MINISTÈRE
DE L'AGRICULTURE
ET DE LA SOUVERAINETÉ
ALIMENTAIRE
Liberté
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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*** *shall 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*** *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;*
    - *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; 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 housed. The "epidemiological unit", is defined by the Delegated Regulation 2023/361, 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).

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 with the number of sheds in 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]. [1]Sampled dead birds are to be stored at negative temperatures while awaiting the results. Where sites are 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 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]The sample size of the 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 the LRUE protocol: https://www.izsvenezie.com/documents/reference-laboratories/avian-influenza/diagnostic-protocols/weekly-pool-sampling-bucket-sampling.pdf

1.1.3. Active surveillance

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

The active surveillance protocol is based on a clinical examination, with the evaluation of the zoo-technical criteria, completed with a monthly virological surveillance.

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[3] 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, in order to confirm/infirm the active circulation of a regulated IA virus, then, if the H5 gene is detected, the laboratory carries out an analysis for the detection of clade 2.3.4.4b.

In addition to this virological surveillance, a serological survey is carried out as a tool for the overall evaluation of the vaccination campaign on a national scale. This serological survey is carried out by the official veterinarians by taking blood samples from 20 vaccinated animals for ELISA-NP analysis in an approved laboratory on each batch before it is sent to the force-feeding room (ducks for foie gras production) or slaughterhouse (ducks for roasting).

HPAI post-vaccination enhanced surveillance and the serological survey		
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

[3] Allowing the detection of a 5% prevalence of HPAI virus infection in the epidemiological unit with a 95% confidence level as provided for in Annex XIII, Part 5 of Delegated Regulation 2023/631.

Scientific basis for the adopted surveillance criteria

Enhanced passive post-vaccination surveillance

This surveillance is based on the collection of 5 dead animals per week for virological analysis.

This sample was chosen on the basis of the method recommended by the European reference laboratory for avian influenza for poultry not showing clinical signs in the event of infection by an HPAI[4] virus, and on the scientific opinion of an EFSA[5] expert group showing that sampling at least 5 dead animals is sufficient to detect HPAI in the event of mortality following HPAI infection.

A higher mortality rate would trigger clinical suspicion and the implementation of event-based surveillance.

Active post-vaccination surveillance

Active surveillance is carried out every 30 days, with a clinical examination of the animals and systematic sampling of 60 vaccinated animals for virological analysis (pool of 5 swabs). The purpose of this sample is to look for an event assessed as having a low risk of occurrence. A prevalence of 5% of infection by the highly pathogenic avian influenza virus in the epidemiological unit was therefore chosen, with a confidence level of 95%. The objective of this active surveillance is therefore to ensure, at the 5% limit prevalence rate (LPR) and 95% confidence index (CI), the absence of asymptomatic viral circulation in the flock during rearing.

In addition to this virological monitoring, a serological survey is carried out on 20 vaccinated animals from each batch at the end of production, by using the ELISA NP (individual test). This serological survey is being carried out in order to build up a database that can be used to assess the overall impact of the vaccination campaign on controlling the circulation of the HP avian influenza virus and to confirm the effectiveness of detection by the 3 levels of surveillance (event-based, passive and active).

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).

[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

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 official order of 16 March 2016** concerning levels of epizootic risk due to infection of wild birds by Highly Pathogenic Avian Influenza and the associated systems of surveillance and prevention for poultry and other captive birds:
  https://www.legifrance.gouv.fr/loda/id/JORFTEXT000032320450/2021-10-01/

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

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