

NATIONAL OPERATING POLICY AND PROCEDURES FOR THE USE OF AVIAN INFLUENZA (AI) VACCINE IN THE EVENT OF AN AI OUTBREAK IN AUSTRALIA

**A guidance document prepared by the National Avian Influenza Vaccine Expert Group,
a working group of Animal Health Committee
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PURPOSE

Australia's preferred approach to an outbreak in domestic/captive birds of highly pathogenic avian influenza (HPAI) or low pathogenicity AI (LPAI) of the H5 or H7 subtypes is to achieve freedom without vaccination. However, in the event of an outbreak of HPAI or LPAI (H5/H7) in Australia, vaccination of poultry and other birds may be used to assist in controlling the outbreak. This document should be read in conjunction with AUSVETPLAN *Disease strategy: Avian influenza*¹ which provides details of Australia's approach to the management of outbreaks of AI.

This document sets out nationally agreed policy and procedures for using AI vaccines in Australia. The receipt, storage, distribution and administration of avian influenza vaccines, and requirements following vaccination, are outlined here.

This document may be used by SCEAD² or by disease control agencies to develop detailed Standard Operating Procedures (SOPs) that will ensure implementation in a timely and effective manner at the local level.

SCOPE

This document covers the use of avian influenza vaccines during an AI outbreak in Australia including:

- the vaccination of poultry³, aviary, cage and other captive birds during an AI outbreak in Australia, under an approved Emergency Animal Disease Response Plan (EADRP)
- the provision of guidelines for application to use AI vaccine outside an approved EADRP in poultry, aviary and caged birds (Annex 1)
- the vaccination of zoo birds, valuable bird collections, captive rare breeds and captive endangered species (Annex 2).

1 INTRODUCTION

1.1 If vaccination were to be undertaken, only vaccines that meet regulatory requirements will be used.

¹ The AUSVETPLAN Avian Influenza Disease Strategy (Edition 3, Version 3.3, 2008); [http://www.animalhealthaustralia.com.au/fms/Animal%20Health%20Australia/AUSVETPLAN/AI3_3-35FINAL\(21Jul08\).pdf](http://www.animalhealthaustralia.com.au/fms/Animal%20Health%20Australia/AUSVETPLAN/AI3_3-35FINAL(21Jul08).pdf)

² SCEAD – the Subcommittee on Emergency Animal Diseases, a committee that has representation from the Australian government, state and territory governments, and Animal Health Australia. SCEAD is chaired by the Animal Health Committee program leader for emergency animal diseases (traditionally the Australian Chief Veterinary Officer)

³ Poultry are defined as chickens, turkeys, guinea fowl, ducks, geese, quails, pigeons, pheasants, partridges, ostriches and emus reared or kept in captivity.

- 1.2 The Australian Chief Veterinary Officer holds import permits for four inactivated whole virus vaccines (Poulvac FluFend i AI H5N9, Poulvac FluFend i AI H7N1, Nobilis Influenza H5N2 and Nobilis Influenza H7N1). Following importation, vaccine will be held in a quarantine-approved premises (QAP) until vaccination is authorised by the Consultative Committee on Emergency Animal Diseases (CCEAD). Use of a vaccine will be under the control of the jurisdictional Chief Veterinary Officers (CVOs) in accordance with a decision by CCEAD/ National Management Group (NMG).
- 1.3 When making a decision about vaccination, CCEAD/NMG may seek expert advice. To assist CCEAD in deciding whether to use vaccination as part of the response to an AI outbreak, a decision support tool (Annex 3) has been developed.
- 1.4 CCEAD may consider proposals, from individuals or interest groups, on a case by case basis during an AI outbreak, for vaccination outside of an emergency response plan. For example, requests may be considered where a proponent can substantiate a case for protection of birds considered at risk of infection, of high value birds or a high risk scenario that cannot be managed by other means. Following such a request, any decision to permit vaccination that is not part of an Emergency Animal Disease Response Plan (EADRP) will be subject to specific requirements. In coming to a decision, CCEAD will consider, *inter alia*, expert advice, the availability of vaccine and the resources needed to undertake the proposal. Any costs of vaccination of this nature will not be met by governments nor fall under the Emergency Animal Disease Response Agreement (EADRA) cost-sharing arrangements.
- 1.5 CCEAD will not approve vaccination:
- in the absence of HPAI or LPAI (H5/H7) in domestic or captive birds in Australia or
 - where it may compromise achievement of eradication.
- 1.6 CCEAD will not approve vaccination of birds or flocks that cannot be held and monitored until destruction, slaughter, death or demonstration of freedom from infection.
- 1.7 CCEAD will not approve vaccination of birds or flocks⁴ that are known to be **infected** with HPAI. AUSVETPLAN requires that infected poultry flocks are subject to destruction as soon as practical. However, AUSVETPLAN provides for vaccination of **uninfected flocks** as part of a management strategy in infected premises if it can be proven that such flocks are epidemiologically separate from infected flocks on the same premises.
- 1.8 Vaccination will only be undertaken by approved personnel. State/territory CVOs will determine the requirements for approval of personnel within their jurisdiction.

⁴ Flock – a flock is all poultry of the same health status on the same premises or in the same enclosure and constituting a single epidemiological unit. In housed poultry this will include all birds sharing the same airspace. There may be more than one flock on a premises.

- 1.9 Requirements for vaccinated birds/flocks may include flock identification, record keeping, monitoring and surveillance requirements, and movement controls, which, in general, will be part of the Restricted Area and Control Area movement controls in the area being vaccinated, as outlined in AUSVETPLAN.

2 DECISION TO ORDER VACCINE

- 2.1 CCEAD and NMG may, as part of an approved EAD Response Plan, request Animal Health Australia (AHA) to order a specified quantity of AI vaccine. This can be done immediately the subtype of the virus has been determined, a process which may take several days following receipt of a virus isolate at CSIRO-AAHL, Geelong.
- 2.2 CCEAD may approve use of vaccination for birds and flocks outside an EAD response plan (see Annexes 2 and 3). CCEAD may request AHA to order a specified quantity of AI vaccine for this purpose. Use of this vaccine will be under official control as described in 1.2 above.

3 DELIVERY OF VACCINE TO AUSTRALIA

- 3.1 Depending on supply arrangements in place at the time, the vaccine will be ordered and delivered to an appropriate airport.

