WOAH avian influenza control standards and vaccination guidelines

Presented at the SASVEPM webinar on the "Threat of emerging H5 and H7 avian influenza viruses to the regional poultry market: global overview and sustainable control measures applicable to southern Africa", held on the 14 March 2024 from 13:00pm - 15:30pm

Presented by

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Presentation Layout

- General information update on AI
- WOAH Standards on AI
- Animal Health Forum platform (90GS in May 2023)
- Resolution No 28
- Vaccination against AI
- Conclusion

WOAH Centenary Celebrations!!!

An International Standard setting body for **Animal health, Welfare and Veterinary Public Health (Zoonosis)**

Formed in 1924 (25th January) > > > > >

Currently 183 member countries

Headquarters in Paris, France.

13 Regional and Sub-Regional offices

General Update on Avian Influenza - Worldwide Situation January 2024

- AI continues to spread, evidenced by increase in the number of;
  - affected countries,
  - outbreaks,
  - domestic and wild animal species affected.

- Reduced viral diversity, 94% of virus typed correspond to subtype H5N1 clade 2.3.4.4b

- Persistence of the virus during previously undetected periods - reduced seasonality

- Very few sporadic human cases

- WOAH continuously collects and disseminates information through WAHIS and its website.

General Update on Avian Influenza - WOAH-FAO Collaboration

- 2008 GF-TADS HPAI Global strategy was focused on emerging H5N1 subtypes.
- The new draft Global strategy (2024-2033) aims to safeguard poultry production, contribute to human and wildlife health protection, and transform poultry value chains towards a resilient agrifood system
- The draft strategy is currently under consultations with different stakeholders including Members. The aim is to launch in May 2024.
- OFFLU (OIE-FAO FLU network) remains a scientific reference to provide expert advice on AI – publishing statement and guidelines where new scientific information on AI becomes available (OFFLU website).
- OFFLU experts participate in the WHO vaccine composition meeting (VCM) to support WHO in the selection of the appropriate animal influenza strains to be included in the human vaccines
- OFFLU has recently published the report of the project 'Avian influenza Matching" which provides information on antigenic characteristics of circulating viruses to facilitate selection of appropriate vaccines for poultry.
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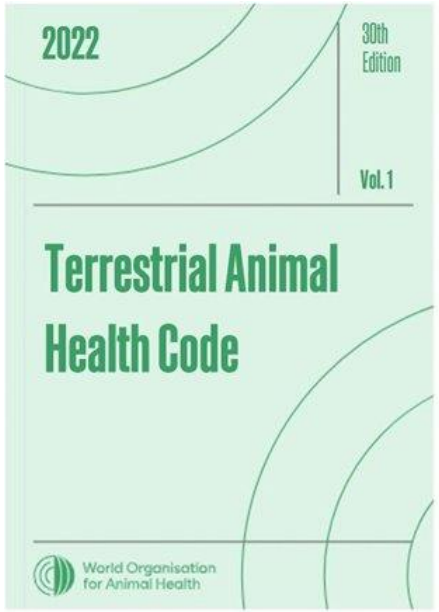
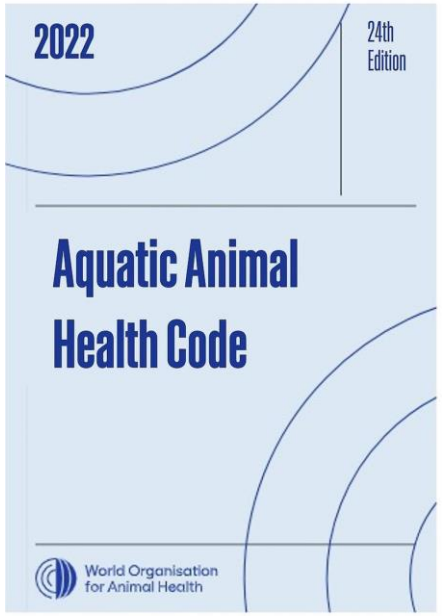
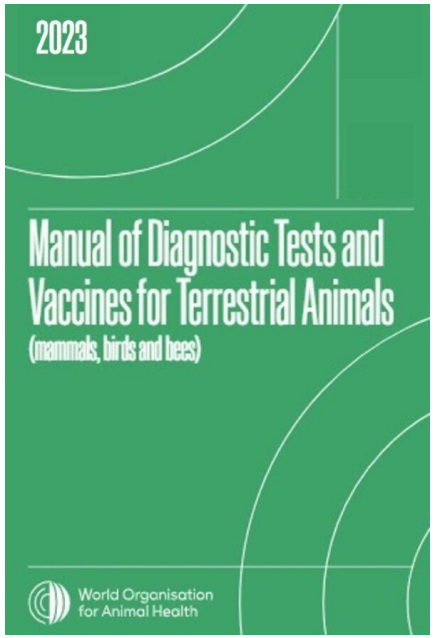
WOAH international standards on AI

