



HIGHLY PATHOGENIC AVIAN INFLUENZA IN THE EU -vaccination-

*ANIMAL HEALTH ADVISORY COMMITTEE
11 June 2024*

European Commission,
DG Health and Food Safety
Unit G2 – Animal Health

Outline of the presentation

- ❑ Vaccination and scientific trials in certain EU Member States
- ❑ Work of EFSA on HPAI vaccination – part 2

HPAI VACCINATION plans and trials

in certain EU Member States

Preventive vaccination in poultry

France - ducks (foie gras)

Strategy

- Preventive vaccination

Species

- Ducks (Barbarie, mulard and Pékin)

Zone

- All of the France mainland (except Corsica)

Period

- One year, from October 2023

64
million

Number of
ducks

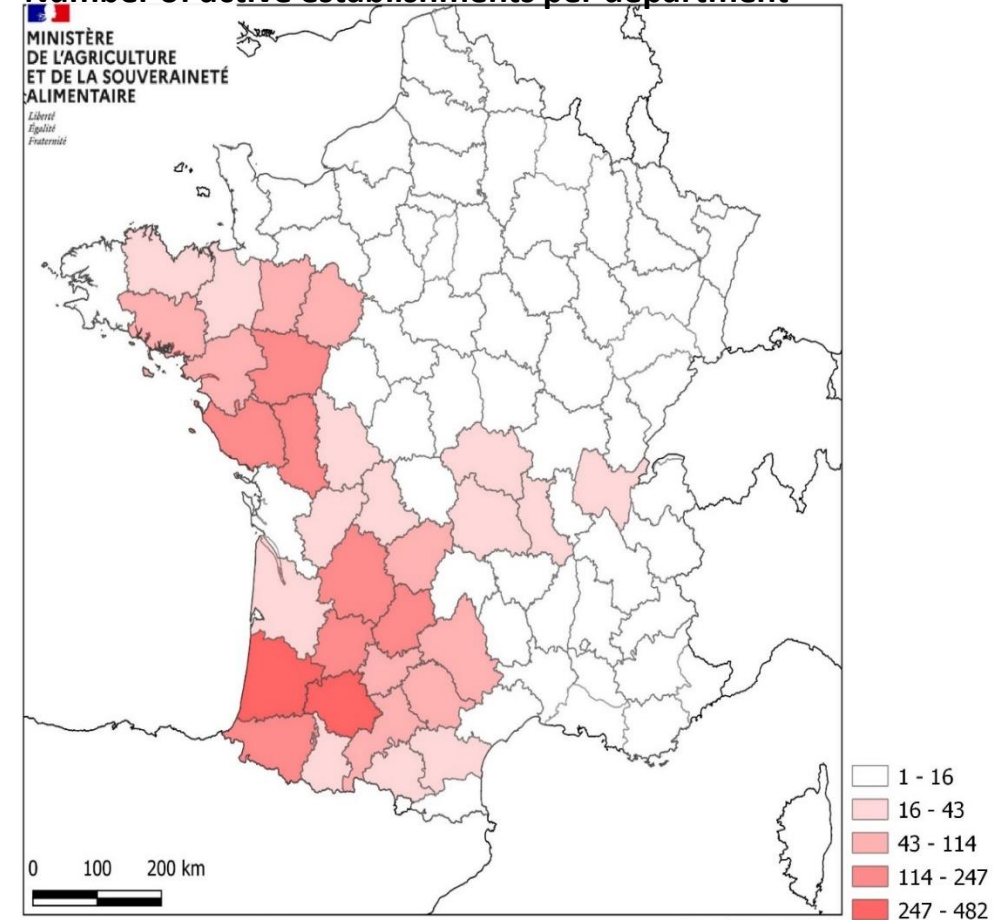


2700

Number of
establishments



Number of active establishments per department



Référentiel : © IGN Données : DGAL/MASA

Date d'édition : 05/09/2023

The vaccine used

▪ **The used vaccine should:**

- Be effective on the HPAI clade 2.3.4.4.b strain
- Have the capacity for a DIVA strategy using the NP ELISA serology
- Have an authorisation for use, issued by the ANMV (The National Veterinary Medicines Agency)