4 INITIAL STORAGE, WAREHOUSING AND DISTRIBUTION OF VACCINE

- 4.1 AHA will arrange delivery, storage and distribution of vaccine under the direction of CCEAD, ensuring maintenance of cold chain in accordance with the manufacturer's recommendations.
- 4.2 At a State Disease Control Headquarters (SDCHQ) or Local Disease Control Centre (LDCC), there should be a vaccination manager fulfilling the roles as specified in the AUSVETPLAN Control Centre Management Manual Part 2.

5 USE OF AI VACCINE DURING AN OUTBREAK

- 5.1 AI vaccine will be administered by trained personnel approved by the CVO or delegate (e.g. Vaccination Manager).
- 5.2 The use of professional vaccination providers should be considered to improve the efficiency and animal welfare outcomes of vaccination, and to train additional personnel for vaccination teams. Vaccination teams should use, as much as possible, on-farm labour to complete the task. It is not necessary that a veterinarian is a member of each team; however, the vaccination teams must be under supervision of jurisdictional personnel.
- 5.3 Vaccination team members must not have contact with other birds outside the Restricted Area for the duration of their involvement in the campaign. Campaign biosecurity precautions must be applied between flocks.

5.4 Training of teams will cover:

- essential facts about AI
- essential facts about poultry farms and/or other enterprises
- Occupational Health & Safety (OH&S) issues pertaining to AI and to administration of inactivated vaccines
- manufacturers' instructions on vaccine label/leaflet
- handling of birds
- organisational procedures with respect to the operation of teams from LDCCs
- the use of equipment (e.g. vaccination guns, personal protective equipment)
- cleaning and disinfection and related biosecurity procedures (see Section 5.14)
- excluding contact with birds not part of the eradication campaign
- record keeping and vaccine inventory controls.

5.5 The OH&S measures to be taken in Australia have been agreed nationally and human risk aspects will be coordinated by local public health authorities. These authorities will be guided and coordinated by the National Influenza Pandemic Action Committee (NIPAC). National guidelines for the protection of people exposed to infected or potentially infected birds are set out in Appendix 2 of the AUSVETPLAN *Disease strategy: Avian influenza*. The full document is available on the Department of Health and Ageing website⁵.

Manufacturers issue Material Safety Data Sheets (MSDS) pertaining to their products. Vaccine MSDS should be consulted for guidelines for safely handling vaccines. For guidelines on vaccination with inactivated vaccine see Annex 4.

5.6 Before vaccination commences, it is necessary to ensure that the birds or flocks to be vaccinated are demonstrated free from infection (e.g. through dead bird testing or live bird sampling). Only flocks testing negative for AI by PCR and with no clinical signs consistent with AI will be vaccinated.

5.7 Because a prior inspection and testing routinely takes place, personnel engaged in vaccination activities are unlikely to come in contact with sick birds. Nevertheless, in accordance with AUSVETPLAN and current national guidelines, it is recommended that personnel be vaccinated with the currently available human seasonal influenza vaccine.

5.8 Vaccination teams and other personnel must be supplied with personal protective equipment (PPE) as described in Appendix 2 of the AUSVETPLAN *Disease strategy: Avian influenza*. PPE will be provided by the LDCC.

5.9 Vaccination teams will be withdrawn from sheds/properties where AI is suspected, e.g. due to clinical signs suggestive of AI. In doing so, biosecurity protocols should be followed and all relevant items sealed into clinical waste bags for disposal. Teams would be redeployed after suitable biosecurity protocols and health guidelines have been followed in accordance with specific circumstances and

⁵ <http://www.health.gov.au/internet/main/publishing.nsf/Content/avian-influenza-poultry-guidelines.htm>

AUSVETPLAN procedures for ‘contaminated’ personnel. Vaccination teams visiting farms that are subsequently confirmed to be infected will be stood down for 7 days and referred to health authorities for assessment.

5.10 Vaccination teams are responsible for vaccination, bird or flock identification and record keeping of the numbers of vaccine bottles used and the number and type of birds vaccinated.

5.11 Farms within the restricted area will be identified for vaccination by the Vaccination Manager (LDCC) in accordance with the approved EAD Response Plan for the jurisdiction. Vaccination outside the restricted area will be coordinated by SDCHQ. Jurisdictional personnel will account for vaccine used on farm. If possible, LDCC personnel should attend the farm and supervise the biosecurity and vaccination operation.

5.12 After a decision has been made that vaccine will be used, a number of factors will be taken into account when considering which farms will be identified for vaccination.

- Inactivated vaccines may be administered to chickens from 2 weeks of age.
- Birds with a short life span (such as meat chickens, meat ducks and quails) would not generally be considered for vaccination, but may be removed from the vaccination area by depopulation or early processing.
- Birds with a longer life span (e.g. breeders, layers, meat turkeys, other valuable birds) present in the vaccination area at the time of the outbreak may be considered for vaccination.
- The objectives of vaccination will be taken into account when considering which birds to vaccinate (see Annex 1 – A decision making model for use of vaccination in an avian influenza outbreak).

5.13 There is no restriction on the number of farms that can be vaccinated in one day, providing: the risk that the farms are infected has been assessed as low; appropriate biosecurity precautions are taken, and personnel and vaccine are available.

5.14 Biosecurity for vaccination teams is critical. Personal decontamination must be undertaken when entering and leaving a property to prevent spread of important avian pathogens between farms. Vaccination teams must shower on and shower off the property, to reduce the potential for spread of endemic avian pathogens between farms undergoing vaccination. The provision of showering facilities is the responsibility of the jurisdiction. The AUSVETPLAN *Operational procedures manual: Decontamination*⁶ should be consulted regarding the most appropriate means of decontamination and disposal.

5.15 Waste material must be disposed of in accordance with clinical waste OH&S requirements. LDCC should arrange collection and/or disposal of vaccination waste.

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[http://www.animalhealthaustralia.com.au/fms/Animal%20Health%20Australia/AUSVETPLAN/DECON3_2-01FINAL\(12Dec08\).pdf](http://www.animalhealthaustralia.com.au/fms/Animal%20Health%20Australia/AUSVETPLAN/DECON3_2-01FINAL(12Dec08).pdf)

Identification of vaccinated animals

5.16 Appropriate records must be kept that identify vaccinated birds or flocks, recognising that the identification of individual birds within commercial poultry flocks would not be practical.

5.17 Flocks or birds that have been vaccinated must be traceable until the end of their life or until the emergency response (including surveillance for proof of freedom) is complete.

5.18 Identification of individual vaccinated birds may be necessary on some non-commercial enterprises, small holdings and zoos.