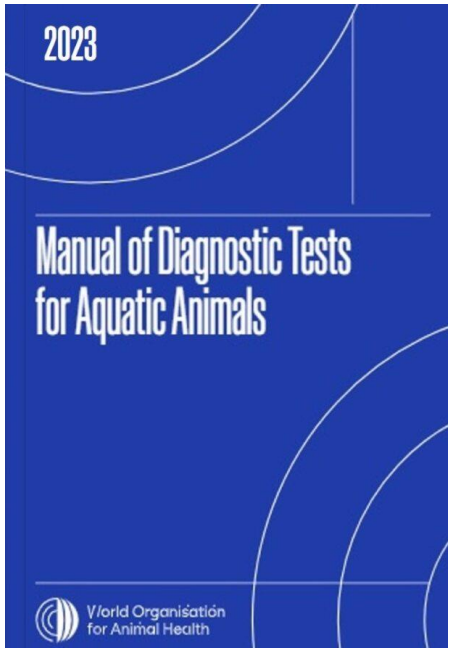
- **Terrestrial Manual Chapter 3.3.4** Avian influenza (including infection with high pathogenicity avian influenza viruses) is currently under the revision. To be adopted in May 2025

- **Terrestrial Code Chapter 10.4** Infection with high pathogenicity avian influenza virus is up to date - no further revision is envisaged in the short term.









The Animal Health Forum (AHF) on Avian Influenza

- AHF is a new discussion format introduced to explore the challenges for the global control of HPAI following a technical item: *"Strategic Challenges in the Global Control of High Pathogenicity Avian Influenza"* - **Policy to Action**
- The AHF highlighted that –
  - ✓AI is a **One Health problem** and must be tackled through a **holistic ecosystem health approach**
  - ✓**Trust, transparency and collaboration** is critical to address this disease threat and the challenges it brings
  - ✓**OFFLU is important** to provide diagnostic expertise and vital genetic and antigenic information to enable matching of vaccines to field strains
  - ✓**There will not be a one size fits all approach** and further guidance is needed to provide direction to implement the provisions in the WOAH Terrestrial Code to minimize impacts on trade and economics.
- AHF resulted in **Resolution No. 28** on the Technical Item, which spells out recommendations for WOAH, Members and Partners to deal with the global threat of HPAI. https://www.woah.org/app/uploads/2023/06/a-resos-2023-all.pdf

Resolution 28: Recommendations to Members

90th General Session
World Organisation for Animal Health

World Assembly
Paris, 21-25 May 2023

GS

RESOLUTIONS

Adopted by the World Assembly of Delegates

During the 90th General Session

21 – 25 May 2023

LIST OF RESOLUTIONS

Administrative resolutions:

Technical resolutions

Resolution 28: Recommendations to Members

- Resolution No.28 ***'Strategic Challenges in the Global Control of HPAI'*** adopted during the 90th General session provided key recommendations for WOAH, Members and partners to effectively address the HPAI global threat.

- An internal implementation framework and an associated M&E tool was developed for effective implementation of the resolution's recommendations.

- A WOAH internal Coordination Group was developed to ensure WOAH coordinated approach to support our Membership.

Resolution 28: Recommendations to Members

- Maintain transparency through timely and comprehensive reporting of avian influenza events to WOAH as described in the Terrestrial Animal Health Code.

