19 October 2023

Standing Committee on Plants, Animals, Food and Feed

Section Animal Health and Welfare

AHW.A.12.EFSA

VACCINATION OF POULTRY AGAINST HPAI – PART 1

AVAILABLE VACCINES AND VACCINATION STRATEGIES

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EUROPEAN FOOD SAFETY AUTHORITY

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

→ **by March 2024**

https://open.efsa.europa.eu/study-inventory/EFSA-Q-2022-00550

TOR 1 – AVAILABLE VACCINES

TOR 1 – AVAILABLE VACCINES

- **Inactivated vaccines** or **vaccines based on technologies other than live attenuated AIV**
- Prototypes of vaccines still in an early stage of development have been only mentioned when relevant

- **Data sources**:
  information retrieved by the literature review
  pharmaceutical company websites
  responses to the survey and network consultation

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EUROPEAN MEDICINES AGENCY
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TOR 1 –VACCINE TYPE AND TECHNOLOGIES

Large array of **vaccine types and technologies** available with only a small proportion produced commercially and used in the field outside of scientific studies:

- classical **oil-adjuvanted inactivated whole virus** vaccines remain the most widely used (not bound to poultry species-specific limitations, allows for easy manufacturing and offers potential versatility in strain adjustment) but not for DIVA strategies differently from the **recombinant** ones that can rely on already commercially available and consolidated serological assays
- Although there is no specific experience with AI **vectored vaccines** in the EU, the same vector backbone technology (e.g. recombinant HVT) is widely used for prevention of other diseases (e.g, IBD, NDV, ILT)
- **Nucleic acid-based** vaccines hold promise for the poultry sector particularly for their characteristic to allow for a smooth adaptation to the circulating strains compared with whole virus vaccines

TOR 1 - AVAILABLE VACCINES AND CHARACTERISTICS

- There is a significant **lack of usable and harmonised data** regarding the **characteristics** of available vaccines
- Most available poultry vaccines are designed for and evaluated in **chickens**
- Most of the available vaccines **administered through injection**
- 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
- Certain live vectored vaccines (**HVT**) are less affected by maternal immunity and can be given early even in the presence of maternally derived antibodies
- **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)

TOR 1 – VACCINE CHARACTERISTICS

Technology	Poultry species (experimental data)	Administration route	Vaccine name	Estimated antigenic distance (AU)	Lineage, clade	Predicted efficacy of a vaccine to stop sustained HPAIV transmission in a vaccinated population (VE_T)
Inactivated full virus	Chickens (Pekin ducks, turkeys)	Subcutaneous or intramuscular	Nobilis Influenza H5N2(NL)	4.37	Eurasian H5	< 0.5 in chickens after 1 dose
Inactivated full virus	Poultry (Muscovy ducks)	Subcutaneous	Vaxigen Flu H5N8(IT)	2.32	2.3.4.4b	in chickens >0.9; in Muscovy ducks <0.5 after 1 dose, >0.9 after 2 doses
Subunit	Chickens (Muscovy, Pekin, mule ducks, turkeys)	Subcutaneous	Volvac B.E.S.T. AI + ND(FR, IT)	4.18	2.3.2	In mule duck > 0.9 (after 2 doses); in Muscovy ducks 0.8-0.9 after 1 dose, >0.9 after 2 doses; in Pekin ducks >0.9
Live vector	Chickens (ducks, turkeys)	In ovo or subcutaneous	Vectormune AI(IT, NL)	4.18	2.2	in chickens > 0.9; in turkeys 0.5-0.8
Replicon	(ducks, geese, chickens, zoo birds)	Intramuscular	Duck H5-SRV vaccine®(FR, HU)	2.32	2.3.4.4b	> 0.9 in mule ducks
Nucleic acids (DNA)	(chickens, turkeys)	Intramuscular	ExactVac – Vaxliant ENABLE adjuvant(IT, NL)	2.51	2.3.4.4a	<0.5 in chickens after 1 dose

The only authorised in the EU

DIVA strategies

TOR 1 - RECOMMENDATIONS

- Generate **suitable and harmonised data on**:
  - 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**
  - **VE** to reduce $R_0<1$ under **experimental** condition and to assess **effectiveness in field trials** taking into account regional differences

- The development of **mass applicable** AI vaccines
- The **rapidly update** if required based on the antigenic match; for this purpose, continuous surveillance efforts to **monitor virus evolution** are needed

