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VACCINATION OF POULTRY AGAINST HPAI – PART 2 SURVEILLANCE AND RISK MITIGATION STRATEGIES

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TERM OF REFERENCES

1. Update on the **available vaccines**
2. Vaccination **strategies**



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH



available at:

<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>



SURVEILLANCE ACCORDING TO DELEGATED REGULATION (EU) 2023/361

Type of vaccination	Surveillance				
	Surveillance category	Testing procedure	Frequency	Minimum detectable prevalence/type of information collected	Duration
Emergency protective	Reinforced laboratory	Virological	2 weeks	5% prevalence with 95% confidence level	According to the duration of the recovery period
	Reinforced clinical	-	-	-	-
Preventive	Enhanced passive	Virological	Weekly	Representative sample of dead birds	As long as there are vaccinated birds in the establishment
	Active	Clinical examination	30 days	Clinical examination of poultry, check of production records, check of health records of each epidemiological unit	
		Serological or virological	30 days	5% prevalence with 95% confidence level (representative sample)	



SURVEILLANCE – EMERGENCY VACC

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EMERGENCY VACCINATION

Surveillance strategy	Emergency protective vaccination scenario – Surveillance within the vaccination zone			
	Strategy E1	Strategy E2	Strategy E3	Strategy E4
Objective of surveillance	HPAIV early detection (to be implemented also in the peri-vaccination zone)	Assessment of vaccination effectiveness	Demonstrating freedom from HPAIV in the vaccinated establishment (to authorise the movement of birds from that establishment)	Demonstrating freedom from HPAIV in the vaccinated zone

identification of HPAIV to remove the establishment before it transmits the infection to other establishments

→ **R_h** as a measure of transmission

→ **surveillance is effective** if contributes to **R_s < 1**



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
→ **$R_s < 1$**



E1, LAYERS

Efficacy of surveillance options for early detection of vaccinated-infected flocks

In flocks >3000

Results are reported only for effective surveillance strategies

**Turkeys:
similar results**

Sample type (diagnostic test)	Sample size	Sampling interval (days)	Percentage of outbreak simulations with the probabilities of escaping detection below 1% ^b	Detection time as days post introduction (median (2.5–97.5 CI))	Prevalence (%) infectious birds (median (2.5–97.5 CI))	Prevalence (%) recovered birds (median (2.5–97.5 CI))	R_h/R_s (reproduction number) (median (2.5–97.5 CI))	
Passive reporting (reference)				31 (25–43)	3.93 (3.44–4.5)	2.16 (1.86–2.46)	1.4	
Mortality threshold (0.13%)				28 (22–39)	2.35 (2.01–2.75)	1.26 (1.06–1.49)	1.09 (1.04–1.1)	
Dead birds (qPCR)	≤ 5	7	99%	20 (14–31)	0.34 (0.25–0.43)	0.18 (0.11–0.24)	0.13 (0.1–0.16)	
		14	90%					
		21	51%					
		30	0%					
		≤ 10	7	99%	18 (13–30)	0.26 (0.19–0.34)	0.14 (0.08–0.19)	0.1 (0.08–0.13)
			14	98%	21 (15–33)	0.44 (0.35–0.56)	0.23 (0.15–0.31)	0.17 (0.15–0.2)
	21		94%					
	30		84%					
	≤ 15		7	99%	18 (13–30)	0.26 (0.19–0.33)	0.13 (0.08–0.19)	0.1 (0.08–0.13)
			14	99%	20 (15–32)	0.41 (0.32–0.52)	0.21 (0.15–0.29)	0.16 (0.14–0.19)
		21	97%	22 (16–34)	0.56 (0.45–0.71)	0.3 (0.21–0.39)	0.22 (0.19–0.26)	
		30	92%					
Live birds (qPCR)		60	14	72%				
			30	30%				
	120	14	89%					
		30	69%					
Live birds (serology)	60	14	47%					
		30	9%					

E1, DUCKS

Efficacy of different surveillance options for early detection of vaccinated-infected flocks