6 MOVEMENT CONTROLS OVER VACCINATED LIVESTOCK, THEIR PRODUCTS & PREMISES

6.1 Birds vaccinated as part of the AI outbreak response will be subject to movement controls, similar to those imposed for unvaccinated birds in Restricted and Control Areas. (Refer to Section 4.2 in the *AUSVETPLAN Disease strategy: Avian influenza*), as long as there remains a risk of virus remaining in the environment.

6.2 Animal products derived from vaccinated livestock are likely to be subject to the same movement restrictions/permit requirements applying to products from the declared disease control area in which the livestock and products originate.

6.3 There is no risk to humans from consuming products from vaccinated animals.

6.4 If vaccinated birds are designated for destruction or slaughter⁷, timeframes can be specified to accommodate production cycles (where this is appropriate and does not compromise the eradication strategy). Where vaccinated birds are to be slaughtered, consignment to slaughter shall be under permit.

6.5 Facilities in which a vaccinated flock is being replaced by an unvaccinated flock should be decontaminated according to the *AUSVETPLAN Decontamination Manual*, unless the vaccinated flocks have been tested to demonstrate freedom from infection with AI field virus.

6.6 Movement controls may be required if vaccination is undertaken outside a declared area (including vaccination outside the EADRP). Further details can be found in Annexes 2 and 3.

7 MONITORING OF VACCINATED BIRDS

7.1 The purposes of post-vaccination inspection, monitoring and surveillance are to ensure that no covert infection is occurring in vaccinated flocks, and to demonstrate freedom from infection at the conclusion of the emergency response. Appropriate surveillance tools could include:

⁷ 'Slaughter' refers to processing for human or animal consumption

- dead bird testing
- placement of sentinel birds
- use of appropriate, nationally-agreed tests
- heterologous neuraminidase antigen testing (DIVA⁸) if appropriate to the vaccine selected.

Vaccinated flocks may also be subject to additional health monitoring through examination of production records, mortality records and dead bird monitoring and sampling.

7.2 Serological testing of some vaccinated flocks may be done in order to monitor immune response to vaccine, particularly in the early stages of a vaccination program. Sampling may occur at the point of slaughter (if animals are to be slaughtered).

7.3 It is not necessary for vaccinated flocks/birds to be destroyed providing the flock is demonstrated to be free from infection with the outbreak AI virus. Proof of freedom can be demonstrated by testing sentinel birds and/or a sample of the flock to prove that there is no AI virus present.

7.4 Premises/flocks will be released from monitoring requirements once

- the vaccinated flock has been slaughtered and measures have been taken to ensure that there is no infection remaining on the premises, *or*
- the outbreak is declared to be eradicated *and* the flock is demonstrated to be free of infection.

8 INVENTORY CONTROL

8.1 A national inventory control system should be initiated to account for imported and distributed vaccine. AHA will arrange inventory control of vaccine.

8.2 It is advisable that inventory control is practiced throughout the vaccine distribution chain:

- initial point of delivery and storage
- state distribution point(s)
- LDCC(s) or forward command posts (FCP)
- vaccination teams.

8.3 LDCCs will record vaccinated properties, vaccination teams, the numbers and identifications of vaccinated birds or flocks (where appropriate), vaccine batch numbers, dates, and other information. Vaccine stock movements in and out of the LDCC or FCP should be recorded.

8.4 The Vaccination Manager at an LDCC will need to carefully plan vaccine allocation to teams to maximise efficiency of administration but minimise vaccine wastage.

⁸ DIVA – Differentiating infected from vaccinated animals

9 EXIT STRATEGY

9.1 Where vaccination is undertaken, the controls placed on the vaccinated flock must include a clear end point.

9.2 Vaccination will only be permitted while there is risk of infection. No further vaccination will be permitted, after a specified period following stamping out of the last known naturally-infected bird.

9.3 If HPAI or LPAI (H5/H7) were to become endemic in Australia, this vaccination guide would be reviewed.

Annexes

Annex 1: Guidelines for applicants: proposal to vaccinate poultry, aviary and caged birds against avian influenza outside an approved Emergency Animal Disease Response Plan

Annex 2: Guidelines for applicants: proposal to vaccinate birds in zoos or collections against avian influenza outside an approved Emergency Animal Disease Response Plan

Annex 3: A decision support tool for use of vaccination in an avian influenza outbreak

Annex 4: Vaccination with inactivated (killed) vaccine

ANNEX 1: GUIDELINES FOR APPLICANTS: PROPOSAL TO VACCINATE POULTRY, AVIARY AND CAGED BIRDS AGAINST AVIAN INFLUENZA OUTSIDE AN APPROVED EMERGENCY ANIMAL DISEASE RESPONSE PLAN

This annex must be read in conjunction with the National Operating Procedures and Policy for the use of Avian Influenza (AI) vaccine in the event of an AI outbreak in Australia.

Purpose

These guidelines provide **assistance** to applicants considering applying for permission to use avian influenza (AI) vaccines during an emergency response⁹, in flocks or individual birds which are situated:

- outside an area subject to an emergency response and movement restrictions
- inside an area that is subject to an emergency response, but in which vaccination is not being undertaken (or is not being undertaken on a specific enterprise) as part of the emergency response.

The required application form can be found in these guidelines.

Scope

These guidelines apply to vaccination of poultry, aviary and caged birds against influenza A subtypes H5 and H7.

Considerations

Vaccination will only be approved if the agent which is subject to the emergency response is present in Australian bird populations. Vaccination of birds against these subtypes of AI outside of emergency or strategic responses, as approved by the Consultative Committee on Emergency Animal Diseases (CCEAD), will only be permitted in special circumstances.

Applicants should refer to the current Avian Influenza AUSVETPLAN disease strategy document for further information about the disease and response options¹⁰.

Applicants should seek expert advice from a registered veterinarian with expertise and experience in poultry/avian health before applying to use AI vaccines. This advice should cover the following:

- the level of protection provided by vaccination of different species and ages of birds
- health status of the population being vaccinated and how it might influence the response to vaccination
- the antigenic relatedness of the vaccine strain and field strain
- the recommended vaccination regime for the bird/flock type
- the costs of diagnostic testing, vaccination, and post-vaccination monitoring.

⁹ An emergency response refers to actions taken to control or eradicate an outbreak of AI, such as those described in AUSVETPLAN.

¹⁰ AUSVETPLAN manuals can be found on the Animal Health Australia website at <http://www.animalhealthaustralia.com.au>

The use of vaccine may result in quarantine restrictions, affect how commercial parties view the health status of the flock and have other commercial and social impacts.