TOR 2 – VACCINATION STRATEGIES

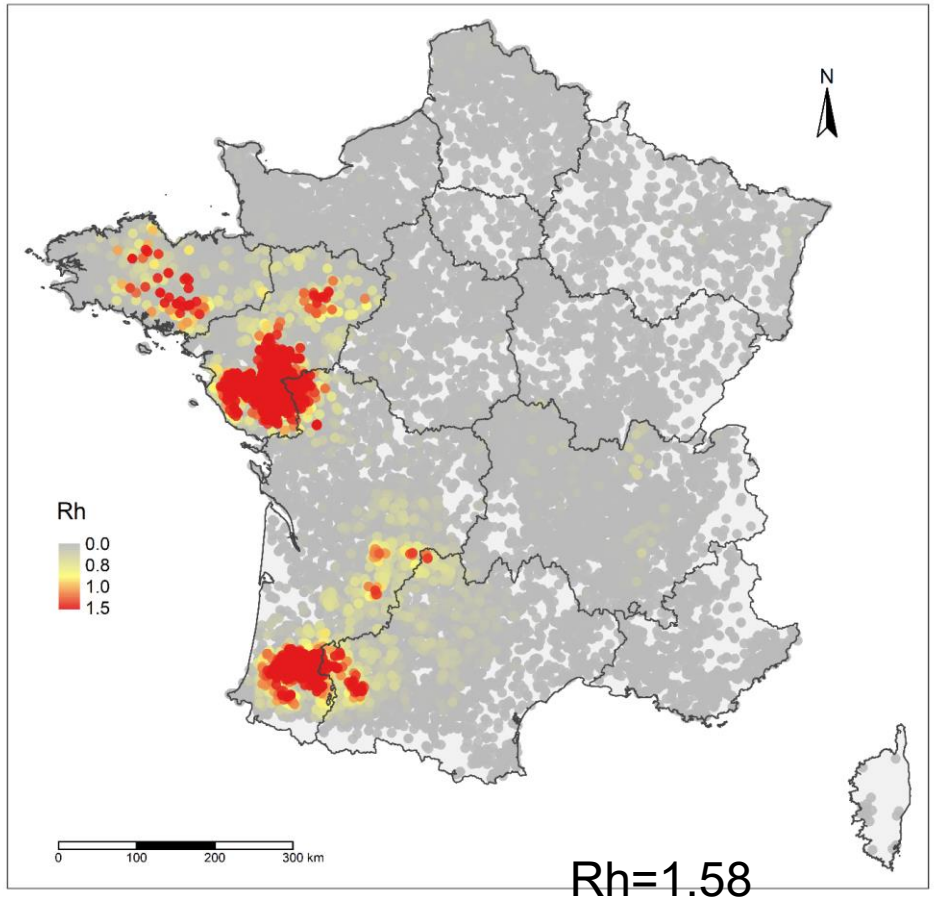
TOR 2 – VACCINATION STRATEGY SCENARIOS

- A number of specific **vaccination scenarios** focussing on the main domestic poultry species - **ducks**, **turkeys**, **chickens** - were defined using data from **France, Italy and the Netherlands** as case studies
- The virus was assumed to be introduced via wild birds into **densely populated poultry areas**, where the risk of between-farm transmission is the highest
- The **between-farm transmission** and the **impact of the vaccination scenarios** were then investigated using a **SEIR** model framework incorporating a **spatial kernel** for between-farm transmission dynamics

likelihood of virus transmission between farms is dependent on the distance between the source farm i and the destination farm j and the corresponding poultry type

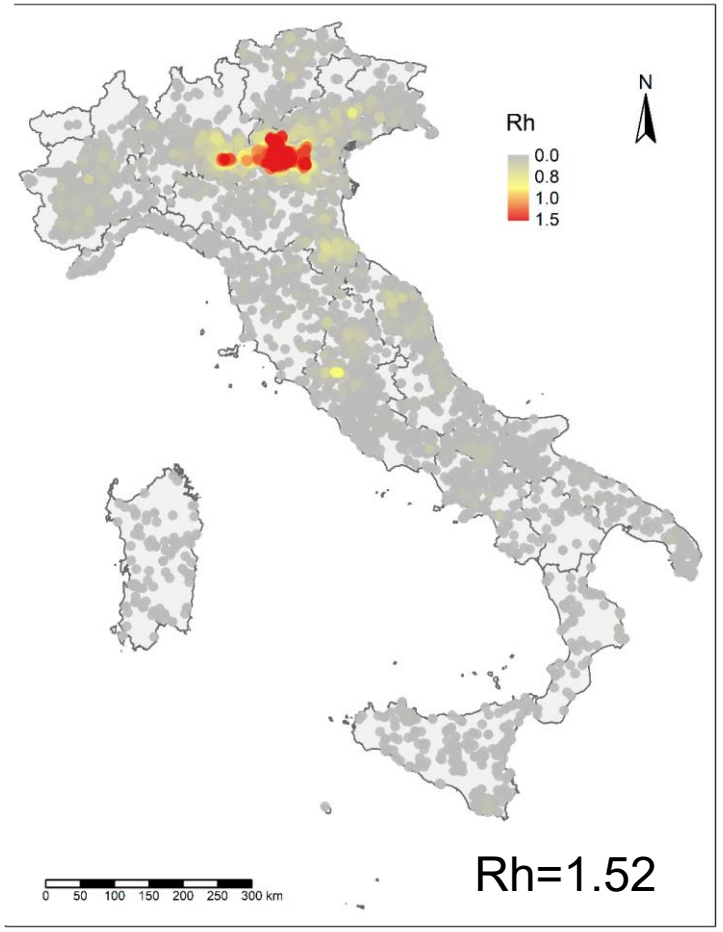
TOR 2 – TRANSMISSION MAPS

Rh are the between-farm reproduction numbers quantified using the kernel. Areas where Rh > 0.8 are considered high-risk areas for transmission



