RNA coding for the viral haemagglutinin of HPAI H5N8. For Mulard, Muscovy and Pekin ducks, an intramuscular injection is administered twice at an interval of 3 or 4 weeks from one day of age.

The French government covered 85% of the costs for the delivery of the vaccination programme in the first year and has committed to cover 70% of the costs for the second year. 141 million doses of vaccine were purchased for the first year of the programme, October 2023 to September 2024, and 67.75 million doses have been purchased for the first 6 months of the second year of the programme.

VMs must supervise the first vaccination on each establishment to ensure technical competence of those performing vaccination. Vaccination can be carried out by practising veterinarians (VHs, VSs and VMs) or, under Article L.243-2 of the rural and maritime fisheries code, owners or keepers of poultry or their employees and technical workers. If using vaccination teams, farmers and/or intertrade groups are responsible for their hire and cost. VMs also supervise the post-vaccination surveillance programmes supporting the HPAI vaccination programme: enhanced passive surveillance and active surveillance.

## **2.4.2 Information systems supporting the vaccination programme**

Annex V of Delegated Regulation 2023/361 stipulates the minimum information to be recorded during a HPAI vaccination programme. There are several information systems used to fulfil this legal obligation and to support the programme: Calypso, SIGAL, ATMC and BD Avicole, CartoGIP, and Expadon 2. Their uses are described briefly below.

**Calypso** is an online application designed for the HPAI vaccination programme, which enables data and information to be uploaded and downloaded between veterinarians and all levels of the CA. The CA uses Calypso to verify compliance with vaccination and to authorise payments to VMs in vaccination delivery and active post-vaccination surveillance. VMs use Calypso to order vaccines, record vaccination dates, issue vaccination certificates, record active post-vaccination surveillance sampling visits, issue post-vaccination surveillance certificates, and declare sites that are eligible for vaccination.

**SIGAL** allows laboratory testing results to be shared between all levels of the CA and laboratories. Laboratories enter the results of post-vaccination surveillance testing into SIGAL. VMs and the CA use SIGAL to access testing results relevant to them.

**ATMC** and **BD Avicole** are databases used by meat duck and foie gras duck farmers and intertrade groups to record and declare their bird placements and movements. These systems create the IMEP (batch) number that follows batches of ducks from hatch throughout production. The systems were created by industry, but the competent authority has permanent access for animal health management.

**CartoGIP** is a risk management tool that uses information fed from ATMC, BD Avicole and Calypso to map out regions of risk accounting for poultry density, wild bird migratory patterns and weather conditions. The tool also shows HPAI vaccination coverage and outbreak restriction zones. Automatic notifications are sent to intertrade groups when the status of a restriction zone changes.

**Expadon 2** is a digital platform used by the French authorities to manage export certifications and to provide regulatory information to official veterinarians and operators regarding exports.

Overall, communication between the CA and stakeholders involved in the vaccination programme is effective, supported by appropriate use of the available information systems to monitor vaccination uptake and compliance.

During the audit, the CA and VMs confidently demonstrated their use of these systems. CartoGIP is an effective tool for notifying stakeholders of high-risk areas and restriction zones, as well as mapping participation in the vaccination programme. Calypso is valuable for the CA to monitor compliance with vaccination and post-vaccination surveillance. SIGAL is used effectively to communicate laboratory results between different parties. Since spring 2024, some laboratory testing results have been uploaded from SIGAL to Calypso. Plans to fully integrate these systems will streamline the process for checking results and verifying compliance with post-vaccination surveillance requirements.

## 2.5 Veterinary laboratories

### 2.5.1 Government and private laboratory structure and responsibilities

The National Reference Laboratory (NRL) for AI and Newcastle Disease is located in Ploufragan, Brittany, and operates within the French Agency for Food, Environmental and

Occupational Health & Safety (ANSES) laboratory network. The NRL serves as the central coordinating body, providing professional and technical leadership for other government and private laboratories in the laboratory network.

The NRL's responsibilities include providing guidance on testing protocols and kits, investigating potential issues, organising inter-laboratory ring testing, taking part in international proficiency testing, and conducting further genomic analysis from positive notifiable avian disease (NAD) testing results.

The NRL does not engage in frontline diagnostic testing, such as suspect case investigations or post-vaccination surveillance activities. However, downstream follow-up activities are within its remit, for example, troubleshooting ambiguous results or whole genome sequencing and genotyping analysis. The NRL has evaluated the implementation of the vaccination programme and associated surveillance strategies. This includes through ad hoc research activities, including experimental HPAI infection in avian species.

The laboratory network includes the NRL and 40 additional laboratories distributed nationwide. 18 of these are approved laboratories, which are funded and managed by the départements. 22 are recognised laboratories, which are privately owned and managed. Private laboratories may apply for approved status with the selection process guided by the competent authority. The NRL and all approved and recognised laboratories are ISO 17025 certified and accredited by COFRAC (the French Accreditation Committee for laboratory accreditation). Both approved and recognised laboratories must meet the same rigorous quality standards, AI testing accreditation and successful participation in biennial ring tests organized by the NRL. The only difference between approved and recognised laboratories is the type of testing they are authorised to perform by DGAL and ANSES.