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

Vaccine/fabricant	Species	Administration route	Number of primary injections	Vaccine storage	Shelf life	DIVA ELISA NP serology
Volvac BEST AI+ND BOERHINGER INGELHEIM	Chicken Pékin duck Barbarie duck Mulard duck	SC	Chicken : 1 Barbarie, mulard Ducks: 2 (from day 10) Pékin Ducks: 2 (from day 1)	+5°C	24 months	Yes

HPAI situation in France in 2023 – 2024 epidemic season

Comparison with the previous season:

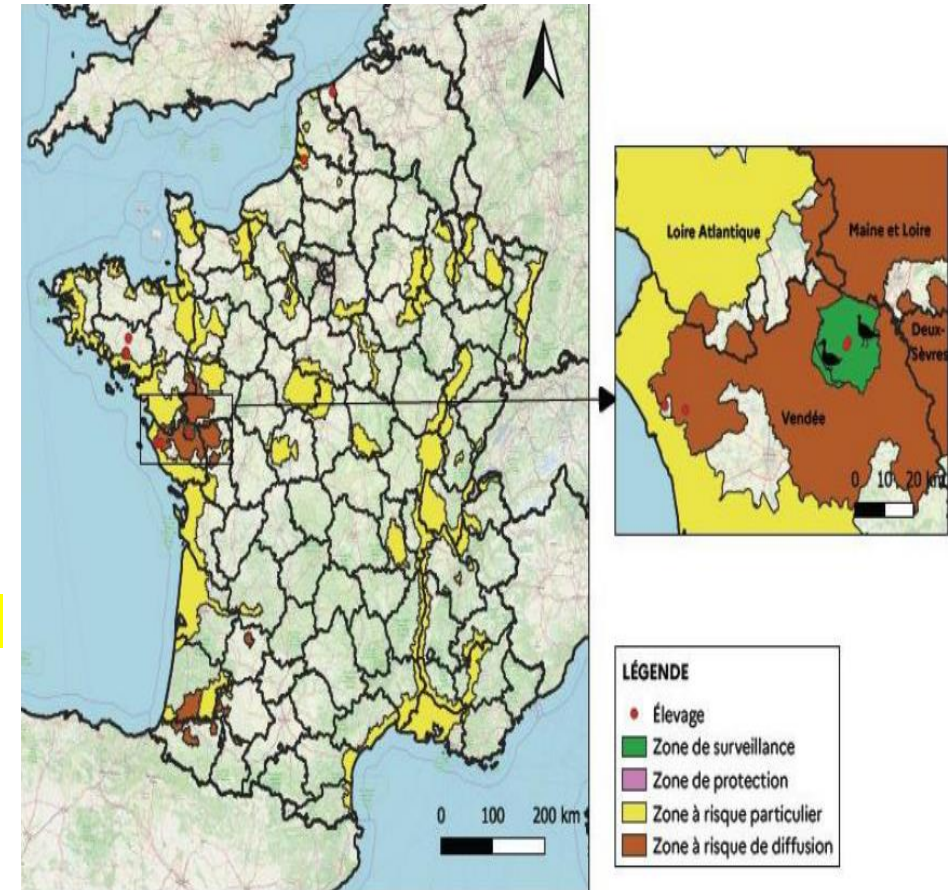
- **10** outbreaks of HPAI **compared to 345** last year during the same period
- fewer cases in wildlife in 2023/2024 compared to the previous season

Information on the 10 H5N1 outbreaks (clade 2.2.3.4.b):

- **6 turkey farms**
- **1 laying hen farm**
- **2 Barbarie duck farms**, epidemiologically linked and **vaccinated** (“old 74 days” and “young 24 days”)
- **1 breeding duck farm, not vaccinated**

Current status:

- **Evaluation** of the vaccination strategy
- ⁶preparing for **extending** the vaccination plan after October 2024



Preventive vaccination of birds in zoos ("confined establishments")

Netherlands

- Preventive vaccination programme in 13 zoos (since October 2023)
- Vaccine used: Nobilis Influenza H5N2



Spain

- Preventive vaccination programme in 1 zoo (since winter 2023/2024)
- Vaccine used: Nobilis Influenza H5N2

Ireland

- Preventive vaccination programme in 4 zoos (since winter 2023/2024)
- Vaccine used: Nobilis Influenza H5N2



