

	<b>DEPARTMENT OF AGRICULTURE, LAND REFORM AND RURAL DEVELOPMENT DIRECTORATE: ANIMAL HEALTH</b>
	<b>HIGHLY PATHOGENIC AVIAN INFLUENZA VACCINATION STRATEGY SOUTH AFRICA</b>
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## **Executive summary**

The purpose of developing the “Highly pathogenic avian influenza vaccination strategy, South Africa” is to set out and clarify the process to be followed when using vaccination against highly pathogenic avian influenza for the control of the disease in poultry; and to provide guidelines on the implementation of the strategy.

Vaccination against Highly Pathogenic Avian Influenza (HPAI) was previously not permitted in South Africa as in most countries in the world. A number of outbreaks of HPAI in chickens in the second half of 2023, coupled with global discussion on HPAI vaccination, sparked renewed consultations on the possible use of vaccination as a disease control measure to control HPAI outbreaks. Considering that HPAI vaccines do not prevent infection or viral shedding, several factors need to be considered, including the safety, quality and efficacy of the vaccine used, the biosecurity, surveillance, record and movement control measures required for approval of vaccination on farm level as well as how to manage vaccinated farms that become HPAI infected.

# 1. DEFINITIONS/ GLOSSARY OF TERMS/ ACRONYMS

## Definitions:

**Authorized person** - means any person authorized to exercise or perform any power or duty, or requested to render any service, by the Director Animal Health under section 3 (1) as per the Animal Diseases Act 1984 (Act 35 of 1984);

**Compartment** - An animal subpopulation contained in one or more establishments, separated from other susceptible populations by a common biosecurity management system, and with a specific animal health status with respect to one or more infections or infestations for which the necessary biosecurity, surveillance and other control measures have been applied for disease prevention and control in a country or zone or for the purposes of international trade. Chicken facilities that wish to be registered as compartments must comply with the requirements of “VPN/44/2012-01 Standard for the inspection of poultry farms for export”.

**Competent Authority** - means the Governmental Authority, comprising veterinarians, other professionals and paraprofessionals, having the responsibility and competence for ensuring or supervising the implementation of animal health and welfare measures, international veterinary certification and other standards and recommendations in the whole territory.

**Officer or designated official** - means a person or body officially appointed to a task or duty by the DAH of DALRRD under Section 3 “Authorized Persons” of the ADA and Regulations.

**Owner** - means, in relation to any controlled animal or thing, or any other moveable property, the person in whom the ownership in respect of such animal, thing or property is vested, including the person having the management, custody or control of such animal, thing or property, or having it in his possession for purposes of any treatment or care or, for the purposes of sections 9 (2) and 11 (1) (b), in the case of wild or foreign animals found on land or among animals, the owner or manager, or owner, respectively, in respect of such land or animals (as per the ADA).

**Passive surveillance** - means a monitoring system that depends on owners/veterinarians/any involved persons recognising and notifying the state veterinarian of suspect cases of an infectious disease or of circumstances where an infectious disease may be involved.

**Quarantine** - means the isolation of controlled animals or things (Section 13 of the ADA Regulations) under supervision of the responsible State Veterinarian, to prevent spread of infection from the infected foci to other susceptible populations outside the boundaries of the infected foci. Removal of any controlled animal or thing from a quarantined property is only permitted with written authorisation from the state veterinarian.

**Responsible person** - means a manager or owner of land or an owner of animals.

**Responsible State Veterinarian** - means that SV who is responsible for the control of animal diseases in a specific area.

**The Act** - unless otherwise specified means the Animal Diseases Act 1984 (Act 35 of 84) and includes the Animal Diseases Regulations, R2026 of 26 September 1986, as amended.

**Veterinarian** - means a qualified veterinarian according to the Veterinarians and Para-veterinarians Professions Act 1982 (Act no 19 of 82) and registered with the South African Veterinary Council.

## **Acronyms:**

<b>ADA</b>	Animal Diseases Act 1984 (Act no 35 of 1984) and Animal Diseases Regulations (R2026 of Sep 1986) as amended.
<b>AHT</b>	Animal Health Technician
<b>DAH</b>	Directorate: Animal Health
<b>DALRRD</b>	Department of Agriculture, Land Reform & Rural Development
<b>PPE</b>	Personal Protective Equipment
<b>SANAS</b>	South African National Accreditation System
<b>SAVC</b>	South African Veterinary Council
<b>SOP</b>	Standard Operating Procedure
<b>SV</b>	State Veterinarian/ Official Veterinarian
<b>VIP</b>	Veterinary Import Permit

## **2. LEGAL BASIS**

In terms of the Animal Diseases Act, 1984 (Act No 35 of 1984), a controlled animal disease is defined as any animal disease in respect of which any general or particular control measure has been prescribed as well as any animal disease which is not indigenous or native to the Republic. All strains of avian influenza are classified as controlled animal diseases as defined in section 1 of the Animal Diseases Act, 1984 (Act no. 35 of 1984) and control measures for all strains of avian influenza have been prescribed in terms of section 9 of the Act in the Animal Diseases Regulations, No. R. 2026 of 26 September 1986, Table 2, as amended from time to time. All statutory disease control requirements applicable to controlled diseases are applicable to all avian influenza strains.

