22-23 October 2024, WOAH, Paris
Vaccination and Surveillance for HPAI in Poultry:
Current Situation and Perspectives

VACCINATION OF POULTRY AGAINST HPAI SURVEILLANCE AND RISK MITIGATION STRATEGIES

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TERM OF REFERENCES

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

→ 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

EUROPEAN MEDICINES AGENCY
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SURVEILLANCE ACCORDING TO RULES IN PLACE

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 [illegible]covery
Preventive	[illegible]	[illegible] examination	[illegible]	[illegible] of production records, check of health records of each epidemiological unit	[illegible]as [illegible]e [illegible]ed [illegible]the [illegible]nment
	[illegible]	Serological or virological	30 days	5% prevalence with 95% confidence level (representative sample)	

According to **WOAH**:
→ where vaccination is carried out, surveillance for **demonstration of freedom** from HPAI requires that **all vaccinated flocks** are tested to prove absence of viral circulation with a frequency that is proportional to the risk in that zone

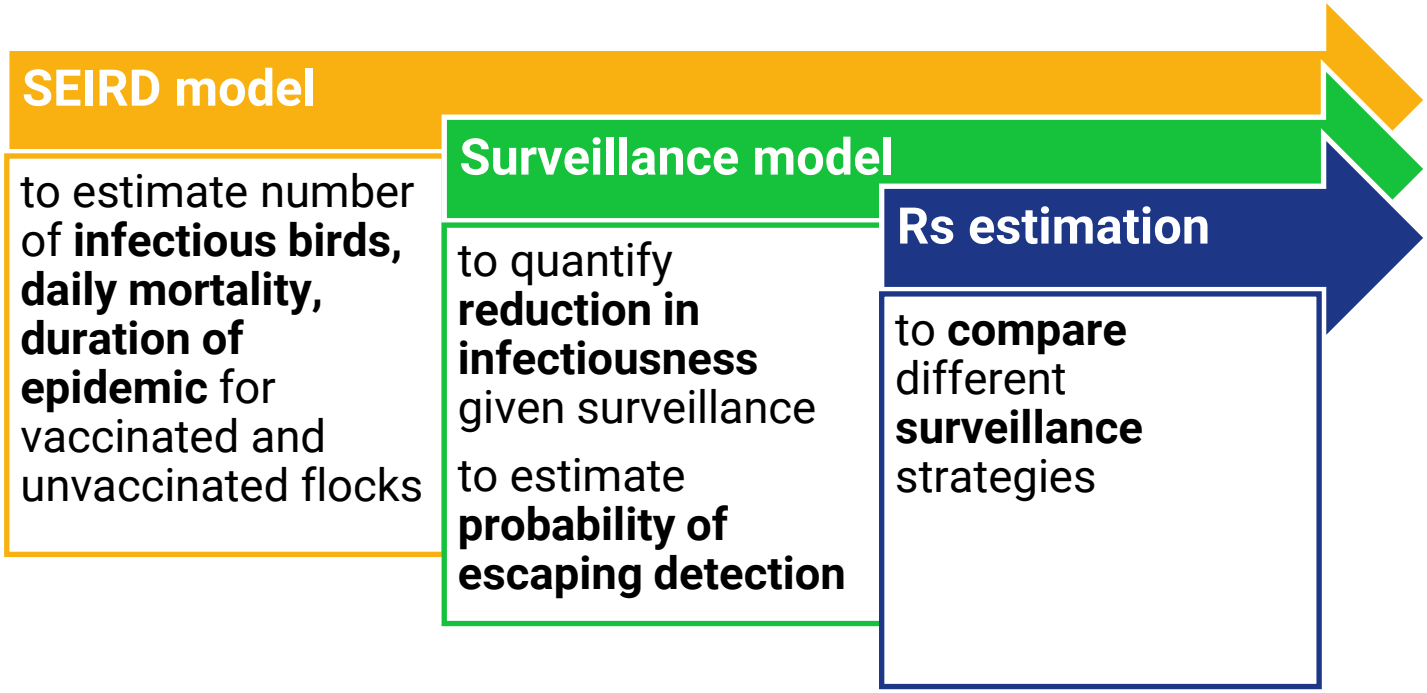
SURVEILLANCE – EMERGENCY VACC

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
→ **Rh** as a measure of transmission

EMERGENCY VACCINATION: EARLY DETECTION



A strategy is effective if

→ probability to **escape detection <0.01** for more than 95% of the outbreak simulations

→ **Rs < 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

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%				

Turkeys: similar results

E1, DUCKS

Efficacy of 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_h/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]				
		30	0%				
	≤ 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%				
		30	36%				
	≤ 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)
		30	89%				
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

