



HIGHLY PATHOGENIC AVIAN INFLUENZA IN THE EU -vaccination-

*ANIMAL HEALTH ADVISORY COMMITTEE
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European Commission,
DG Health and Food Safety
Unit G2 – Animal Health

Outline of the presentation

- ❑ EU rules on vaccination
- ❑ Vaccination and scientific trials in certain EU Member States
- ❑ Work of EFSA on HPAI vaccination – part 1 of two opinions

AHL: Rules for the use of VMPs for disease prevention and control

Article 46(1)

Provides for the possibility for the Member States to take measures concerning **the use of (ALL) veterinary medicinal products** to ensure the most efficient **prevention or control of (ALL) listed diseases**. These measures may cover prohibitions, restrictions and compulsory use of veterinary medicinal products and must be previously assessed as **appropriate and necessary**.

Article 47(1) (empowerment)

Empowers the Commission to adopt **delegated acts** concerning:

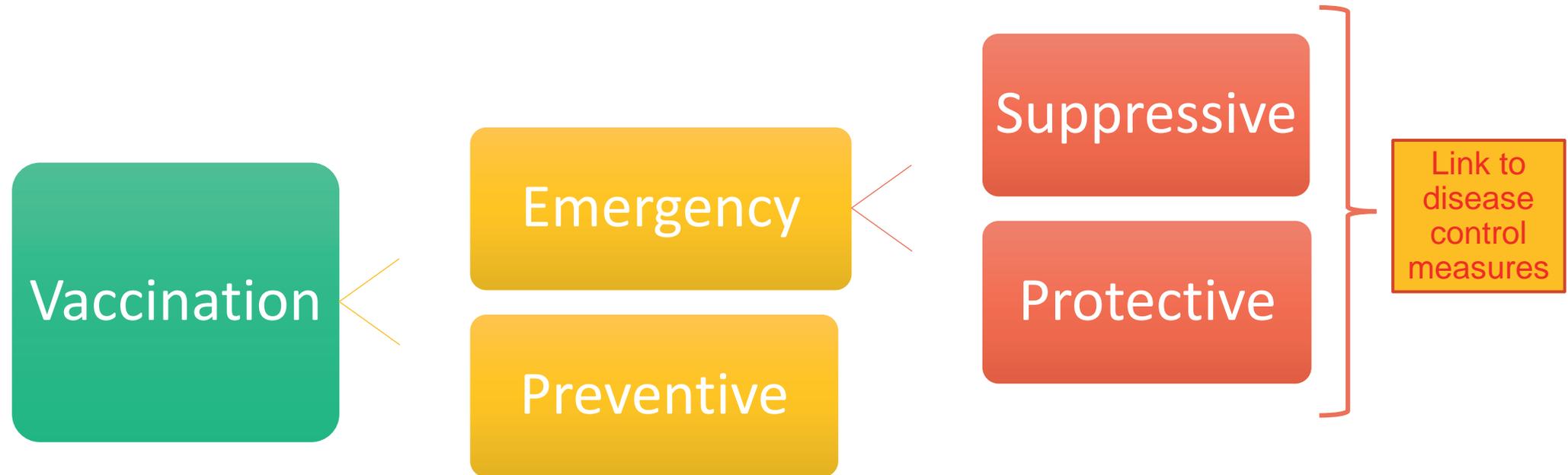
- ✓ prohibitions and restrictions on the use of veterinary medicinal products;
- ✓ specific conditions for the use of veterinary medicinal products for a specific listed disease;
- ✓ risk-mitigation measures to prevent the spread of listed diseases through animals treated with the veterinary medicinal products or products from such animals;
- ✓ surveillance for specific listed diseases following the use of vaccines and other veterinary medicinal products.

