MINISTÈRE
DE L'AGRICULTURE
ET DE LA SOUVERAINETÉ
ALIMENTAIRE
Liberté
Égalité
Fraternité

General Directorate for Food

OFFICIAL VACCINATION PLAN

HIGHLY PATHOGENIC AVIAN INFLUENZA (HPAI)

FACT SHEET 5 – POST-VACCINATION SURVEILLANCE

Implementation of a vaccination plan must go hand in hand with a system of strict surveillance in accordance with the provisions contained in European regulations, as well as in line with the recommendations of the Terrestrial Animal Health Code of the World Organisation for Animal Health (WOAH) and the opinions issued by EFSA (European Food Safety Authority).

THE REGULATORY FRAMEWORK FOR SURVEILLANCE FOLLOWING PREVENTIVE VACCINATION

Delegated regulation (EU) 2023/361 allows for the possibility of vaccination against HPAI in the European Union and provides for vaccination strategies that may be implemented for HPAI. In France, only the preventive vaccination strategy has been selected as a possible option at the present time.

According to the aforementioned regulation (cf. Annex XIII, part 5), when undertaking preventive vaccination, the competent authority must put in place a system of enhanced surveillance that meets the following conditions:

- ***enhanced passive surveillance*** *is to be implemented in the vaccinated establishments by weekly virological testing of a representative sample of dead birds collected within one week;*
- *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* ***clinical examination*** *to 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;*
    - ***collection of representative samples*** *for laboratory surveillance by serological or virological testing to enable detection of a 5% prevalence rate for HPAI virus infection in the epidemiological unit with a confidence interval 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; vaccinated captive birds from confined establishments are exempted from the surveillance.*

THE POST-VACCINATION SURVEILLANCE PROGRAMME IN FRANCE

Implementation of preventive vaccination in France is to be accompanied by post-vaccination surveillance in the forms of passive surveillance (event-based and enhanced) and active surveillance based on the provisions of regulation 2023/361.

Post-vaccination surveillance must be carried out in all epidemiological units, where vaccinated animals are kept. The "epidemiological unit" is defined by the Delegated Regulation 2023/361, as a group of animals with the similar level of exposure to a pathogen, which is equivalent to the farm site (which may consist of several buildings).

1.1.1. Event-based surveillance

The purpose of event-based surveillance is to ensure the earliest possible detection of cases of HPAI in domestic birds linked to circulation of a strain not targeted by the vaccine or to a failure of vaccination.

All holders of birds must ensure their surveillance in order to detect the appearance of symptoms of disease or the presence of dead captive or wild birds. They must declare to a veterinarian any abnormal or unexplained behaviour by birds without delay, in addition to any sign of disease, and most notably any triggering of the alert criteria set out in Annex I of the ministerial order of 16/03/2016. Event-based surveillance tests are to be carried by approved laboratories.

1.1.2. Enhanced passive surveillance

The purpose of this form of surveillance is to enable detection of circulation of the virus.

The surveillance is conducted at the level of the epidemiological unit, allocating the (vaccinated) dead birds tested in accordance to the number of buildings within the epidemiological unit. This surveillance applies to facilities where birds are reared and where force-feeding (*gavage*) is carried out.

The sampling protocol involves the taking by the farmer or a technical worker of tracheal or oropharyngeal swabs from recently deceased birds up to a maximum of five dead birds per week[1]. In sites holding multiple species of birds, samples shall be taken exclusively from vaccinated birds present in the facility where they are reared.

The samples are to be sent to recognised laboratories. Following arrival at the laboratory, the swabs are to be pooled in groups of five and subjected to M gene RT-PCR analysis in the recognised laboratory facilities (this equates to a single RT-PCR point per epidemiological unit per week)[2]. In the event of a positive result, further sampling must be conducted for analysis by an approved laboratory.

1.1.3. Active surveillance

The purpose of active surveillance is to enable detection of low-level circulation of the virus.

[1] The sample size of dead birds is based on the EFSA advice: https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2021.6372.

[2] The method is based on EURL Protocol: https://www.izsvenezie.com/documents/reference-laboratories/avian-influenza/diagnostic-protocols/weekly-pool-sampling-bucket-sampling.pdf

The active surveillance protocol is based on monthly virological surveillance supplemented by serological surveillance on poultry batch completion.

Such active surveillance must be applied by a veterinary empowered to do so (official veterinarians).

The active surveillance protocol involves the collection of samples at least every 30 days in the form of tracheal or oropharyngeal swabs from 60 vaccinated birds[2] from across the farm for virological testing by M gene RT-PCR in an approved laboratory. In the event of a positive result, the approved laboratory must screen for H5/H7.