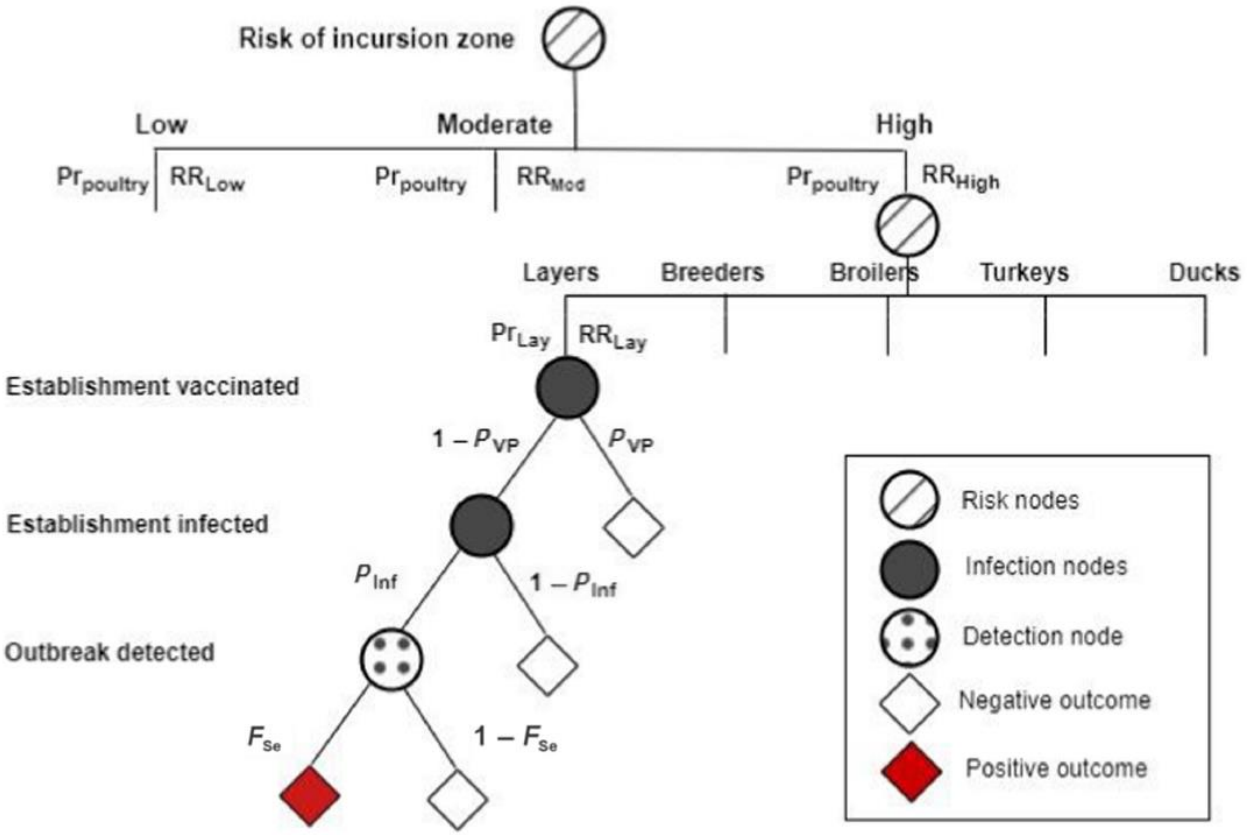
Surveillance strategy	Preventive vaccination scenario – Surveillance within vaccination zone			
	Strategy P1	**Strategy P2**	**Strategy P3**	**Strategy P4**
Objective of surveillance	Early detection in case of HPAIV introduction	Assessment of level of immune response induced by vaccination	Demonstrating 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

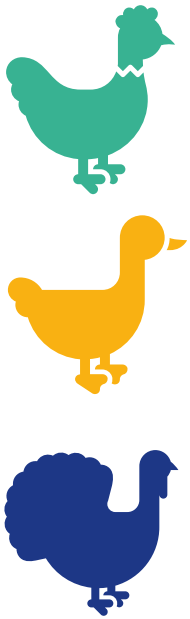
probability that the population is free from HPAI, given that surveillance did not detect any infected establishment and assuming perfect specificity

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

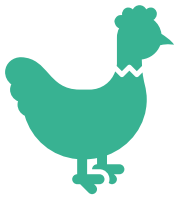
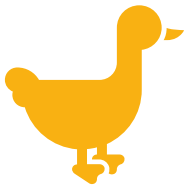
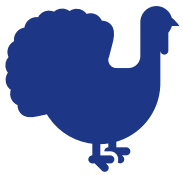