Regulation 1 of the Animal Disease Regulations R2026 of 1986 defines poultry as all pigeons, ducks, geese, fowl, turkeys, cage birds, muscovies, domesticated ostriches, tamed wild birds and wild birds kept in captivity.

In terms of the Animal Diseases Act 1984 (Act 35 of 1984) and Regulations, any suspicion of infection with any avian influenza strain or a case of infection with any avian influenza strain must be reported to the local state veterinarian and in turn to the national Director: Animal Health

- a) Section 11(1)(b)(ii) of the Animal Diseases Act 1984 (Act 35 of 1984) and Regulations states: *“Any owner or manager of land on which there are animals, and any owner in respect of animals, shall, whether or not such owner or manager has obtained advice regarding the health, or any certificate of fitness or health of the animals in terms of section 13(1)(c), from the director, whenever such animals have become or can reasonably be suspected of having become infected with any controlled animal disease, immediately report such incidence in the prescribed manner to the director.”*
- b) Section 11(2) of the Animal Diseases Act 1984 (Act 35 of 1984) and Regulations as amended states: *“A veterinarian or any other person who finds the incidence or suspected incidence of any controlled animal disease in any animal or progeny or product thereof, shall immediately report such incidence to the director”.*
- c) Regulation 12 (1) of the Animal Diseases Act 1984 (Act 35 of 1984) and Regulations as amended states that *“the reporting of the incidence or suspected incidence of a controlled animal disease by a responsible person in terms of section 11(1)(b)(ii) of the Act shall forthwith be done verbally to the responsible State Veterinarian or responsible technical officer, and shall be confirmed in writing as soon as possible thereafter.”*

Section 11(1) of the Animal Diseases Act, 1984 (Act No 35 of 1984), places certain obligations on the owner or manager of land on which there are animals and the owner of such animals to, amongst others, take all reasonable steps to prevent the infection of the animals with any animal disease and the spreading thereof from the relevant land or animals, or steps which are necessary for the eradication of animal diseases on the land or in respect of the animals.

In terms of Regulation 11(1) of the Animal Disease Regulations R2026 of 1986, the responsible person shall in respect of their susceptible, in-contact or infected animals, also apply the applicable controlled veterinary act specified in Table 2 of the Animal Disease Regulations R2026 of 1986 to such animal and the progeny or product thereof. Table 2 of the Animal Disease Regulations R2026 of 1986 contains two separate entries related to avian influenza, one for Avian influenza other than Highly pathogenic avian influenza/Notifiable avian influenza and one for Highly Pathogenic Avian Influenza.

- Table 2 prescribes that all poultry infected or in contact with Avian influenza other than Highly Pathogenic Avian Influenza/Notifiable avian influenza shall be isolated and dealt with as determined by the Director: Animal Health.
- Table 2 further prescribes that all poultry infected or in contact with Highly Pathogenic Avian Influenza (HPAI) shall be isolated and destroyed under supervision of an officer.

For poultry destroyed as infected or in contact animals in terms of Table 2 of the Regulations of the Animal Diseases Act, 1984 (Act No 35 of 1984), an application for consideration of compensation may be made in terms of Section 19 and Regulation 30:

- Section 19 of the Animal Diseases Act 1984 (Act no 35 of 84) “Compensation” states that:

*“The owner of any animal or other thing which has been destroyed or otherwise disposed of pursuant to any control measure, or any provision of section 17 (3) or (5), or any other provision of this Act, by the director or on his authority, may submit an application for compensation for the loss of the animal or thing to the director.*

*The director may, taking into consideration –*

*the applicable compensation, based on a fair market value of the animal or thing, which has been prescribed for purposes of this section or, where no compensation has been so prescribed, any amount fixed by him in accordance with any criterion deemed applicable by him; ..... fix a fair amount as compensation.”*

- Regulation 30 of the Animal Diseases Act 1984 (Act no 35 of 84) entitled “Compensation” states that: *“When compensation is payable to a responsible person in terms of section 19 of the Act, the applicable compensation shall be determined by the director.”*