The 18 approved laboratories perform official AI diagnostics and surveillance testing, including both enhanced passive and active surveillance testing of vaccinated flocks. They are authorised by the Ministry of Agriculture and Food Sovereignty to conduct a wide array of NAD testing. This includes serology tests (HAIT, AGID, ELISA), RT-PCR for avian influenza A viruses (M gene), subtyping (H5/H7), and pathotyping RT-PCRs. Some approved laboratories also perform virus isolation in eggs, but only the NRL is authorised to conduct Intravenous Pathogenicity Index (IVPI) testing. Further genomic analyses are primarily conducted by the NRL, with some approved laboratories, such as Zoopole, Ploufragan (LDA22) possessing limited capacity in this area.

The 22 recognised laboratories provide testing services tailored to industry requirements and conduct enhanced passive surveillance testing to support the HPAI vaccination programme. The recognised laboratories are not authorised to conduct the active surveillance testing supporting the HPAI vaccination programme.

## **2.5.2 Capacity and quality systems**

The laboratory network is extensive, with 14 approved laboratories equipped to handle suspect NAD case investigations. The network has the appropriate capacity to manage post-vaccination surveillance, even during periods of high sample volumes due to AI

outbreaks. During the audit, the approved laboratory visited reported a maximum daily capacity of 2,000 PCR tests, while the NRL indicated a maximum capacity of 3,000 PCR tests per day. Multiple commercial and in-house diagnostic kits (for example PCR and ELISA) are accredited and used, ensuring adequate supplies and contingency measures. The NRL oversees the validation of diagnostic kits and maintains a list of acceptable kits for use by laboratories in the network. BSL-2+ or BSL-3 facilities are available at the NRL and in certain approved laboratories (e.g. Zoopole, Ploufragan (LDA22)).

Biennial ring tests are mandatory for laboratory accreditation, with test permissions revoked in the event of non-compliance. The audit team confirmed acceptable ring testing outcomes at Zoopole, Ploufragan (LDA22). The NRL participates in international proficiency testing coordinated by WOH Accredited Laboratories, such as the EU Reference Laboratory. Evidence of equipment validation, staff training, and compliance with quality standards was observed during the audit at Zoopole, Ploufragan (LDA22).

### **2.5.3 Sampling, testing, and reporting**

Laboratory submission forms accompany all samples at arrival. Post-vaccination active surveillance samples consist of 60 oropharyngeal swabs from live birds, pooled in groups of 5 for laboratory processing. Enhanced passive surveillance samples should consist of 5 oropharyngeal swabs from carcasses, moribund or live birds, processed in a single pool.

Front-line diagnostic testing includes real-time RT-PCR for M gene, H5/H7, high-pathogenicity H5, and serology (ELISA, AGID, HAIT). The NRL allows the use of specific commercial kits, which are listed for use by approved and recognised laboratories.

Laboratories utilise local laboratory information management systems (LIMS), which interface with the SIGAL platform for data submission. Negative results are communicated to the local Département Directorate, VM, farmer, and relevant intertrade group by email. Positive results are communicated by phone to the local Département Directorate. The NRL is provided with all surveillance results.

Active and enhanced passive surveillance results are uploaded to the SIGAL information system. Private recognised laboratories face intermittent connectivity issues with the SIGAL system, causing delays in reporting negative passive surveillance results. The reporting of positive results is unaffected.

The audit team noted that there were inconsistencies in sample submission, with laboratories receiving pooled samples not always meeting the required total sample number for both the enhanced passive and active surveillance programmes. The CA relies on laboratories to highlight non-compliances. However, there was no guidance available to the laboratory network on how to monitor inconsistencies in sample submissions and when to flag non-compliance to local Département Directorates for further follow up. This may result in the post-vaccination surveillance testing not fulfilling the requirements specified in Regulation 2023/361. A clear mechanism should be in place for these errors to be flagged to local Département Directorates and rectified.

Recommendation 1: DGAL to provide guidance to laboratories on when to highlight sampling non-compliances to local Département Directorates

Overall, procedures for reporting positive results are robust and compliant with regulatory standards. No specific concerns were found in the laboratory network and its operation during the audit.

## 2.6 Surveillance

### 2.6.1. Overview of surveillance

There are 3 surveillance programmes supporting the HPAI vaccination programme in ducks:

- event-based passive surveillance when there is suspicion of HPAI
- enhanced passive surveillance in vaccinated duck flocks
- active surveillance in vaccinated duck flocks

Active and passive national AI surveillance programmes for wild birds are also ongoing in France.

Event-based passive surveillance applies to all avian species. The additional post-vaccination enhanced passive and active surveillance programmes have been implemented on farms with vaccinated ducks since the start of the HPAI vaccination programme and are based on the provisions in Regulation 2023/361.