In flock ≥ 6000

Results are reported only for effective surveillance strategies

Sample type (diagnostic test)	Sample size	Sampling interval (days)	Percentage of outbreak simulations with the probabilities of escaping detection below 1% ^b	Detection time as days post-introduction (median (2.5–97.5 CI))	Prevalence (%) infectious birds (median (2.5–97.5 CI))	Prevalence (%) recovered birds (median (2.5–97.5 CI))	R_n/R_s (reproduction number) (median (2.5–97.5 CI))
Passive reporting (reference)				23 (19–32)	20.5 (18.9–22.3)	33.31 (29.26–37.26)	1.8
Mortality threshold (0.17%)				17 (13–26)	5.84 (4.83–7.22)	6.13 (4.9–7.28)	0.62 (0.49–0.63)
Dead birds (qPCR)	≤ 5	7	98%	15 (11–24)	3.09 (2.51–3.86)	3.09 (2.33–3.88)	0.21 (0.18–0.26)
		14	70%				
		21	0 ^b				
	≤ 10	7	99%	14 (11–23)	2.35 (1.87–3.02)	2.35 (1.74–3)	0.17 (0.14–0.19)
		14	97%	16 (12–25)	4.29 (3.48–5.19)	4.37 (3.34–5.38)	0.3 (0.26–0.34)
		21	89%				
	≤ 15	7	99%	14 (10–23)	2.33 (1.86–2.96)	2.3 (1.72–2.99)	0.16 (0.14–0.19)
		14	98%	16 (12–24)	3.93 (3.18–4.8)	3.99 (2.97–4.94)	0.28 (0.24–0.32)
		21	96%	17 (13–26)	5.5 (4.54–6.68)	5.75 (4.43–6.97)	0.39 (0.35–0.44)
Live birds (qPCR)	60	14	97%	17 (13–25)	4.95 (4.03–5.98)	5.05 (3.9–6.34)	0.35 (0.32–0.39)
		30	44%				
	90	14	98%	15 (12–24)	3.34 (2.64–4.11)	3.33 (2.49–4.17)	0.23 (0.21–0.26)
		30	93%				
Live birds (serology)	60	14	97%	17 (13–25)	5.16 (4.25–6.28)	5.34 (4.17–6.62)	0.36 (0.29–0.44)
		30	93%				