Vaccine trials/ research

Netherlands

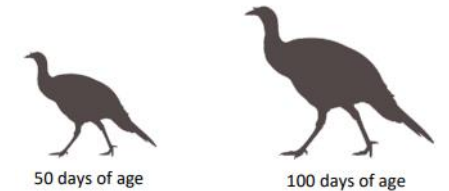
- vaccine efficacy trial in laying hens in high containment unit in lab (2022)
- field trial in laying hens (September 2023-2025) with 2 HVT-vector vaccines
- possible small-scale pilot to start end 2024, depending on outcomes field study



Italy

- lab vaccine efficacy trials in turkey (since 2022)
- testing different vaccines, in various combinations (first dose, booster)
- assessment of reduction of virus shedding and clinical and virological protection

Challenge



A/turkey/Italy/21VIR9520-3/2021
10⁶ EID₅₀
(2.3.4.4b clade)

Hungary

- field trial in geese in 2022-2023
- field safety and efficacy tests
- AI H5-vaccine (synthetic RNA)
- vaccination in the hatchery, booster at 4 weeks of age



Work of EFSA on HPAI vaccination

TERM OF REFERENCES

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



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

<https://www.efsa.europa.eu/en/efsajournal/pub/8271>

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

➔ **available at:**

<http://www.efsa.europa.eu/en/efsajournal/pub/8755>

TOR 3:

Post – vaccination **SURVEILLANCE:**

Diagnostic methods

Emergency vaccination

Preventive vaccination

DIAGNOSTIC METHODS: RECOMMENDATIONS

- The vaccination plan should already **pre-select the most appropriate diagnostic** assays
- Member States are encouraged to conduct **additional studies to collect field experience** and validation data on alternative diagnostic methods in vaccinated establishments
- The use of **diagnostic methods with high sensitivity** is recommended
→ **molecular methods (PCR)**
- **Serological** results when aiming at demonstrating **disease freedom must be confirmed** with molecular virological investigations



EMERGENCY VACCINATION: EARLY DETECTION

SEIRD model

to estimate number of **infectious birds**, **daily mortality**, **duration of epidemic** for vaccinated and unvaccinated flocks

Surveillance model

to quantify **reduction in infectiousness** given surveillance
to estimate **probability of escaping detection**

Rs estimation

to **compare** different **surveillance** strategies

A strategy is effective if
→ probability to **escape detection** **<0.01** for more than 95% of the outbreak simulations
→ **Rs < 1**

Assessment performed separately for:

- Chicken layers
- Ducks
- Turkeys

Sample type:

- Mortality threshold
- Dead birds (qPCR):
different sample size and sampling interval
- Live birds (qPCR)
- Live birds (serology)

EMERGENCY VACCINATION: RECOMMENDATIONS

- **Molecular testing of dead** birds is recommended for early detection surveillance
- The effectiveness of surveillance is increased by the **repeated sampling** in time
- **Chicken layers, ducks and turkeys:** a number of effective options testing **dead birds** have been identified
- **Ducks:** alternatives can be carried out testing **live** ducks or based on **mortality threshold but not recommended**
- **Effective options** should be selected according to **country's specific circumstances** and resources