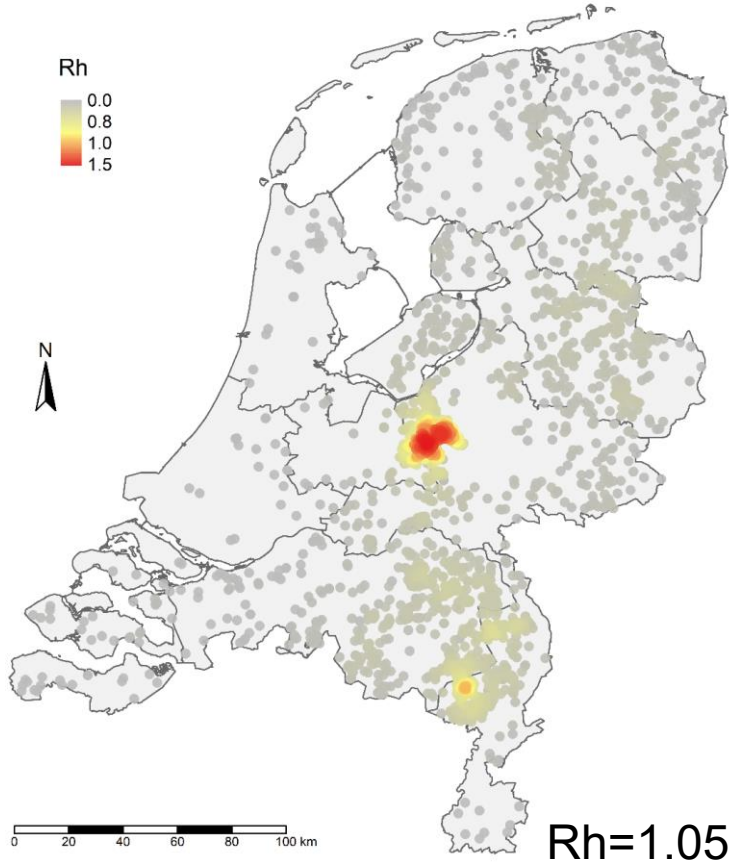
Rh=1.58

(farm density > 0.54 farm/km2)



Rh=1.52

(farm density > 0.52 farm/km2)



Rh=1.05

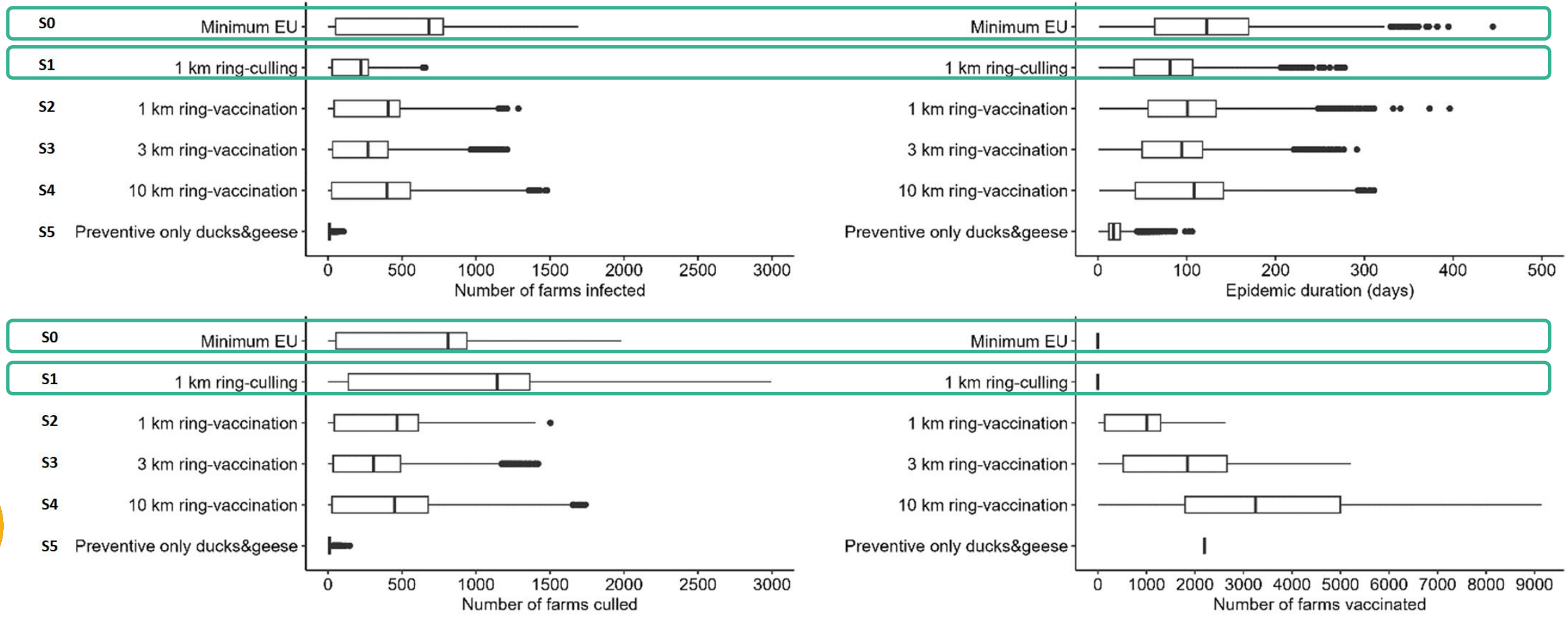
(farm density > 0.84 farm/km2)

