Evaluation of the epidemiological situation in the context of controlling HPAI through the implementation of preventive vaccination in poultry in Bulgaria
EU VET Initiative

10 - 12 September 2024

PAFF Committee, 24-25th October 2024

Terms of reference:

In response to HPAI epidemiological situation in Bulgaria and demand of HPAI poultry vaccination

Providing on-the-spot assistance

- scientific, technical, managerial and practical aspects on the development and refinement of the most suitable preventive and control measures for HPAI
- especially in the context of controlling HPAI through the implementation of preventive vaccination in poultry

Experts: Luis Romero (ES) – team leader, Dr. Paul Leijs (NE) and Dr. Calogero Terregino (IT; EURL)

Meetings held during the mission

Day 1.

- *BFSA, central competent authority*
- *Representatives from HPAI National Reference Laboratory*

Day 2.

- *BFSA, central competent authority*
- *Ministry of Agriculture and Food*
- *Bulgarian poultry sector organizations*

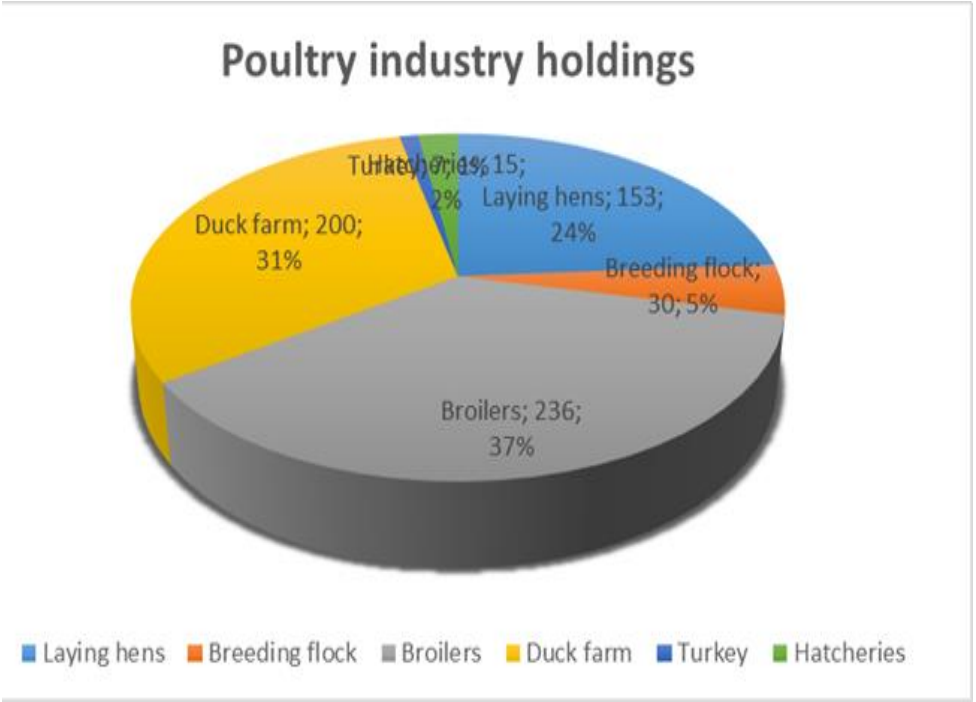
Day 3.

- *BFSA, central competent authority*

Headquarters of the Bulgarian Food Safety Agency (BFSA)