To supplement the above, serological surveillance based on blood samples from 20 vaccinated birds[3] for NP ELISA assay in an approved laboratory on each batch prior to transfer to the force-feeding (*gavage*) facility (ducks used for foie gras production) or the slaughterhouse (table birds).

Where serological testing is positive, the results of RT-PCR on swabs taken at the same time as the blood samples will allow the presence of active viral circulation to be confirmed or ruled out.

The following table summarises HPAI post-vaccination enhanced surveillance:

HPAI enhanced post-vaccination surveillance		
Parameters	Enhanced passive surveillance	Active surveillance
Where?	The epidemiological unit	
Who?	Farmer or technical worker	Official veterinary
Frequency?	Weekly	Every 30 days: virological testing On batch completion: serological testing
How?	Swabs (tracheal/oropharyngeal) from 5 dead birds	Every 30 days : Swabs (tracheal/oropharyngeal) from 60 birds; At batch completion: blood samples from 20 birds
Testing?	Virological using M gene RT-PCR. If the result is positive, screening for H5/H7	Virological using M gene RT-PCR (If the result is positive, screening for H5/H7) and NP ELISA serology
Type of laboratory?	A recognised laboratory	An approved laboratory

[2] Allowing detection of 5% prevalence of infection by the Highly Pathogenic Avian Influenza virus in the epidemiological unit with a confidence interval of 95% as specified by Annex XIII, part 5, of delegated regulation 2023/631.

[3] Allowing, as a supplement to virological surveillance, detection of 20% prevalence of infection by the Highly Pathogenic Avian Influenza virus in the epidemiological unit with a confidence interval of 95%.

The scientific basis for the chosen surveillance criteria

Enhanced post-vaccination surveillance

This surveillance is based on virological testing of weekly samples of five dead birds.

Each sample is to be chosen according to the method recommended by the European reference laboratory for avian influenza for poultry showing no clinical signs of HPAI viral infection[4], as well as on the scientific opinion of an EFSA expert group[5], showing that samples of at least five dead birds are sufficient to allow detection of HPAI in the event of mortality occurring following HPAI infection.

Higher levels of mortality would trigger clinical suspicion followed by application of event-based surveillance.

Active post-vaccination surveillance

Active surveillance is carried out every 30 days and involves clinical examination of the birds and systematic sampling of 60 vaccinated birds for virological testing. The purpose of these samples is to detect events assessed as having low risk of occurrence. A decision has therefore been taken to apply a level of 5% prevalence of infection by the highly pathological avian influenza virus in the epidemiological unit with a 95% confidence interval. The aim of active surveillance is therefore to obtain certainty, subject to the 5% prevalence threshold (*taux de prévalence limite* - TPL) and a confidence index (*indice de confiance* - IC) of 95%, that asymptomatic viral circulation is absent in the current batch of farmed birds.

This virological surveillance is supplemented by Elisa NP serological testing carried out by the authorised veterinarian on 20 vaccinated birds in each batch at the end of production. Such surveillance is conducted in order to obtain certainty that the birds have not been subject in the past to silent infection by an avian influenza virus (all sub-types included). A very low level of circulation would be maintained over time, leading to seroconversion of a large majority of the birds, and for that reason a prevalence threshold of 15% and a confidence interval of 95% are considered sufficient.

[4] https://www.izsvenezie.com/documents/reference-laboratories/avian-influenza/diagnostic-protocols/weekly-pool-sampling-bucket-sampling.pdf
[5] https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2021.6372

THE NETWORK OF RECOGNISED AND APPROVED LABORATORIES

Application of post-vaccination surveillance is reliant on a network of approved and recognised laboratories.

Enhanced passive surveillance

Enhanced passive surveillance, equating to self-inspection, can be carried out by recognised laboratories.

Active surveillance

Active surveillance is conducted in laboratories with Ministry approval for the execution of virological testing (using RT-PCR) and serological testing (NP ELISA).

For more information:

- **Commission delegated regulation (EU) 2023/361** of 28 November 2022 supplementing Regulation (EU) 2016/429 of the European Parliament and the Council as regards rules for the use of certain veterinary medicinal products for the purpose of prevention and control of certain listed diseases:
  https://eur-lex.europa.eu/legal-content/FR/TXT/PDF/?uri=CELEX:32023R0361&qid=1681975761645&from=FR

- **The list of official and recognised animal health laboratories in France**:
  https://agriculture.gouv.fr/laboratoires-officiels-et-reconnus-en-sante-animale