

6 April 2023

FVE/PVSGEU – Highly Pathogenic Avian
Influenza preparedness

MANDATE ON VACCINATION AGAINST HIGHLY PATHOGENIC AVIAN INFLUENZA

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BACKGROUND

- **Vaccination** against HPAI in EU was **prohibited** in accordance with the provisions laid down in Chapter IX of Directive 2005/94/EC
- In the last three **epidemic seasons of HPAI**, the EU faced a constant increase in the detection of the virus in wild birds. Multiple serotypes of the HPAI virus, consequence of multiple reassortant events, have co-circulated during the same epidemic seasons
- Areas with high concentration of **poultry have faced serious challenges** to prevent the introduction and spread of the virus within establishments
- Consequently, the Member States are looking for **solutions to increase their ability to prevent and control HPAI by using vaccination** as an additional tool to the already available preventive and control measures



BACKGROUND

20.2.2023

EN

Official Journal of the European Union

L 52/1

II

(Non-legislative acts)

REGULATIONS

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



TERM OF REFERENCES

1. Update on the available vaccines against HPAI for poultry
2. Vaccination strategies

→ **by July 2023**

3. Surveillance in the vaccinated zone and/or vaccinated establishments
4. Restrictions and risk mitigation measures to be applied in a vaccinated establishment or a vaccination zone

→ **by March 2024**

TOR 1- AVAILABLE VACCINES

Identify and describe the vaccines that may be available for vaccination of poultry:

- a) suitability to be used for **different species** of poultry
- b) capacity to protect against the currently circulating **strains** of HPAI virus, to be adjusted to the future strains of HPAI virus, to protect against multiple strains and to be used in the context of **DIVA**
- c) **effectiveness** in preventing the infection with HPAI viruses
- d) potential **drawbacks**, such as shedding virus

TOR 2- VACCINATION STRATEGIES

Assess the suitable **vaccination strategies** to be implemented (emergency suppressive, emergency protective, preventive):

- a) **objectives** of such strategy (e.g. maintain freedom of disease status, rapid eradication, or minimise losses with the eradication of outbreaks)
- b) **risk factors** that would trigger the need for vaccination to complement the preventive or control tools (e.g. high risk areas for the introduction and spread of HPAI viruses, type of production and industry practices, density of poultry establishments)



TOR 2- VACCINATION STRATEGIES

For the different vaccination strategies assess and recommend on:

- a) suitability of establishing **vaccination or peri-vaccination zones**, on the criteria to be considered when establishing such zones and on the **minimum size** of those zones;
- b) **minimum coverage** to be ensured in the vaccinated flock, establishment and zone in order to:
 - I. **reach the objective**, in particular in areas with specific risks such as high density of different poultry species, proximity to high-risk wild bird habitats or type of production
 - II. **prevent mutations** of the HPAI viruses following circulation in an environment with insufficient immune response
- c) the **type of vaccine** that might be used



TOR 3- SURVEILLANCE IN VACCINATED AREAS

3.1. Assess the suitability and effectiveness of the **reinforced surveillance** set out in Part 2 and in point 2 of Part 5 of HPAI Annex to the Delegated Regulation to **early detect** infection in the vaccinated flocks and to **prevent spread** of the HPAI virus by movement of birds and their products from vaccinated establishments/flocks.

The above assessment should include scenarios depending on different vaccination strategies



TOR 3: SURVEILLANCE IN VACCINATED AREAS

3.2. Provide for alternative suitable surveillance approaches/strategies indicating the minimum level and duration of surveillance required in a vaccinated establishment, including sampling schemes and testing procedures, to:

- a) **ensure early detection** of infection with HPAI viruses
- b) be implemented as additional guarantees to **authorize the movement** of vaccinated and non-vaccinated poultry and poultry products within the vaccinated zone and from the vaccinated zone or establishment to outside that zone or establishment
- c) be implemented **after cessation** of vaccination as necessary risk mitigation measure to authorize movement of birds and their products from those establishments



TOR 3- SURVEILLANCE IN VACCINATED AREAS

3.3. Taking into account the **WOAH standards** explore and provide for **alternative suitable surveillance** approaches/strategies to be implemented in a vaccination zone to **demonstrate freedom** from HPAI based on representative sampling of the vaccinated (and not vaccinated) establishments within a vaccination zone




TOR 4: RISK MITIGATION MEASURES

4.1. Assess the suitability of the restrictions and risk mitigation measures set out in the Delegated Regulation to prevent the spread of HPAI viruses, **enabling safe movement** of poultry and their products following emergency and preventive vaccination, respectively

4.2. Explore and **provide for alternative** (to those referred in 4.1.) suitable movement restrictions and risk mitigation measures required to prevent the spread of virus by movement of birds or their products from a vaccinated establishment/vaccination zone





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