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

Directorate General for Food

OFFICIAL VACCINATION PLAN

HIGHLY PATHOGENIC AVIAN INFLUENZA (HPAI)

FACT SHEET 4 – A DESCRIPTION OF THE VACCINE USED

THE REGULATORY FRAMEWORK FOR VACCINE AUTHORISATION

National and EU regulations provide for the possibility of recourse to vaccination against HPAI using a vaccine covered by an authorisation. The regulatory references governing vaccine use are as follows:

- Regulation (EU) 2016/429 on transmissible animal diseases ('Animal Health Law') sets out in Article 46 the criteria for the use of veterinary medicinal products for the purposes of prevention and control of animal diseases.
- Delegated regulation (EU) 2023/361 establishes the European regulatory framework for vaccination against category A diseases, HPAI included.
- Regulation (EU) 2019/6 establishes the rules governing the placing on the market, manufacturing, import, export, supply, distribution, pharmacovigilance, control and use of veterinary medicinal products.

If it is to be marketed in France, a medicinal product or vaccine manufactured on an industrial basis must be covered by a marketing authorisation issued by the European Medicines Agency (EMA) or, failing this, an authorisation for temporary use (ATU) issued by the French Agency for Veterinary Medicinal Products (ANMV).

In accordance with Article 110.2 of regulation (EU) 2019/6, the ANMV may, in cases of especial urgency and for listed diseases, these being detailed in Article 5 of regulation (EU) 2016/429, authorise the use of a veterinary medicinal product or vaccine not covered by an authorisation at European Union level. For this, the pharmaceutical firm must apply for an ATU to the ANMV in accordance with Article L.5141-10 of the French public health code. For such an authorisation to be granted, the pharmaceutical quality of the vaccines must be deemed satisfactory, and the outcome of assessments conducted by the ANMV as to their safety for health must be favourable.

The list of vaccines covered by an ATU is regularly updated on the ANMV website:
https://www.anses.fr/fr/content/médicaments

THE VACCINE USED

The vaccination programme provides for the exclusive use of vaccines that are effective against the clade 2.3.4.4.b strain of HPAI and offering the possibility for a DIVA strategy based on NP ELISA serology. There are currently two vaccines that meet these criteria and are covered by an ATU.

VOLVAC B.E.S.T. AI + ND vaccine:

- **Manufacturer**: BOEHRINGER INGELHEIM ANIMAL HEALTH FRANCE
- **A summary of the characteristics of this vaccine** is available via the following link: https://www.anses.fr/fr/system/files/90055_ATU_M_11-07 25%20ANNEXE.pdf
- **Vaccine type**: an inactivated subunit vaccine containing the H5 hemagglutinin of the H5N1 strain of the Avian Influenza virus produced using the Baculovirus expression system (Baculovirus Expression System Technology (B.E.S.T.)) and the inactivated La Sotadu strain of the Newcastle disease virus.
- **Target species:** Mulard ducks, Muscovy ducks, Pekin ducks
- **Method and route of administration:**

  Route of administration: subcutaneous.

  Mulard ducks and Muscovy ducks, 10 days of age and older: administer one dose per bird and a second dose 18 days later.

  Mulard ducks, 1 day of age and older: administer one dose per bird and a second dose 28 days later.

  Pekin ducks, 1 day of age and older: administer one dose per bird and a second dose 18 days later.

  Muscovy ducks, 1 day of age and older: administer one dose per bird and a second dose 21 days later.

  The injection volume is 0.5 mL per dose
- **Storage:** between 2°C and 8 °C.
- **Available presentation**: 500ml vial (1,000 doses).

CEVA RESPONS AI H5 vaccine

- **Manufacturer**: CEVA SANTE ANIMALE

  A summary of the characteristics of this vaccine is available via the following link: https://www.anses.fr/fr/system/files/90053_ATU_M_18_06_25_ANNEXE.pdf
- **Vaccine type**: self-amplifying RNA coding for the viral hemagglutinin of H5N8 Avian Influenza virus.
- **Target species**: Mulard, Muscovy and Pekin ducks
- **Method and route of administration:**

Route of administration: intramuscular.