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





SURVEILLANCE – PREVENTIVE VACC



PREVENTIVE VACCINATION

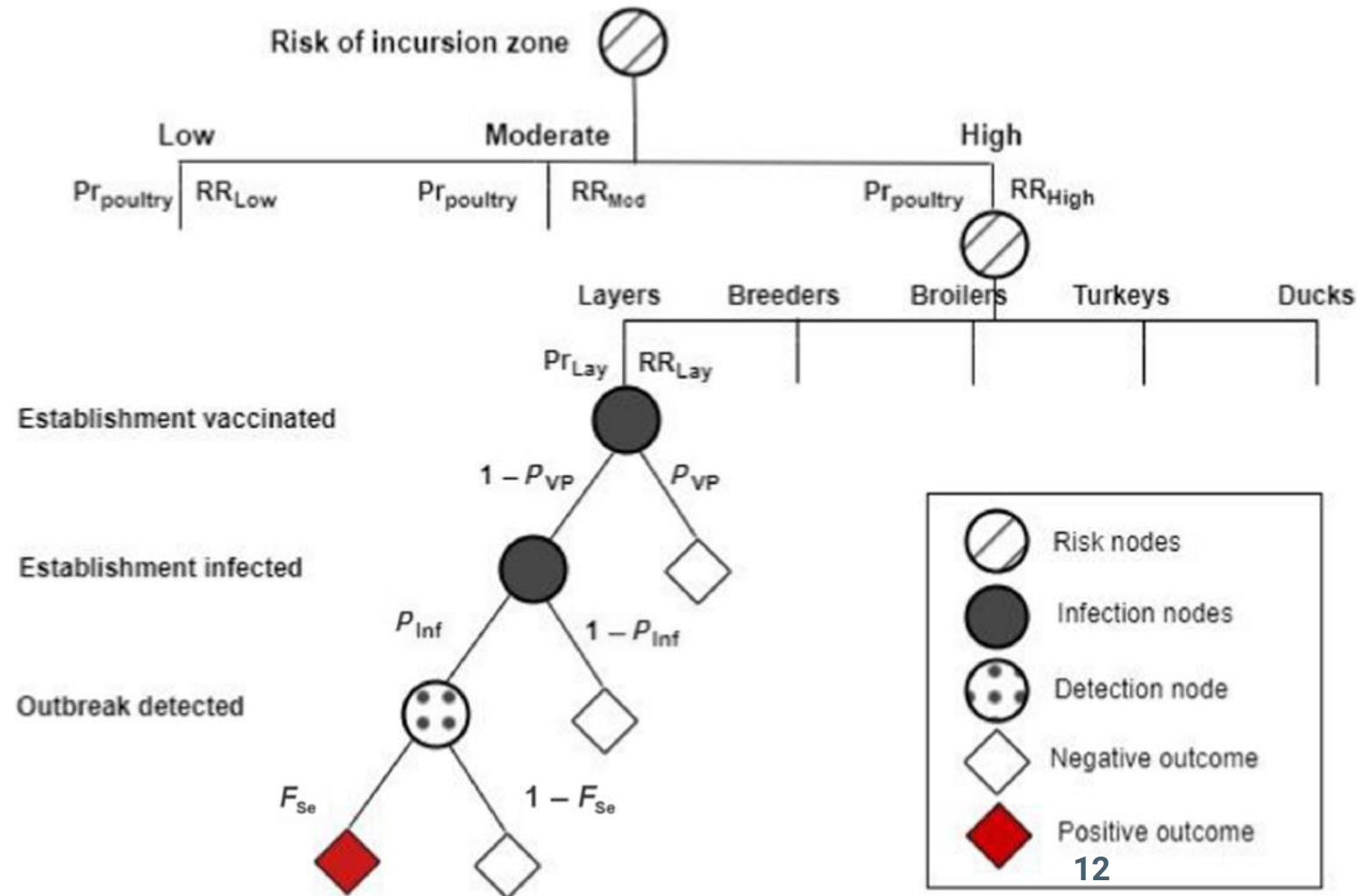
Surveillance strategy	Preventive vaccination scenario – Surveillance within vaccination zone			
	Strategy P1	Strategy P2	Strategy P3	Strategy P4
Objective of surveillance	Early detection in case of HPAIV introduction	Assessment of level of immune response induced by vaccination	Demonstrating freedom from HPAIV in the vaccinated establishment (to authorise the movement of birds from that establishment)	Demonstrating freedom from HPAIV in the vaccinated area (considering that also non-vaccinated establishments might be present)

the probability that at least one infected establishment is detected by the surveillance

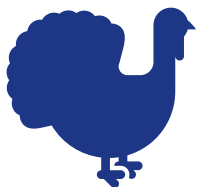
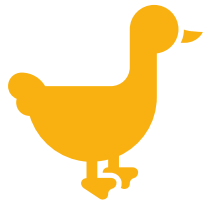
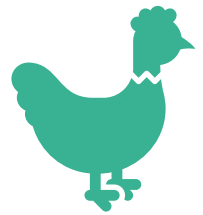
probability that the population is free from HPAI, given that surveillance did not detect any infected establishment and assuming perfect specificity

PREVENTIVE VACCINATION: APPROACH

- **Scenario tree models** to estimate the sensitivity of the surveillance system to **demonstrate freedom** and to **early detect** HPAI
- Active surveillance assumed in all vaccinated flocks by collecting **every 30 days** up to a number of **15** dead birds to be tested by **qPCR**, and passive surveillance in unvaccinated flocks
- Scenarios with **variations in sampling intervals** (30, 15, 7 days) and **proportions of vaccinated flocks** (100%, 50%, 25%) explored