In the event or suspicion of an outbreak of HPAI the ‘*Guidelines for Control Measures Following a Suspect/Confirmed Highly Pathogenic Avian Influenza Outbreaks in Chickens – Version 1 May 2021*’, hereafter called “*HPAI Outbreak Guidelines*”, apply - together with its Annexure called ‘*Annex A – Exemption from Destruction of Chickens Infected or In-Contact with Highly Pathogenic Avian Influenza (HPAI)*’ that deal with any exemptions to the prescribed HPAI control measures (in reference to Paragraph 1.3. of the *HPAI Outbreak Guidelines*’), hereafter called ‘*Exemption Annex to HPAI Outbreak Guidelines*’.

Regulation 11 (2)(a) states that *“a responsible state veterinarian may if he is satisfied by the circumstances of a responsible person or his land or animals and that the achievement of the controlled purpose concerned will not be defeated thereby, and subject to the written approval of the director and for the time period as determined by the director and subject to the conditions as determined by the director, grant to a responsible person written postponement from compliance with a particular controlled veterinary act;...”*

With regard to the prescribed destruction of chickens infected or in-contact with HPAI in Tabel 2 of the Regulations, the Director: Animal Health has applied her mind to the destruction of chickens on an HPAI infected site that had been vaccinated against HPAI and that are not severely sick and / or dying despite being HPAI infected or in-contact and / or suspected to be HPAI infected and/or in-contact chickens and has determined that the controlled purpose will not be defeated by indefinitely postponing the destruction of such vaccinated chickens, subject to all provisions of the “*Exemption from destruction of chickens*

*infected or in-contact with Highly Pathogenic Avian Influenza (HPAI) - Annexure to “Guidelines for control measures following a suspect / confirmed HPAI outbreak in chickens.”* that has to be consulted in this regard.

### **3. BACKGROUND**

The H5 and H7 subtypes of HPAI have become endemic in aquatic wild bird populations across the globe over the past decade. It is likely that the source of introduction of AI viruses into a country and the associated subsequent outbreaks is through migratory wild birds and onward local spread. Increasing endemicity of AI viruses including the Clade 2.3.4.4b HPAI H5 strains in wild birds has shifted the epidemiology of the disease and increased the risk of more frequent outbreaks in poultry.

The general reluctance to vaccinate for HPAI before now has been primarily due to the inability of avian influenza vaccines to prevent infection with and subsequent shedding of HPAI virus. This can lead to both spread of disease but also severe challenges in surveillance for the virus and proof of disease freedom for trade purposes. Maximum vaccine efficacy (including reduced virus shedding) is seen when vaccines are closely matched to the circulating field viruses, but AI viruses evolve rapidly and vaccination may accelerate evolution away from the vaccine strain. Surveillance must therefore ensure that field viruses are detected and genetically sequenced, to allow updating of vaccine strains when necessary. As passive, clinical surveillance becomes less sensitive when vaccination is deployed, biosecurity and surveillance strategies need to be adapted to minimize the animal and public health risks associated with the circulation of HPAI viruses. Please refer to the attached Addendum on this HPAI Vaccination Strategy for more detail.

To reduce the number of chickens becoming infected, prevent spillover into mammals and reduce the zoonotic and possibly pandemic risks, it has become clear that the world needs to consider a new strategy in the control of HPAI. The International Alliance for Biological Standardization (IABS) met in Paris in October 2022 to consider the merits for the widespread use of HPAI vaccines. Since this meeting, there have been further discussions about HPAI vaccination at a meeting hosted by *inter alia* the WOA and the FAO during May 2023 to guide the worldwide developments towards the facilitation of HPAI vaccination. This document aims to bring the South African position on vaccination against HPAI in line with the international position and to provide for scientifically justifiable conditions to minimize the potential risks associated with HPAI vaccinated flocks.

#### **4. OBJECTIVES OF THIS DOCUMENT**

The objectives of this Highly Pathogenic Avian Influenza Vaccination Strategy document are to provide standards and criteria for the following:

- Requirements/characteristics of HPAI vaccines to be used in the vaccination strategy
- Approval requirements and process for farms that could qualify for the use of HPAI vaccine, including biosecurity
- Surveillance requirements for vaccinated farms
- Movement control from vaccinated farms
- Actions in the event of an outbreak of HPAI on a vaccinated farm
- Exit strategy towards cessation of the use of vaccination in an approved farm