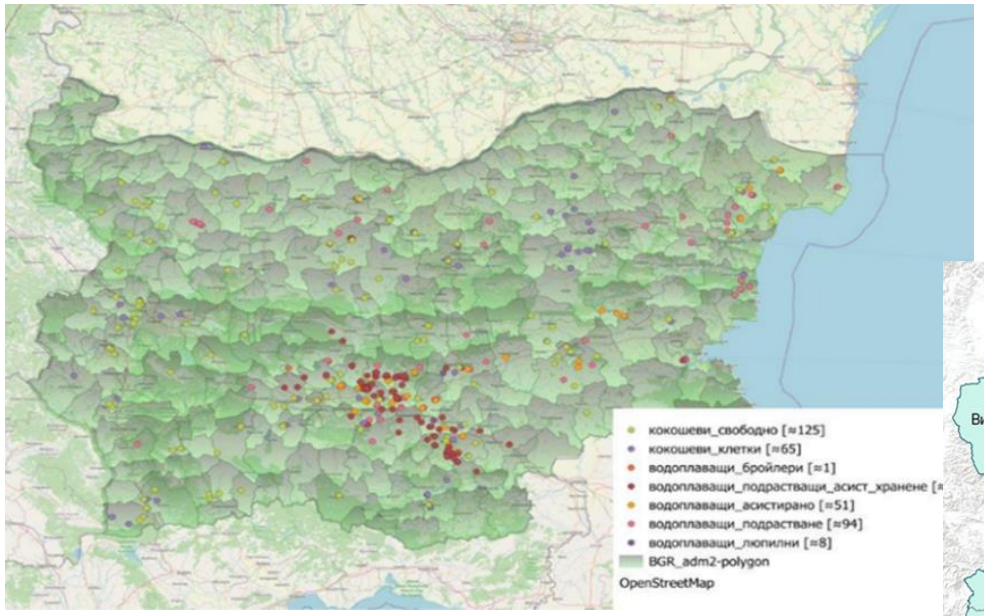
Poultry production sector in Bulgaria (I)

Category	Holdings, n	Poultry, n
Laying hens	153	3 600 000
Breeding flock	30	2 000 000
Broilers	236	10 000 000
Ducks farm	200	3 000 000
Turkey	7	3500
Hatcheries	15	



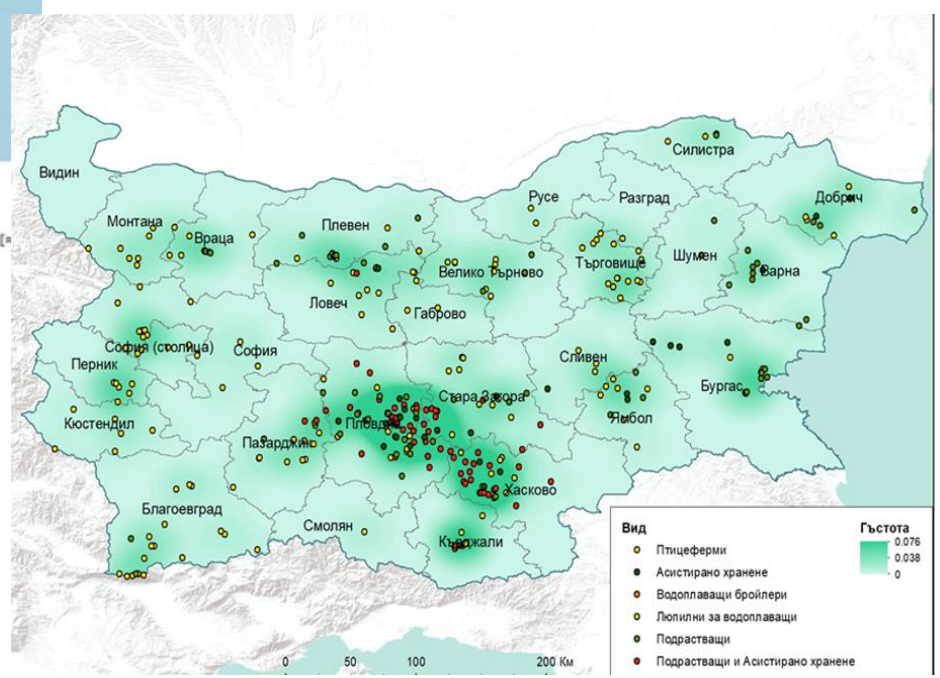
Distribution of poultry farms by categories (2023)

Poultry production sector in Bulgaria (II)