PREVENTIVE VACCINATION: ASSESSMENT



Sampling scheme	% farms under surveillance	EDSe	Pfree
molecular testing up to 15 dead birds monthly	100%	92%	>99%
		74%	>99%
		93%	>99%

PREVENTIVE VACCINATION: ASSESSMENT

	% farms under surveillance				
	100%	50%	25%	EDSe	Pfree
	monthly	-	weekly	>92%	>99%
	monthly	every 2 weeks	-	>74%	>98%
	monthly	-	weekly	>93%	>98%

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 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

EMERGENCY VACCINATION: RECOMMENDATIONS

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

Working group experts

- BORTOLAMI Alessio (EURL)
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- GUINAT Claire (ENVT)
- HARDER Timm (FLI)
- SCOLAMACCHIA Francesca (EURL)
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- Italy
- France
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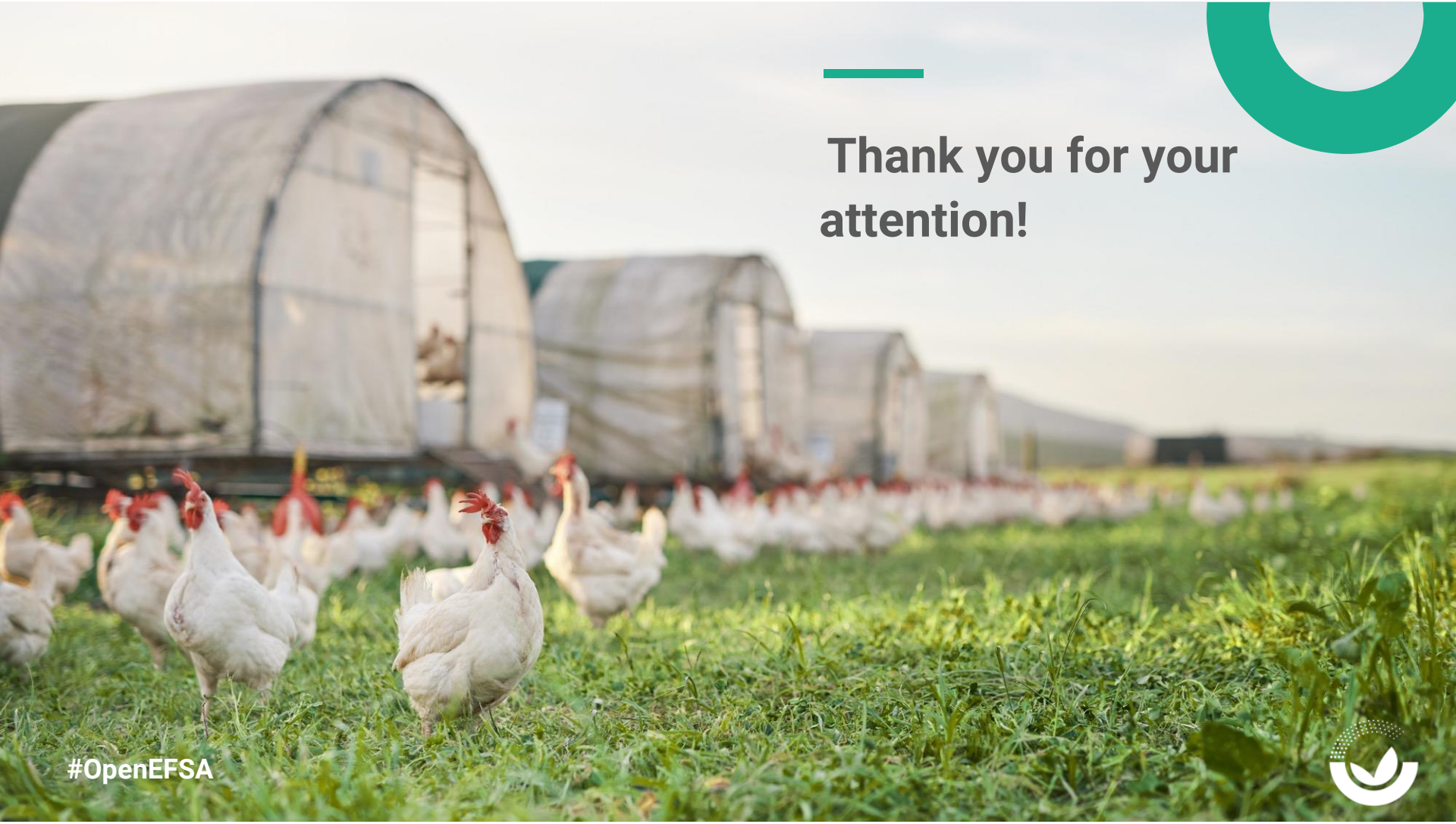
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