

Highly Pathogenic Avian Influenza and vaccinal strategy implementation Position Paper, 1st March 2023

The Poultry Veterinary Study Group of the EU in its previous position paper 'Highly Pathogenic Avian Influenza and sustainability of the global poultry industry' proposed that governments and industry should seriously consider the options to use modern vaccines to control Highly Pathogenic Avian Influenza (HPAI) particularly as in some circumstances the classical approach of management of this disease (i.e., diagnosis, stamping out and eradication) alone, is no longer socially and economically acceptable to poultry producers and wider stakeholders. PVSGEU members acknowledged that such a vaccination approach can only be used in association with robust biosecurity measures and will need to be accompanied with comprehensive monitoring and surveillance, with the objective to detect any HPAI virus circulation on vaccinated flocks. If a flock is contaminated it will have to be stamped out to provide confidence to trading partners that allows trade in poultry and poultry products to continue without disruption. Only a fully approved package with Europe-wide consensus could allow member states to better protect their poultry and poultry producers against HPAI outbreaks in certain seasons, geographical areas or better protect some higher risk poultry production (e.g., free range poultry or waterfowl). This would provide benefits to national and international poultry farming and animal welfare.

Further to the previous PVSGEU position paper, we have seen another dramatic season of HPAI with numerous incursions into commercial poultry across Europe in winter 2021 and spring 2022. This has affected 37 European countries and resulted in an estimate mortality or culling of 50 million of

domestic poultry and more than 3.800 detections in wild birds (EFSA Avian influenza overview September - December 2022). The current clade 2.3.4.4b H5N1 has become the dominant clade infecting a wide range of domestic poultry and wild bird species, the latter with resultant high mortality levels in vulnerable breeding colonies across Europe (https://www.efsa.europa.eu/en/news/avianinfluenza-cases-poultry-and-water-birds-rise). Infections of strategic sites (including parent flocks and higher genetic populations) have been reported across Europe in this last AI season which has impacted on the availability of valuable breeding stock for commercial poultry production. More worryingly, this particular clade of H5N1 has become endemic in the resident wild bird populations in many countries supporting the persistence of the virus through the summer months when the migratory bird population has left for their summer breeding grounds. Circulation of the virus in wild birds raises concern for biodiversity especially where unique breeding colonies of wild birds have been infected (e.g., Bass rock Gannet colony). The changing epidemiology of HPAI and the impact it is having on poultry producers and their stock has resulted in debates within scientific, poultry professional and political communities about the role of vaccination for control of this disease. Moreover, the submitted 'COMMISSION DELEGATED REGULATION (EU) 2023/361 of 28 November 2022 as regards rules for the use of certain veterinary medicinal products for the purpose of prevention and control of certain listed diseases (such as HPAI) will give professionals a regulatory framework for the implementation of a vaccination strategy. Some countries have already undertaken scientific and/or pragmatical assessments (logistic, labour, cost) of the implementation of vaccination strategies. In this position paper, PVSGEU wants to highlight key points that we consider to be of paramount importance in the implementation of a successful vaccination strategy.

Defining a thorough vaccination strategy. Experience has shown that HPAI can spread rapidly within poultry dense areas and implementing a vaccination strategy would require considerable logistic resources. Therefore, it is generally agreed that a preventive vaccination policy is likely to be more successful and achievable than an emergency vaccination policy. As such, epidemiological inputs are crucial to define in advance the most appropriate target species, production cycle types, geographical zones and vaccination timing of the year. It seems intuitive that by vaccinating more species, across broader geographic zones, the greater the probability of controlling the circulation of the virus amongst the poultry farms.

However, a careful approach should be considered to prioritize vaccination based on:

- the most relevant species based on their susceptibility to virus (such as ducks or turkeys)
- husbandry management (such as life cycle or outdoor access) and
- industry organisation (such as movement of animals during production cycle).