Geographical distribution of poultry farms in Bulgaria by categories

Density of poultry farms in Bulgaria



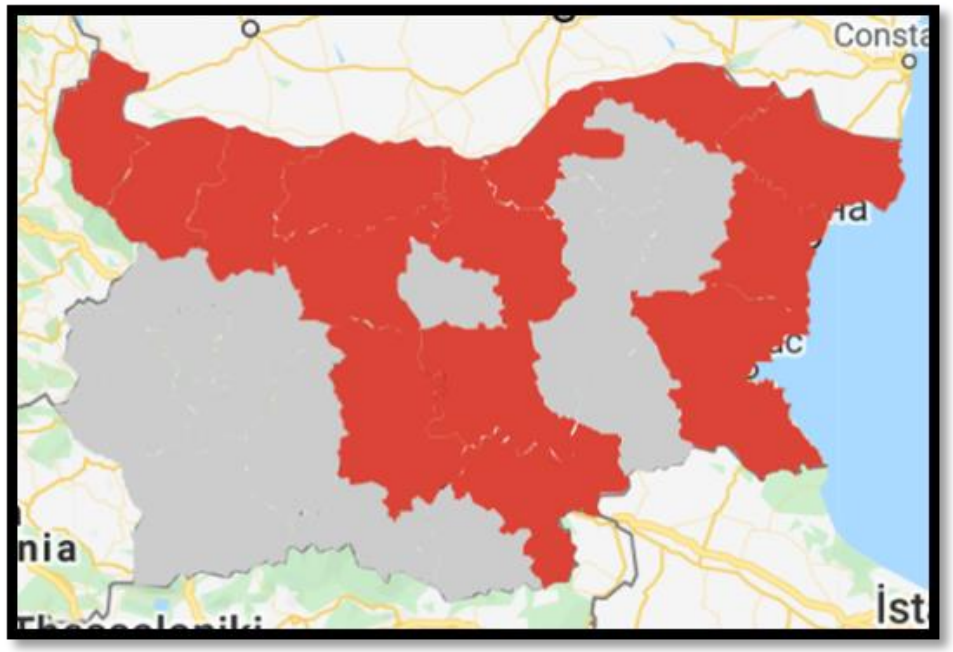
AI surveillance program in Bulgaria (I)

The surveillance design in the program is based on two approaches: risk-based sampling and the representative sampling.

All regions crossed by the Danube river are considered as regions with high risk of AI.

Concerning the migratory wild birds, the regions of Silistra, Dobrich, Varna and Burgas are the regions where pass a migratory route (named Via Pontica).

Based on these facts, 14 out of the 29 administrative regions are identified as such of higher risk with regards to AI.



AI surveillance program in Bulgaria (II)

The national plan for avian influenza surveillance in Bulgaria is part of the overall program approved by European Commission which is reviewed every three years.

The mentioned program has an active and passive surveillance component, including poultry farms and wild birds.

Reinforced passive and active surveillance is performed in poultry holdings located in the 14 higher risk regions, including regular check of dead birds, monitoring of mortality, and serological and virological surveilance.

HPAI control plan in Bulgaria

- From the 1st of October until the 31st of March, it is mandatory to keep all poultry confined inside the holding.

- Open door exhibitions are forbidden throughout the year.

- In case of HPAI outbreak in poultry all the relevant control measures set up in Commission Delegated Regulation (EU) 2020/687: stamping out of affected holdings, disposal of carcasses and products, and cleaning and disinfection of premises, establishment of protection and surveillance zones, restriction of movements of poultry and products, enhance of surveillance and biosecurity measures.