Part 5 of Annex XIII of Regulation 2023/361 specifies the post-vaccination surveillance sampling requirements:

“2. Reinforced surveillance to be implemented in case of preventive vaccination:

2.1 enhanced passive surveillance shall be implemented in the vaccinated establishments by weekly virological testing of a representative sample of dead birds collected within one week;

2.2. after the start of vaccination, the following active surveillance has to be carried out by an official veterinarian in vaccinated establishments at least every 30 days to detect occurrence of infection with HPAI field virus:

(a) a clinical examination that shall include a check of the production records and health records of the establishment in each epidemiological unit, including an evaluation of its clinical history and clinical examinations of the poultry or captive birds;

(b) a collection of representative samples for laboratory surveillance by serological or virological testing to enable detection of a prevalence of HPAI virus infection in the epidemiological unit of 5% with a confidence level of 95%, using appropriate methods and protocols that allow early detection of the virus and taking into account the specific characteristics of the vaccine used;”

For the purposes of the vaccination programme, the “epidemiological unit” is defined as “a group of animals with a similar probability of exposure to a pathogen, it is assimilated to the farm site (which may consist of several buildings)”. For the enhanced passive and active surveillance programmes, each farm is considered a single epidemiological unit and testing is required by the CA at the farm level and not the flock level.

In addition to the post-vaccination surveillance, if ducks are being moved within or from a high-risk area, virological surveillance of 20 tracheal/oropharyngeal swabs are collected within 72 hours prior to movement. Negative results must be received before movement.

In the first year of the vaccination programme, sampling for serological surveillance was performed at batch completion. Twenty blood samples were taken for testing with NP ELISA at slaughter or on movement to fattening units for foie gras birds. Ducks are very susceptible to AI and free-range poultry flocks are easily exposed to AI viruses circulating within wild bird populations. In birds vaccinated against H5, both H5 HAIT and H5 ELISA testing will be positive. The NP ELISA is required to differentiate between vaccinated and infected birds and as such is used as the DIVA strategy for France’s HPAI vaccination programme. However, NP ELISA testing cannot differentiate between flocks infected with HPAI and those infected with other subtypes and LPAI strains.

During the serological surveillance, data was not found to be useful because duck flocks were positive on NP ELISA and the type of infection could not be differentiated. This serological surveillance programme is not being continued for the second year of the HPAI vaccination programme. It was not used as part of the official post-vaccination surveillance programme but instead to assess field challenge in vaccinated flocks. Discontinuation of this serological surveillance is not of concern if the existing surveillance requirements and recommendations in this report for post-vaccination enhanced passive and active surveillance are complied with.

A report of the surveillance results for the first year of the vaccination programme is due to be published but was not publicly available at the time of the audit and could not be shared with the audit team.

A summary of the sampling protocol for the post-vaccination enhanced passive and active surveillance programmes is summarised in Table 3 and described in more detail below.

**Table 3: Summary of France’s HPAI post-vaccination enhanced surveillance programme<sup>1</sup>**

Parameters	Enhanced passive surveillance	Active surveillance	Active surveillance
<b>Type</b>	<b>Virological</b>	<b>Virological<sup>2</sup></b>	<b>Serological<sup>3</sup></b>
<b>Where</b>	The epidemiological unit <sup>4</sup>	The epidemiological unit <sup>4</sup>	The epidemiological unit <sup>4</sup>
<b>Who</b>	Farmer or technical worker	Mandated veterinarian (VM)	Mandated veterinarian (VM)
<b>Frequency</b>	Weekly	Every 30 days	On batch completion (transfer to force-feeding or movement to slaughter)
<b>How</b>	One pool of 5 tracheal/oropharyngeal swabs from dead or moribund or live ducks	60 swabs (tracheal/oropharyngeal swabs in pools of 5 swabs)	20 blood samples (individual testing)
<b>Testing</b>	Virological testing using M gene RT-PCR (if positive, screen for H5/H7)	Virological testing using M gene RT-PCR (if positive, screen for H5/H7)	Serological testing using NP ELISA
<b>Type of laboratory</b>	Recognised (confirmed assessed by the NRL) or approved laboratory (confirmed ISO1705 accredited minimum)	Approved laboratory (confirmed ISO1705 accredited minimum)	Approved laboratory (confirmed ISO1705 accredited minimum)

<sup>1</sup> Table adapted from [‘Factsheet 5 – Post-Vaccination Surveillance’](#).

<sup>2</sup> Active virological surveillance protocol is designed to allow detection of 5% prevalence of HPAI infection in the epidemiological unit with a confidence level of 95% as specified by Part 5 of Annex XIII of Regulation 2023/361.

<sup>3</sup> Serological surveillance at batch completion for research purposes was designed to allow detection of 20% prevalence of HPAI infection in the epidemiological unit with a confidence level of 95%. This has been discontinued for second year of vaccination programme.

<sup>4</sup> “Epidemiological unit” is defined for the purposes of the HPAI vaccination programme as “a group of animals with a similar probability of exposure to a pathogen, it is assimilated to the farm site (which may consist of several buildings)”.

## 2.6.2 Event-based passive surveillance in poultry

Event-based passive surveillance in poultry is routine passive surveillance for suspect cases of NAD and applies to all avian species, including vaccinated and unvaccinated ducks. During the audit, farmers, industry representatives and private veterinarians understood the importance of passive surveillance for the prompt detection of disease and prevention of spread. All parties were familiar with the means for immediate reporting any suspicion of NAD to the CA.