TOR 2 – VACCINATION SCENARIOS

Scenario 0 (S0)	**No vaccination** Culling in all infected poultry farms
Scenario 1 (S1)	**No vaccination** Culling in all infected poultry farms Preventive ring **culling** in all poultry farms within **1-km** radius of infected poultry farms

TOR 2 – VACCINATION SCENARIOS

Results from the model simulation for each scenario in **France**



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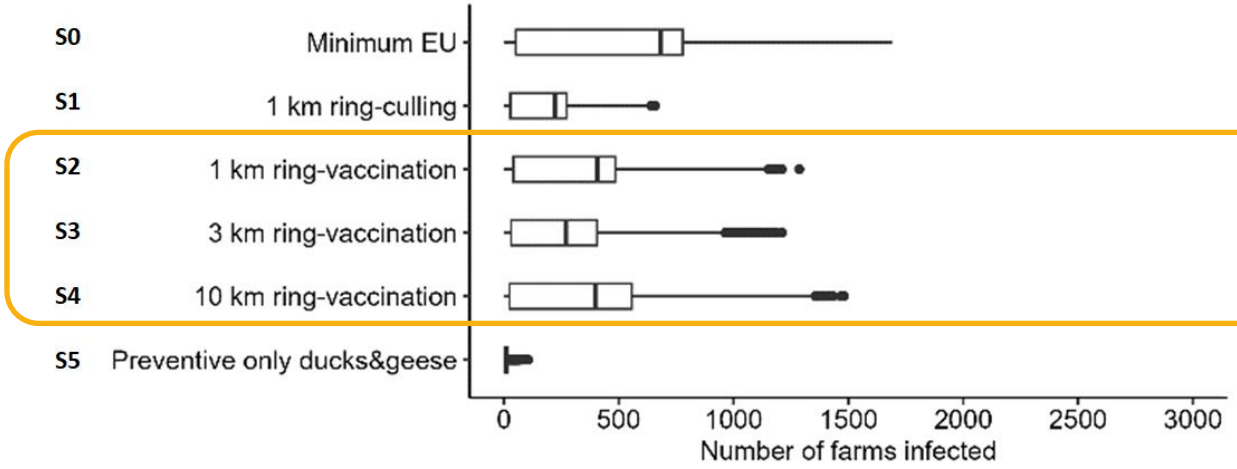