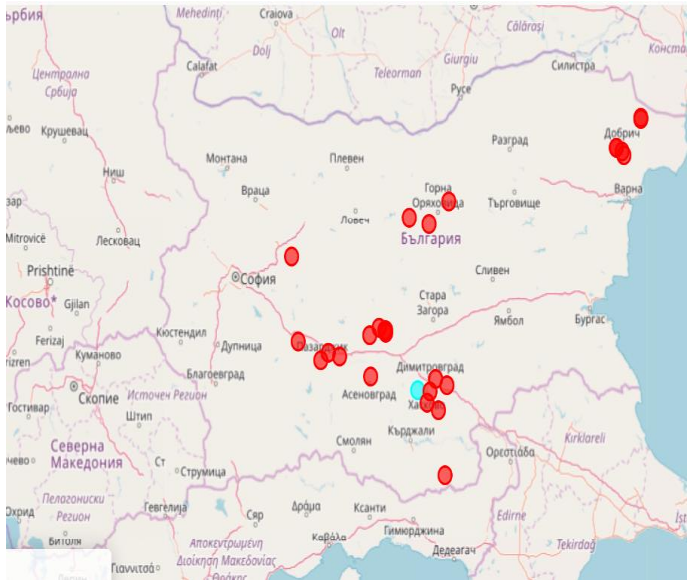
HPAI further control measures

I. Reorganization of duck sector: the whole cycle/life in one holding or in different holdings but belonging to the same owner/company. This measure aims at decreasing the movement of ducks from farm to farm and avoiding one farm (gavage) to be used by different owners/companies.

II. Transport of ducks: separate transport means to be used for ducks and Galliformes. GPS equipment for all poultry transport means in order to allow the traceability of poultry movement.

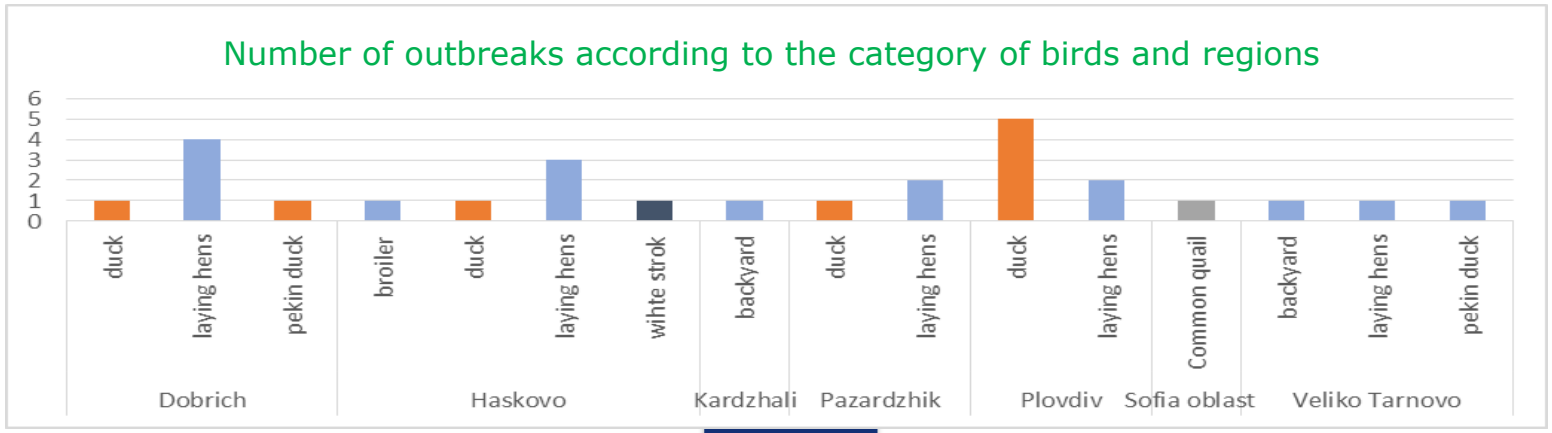
III. Established a sanitary period of at least 21 days (one incubation period: a ban for restocking of the duck farms once per year. During the sanitary periods, cleaning and disinfection of all premises will be carried out.

