MINISTÈRE
DE L'AGRICULTURE
ET DE LA SOUVERAINETÉ
ALIMENTAIRE

Liberté
Égalité
Fraternité

French General Directorate for Food

ACTION PLAN FOR VACCINATION AGAINST HIGHLY PATHOGENIC AVIAN INFLUENZA (HPAI)

The reinforced post-vaccination surveillance programme

Implementation of a vaccination plan must go hand in hand with a system of strict surveillance compliant with the provisions contained in European regulations and 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 IN THE EVENT OF 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, a strategy for preventive vaccination is the only possible option at the present stage.

According to the same regulation (cf. Annex XIII, part 5), when implementing preventive vaccination, the competent authority is to put in place a system of reinforced surveillance that meets the conditions set out below:

- ***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

In the event of vaccination being carried out in France, post-vaccination surveillance will be implemented in the forms of passive surveillance (early warning system and enhanced passive surveillance) and active surveillance.

1. Early warning system

The purpose of early warning system is to detect cases of HPAI in domestic birds as early as possible.

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 March 2016.

2. Enhanced passive surveillance

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

The surveillance is conducted at the level of the epidemiological unit, allocating the dead birds analysed (vaccinated and unvaccinated) in accordance with the number of buildings forming the epidemiological unit.

The sampling protocol includes the taking of tracheal or oropharyngeal swabs from recently deceased birds up to a maximum of five dead birds per week. The swabs should then be pooled in groups of five and subjected to PCR analysis.

This testing should be conducted in recognised laboratories, a list of which is published in an official order by the Ministry of Agriculture.

3. Active surveillance

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

This form of surveillance is conducted at the level of the epidemiological unit, allocating samples in accordance with the number of buildings.

The sampling protocol should be applied to a representative sample of 60 vaccinated birds per epidemiological unit for execution of serological or virological testing. This surveillance is to be conducted at least every 30 days over the whole lifetime of the birds.

- Virological testing:
    - This method allows early-stage detection of viral infection.
    - This form of surveillance requires sampling by tracheal or oropharyngeal swabs subsequently pooled in groups of five for PCR analysis.

- Serological testing:
    - This method provides information on the serological history of vaccinated birds in the event of recourse to novel vaccination technologies.
    - This form of surveillance requires blood samples to be taken for subsequent NP ELISA assay, which will allow viral infection to be detected. Where necessary, a

combination of NP ELISA with HAI[1] or H5 ELISA assays will provide additional certainty as to the vaccination status of the birds concerned.

These tests are to be carried by approved laboratories.

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/EN/TXT/PDF/?uri=CELEX:32023R0361&qid=1681975761645&from=EN

- **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

[1] Hemagglutination inhibition