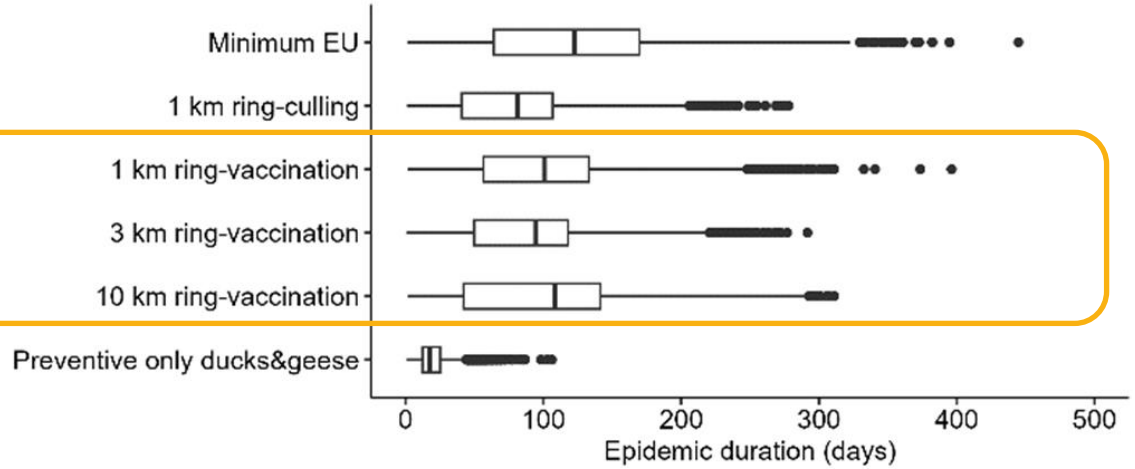

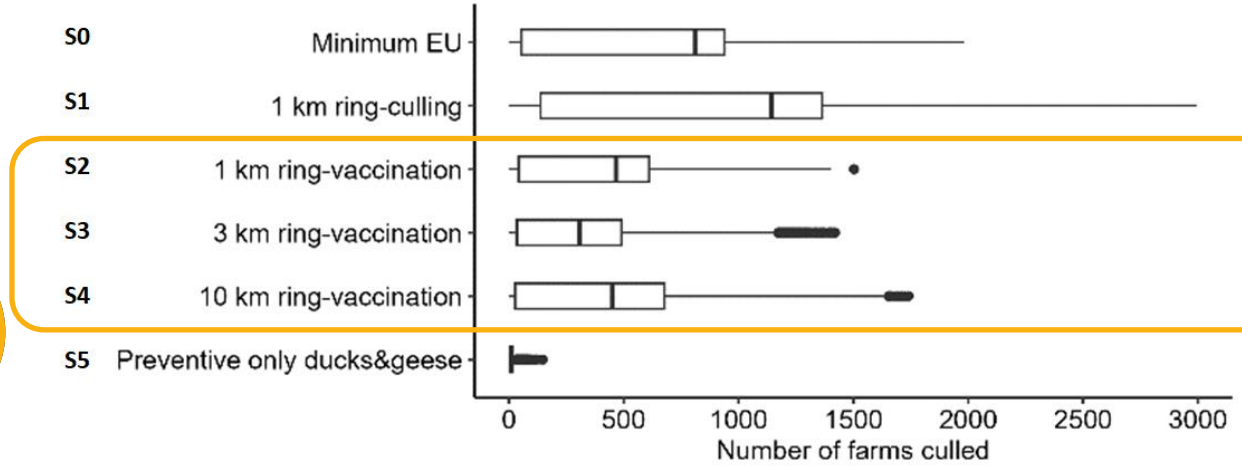

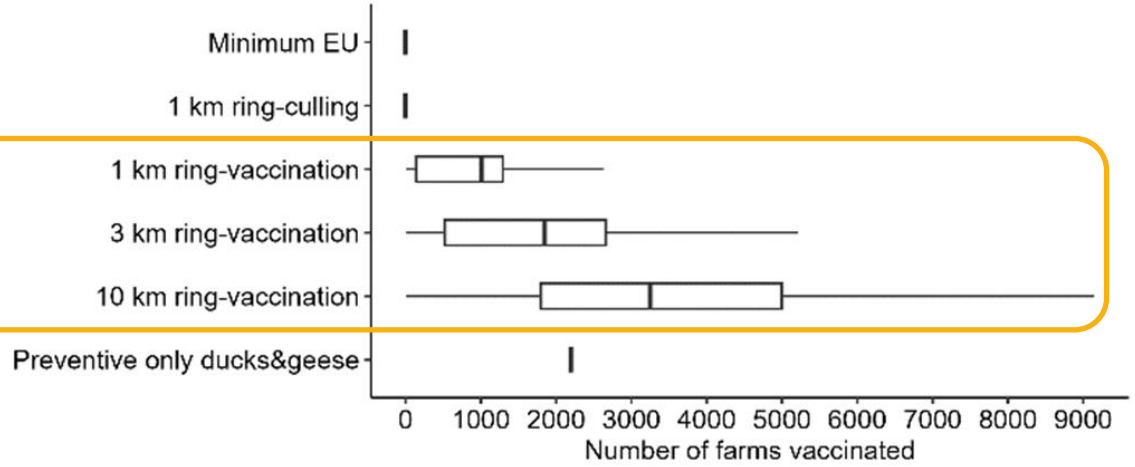

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