EMERGENCY SURVEILLANCE IN PERI-VACCINATION ZONE

Radius

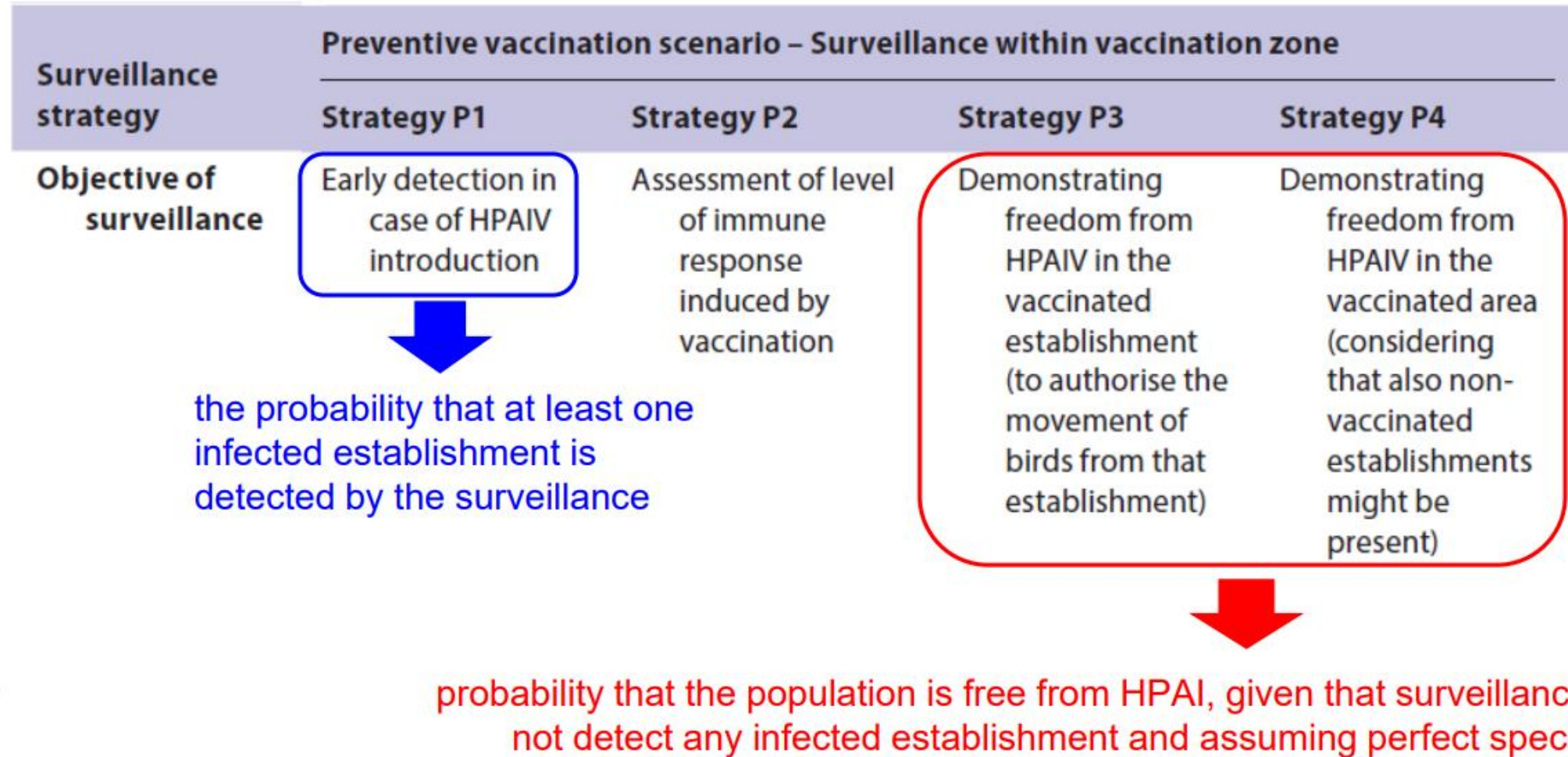
- to contain the spread of the disease avoiding any jump outside the area with 95% confidence → a **10 km zone radius** would be needed (worst case probability of jump spread 0.004 with probability of containment equal to 96%)

Type of surveillance

- **vaccinated** establishments → the options are those for E1
- **unvaccinated** establishment → passive surveillance in gallinaceous species and weekly bucket sampling of all dead birds (up to 15) in Anseriformes