The French domestic legal requirements for passive surveillance disease reporting are specified in Article 22 of the Ministerial Decree of 25 September 2023 on surveillance, prevention, control and vaccination against HPAI. The requirements are sufficiently robust to ensure detection of disease at an early stage. For a flock of more than 250 poultry or captive birds, the triggers for reporting and immediate investigation by a VS are:

- a. a threefold increase in normal daily mortality
- b. any drop in daily feed or water consumption of more than 25%
- c. any drop in egg laying of more than 15% over one day or more than 5% per day for 3 consecutive days

Any suspicion of NAD must be immediately reported by the VS to the CA. Reports of suspicion are usually made by a farm's VS to the local Département Directorate. Following notification of suspect NAD in vaccinated or unvaccinated birds, the Département Directorate will immediately investigate and follow national and EU legislation and existing contingency plans to implement the necessary disease control measures.

## 2.6.3 Active surveillance in vaccinated duck flocks

Active surveillance is implemented to detect low-level or sub-clinical circulation of HPAI virus where birds are not showing clinical signs. Active surveillance sampling and testing is funded by the CA. Sampling is performed by the farm's VS in their capacity as a VM. It includes clinical examination of each flock, and collection of 60 tracheal or oropharyngeal swabs from vaccinated birds every 30 days (+/- 10 days) split evenly across all houses on the farm. These swabs are pooled into 12 pools of 5 swabs for virological testing using M gene RT-PCR. If the test result is positive, screening for H5/H7 is carried out. If H5 positive, analysis for the detection of clade 2.3.4.4b, is performed.

The VM creates a record of each visit for active surveillance sampling in the Calypso information system and issues a certificate of good health ('Bonne Sante'). At the final active surveillance visit before slaughter, the VM issues a post-vaccination surveillance certificate, which is generated in the Calypso information system and verifies compliance with all aspects of the post-vaccination surveillance. The records in Calypso are used by the Département Directorates to authorise payment to the VM for fulfilling this mandated duty and to verify compliance with the active surveillance visits.

Only approved laboratories are authorised to test active surveillance samples. Approved laboratories upload all active surveillance results to the SIGAL information system and separately email results to the local Département Directorate, VM, farmer, and relevant intertrade group. In the event of a positive result, the approved laboratory notifies the local Département Directorate before other parties.

All positive and negative active surveillance testing results are available in SIGAL. Active surveillance is monitored by the local Département Directorate through manual verification of results emailed by approved laboratories which are cross referenced with visit records in Calypso and laboratory testing results in SIGAL. Since spring 2024, results have also been uploaded from SIGAL to Calypso. Multiple information systems are required to verify active surveillance programme sampling and testing. However, the combination of records in SIGAL, Calypso and emailed results provides Département Directorates with a good overview of the activities of VMs and approved laboratories.

Département Directorates are not actively monitoring that the required 60 oropharyngeal/tracheal swabs are always submitted by VMs to approved laboratories. The CA relies on approved laboratories to highlight major non-compliances but has not provided clear guidelines for monitoring compliance with sampling requirements to laboratories. As detailed in Recommendation 1, DGAL should provide guidance to laboratories on when to highlight non-compliances in sampling to local Département Directorates.

#### **2.6.4 Enhanced passive surveillance in vaccinated duck flocks**

Enhanced passive surveillance is performed by the farmer. It involves the collection and submission of one pool of 5 tracheal or oropharyngeal swabs from 5 recently deceased birds once per week from each establishment. Each farm is considered a single epidemiological unit. The CA requires that enhanced passive surveillance sampling is performed at the farm level basis. The 5 swabs are usually collected from across all houses on the farm although some (especially duck meat) farms proactively sample each house separately.

The swabs are submitted to approved or recognised laboratories for virological testing using M gene RT-PCR. If the result is positive, screening is carried out for H5/H7, and, if H5 positive, analysis for the detection of clade 2.3.4.4b is performed. Enhanced passive surveillance sampling and testing is funded by industry.

Farmers were confident in performing the sampling with technical support provided through the intertrade groups, and on-site support provided by these groups and private veterinarians where required. CA technical instructions on how to perform sampling have been distributed to farmers and are publicly available.

Sampling at the farm level instead of at the flock (airspace or house) level will result in a decrease in the sensitivity of the surveillance overall. The challenge studies carried out in France and published by ANSES found that viral shedding is likely to be significantly

reduced in vaccinated ducks<sup>3</sup>. Although this is a positive outcome of vaccination, potential infection may be missed by the current enhanced passive surveillance unless the level of sampling is adjusted so it remains statistically valid for farms of different sizes. As vaccinated flocks exposed to the virus are less likely to have a high level of virus circulation, the current approach of collecting 5 dead birds per week from multiple houses on one farm will not be sensitive enough to detect infection promptly. This is particularly relevant for larger premises with multiple buildings. This recommendation aligns with EFSA's Scientific Opinion<sup>4</sup>.