Vaccination principles

- The use of AI vaccines in Australia is only permitted in accordance with a decision by CCEAD. If a decision is made to vaccinate, the strategic priorities will be to stop the spread of the outbreak and to protect rare, endangered, and valuable birds
- If an emergency response to an H5 or H7 sub type AI virus is undertaken in Australia, the primary aim is to eradicate the disease without vaccination
- The use of AI vaccination is subject to approval by the Chief Veterinary Officer (CVO)¹¹ in all circumstances
- Vaccines will be under the control of the jurisdictional CVO of the state or territory where vaccination is proposed
- Only vaccines which meet regulatory requirements will be used.

Vaccination of birds/flocks not included in the EADRP

Applications for voluntary vaccination of birds or flocks outside EADRP will be evaluated on a case by case.

In such cases the following is required:

1. A written proposal to the jurisdictional CVO describing the enterprise and the specific reasons for proposing to vaccinate outside the emergency response guidelines. The proposal should provide full details of the birds to be vaccinated, intended future use of the birds, how flocks or birds will be identified, biosecurity arrangements and other matters that may be relevant. The attached form should be used to provide the required information.
2. The jurisdictional CVO may consult with CCEAD before permitting such vaccination.
3. Agreement of the applicant to meet the costs of the vaccine, vaccination, monitoring and testing of vaccinated birds/flocks.
4. Agreement and ability of the applicant to meet the requirements for vaccinated birds/flocks including health monitoring, identification of birds, maintenance of biosecurity, movement controls, maintenance of records and any other risk management requirements.

Issues that will be considered when assessing the application include

- the national or state interests, including effect of vaccination on the jurisdiction's ability to demonstrate freedom from AI
- risk of AI entering the flock
- availability of vaccines and likely future demands on their supply. If vaccines are in short supply, vaccination outside the emergency response will be approved only in exceptional circumstances

¹¹ jurisdictional CVO - Chief veterinary officer of the state or territory in which vaccination is proposed

- the potential need that may arise to cull vaccinated birds if infection enters the vaccinated flock, regardless of absence of clinical signs
- Likely efficacy of vaccine

Once a decision is made for voluntary vaccination of a specific flock, the following minimum monitoring and surveillance requirements must be met:

- access to the premises by veterinarians or officials employed by or working for the jurisdiction
- pre-assessment of the flock/birds requesting vaccination to ensure ability to comply with the requirements
- assessment of the AI status of the flock by serology and viral sampling before vaccination takes place
- follow-up of AI status of the flock by serological and viral sampling.

The frequency of monitoring will be risk-based and will depend on individual circumstances including flock size, movements of products or birds, biosecurity level, locality etc.

As part of the approval, the applicant may be required to post a surety with the jurisdiction to cover their anticipated costs.

Application form for non-emergency vaccination

(To be submitted to the Chief Veterinary Officer of the state or territory in which the birds to be vaccinated are resident)

Please note that this application is likely to be approved only in exceptional circumstances or for special flocks/birds.

I, the owner/manager of the flock/birds located at

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hereby apply to have my flock/birds considered for vaccination under these guidelines (Guidelines for applicants: proposal to vaccinate against avian influenza outside of a strategic or emergency response (non-emergency vaccination)).

I declare that the flock/bird is of exceptional value and I am able to meet the following conditions and expenses:

1. The applicant will bear the cost of the vaccine, vaccination and any other associated costs involved in monitoring and testing at an approved laboratory.
2. Regular effective monitoring of the AI status of the flock/bird will take place, as described in the Monitoring and Testing Schedule in this document.
3. An approved biosecurity plan is in place or will be implemented at the premises.
4. The vaccinated birds or flock will be identified and records maintained.
5. The flock will be subject to sampling to demonstrate freedom from AI infection (H5 or H7 subtypes) at any stage after vaccination. I note that the flock may be subject to culling, if found to be infected despite vaccination.
6. The flock and associated products will be subject to official movement controls.
7. An approved veterinarian will be nominated to supervise and monitor the health of the flock/bird.

Brief description of the birds/flock I am seeking to vaccinate

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What are the reasons for seeking approval to vaccinate the flock/birds? (Please provide details).....

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Brief description of the biosecurity standards under which the flock/birds are kept, or the biosecurity standards which will be implemented if vaccination is approved (attach a copy of the biosecurity plan for the premises and describe how it is monitored).

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Brief description of waste disposal including dead birds, used litter etc

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Please circle whichever of the following applies to the premises and flock

Birds are kept in an enclosure secured against animal and human intruders Yes No

The enclosure prevents direct contact with wild birds Yes No

The enclosure prevent direct contact with wild waterfowl Yes No

Water and feed is provided in a secure enclosure Yes No

Water supply is from town water or other sources (circle please) Town Other

Please specify the water source if not town water

If water is not from town water please indicate the treatment and the monitoring schedule of the water to prevent contamination with hazardous biological agents

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Please estimate the number **and type** (waterfowl or others) of wild birds in the immediate environment where the flock is kept.

None A few Many Others

Details.....
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How far are/is the flock's enclosure/s from a wetland, a dam, creek or other large body of water?

Name of nominated supervising veterinarian¹²

Signature of supervising veterinarian.....

Address.....

Phone number

email.....

Please indicate the possible movements of products or birds from the vaccinated flock in the 3 months following vaccination.

(Please note that these movements are likely to be subject to official control whether or not the flock is kept in a restricted or control area. Some movements may not be permitted; some movements may be allowed only under permit.)

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Please provide a schedule of anticipated movements if applicable

DATE	NUMBERS	DESTINATION	TRANSPORT
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¹² Nominated veterinarian must be a registered veterinarian with expertise and experience in poultry/avian health

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Please note that the applicant is expected to cover the full cost of any monitoring and testing that may be imposed following a decision to vaccinate.

I(name).
Declare the above to be correct and agree to the above conditions and undertake to report to the jurisdiction any changes in the health or behaviour of the flock (decreased water or feed intake), any mortality and any clinical signs immediately when noticed.

Signature.....

Date.....

Signature of witness (JP or other approved signatories)

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Date.....

Location.....