#### **5. REQUIREMENTS FOR USE OF HPAI VACCINES**

- 5.1 Full registration with Act 36, the Fertilizers, Farm Feeds, Seeds and Stock Remedies Act, Act 36 of 1947, with proven safety, efficacy and quality.
- 5.2 No live whole Avian Influenza virus vaccines will be considered for approval.
- 5.3 All importation, local production, storage, distribution and administration of the HPAI vaccines will be subject to written approval by the DAH.
- 5.4 Suitability for DIVA serology is not a compulsory requirement but will be an additional advantage.
- 5.5 Vaccine can only be released to individuals for use in approved farms as stipulated in the permission document from the Director, with these individuals limited to SAVC registered private veterinarians who will take full responsibility that the vaccine and vaccination conditions are met. State veterinarians are excluded from performing this role, because their function is to implement the necessary regulatory control measures.

#### **6. APPROVAL OF FARMS TO ALLOW HPAI VACCINATION, INCLUDING BIOSECURITY**

- 6.1 Compliance with the ZA compartmentalisation requirements (VPN 44) or equivalent biosecurity measures must be demonstrated by the farm owner and certified by the private consulting veterinarian responsible for the premises in consultation and concurrence with the State Veterinarian.
- 6.2 Vaccinated farms will be removed from the NAI free compartment list. Vaccinated farms will remain on the ZA approved list, if they show continuous compliance to the increased surveillance requirements. Broiler farms that receive day old chicks from eggs originating from vaccinated



farms, and layer farms receiving vaccinated stock, will also be removed from the NAI free compartment list, pending further negotiations with our trade partners.

- 6.3 All poultry farms "downstream" in the production chain that receive vaccinated birds or hatchlings from vaccinated birds must also be HPAI vaccination approved farms, i.e., either be ZA registered compartments or must have the same level of biosecurity and will be subject to the same conditions. No birds may be moved off any HPAI vaccinated premises or those receiving birds from HPAI vaccinated premises unless to another HPAI vaccination approved establishment or for direct slaughter. The proposed destination of all birds from the farm applying for HPAI vaccination approval have to be provided as well as the name and address of the slaughterhouse as applicable.
- 6.4 Farms wishing to vaccinate should submit their application via the State Veterinarian and Provincial Director, for Director Animal Health's approval, detailing the following information:
- 6.4.1 Current ZA approval certificate, or a completed inspection report as per VPN 44.
  - 6.4.2 Agreement in writing by the owner to comply with all the requirements of this document.
  - 6.4.3 Identification of all farms in the production chain (include farm name, local municipality, GPS coordinates, owner) and any egg packing stations, with supporting letters that all these farms comply with the requirements for vaccination.
  - 6.4.4 Name and letter from abattoir where birds will be slaughtered.
  - 6.4.5 Total number of birds on the premises to be vaccinated.
  - 6.4.6 Clear timelines of when birds would need to be moved from farm to other farms (as listed in 6.3.3 above)
  - 6.4.7 Undertaking that surveillance as stipulated will be conducted at owners' cost.
  - 6.4.8 SOPs and / or templates for the records that will be kept for the compliance with all biosecurity and surveillance and movement control conditions as described in this document. These SOPs and / or templates must make provision for endorsements by the supervising private consulting veterinarian.
  - 6.4.9 Expected normal production, morbidity and mortality parameters for the facilities involved.
  - 6.4.10 A signed letter by the farm's consulting veterinarian undertaking to assume full responsibility for all measures contained in this document. The letter should specify whether the private consulting veterinarian will personally supervise all the biosecurity, record and surveillance conditions, including the taking of samples for surveillance purposes, or whether a SAVC registered AHT will be appointed for the farm to provide the required functions under supervision of the consulting veterinarian , in which case the name and details of the AHT must be supplied together with his / her signature on the documents.
- 6.5 The Director Animal Health will evaluate the applications and approve farms that comply with all requirements. Such approval will be valid for 12 months, whereafter a new application must be submitted in the same manner as the original application.

## **7. PROCESS FLOW FOR DISTRIBUTION AND USE OF VACCINE ON APPROVED FARMS**

- 7.1 Once the National Director has approved the farm for vaccination, the decision to vaccinate or not to vaccinate in a specific production cycle should be considered by the private veterinarian, informed by a risk assessment. If the private veterinarian is satisfied that vaccination is indicated, he/she needs to provide a prescription for a specific amount of vaccine covering the specified number of chickens on the farm to be vaccinated for a single production cycle, with full motivation, to the Director Animal Health. A signed letter by the private veterinarian must also be included, undertaking to assume responsibility for all measures contained in this document. This letter must be countersigned by the relevant AHT if a designated AHT is going to be involved in conducting some of the functions under supervision of the private veterinarian.
- 7.2 Once the Director has endorsed the prescription, it can be presented to the HPAI Vaccine Registration Holder who then may release the specified number of doses of the HPAI vaccine into the personal care of the private veterinarian who remains responsible for its use on the specific farm. Permission to vaccinate will be given per production cycle on a specified property.