**Recommendation 2: Enhanced passive surveillance sampling to be carried out at the flock (airspace or house) level for all farms exporting meat and meat products from vaccinated ducks to Great Britain**

The official enhanced passive surveillance programme has been amended for the second year of the vaccination programme so that the farmer does not have to collect samples in the weeks where the VM is collecting samples for active surveillance. The CA recommends that when the VM collects the 60 samples for active surveillance, 5 of them are collected from dead or moribund animals. These samples are supplemented by healthy ducks if 5 samples from dead or moribund animals cannot be taken.

It was reported that the VM may only sample live birds when collecting samples for active surveillance, even if dead birds are available. If active surveillance sampling is only conducted on live birds, this means that in these weeks, samples are not collected from dead or moribund birds and enhanced passive surveillance is not undertaken. Testing samples from dead birds increases the probability of and decreases the time to HPAI detection<sup>5</sup>.

If the farmer has not collected samples for enhanced passive surveillance in the week where the VM is collecting samples for active surveillance, the CA must ensure VMs collect 5 samples from dead or moribund animals where available.

**Recommendation 3: The competent authority must ensure that enhanced passive surveillance sampling is carried out on a weekly basis throughout production irrespective of other types of sampling undertaken**

Both approved and recognised laboratories are authorised to test enhanced passive surveillance samples. Laboratories upload results to the SIGAL information system and separately email results to the local Département Directorate, VM, farmer, and relevant intertrade group. This approach enables the CA, VM and intertrade group to verify farmer

---

<sup>3</sup>Experimental vaccination of mule ducks under field conditions against highly pathogenic avian influenza A (H5N1) virus of clade 2.3.4.4b: [Interim Report 1](#) and [Interim Report 2](#)

<sup>4</sup> [Vaccination of poultry against highly pathogenic avian influenza – Part 2. Surveillance and mitigation measures](#)

<sup>5</sup> [Scientific Opinion on the assessment of the control measures of the category A diseases of Animal Health Law: Highly Pathogenic Avian Influenza](#)

compliance with sampling requirements. As for active surveillance, in the event of a positive result, the laboratory would notify the local Département Directorate before other parties.

At the start of the vaccination programme in October 2023 until April 2024, there was a requirement for up to 5 samples to be collected from dead birds. If there were less than 5 dead birds, less than 5 samples could be submitted. From April 2024, the protocol was amended to require up to 5 samples from dead birds but to include moribund live bird samples if not enough dead birds were available. This was amended again in November 2024, so that if not enough dead or sick birds are available, then live birds must be sampled until 5 samples have been collected. This has been implemented to address limited number of samples submitted by some farmers. Conversely, the audit team also saw evidence that on some establishments, sampling is done at house level, with 5 swabs collected from each house.

It could not be demonstrated how the VM could ensure that the correct number of swabs had been submitted for enhanced passive surveillance testing. There is no record on SIGAL, Calypso or the emailed testing results of how many swabs are submitted in a pool, as results may be reported and paid for as one pooled PCR of up to 5 swabs per farm. As 5 swabs are required for enhanced passive surveillance testing, the CA must provide clear instructions to VMs on ensuring the correct number of swabs have been submitted. As detailed in Recommendation 1, they must also provide guidance to laboratories on when to highlight non-compliances in submitted samples to local Département Directorates for follow-up. This is essential for ensuring consistency and compliance with enhanced passive surveillance requirements by farmers.

The VM is mandated by the CA to be responsible for the enhanced passive surveillance being completed on their designated farms. At the monthly active surveillance visit, the VM verifies whether the weekly enhanced passive surveillance sampling has been submitted by the farmer and if results have been received. The VM signs an attestation on the post-vaccination surveillance certificate issued on the final visit pre-slaughter, stating that the farmer has complied with weekly enhanced passive surveillance. This certificate is required to move birds to slaughter.

There were different understandings between parties as to what compliance with post-vaccination surveillance meant, and what was required to sign the post-vaccination surveillance certificate. For example, VMs and CA officials stated that the attestation on the post-vaccination surveillance certificate only requires the farm to comply with active surveillance sampling and testing for the pre-slaughter post-vaccination surveillance certificate to be issued. However, the post-vaccination certificate states that the farm is compliant with the surveillance required by Point 2 in Part 5 of Annex XIII of Regulation 2023/361, that is both enhanced passive and active surveillance sampling and testing. The CA and all stakeholders must understand that both active and enhanced passive surveillance are mandatory and required for the VM to certify the post-vaccination surveillance certificate.

**Recommendation 4: The competent authority to ensure that mandated veterinarians verify compliance with enhanced passive surveillance, including confirming that the correct number of swabs have been submitted on a weekly basis, before signing the post vaccination surveillance certificate**

The CA is not routinely auditing VMs or verifying that VMs are accurately checking compliance with enhanced passive surveillance requirements and correctly certifying the post-vaccination surveillance certificate. The CA can verify the active surveillance undertaken by VMs through cross referencing of emails, SIGAL and Calypso. However, it is essential that the delivery of all official controls related to the post-vaccination surveillance programme, and in particular verification by the VM of the number of swabs taken during weekly farmer sampling, are routinely audited to ensure consistent delivery across the département or region and at a national level.