Delegated Regulation (EU) 2023/361

on the use of veterinary medicinal products for disease prevention and control

- Published: 20 February 2023
- In force since: 12 March 2023

Vaccination strategies for HPAI



- **Biosecurity** remains the cornerstone as preventive measure to protect poultry from HPAI-infection
- **Stamping out** is still always a compulsory measure in all establishments where HPAI is detected

Specific rules for vaccination against HPAI

Vaccines

- that **do not contain live AI virus** (attenuated or not)

Reinforced surveillance

- **clinical and laboratory** (official activity)
- to assess **effectiveness** (emergency protective vaccination)
- to **early detect infection** with HPAI virus

Risk mitigation measures

- General **prohibition** for movements of vaccinated poultry and their products
- **Derogations** to move, **under conditions**

Traceability/Certificates

- **Emergency vaccination:** certificates for movements from vaccination zone within MS and to other MS
- **Preventive vaccination:** certificates for poultry and hatching eggs when moved to other MS

Risk mitigation measures

- **General prohibition** for movements of vaccinated poultry and their products



Derogations to move, under conditions

	Emergency protective vaccination	Preventive vaccination
Poultry for slaughter	Within restricted zone or as near as possible	National + EU (pre-movement inspection by official vet, and virological test (for Anseriformes) within 72 hours + certification)
Poultry	National (Ready to lay poultry)	National
Captive birds	Based on risk assessment by CA	National + EU (pre-approval of CA from destination and virological test within 72 hours prior movement + certification)
Day-old chicks	National	National + EU (certification)
Hatching eggs	National	National + EU (certification)
Meat	National	National + EU
Eggs for human consumption	National	National + EU

Decision Making - Implementation process for the use of vaccines against HPAI

Member
State

- **Assessment of the situation** based on specific criteria (*Annex II of DR (EU) 2023/361*)
- **DECISION TO VACCINATE** (*strategy selection etc.*)
- Preparation of official vaccination plan (*in accordance with information required in Annex III of DR (EU) 2023/361*)

Member
State

- Preliminary information sent *to the other MS and the COM* (*at least 2 days before start of vaccination*)
- **INITIATION OF VACCINATION**
- Official vaccination plan sent *to the other MS and the COM* (*at the latest 2 weeks after start of vaccination*)

COM

Review of the national measures in the official vaccination plan. May act with additional measures in accordance with Article 71 of Regulation (EU) 2016/429

Member
State

- **Disease-specific surveillance – Risk mitigation measures** (*Annex XIII of DR (EU) 2023/361*)
- **Regular reports** sent *to the other MS and the COM* (*content / intervals according to the vaccination strategy – Annexes V and VI of DR (EU) 2023/361*)

HPAI VACCINATION

experience, trials and plans

in certain EU Member States

Vaccine trials and vaccine programmes in the EU

Scientific trials (not in scope of CIR (EU) 2023/361)

- Germany (geese)
- Hungary (geese)
- Italy (meat turkeys, layer hens and ducks)
- the Netherlands (layer hens)

HPAI vaccination (in accordance with CIR (EU) 2023/361)

- France (ducks)
- Ireland (zoos)
- Netherlands (zoos)

France

Vaccination of
ducks (production
flocks)