- Promptly share samples and virus isolates, virus sequence data, and associated epidemiological information with WOAH Reference Laboratories, OFFLU and deposit sequences in publicly available databases to inform risk managers, thus enabling early detection, rapid response and pandemic preparedness through monitoring the evolution of LPAI and HPAI viruses

- Conduct appropriate, risk-based, comprehensive and systematic monitoring and surveillance in domestic birds, wild birds (e.g., along flyways) and in other susceptible animal species to support early warning and risk management at the human–animal–environment interface.

- Intensify the exchange of relevant information and coordination with public health authorities and other relevant authorities.

Resolution 28: Recommendations to Members

- Support poultry keepers, in particular smallholders, in implementing correct usage of disease preventive and control tools, such as enhanced biosecurity, early identification of clinical signs and reporting, to prevent the introduction and spread of HPAI.
- Respect and implement the adopted WOAH standards and recognise compliant zones and compartments of their trade partners.
- May consider the implementation of vaccination as a complementary disease control tool that is based on sound surveillance and takes into account local factors such as circulating virus strains, risk assessment and vaccination implementation conditions.
- Adopt vaccine best practices (stewardship) and reassess on an ongoing basis the use of appropriately field matched vaccine strains and the continuing need for update of vaccines

Resolution 28: Recommendations to Members

- Develop and implement national disease control and operational plans in cooperation and coordination with wildlife health authorities, public health authorities and the private sector to ensure a multi-stakeholder effort to combat HPAI.
- Support research alliances and global research coordination mechanisms (e.g. STAR-IDAZ, WHO Public Health Research Agenda, OFFLU) to generate scientific knowledge using interdisciplinary approaches and tools, including the development, testing, production and approval of effective vaccines to contribute to the successful control of HPAI.
- Advocate for increased investment in low- and middle-income countries from funding institutions, the private sector, resource partners and development agencies in support of strengthening the human resource capacity and sustainable infrastructure of Veterinary Services, including diagnostic capability and early warning systems.

Vaccination Against AI

- The use of vaccination against avian influenza may be recommended under specific conditions.
- Any vaccine used should comply with the **standards** described in the Terrestrial Manual (Chapter 3.3.4.)., together with **other (horizontal) chapters** on;
  - Chapter 4.18. Vaccination
  - Chapter 1.4 Surveillance
  - Chapter 4.4 Zoning and Compartmentalisation
- Vaccination will not affect the high pathogenicity avian influenza status of a free country or zone if surveillance supports the absence of infection, in accordance with Article 10.4.28.
- Vaccination can be used as an effective complementary control tool when a stamping-out policy alone is not sufficient.
- Whether to vaccinate or not should be decided by the Veterinary Authority on the basis of the avian influenza situation as well as the ability of the Veterinary Services to implement the vaccination strategy, as described in Chapter 4.18.

Vaccination Against AI – Cont...

- According to the survey done as part of the 2023 Technical Item, 19% of WOAH Members implement vaccination, mostly as emergency response
- Trade is the main barrier to initiate vaccination as reported by Members
- Surveillance in vaccinated flocks is considered feasible but could present important technical and logistical challenges.

Vaccination Against AI - Where are we with vaccination?

Key facts;

- Vaccination is recognised in WOAH international standards
- The WOAH provides recommendations on vaccine production requirements for vaccines and on the diagnostic tests for detecting infection in vaccinated flocks
- Vaccines have already been used against HPAI in multiple countries (endemic or high risk)
- Technical/policy challenges (trade)
- Vaccination is not the SILVER bullet but it can play a role

Vaccination Against AI – Vaccination Technical Challenges

- Quality- Only Authorised vaccines. Illegal vaccines!!!!
- Availability - Need sufficient supplies of well-matched vaccine
- Surveillance - Need to be accompanied by a strong surveillance system to demonstrate “freedom” from infection
- Indirect risk - Potential transmission of virus by vaccination teams

Vaccination Against AI - Vaccination Specific Recommendations from Resolutions 28

Resolution no: 28 https://www.woah.org/app/uploads/2023/08/resolution28-strategic-challenges-in-the-global-control-of-high-pathogenicity-avian-influenza.pdf

Recommendations pertaining to AI Vaccination

8. Members, in consultation with the poultry sector may consider the implementation of vaccination as a complementary disease control tool that is based on sound surveillance and takes into account local factors such as circulating virus strains, risk assessment and vaccination implementation conditions.