## **8. SURVEILLANCE REQUIREMENTS FOR VACCINATED FARMS**

- 8.1 The objective of farm level AI virus surveillance is to promptly detect any circulation of AI field virus after introduction into vaccinated poultry flocks, to effectively control the disease and prevent further spread. Vaccination is only one of the tools to lower the risk of introduction, prevent spread after introduction, and facilitate the eradication of the disease. Vaccination is not proven to prevent infection, but rather to increase the virus threshold required to cause infection and to diminish the severity of signs of disease, which is why strict biosecurity is still required.
- 8.2 Given that the sensitivity of both passive clinical and post-mortem surveillance and laboratory tests, especially PCR tests, is highly dependent on the skills of the operator to detect possible symptoms of AI and ensure proper sample handling, it is mandatory that all the surveillance elements below are conducted either by the private consulting veterinarian personally or by the SAVC registered AHT who has been appointed for the farm to provide the required functions under supervision of the consulting veterinarian.
- 8.3 Possible subclinical circulation in vaccinated flocks makes passive surveillance less reliable and HPAI vaccines also cause immune reactions that interfere with certain types of laboratory testing, especially serology. Thus, more intensive laboratory testing including more agent-identification testing has to be conducted on HPAI vaccinated farms.

- 8.4 The deployment of vectored vaccines theoretically allows for the use of DIVA serological tests to distinguish infected from vaccinated birds. Unfortunately, this DIVA serological testing is not possible if whole virus (inactivated) vaccines are used, nor can it be deployed on farms infected with or vaccinated for H6. Given the endemicity of a LPAI H6N2 virus in commercial chickens and the sensitivity and specificity challenges with the Influenza A ELISA DIVA serological test, it has been decided to rather rely on agent identification / PCR laboratory testing alone for the active surveillance strategy as detailed below, even if DIVA vaccines are deployed on the farm.
- 8.5 As vaccine is not proven to prevent infection but rather to increase the virus threshold required, the expected prevalence after virus introduction will be lower than in unvaccinated flocks. It is important to take this into account when calculating the sample sizes to be collected to provide for a high level of confidence that the survey system will detect any introduction of virus. In addition, prevalence assumptions must be tailored to the type of testing and, while longer periods of antibody persistence allow serological tests to detect higher cumulative prevalences, the short duration of virus shedding limits the detection of virus or virus particles to a lower pin-point prevalence for agent identification / PCR tests.
- 8.6 Introduction of an HPAI virus usually infects one house on a farm initially. Its spread to other houses will depend on the biosecurity between the houses and can take a considerable amount of time, Thus, to detect an introduction as soon as possible, it has been decided that a single house represents an epidemiological unit for surveillance purposes as detailed below.
- 8.7 Weekly enhanced passive targeted surveillance
- 8.7.1 Weekly enhanced passive clinical surveillance
- The expected normal production, morbidity and mortality parameters must be established for the site and for every house if the subpopulations of chickens differ between houses.
  - These expected normal production, morbidity and mortality parameters must be monitored weekly under private veterinary supervision with production of a signed off weekly report.
  - Any decrease of production or increase of morbidity or mortality by more than 30% of the normal parameters must be reported immediately to the responsible state veterinarian and a suspect outbreak investigation must be conducted to exclude the presence of HPAI. The fact that the owner and manager are obliged to report to the state veterinarian does Not exonerate the private veterinarian and private AHT from their obligations in this regard.
- 8.7.2 Weekly enhanced passive targeted surveillance of mortalities
- Every mortality in every house must be subjected to post-mortem examinations under private veterinary supervision at least once a week with a weekly signed off post-mortem report.

- Mortalities can be classified as a targeted group with a higher expected prevalence and therefore it has been decided to sample for a ~50% minimum expected prevalence per house and for a minimum 10% prevalence per site.
- The number of samples to be collected amounts to samples from at least 5 dead animals per house to be submitted once every week while it has to be ensured that samples from at least 30 dead animals per site are submitted every week; i.e. in the case of less than 6 (populated) houses on the site, the sampled mortalities per house need to be increased to amount to 30 per site per week - while in the case of more than 6 (populated) houses on a site, the total number per site will amount to more than 30 every week .
- Dead birds showing signs that could be suggestive of avian influenza must be prioritized for submission with the remainder of the sampled birds selected randomly for each house.
- Caecal tonsils, spleen, trachea and lung tissue must be collected in separate containers for every bird with the house identification / number clearly displayed on the container.
- Organ sample containers must be kept cool and transported in triple layer packaging to an accredited and approved laboratory for AI rt-PCR testing.
- A maximum of organ samples from 5 mortalities will be pooled per PCR test at the laboratory, this amounting to at least one PCR result from mortalities per (populated) house per week and a minimum of six PCR results per site per week.