Start

1 October 2023

**64
million**

Number of Ducks



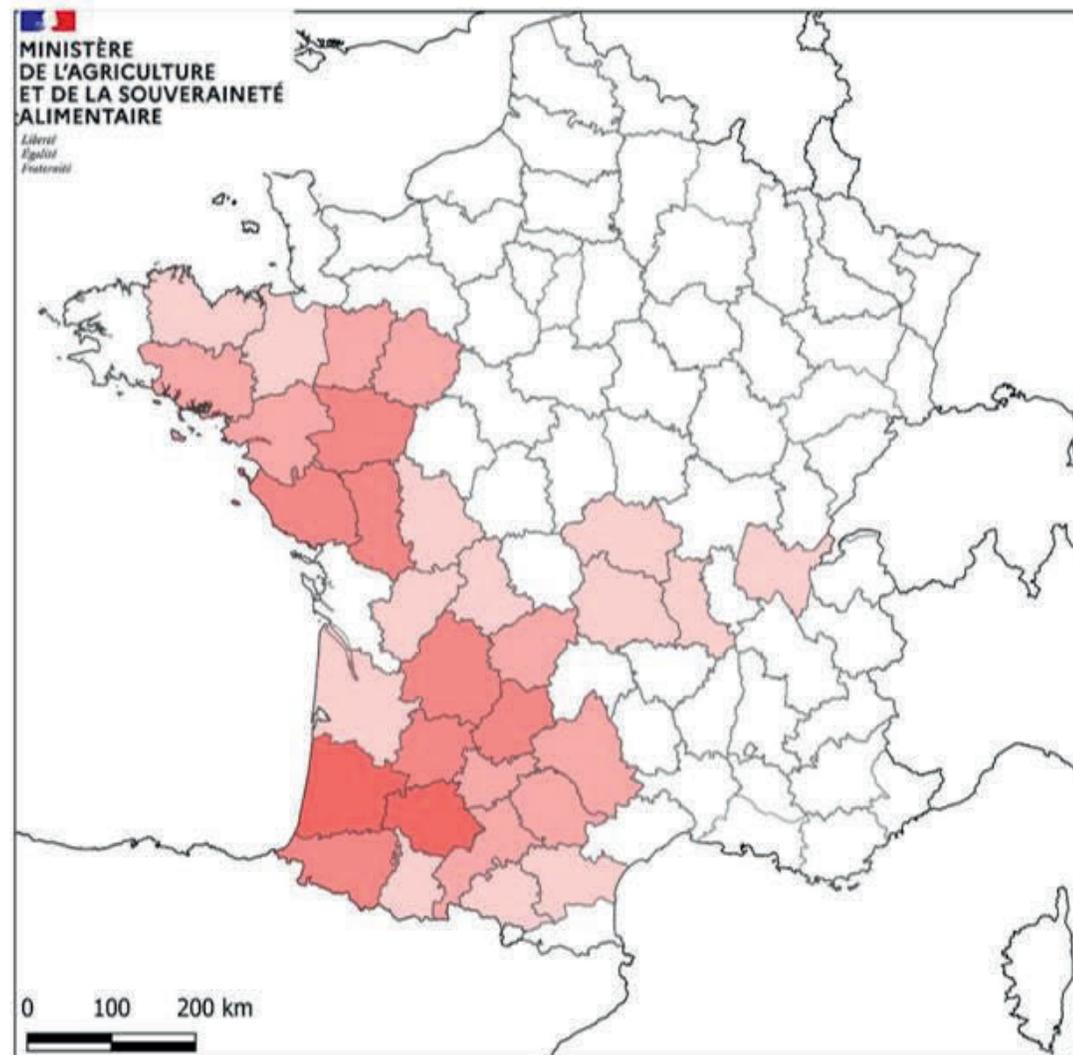
2700

Number of
establishments



Vaccination campaign map

Number of active establishments per department



The main objectives and targets of the vaccination strategy

Strategy

- Preventive vaccination

Species

- Ducks (Barbarie, mulard and Pékin)