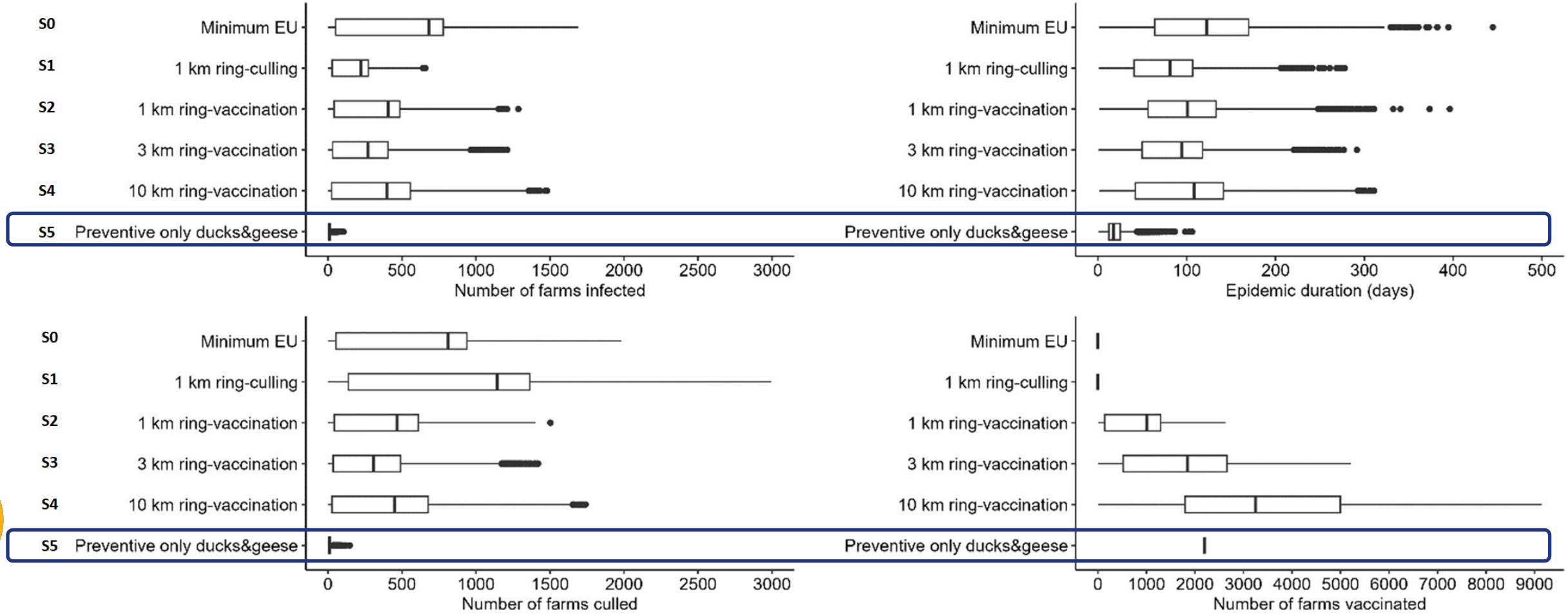
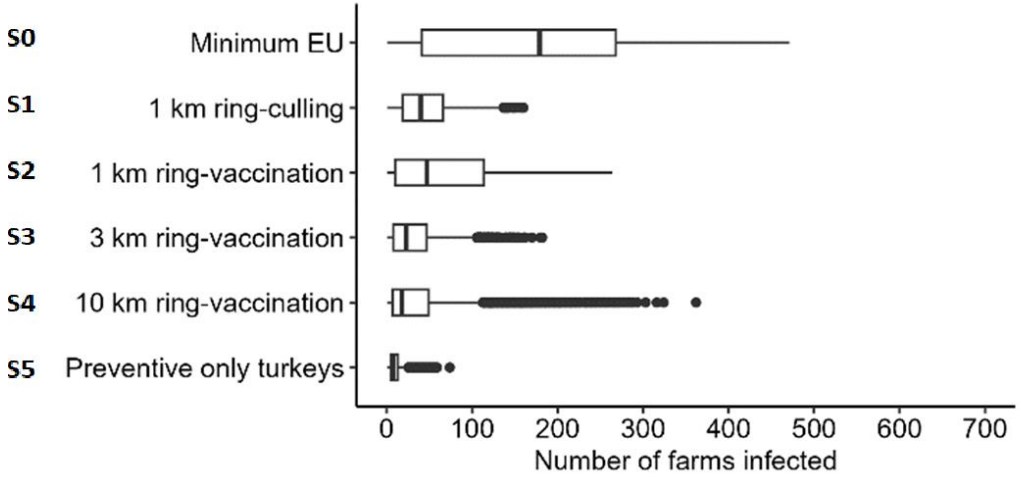
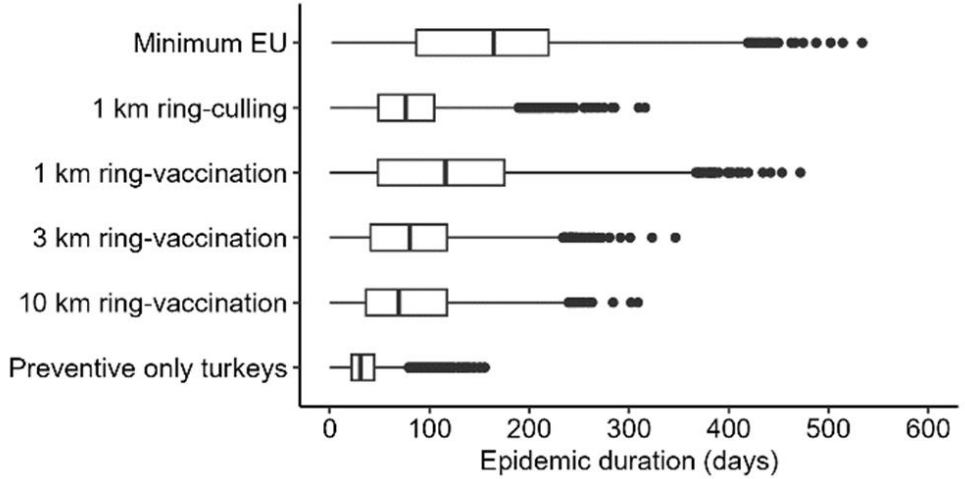
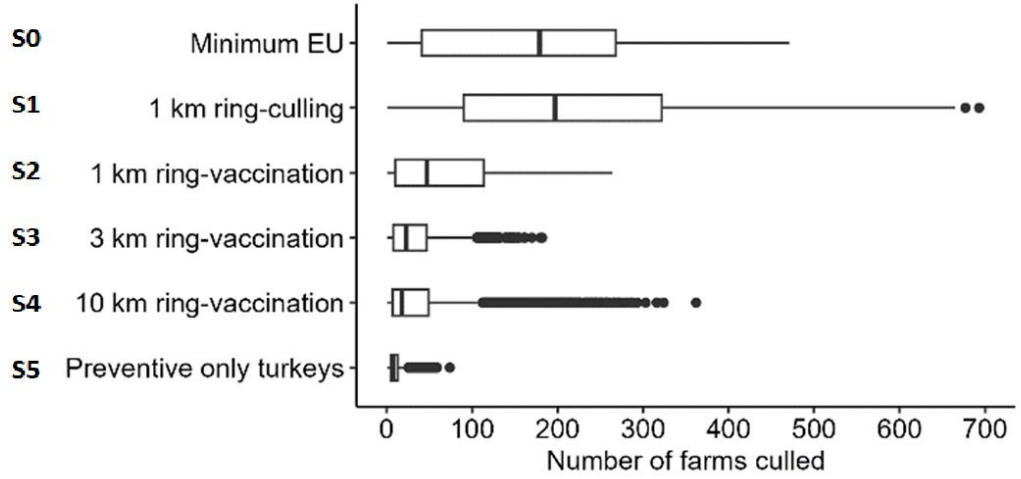