Vaccination of breeders should be carefully considered in the context of the resulting regulatory constraints and to avoid impact on vaccine efficacy in progeny of those breeders. Identification of geographical vaccination zones is of a paramount importance, considering not only wetlands, but more importantly density of poultry farms and connections within farms. Timing of vaccination should be considered based on several parameters, such as wild bird migration periods, but also life duration of commercial poultry. Indeed, for some long-lived poultry, such as layers, vaccination should be implemented several months in advance to ensure birds are fully protected for the period when environmental challenge is highest. Lastly the vaccination strategy should consider the regulatory context for its implementation, including a mandatory vaccination in the defined populations as well as the need for an "exit strategy".

Anticipating vaccine and manpower needs. There are a number of existing modern vaccines against HPAI and if a vaccination policy is adopted more vaccines will be developed with innovative technologies. The advent of newer vaccine technology will result in different vaccination programs. Vaccines pharmaceutical formulation, manufacturing and supply can have a major impact on the logistical implementation of the vaccination strategy. Detailed planning will be required by all stakeholders to ensure adequate supplies of vaccine are available, appropriate for the species to be vaccinated. Those vaccines will need to be produced, distributed and available in a timely manner to the poultry industry for successful vaccination implementation. Vaccine manufacturers will need adequate notice and firm purchase commitments before they plan vaccine production. The manpower resources required to implement a vaccination program will vary depending on the species to be vaccinated, the number of birds to be vaccinated, geographical extent and type of vaccine. Hatchery vaccination is likely to be the most automated process compared to on-farm vaccination. Veterinary professionals will be crucial for organizing and supervising vaccination procedures, and like the vaccination programs, this work needs to be planned well in advance of a vaccination campaign.

Coordinating monitoring strategy. It is expected that vaccination should reduce the likelihood of infection of a vaccinated flock and clinical signs associated with the disease but will not fully exclude a possible infection. Therefore, vaccination must be accompanied by a robust monitoring program to exclude "silent" disease carriage and to assess vaccine intake and response. The 'COMMISSION DELEGATED REGULATION (EU) 2023/361 of 28 November 2022 as regards rules for the use of certain veterinary medicinal products for the purpose of prevention and control of certain listed diseases' (such as HPAI) gives professionals a regulatory framework for the implementation of the monitoring strategy. Review of this document enables countries to plan and evaluate costs, such as veterinary work or laboratory analyses requirements, depending on the vaccine strategy chosen. However, PVSGEU is concerned that the current EU Delegated Act proposes surveillance levels that could quickly become unrealistic from labour or cost perspectives. Therefore, this Act should be reviewed and adapted, especially to be more workable with current veterinary and laboratory resources. As such, delegation of veterinary and diagnostic activities under regulatory and technical supervision should be considered.

Ensuring financial and commercial feasibility. Financial assessment of a HPAI vaccination strategy would not only include vaccination implementation and monitoring costs, but also direct and indirect commercial impact associated with vaccination. Poultry products (i.e., eggs or meat) from vaccinated poultry will necessarily be more costly than from non-vaccinated birds raising the question of national governmental financial support of vaccination. Risk of trade distortion between or within poultry sectors could be an issue and therefore should be reviewed. Discussions between international trading partners must be undertaken to ensure the ability to continue trade of poultry genetics and products without unnecessary barriers. This is particularly important when non-vaccinated populations are in an environment close to vaccinated populations.

In conclusion, PVSGEU believes that a vaccination policy for HPAI alongside robust biosecurity protocols and comprehensive but realistic monitoring and surveillance programs to prove freedom of infection, can be implemented to ensure continued international trade of poultry genetics and products. This will achieve a more sustainable approach in disease prevention and control across the World.

PVSGEU advocates and calls for even closer collaboration between science, the poultry industry and government agencies in developing and implementing vaccination strategies. This will enable an interdisciplinary exchange involving all professionals in the various sectors of poultry production. Only strong coordination, including the use of diagnostic capacities and human resources from the poultry industry to relieve state laboratories and veterinary authorities can lead in a successful vaccination strategy. Confidence must be built for consumers and trading partners that the use of the best possible surveillance program ensures freedom from infection in traded animals and products. Comprehensive implementation is imperative, as an incomplete strategy would result in poor disease control, risking a risk a loss in confidence in vaccination, and loss of trust of stakeholders.

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References

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