**Recommendation 5: Département Directorates to audit how post-vaccination surveillance requirements are delivered or verified by mandated veterinarians**

Not all enhanced passive surveillance results are recorded on SIGAL. This is due to issues with recognised laboratories not uploading negative passive surveillance results due to unfamiliarity with the process and IT system issues. Additionally, the results on SIGAL do not differentiate between individual houses on farms, even if testing is being performed at house level. Whilst the VMs and local Département Directorates are emailed all results of enhanced passive surveillance, which provides a degree of oversight, verification is laborious. Overall, it is difficult for both the CA and VMs to verify compliance across the available records and information systems.

In addition, when recording the active surveillance visit on Calypso, the VM should record if the farm is compliant with the enhanced passive surveillance requirements. However, this information is not always recorded. This then identifies as 'No' for enhanced passive surveillance in the Calypso system on the affected farms' records. This should be actioned as it is mandatory to comply with the requirements for enhanced active surveillance. However, the records are not being monitored or followed up by the local Département Directorates or DGAL to confirm compliance. The CA is overly reliant on the VMs to monitor compliance with enhanced passive surveillance. Ensuring reporting of all enhanced passive surveillance results by recognised laboratories would enable the CA to have greater oversight on the delivery of enhanced passive surveillance.

**Recommendation 6: The competent authority to be able to directly verify compliance with enhanced passive surveillance requirements**

## **2.7 Traceability and export health certification**

According to the Animal Health Law (Regulation (EU) 2016/429), Member States must have a system for identifying and registering kept terrestrial animals, recording their movements, and maintaining up-to-date records. Delegated Regulation (EU) 2019/2035 sets rules for establishments keeping terrestrial animals and their traceability. Specifically, establishments (Article 84 of the Animal Health Law) and transporters (Article 3 of Delegated Regulation

2019/2035) must be registered with the competent authority. Owners and keepers must maintain records of poultry numbers, production performance, morbidity rates, biosecurity measures, and veterinary visits.

Producers of foie gras and meat ducks are required to declare movements in the BD Avicole or ATMC databases, respectively. These databases are used by foie gras and meat duck farmers and intertrade groups to record and declare their bird placements and movements. These systems create an IMEP (batch) number that follows batches of ducks from hatch throughout production. The systems were developed by industry, but the competent authority has permanent access for animal health management purposes.

The meat duck slaughterhouse visited during the audit demonstrated strong traceability from farm to export, with good flow and accurate processes observed. Biosecurity measures, such as vehicle and crate disinfection were in place. There was robust batch traceability through labelling, with clear separation of batches on the slaughter line and good use of internal IT databases. The traceability system demonstrated would allow exports destined for Great Britain to meet additional criteria for certification if required. For example, if exports destined to Great Britain are required to meet additional surveillance criteria, systems such as the one demonstrated would be able to differentiate between batches coming from farms which are compliant with Great Britain's requirements and those that are not.

Export certification is undertaken by government official veterinarians (OVs) employed by the Département Directorates. Export health certificates are signed by OVs in line with Articles 3 and 86-90 of the Official Controls Regulation (EU) 2017/625. Measures are in place to prevent the export of vaccinated birds and their products to Great Britain, including updates provided during biweekly meetings and on the Expadon 2 platform. Written instructions have also been issued to all Département Directorates instructing OVs not to sign export health certificates for vaccinated birds or their products being exported to Great Britain.

Furthermore, model health certificates for Great Britain cannot be certified for consignments of vaccinated birds or their products unless the exporting country's vaccination programme has been approved by Defra. Oversight and quality assurance for export certification procedures is ensured by the competent authority. Exporting slaughterhouses must be approved by the CA. Approved slaughterhouses may be suspended by the CA if approval conditions are not met, with non-compliances resulting in a formal notice and potential revocation. Approval is reinstated when corrective actions have been undertaken and compliance achieved.

Overall, traceability and export certification systems utilise comprehensive electronic systems and demonstrate strong traceability from farm to export. In the event that exports destined to Great Britain are required to meet additional criteria, the level of detail in these systems would allow for batches to be differentiated.

### 3. Conclusions

The audit conducted by Defra in France from 2 to 6 December 2024 provides a comprehensive assessment of the level of effectiveness with which animal health controls, surveillance systems and laboratory procedures supporting the HPAI vaccination programme are implemented in France.

The audit concludes that France has implemented an effective HPAI vaccination programme to reduce the impact of HPAI in commercial ducks through strong collaboration between the competent authority, industry, and laboratory networks. The competent authority has demonstrated clear organisational structure and capacity to implement vaccination and the associated surveillance programmes effectively. The use of VMs for official tasks has ensured the rollout and uptake of the programme in its first year.