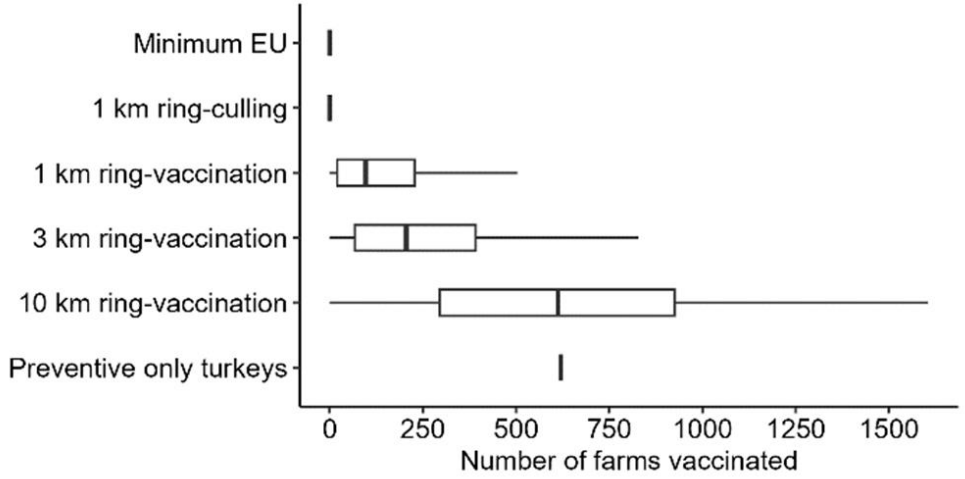
TOR 2 – VACCINATION SCENARIOS

Results from the model simulation for each scenario in **Italy**



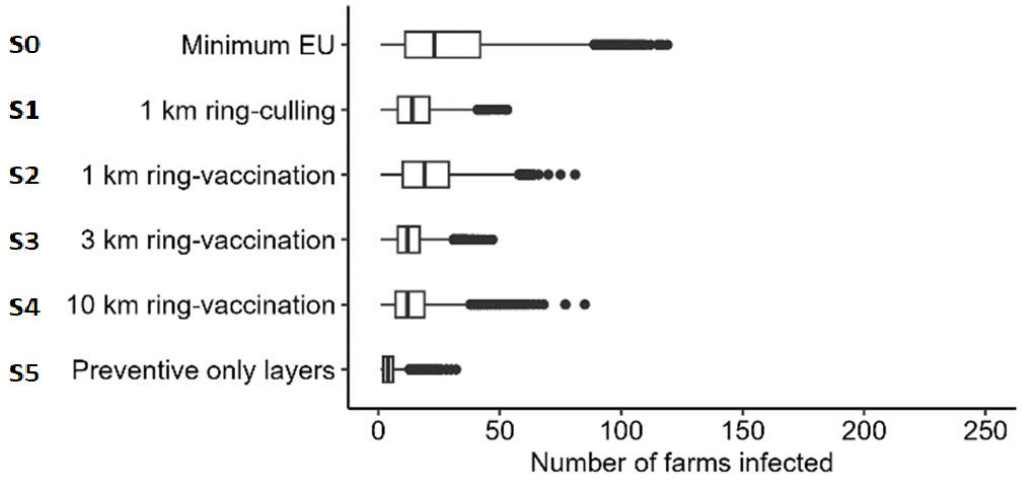


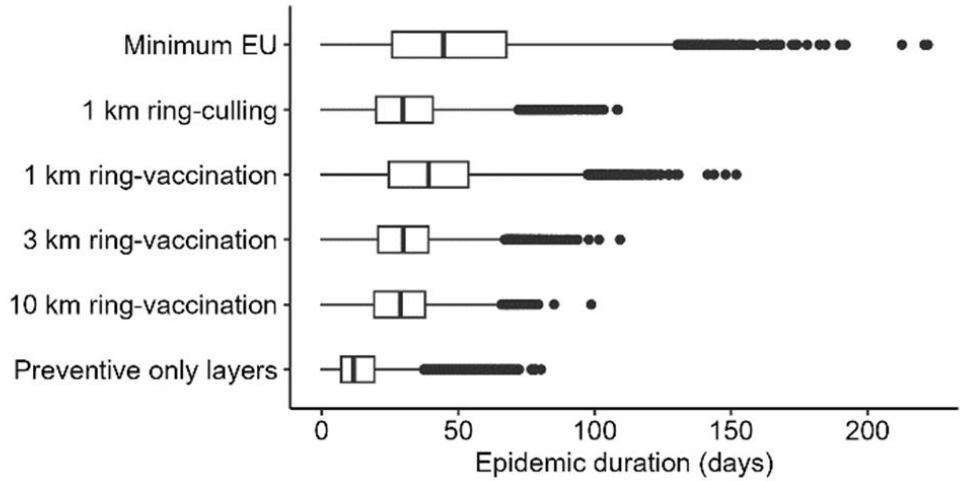


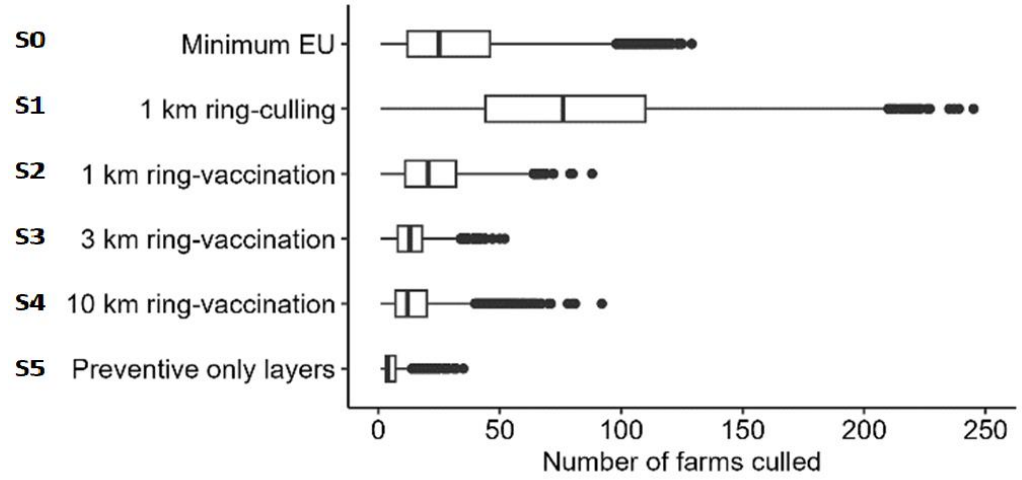


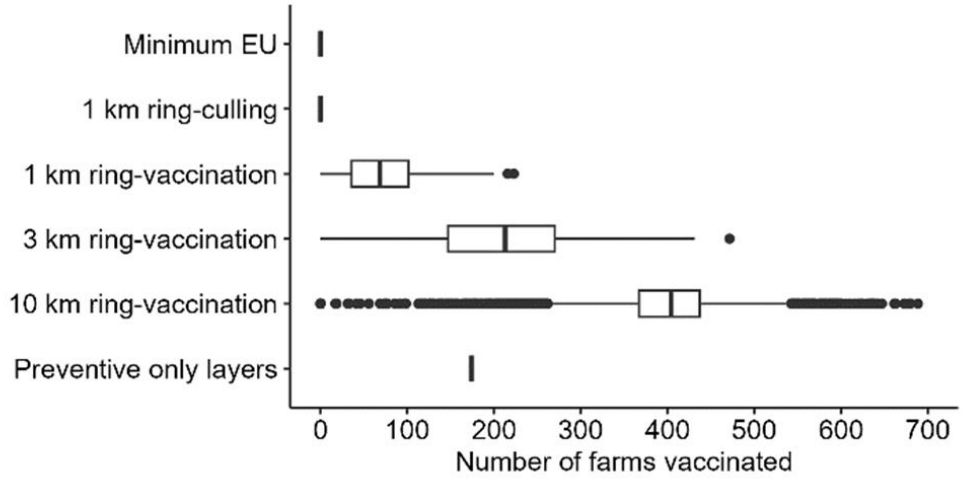
TOR 2 – VACCINATION SCENARIOS

Results from the model simulation for each scenario in **the Netherlands**









TOR 2 – RECOMMENDATIONS

- 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
- **Monitoring of vaccine efficacy over time** should be planned under the implementation of every vaccination strategy, due to possible changes in the antigenicity of circulating HPAI viruses, changes that can also be accelerated by the selection pressure exerted by vaccine-induced immunity

TOR 2 – RECOMMENDATIONS

- 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

THANKS TO ALL THE EXPERTS INVOLVED

Working group experts

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- AZNAR Inmaculada
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- LINDGREN KERO Linnea
- LANFRANCHI Barbara
- MUR Lina


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