Zone

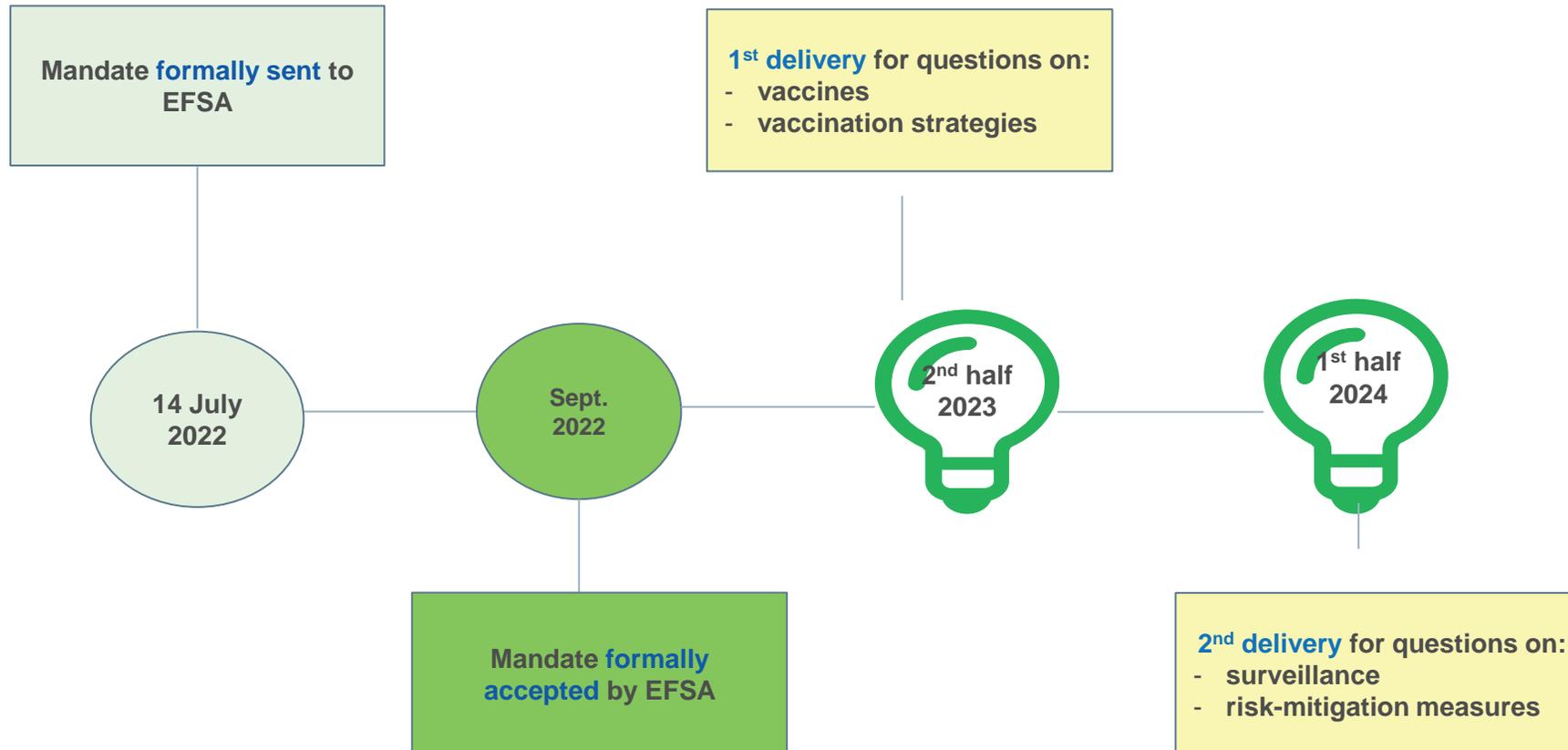
- All of the France mainland (except Corsica)

Period

- All year, from October 2023

Work of EFSA on HPAI vaccination

EFSA mandate for HPAI vaccination



ADOPTED: 13 September 2023

doi: [10.2903/j.efsa.2023.8271](https://doi.org/10.2903/j.efsa.2023.8271)

Published: 10 October 2023 |

Vaccination of poultry against highly pathogenic avian influenza – part 1. Available vaccines and vaccination strategies

Contains:

- an overview of the available HPAI vaccines and their efficacy against currently circulating viruses
- an assessment of various vaccination schemes to inform decisions on possible vaccination strategies.

EFSA's approach

- Information about **available vaccines and their characteristics (TOR 1)** was collected via a literature search, and in a survey that was launched by the European Medicines Agency (EMA) and disseminated by EFSA and the World Organisation for Animal Health (WOAH).