The vaccine must be administered twice at an interval of three or four weeks from one day of age.

The injection volume is 0.2 mL per dose.

- **Storage:**
  - 24 months at a temperature of ≤ -60°C.
  - 28 days at a temperature of ≤ -20°C.
  - 5 days at 2-8°C.
- **Available presentation**:
  - Vaccine suspension: 250-dose and 1,000-dose vials
  - Diluent: 180ml vial (for 1,000 doses).

ORDER FOR SUPPLY OF VACCINES AGAINST THE HPAI VIRUS

2023-2024 vaccination campaign

In order to provide veterinary vaccination supervisors with the vaccines they need to carry out the vaccination campaign, the French Ministry of Agriculture purchased a total of 141 million doses of vaccine for the 2023-2024 vaccination campaign, through two calls for tender for the supply, storage and delivery of vaccine doses.

The first tender, launched in April 2023, was awarded to the manufacturer Boehringer Ingelheim Animal Health France, and resulted in the supply of 80 million doses of Volvac B.E.S.T. vaccine. AI + ND VACCINE.

In December 2023, a second tender for a multi-awarded contract was launched to complete the vaccine dose requirements for the 2023-2024 campaign, enabling France to acquire a further 61 million doses from Boehringer Ingelheim Animal Health France (Volvac B.E.S.T. AI+ND vaccine) and Ceva Santé animale (Ceva Respons AI H5 vaccine)..

2024-2025 vaccination campaign

During the 2024-2025 campaign, the Ministry of Agriculture ordered a total of 142.26 million vaccine doses to cover the vaccination needs for the 12 months of the campaign. This order was placed under contracts concluded in 2023-2024 with Boehringer Ingelheim Animal Health France (Volvac B.E.S.T. AI+ND vaccine) and Ceva Santé Animale (Ceva Respons AI H5 vaccine).

2025-2026 vaccination campaign

For the 2025-2026 campaign, the purchase of the vaccine is the responsibility of the operators, who must order it through their veterinary health officers, mandated to oversee the vaccination.

PROCEDURES FOR VACCINE ADMINISTRATION – SYSTEM FOR SUPERVISING VACCINE ADMINISTRATION

Commission delegated Regulation (EU) 2023/361 of 28 November 2022 supplementing Regulation (EU) 2016/429 requires that the vaccine be administered "under the supervision of an official veterinary". In France, the government empowers a farm's sanitary veterinarian to participate in sanitary control operations such as preventive vaccination against HPAI (cf. Articles L203-7 and L203-8 of the rural and maritime fisheries code). Veterinarians so empowered have the status of official veterinarians under part III of Article L.203-8 of the aforementioned code. Vaccine administration will therefore be supervised by the sanitary veterinarians of farms in their role as government-authorised veterinarians.

Additionally, since vaccination is being carried out under the supervision of a government-authorised veterinarian, it can be carried out by:

- Official veterinarians or other practising veterinarians.
- Farmers (owners or holders of poultry) or their employees under Article L.243-2 of the rural and maritime fisheries code.
- Technical workers under Article L.243-3, point 6, of the rural and maritime fisheries code.

For more information:

- **European Medicines Agency website (EMA) :**
  https://european-union.europa.eu/institutions-law-budget/institutions-and-bodies/search-all-eu-institutions-and-bodies/ema_fr

- **French Agency for Veterinary Medicinal Products (ANMV) :**
  https://www.anses.fr/fr/content/lagence-nationale-du-medicament-veterinaire-missions-et-actions

- **Regulation (EU) 2016/429** of the European Parliament and of the Council of 9 March 2016 on transmissible animal diseases:
  https://eur-lex.europa.eu/legal-content/FR/TXT/PDF/?uri=CELEX:02016R0429-20210421&qid=1639515145830&from=FR

- **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

- **Regulation (EU) 2019/6** of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC:

https://eur-lex.europa.eu/legal-content/FR/TXT/PDF/?uri=CELEX:32019R0006&qid=1684155706191

- **The French rural and maritime fisheries code**: https://www.legifrance.gouv.fr/codes/texte_lc/LEGITEXT000006071367?etatTexte=VIGUEUR