Monitoring and testing schedule

A. All flocks and birds

Pre-vaccination blood collection and tests

- blood will be collected from a predetermined sample size or from the entire flock depending on number of birds in a flock
- blood will be collected before vaccination and tested by an accredited laboratory using an ELISA¹³ test for detection of any antibodies to AI viruses
- available dead or sick birds will be examined and tested for AI viruses
- flock/birds will be considered for vaccination subject to the results of the tests
- if the results of initial testing are positive to AI, the flock/bird will be subject to further testing. Those testing antibody positive to AI subtypes H5 or H7 will not be eligible for vaccination and further testing will be carried out to determine the flock's fate.
- flock sampling may also involve cloacal and oropharyngeal swabs when it is deemed appropriate to determine the health status of the flock
- additional tests on flocks testing positive to influenza A for regulatory purposes will not incur cost to the owner.

B. Flocks able to accommodate sentinel¹⁴ birds

The monitoring and testing schedule for flocks with sentinel birds will include pre-vaccination blood collection and testing as described above. In addition, the following will apply:

B i) Birds on litter

- an appropriate number of sentinel birds (that remain unvaccinated) will be allocated to the flock for monitoring and sampling. The number will vary from a few birds to 100, depending on the size of the flock and the length of anticipated monitoring.
- the sentinel birds need to be distinguishable from the vaccinated birds by colour, sex, species *or* they must be tagged in a manner that will ensure the birds can be readily identified, preferably from a distance within large flocks
- alternatively, sentinels can be placed in different locations of the shed in an enclosure. These birds must be held in such a manner that their health status will reflect that of the vaccinated birds in the flock (this is not a preferred option).
- mortality and morbidity of any birds in the vaccinated flock must be monitored and reported immediately to the jurisdiction and sick and dead birds may be subject to testing
- mortality or morbidity of any sentinel bird would trigger an immediate investigation into the cause of death or clinical signs

¹³ ELISA – enzyme-linked immunosorbent assay – a serological test for antibody to influenza A virus

¹⁴ Sentinel birds are birds that remain unvaccinated. Monitoring and testing of sentinel birds potentially allows detection of 'field' virus circulating within a vaccinated flock.

- in the absence of clinical episodes in sentinels and vaccinated birds, the monitoring schedule will depend on the nature and size of the flock
- intensity of monitoring will be based on risk and determined by the jurisdiction
- birds or flocks found to be positive for H5 or H7 virus at any stage of monitoring will be depopulated (culled).

Commercial breeding birds on litter

In addition to monitoring and reporting of clinical signs, a sample of sentinel birds will be subject to testing by PCR (cloacal and oropharyngeal swabs) and/or serology at intervals of no more than the incubation period of the eggs. At least 48 hours should be allowed for return of results, before the products or day old chicks are due to leave the hatchery.

Depending on the structure of the flock, an optimal number of sentinels to be tested on each occasion will be determined by the authorities.

Day old or hatching eggs from the flock must not be allowed to move from the premises unless

- the sentinel birds show no evidence of clinical signs and
- test results are negative.

B ii) Birds housed in cages

Flocks in cages will require sentinels to be spread in cages optimally among vaccinated birds, but the monitoring procedures will be similar to those for birds on litter.

C. Flocks/birds without sentinels on litter or in cages (including fancy poultry)

Flocks without sentinels will require sampling of the appropriate number of birds.

Monitoring of health status will be as per flocks with sentinels.

D. Flocks with minimal or no movements of products or day old hatching eggs or birds

These flocks impose the lowest risk and may include pets, individual birds or small flocks with few or no movements and with no direct contact with the commercial industry. Such flocks may pose a risk to their owners if they contract an H5 or H7 AI infection.

It is unlikely that placement of sentinels will be practical in these flocks. Nevertheless this is an option that can be explored with individual owners.

Provided these flocks qualify to be considered for vaccination under the non-emergency clause, it is envisaged that these flocks could be monitored at a lower frequency than other categories of flocks.

For practical reasons, the flock may be tested only at the end of the vaccination phase, with serological DIVA or a PCR test to exclude the presence of AI virus.

If the results are negative, the flock released from the vaccination quarantine regimen. If positive, the bird/flock will be destroyed.

Post-vaccination tests (all flocks)

When the outbreak subsides, the flock/sentinels are tested using cloacal and oropharyngeal swabs and blood tests. In flocks where sentinels are not present, serological DIVA testing will be required.

The cost is borne by the owners.

ANNEX 2: GUIDELINES FOR APPLICANTS: PROPOSAL TO VACCINATE BIRDS IN ZOOS AND COLLECTIONS AGAINST AVIAN INFLUENZA OUTSIDE AN APPROVED EMERGENCY ANIMAL DISEASE RESPONSE PLAN

This annex must be read in conjunction with the National Operating Procedures and Policy for the use of Avian Influenza (AI) vaccine in the event of an AI outbreak in Australia.

Purpose

These guidelines provide assistance to applicants applying for permission to use avian influenza vaccines, subtypes H5 and H7, for birds confined as part of a zoo collection during an AI outbreak. The vaccines are intended for birds of significant value, including those which are genetically valuable, endangered or are of individual significance (see below).

Zoos applying for permission to use avian influenza vaccine will be expected to:

- Be members of the Zoo and Aquarium Association (Australasia) or another recognised professional association
- Have a Biosecurity Plan in operation at the premises
- Have established arrangements with a supervising veterinarian/veterinary service
- Have a prioritised list of birds to be vaccinated against avian influenza virus.

Applications for vaccination of captive rare birds and endangered species kept outside of recognised zoo collections will be considered under these guidelines on a case-by-case basis.

Considerations

Vaccination will only be approved if the agent which is subject to the emergency response is present in Australian bird populations. Vaccination of birds against these subtypes of AI outside of emergency or strategic responses, as approved by the Consultative Committee on Emergency Animal Diseases (CCEAD), will only be permitted in special circumstances.

Applicants should refer to the current Avian Influenza AUSVETPLAN disease strategy document for further information about the disease and response options¹⁵.

Applicants should seek expert advice from a registered veterinarian with expertise and experience in zoo/avian health before applying to use AI vaccines. This advice should cover the following:

¹⁵ AUSVETPLAN manuals can be found on the Animal Health Australia website at <http://www.animalhealthaustralia.com.au>

- the level of protection provided by vaccination of different species and ages of birds
- health status of the population being vaccinated and how it might influence the response to vaccination
- the antigenic relatedness of the vaccine strain and field strain
- the recommended vaccination regime for the bird type
- the costs of diagnostic testing, vaccination, and post-vaccination monitoring
- the implications of 'off-label' use of vaccines in zoo birds.

