

French General Directorate for Food

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

France's vaccination strategy

CONTEXT

Many countries around the world are affected by unprecedented episodes of Highly Pathogenic Avian Influenza (HPAI), leading to major economic consequences due to the need for outbreak-related and preventive culling. In recent seasons, the virus has also appeared to be more virulent and contagious.

Recently, disease transmission events to mammals have been detected in Europe, America and Asia. Such factors therefore call for high levels of vigilance with regard to these viruses and the risk they represent for human and animal health.

The scale of these crises makes it necessary to use all available tools and to implement vaccination to supplement prevention and control strategies.

This position is shared at EU level and delegated regulation (EU) 2023/361¹ was published at the end of February 2023, defining the conditions under which vaccination is to be implemented, setting particularly demanding rules for surveillance in accordance with the standards laid down by the World Organisation for Animal Health (WOAH)

The Council of the European Union has recommended in published Conclusions that EU Member States should put in place experimental trials to verify the effectiveness of vaccines and to envisage recourse to vaccination in addition to conventional measures of biosecurity, surveillance, stamping out and cleaning/disinfection.

In this context, France has decided to carry out trials to assess certain vaccines on ducks and to initiate a process of reflection on vaccination with all stakeholders in order to define a vaccination strategy based on scientific research, experimental trials and technical/economic evaluation. The aim is to be ready, if all lights are green, and if the decision is taken, to proceed with vaccination beginning in the autumn.

DEFINITION OF A NATIONAL VACCINATION STRATEGY

An action plan has been built and the principles for use of vaccination have been defined. They are described below:

¹ <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32023R0361&qid=1681975761645&from=EN>

The objective of the French government is to slow the spread of the virus in order to eradicate the disease.

The chosen modalities:

- Preventive vaccination is the only option that can be envisaged at the present stage.
- Vaccination will go hand in hand with a system of strict surveillance in accordance with the provisions set out in the European regulation (delegated EU regulation 2023/361), in line with the recommendations of the WOAHP Terrestrial Animal Health Code.
- The vaccines used must be safe and effective, and authorised by the European Medicines Agency or by the French Agency for Veterinary Medicinal Products (ANMV), as well as being compatible with the application of the DIVA strategy, i.e. the ability to distinguish between antibodies present due to vaccination and antibodies due to infection by a field virus.
- The strategy implemented must lean on the results of trials conducted in France and in four other Member States of the European Union (Netherlands, Italy, Hungary and the Czech Republic) and on the scientific expertise of the French risk assessment agency (ANSES).
- Vaccination is to be a temporary measure forming part of a programme to eradicate the disease. The chosen action plan must detail the conditions governing the cessation of the vaccination programme.

Conditions to be met for implementation:

- Biosecurity continues to be the keystone for HPAI prevention and control.
- Once it is required, vaccination is to be mandatory except in specific cases.
- Implementation of a specific surveillance plan for all vaccinated flocks to permit detection of possible infection by a field virus.
- Vaccination shall not remove the need to eliminate outbreaks, even where vaccination has been carried out, or any other control measure planned under the EU regulation and the WOAHP Code.
- France will not vaccinate breeding stock where produced for export, which will permit importing countries to retain their means for control over day-old chicks and eggs for hatching on reception.

Information on vaccines against the HPAI virus:

Live vaccines, whether or not attenuated, are not authorised by the EU regulation since they do not allow differentiation between vaccinal antibodies and antibodies produced following infection by the virus.

In accordance with Article 110.2 of regulation (EU) 2019/6 on veterinary medicinal products, the French Agency for Veterinary Medicinal Products (ANMV) may, in the event of urgency, allow the use of a vaccine not authorised within the Union. To do so, pharmaceuticals companies must make an application for a temporary use authorisation (ATU) to the ANMV.

The list of vaccines covered by ATUs is regularly updated on the ANMV website:

<https://www.anses.fr/fr/content/médicaments>

On 17 April, the Ministry of Agriculture and Food Sovereignty published a call for tenders for the supply, storage and delivery of vaccine doses. The purpose of this order is to guarantee

availability of an initial quantity of vaccines to allow, if all conditions are met, initiation of the vaccination campaign in the autumn of 2023. The call for tenders provides for supply of up to 80 million doses of vaccines authorised for the species "Mulard duck" and "Muscovy duck".

Post-vaccination surveillance plan:

Delegated regulation (EU) 2023/361 requires a surveillance plan to be implemented on holdings subject to vaccination:

- **Reinforced passive surveillance** based on weekly virological testing of a representative sample of dead birds.
- **Active surveillance** at least every 30 days, to include clinical examination and the taking of representative samples for the purposes of laboratory surveillance (serological or virological testing) to permit detection of 5% prevalence of infection by the HPAI virus with a 95 % confidence.

Vaccination and exports:

Such provisions would allow France to guarantee, in compliance with the WOAHA Code (cf. Article 10.4.28), the HPAI-free status of all or part of its territory and to meet the requirements of importing countries.

In summary:

Vaccination is to be implemented as a temporary measure to supplement the strict control and prevention measures provided for in European regulations (biosecurity, zoning, stamping out) in accordance with the standards laid down by the WOAHA.

The purpose of vaccination is in fact to maximise our chances of eradicating the disease and under no circumstances to mask its low-level circulation. This is all the more necessary because of its potentially zoonotic nature. Our goal, which must be shared internationally, is also to reduce the risks of human exposure.

CHOSEN TIMETABLE AND METHODS FOR DEFINITION OF THE STRATEGY

A steering committee has been set up for the action plan with the task of defining and developing a vaccination strategy against Highly Pathogenic Avian Influenza, in accordance with the undertakings given by the Ministry of Agriculture and Food Sovereignty on 22 December 2022.

Its membership is composed of actors charged with monitoring execution of the Plan: the government administration and concerned public entities (ANSES, ANMV, ENVT), interbranch poultry industry representative bodies, representatives of the veterinary profession and representatives of the veterinary medicines sector. The steering committee is chaired by the General Directorate for Food. A project manager has been appointed for the project.

The Action Plan is structured around five core focuses:

- Vaccines that are available and effective.
- Scenarios plus a strategy.
- A vaccination campaign.
- Action for international negotiation.
- Communication directed at target audiences.

The Action Plan timetable:

- **January 2023:** the first meeting of the steering committee (monthly meeting).
- **April 2023:** the launch of the first call for tenders for vaccine supply to build up stock.
- **April 2023:** a report on the first trial phase on Mulard ducks.
- **May 2023:** a report on the second trial phase.
- **May 2023:** definition of a vaccination strategy taking the following into account:
 - the scientific assessment by ANSES (opinion 2022-SA-0165), and the results of the trials carried out on vaccines by France and other Member States (in the process of publication),
 - discussions in the steering committee,
 - a technical and economic analysis based on a range of scenarios,
 - discussions with third country trade partners (currently ongoing).
- **May 2023:** WOAHA General Session.
- **Autumn 2023:** start of the vaccination plan according to the decisions taken in June if roll-out of a vaccination strategy is validated.

MORE INFORMATION:

<https://agriculture.gouv.fr/influenza-aviaire-le-plan-daction-vaccination-de-la-france>