#### 8.8 Monthly active surveillance

- Apart from samples collected weekly as part of the enhanced passive surveillance system, active surveillance samples must be collected monthly from randomly selected chickens under private veterinary supervision.
- An expected prevalence of 5% per house, representing an epidemiological unit, is considered the internationally accepted baseline for active surveillance. This would amount to 60 birds sampled per (populated) house every month with pooling of samples from 5 birds at the laboratory resulting in 12 PCR results per (populated) house every month. In the interest of practicality and feasibility but allowing for scientific justification and reference to international guidelines, it has been decided to allow for an increase of expected prevalence to 25% per house but correspondingly lower the expected prevalence to 2.5% per site.
- This results in a rounded number of 10 birds to be sampled per month per house with a rounded minimum number of 120 birds to be sampled per month per site; i.e. in the case of less than 12 (populated) houses on the site, the number of sampled birds per house needs to be increased to amount to 120 per site per month - while in the case of more than 12 (populated) houses on a site, the total number of sampled birds per site will amount to more than 120 every month.

- Veterinary oversight is needed with sampling to enable compliance. Private veterinarians will be responsible but must inform State Veterinarians of sampling events. This will allow State Veterinarians to attend should he/she wish to do so.
- Cloacal and tracheal swabs for PCR must be collected from the same birds and placed into a separate container / tube for every bird sampled with the house identification / number clearly displayed on the container / tube.
- Samples must be triple packaged and sent to accredited and approved laboratories for AI rt-PCR testing.
- Swabs of different birds must not be pooled on the farm but sent in a separate container for every bird to the laboratory where a maximum of samples from 5 birds will be pooled per PCR test at the laboratory, this amounting to at least two PCR results from monthly active surveillance per house per month and a minimum of 24 PCR active surveillance results per site per month.

#### 8.9 For both passive weekly and active monthly surveillance

- The submission forms to the laboratory must be completed in full and signed by the private veterinarian in charge of the facility.
- The laboratory must be instructed on the submission form to not pool samples across houses to ensure that every PCR result pertains to a specific house and that the collective PCR results represent all of the epidemiological units on the site.
- Any suspect or positive result must be reported immediately to the responsible state veterinarian and a suspect outbreak investigation must be conducted to exclude the presence of HPAI. The fact that the laboratory is also obliged to report to the state veterinarian does Not exonerate anybody else, i.e. everybody involved, including the responsible owner or manager of the farm and the private veterinarian and private AHT are obliged to report such suspect or positive result immediately.

## **9. MOVEMENT CONTROL APPLICABLE TO VACCINATED FARMS**

- 9.1 All chickens from farms that are approved for HPAI vaccination, I,e, that are either vaccinated or the progeny from vaccinated chickens, remain under movement restriction and may not be moved from the approved premises unless the results of the reinforced passive and active surveillance, implemented in accordance with Point 7. of this document, are negative for detection of infection with HPAI field virus throughout the duration of stay of the vaccinated poultry on the farm.
- 9.2 Vaccinated poultry and the unvaccinated progeny from vaccinated chickens that are less than 12 weeks old may only move to a slaughterhouse for immediate slaughter; or to other establishments approved to receive vaccinated birds.

- 9.3 Abattoirs where vaccinated chickens and the unvaccinated progeny from vaccinated chickens that are less than 12 weeks old will be slaughtered must be specified on the farm's application to vaccinate and the relevant abattoirs must indicate in writing that they will accept the slaughter of these chickens from the specified farm(s). The owner of the vaccinated farm must keep auditable records with a tally of slaughter ready vaccinated birds that are taken for slaughter and the abattoir must also keep in their slaughter records with the farm names, owners and numbers of vaccinated birds delivered to the abattoir for slaughter for audit purposes.
- 9.4 No live vaccinated chickens or unvaccinated progeny from vaccinated chickens that are less than 12 weeks old may be sold or given away for any other purposes, including individual sales of end of production chickens for home slaughter.
- 9.5 Disposal of dead chickens from vaccinated farms by feeding to pigs will not be allowed.
- 9.6 If the results of the reinforced passive and active surveillance, implemented in accordance with Point 7. of this document, are negative for detection of infection with HPAI field virus, unvaccinated chickens older than 12 weeks and products may move without additional restrictions.