The use of vaccine may result in quarantine restrictions, affect how commercial parties view the health status of the flock and have other commercial and social impacts.

Inactivated vaccines induce protective antibody titres in most species when administered twice and when dosage is adjusted to accommodate body weight. Inactivated vaccines can be used to protect a variety of bird species, including valuable or endangered bird species. Generally the efficiency of the vaccine in non-poultry species has not been validated.

Vaccination may provide a level of protection against avian influenza infection, but the main safeguard is to prevent exposure of valuable birds through effective biosecurity. Vaccinated birds exposed to AI, although protected from clinical disease may still transmit virus.

Vaccination **must** be seen as an adjunct, not an alternative, to good biosecurity.

The uncertainties that vaccination will involve must be accepted. However, in approved zoos and collections, collection birds will be kept under constant veterinary supervision in a controlled and limited location. Zoos should remain alert to the possibility that vaccinated collection birds may shed unidentified virus, and should minimise risks by ensuring high level biosecurity practices.

Birds kept in zoos do not normally come into contact with poultry or other captive birds outside the collection, and thus they do not pose a risk of contamination for poultry or other captive birds. It is understood that zoo employees follow strict practices to minimise the risk of disease transmission, should they come into contact with birds outside the zoo.

Given the value of some zoo birds, avian influenza vaccination constitutes an appropriate *preventative measure*. All birds of significant value can be considered for vaccination but this may not significantly increase their protection if they are already housed in biosecure units (e.g. caged passerines). The risks of handling birds for vaccine administration and mandatory monitoring may be greater than that of these birds becoming infected.

Priority list for zoo birds of significant value

The following list of bird groups has been identified in priority order for AI vaccination in the event of an AI outbreak threatening a zoo or valuable bird collection:

1. Birds from listed endangered species (The Environment Protection and Biodiversity Conservation Act 1999 (EPBC Act) List of Threatened

Species will be used to define endangered Australian birds. The IUCN Red List will be used to determine the endangered status of all other birds.

2. Birds from species or subspecies which are rare, or which have poor genetic or numerical representation within Australia
3. Birds from species which would be difficult to replace
4. Individual birds which are valuable due to their educational importance
5. Individual birds which represent a significant investment in resources (for example, birds trained for free-flight bird shows).

Vaccination principles

1. The use of avian influenza vaccination is subject to approval by the jurisdictional Chief Veterinary Officer, in accordance with a decision by the Consultative Committee for Emergency Animal Disease (CCEAD).
2. If an emergency response to an H5 or H7 subtype AI virus is undertaken in Australia, the primary aim is to eradicate the disease without vaccination. If a decision is made to vaccinate, the strategic priorities will be to stop the spread of the outbreak and to protect rare, endangered and valuable birds.
3. Vaccines will be under the control of the jurisdictional Chief Veterinary Officer (CVO) of the state or territory where vaccination is proposed.
4. Vaccination for protection against avian influenza will only be **considered** if there is a threat that LPAI H5/H7 is spreading in captive birds, or the existence of HPAI in Australia is suspected or confirmed. **Avian influenza infections classified as HPAI or LPAI in wild birds are not considered to pose an immediate threat to Australia's domestic or zoo birds, or public health.**
5. Only vaccines which meet regulatory requirements will be used.

Specific details

Prioritisation	Applicants must have a prioritised list of species and individual birds to be vaccinated against avian influenza virus. Priority is to be guided by the Priority List for Zoo Birds of significant value. Applicants must provide the list of birds to be vaccinated to the approval authority.
Identification	Birds must be individually identified with a permanent method of identification (metal leg band or microchip).
Record keeping	Written records of individual, date, route, dose and type of vaccine used, testing protocols, post mortem investigation and disposal of any unused vaccine must be kept for at least 10 years.
Duration	The primary vaccination program should be completed as quickly as possible (ideally within one week of commencement). Booster vaccines, if used, should be completed four to six weeks after primary vaccination.

Standstill of birds and bird products	<p>Movements may be permitted under permit between approved premises with the following words added to the certification “<i>birds conform to approval XXX vaccinated against AI onVaccine.....</i>”</p> <p>(Bird products from vaccinated birds shall not be used as food for any species).</p>
Execution of the program	<p>Vaccination shall be carried out under the authority of the Chief Veterinary Officer of the jurisdiction. Vaccinators should receive appropriate training in use of inactivated vaccines.</p> <p>Where appropriate and as required on approval of the application, blood and other diagnostic samples shall be taken prior to and following primary and booster vaccination for testing at an approved laboratory for avian influenza. Collection and processing of diagnostic samples to monitor the vaccination program will be under the guidance and advice of CCEAD. A written record of the test results must be kept by the applicant for at least 10 years.</p>
Vaccine to be used	Inactivated registered vaccines used in accordance with the instructions of the manufacturer and/or the veterinary authorities.
Costs	Where vaccination in zoos is part of a response plan agreed by CCEAD under the EADRA, cost sharing will be in accordance with the EADRA. All costs of vaccination not included in the emergency animal disease response plan are to be borne by the applicant. Applicant must satisfy themselves as to cost of vaccination and any potential monitoring before making an application to vaccinate. Potential requirements can be discussed with the appropriate authorities when developing the application.
During and on completion of the vaccination	Details including laboratory or pathology results will be supplied to the State authorities.

Key issues that will be considered by the relevant authority when assessing the application are:

1. Availability of vaccines and future demands on their supply.
2. Ability of the applicant to meet the cost of the vaccine, vaccination and any other associated costs involved in vaccination and monitoring.
3. Ability of the applicant to meet the requirements associated with such vaccination including health monitoring, identification of birds, maintenance of biosecurity, movement controls, maintenance of records and any other requirements to manage risk.
4. National or State interests.
5. Risk factors to avian influenza virus entering the bird collection.
6. Need to demonstrate freedom from LPAI (H5/H7) or HPAI infection before birds can be moved from the premises.

Application Form for vaccination

I, the owner/manager of the birds located at

.....
.....
.....
.....

Hereby apply to be considered for AIV vaccination of birds (listed below) under the conditions outlined in AUSVETPLAN.

I understand that the following conditions must be met in order to be considered;

1. The birds are confined as part of a collection.
2. The birds are genetically valuable or endangered or are of individual significance.
3. I agree to meet the cost of the vaccine, vaccination and any other associated costs involved in vaccination and monitoring, including testing at an approved laboratory.
4. An approved biosecurity program is implemented for the collection.
5. Individual vaccinated birds will be permanently identified by metal leg band or microchip.
6. Written records of individual bird, date, route, dose and type of vaccine used, testing protocols, post mortem investigation and disposal of any unused vaccine must be kept for at least 10 years.
7. A veterinarian will be nominated and have agreed to supervise and monitor the health of the collection, including clinical and faecal monitoring, and to provide reports to the jurisdictional authorities as required.