9. Members adopt vaccine best practices (stewardship) and reassess on an ongoing basis the use of appropriately field matched vaccine strains and the continuing need for update of vaccines.

10. Members respect and implement the adopted WOAH standards and recognise compliant use of vaccination without negative consequences on trade, when the vaccination programme is supported by vaccination monitoring and disease surveillance systems that can demonstrate the effectiveness of vaccination and absence of infection.

11. WOAH, with the support of its Reference Laboratories and OFFLU, provide up-to-date information to Members, the poultry sector and vaccine manufacturers on the genetic and antigenic characterisation of circulating virus strains, including comparison with existing vaccines, to infer levels of protection.

12. Members ensure the use of authorised vaccines manufactured according to WOAH standards that are effective against circulating strains and regularly share information related to the effectiveness of the vaccination programme and their surveillance system to inform changes in vaccination strategies and policy.

Benefits of the Poultry Vaccination

Poultry vaccination can no longer be excluded from the available alternatives and should be considered a complementary tool. When scientifically justified, it offers several advantages:

- **Reduced virus circulation** *within and between flocks and lower risk of spillover to wildlife*.
- **Reduced economic losses,** both direct (e.g. bird deaths) and indirect (e.g. mass culling and trade disruption). When properly implemented, avian influenza vaccination is compatible with safe trade, according to WOAH international standards.
- **Lower risk of human exposure** to avian influenza viruses, and thus of a potential pandemic, in line with the One Health approach.
- **Minimised environmental impact** by reducing the risk of spill over to wild animals.
- **Incentives for innovative research** to maintain the efficacy of vaccines over time, thanks to the experience gained. This encourages manufacturers to develop and improve access to effective and up-to-date vaccines.

Policy brief

December 2023

Avian influenza vaccination: why it should not be a barrier to safe trade

Executive summary

Since 2005, avian influenza has had a staggering toll, with over 500 million birds lost to the disease worldwide [1]. Its devastating impact extends beyond domestic and wild birds, threatening livelihoods, food security and public health. The recent shift in the disease's ecology and epidemiology has heightened global concern as it has spread to new geographical regions. It has also caused unusual die-offs in wild birds and led to an alarming increase in mammalian cases. The rapidly evolving nature of avian influenza and **changes in its patterns of spread** [2] require a review of existing prevention and control strategies. To effectively contain the disease, protect the economic sustainability of the poultry sector and reduce potential pandemic risks, all available tools must be reconsidered – including vaccination.

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The current spread of avian influenza is a major concern for the poultry industry, public health and biodiversity. Given recent developments in its epidemiology, and the increasing

Key facts

The epidemiology of avian influenza is evolving: the disease is gradually losing its seasonal nature, and high pathogenicity strains are circulating in wild birds.

As described in WOAH standards [6], the decision to vaccinate poultry must be:

- part of a **broader avian influenza control strategy** with an **exit plan;**
- accompanied by an solid **monitoring and surveillance system** for domestic and wild bird populations to guide the **selection of appropriate vaccine strains;**
- based on the availability of **sufficient financial, technical and human resources** for disease surveillance and the maintenance of effective vaccination campaigns;
- combined with the enforcement of relevant **regulations**, including licensing, quality control, and safety standards for vaccines.

The **maintenance of vaccinations** should rely on the regular **evaluation of vaccination programmes** to gather evidence on their effectiveness and adjust them as necessary, based on surveillance data and scientific developments.