## **10. ACTIONS IN THE EVENT OF HPAI OUTBREAK ON VACCINATED FARM**

- 10.1 In the event or suspicion of an outbreak of HPAI on a vaccinated farm, the farm will be placed under quarantine and the outbreak must be reported to the Competent Authority in the normal manner.
- 10.2 In the event or suspicion of an outbreak of HPAI the 'Guidelines for Control Measures Following a Suspect/Confirmed Highly Pathogenic Avian Influenza Outbreaks in Chickens – Version 1 May 2021' (the 'HPAI Outbreak Guidelines') apply - together with its Annexure called 'Annex A – Exemption from Destruction of Chickens Infected or In-Contact with Highly Pathogenic Avian Influenza (HPAI)' (the 'Exemption Annex to HPAI Outbreak Guidelines') that details the conditions applicable to such exemptions.
- 10.3 All of the houses and units on a vaccinated site that became infected with HPAI have to be considered infected and / or in-contact with the disease. However, the DAH has exempted such infected and in-contact chickens from destruction provided the conditions detailed in the 'Exemption Annex to HPAI Outbreak Guidelines' are fulfilled. The 'HPAI Outbreak Guidelines' describe all applicable control measures on HPAI infected farms and remain fully applicable for HPAI vaccinated and subsequently HPAI infected sites on which the owner or manager take the decision to apply the exemption from destruction subject to the conditions detailed in the 'Exemption Annex to HPAI Outbreak Guidelines'.

## 11. EXIT STRATEGY

- 11.1 The competent authority shall determine the duration of vaccination approval.
- 11.2 This document may be reviewed on an annual basis.
- 11.3 To re-gain “unvaccinated” (NAI free list) status, the farm must be depopulated, cleaned and disinfected. The responsible state veterinarian must inform the National Director Animal Health, to remove the farm from the list of vaccinated farms. The normal requirements for listing on the NAI free list must then be complied with, before the farm is included on the NAI free list.

FINAL

## **ADDENDUM**

### **Additional background on adaptation of biosecurity and surveillance strategies to mitigate the risks associated with HPAI vaccination.**

Discussions on the possibility, desirability and required risk mitigation for HPAI vaccination in chickens between government and the poultry industry have been conducted since South Africa's first HPAI outbreak in chickens in 2017. While this current strategy was still being developed and any use of these vaccines was obviously subject to policy finalization, the registration of suitable HPAI vaccines was discussed since 2021 with specific conditions laid down by the Director: Animal Health. Finalization of this policy was pursued after the renewed surge of HPAI Clade 2.3.4.4.b H5 chicken farm outbreaks that started in 2021, with a new strain of this virus taking over in 2023 and became a priority due to the 2023 HPAI H7N6 chicken farm outbreaks that affected an unprecedented number of chicken farms.

The worldwide increase in poultry HPAI events and outbreaks has led to higher risks for mammals, including people, who may become infected - with the well-documented ability of influenza viruses to adapt to alternative hosts possibly resulting in future epizootics and even pandemics. The increasing number of documented HPAI infections in a wide variety of mammal species worldwide since 2022 has become a serious cause for concern and, together with the increasing burden of the disease on the worldwide poultry industry, has been the major motivation for worldwide considerations of using HPAI vaccines to reduce the amount of virus circulating in the environment.

The main reason for using HPAI vaccines is that they increase the infective dose required to infect poultry, including chickens, and, if infection still occurs, they reduce the amount of virus being shed and thus decrease the potential for transmission to other farms as well as to other mammals, including humans. However, while HPAI vaccines have been demonstrated to be effective for protection of poultry against the disease, with immunized chickens showing less or no symptoms, they are, like almost all vaccines, much less effective in preventing infection.

Given the above, vaccines, including HPAI vaccines, can never be regarded as a replacement for biosecurity, i.e. all efforts must be made to prevent the infection entering a flock. As a matter of fact, biosecurity has to be particularly good in vaccinated flocks because passive surveillance based on detection of disease symptoms is less effective and without good biosecurity the disease, should it be introduced, has an increased chance of spreading to other farms and other species before it is detected.

While HPAI vaccines have been around for many decades, their use has been controversial, mainly because of the potential of the virus to continue infecting and circulating in vaccinated flocks. Such circulation in vaccinated flocks may occur at subclinical levels that are more difficult to detect. This increases the potential for the virus to spread to other flocks as well as to mammals and even people. It



may also promote the emergence of escape mutants, i.e. for the virus to mutate out of the reach of the vaccines being used.