Description of the birds you are seeking to vaccinate (species and number). Provide details about the genetic or historic values (see footnote 1)

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What are the reasons for seeking approval to vaccinate?

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Information about the biosecurity program under which the birds are kept.

(Attach a copy of your Biosecurity Plan for the zoo/avian collection and describe how it is implemented and monitored)

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Brief description of waste disposal including dead birds, waste water, feed and manure.

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Please tick or circle the following

Birds are kept in a secured enclosure Yes No

Please describe the type of enclosure (If birds on priority list are held in numerous different enclosures, please describe each enclosure type and list the priority species and individuals within)

- Fully enclosed indoor enclosure
- Fully enclosed area (open wire mesh walls, solid roof structure)
- Fully enclosed area,(open wire mesh walls and roof structure)
- Open enclosure (fence only with no roof)
- Open area (no fence/ enclosure)

Water and feed is provided in a secure enclosure Yes No

Water supply is from town water or other sources Town Other sources

Please specify the water source if not town water

.....

If water is not from town water please indicate the treatment of the water to prevent contamination with hazardous biological agents

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.....

Can non-captive wild birds come into direct contact with birds in their secure enclosures? If yes briefly provide details

.....
.....

Please estimate the number and type of wild birds in the immediate environment where the flock is kept

None.....

A few.....

Many.....

Others.....

What level of direct or indirect exposure would the vaccinated birds have to wild water birds?

High..... Medium..... Low..... Very Low..... None.....

(please tick and briefly describe the type of interaction with wild water birds)

.....

.....

.....

What level of direct or indirect exposure would the vaccinated birds have to other wild birds?

High..... Medium..... Low..... Very Low..... None.....

(please tick and briefly describe the type of interaction with other wild birds)

.....

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Name of nominated supervising veterinarian.....

Signature of supervising veterinarian.....

email.....

Phone number

Please indicate the possible movements of vaccinated birds in the 3 months following vaccination (note these movements will likely be subject to official control);

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Please provide a schedule of anticipated movements if applicable

DATE	NUMBERS	DESTINATION	TRANSPORT
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Please note that if the application is successful the applicant will cover the cost of any monitoring and testing required as a result of vaccination.

Iagree to the above conditions and undertake to report immediately to the jurisdiction any changes in the health or behaviour of the vaccinated birds (decreased water or feed intake), any mortality and any clinical signs when noticed.

Signature.....

Date.....

ANNEX 3: A DECISION SUPPORT TOOL FOR USE OF VACCINATION AS PART OF A RESPONSE TO AN AVIAN INFLUENZA OUTBREAK

Given the different ways that vaccination may be used, a decision on whether to use it or not in the face of an AI outbreak has to be considered in the context of both short term and longer term objectives.

The key issue in considering the most desirable strategy for disease management is the extent to which the disease can be controlled with available resources. This in turn will largely be determined by where the outbreak has occurred and the extent to which it has spread across and within poultry industry compartments. Disease occurring on circumscribed properties within a single compartment lends itself to eradication by stamping out, whereas an outbreak in a high density poultry production area where there is already evidence of spread across and between different industry sectors indicates that control may be more difficult to achieve.

This decision support tool can be used at the beginning of an AI outbreak, to evaluate separate outbreak foci, and each time circumstances change during a response to an outbreak.

Definitions:

- **Protective vaccination:** vaccination of particular groups of birds in an area to protect them from infection. Vaccination would generally be undertaken *outside* the known infected area
- **Suppressive vaccination:** vaccination carried out *within* the known infected area where it is considered that there is an urgent need to reduce the amount of virus circulating and hence the risk of spread beyond the area
- **Targeted vaccination:** vaccination carried out to protect particularly valuable commercial flocks (e.g. high value genetic stock), or rare or endangered species/breeds.

Table: Decision criteria for AI vaccination

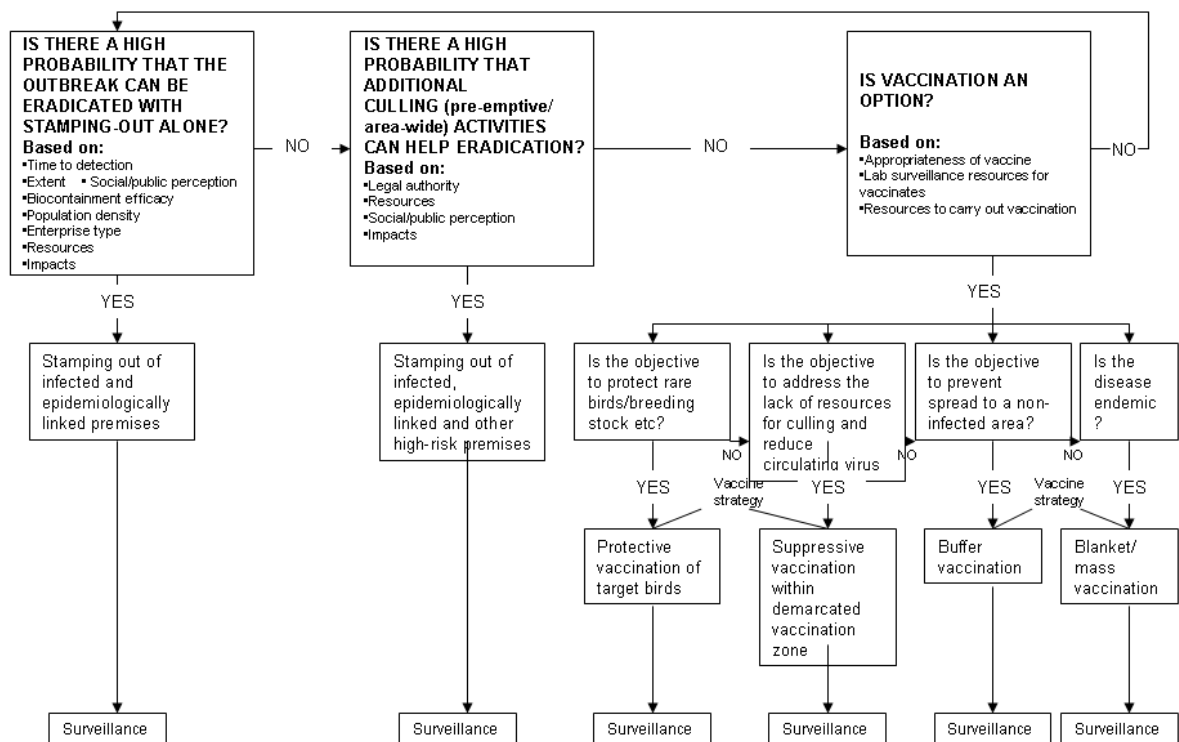
Criteria	For vaccination	Against vaccination
Location	In significant poultry producing area	Isolated farm
Poultry density (numbers of establishments and birds in immediate vicinity)	High	Low
Clinical impact	Significant number of sick and dead birds	Mortality low
Extent of movements (bird/product/fomites) that have occurred in and around infected premises	Extensive	Limited
Evidence of spread	Multiple outbreaks involving different industry sectors (compartments)	Little evidence
Likelihood of spread	Potential to enter multiple properties in different compartments	Extensive spread unlikely
history of spread in similar situations	Spread to multiple properties in different compartments	Spread was very limited
Spatial distribution of outbreaks	Widespread	Restricted
Suitable vaccine	Available	Not available
Resource availability (for stamping	Adequate	Limited