Post-vaccination surveillance is crucial to ensure the virus is not circulating undetected in subclinically infected vaccinated ducks, despite reduced viral shedding and transmission. Proper certification of post-vaccination certificates based on verification of compliance with all elements of the surveillance programme required by legislation and addressing sampling frequency are essential. Furthermore, sampling for the enhanced passive surveillance programme should be carried out at the flock (airspace or house) level to increase the sensitivity of the surveillance overall.

The laboratory network, overseen by the NRL, provides appropriate testing procedures, though improvements in reporting negative results and handling guidance for non-compliances in sample submissions are needed. Traceability and export certification systems show robust traceability from farm to the point of export, with the capability to meet any potential additional criteria for exports to Great Britain.

The report makes recommendations to the French competent authorities in relation to observations and findings of the audit. They are set out in the recommendations in the corresponding sections of this report and below.

### 4. Recommendations

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

**Recommendation 1:** DGAL to provide guidance to laboratories on when to highlight sampling non-compliances to local Département Directorates.

**Recommendation 2:** Enhanced passive surveillance sampling to be carried out at the flock (airspace or house) level for all farms exporting meat and meat products from vaccinated ducks to Great Britain.

**Recommendation 3:** The competent authority must ensure that enhanced passive surveillance sampling is carried out on a weekly basis throughout production irrespective of other types of sampling undertaken.

**Recommendation 4:** The competent authority to ensure that mandated veterinarians verify compliance with weekly enhanced passive surveillance, including confirming that the correct number of swabs have been submitted on a weekly basis, before signing the post vaccination surveillance certificate.

**Recommendation 5:** Département Directorates to audit how post-vaccination surveillance requirements are delivered or verified by mandated veterinarians.

**Recommendation 6:** The competent authority to be able to directly verify compliance with enhanced passive surveillance requirements.

# Abbreviations

ANMV	Agence Nationale du Médicament Vétérinaire (French National Agency for Veterinary Medicines)
ANSES	Agence Nationale de Sécurité Sanitaire de l'Alimentation (French Agency for Food, Environmental and Occupational Health & Safety)
ANVOL	Association Nationale Interprofessionnelle de la Volaille de Chair (French National Poultry Association)
APHA	Animal and Plant Health Agency
AGID	Agar Gel Immunodiffusion Assay
AI	Avian Influenza
AIV	Avian Influenza virus
BICMA	Bureau de l'Identification et du Contrôle des Mouvements des Animaux (Office for Animal Identification and Movement Control)
BSA	Bureau de la Santé Animale (Office for Animal Health)
CA	Competent Authority
CIFOG	Comité Interprofessionnel des Palmipèdes à Foie Gras (Professional Trade Association for Foie Gras)
CICAR	Comité Interprofessionnel du Canard à Rôtir (Professional Trade Association for Meat Ducks)
COFRAC	COmité FRançais d'ACcréditation (French Accreditation Committee)
CRPM	Code Rural et de la Pêche Maritime (Rural and Maritime Fishing Code)
DDPPs	Direction Départementale de la Protection des Populations (Département Directorate)
DD(ETS)PPs	Direction Départementale de l'Emploi, du Travail, des Solidarités et de la Protection des Populations ((Département Directorate)
Defra	Department for Environment, Food and Rural Affairs
DRAAF	Direction Régionale de l'Alimentation, de l'Agriculture et de la Forêt
DGAL	General Directorate for Food
DIVA	Differentiating Infected from Vaccinated Animals
EU	European Union
ELISA	Enzyme-Linked Immunosorbent Assay
ENVT	L'École Nationale Vétérinaire de Toulouse (National Veterinary School of Toulouse)
FranceAgriMer	L'Établissement National des Produits de l'Agriculture et de la Mer (National Establishment for Agriculture and Seafood)
HAIT	Haemagglutination Inhibition Testing
HPAI	Highly Pathogenic Avian Influenza
ITAVI	Institut Technique de l'Aviculture (French Technical Institute for Poultry)
IVPI	Intravenous Pathogenicity Index
LIMS	Laboratory Information Management System
LPAI	Low Pathogenicity Avian Influenza
NAD	Notifiable Avian Disease
NP ELISA	Nucleoprotein Enzyme-Linked Immunosorbent Assay
NRL	National Reference Laboratory
OV	Official Veterinarians
PCR	Polymerase Chain Reaction
RT-PCR	Reverse Transcription Polymerase Chain Reaction
SIMV	Syndicat de l'Industrie du Médicament et du Diagnostic Vétérinaires (Union of the Veterinary Medicine and Diagnostics Industry)

SNA	Syndicat National des Accouveurs (French National Hatchery Association)
SPS	Sanitary and Phytosanitary
SRAL	Service Régional de l'Alimentation (Regional Food Service)
VH	Vétérinaires Habilités (Authorised Veterinarians)
VM	Vétérinaires Mandatés (Mandated Veterinarians)
VS	Vétérinaires Sanitaire (Sanitary Veterinarians)

# ANNEX I

The legislation of Great Britain relevant to the audit is listed below:

- Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 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 products
- 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
- The Avian Influenza and Influenza of Avian Origin in Mammals (England) (No.2) Order 2006
- The Avian Influenza and Influenza of Avian Origin in Mammals (Wales) Order 2006
- The Avian Influenza and Influenza of Avian Origin in Mammals (Wales) (No.2) Order 2006
- The Avian Influenza and Influenza of Avian Origin in Mammals (Scotland) Order 2006
- The Avian Influenza (H5N1 in Poultry) (Scotland) Order 2007
- The Avian Influenza (H5N1 in Wild Birds) (England) Order 2006
- The Avian Influenza (H5N1 in Wild Birds) (Wales) Order 2006
- The Avian Influenza (H5N1 in Wild Birds) (Scotland) Order 2006
- The Avian Influenza (H5N1 in Wild Birds) (Scotland) Order 2007
- The Avian Influenza (Preventive Measures) Regulations 2005
- The Avian Influenza (Preventive Measures) (No 2) Regulations 2005
- The Avian Influenza (Preventive Measures) (England) Regulations 2006
- The Avian Influenza (Preventive Measures) (Wales) Regulations 2005
- The Avian Influenza (Preventive Measures) (Wales) (No.2) Regulations 2005
- The Avian Influenza (Preventive Measures) (Wales) Regulations 2006
- The Avian Influenza (Preventive Measures) (Scotland) Regulations 2005
- The Avian Influenza (Preventive Measures) (Scotland) Order 2007
- The Avian Influenza (Vaccination) (England) Regulations 2006
- The Avian Influenza (Vaccination) (Wales) (No.2) Regulations 2006
- The Avian Influenza (Slaughter and Vaccination) (Scotland) Regulations 2006
- The Avian Influenza and Newcastle Disease (England and Wales) Order 2003
- The Avian Influenza and Newcastle Disease (Biosecurity Guidance and Disease Control (Slaughter) Protocol) (England and Wales) Order 2003
- The Avian Influenza and Newcastle Disease (Contingency Planning) (England) Order 2003
- The Avian Influenza and Newcastle Disease (Contingency Planning) (Wales) Order 2005
- Animal Health Act 1981

- Animal Health Act 1981 as amended by the Animal Health and Welfare (Scotland) Act 2006
- Diseases of Poultry (England) Order 2003
- Diseases of Poultry (Wales) Order 2003
- Diseases of Poultry (Scotland) Order 2003
- The Products of Animal Origin (Disease Control) (England) Regulations 2008
- The Products of Animal Origin (Disease Control) (Wales) Regulations 2008
- The Products of Animal Origin (Disease Control) (Scotland) Order 2008
- Notifiable Avian Disease Control Strategy for Great Britain

## ANNEX II

Key national legislation of France relevant to the audit scope includes:

- Ministerial Decree of September 25, 2023 on surveillance, prevention, control and vaccination against highly pathogenic avian influenza (HPAI). This Decree is a group of 7 Ministerial Decrees in accordance with the European Regulations published by the French government
- Ministerial Decree of September 29, 2021 on biosecurity regulation covering measures to be applied by operators and professionals keeping poultry
- Article L 203–8 of the Rural and Maritime Fishing Code (Code Rural et de la Pêche Maritime (CRPM)) which specifies that the administrative authority can mandate sanitary veterinarians to execute animal health policy operations on behalf of the State
- The National Order of Veterinarians of August 23, 1947, updated to law No. 2014-1170 of October 13, 2014 which created the institution as a professional order to oversee the veterinary profession in France
- Article 37 of EU Regulation 2017/625 stipulates that official laboratories must be accredited against standard ISO 17025
- French national regulation (Article R.202-13 of the CRPM) which stipulates that as soon as the official laboratory is accredited, it has the duty to inform the competent authority of any changes regarding its equipment, staff, legal status and scope of accreditation

The principal acts and regulations on animal health and veterinary public health controls in France include:

- EU Regulation 2016/429 on transmissible animal diseases ('Animal Health Law')
- EU Commission Delegated Regulation 2023/361 as regards rules for the use of certain veterinary medicinal products for the purpose of prevention and control of certain listed diseases

Further related acts and regulations include:

- EU Commission Delegated Regulation 2020/687 of 17 December 2019 supplementing Regulation (EU) 2016/429 of the European Parliament and the Council, as regards rules for the prevention and control of certain listed diseases
- EU Commission Delegated Regulation 2020/688 of 17 December 2019 supplementing Regulation (EU) 2016/429 of the European Parliament and the Council, as regards animal health requirements for movements with the Union of terrestrial animals and hatching eggs
- EU Commission Delegated Regulation 2020/689 of 17 December 2019 supplementing Regulation (EU) 2016/429 of the European Parliament and the Council, as regards rules for surveillance, eradication programmes, and disease-free status for certain listed and emerging diseases
- EU Commission Delegated Regulation 2019/2035 of 28 June 2019 supplementing Regulation (EU) 2016/429 of the European Parliament and the Council as regards rules for establishments keeping terrestrial animals and hatcheries, and the traceability of certain kept terrestrial animals and hatcheries, and the traceability of certain kept terrestrial and hatching eggs
- EU Regulation 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC.
- EU Regulation 2017/625 of the European Parliament and of the Council of 15 March 2017 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 products