Data were also collected through consultation of the EU Reference Laboratory (EURL) and the National Reference Laboratory (NRL) network, and directly from pharmaceutical companies' websites.

- The effectiveness of **vaccination strategies (TOR 2)** was simulated using mathematical modelling.

Focus on the main domestic poultry species - ducks, turkeys, chickens- using data from France, Italy and the Netherlands as case studies

Outcomes for TOR 1

Types and characteristics of available vaccines

- Updated information was provided on **types and characteristics of available vaccines** against HPAI.
- There is **only one authorized** vaccine against HPAI in chickens **in the EU**.
- **Minimum age for the first administration** varies, **ranging from 1 day to 6 weeks** of age, with some live vectored vaccines administered in-ovo/in the hatchery
- Humoral **immunity** has been measured **from 10 to 14 days following primary vaccination**, however **more time or even successive vaccine doses** may be required to **obtain full protective immunity**; for HVT there is slower onset of immunity (4 weeks)

Outcomes for TOR 1

Vaccine types and technologies – recommendations

- Generate **suitable and harmonised data** :
 - the **onset and duration of immunity** particularly for long living poultry types
 - the **impact of maternal immunity**
 - the indications of vaccines for **poultry species other than chickens** and considering **different poultry production types**
- The development of **mass applicable AI vaccines**
- The authorized vaccines should be **rapidly updated** if required based on the match with the circulating strains;
- In the **planning of a vaccination programme** it is recommended:
 - to **avoid interference** with maternal and vector-related immunity
 - to **overcome immunity waning** over time (subsequent use of different vaccines)

Outcomes for TOR 2

Vaccination strategy - **scenarios**

When planning a vaccination programme, the **most adequate vaccine** type and vaccination scheme **should be selected** considering the epidemiological situation, antigenic distance from the circulating strain, population-specific parameters (poultry species, age, production type, other vaccination programs), supervision capacities and the vaccination strategy:

- **emergency protective**

- ✓ inactivated vaccines that can be administered to all poultry species/production types/age, leading to rapid onset of immunity and short antigenic distance should be used; also,
- ✓ in principle, a single dose of an effective vaccine would be sufficient to curtail the between farms virus transmission

- **preventive**

- ✓ could target those species/poultry types most susceptible and/or infectious in the area at the highest risk of infection;
- ✓ in addition to inactivated vaccines, vectored vaccines are suitable for vaccinating *in ovo* and day-old;

- 19 ✓ repeated vaccination will be needed to ensure continued protection

Outcomes for TOR 2 - vaccination scenarios

Recommendations for policy makers and risk managers:

- To minimise the number of infected and culled farms and epidemic duration, **preventive vaccination of the most susceptible and/or infectious poultry species is recommended in high-risk transmission areas**. Depending on the region, these species are ducks, geese, turkeys and layers chickens
- In case of an outbreak in a high-risk transmission area, **emergency protective vaccination in a 3-km radius is recommended**, as it showed to be the most effective strategy among the three emergency vaccination scenarios tested
- For **areas with high risk of introduction from wild birds and low farm density**, **preventive vaccination** could be considered to reduce the number of outbreaks resulting from primary introductions
- It is a crucial prerequisite that **vaccination should not replace other preventive and control measures** such as infection monitoring in wild birds, early detection and biosecurity, but complement them to reinforce their impact, so to adopt an integrated disease prevention and control approach

Recommendations - for the research community

The scientific opinion includes recommendations for future scientific studies on HPAI vaccines in terms of:

- the **types of vaccines to develop** and for which **bird species**,
- the **aspects** of the vaccines **that should be researched**, and
- the **type of studies that should be conducted**.

Next part of the EFSA scientific opinion on HPAI vaccination

- Assessment of the **surveillance** and **risk mitigation measures**
- Expected: March 2024

Thank you



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