PREVENTIVE VACCINATION: ASSESSMENT



Sampling scheme

molecular testing up to 15 dead birds monthly

% farms under surveillance

100%

EDSe

92%

74%

93%

Pfree

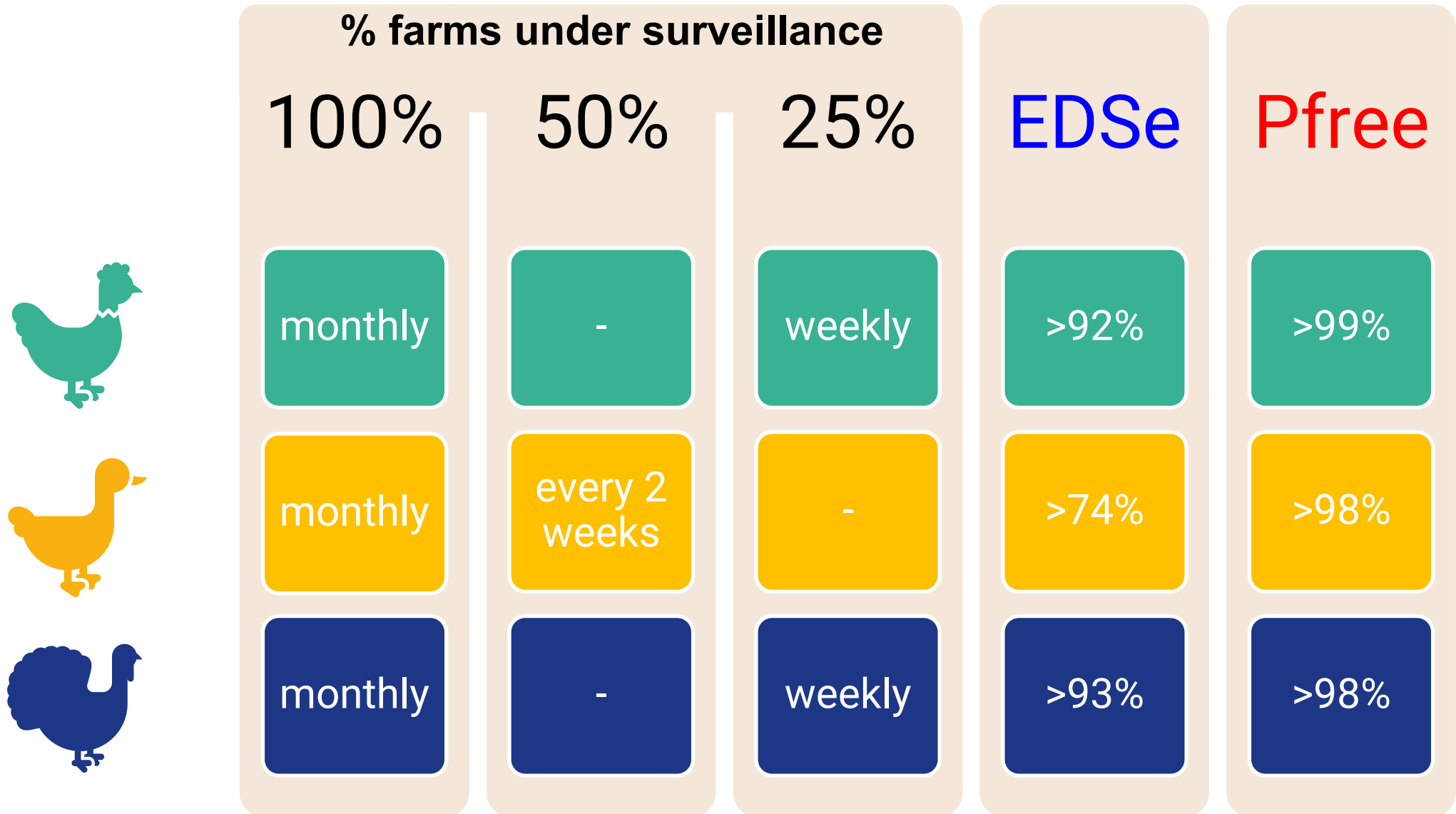
>99%

>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**





RISK MITIGATION MEASURES



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
- testing could coincide with the sampling session of the surveillance in place

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



THANKS TO ALL THE EXPERTS INVOLVED

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**Thank you for your
attention!**

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