PREVENTIVE VACCINATION



PREVENTIVE VACCINATION: ASSESSMENT



Sampling
scheme

molecular
testing up
to 15
dead
birds
monthly

% farms
under
surveillance

100%

EDSe

92%

74%

93%

Pfree

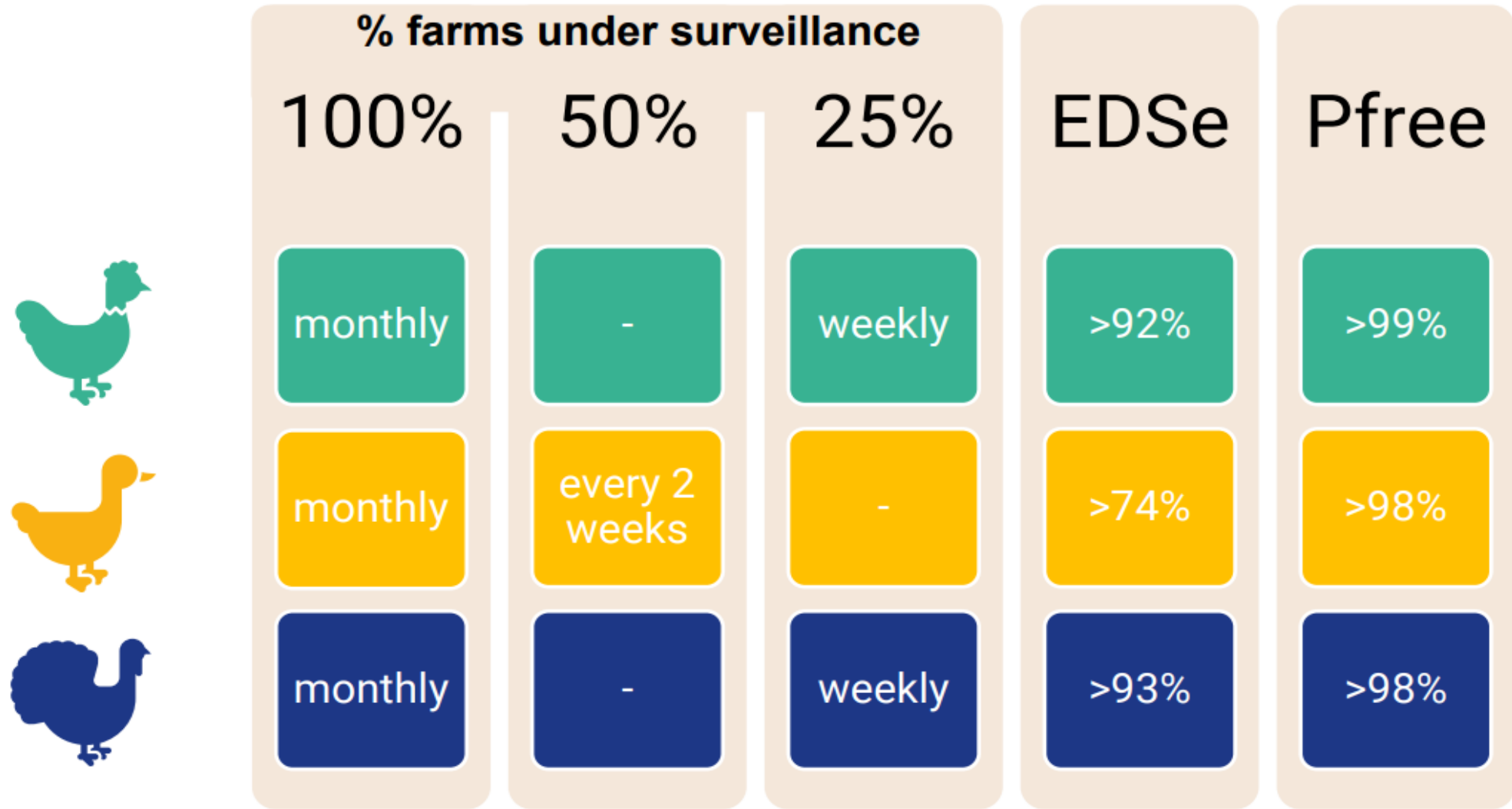
>99%

>99%

>99%



PREVENTIVE VACCINATION: ASSESSMENT



PREVENTIVE VACCINATION: RECOMMENDATIONS

- **Many options available**
 - **Molecular** virological testing of up to **15 dead birds every 30** days in vaccinated flocks is recommended to effectively **demonstrate disease freedom with > 99% confidence** within high-risk zones for HPAIV infection
 - If the aim is to **increase the early detection** surveillance sensitivities, then it is recommended to **reduce the sampling intervals**
- Maintaining **passive surveillance efforts in unvaccinated** establishments in vaccinated zones is recommended to enhance the overall sensitivity of the surveillance system
- **MSs** will need to make a dedicated **plan according to their situation**

TOR 4 – RISK MITIGATION STRATEGIES

To enable safe movement of vaccinated birds EFSA recommends:

Emergency vaccination

- existing rules set out in Reg 2023/361 and Reg 2020/687 are valid and **molecular testing is recommended**: all up to a number of 15 dead birds no earlier than 72 h before movement

Preventive vaccination

- existing rules set out in Reg 2023/361 are valid
- if the vaccinated establishment is **not under surveillance**, **molecular testing is recommended**: all up to 15 dead birds should be tested no earlier than 72 h before movement



Thank you



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