out, decontamination, disinfection)		
Resources for vaccination (adequate stocks, trained personnel, other logistics)	Adequate	Limited
Origin of outbreaks (traceability)	Unknown; disease entry possibly across a wide front	Known to be a single point of introduction
Suspect case reports	Rising rapidly	Shallow or slow rise
Industry support for stamping out	Low	High
Public reaction to stamping out policy	Strong	Weak
Surveillance and laboratory resources to carry out post-vaccination surveillance	Strong	Weak

Control strategy decision support tool

A decision support tool for AI control/eradication is shown below.

Avian Influenza Control Strategy Decision Support Tool



When written in programming style, the above decision tree translates as follows:

STRATEGY FOR CONTROLLING AI

- IF ASSESSMENT OF THE OUTBREAK INDICATES:
 - The time to detection was short (i.e. the outbreak is in its very early stages;
 - There are indications that the extent of spread is limited;
 - Movement restrictions and other biocontainment efforts are working;

- There is a low density of commercial flocks in the area involved;
- There are a limited number of species involved few/no non-commercial flocks;
- The main type of operation involved is commercial;
- Mainly production birds are involved and not long-lived birds (breeding stock);
- There are sufficient physical and human resources to deal with depopulation and surveillance activities;
- Public perception will not be strongly against culling
- Economical and trade impacts will be small;
- Resources for stamping out are adequate

THEN:

STAMPING OUT IS A FEASIBLE (AND PREFERRED) OPTION

ELSE:

GOTO 4

2. IF STAMPING OUT ON ITS OWN NOT CONSIDERED ADEQUATE TO ERADICATE DISEASE, AND,

- There is legal authority for additional culling activities;
- There are sufficient resources available to accomplish additional depopulation;
- There is public acceptance of destruction of potentially healthy birds;
- Economic and trade impacts will be small;

THEN:

CONSIDER ADDITIONAL CULLING MEASURES (SUCH AS PRE-EMPTIVE OR AREA-WIDE CULLING)

ELSE:

GOTO 4

3. VACCINATION OPTIONS MUST BE CONSIDERED PROVIDED THAT:

- Appropriate vaccine is available;
- Laboratory and other resources are available for the surveillance of vaccinates;
- Human resources to carry out vaccination are available.

4. CONSIDER OBJECTIVES OF VACCINATION

5. IF VACCINATION IS FOR PROTECTION OF RARE SPECIES OR BREEDING STOCK

THEN:

CONSIDER VOLUNTARY PROTECTIVE VACCINATION OF TARGET BIRDS/GROUPS.

7. IF RESOURCES TO CULL INFECTED BIRDS ARE NOT ADEQUATE AND THERE IS A NEED TO REDUCE THE AMOUNT OF CIRCULATING VIRUS

THEN:

CONSIDER SUPPRESSIVE VACCINATION – ALL PREMISES WITHIN A DESIGNATED VACCINATION ZONE

8. IF VACCINATION TO PREVENT SPREAD OF INFECTION TO NEW AREA (CONTAINMENT)

THEN:

CONSIDER VACCINATION OF BUFFER AROUND PERIMETER OF INFECTED ZONE;

9. IF DISEASE IS WIDESPREAD AND BECOMING ENDEMIC

THEN:

CONSIDER MASS VACCINATION

Annex 4

Vaccination with inactivated (Killed) Vaccine

What is inactivated vaccine?

‘Inactivated vaccine’ is vaccine that underwent some treatment resulting in inactivation of the virus (death of the virus) contained within the vaccine.

The additives used in inactivated vaccines (adjuvants) result in a slow release of the protective element into the bird body with subsequent prolonged and consistent protection.

Vaccination

- The site of injection is either the breast muscle or thigh (intramuscularly) or the neck (subcutaneously).
- Inexperienced operators are advised to inject the breast as no vital organs could be damaged using this method.
- The full recommended dose must be administered in accordance with manufacturer’s instructions.
- The use of a vaccination gun is recommended.
- The vaccination gun must be designed for the specific bottle in which the vaccine is supplied.
- Shake the bottle well before and during use.
- If in doubt about individual bird missing the injection, administer another dose. The vaccine has a good safety margin and a double dose will not harm the bird.
- If vaccination of a flock is planned over more than one day, the manufacturer’s instructions should be followed regarding re-use of opened vaccine bottles.
- Vaccination needles used for injecting must not be inserted into vaccine bottles.
- Vaccination guns must be sterilised prior to next use. Only new or sterilised material and equipment should be taken on to a farm.
- Automatic multi-dose vaccination syringes are recommended and needles should be regularly changed to ensure sharpness.

Side effects

- Handling of birds in lay may result in a small drop in egg production.
- In cage facilities, it is important to return vaccinated birds to their original cages to avoid disruption of the pecking order.
- In barn or free range situations, pile-ups of birds could result in significant losses.
- A slight swelling at the site of the injection may persist for several weeks.
- Mortality can occur in a few cases.

Safety

The vaccine is safe.

There are no required withholding periods for bird meat or eggs.

In case of accidental self-injection or accidental injection of a team member seek medical advice immediately. The adjuvant is an irritant and may cause massive swelling if injected into confined spaces like joints.