International cooperation, including trade

The implementation of avian influenza vaccination programmes requires a careful balance between disease control and maintenance of safe international trade. Prior to exchange, trading partners should:

- establish mechanisms to ensure **cooperation and transparent communication** between relevant stakeholders, including ministries, Veterinary Authorities and producers;
- engage in bilateral discussions to agree on certification requirements and trade protocols, and to address trade concerns, so **mutual recognition** can be ensured **in peacetime.**

Ultimately, **multilateral dialogue and adherence to WOAH standards** are key to ensuring that if a country decides to introduce vaccination against avian influenza, it will be carried out appropriately, without sanitary risks and will not form an unnecessary barrier to safe trade. Efforts should be made to maintain open lines of communication, thus minimising trade disruption while protecting animal health and welfare, as well as human and environmental health.

References

1. WAHIS data, WOAH.
2. Infographic: Avian influenza: understanding new dynamics to better combat the disease, WOAH; 2023.
3. EFSA AHAW Panel (EFSA Panel on Animal Health and Animal Welfare), European Union Reference Laboratory for Avian Influenza, Nielsen S. S. *et al.* EFSA Scientific Opinion: Vaccination of poultry against highly pathogenic avian influenza–part 1. Available vaccines and vaccination strategies. *EFSA Journal*, 21(10), 1-87; 2023.
4. Avian influenza situation reports, WOAH.
5. Ongoing avian influenza outbreaks in animals pose risk to humans, FAO-WHO-WOAH; July 2023.

Considering vaccination as part of available avian influenza control measures

Traditionally, HPAI has been of concern mainly in domestic birds, with its control envisaged at farm level. Current transmission patterns show it is now circulating in wild bird populations, driving its spread not only across different farms, but also within farms. In practice, this has made it **more and more difficult to protect a farm from disease introduction**, due to increased exposure, both from neighbouring poultry farms and wild birds.

There has been a global rise in HPAI outbreaks [4] and an increase in the genetic diversity of circulating virus strains. Thus, the **use of sanitary control measures alone may no longer be a sustainable solution** to effectively contain the disease. One such measure is the systematic mass culling of poultry, which results in heavy economic losses for farmers, has a lasting impact on their livelihoods and raises social, animal welfare and environmental concerns. Due to its negative impact on the sustainability of production practices and the image of the poultry industry to consumers, its acceptability must be scrutinised.

Measures such as surveillance for early detection and monitoring of avian influenza viruses, preventive health measures (biosecurity) and disease control measures (culling, movement controls, quarantine) remain at the core of any avian influenza control strategy.

However, **poultry vaccination can no longer be excluded from the available alternatives and should be considered a complementary tool.** When scientifically justified, it offers several advantages:

- **Prevention and control of outbreaks in vaccinated domestic bird populations** resulting in reduced virus circulation within and between flocks and lower risk of spillover to wildlife.
- **Reduced economic losses,** both direct (e.g. bird deaths) and indirect (e.g. mass culling and trade disruption). When properly implemented, avian influenza vaccination is compatible with safe trade, according to WOAH international standards.
- **Lower risk of human exposure** to avian influenza viruses, and thus of a potential pandemic, in line with the One Health approach.
- **Minimised environmental impact** by reducing the risk of spill over to wild animals.
- **Incentives for innovative research** to maintain the efficacy of vaccines over time, thanks to the experience gained. This encourages manufacturers to develop and improve access to effective and up-to-date vaccines.

In certain socioeconomic contexts, vaccination against avian influenza can contribute to the overall sustainability of the poultry industry and to the preservation of outdoor production systems. These are often a cultural heritage, even though such systems are not optimal in their biosecurity. It helps to maintain the health of domestic and wild birds, ensuring a stable supply of poultry products for consumers and preserving biodiversity. In addition, vaccination programmes with pre-established risk-based protocols enhance a country's outbreak preparedness, both in the speed of response and preparation for the increased risk.

