# INTERNATIONAL ALLIANCE FOR BIOLOGICAL STANDARDIZATION (IABS) CONFERENCE ON VACCINATION STRATEGIES TO PREVENT AND CONTROL HIGH PATHOGENICITY AVIAN INFLUENZA: REMOVING UNNECESSARY BARRIERS FOR USAGE, PARIS – FRANCE, October 25 - 26, 2022

### MAJOR CONCLUSIONS AND RECOMMENDATIONS FROM THE MEETING

These conclusions and recommendations were developed based on information presented during the scientific sessions, a series of facilitated breakout sessions during the Workshop, and a summary session at the end of the workshop. All participants were invited to comment on the draft version.

## **MAJOR CONCLUSIONS:**

### Why use vaccines?

The costs associated with outbreaks of high pathogenicity avian influenza (HPAI) are huge for affected farms and communities. HPAI threatens food security and the sustainability of certain types of poultry production

The risk for introductions of HPAI in poultry has increased markedly since 2.3.4.4b clade of Eurasian HPAI virus has become endemic in wild birds

Additional measures are needed to prevent HPAI, given the extent of infection in wild birds, the evidence of increased outbreaks and the large number of poultry that have been destroyed because of this disease. The safe disposal of these carcasses remains a challenge.

Vaccination can provide an extra layer of protection, reduce the quantities of circulating virus and the number of farms on which stamping out is required. However, there is still reluctance to deploy it in some countries.

Concerns have been expressed about the adverse effects on public attitudes if reliance on stamping out continues as the main control method. Vaccination will help to overcome these concerns.

Many of the barriers to vaccination are either assumed or can be overcome. Two issues will likely take longer than others to be overcome – trade issues and availability of suitable, commercially available vaccines.

## Trade issues as a barrier to vaccination

Trade concerns center on non-acceptance, by importing countries, of any poultry products or birds if vaccines are used (even if limited vaccination is being used or it is only being used in certain sectors, such as vaccination in turkeys but not in broilers). This non-acceptance is based largely upon concerns, addressed in this meeting, that vaccination may mask HPAI infection and therefore remains the main barrier to implementing vaccination programs, especially in countries with well-established valuable export markets.

Use of vaccines does not alter avian influenza status from a trade perspective (World Organization for Animal Health [WOAH] Terrestrial Code Article 10.4.1. Provision 6) if an appropriate surveillance system is in place that demonstrate supports the absence of HPAI infection in poultry.

Therefore, trade concerns are inextricably linked to having in place appropriate surveillance systems, acceptable to trading partners, to demonstrate freedom of HPAI infection in vaccinated flocks

Appropriate systems for surveillance can be developed but must also be cost-effective. There are still some gaps in knowledge, especially on relevant sample numbers, methods for targeted surveillance and the role of environmental samples as part of a multi-layered surveillance system. Surveillance systems, developed for and used in unvaccinated flocks, need to be adapted to reflect the expected lower prevalence of infection in vaccinated flocks, if it occurs.

Routine dead bird testing has been recommended as a core component of surveillance systems

Serological response to vaccination provides assurance that birds have responded appropriately to vaccination

Capacity for surveillance programs must be available and in some parts of the world may require use of accredited private laboratories and farmer-collected samples

Serological DIVA tests will likely be part of some surveillance programs, but their limitations need to be recognized in places where other avian influenza viruses are circulating.

## Vaccination and public health

Vaccination of poultry is not a threat to public health, in fact, it helps to protect humans from infection by preventing or greatly reducing poultry infection and environmental contamination, the source of virus for human exposure and infection

# Vaccine availability and vaccination

A limited number of vaccines are available for use in the EU and USA at present, and will only become available if vaccine producers identify a viable market for their products

Most currently available vaccines in the EU and USA are administered by injection and are DIVA compatible.

Vaccination would be aided if a safe product could be developed, incapable of reassortment or reversion to virulence, that can be delivered by mass application on farms.

Avian influenza vaccination programs, if/when introduced to commercial farms, need to consider, and align with existing vaccination programs against other avian pathogens

True silent infection (sustained transmission but no birds getting sick or dying from the disease) in well vaccinated flocks exposed to virus occurs rarely in chickens. Transmission of infection following virus incursion is unlikely to occur in flocks with good immunity. If

transmission does occur, few vaccinated flocks will be 100% immune and birds with low or no protection will develop disease allowing detection of virus. In domestic ducks, silent infection already occurs in unvaccinated flocks.

If emergency vaccination is to be used, a vaccine bank or alternative means of rapidly acquiring vaccine is required.

Several countries where virus is endemic have vaccination programs in place for antigenic characterization of viruses and updating of vaccines.

Systems for allowing changes of vaccine antigens using "cassette" systems, as permitted in some countries, facilitate rapid updating of inactivated (non-replicating) vaccines without requirements for full re-registration of products

Antigenic variant strains of HPAI virus that develop in one country can find their way to other countries, including those where viruses are not endemic in poultry (e.g., current clade 2.3.4.4b viruses)

Vaccines that are a poor match to circulating strains (not providing protection or providing sub-optimal protection in experimental studies) should not be used. Therefore, ongoing surveillance and analysis of circulating HPAI viruses in wild birds is essential to a successful domestic poultry vaccination program.

Vaccines that induce cellular immunity, such as vector vaccines, help to broaden protection against antigenic variants

## **RECOMMENDATIONS**

That consideration be given to the following:

Formation of a consultative committee on vaccination, involving a range of stakeholders including representation from countries using or considering vaccines, vaccine manufacturers, the poultry sector, trading partners and Food and Agriculture Organization (FAO)/WOAH/World Health Organization, to provide support to greater usage of vaccination in association with other control measures

Implementation of trial vaccination in the field in multiple countries that are not currently using vaccines, once current laboratory-based trials on vaccines in the EU are completed. This would proceed once there is agreement from trading partners that the trials would not affect trade from the countries where vaccination is being used. It may involve vaccination in selected areas or types of poultry only.

Farms in these pilot trials should be closely monitored to demonstrate response to vaccine, freedom from HPAI infection, and to assess issues such as suitability of different vaccines for different types of birds, costs and issues associated with vaccination.

These trials provide opportunities to assess and develop appropriate surveillance programs, including various alternatives such as greater usage of environmental samples, testing of routine dead birds, and using sufficient birds from vaccinated farms taken to laboratories for challenge studies to mimic the field situation

Continue to promote the value and importance of vaccination, building on the momentum from this meeting

Support the WOAH/FAO Animal Influenza Network (OFFLU) AIM (Avian Influenza Matching) program through provision of isolates or genetic material from new isolates

Countries where infection is endemic to continue monitoring for antigenic changes and updating vaccines and to look at ways to reduce the likelihood of vaccinated flocks being infected, including changes in the way birds are reared and sold (such as greater use of disease-free compartments and less reliance on live bird sales)

Translational research is needed to take information from fundamental vaccine studies to commercial products to make effective use of advances in vaccine technology

Templates for risk assessments for onward spread of HPAI should be developed for birds and products from vaccinated and unvaccinated flocks