HPAI epidemiological situation (2023-Aug 24)



Year	Outbreaks, n	Affected poultry, n
2023	11	1353308
2024	16 (1 in wild birds)	796423

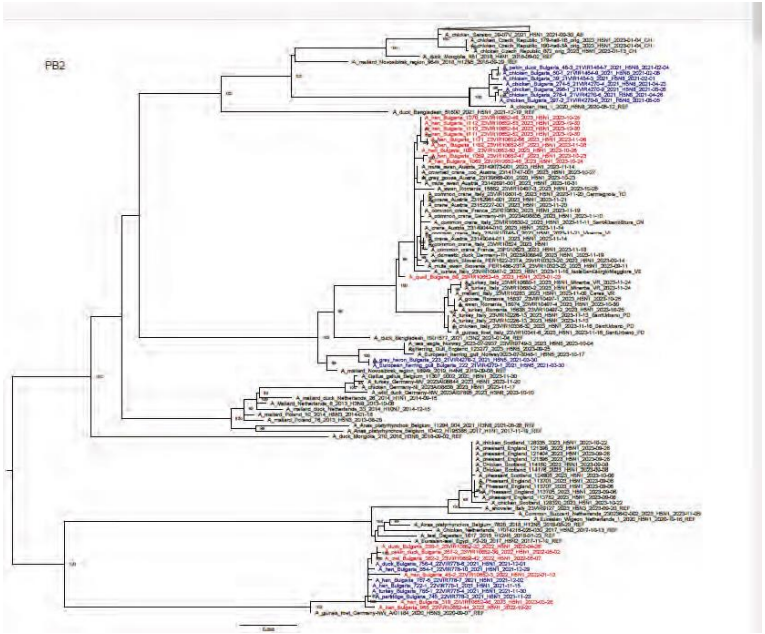
- 2023-2024 – 27 outbreaks (1 in wb)
- Total number of poultry affected – 2 149 731 poultry



Phylogenetic Analysis and epidemiological considerations

The phylogenetic analyses of the HPAI viruses identified in the country suggest both persistent circulation of some genotypes in poultry farms and the emergence of new ones.

Epidemiological studies often point to problems and gaps in biosecurity as a mechanism for the entry and spread of HPAI viruses within and between establishments.



Activities and diagnostic capacity of the AI NRL and private laboratories

Weaknesses:

Limited human and material resources in the AI NRL.

Virus isolation, pathotyping tests and sequencing are not performed at NRL so far.

Private laboratories are also involved in AI surveillance in the country. In the draft vaccination plan it is proposed that these private laboratories will perform weekly testing of samples of dead birds from vaccinated holdings. Nevertheless, these private laboratories are not under supervision of the NRL.

HPAI vaccination strategy: draft vaccination plan in poultry (I)

Order No RD09-1163/13.11.2023 of the Minister for Agriculture and Food, established a working group of experts composed by representatives from the Ministry of Agriculture and Food, BFSA, Risk Assessments Unit and relevant stakeholders.

*This group of experts has elaborated a document on **"Analysis of need to develop a vaccination strategy against highly pathogenic avian influenza in the Bulgarian poultry sector"**.*

HPAI vaccination strategy: draft vaccination plan in poultry (II)

Different vaccination strategies were considered, from the vaccination of all laying hen farms or duck farms across the country, to the vaccination of one of both categories only in high-risk regions.

Bulgarian authorities, with the agreement of poultry industry, have decided to develop a draft of vaccination plan as a pilot project. This draft has been elaborated following the criteria set up in Part I of Annex III of Regulation 2023/361.

HPAI pilot vaccination project (I)

Vaccination of 2 hatcheries and 10 laying hen holdings where the pullets will be introduced beside the non-vaccinated productive laying hens.

HPAI pilot vaccination project (II)

Hatchery (1) produces its own hatchery eggs, but it also collects hatchery eggs from other breeder farms, vaccinating them on demand with vaccine for H5 HPAIV.

It would deliver the vaccinated one-day-old chicks to the designated farms, and it would also export non vaccinated one-day-old chicks to other member states.

HPAI pilot vaccination project (III)

Hatchery (2) has a closed system, producing its own hatchery eggs and after vaccination it would rear these pullets and let them produce.

HPAI pilot vaccination project (IV)

The vaccine selected is Innovax-ND-H5, a live recombinant vaccine against Newcastle disease, AI and Marek's disease, developed by Intervet International B.V.

It can be administrated in ovo or subcutaneously in one-day-old chicken with a single injection (no booster is needed).