Responsibilities of countries opting for poultry vaccination

Avian influenza vaccination should be considered as part of a broader disease prevention and control strategy. This must include other provisions, such as biosecurity measures, disease surveillance for early detection, rapid response to outbreaks and a well-planned exit strategy. Vaccination can be a temporary measure to better control the disease situation. National Veterinary Authorities [6] are charged with the decision to vaccinate based on a risk-evaluation, which depends on several factors and involves varied responsibilities, including:

- The availability of **high quality and reliable registered vaccines** that meet WOAH international standards [7] and remain effective against circulating strains. Vaccine composition must be under constant review to respond to changing circumstances and epidemiology.
- Sufficient **surveillance capacity** to demonstrate that vaccination does not interfere with virus monitoring and early detection of outbreaks in vaccinated and unvaccinated bird populations. Robust surveillance systems are essential to monitor the potential presence of avian influenza viruses in domestic and wild birds, as well as in mammals. This determines which strains are circulating and ensures that immunisation targets are met, and appropriate control measures are implemented. However, building and maintaining this capacity is resource-intensive and not possible in all countries.
- The **commitment of poultry producers** to adhere to the disease control strategy in place.
- **Data collection from producers and veterinarians** on the duration of protection provided by vaccination and the time of virus shedding after vaccination if live vaccines are used. Such data will help to better define vaccination strategies.
- The capacity to ensure the **traceability of the entire process**, from vaccine production to on-farm administration and post-vaccination monitoring, including the traceability of vaccinated animals and their products.

Vaccine selection, vaccination protocols and monitoring are critical components of a successful vaccination programme. The level of flock immunity required to prevent transmission hinges on several factors. Depending on the disease epidemiology, Veterinary Authorities – in consultation with the poultry sector – may decide to vaccinate only certain species in a selection of production systems [8].

Vaccination is compatible with the pursuit of safe trade in poultry and poultry products

To date, despite the global crisis, vaccination has been used only in a limited number of countries as a preventive, emergency or systematic measure to protect poultry or other captive bird populations from HPAI. Concerns about international trade restrictions hamper its use, although **the inclusion of vaccination as a control tool has been endorsed by international standards** adopted by the World Assembly of WOAH national Delegates.

Unjustified trade restrictions on poultry and poultry products from vaccinated flocks have a huge impact on a sector that contributes significantly to global food security and the economy. In fact, poultry meat exports account for 11% of total production, while egg exports account for 3% of production [9]. Imports of commercial genetic stocks of poultry are also essential to support meat and egg production systems of all countries. In addition, poultry meat and eggs are a low-cost, high-quality, low-fat protein food source, providing commodity redistribution and economic benefits and supporting the livelihoods of small-scale farmers. It is vital to maintain their international trade while ensuring the safety of these exchanges. This can be guaranteed in two ways:

- **Countries that vaccinate** will need to provide appropriate certification to their trading partners to ensure that their measures comply with WOAH science-based international standards. They must also demonstrate their plans to carry out necessary surveillance of circulating strains once vaccination is in place, and their **capacity to prove the absence of virus circulation**.
- **Importing countries** should make risk-based decisions and implement science-informed measures that allow for safe trade while preventing the spread of avian influenza. This is critical to avoid the closure of trade borders and the subsequent economic consequences for the poultry industry, farmers and consumers.

In accordance with WOAH international standards, the use of vaccination does not affect the status of a country or zone as being HPAI-free if surveillance supports the absence of infection. Trade in poultry and poultry products can be conducted safely alongside vaccination.

81% **of WOAH Members** (107/133 answers) did not use any sort of avian influenza vaccination in the past five years [10], whereas 112 countries and territories reported disease presence over this period [1].

Global initiatives for Avian Influenza prevention and control

The OFFLU network- Avian influenza matching (AIM) pilot project completed.

- information on antigenic characteristics of circulating viruses
- update of poultry vaccine antigens in places where vaccines are being used

https://www.offlu.org/wp-content/uploads/2023/11/OFFLU-AIM-REPORT-2023.pdf

GF-TAD HPAI global Strategy: Drafting process ongoing. External consultation with Members expected in March/April 2024

Meeting on HPAI vaccination and surveillance-WOAH will host a meeting in collaboration with IABS (Internation Alliance for Biological Standardisation) on 22 - 23 October 2024.

OFFLU annual report 2023

World Organisation for Animal Health Founded as OIE
Organisation mondiale de la santé animale Fondée en tant qu'OIE
Organización Mundial de Sanidad Animal Fundada como OIE

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Thank you

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