Influenza vaccines in general have to be H-type and even strain specific, i.e. a situation in which more than one HPAI virus is present in the country, like the 2023 situation in South Africa, may require several vaccines to cover both H-types, with all vaccines having to be monitored continuously to ensure that they remain effective against the prevalent strains.

The potential for subclinical infection and the risk of escape mutant strains makes it mandatory to conduct intensified active sampling and laboratory-based surveillance in flocks vaccinated against HPAI – this in order to be able to detect even low-grade subclinical HPAI infections as well as monitor the appearance of mutated strains of the disease. Passive surveillance that merely observes for disease symptoms is not sufficient in HPAI vaccinated flocks. As HPAI vaccines also cause immune reactions that interfere with certain types of laboratory testing, especially serology, more agent-identification testing has to be conducted in HPAI vaccinated farms, normally in the form of PCR testing.

In line with the above, the WOAHA has adopted the possibility of HPAI vaccination into its Terrestrial Animal Health Code Guidelines several years ago - with the proviso that such active and targeted surveillance has to be scientifically justifiable and robust enough to demonstrate the absence of infection in vaccinated flocks in order to safeguard animal and public health as well as for trade purposes.

In addition, as the immunity from HPAI vaccines generally lasts for the life-time of a bird, the vaccinated poultry have to remain under life-long intensified biosecurity and surveillance. This implies that, should they be sold live at any stage, such sale and movement will have to be subject to them being transferred to a property that practices the same intensified biosecurity and surveillance, i.e. that qualifies for HPAI vaccinated chickens as per the conditions laid down in South Africa's HPAI Vaccination Strategy. The same requirement applies to hatchlings from HPAI vaccinated parent flocks that will have maternal immunity for at least 4 – 6 weeks, i.e., basically the whole lifespan of a broiler chicken.

Furthermore, should an HPAI vaccinated flock become infected with the strain of HPAI contained in the vaccine that was used, some or all of the chickens are likely to be sufficiently protected against the disease to be able to survive, either because they did not become infected or, more likely, because they were partially or completely protected against the disease and thus show mild or no symptoms despite being infected. Given the above-mentioned challenges associated with the increased risk of subclinical disease and the lower sensitivity of clinical surveillance and laboratory testing in vaccinated chickens, all of the houses and units on a vaccinated site that became infected with HPAI have to be considered infected and / or in-contact with the disease.

On the other hand, if some or all of the chickens on an HPAI vaccinated and subsequently infected site are not severely sick and / or dying despite being regarded as infected or in-contact and / or suspected to be infected or in-contact, the disease risk will be substantially lower because the amount of virus being shed tends to be proportional to the severity of the symptoms. It is thus possible without defeating the

controlled purpose and even imperative for food security reasons that the productive and / or genetic value of these chickens be preserved by exempting them from the prescribed destruction in terms of Table 2 of the Animal Diseases Regulations. However, the following associated risks would have to be addressed adequately, namely:

- a) the risk of prolonged and possibly subclinical circulation of virus that may increase the risk of spread of the disease and an increased risk of contact with other animals and humans – these to be addressed by appropriately enhanced biosecurity conditions even more than was already required to qualify for permission to vaccinate against HPAI; and
- b) the risk of subclinical disease as well as the prolonged circulation of the virus resulting in the emergence of mutant strains that make it more difficult to rely on clinical passive surveillance alone and thus require a further increase in the level of active surveillance , including increased deployment of laboratory agent identification methods , i.e. over and above those deployed routinely in HPAI vaccinated flocks, in order to be able to satisfactorily determine the end of the outbreak;

The above thus being the conditions under which the Director: Animal Health has granted Exemption from destruction to HPAI vaccinated and infected flocks.

In the event or suspicion of an outbreak of HPAI the **'Guidelines for Control Measures Following a Suspect/Confirmed Highly Pathogenic Avian Influenza Outbreaks in Chickens – Version 1 May 2021'** (hereafter called the 'HPAI Outbreak Guidelines') apply - together with its Annexure called **'Annex A – Exemption from Destruction of Chickens Infected or In-Contact with Highly Pathogenic Avian Influenza (HPAI)'** (hereafter called the 'Exemption Annex to HPAI Outbreak Guidelines') that details the conditions applicable to such exemptions. The 'HPAI Outbreak Guidelines' describe all applicable control measures on HPAI infected farms and remain fully applicable for HPAI vaccinated and subsequently HPAI infected sites on which the owner or manager take the decision to apply the exemption from destruction subject to the conditions detailed in the 'Exemption Annex to HPAI Outbreak Guidelines'.