Duration of immunity against HPAI for a minimum of 4 months (guaranteed by the manufacturer when the vaccination plan is drawn up)

Critical points identified in the HPAI pilot vaccination project and during the EUVET mission

Certain weaknesses can be detected in it:

- Inadequate level of biosecurity on the farms to be vaccinated;

- Insufficient information about the virus circulation and strains in wildlife

- Absence of a database to record information on vaccination and its traceability;

- Duration of vaccination not determined;

- Unclear hygiene and biosecurity requirements for vaccinated holdings;

- The co-housing of vaccinated and non-vaccinated poultry flocks on the same holding;

- Uncertainty about the impact of vaccination on international trade in poultry and poultry products.

Overall conclusions (I)

- The risk of introduction of HPAI viruses from the wild should be considered high due to the presence of many wetlands and breeding areas for migratory birds.

- Phylogenetic analyses suggest that the HPAI virus may have been circulating undetected in unknown reservoirs for several months.

- Surveillance and biosecurity in poultry holdings could be not good enough.

Overall conclusions (II)

- Vaccination could be a tool to prevent the introduction of the virus, but other essential tools to prevent the spread of the virus and the control HPAI must first be optimized.

- The Bulgarian competent authority has performed a lot of work with their preparations for their plan of vaccination. Nevertheless, some weak points have not been fully covered yet.

Recommendations on the strategy of implementing a HPAI preventive vaccination plan in poultry

Surveillance

AI surveillance should be improved:

- *In wild birds: identifying the strategic areas and selecting and sampling the most appropriate target species in a representative manner. The use of models such as EFSA's Bird flu radar can be helpful in a strategic surveillance and risk analysis plan.*
- *In poultry: cooperation of the Bulgarian poultry industry. The Bulgarian competent authority should increase the efficiency of active surveillance in the farms by regularly collecting dead birds and/or to sample animals with suspected clinical signs. In duck farms, active surveillance should be carried out if no dead birds are found.*

AI National Reference Laboratory

- *The staff capacity and resources of the NRL should be increased for the HPAI surveillance, and the strengthened monitoring foreseen in case of implementation of the vaccination plan.*
- *The NRL should supervise the private laboratories that are foreseen to perform the AI diagnosis for the monitoring of vaccinated holdings.*
- *Collaboration with the EURL should be improved by training staff, implementing the most appropriate diagnostic tests and reducing the time taken to send samples for sequencing.*

Biosecurity:

- *Strengthen awareness, preparedness and training of veterinarians and farmers on biosecurity is the main issue that should be improved in the poultry industry.*

- *This should also include a review of the production systems in order to reduce the risk of spread of the disease for example by reducing the density of avian influenza susceptible animals in same critical areas and the number of movements between holdings.*

Vaccination plan

- *All topics according the 2023/361 are covered, but detailed information on several topics is lacking and should be fully completed before implementation is possible.*
- *The co-housing of vaccinated and non-vaccinated poultry flocks on the same holding should be discouraged as this would greatly reduce the effectiveness of vaccination and increase the risk of mistaking vaccinated birds for non-vaccinated birds and vice versa, and epidemiological research can be made more difficult by this.*
- *The choice of the vaccine should take into account the data from the phylogenetical analysis of viruses identified the recent outbreak in order to have a high antigenic match with the circulating strains and to ensure protective immunity throughout the production period of the vaccinated bird.*

Data records:

- *The database required by Regulation 2023/361 is not yet in place. This should be tested and operational before the vaccination plan is implemented.*

Final recommendation

- *At this moment Bulgaria is not ready to implement the vaccination against HPAI in accordance with the Regulation 2023/361.*

- *Any vaccination plan should be postponed until all gaps are filled.*

- *All stakeholders of the poultry industry should fully agree on the final vaccination plan before it is implemented.*

The EU-VET team would like to thank all colleagues from Bulgaria for their great support and help!

The working atmosphere during the mission was excellent. The colleagues from Bulgaria gave all their support and assistance to facilitate a fruitful mission. Thank you so much!!!